



Ministry of Health & Family Welfare  
Government of India



# Technical Specifications of Medical Devices for **NEONATAL & PEDIATRIC CARE ICUs**





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Technical Specifications of  
Medical Devices for  
**NEONATAL & PEDIATRIC CARE ICUs**





भारत सरकार  
स्वास्थ्य एवं परिवार कल्याण विभाग  
स्वास्थ्य एवं परिवार कल्याण मंत्रालय  
Government of India  
Department of Health and Family Welfare  
Ministry of Health and Family Welfare

Dated : 29<sup>th</sup> April, 2015

## MESSAGE

Ministry of Health and Family Welfare in its endeavor to achieve highest standards of health for the people has undertaken several programmatic and institutional strengthening measures. National Health Mission is one such programmatic intervention aimed at improved overall health with special focus in energizing rural health infrastructure and services. Providing essential medical equipment is a critical component of strengthening health infrastructure. However, rapidly changing technologies, complexity associated with medical equipment and high costs of procurement - all these make selection of appropriate and cost effective equipment a challenging task. I am happy to note that National Health Systems Resource Centre (NHSRC) under the guidance of experts and with active participation of stakeholders have developed technical specifications of commonly procured medical devices to facilitate procurements by State / UT Governments. I am sure that you will find these very helpful. The specifications are suggestive and we have tried to keep them generic. However, we would welcome any suggestions for further improvement in these specifications.

  
(B.P. Sharma)

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भारत सरकार  
स्वास्थ्य एवं परिवार कल्याण मंत्रालय  
निर्माण भवन, नई दिल्ली - 110011  
**GOVERNMENT OF INDIA**  
**MINISTRY OF HEALTH & FAMILY WELFARE**  
**NIRMAN BHAVAN, NEW DELHI-110011**

## MESSAGE

Under National Health Mission, support is being provided to all States/UTs for improving quality of health services and improving necessary infrastructure including medical equipment. Providing for adequate, safe and appropriate medical equipment at all levels of public health facilities remains a focus for the Government. Given the challenges of procurement it is necessary to have generic specifications for medical equipment. Cost, utility, availability in domestic market, maintenance and patient safety are crucial issues to be considered while procuring medical devices. I am pleased to note that these have been adequately considered by NHSRC while preparing the specifications. Keeping them as reference specifications while undertaking procurement will reduce costs of procurement, maintenance problems and procurement lead time. I am happy to note that NHSRC, has filled in an important technical gap by providing these specifications and I am sure that technical specifications suggested here will serve as a reference for procurement of medical devices under the National Health Mission.

We would be happy to have your valuable suggestion on improving these.

**(C.K. Mishra)**

New Delhi  
29<sup>th</sup> April, 2015







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भारत सरकार  
स्वास्थ्य एवं परिवार कल्याण मंत्रालय  
निर्माण भवन, नई दिल्ली – 110011  
GOVERNMENT OF INDIA  
MINISTRY OF HEALTH & FAMILY WELFARE  
NIRMAN BHAVAN, NEW DELHI - 110011

31<sup>st</sup> April 2015

## MESSAGE

National Health Systems Resource Centre which is also a WHO collaborating centre for priority medical devices & health technology policy; in consultation with users, care providers, engineers, medical technologists and representatives from medical devices manufacturers association has formulated technical specifications for commonly used medical devices. Specifications are suggestive in nature and any specific requirement needs to be incorporated at the time of procurement. However having well deliberated specification at one place should considerably reduce the procurement cost & time and improve quality of procurement extensively. The specifications suggested herein are an outcome of several rounds of consultations with experts, user clinicians & care providers, medical technologists & engineers and industry stake holders. While effort has been made to make the specifications as generic as possible and consensus and technical appropriateness has been the corner stone of this technical exercise. We would welcome suggestions from the States.

(Manoj Jhalani)



# Acknowledgement

Medical devices are a very important part of health care and their use is increasing by the day. Technical specifications play an important role in identification, selection and procurement of appropriate and cost effective medical devices. Consistency and standardization in technical specifications promotes positive competition and reduces effective costs. It also promotes uniformity in user training and smooth maintenance of equipment. In order to address the variation in technologies many of which could be add-ons, separate exercises were undertaken for specific categories of medical devices procured under National Health Mission. The experts consulted for specifications formulation exercises included clinicians, medical technologists, maintenance experts and also representatives from manufactures' industry associations. Specifications for medical devices for Special Neonatal Care Units, Neonatal and Pediatric Care Units, Ambulances, Operation Theatre for district sub-district levels, Rashtriya Bal Suraksha Karyakaram, Laboratory & Radiology equipment, Skill laboratory program are an outcome of intense participation, deliberation, technical research and inputs from experts. These include experts from prestigious institutions such as AIIMS, PGIMER-Chandigarh, RML Hospital, Safdarjung Hospital, Sree Chitra Institute of Medical Sciences & Technology, Central Scientific Instrument Organisation, Hindustan Life Care Limited, IITs, to name a few. Overall review by DGHS provided further validation to the technical work. Division of Healthcare Technology, NHSRC being the technical secretariat for this work played a pivotal role and names of following professionals deserve special mention: Jitendar Sharma, Mohammad Ameer, Anurag, Swati Barwala, Prabhat Arora, Kavita Kachroo, Akriti Chahar, Pankaj Parashar, Prashant Tiwari, Ashfaq Ashraf and Anjanaya. I am sure that specifications confirming to adequate standards of safety and accuracy shall be immensely useful for the states in undertaking appropriate and cost effective procurement of medical devices.

**Dr. Sanjiv Kumar**  
**Executive Director**



# DIRECT OPHTHALMOSCOPE

|                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no.:                                                                 | 3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Date:                                                                        | SEPT 2014                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Done by : (name/institution)                                                 | HCT/NHSRC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| NAME AND CODING                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| GMDN name                                                                    | Ophthalmoscope                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| GMDN code (s)                                                                | CT 1184                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| GENERAL                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 1. USE                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 1.1                                                                          | <b>Clinical purpose</b><br>Direct ophthalmoscope is a hand-held and battery powered device containing illumination and viewing optics to examine the cornea, aqueous, lens, vitreous, and the retina of the eye.                                                                                                                                                                                                                                                                                                                                                                                      |
| 1.2                                                                          | <b>Used by clinical department/ward</b><br>NICU & PICU                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| TECHNICAL                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 2. TECHNICAL CHARACTERISTICS                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 2.1                                                                          | <b>Technical characteristics (specific to this type of device)</b><br>1) Should have on/off button for illumination and battery operated;<br>2) Should have rotating knob to control the intensity of the ophthalmoscope and should be used with filters that eliminate UV radiation (<400nm) and, whenever possible, filters that eliminate short-wavelength blue light (<420nm);<br>3) Should have the range of +20 to -20 in single dioptre steps to ensure easy examination of all ocular structures;<br>4) Should have apertures shape: Large spot, small spot, slit, central net, and red free; |
| 2.2                                                                          | <b>User's interface</b><br>Manual                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 2.3                                                                          | <b>Software and/or standard of communication (where ever required)</b><br>NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 3. PHYSICAL CHARACTERISTICS                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 3.1                                                                          | <b>Dimensions (metric)</b><br>Max: 50mm x 50mm x 250mm.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 3.2                                                                          | <b>Weight (lbs, kg)</b><br>NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 3.3                                                                          | <b>Configuration</b><br>NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 3.4                                                                          | <b>Noise (in dBA)</b><br>NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 3.5                                                                          | <b>Heat dissipation</b><br>NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 3.6                                                                          | <b>Mobility, portability</b><br>Handheld device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO <sub>2</sub> ....) |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 4.1                                                                          | <b>Power Requirements</b><br>NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 4.2                                                                          | <b>Battery operated</b><br>Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 4.3                                                                          | <b>Tolerance (to variations, shutdowns)</b><br>NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 4.4                                                                          | <b>Protection</b><br>NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 4.5                                                                          | <b>Power consumption</b><br>NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |

| 5. ACCESSORIES, SPARE PARTS, CONSUMABLES         |                                                                                                                                     |                                                                                                                                                                                                                                                                                                         |
|--------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 5.1                                              | Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)                    | 1) Replacement bulb/illumination source -2 Nos.<br>2) Storage case (rigid and steady).                                                                                                                                                                                                                  |
| BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS  |                                                                                                                                     |                                                                                                                                                                                                                                                                                                         |
| 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS |                                                                                                                                     |                                                                                                                                                                                                                                                                                                         |
| 6.1                                              | Atmosphere/Ambiance (air conditioning, humidity, dust...)                                                                           | 1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90% in ideal circumstances.<br>2) Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. |
| 6.2                                              | User's care, Cleaning, Disinfection & Sterility issues                                                                              | Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.                                                                                               |
| 7. STANDARDS AND SAFETY                          |                                                                                                                                     |                                                                                                                                                                                                                                                                                                         |
| 7.1                                              | Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international | 1) Should have IEC 60601-1/IEC 60601-1-2/CE (EU) certificate;<br>2) Optical radiation hazards with ophthalmoscopes: ISO 10942 or ISO 15004;<br>3) Manufacturer/supplier should have ISO 13485 certificate for quality standard;                                                                         |
| 8. TRAINING AND INSTALLATION                     |                                                                                                                                     |                                                                                                                                                                                                                                                                                                         |
| 8.1                                              | Pre-installation requirements: nature, values, quality, tolerance                                                                   | NA                                                                                                                                                                                                                                                                                                      |
| 8.2                                              | Requirements for sign-off                                                                                                           | Certificate of calibration and inspection from the manufacturer.                                                                                                                                                                                                                                        |
| 8.3                                              | Training of staff (medical, paramedical, technicians)                                                                               | 1) Training of users on operation and basic maintenance;<br>2) Advanced maintenance tasks required shall be documented.                                                                                                                                                                                 |
| 9. WARRANTY AND MAINTENANCE                      |                                                                                                                                     |                                                                                                                                                                                                                                                                                                         |
| 9.1                                              | Warranty                                                                                                                            | 3 years including bulb.                                                                                                                                                                                                                                                                                 |
| 9.2                                              | Maintenance tasks                                                                                                                   | 1) Maintenance manual detailing;<br>2) Complete maintenance schedule;                                                                                                                                                                                                                                   |
| 9.3                                              | Service contract clauses, including prices                                                                                          | 1) The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee/warranty period should be attached;<br>2) Free servicing (min. 2/year) during warranty period;                                                                   |
| 10. DOCUMENTATION                                |                                                                                                                                     |                                                                                                                                                                                                                                                                                                         |
| 10.1                                             | Operating manuals, service manuals, other manuals                                                                                   | Should provide 2 sets (hardcopy) of:<br>1) User, technical, maintenance and service manuals to be supplied along with machine diagrams;<br>2) List of equipment and procedures required for local calibration and routine maintenance;<br>3) Certificate of calibration and inspection;                 |
| 10.2                                             | Other accompanying documents                                                                                                        | List of important spares and accessories, with their part numbers and cost;                                                                                                                                                                                                                             |
| 11. NOTES                                        |                                                                                                                                     |                                                                                                                                                                                                                                                                                                         |
| 11.1                                             | Service Support Contact details (Hierarchy Wise; including a toll free/landline number)                                             | Contact details of manufacturer, supplier and local service agent to be provided;<br>Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer;                                                                                                                                                 |
| 11.2                                             | Recommendations or warnings                                                                                                         | Any warning signs would be adequately displayed .                                                                                                                                                                                                                                                       |

# MOBILE X-RAY

|                                |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|--------------------------------|-------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                  |                                                             | 4.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Date:                          |                                                             | 27/2/2015                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Done by : (name / institution) |                                                             | HCT/ NHSRC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| NAME AND CODING                |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| GMDN name                      |                                                             | Basic diagnostic x-ray system                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| GMDN code(s)                   |                                                             | CT 692                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| GENERAL                        |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 1 USE                          |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 1.1                            | Clinical purpose                                            | General-purpose mobile diagnostic x-ray system used in a variety of routine x-ray imaging applications.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 1.2                            | Used by clinical department/ ward                           | Radiology services in NICU & PICU                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| TECHNICAL                      |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 2 TECHNICAL CHARACTERISTICS    |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 2.1                            | Technical characteristics (specific to this type of device) | <ol style="list-style-type: none"> <li>1) High Frequency generator of 40KHz or more compatible with conventional and computerized radiography.</li> <li>2) Must have a digital display of mAs and kV, and an electronic timer.</li> <li>3) Ergonomically designed unit with total soft touch switches for various operations.</li> <li>4) Self Diagnostic Program with indicators for earthing fault error, KV error or filament error.</li> <li>5) kV range at least 40kV to 125kV, digitally displayed mAs range at least 0.5 to 200 mAs or more.</li> <li>6) Exposure time range at least 1 ms to 5s.</li> <li>7) Automatic exposure control facility required.</li> <li>8) Tube power rating at least 20 kW.</li> <li>9) Adjustable multileaf collimator, rotatable <math>\pm 90</math> deg with patient centering light.</li> <li>10) Must be supplied with protective dust cover at least for control panel.</li> <li>11) Should be compatible with various basinet size in NICU &amp; PICU.</li> <li>12) The generator should have microprocessor/micro-controller based electric overload system.</li> </ol> |
| 2.2                            | Settings                                                    | <ol style="list-style-type: none"> <li>1) KV increase &amp; decrease switches.</li> <li>2) mAs increase &amp; decrease switches.</li> <li>3) Machine On/Off Switch.</li> <li>4) Collimator lamp On/Off switch.</li> <li>5) X-rays ON indicator should available.</li> <li>6) Foot switch should available for trigger X-rays.</li> </ol>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 2.3                            | User's interface                                            | The exposure release switch should be detachable, with a cord of at least 5 meters long.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |

|                                                                                   |                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----------------------------------------------------------------------------------|--------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2.4                                                                               | Software and/or standard of communication                    | in built;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>3 PHYSICAL CHARACTERISTICS</b>                                                 |                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 3.1                                                                               | Dimensions (metric)                                          | Unit should have max. 7 foot in height, 2 foot in width and 5 foot in length.                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 3.2                                                                               | Weight (lbs, kg)                                             | Maximum 500 Kg.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 3.3                                                                               | Configuration                                                | <ol style="list-style-type: none"> <li>1) The unit must have an effective braking system for parking, transport and emergency braking.</li> <li>2) The tube stand must be fully counterbalanced for rotation in all directions.</li> <li>3) It must have an articulated arm for imaging with any patient position.</li> <li>4) All cables should be concealed in the arm system.</li> </ol>                                                                                                                                            |
| 3.4                                                                               | Noise (in Dba)                                               | <60dB;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 3.5                                                                               | heat dissipation                                             | Should maintain normal temp and the heat disbursed through a exhaust fan.                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 3.6                                                                               | Mobility, portability                                        | <ol style="list-style-type: none"> <li>1) When motor or battery is non-functional, free movement by pushing must be possible with 360 degree rotation and manual locking for various movement.</li> <li>2) The unit must have cassette storage facility.</li> <li>3) Motorized movement capable of ascending slope of up to 7 deg from horizontal.</li> <li>4) Unit base wheels must be easily accessible for cleaning.</li> <li>5) Whole unit moved by battery powered motor or pushed by operator to required department.</li> </ol> |
| <b>4 ENERGY SOURCE (electricity, ups, solar, gas, water, CO<sub>2</sub> ....)</b> |                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 4.1                                                                               | Voltage (value, AC or DC, monophase or triphase)             | Input: 220VAC $\pm$ 10%, 50 Hz.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 4.2                                                                               | Battery operated                                             | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 4.3                                                                               | Tolerance (to variations, shutdowns)                         | Resettable over-current breaker to be fitted on both live and neutral supply lines.                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 4.4                                                                               | Protection                                                   | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 4.5                                                                               | Power consumption                                            | Voltage corrector / stabilizer to allow operation at $\pm$ 10% of local rated voltage.                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 4.6                                                                               | Other energy supplies                                        | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>5 ACCESSORIES, SPARE PARTS, CONSUMABLES</b>                                    |                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 5.1                                                                               | Accessories (mandatory, standard, optional)                  | To be supplied with 2 Nos. adult size protective lead apron and 1 No. child/ neonate size protective lead shield.                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 5.2                                                                               | Spare parts (main ones)                                      | Control cable, transformer, exposure switch.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 5.3                                                                               | Consumables / reagents (open, closed system)                 | X-ray films dealt in different tender.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 5.4                                                                               | Others                                                       | Radiation hazard warning signs to be supplied with unit.                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS</b>                            |                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 6.1                                                                               | Atmosphere / Ambiance (air conditioning, humidity, dust ...) | <ol style="list-style-type: none"> <li>1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90% in ideal circumstances.</li> <li>2) Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.</li> </ol>                                                                                                                                                                        |
| 6.2                                                                               | User's care, Cleaning, Disinfection & Sterility issues       | Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.                                                                                                                                                                                                                                                                                                                              |



| 7 STANDARDS AND SAFETY      |                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 7.1                         | <b>Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international</b> | <ol style="list-style-type: none"> <li>1) Electrical safety conforms to standards for electrical safety IEC-60601, Class I.</li> <li>2) Radiation safety to be certified to IAEA standards and AERB type approval (national standards).</li> <li>3) Shall meet IEC 60601-1, IEC 60601-1-2, IEC 60601-1-3 and IEC 60601-2-28 (X-ray Tube) standard requirement.</li> <li>4) Manufacturer / supplier should have ISO 13485 certificate for quality standard.</li> </ol> |
| 8 TRAINING AND INSTALLATION |                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 8.1                         | <b>Pre-installation requirements: nature, values, quality, tolerance</b>                                                                   | <ol style="list-style-type: none"> <li>1) Dosimeter should be available with the operator.</li> <li>2) Lead gown to be supplied for the operator.</li> </ol>                                                                                                                                                                                                                                                                                                          |
| 8.2                         | <b>Requirements for sign-off</b>                                                                                                           | <ol style="list-style-type: none"> <li>1) Supplier to perform installation, safety and operation checks before handover.</li> <li>2) Local clinical staff to affirm completion of installation.</li> </ol>                                                                                                                                                                                                                                                            |
| 8.3                         | <b>Training of staff (medical, paramedical, technicians)</b>                                                                               | <ol style="list-style-type: none"> <li>1) Training of users in operation and basic maintenance shall be provided.</li> <li>2) Training of users in radiation safety shall be provided.</li> </ol>                                                                                                                                                                                                                                                                     |
| 8.4                         | <b>Others</b>                                                                                                                              | Advanced maintenance tasks required shall be documented.                                                                                                                                                                                                                                                                                                                                                                                                              |
| 9 WARRANTY AND MAINTENANCE  |                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 9.1                         | <b>Warranty</b>                                                                                                                            | 3 years;                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 9.2                         | <b>Maintenance tasks</b>                                                                                                                   | Maintenance manual detailing complete maintaining schedule.                                                                                                                                                                                                                                                                                                                                                                                                           |
| 9.3                         | <b>Service contract clauses, including prices</b>                                                                                          | Free servicing ( min. 3/year) during warranty period.                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 9.4                         | <b>Others</b>                                                                                                                              | The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee / warranty period should be attached.                                                                                                                                                                                                                                                                                             |
| 10 DOCUMENTATION            |                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 10                          | <b>Operating manuals, service manuals, other manuals</b>                                                                                   | Should provide 2 sets(hardcopy) of:- <ol style="list-style-type: none"> <li>1) User, technical, maintenance and service manuals along with machine diagrams.</li> <li>2) Advanced maintenance tasks documentation.</li> </ol>                                                                                                                                                                                                                                         |
| 10                          | <b>Other accompanying documents</b>                                                                                                        | <ol style="list-style-type: none"> <li>1) Certificate of calibration and inspection to be provided.</li> <li>2) List to be provided of important spares and accessories, with their part numbers and cost.</li> </ol>                                                                                                                                                                                                                                                 |
| 10                          | <b>Recommendations for maintenance</b>                                                                                                     | List to be provided of equipment and procedures required for local calibration and routine maintenance.                                                                                                                                                                                                                                                                                                                                                               |
| 10                          | <b>Others</b>                                                                                                                              | Contact details of manufacturer, supplier and local service agent to be provided.                                                                                                                                                                                                                                                                                                                                                                                     |
| 11 NOTES                    |                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 11                          | <b>Other information</b>                                                                                                                   | Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer.                                                                                                                                                                                                                                                                                                                                                                                                    |
| 11                          | <b>Recommendations or warnings</b>                                                                                                         | Any recommendations for best use and supplementary warning for safety should be declared.                                                                                                                                                                                                                                                                                                                                                                             |

# BILIRUBINOMETER

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|--------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                  | 4                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Date:                          | 27/2/2015                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Done by : (name / institution) | HCT/NHSRC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| NAME AND CODING                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| GMDN name                      | Bilirubinometer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| GMDN code(s)                   | CT834                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| GENERAL                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 1 USE                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 1.1                            | <b>Clinical purpose</b><br>Determining the concentration of bilirubin in the blood or other clinical specimen, most commonly to rapidly assess hyperbilirubinemia in neonates.                                                                                                                                                                                                                                                                                                                                                                                                            |
| 1.2                            | <b>Used by clinical department/ward</b><br>NICU/PICU                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| TECHNICAL                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 2 TECHNICAL CHARACTERISTICS    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 2.1                            | <b>Technical characteristics (specific to this type of device)</b><br>1) Sample volume of < 100 µL required, automatic calibration facility.<br>2) Total bilirubin concentration measurable (at least) in range of 0 to 30 mg/dl.<br>3) Time for total concentration measurement: ≤ 5 seconds.<br>4) Should have filters: 455 and 575 nm (± 2%).<br>5) Should have error rate less than 5%.<br>6) Should have resolution- 0.1 mg/dl.<br>7) Automatic correction for Hemoglobin.<br>8) Measuring cell: Direct Hematocrit capillary readings.<br>9) heparinized hematocrit glass capillary. |
| 2.2                            | <b>Settings</b><br>Method to recalibrate / save current calibration, set sample size.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 2.3                            | <b>User's interface</b><br>Manual interface.<br>Backlit display with easy viewing in all ambient light levels.                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 2.4                            | <b>Software and/or standard of communication(where ever required)</b><br>Inbuilt software.<br>Convenient and quick USB interface.                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 3 PHYSICAL CHARACTERISTICS     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 3.1                            | <b>Dimensions (metric)</b><br>Approx. 110 x 150 x 200 mm.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 3.2                            | <b>Weight (lbs, kg)</b><br>5 kg - 15 kgs                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 3.3                            | <b>Configuration</b><br>(Ex : Compact, modular, to be fixed to walls, ceiling, etc).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 3.4                            | <b>Noise (in dBA)</b><br><60dB                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 3.5                            | <b>Heat dissipation</b><br>Heat Dissipation:<br>Should maintain nominal temp and the heat should be disbursed through an cooling mechanism.                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 3.6                            | <b>Mobility, portability</b><br>Easy and safe transport to be possible by hand, stable when tabletop mounted;                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |

| 4 ENERGY SOURCE (Electricity, Ups, Solar, Gas, Water, Co2 ....) |                                                                                                                                    |                                                                                                                                                                                                                                                                                                               |
|-----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4.1                                                             | Power Requirements                                                                                                                 | 220VAC $\pm$ 10%, 50 Hz;                                                                                                                                                                                                                                                                                      |
| 4.2                                                             | Battery operated                                                                                                                   | Yes (optional)                                                                                                                                                                                                                                                                                                |
| 4.3                                                             | Tolerance (to variations, shutdowns)                                                                                               | Voltage corrector / stabilizer to allow operation at $\pm$ 10% of local rated voltage.                                                                                                                                                                                                                        |
| 4.4                                                             | Protection                                                                                                                         | NA                                                                                                                                                                                                                                                                                                            |
| 4.5                                                             | Power consumption                                                                                                                  | NA                                                                                                                                                                                                                                                                                                            |
| 4.6                                                             | Other energy supplies                                                                                                              | Length of mains power cable should be at least 3 meters.                                                                                                                                                                                                                                                      |
| 5 ACCESSORIES, SPARE PARTS, CONSUMABLES                         |                                                                                                                                    |                                                                                                                                                                                                                                                                                                               |
| 5.1                                                             | Accessories (mandatory, standard, optional)                                                                                        | Hard and splash-proof case to be supplied.                                                                                                                                                                                                                                                                    |
| 5.2                                                             | Spare parts (main ones)                                                                                                            | 1) Spare/replaceable fuses - 2 sets.<br>2) Reagents and capillary tubes sufficient for minimum 100 tests.<br>3) Reagents and consumables per test should be declared.                                                                                                                                         |
| 5.3                                                             | Consumables / reagents (open, closed system)                                                                                       | 1) Capillary tubes, haemofluorometric reagents (e.g., aqueous cyanide salt with stabilizers, if applicable).<br>2) Price of all Consumables to be mentioned.                                                                                                                                                  |
| BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS             |                                                                                                                                    |                                                                                                                                                                                                                                                                                                               |
| 6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS                  |                                                                                                                                    |                                                                                                                                                                                                                                                                                                               |
| 6.1                                                             | Atmosphere / Ambiance (air conditioning, humidity, dust ...)                                                                       | 1) Operating condition:<br>Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90% in ideal circumstances.<br>2) Storage condition:<br>Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. |
| 6.2                                                             | User's care, Cleaning, Disinfection & Sterility issues                                                                             | Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.                                                                                                     |
| 7 STANDARDS AND SAFETY                                          |                                                                                                                                    |                                                                                                                                                                                                                                                                                                               |
| 7.1                                                             | Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type);Local and/or international | 1) Should be CE (EU)/FDA (US) approved product.<br>2) Manufacturer / supplier should have ISO 13485 certificate for quality standard.<br>3) Should have IEC 61010 certificate.                                                                                                                                |
| 8 TRAINING AND INSTALLATION                                     |                                                                                                                                    |                                                                                                                                                                                                                                                                                                               |
| 8.1                                                             | Pre-installation requirements: nature, values, quality, tolerance                                                                  | Availability of 5Amps electrical socket.                                                                                                                                                                                                                                                                      |
| 8.2                                                             | Requirements for sign-off                                                                                                          | 1) Supplier to perform installation, safety and operation checks before handover.<br>2) Local clinical staff to affirm completion of installation.                                                                                                                                                            |
| 8.3                                                             | Training of staff (medical, paramedical, technicians)                                                                              | 1) Training of users on operation and basic maintenance.<br>2) Advanced maintenance tasks required shall be documented.                                                                                                                                                                                       |
| 9 WARRANTY AND MAINTENANCE                                      |                                                                                                                                    |                                                                                                                                                                                                                                                                                                               |
| 9.1                                                             | Warranty                                                                                                                           | 3 years                                                                                                                                                                                                                                                                                                       |
| 9.2                                                             | Maintenance tasks                                                                                                                  | 1) Maintenance manual detailing.<br>2) Complete maintenance schedule.                                                                                                                                                                                                                                         |
| 9.3                                                             | Service contract clauses, including prices                                                                                         | 1) The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee / warranty period should be attached.<br>2) Free servicing ( min. 2/year) during warranty period.                                                                      |

| 10 DOCUMENTATION |                                                                                                |                                                                                                                                                                                                                                                                                                                                                                            |
|------------------|------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10.1             | <b>Operating manuals, service manuals, other manuals</b>                                       | <p>Should provide 2 sets(hardcopy) of:-</p> <ol style="list-style-type: none"> <li>1) User, technical and maintenance manuals to be supplied in english/hindi language along with machine diagrams.</li> <li>2) List of equipment and procedures required for local calibration and routine maintenance.</li> <li>3) Certificate of calibration and inspection.</li> </ol> |
| 10.2             | <b>Other accompanying documents</b>                                                            | List of important spares and accessories, with their part numbers and cost.                                                                                                                                                                                                                                                                                                |
| 11 NOTES         |                                                                                                |                                                                                                                                                                                                                                                                                                                                                                            |
| 11.1             | <b>Service Support Contact details (Hierarchy Wise; including a toll free/landline number)</b> | <p>Contact details of manufacturer, supplier and local service agent to be provided.</p> <p>Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer.</p>                                                                                                                                                                                                         |

# ECG UNIT

|                              |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|------------------------------|-------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                |                                                             | 1.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Date:                        |                                                             | SEPT 2014                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Done by : (name/institution) |                                                             | HCT/NHSRC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| NAME AND CODING              |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| GMDN name                    |                                                             | Multichannel Electrocardiographic                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| GMDN code(s)                 |                                                             | CT 1115                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| GENERAL                      |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 1. USE                       |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 1.1                          | Clinical purpose                                            | Continuously detect, measure, and display a patient's electrocardiogram (ECG) through leads and sensors attached to the patient.                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 1.2                          | Used by clinical department/ward                            | All                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 1.3                          | Overview of functional requirements                         | <p>Continuous display of patient ECG and heart rate on screen.</p> <p>Allows display of single, 5 lead ECG or simultaneous display of at least 5 waves selected from up to 12 points.</p> <p>Operator can set audiovisual alarm levels for low or high heart rate.</p> <p>Operates from mains voltage or from internal rechargeable battery.</p> <p>Patient connectors that are sterilisable and reusable are preferred, though reusable cables that attach to disposable connection patches are also acceptable.</p> <p>Hard copy printout of traces will be required.</p> |
| TECHNICAL                    |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 2. TECHNICAL CHARACTERISTICS |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 2.1                          | Technical characteristics (specific to this type of device) | <ol style="list-style-type: none"> <li>Heart rate measurement range to be at least 30 to 250 bpm, with accuracy better than <math>\pm 5</math> bpm.</li> <li>Heart rate trend display of at least previous 24 hours.</li> <li>Arrhythmia detection facility required; minimum gradation of 1 bpm.</li> <li>Heart rate measurement range to be at least 30 to 250 bpm, with accuracy better than <math>\pm 5</math> bpm.</li> </ol>                                                                                                                                          |
| 2.2                          | Settings                                                    | Audiovisual alarms required: high and low heart rate (operator variable settings), cardiac arrhythmia, sensor/wire disconnected, low battery.                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 2.3                          | User's interface                                            | Manual                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 2.4                          | Software and/or standard of communication                   | In built                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 3. PHYSICAL CHARACTERISTICS  |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 3.1                          | Dimensions (metric)                                         | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 3.2                          | Weight (lbs, kg)                                            | less than 5 kgs                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 3.3                          | Configuration                                               | <p>Case is to be hard and splashproof.</p> <p>Display must allow easy viewing in all ambient light levels.</p> <p>Supplied in protective case for clean storage and safe transport.</p>                                                                                                                                                                                                                                                                                                                                                                                     |

|                                                                                    |                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                              |
|------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3.4                                                                                | Noise (in dBA)                                                                                                                      | <50 dB                                                                                                                                                                                                                                                                                                                                                       |
| 3.5                                                                                | heat dissipation                                                                                                                    | Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through a exhaust cooling fan.                                                                                                                                                                                                                                               |
| 3.6                                                                                | Mobility, portability                                                                                                               | Supplied in protective case for clean storage and safe transport.                                                                                                                                                                                                                                                                                            |
| <b>4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO<sub>2</sub> ....)</b> |                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                              |
| 4.1                                                                                | Voltage (value, AC or DC, monophasic or triphase)                                                                                   | 220 to 240V, 50 Hz                                                                                                                                                                                                                                                                                                                                           |
| 4.2                                                                                | Battery operated                                                                                                                    | Battery powered, silenceable alarm for power failure.<br>Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit.<br>Internal, replaceable, rechargeable battery allows operation for at least one hour in the event of power failure.                                                              |
| 4.3                                                                                | Tolerance (to variations, shutdowns)                                                                                                | Voltage corrector/stabilizer to allow operation at $\pm 30\%$ of local rated voltage.                                                                                                                                                                                                                                                                        |
| 4.4                                                                                | Protection                                                                                                                          | Electrical protection provided by fuses in both live and neutral supply lines.                                                                                                                                                                                                                                                                               |
| 4.5                                                                                | Power consumption                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                              |
| 4.6                                                                                | Other energy supplies                                                                                                               | Mains cable to be at least 3m length.                                                                                                                                                                                                                                                                                                                        |
| <b>5. ACCESSORIES, SPARE PARTS, CONSUMABLES</b>                                    |                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                              |
| 5.1                                                                                | Accessories (mandatory, standard, optional)                                                                                         | 12 lead ECG cable.<br>5 lead ECG cable (if option offered).<br>100 sets of ECG connection electrodes (if disposable type).<br>5 sets of ECG connection electrodes (if reusable type).                                                                                                                                                                        |
| 5.2                                                                                | Spare parts (main ones)                                                                                                             | Two sets of spare fuses (if non-resettable fuses used)                                                                                                                                                                                                                                                                                                       |
| 5.3                                                                                | Consumables/reagents (open, closed system)                                                                                          | 5 tubes electrode gel (if required)                                                                                                                                                                                                                                                                                                                          |
| <b>6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS</b>                            |                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                              |
| 6.1                                                                                | Atmosphere/Ambiance (air conditioning, humidity, dust ...)                                                                          | Operating condition:<br>– Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances.                                                                                                                                                                                               |
| 6.2                                                                                | User's care, Cleaning, Disinfection & Sterility issues                                                                              | The case is to be cleanable with alcohol or chlorine wipes.                                                                                                                                                                                                                                                                                                  |
| <b>7. STANDARDS AND SAFETY</b>                                                     |                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                              |
| 7.1                                                                                | Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international | Should be FDA/CE approved product; Manufacturer/supplier should have ISO 13485 certificate for quality standard. Electrical safety conforms to standards for electrical safety IEC-60601-1.<br>Shall meet IEC-60601-1-2 (General requirements for safety - electromagnetic compatibility) and IEC 60601-2-25 (essential performance of electrocardiographs). |
| <b>8. TRAINING AND INSTALLATION</b>                                                |                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                              |
| 8.1                                                                                | Pre-installation requirements: nature, values, quality, tolerance                                                                   | Availability of 5 amp/15 amp. Electrical socket.                                                                                                                                                                                                                                                                                                             |
| 8.2                                                                                | Requirements for sign-off                                                                                                           | Supplier to perform installation, safety and operation checks before handover.<br>Local clinical staff to affirm completion of installation.                                                                                                                                                                                                                 |
| 8.3                                                                                | Training of staff (medical, paramedical, technicians)                                                                               | Training of users in operation and basic maintenance shall be provided.<br>Advanced maintenance tasks required shall be documented.                                                                                                                                                                                                                          |
| <b>9. WARRANTY AND MAINTENANCE</b>                                                 |                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                              |
| 9.1                                                                                | Warranty                                                                                                                            | 3 year                                                                                                                                                                                                                                                                                                                                                       |

|                          |                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|--------------------------|----------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 9.2                      | <b>Maintenance tasks</b>                                 | Maintenance manual detailing complete maintaining schedule.                                                                                                                                                                                                                                                                                                                                                                            |
| 9.3                      | <b>Service contract clauses, including prices</b>        | Warranty of one year with free servicing (min. 3) during warranty.                                                                                                                                                                                                                                                                                                                                                                     |
| 9.4                      | <b>Others</b>                                            | The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee/warranty period should be attached.                                                                                                                                                                                                                                                                |
| <b>10. DOCUMENTATION</b> |                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 10.1                     | <b>Operating manuals, service manuals, other manuals</b> | User, technical and maintenance manuals to be supplied in english language.<br>Certificate of calibration and inspection to be provided.<br>List to be provided of equipment and procedures required for local calibration and routine maintenance.<br>List to be provided of important spares and accessories, with their part numbers and cost.<br>Contact details of manufacturer, supplier and local service agent to be provided. |
| 10.2                     | <b>Other accompanying documents</b>                      | User/Technical/Maintenance manuals to be supplied in English.                                                                                                                                                                                                                                                                                                                                                                          |
| <b>11. NOTES</b>         |                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 11.1                     | <b>Other information</b>                                 | Any Contract (AMC/MC/add-hoc) to be declared by the manufacturer.                                                                                                                                                                                                                                                                                                                                                                      |
| 11.2                     | <b>Recommendations or warnings</b>                       | Any recommendations for best use and supplementary warning for safety should be declared.                                                                                                                                                                                                                                                                                                                                              |

# LOW COST GLUCOMETER

|                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                                                                | 1.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Date:                                                                        | 3/9/2014                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Done by : (name/institution)                                                 | HCT/NHSRC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| NAME AND CODING                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| GMDN name                                                                    | Glucose self-testing                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| GMDN code(s)                                                                 | CT296                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| GENERAL                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 1. USE                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 1.1                                                                          | <b>Clinical purpose</b><br>It intended to be used together for testing, either at the point-of-care or in self-testing by a layperson, for the quantitative measurement of glucose and/or ketones in a whole blood clinical specimen.                                                                                                                                                                                                                                                        |
| 1.2                                                                          | <b>Used by clinical department/ward</b><br>All                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| TECHNICAL                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 2. TECHNICAL CHARACTERISTICS                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 2.1                                                                          | <b>Technical characteristics (specific to this type of device)</b><br>Should have reading range/linearity from 30 to 600 mg/dl;<br>Should have a maximum reading time of less than 10 seconds;<br>Should use a minimum blood sample less than 1.5µl;<br>Should have a minimum memory of 50 tests; accuracy +/-10% and reproducibility +/-5%;<br>Packing of strips should be such that there are not more than 50 strips/pack. The strips should be readily available throughout the country; |
| 2.2                                                                          | <b>Settings</b><br>Should have automatic code detection facility , display of sugar in Mg/dl and NOT in mili moles.                                                                                                                                                                                                                                                                                                                                                                          |
| 2.3                                                                          | <b>User's interface</b><br>LCD display                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 2.4                                                                          | <b>Software and/or standard of communication (where ever required)</b><br>inbuilt; .Should have facility to ensure accuracy of measurements.                                                                                                                                                                                                                                                                                                                                                 |
| 3. PHYSICAL CHARACTERISTICS                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 3.1                                                                          | <b>Dimensions (metric)</b><br>Handheld device                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 3.2                                                                          | <b>Weight (lbs, kg)</b><br>Handheld device                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 3.3                                                                          | <b>Configuration</b><br>Electrochemical/colorimetric/color sensing technology.                                                                                                                                                                                                                                                                                                                                                                                                               |
| 3.4                                                                          | <b>Noise (in dBA), heat dissipation</b><br>NA                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 3.5                                                                          | <b>Mobility, portability</b><br>Handheld                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO <sub>2</sub> ....) |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 4.1                                                                          | <b>Power Requirements</b><br>Battery powered                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 4.2                                                                          | <b>Battery operated</b><br>3-volt lithium coin cell battery or 2 x (AAA) Alkaline Batteries.                                                                                                                                                                                                                                                                                                                                                                                                 |



|                                                         |                                                                                                                                     |                                                                                                                                                                                                                                                    |
|---------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4.3                                                     | Tolerance (to variations, shutdowns)                                                                                                | NA                                                                                                                                                                                                                                                 |
| 4.4                                                     | Protection                                                                                                                          | NA                                                                                                                                                                                                                                                 |
| 4.5                                                     | Power consumption                                                                                                                   | NA                                                                                                                                                                                                                                                 |
| 4.6                                                     | Other energy supplies                                                                                                               | NA                                                                                                                                                                                                                                                 |
| <b>5. ACCESSORIES, SPARE PARTS, CONSUMABLES</b>         |                                                                                                                                     |                                                                                                                                                                                                                                                    |
| 5.1                                                     | Accessories & Spare parts                                                                                                           | NA                                                                                                                                                                                                                                                 |
| 5.2                                                     | Consumables/reagents (open, closed system)                                                                                          | Glucose strips(able to use capillary blood samples) with availability in local market, shelf life of strips should be 12 months, the cost of strips for the next five years should be declared (for cost comparison)- with use of two strips/ day. |
| <b>BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS</b>  |                                                                                                                                     |                                                                                                                                                                                                                                                    |
| <b>6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS</b> |                                                                                                                                     |                                                                                                                                                                                                                                                    |
| 6.1                                                     | Atmosphere/Ambiance (air conditioning, humidity, dust...)                                                                           | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.                    |
| 6.2                                                     | User's care, Cleaning, Disinfection & Sterility issues                                                                              | The unit should be cleanable with alcohol.                                                                                                                                                                                                         |
| <b>7. STANDARDS AND SAFETY</b>                          |                                                                                                                                     |                                                                                                                                                                                                                                                    |
| 7.1                                                     | Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international | US FDA or CE (EU) and BIS or ISO 13485 certified.                                                                                                                                                                                                  |
| <b>8. TRAINING AND INSTALLATION</b>                     |                                                                                                                                     |                                                                                                                                                                                                                                                    |
| 8.1                                                     | Pre-installation requirements: nature, values, quality, tolerance                                                                   | NA                                                                                                                                                                                                                                                 |
| 8.2                                                     | Requirements for sign-off                                                                                                           | NA                                                                                                                                                                                                                                                 |
| 8.3                                                     | Training of staff (medical, paramedical, technicians)                                                                               | Required                                                                                                                                                                                                                                           |
| <b>9. WARRANTY AND MAINTENANCE</b>                      |                                                                                                                                     |                                                                                                                                                                                                                                                    |
| 9.1                                                     | Warranty                                                                                                                            | 2 years; shelf life of minimum 12 months for strips from the date of manufacture; strips should work minimum 3 months from opening of pack.                                                                                                        |
| 9.2                                                     | Maintenance tasks                                                                                                                   | Should require no routine maintenance.                                                                                                                                                                                                             |
| 9.3                                                     | Service contract clauses, including prices                                                                                          | Should have life time replacement offer.                                                                                                                                                                                                           |
| <b>10. DOCUMENTATION</b>                                |                                                                                                                                     |                                                                                                                                                                                                                                                    |
| 10.1                                                    | Operating manuals, service manuals, other manuals                                                                                   | Required                                                                                                                                                                                                                                           |
| 10.3                                                    | Recommendations for maintenance                                                                                                     | To Be provided during installation                                                                                                                                                                                                                 |
| <b>11. NOTES</b>                                        |                                                                                                                                     |                                                                                                                                                                                                                                                    |
| 11.1                                                    | Service Support Contact details (Hierarchy Wise; including a toll free/landline number)                                             | Should provide complete contact details of sales and service departments.                                                                                                                                                                          |
| 11.2                                                    | Recommendations or warnings                                                                                                         |                                                                                                                                                                                                                                                    |

# BLOOD GAS ANALYZER

|                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                | 2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Date:                        | JULY 2014                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Done by : (name/institution) | HCT/NHSRC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| NAME AND CODING              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| GMDN name                    | Blood gas monitors/monitoring systems and associated devices.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| GMDN code(s)                 | CT262                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| GENERAL                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 1. USE                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 1.1                          | <b>Clinical purpose</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|                              | Determining the concentration of bilirubin in the blood or other clinical specimen, most commonly to rapidly assess hyperbilirubinemia in neonates.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 1.2                          | <b>Clinical department/ward</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|                              | NICU/PICU                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| TECHNICAL                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 2. TECHNICAL CHARACTERISTICS |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 2.1                          | <b>Technical characteristics</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|                              | 1) Should measure analyte pH and minimum measuring range 6.8 -7.8 pH Units with resolution of 0.01;<br>2) Should measure analyte PO <sub>2</sub> and minimum measuring range 0-760mmHg;<br>3) Should measure analyte pCO <sub>2</sub> and minimum measuring range 5-100 mm Hg;<br>4) Should measure analyte Na <sup>+</sup> and minimum measuring range 100-180mmol/L;<br>5) Should measure analyte K <sup>+</sup> and minimum measuring range 1-10mmol/l;<br>6) Should measure analyte Ca <sup>++</sup> and minimum measuring range 0.25-5.00mmol/l;<br>7) Should measure analyte Hct and minimum measuring range 15-70%;<br>8) Should calculate analyte tHb and minimum measuring range 3.0 -23g/dL;<br>9) Should have feature of data storage for minimum 50 samples results<br>10) Software includes printouts of Levey-Jenning charts for quality control requirements;<br>11) Should have disposable cartridges for 300 a minimum of 300 samples; no membrane maintenance or replacement is required;<br>14) External source of gas not required (not mandatory);<br>15) Analyzing time should have <120 seconds;<br>16) Should provide automatic error detection; |
| 2.3                          | <b>Settings</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|                              | Method to recalibrate/save current calibration, set sample size.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 2.4                          | <b>User's interface</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|                              | Backlit display with easy viewing in all ambient light levels.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 2.5                          | <b>Software and/or standard of communication</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|                              | Electronic                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |

| 3. PHYSICAL CHARACTERISTICS                                                  |                                                                                                                                     |                                                                                                                                                                                                                                                                                                         |
|------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3.1                                                                          | Dimensions (metric)                                                                                                                 | NA                                                                                                                                                                                                                                                                                                      |
| 3.2                                                                          | Weight (lbs, kg)                                                                                                                    | Max. 10 kgs excluding the cartridges                                                                                                                                                                                                                                                                    |
| 3.3                                                                          | Configuration                                                                                                                       | Should have compact size;                                                                                                                                                                                                                                                                               |
| 3.4                                                                          | Noise (in dBA)                                                                                                                      | <60dB                                                                                                                                                                                                                                                                                                   |
| 3.5                                                                          | heat dissipation                                                                                                                    | heat disbursed through a exhaust fan (if applicable).                                                                                                                                                                                                                                                   |
| 3.6                                                                          | Mobility, portability                                                                                                               | Easy and safe transport to be possible by hand, stable when tabletop mounted.                                                                                                                                                                                                                           |
| 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO <sub>2</sub> ....) |                                                                                                                                     |                                                                                                                                                                                                                                                                                                         |
| 4.1                                                                          | Voltage (value, AC or DC, monophasic or triphasic)                                                                                  | 220VAC $\pm$ 10%, 50 Hz                                                                                                                                                                                                                                                                                 |
| 4.2                                                                          | Battery operated                                                                                                                    | Yes                                                                                                                                                                                                                                                                                                     |
| 4.3                                                                          | Tolerance (to variations, shutdowns)                                                                                                | Voltage corrector/SMPS, stabilizer to allow operation at $\pm$ 10% of rated voltage, Electrical protection by resettable over-current breakers or replaceable fuses fitted in both live and neutral lines.                                                                                              |
| 4.4                                                                          | Protection                                                                                                                          | Resettable over-current mains fuse to be incorporated;                                                                                                                                                                                                                                                  |
| 4.5                                                                          | Power consumption                                                                                                                   | NA                                                                                                                                                                                                                                                                                                      |
| 4.6                                                                          | Other energy supplies                                                                                                               | Power cable to be at least 3mtr in length;                                                                                                                                                                                                                                                              |
| 5. ACCESSORIES, SPARE PARTS, CONSUMABLES                                     |                                                                                                                                     |                                                                                                                                                                                                                                                                                                         |
| 5.1                                                                          | Accessories (mandatory, standard, optional)                                                                                         | Hard and splash-proof case to be supplied;                                                                                                                                                                                                                                                              |
| 5.2                                                                          | Spare parts (main ones)                                                                                                             | Two sets of spare/replaceable fuses, reagents and capillary tubes sufficient for 100 tests;                                                                                                                                                                                                             |
| 5.3                                                                          | Consumables/reagents (open, closed system)                                                                                          | 1) Cartridges-combination of various tests;<br>2) External source of gas (if applicable);                                                                                                                                                                                                               |
| 5.4                                                                          | Others                                                                                                                              |                                                                                                                                                                                                                                                                                                         |
| 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS                             |                                                                                                                                     |                                                                                                                                                                                                                                                                                                         |
| 6.1                                                                          | Atmosphere/Ambiance (air conditioning, humidity, dust ...)                                                                          | 1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90% in ideal circumstances;<br>2) Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%; |
| 6.2                                                                          | User's care, Cleaning, Disinfection & Sterility issues                                                                              | The case is to be cleanable with alcohol or chlorine wipes                                                                                                                                                                                                                                              |
| 7. STANDARDS AND SAFETY                                                      |                                                                                                                                     |                                                                                                                                                                                                                                                                                                         |
| 7.1                                                                          | Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international | 1) FDA (US)/CE (EU) from authorized third party and BIS/ISO 13485<br>2) Should be IEC 61010 certificate from a notified agency                                                                                                                                                                          |
| 8. TRAINING AND INSTALLATION                                                 |                                                                                                                                     |                                                                                                                                                                                                                                                                                                         |
| 8.1                                                                          | Pre-installation requirements: nature, values, quality, tolerance                                                                   | 1) Availability of 5 Amps/15Amps. electrical socket;                                                                                                                                                                                                                                                    |
| 8.2                                                                          | Requirements for sign-off                                                                                                           | 1) Supplier to perform installation, safety and operation checks before handover;<br>2) Local clinical staff to affirm completion of installation;                                                                                                                                                      |

|                                    |                                                              |                                                                                                                                                                                                                                                                                                           |
|------------------------------------|--------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8.3                                | <b>Training of staff (medical, paramedical, technicians)</b> | 1) Training of users on operation and basic maintenance;<br>2) Advanced maintenance tasks required shall be documented;                                                                                                                                                                                   |
| <b>9. WARRANTY AND MAINTENANCE</b> |                                                              |                                                                                                                                                                                                                                                                                                           |
| 9.1                                | <b>Warranty</b>                                              | 3 years;                                                                                                                                                                                                                                                                                                  |
| 9.2                                | <b>Maintenance tasks</b>                                     | 1) Maintenance manual detailing;<br>2) Complete maintenance schedule;                                                                                                                                                                                                                                     |
| 9.3                                | <b>Service contract clauses, including prices</b>            | 1) The spare, accessories & consumables price list required for maintenance and repairs in future after guarantee/warranty period should be attached;<br>2) Warranty of three years with free servicing (min. 6) during warranty;                                                                         |
| <b>10. DOCUMENTATION</b>           |                                                              |                                                                                                                                                                                                                                                                                                           |
| 10                                 | <b>Manuals</b>                                               | Should provide 2 sets (hardcopy) of:-<br>1) User, technical and maintenance manuals to be supplied in english/hindi language along with machine diagrams;<br>2) List of equipment and procedures required for local calibration and routine maintenance;<br>3) Certificate of calibration and inspection; |
| 10                                 | <b>Other accompanying documents</b>                          | List of important spares and accessories, with their part numbers and cost;                                                                                                                                                                                                                               |
| <b>11. NOTES</b>                   |                                                              |                                                                                                                                                                                                                                                                                                           |
| 11                                 | <b>Other information</b>                                     | Contact details of manufacturer, supplier and local service agent to be provided;<br>Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer;                                                                                                                                                   |
| 11                                 | <b>Recommendations or Warnings</b>                           | Any recommendations for best use and supplementary warning for safety should be declared                                                                                                                                                                                                                  |

# TRANSILLUMINATOR COLD LIGHT SOURCE

|                                                                  |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|------------------------------------------------------------------|----------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                                                    |                                                                | 2                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Date:                                                            |                                                                | 26/2/2015                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Done by : (name / institution)                                   |                                                                | HCT/NHSRC                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| NAME AND CODING                                                  |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| GMDN name                                                        |                                                                | Light Sources                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| GMDN code(s)                                                     |                                                                | CT1856                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| GENERAL                                                          |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 1. USE                                                           |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 1.1                                                              | Clinical purpose                                               | Clod light source is used for accessing tiny arteries and veins of the babies.                                                                                                                                                                                                                                                                                                                                                                      |
| 1.2                                                              | Used by clinical department/ward                               | NICU and PICU                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| TECHNICAL                                                        |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 2. TECHNICAL CHARACTERISTICS                                     |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 2.1                                                              | Technical characteristics (specific to this type of device)    | 1) Should have light intensity controlled with smooth rotary potentiometer/ pressing button.<br>2) Should have output power 250 Watts (24 Volts)/ 150Watts (12 Volts).<br>3) Should have minimum dual control having 2 halogen/xenon/led lamps.<br>4) Should have SMPS based design ensures smooth working of light source within the voltage variation.<br>5) Should have fibre optic light cable 4.5mm - 10mm in diameter, 250cm-300cm in length. |
| 2.2                                                              | User's interface                                               | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 2.3                                                              | Software and/or standard of communication(where ever required) | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 3. PHYSICAL CHARACTERISTICS                                      |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 3.1                                                              | Dimensions (metric)                                            | 30cm H x 30cm W x 50cm ± 20 %                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 3.2                                                              | Weight (lbs, kg)                                               | Upto 5kg                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 3.3                                                              | Configuration                                                  | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 3.4                                                              | Noise (in dBA)                                                 | <60db                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 3.5                                                              | Heat dissipation                                               | Heat disbursed through a exhaust fan (if applicable).                                                                                                                                                                                                                                                                                                                                                                                               |
| 3.6                                                              | Mobility, portability                                          | Hand held device                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 4.1                                                              | Power Requirements                                             | 220VAC ± 10%, 50Hz                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 4.2                                                              | Battery operated                                               | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 4.3                                                              | Tolerance (to variations, shutdowns)                           | Voltage corrector / stabilizer to allow operation at ± 10% of local rated voltage, Electrical protection by resettable over-current breakers or replaceable fuses fitted in both live and neutral lines.                                                                                                                                                                                                                                            |
| 4.4                                                              | Protection                                                     | Resettable over-current mains fuse to be incorporated.                                                                                                                                                                                                                                                                                                                                                                                              |
| 4.5                                                              | Power consumption                                              | Max. 250W                                                                                                                                                                                                                                                                                                                                                                                                                                           |

| 5. ACCESSORIES, SPARE PARTS, CONSUMABLES            |                                                                                                                                     |                                                                                                                                                                                                                                                                                                          |
|-----------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 5.1                                                 | Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)                  | 1) Mains 3m power cord 1 No.<br>2) Illumination spare lamp 2nos.<br>3) Consumables if any (proprietary/open) should be mentioned along with rates                                                                                                                                                        |
| BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS |                                                                                                                                     |                                                                                                                                                                                                                                                                                                          |
| 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS    |                                                                                                                                     |                                                                                                                                                                                                                                                                                                          |
| 6.1                                                 | Atmosphere / Ambiance (air conditioning, humidity, dust ...)                                                                        | 1) Operating condition: Capable of operating continuously in ambient temperature of -10 to 40 deg C and relative humidity of 15 to 90% in ideal circumstances.<br>2) Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. |
| 6.2                                                 | User's care, Cleaning, Disinfection & Sterility issues                                                                              | The case is to be cleanable with alcohol or chlorine wipes.                                                                                                                                                                                                                                              |
| 7. STANDARDS AND SAFETY                             |                                                                                                                                     |                                                                                                                                                                                                                                                                                                          |
| 7.1                                                 | Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international | 1) Should be CE approved product.<br>2) Manufacturer/supplier should have ISO 13485 certificate for quality standard.<br>3) Electrical safety conforms to standards for electrical safety IEC-60601-1, IEC 60601-1-2 and IEC 60601-2-18.                                                                 |
| 8. TRAINING AND INSTALLATION                        |                                                                                                                                     |                                                                                                                                                                                                                                                                                                          |
| 8.1                                                 | Pre-installation requirements: nature, values, quality, tolerance                                                                   | Availability of 15 Amps. electrical socket.                                                                                                                                                                                                                                                              |
| 8.2                                                 | Requirements for sign-off                                                                                                           | 1) Supplier to perform installation, safety and operation checks before handover.<br>2) Local clinical staff to affirm completion of installation.                                                                                                                                                       |
| 8.3                                                 | Training of staff (medical, paramedical, technicians)                                                                               | 1) Training of users on operation and basic maintenance.<br>2) Advanced maintenance tasks required shall be documented.                                                                                                                                                                                  |
| 9. WARRANTY AND MAINTENANCE                         |                                                                                                                                     |                                                                                                                                                                                                                                                                                                          |
| 9.1                                                 | Warranty                                                                                                                            | 3 years;                                                                                                                                                                                                                                                                                                 |
| 9.2                                                 | Maintenance tasks                                                                                                                   | 1) Maintenance manual detailing.<br>2) Complete maintenance schedule.                                                                                                                                                                                                                                    |
| 9.3                                                 | Service contract clauses, including prices                                                                                          | 1) The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee / warranty period should be attached.<br>2) Free servicing ( min. 2/year) during warranty period.                                                                 |
| 10. DOCUMENTATION                                   |                                                                                                                                     |                                                                                                                                                                                                                                                                                                          |
| 10                                                  | Operating manuals, service manuals, other manuals                                                                                   | Should provide 2 sets(hardcopy) of:-<br>1) User, technical and maintenance manuals to be supplied in english/hindi language along with machine diagrams.<br>2) List of equipment and procedures required for local calibration and routine maintenance.<br>3) Certificate of calibration and inspection. |
| 10                                                  | Recommendations for maintenance                                                                                                     | List of important spares and accessories, with their part numbers and cost.                                                                                                                                                                                                                              |
| 11. NOTES                                           |                                                                                                                                     |                                                                                                                                                                                                                                                                                                          |
| 11                                                  | Service Support Contact details (Hierarchy Wise; including a toll free/landline number)                                             | Contact details of manufacturer, supplier and local service agent to be provided. Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer.                                                                                                                                                     |
| 11                                                  | Recommendations or warnings                                                                                                         | Any recommendations for best use and supplementary warning for safety should be declared.                                                                                                                                                                                                                |

# CPAP

|                                |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|--------------------------------|----------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                  |                                                                | 3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Date:                          |                                                                | 27/2/2015                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Done by : (name / institution) |                                                                | HCT/NHSRC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| NAME AND CODING                |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| GMDN name                      |                                                                | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| GMDN code(s)                   |                                                                | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| GENERAL                        |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 1. USE                         |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 1.1                            | Clinical purpose                                               | Non invasive resp. support (CPAP) for Newborn infant                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 1.2                            | Used by clinical department/ ward                              | NICU and PICU                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| TECHNICAL                      |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 2. TECHNICAL CHARACTERISTICS   |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 2.1                            | Technical characteristics (specific to this type of device)    | 1) Device should able to deliver CPAP of 1 to 10 cmH2O increments of 1cm, using a under water bubble system.<br>2) The device should have a in-built air oxygen blender to deliver FiO2 21% to 100% (+/- 2 %) with an adjustable flow in the range of 0 -15 L/min (+/- 0.5 L/min);<br>3) Should have a heated wire servo controlled humidifier with display temp near patient end of the circuit; to be supplied with 2 reusable infant water chamber;<br>4) Should be supplied with 2 reusable heated wire silicone tubing circuit for infant/Newborn;<br>5) Should be able to deliver CPAP using available patient interfaces nasal prongs/nasopharyngeal prongs;<br>6) For devices based on underwater bubble systems the water chamber should be reusable; to be supplied with 2 reusable water chamber;<br>7) Should be provided pressure release valve at 15cmH2O to 17cmH2O; |
| 2.2                            | User's interface                                               | For a flow driving system a pressure display is required<br>Audio visual alarm for low pressure, high pressure, power failure, low O2,                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 2.3                            | Software and/or standard of communication(where ever required) | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 3. PHYSICAL CHARACTERISTICS    |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 3.1                            | Dimensions (metric)                                            | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 3.2                            | Weight (lbs, kg)                                               | <8kgs                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 3.3                            | Configuration                                                  | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 3.4                            | Noise (in dBA)                                                 | <60dB; Alarm > 65dB                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

|                                                                                    |                                                                                                                                    |                                                                                                                                                                                                                                                                                                         |
|------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3.5                                                                                | Heat dissipation                                                                                                                   | Yes                                                                                                                                                                                                                                                                                                     |
| 3.6                                                                                | Mobility, portability                                                                                                              | Portable                                                                                                                                                                                                                                                                                                |
| <b>4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO<sub>2</sub> ....)</b> |                                                                                                                                    |                                                                                                                                                                                                                                                                                                         |
| 4.1                                                                                | Power Requirements                                                                                                                 | 220VAC, 50 Hz                                                                                                                                                                                                                                                                                           |
| 4.2                                                                                | Battery operated                                                                                                                   | with at-least 6 hours battery backup                                                                                                                                                                                                                                                                    |
| 4.3                                                                                | Tolerance (to variations, shutdowns)                                                                                               | ± 10% of input                                                                                                                                                                                                                                                                                          |
| 4.4                                                                                | Protection                                                                                                                         | OVP, earth leakage protection                                                                                                                                                                                                                                                                           |
| 4.5                                                                                | Power consumption                                                                                                                  | <140Watt                                                                                                                                                                                                                                                                                                |
| 4.6                                                                                | Other energy supplies                                                                                                              | electric/battery driven                                                                                                                                                                                                                                                                                 |
| <b>5. ACCESSORIES, SPARE PARTS, CONSUMABLES</b>                                    |                                                                                                                                    |                                                                                                                                                                                                                                                                                                         |
| 5.1                                                                                | Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)                 | 1) Each device should be provided with 30 nasal prongs (Atleast three sizes suitable for neonates weighing <1000grms, 1000-1500grms & >1500grms)<br>2) Air and O <sub>2</sub> hose of 3m length each along with the appropriate socket;                                                                 |
| <b>BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS</b>                         |                                                                                                                                    |                                                                                                                                                                                                                                                                                                         |
| <b>6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS</b>                             |                                                                                                                                    |                                                                                                                                                                                                                                                                                                         |
| 6.1                                                                                | Atmosphere / Ambiance (air conditioning, humidity, dust ...)                                                                       | 1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90% in ideal circumstances.<br>2) Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. |
| 6.2                                                                                | User's care, Cleaning, Disinfection & Sterility issues                                                                             | 1) Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.                                                                                            |
| <b>7. STANDARDS AND SAFETY</b>                                                     |                                                                                                                                    |                                                                                                                                                                                                                                                                                                         |
| 7.1                                                                                | Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type);Local and/or international | 1) CE(EU) and BIS/ISO 13485:2003;<br>2) IEC-60601-1-2:2007; IEC 60601-1-8-2006; IEC 60601-1-SER-Ed 1.0-2011; IEC/TRF 60601-1-8 Ed4.0-2010; ISO 15001-2010 (Anesthetic & respiratory equipment- compatibility with oxygen)                                                                               |
| <b>8. TRAINING AND INSTALLATION</b>                                                |                                                                                                                                    |                                                                                                                                                                                                                                                                                                         |
| 8.1                                                                                | Pre-installation requirements: nature, values, quality, tolerance                                                                  | electrical sockets; Oxygen supply                                                                                                                                                                                                                                                                       |
| 8.2                                                                                | Requirements for sign-off                                                                                                          | Supplier to perform installation, safety and operation checks before handover<br>Local clinical staff to affirm completion of installation                                                                                                                                                              |
| 8.3                                                                                | Training of staff (medical, paramedical, technicians)                                                                              | Training of users in operation and basic maintenance shall be provided<br>Advanced maintenance tasks required shall be documented                                                                                                                                                                       |
| <b>9. WARRANTY AND MAINTENANCE</b>                                                 |                                                                                                                                    |                                                                                                                                                                                                                                                                                                         |
| 9.1                                                                                | Warranty                                                                                                                           | 3 years;                                                                                                                                                                                                                                                                                                |
| 9.2                                                                                | Maintenance tasks                                                                                                                  | 1) Maintenance manual detailing;<br>2) Complete maintenance schedule;                                                                                                                                                                                                                                   |
| 9.3                                                                                | Service contract clauses, including prices                                                                                         | 1) The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee / warranty period should be attached;<br>2) warranty of three years with free servicing ( min. 6) during warranty;                                               |



| 10. DOCUMENTATION |                                                                                                |                                                                                                                                                                                                                                                                                         |
|-------------------|------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10                | <b>Operating manuals, service manuals, other manuals</b>                                       | Should provide 2 sets(hardcopy) of:-<br>1) User, technical, maintenance and service manuals to be supplied along with machine diagrams;<br>2) List of equipment and procedures required for local calibration and routine maintenance;<br>3) Certificate of calibration and inspection; |
| 10                | <b>Recommendations for maintenance</b>                                                         | List of important spares and accessories, with their part numbers and cost;                                                                                                                                                                                                             |
| 11. NOTES         |                                                                                                |                                                                                                                                                                                                                                                                                         |
| 11                | <b>Service Support Contact details (Hierarchy Wise; including a toll free/landline number)</b> | Contact details of manufacturer, supplier and local service agent to be provided;<br>Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer;                                                                                                                                 |
| 11                | <b>Recommendations or warnings</b>                                                             | Any warning signs would be adequately displayed                                                                                                                                                                                                                                         |

# INTENSIVE CARE VENTILATOR (NEONATAL & PEDIATRICS)

|                                |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|--------------------------------|-------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                  |                                                             | 3.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Date:                          |                                                             | 27/2/2015                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Done by : (name / institution) |                                                             | HCT/ NHSRC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| NAME AND CODING                |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| GMDN name                      |                                                             | Intensive care ventilator                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| GMDN code(s)                   |                                                             | CT2175                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| GENERAL                        |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 1. USE                         |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 1.1                            | Clinical purpose                                            | To provide automated, alveolar ventilatory support for patients in emergency situations.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 1.2                            | Used by clinical department/ ward                           | Emergency /Critical Care (NICU/PICU)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| TECHNICAL                      |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 2. TECHNICAL CHARACTERISTICS   |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 2.1                            | Technical characteristics (specific to this type of device) | <ol style="list-style-type: none"> <li>1) Should have facility for Invasive and Non-Invasive ventilation;</li> <li>2) Microprocessor Control suitable for Neonatal and Pediatric ventilation;</li> <li>3) Should have modes of ventilation equipped with newer modes of ventilation: <ol style="list-style-type: none"> <li>3.1) Assist/ Control</li> <li>3.2) Volume control</li> <li>3.3) Pressure control</li> <li>3.4) Pressure support</li> <li>3.5) SIMV with pressure support (Pressure and volume control)</li> <li>3.6) PEEP</li> <li>3.7) Inverse ratio Ventilation</li> <li>3.8) Non invasive ventilation-BIPAP, CPAP</li> <li>3.9) Apnea ventilation, user selectable, volume &amp; pressure control;</li> </ol> </li> <li>4) Should have built in color screen TFT/LCD display of minimum 8" for display of waveforms and monitored value;</li> <li>5) Should have inbuilt facility to upgrade with EtcO<sub>2</sub>;</li> <li>6) Should have facility to measure and display of the following parameters: <ol style="list-style-type: none"> <li>6.1) Airway Pressure (Peak &amp; Mean)</li> <li>6.2) Tidal volume (Inspired &amp; Expired)</li> <li>6.3) Minute volume (Inspired &amp; Expired)</li> <li>6.4) Respiratory mechanics</li> <li>6.5) Spontaneous Minute Volume</li> <li>6.6) Total Frequency</li> <li>6.7) FiO<sub>2</sub> dynamic</li> <li>6.8) Intrinsic PEEP</li> <li>6.9) Plateau Pressure</li> <li>6.10) Resistance &amp; Compliance</li> </ol> </li> </ol> |

|                                                                                    |                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|------------------------------------------------------------------------------------|------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                    |                                                                        | 6.11) Use selector Alarms for all measured & monitored parameters<br>6.12) Occlusion Pressure<br>6.13) Pressure Flow & Volume curves;<br>7) Automatic compliance and leakage compensation for circuit and ET tube;<br>8) Should have facility of log book, for events and alarms with date & time;<br>9) Should have following setting;<br>9.1) Tidal volume (Minimum 2ml, Maximum up to 2000ml); pre-set range for both neo-natal & pediatric modes to be provided<br>9.2) Inspiratory pressure (upto 60cm of H <sub>2</sub> O);<br>9.3) Respiratory rate 1 to 80 bpm;<br>9.4) Apnea back up rate;<br>9.5) CPAP/PEEP;<br>9.6) Pressure support;<br>9.7) FiO <sub>2</sub> setting range between 21% and 100%;<br>9.8) Pause time;<br>9.9) Pressure/flow Trigger;<br>9.10) Inspiratory flow up to 120 Lpm;<br>10) Oxygen cylinder/central pipeline connector/(to be supplied along with the machines) should be compatible with ventilator;<br>11) Disposable Heat Moisture Exchanger, qty 100 to be supplied with unit |
| 2.3                                                                                | <b>User's interface</b>                                                | Manual and Automatic                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 2.4                                                                                | <b>Software and/or standard of communication (where ever required)</b> | 1) Inbuilt software;<br>2) Convenient and quick USB interface;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>3. PHYSICAL CHARACTERISTICS</b>                                                 |                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 3.1                                                                                | <b>Dimensions (metric)</b>                                             | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 3.2                                                                                | <b>Weight (lbs, kg)</b>                                                | <50kg including trolley                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 3.3                                                                                | <b>Configuration</b>                                                   | 1) Compatible hinged arm for holding the circuit;<br>2) Should have caster with braking system;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 3.4                                                                                | <b>Noise (in dBA), heat dissipation</b>                                | 1) Noise of device operation max- 50dB(A);<br>2) Should have audio visual alarm for battery low, source gas low and high/low pressure in the breathing circuit or source gas inlet;<br>3) Should maintain nominal Temp of the control unit and the heat should be dissipated through an cooling mechanism;<br>4) Alarm volume - min. 65dB                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 3.5                                                                                | <b>Mobility, portability</b>                                           | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO<sub>2</sub> ....)</b> |                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 4.1                                                                                | <b>Power Requirements</b>                                              | Input voltage 220 VAC, 50Hz;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 4.2                                                                                | <b>Battery operated</b>                                                | 1) Battery powered, silenceable alarm for power failure.<br>2) Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit.<br>3) Internal, replaceable, rechargeable battery allows operation for at least four hour in the event of power failure                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 4.3                                                                                | <b>Tolerance (to variations, shutdowns)</b>                            | Voltage corrector / stabilizer to allow operation at $\pm 10\%$ of 220V AC. Use of SMPS to correct voltage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 4.4                                                                                | <b>Protection</b>                                                      | 1) Electrical protection, resettable over current breakers or replaceable fuses (fitted in both live and neutral lines);<br>2) Leakage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 4.5                                                                                | <b>Power consumption</b>                                               | TO be declared by the supplier                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

| 5. ACCESSORIES, SPARE PARTS, CONSUMABLES         |                                                                                         |                                                                                                                                                                                                                                                                                                               |
|--------------------------------------------------|-----------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 5.1                                              | Accessories & Spares                                                                    | 1) Full face mask- 5 Nos each of 0,1 and 3<br>2) Nasal cannulae for neonates- 5 nos<br>3) Reusable breathing circuit of silicone material (5Nos)<br>4) Air & oxygen hose- 1 each                                                                                                                              |
| 5.3                                              | Consumables / reagents (open, closed system)                                            | NA                                                                                                                                                                                                                                                                                                            |
| 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS |                                                                                         |                                                                                                                                                                                                                                                                                                               |
| 6.1                                              | Atmosphere / Ambiance (air conditioning, humidity, dust ...)                            | 1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90% in ideal circumstances.<br>2) Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.       |
| 6.2                                              | User's care, Cleaning, Disinfection & Sterility issues                                  | Complete unit to be easily washable and sterilizable using alcohol and other chemical agents.                                                                                                                                                                                                                 |
| 7. STANDARDS AND SAFETY                          |                                                                                         |                                                                                                                                                                                                                                                                                                               |
| 7.1                                              | Certifications                                                                          | 1) FDA (US) /CE (EU) from authorized third party and BIS/ISO 13485<br>2) Relevant IEC-60601-Part 1 & 2, certificates by a notified agency                                                                                                                                                                     |
| 7.2                                              | Local and/or international                                                              | Manufacturer / supplier should have ISO certificate for quality standard.                                                                                                                                                                                                                                     |
| 8 TRAINING AND INSTALLATION                      |                                                                                         |                                                                                                                                                                                                                                                                                                               |
| 8.1                                              | Pre-installation requirements: nature, values, quality, tolerance                       | 1) Availability of 5 amp/15 Amp. electrical sockets;<br>2) Oxygen supply;<br>3) Medical air supply;                                                                                                                                                                                                           |
| 8.2                                              | Requirements for sign-off                                                               | 1) Supplier to perform installation, safety and operation checks before handover;<br>2) Local clinical staff to affirm completion of installation                                                                                                                                                             |
| 8.3                                              | Training of staff (medical, paramedical, technicians)                                   | 1) Training of users in operation and basic maintenance shall be provided;<br>2) Advanced maintenance tasks required shall be documented                                                                                                                                                                      |
| 9. WARRANTY AND MAINTENANCE                      |                                                                                         |                                                                                                                                                                                                                                                                                                               |
| 9.1                                              | Warranty                                                                                | 3 years                                                                                                                                                                                                                                                                                                       |
| 9.2                                              | Maintenance tasks                                                                       | 1) Maintenance manual detailing;<br>2) Complete maintenance schedule;                                                                                                                                                                                                                                         |
| 9.3                                              | Service contract clauses, including prices                                              | 1) The spare, accessories & consumables price list required for maintenance and repairs in future after guarantee / warranty period should be attached;<br>2) Free servicing during warranty period;                                                                                                          |
| 10. DOCUMENTATION                                |                                                                                         |                                                                                                                                                                                                                                                                                                               |
| 10                                               | Operating manuals, service manuals, other manuals                                       | Should provide 2 sets(hardcopy) of:-<br>1) User, technical, maintenance and service manuals to be supplied along with machine diagrams;<br>2) List of equipment and procedures required for routine calibration and routine maintenance;<br>3) Certificate of calibration to be provided by the manufacturer; |
| 10                                               | Other accompanying documents                                                            | List to be provided of important spares and accessories, with their part numbers and cost.                                                                                                                                                                                                                    |
| 11. NOTES                                        |                                                                                         |                                                                                                                                                                                                                                                                                                               |
| 11                                               | Service Support Contact details (Hierarchy Wise; including a toll free/landline number) | 1) Contact details of manufacturer, supplier and local service agent to be provided;<br>2) Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer;                                                                                                                                                 |
| 11                                               | Recommendations or warnings                                                             | Any warning signs would be adequately displayed                                                                                                                                                                                                                                                               |

# TRANSPORT VENTILATOR (NEONATAL & PEDIATRICS)

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|--------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                  | 3.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Date:                          | 26/2/2015                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Done by : (name / institution) | HCT/ NHSRC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| NAME AND CODING                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| GMDN name                      | Transport pneumatic high-frequency ventilator                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| GMDN code(s)                   | CT2175                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| GENERAL                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 1. USE                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 1.1                            | <b>Clinical purpose</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|                                | To provide automated, alveolar ventilatory support for patients during interhospital or intrahospital transport, and in emergency situations.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 1.2                            | <b>Used by clinical department/ ward</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|                                | Emergency /Critical Care                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| TECHNICAL                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 2. TECHNICAL CHARACTERISTICS   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 2.1                            | <b>Technical characteristics (specific to this type of device)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|                                | <ol style="list-style-type: none"> <li>1. Mountable transport ventilator (Neonate/Paediatric).</li> <li>2. Invasive Modes (CMV and SIMV) and Non-invasive Mode (CPAP).</li> <li>3. Pressure controlled - Pressure upto 15mmHg.</li> <li>4. Respiration Rate upto 40.</li> <li>5. There should be two FiO2 setting range between 21% and 100%. Setting 100% FiO2 should be mandatory.</li> <li>6. PEEP 0-20 cm of water.</li> <li>7. Trigger sensitivity - Pressure.</li> <li>8. The associated cylinder(to be supplied along with the machines) should be such that it could be locally filled.</li> <li>9. Oxygen Cylinder connector(to be supplied along with the machines) should be compatible with ventilator.</li> <li>10. Audio and visual alarm for disconnection and high pressure.</li> <li>11. The device should be capable of operation in various environments such as Emergency, Ambulance, Aircraft,Hospital and MRI.</li> <li>12. The device should be MRI conditioned up to 3 Tesla, 430 G/cm.</li> </ol> |
| 2.3                            | <b>User's interface</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|                                | Automatic                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 2.4                            | <b>Software and/or standard of communication(where ever required)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|                                | inbuilt                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 3. PHYSICAL CHARACTERISTICS    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 3.1                            | <b>Dimensions (metric)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|                                | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 3.2                            | <b>Weight (lbs, kg)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|                                | <8kgs                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 3.3                            | <b>Configuration</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|                                | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

|                                                                                    |                                                                   |                                                                                                                                                                                                                                          |
|------------------------------------------------------------------------------------|-------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3.4                                                                                | Noise (in dBA), heat dissipation                                  | Should have audio visual alarm for disconnection and high pressure.                                                                                                                                                                      |
| 3.5                                                                                | Mobility, portability                                             | Yes                                                                                                                                                                                                                                      |
| <b>4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO<sub>2</sub> ....)</b> |                                                                   |                                                                                                                                                                                                                                          |
| 4.1                                                                                | Power Requirements                                                | 220 to 240V, 50 Hz; electricity and battery driven; should be compatible with ambulance power supply system with other life saving equipments running parallel in the ambulance.                                                         |
| 4.2                                                                                | Battery operated                                                  | with atleast 6 hours battery backup                                                                                                                                                                                                      |
| 4.3                                                                                | Tolerance (to variations, shutdowns)                              | ± 10% of input                                                                                                                                                                                                                           |
| 4.4                                                                                | Protection                                                        | OVP, earth leakage protection.                                                                                                                                                                                                           |
| 4.5                                                                                | Power consumption                                                 | <140Watt                                                                                                                                                                                                                                 |
| <b>5. ACCESSORIES, SPARE PARTS, CONSUMABLES</b>                                    |                                                                   |                                                                                                                                                                                                                                          |
| 5.1                                                                                | Accessories & Spares                                              | full face mask, 4 reusable breathing circuit of silicone material(2 for pediatric and 2 for neonates), carry bag, ventilator connecting tubes.                                                                                           |
| 5.3                                                                                | Consumables / reagents (open, closed system)                      | battery, leakage adapter.                                                                                                                                                                                                                |
| <b>6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS</b>                            |                                                                   |                                                                                                                                                                                                                                          |
| 6.1                                                                                | Atmosphere / Ambiance (air conditioning, humidity, dust ...)      | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.<br>Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.       |
| 6.2                                                                                | User's care, Cleaning, Disinfection & Sterility issues            | The unit should be cleanable with alcohol and/or other chemical agents.                                                                                                                                                                  |
| <b>7. STANDARDS AND SAFETY</b>                                                     |                                                                   |                                                                                                                                                                                                                                          |
| 7.1                                                                                | Certifications                                                    | FDA (US) /CE (EU) and BIS/ISO 13485:2003; IEC-60601-1-2; ISO 15001-2010 (Anesthetic & respiratory equipment- compatibility with oxygen).<br>Certificate of approval for transport ventilator.                                            |
| <b>8. TRAINING AND INSTALLATION</b>                                                |                                                                   |                                                                                                                                                                                                                                          |
| 8.1                                                                                | Pre-installation requirements: nature, values, quality, tolerance | electrical sockets; Oxygen supply.                                                                                                                                                                                                       |
| 8.2                                                                                | Requirements for sign-off                                         | Supplier to perform installation, safety and operation checks before handover.<br>Local clinical staff to affirm completion of installation.                                                                                             |
| 8.3                                                                                | Training of staff (medical, paramedical, technicians)             | Training of users in operation and basic maintenance shall be provided.<br>Advanced maintenance tasks required shall be documented.                                                                                                      |
| <b>9. WARRANTY AND MAINTENANCE</b>                                                 |                                                                   |                                                                                                                                                                                                                                          |
| 9.1                                                                                | Warranty                                                          | 3 years                                                                                                                                                                                                                                  |
| 9.2                                                                                | Maintenance tasks                                                 | maintenance manual detailing complete maintaining schedule.                                                                                                                                                                              |
| 9.3                                                                                | Service contract clauses, including prices                        | warranty of three year with free servicing ( min. 3) during warranty.                                                                                                                                                                    |
| 9.4                                                                                | Others                                                            | The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee / warranty period should be attached.                                                                |
| <b>10. DOCUMENTATION</b>                                                           |                                                                   |                                                                                                                                                                                                                                          |
| 10.1                                                                               | Operating manuals, service manuals, other manuals                 | User and maintenance manuals to be supplied in English language.<br>Certificate of calibration and inspection to be provided.<br>List to be provided of equipment and procedures required for local calibration and routine maintenance. |

|                  |                                                                                                |                                                                                                                                                                                 |
|------------------|------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                  |                                                                                                | List to be provided of important spares and accessories, with their part numbers and cost.<br>Contact details of manufacturer, supplier and local service agent to be provided. |
| 10.2             | <b>Other accompanying documents</b>                                                            | User/Technical/Maintenance manuals to be supplied in English.                                                                                                                   |
| <b>11. NOTES</b> |                                                                                                |                                                                                                                                                                                 |
| 11.1             | <b>Service Support Contact details (Hierarchy Wise; including a toll free/landline number)</b> | Contact details of manufacturer, supplier and local service agent to be provided.                                                                                               |
| 11.2             | <b>Recommendations or warnings</b>                                                             | Any warning signs would be adequately displayed.                                                                                                                                |

# DEFIBRILLATOR

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                  | 2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Date:                          | 26/2/2015                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Done by : (name / institution) | HCT/NHSRC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| NAME AND CODING                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| GMDN name                      | Defibrillators                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| GMDN code(s)                   | CT1150                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| GENERAL                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 1. USE                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 1.1                            | <b>Clinical purpose</b><br>Defibrillation is a common treatment for life-threatening cardiac dysrhythmias, ventricular fibrillation and pulseless ventricular tachycardia. Defibrillation consists of delivering a therapeutic dose of electrical energy to the heart with a device.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 1.2                            | <b>Used by clinical department/ ward</b><br>NICU and PICU                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| TECHNICAL                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 2. TECHNICAL CHARACTERISTICS   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 2.1                            | <b>Technical characteristics (specific to this type of device)</b> <ol style="list-style-type: none"> <li>1) The Defibrillator should have biphasic technology having energy selection of 1-200 Joules.</li> <li>2) The machine should have facility for ECG monitoring, defibrillation, transcutaneous pacing, defibrillation and synchronized cardioversion with CPR feedback to measure chest compression rate and depth in real time and visual on screen feedback.</li> <li>3) Machine must be with sweep rate 25mm/sec, 50mm/sec.</li> <li>4) It should be capable of monitoring ECG through ECG cables, electrodes &amp; paddles.</li> <li>5) Machine should have 24 hour trend storage facility.</li> <li>6) The machine should have defibrillator facility for neonatal and pediatric patients.</li> <li>7) The machine should have ECG waveform display with provision for synchronization.</li> <li>8) The machine should be compact, portable with built in rechargeable battery &amp; light weight.</li> <li>9) The machine should have inbuilt auto &amp; manual recorder for printing ECG trace &amp; stored information.</li> <li>10) The machine should have user selectable alarms setting.</li> <li>11) The machine should work on mains (without battery) and on battery as well.</li> <li>12) The machine should have AED feature as inbuilt with manual override for manual operations.</li> </ol> |
| 2.2                            | <b>User's interface</b><br>Manual/Automatic                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |



|                                                                         |                                                                                                                                     |                                                                                                                                                                                                                                                                                                              |
|-------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2.3                                                                     | Software and/or standard of communication(where ever required)                                                                      | 1)Inbuilt software.<br>2)Convenient and quick USB interface.                                                                                                                                                                                                                                                 |
| <b>3. PHYSICAL CHARACTERISTICS</b>                                      |                                                                                                                                     |                                                                                                                                                                                                                                                                                                              |
| 3.1                                                                     | Dimensions (metric)                                                                                                                 | NA                                                                                                                                                                                                                                                                                                           |
| 3.2                                                                     | Weight (lbs, kg)                                                                                                                    | Max 10kg                                                                                                                                                                                                                                                                                                     |
| 3.3                                                                     | Configuration                                                                                                                       | Should have audio visual alarm for battery low.                                                                                                                                                                                                                                                              |
| 3.4                                                                     | Noise (in dBA)                                                                                                                      | <60db                                                                                                                                                                                                                                                                                                        |
| 3.5                                                                     | Heat dissipation                                                                                                                    | 1) Should maintain nominal Temp of the control unit and the heat should be disbursed through an cooling mechanism.                                                                                                                                                                                           |
| 3.6                                                                     | Mobility, portability                                                                                                               | Portable                                                                                                                                                                                                                                                                                                     |
| <b>4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)</b> |                                                                                                                                     |                                                                                                                                                                                                                                                                                                              |
| 4.1                                                                     | Power Requirements                                                                                                                  | Input voltage 220 VAC +_10%, 50Hz;                                                                                                                                                                                                                                                                           |
| 4.2                                                                     | Battery operated                                                                                                                    | 1) Battery powered, silenceable alarm for power failure.<br>2) Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit.<br>3) Internal, replaceable, rechargeable battery allows operation for a minimum of two hour in the event of power failure. |
| 4.3                                                                     | Tolerance (to variations, shutdowns)                                                                                                | Voltage corrector / stabilizer to allow operation at $\pm 15\%$ of local rated voltage. Use of SMPS to correct voltage.                                                                                                                                                                                      |
| 4.4                                                                     | Protection                                                                                                                          | 1) Electrical protection, resettable over current breakers or replaceable fuses (fitted in both live and neutral lines).<br>2) Leakage                                                                                                                                                                       |
| 4.5                                                                     | Power consumption                                                                                                                   | NA                                                                                                                                                                                                                                                                                                           |
| <b>5. ACCESSORIES, SPARE PARTS, CONSUMABLES</b>                         |                                                                                                                                     |                                                                                                                                                                                                                                                                                                              |
| 5.1                                                                     | Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)                  | 1) Machine must be supplied with ECG cable, Battery, Paddle (Adult integrated with pediatric).<br>2) 3 No. Reusable CPR feedback sensor.<br>3) 300 gel sheet or pads for monitoring and defibrillation.                                                                                                      |
| <b>BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS</b>              |                                                                                                                                     |                                                                                                                                                                                                                                                                                                              |
| <b>6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS</b>                  |                                                                                                                                     |                                                                                                                                                                                                                                                                                                              |
| 6.1                                                                     | Atmosphere / Ambiance (air conditioning, humidity, dust ...)                                                                        | 1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90% in ideal circumstances.<br>2) Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.      |
| 6.2                                                                     | User's care, Cleaning, Disinfection & Sterility issues                                                                              | 1) Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.                                                                                                 |
| <b>7. STANDARDS AND SAFETY</b>                                          |                                                                                                                                     |                                                                                                                                                                                                                                                                                                              |
| 7.1                                                                     | Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international | 1) FDA (US) /CE (EU) from authorized third party and BIS/ISO 13485.<br>2) Relevant IEC-60601-Part 1 & 2, certificates by a notified agency.                                                                                                                                                                  |
| <b>8. TRAINING AND INSTALLATION</b>                                     |                                                                                                                                     |                                                                                                                                                                                                                                                                                                              |
| 8.1                                                                     | Pre-installation requirements: nature, values, quality, tolerance                                                                   | 1) Availability of 5 amp/15amp socket.<br>2) Safety and operation check before handover.                                                                                                                                                                                                                     |

|                                    |                                                                                                |                                                                                                                                                                                                                                                                                                |
|------------------------------------|------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8.2                                | <b>Requirements for sign-off</b>                                                               | 1) Supplier to perform installation, safety and operation checks before handover.<br>2) Local clinical staff to affirm completion of installation.                                                                                                                                             |
| 8.3                                | <b>Training of staff (medical, paramedical, technicians)</b>                                   | 1) Training of users on operation and basic maintenance.<br>2) Advanced maintenance tasks required shall be documented.                                                                                                                                                                        |
| <b>9. WARRANTY AND MAINTENANCE</b> |                                                                                                |                                                                                                                                                                                                                                                                                                |
| 9.1                                | <b>Warranty</b>                                                                                | 3 years                                                                                                                                                                                                                                                                                        |
| 9.2                                | <b>Maintenance tasks</b>                                                                       | 1) Maintenance manual detailing.<br>2) Complete maintenance schedule.                                                                                                                                                                                                                          |
| 9.3                                | <b>Service contract clauses, including prices</b>                                              | 1) The spare, accessories & consumables price list required for maintenance and repairs in future after guarantee / warranty period should be attached.<br>2) Free servicing during warranty period.                                                                                           |
| <b>10. DOCUMENTATION</b>           |                                                                                                |                                                                                                                                                                                                                                                                                                |
| 10                                 | <b>Operating manuals, service manuals, other manuals</b>                                       | Should provide 2 sets(hardcopy) of:-<br>1) User, technical, maintenance and service manuals to be supplied along with machine diagrams.<br>2) List of equipment and procedures required for local calibration and routine maintenance.<br>3) Certificate of calibration from the manufacturer. |
| 10                                 | <b>Recommendations for maintenance</b>                                                         | List of important spares and accessories, with their part numbers and cost.                                                                                                                                                                                                                    |
| <b>11. NOTES</b>                   |                                                                                                |                                                                                                                                                                                                                                                                                                |
| 11                                 | <b>Service Support Contact details (Hierarchy Wise; including a toll free/landline number)</b> | 1) Contact details of manufacturer, supplier and local service agent to be provided.<br>2) Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer.                                                                                                                                  |
| 11                                 | <b>Recommendations or warnings</b>                                                             | Any warning signs would be adequately displayed.                                                                                                                                                                                                                                               |

# NEBULIZER (ELECTRIC)

|                                                                              |                                                                                                                                                                                                       |
|------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                                                                | 2.0                                                                                                                                                                                                   |
| Date:                                                                        | SEPT 2014                                                                                                                                                                                             |
| Done by : (name/institution)                                                 | HCT/NHSRC                                                                                                                                                                                             |
| NAME AND CODING                                                              |                                                                                                                                                                                                       |
| GMDN name                                                                    | Nebulizing systems                                                                                                                                                                                    |
| GMDN code(s)                                                                 | CT1097                                                                                                                                                                                                |
| GENERAL                                                                      |                                                                                                                                                                                                       |
| 1. USE                                                                       |                                                                                                                                                                                                       |
| 1.1                                                                          | <b>Clinical purpose</b><br>designed to generate aerosolized medication/fluids (finely dispersed airborne droplets in a liquid phase) intended to be inhaled by a patient with a respiratory disorder. |
| 1.2                                                                          | <b>Used by clinical department/ward</b><br>All                                                                                                                                                        |
| TECHNICAL                                                                    |                                                                                                                                                                                                       |
| 2. TECHNICAL CHARACTERISTICS                                                 |                                                                                                                                                                                                       |
| 2.1                                                                          | <b>Technical characteristics (specific to this type of device)</b><br>Medicine cup capacity of minimum 5ml.                                                                                           |
| 2.2                                                                          | <b>Settings</b><br>Manual                                                                                                                                                                             |
| 2.3                                                                          | <b>User's interface</b><br>Manual                                                                                                                                                                     |
| 2.4                                                                          | <b>Software and/or standard of communication (where ever required)</b><br>NA                                                                                                                          |
| 3. PHYSICAL CHARACTERISTICS                                                  |                                                                                                                                                                                                       |
| 3.1                                                                          | <b>Dimensions (metric)</b><br>Should be compact                                                                                                                                                       |
| 3.2                                                                          | <b>Weight (lbs, kg)</b><br><2kg.                                                                                                                                                                      |
| 3.3                                                                          | <b>Configuration</b><br>                                                                                                                                                                              |
| 3.4                                                                          | <b>Noise (in dBA), heat dissipation</b><br><60dBA                                                                                                                                                     |
| 3.5                                                                          | <b>Mobility, portability</b><br>Yes                                                                                                                                                                   |
| 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO <sub>2</sub> ....) |                                                                                                                                                                                                       |
| 4.1                                                                          | <b>Power Requirements</b><br>220 V AC + 10%, 50Hz power supply; 5A plug;                                                                                                                              |
| 4.2                                                                          | <b>Battery operated</b><br>NA                                                                                                                                                                         |
| 4.3                                                                          | <b>Tolerance (to variations, shutdowns)</b><br>± 10% of input AC                                                                                                                                      |
| 4.4                                                                          | <b>Protection</b><br>Electrical protection by resettable overcurrent breakers or replaceable fuses, fitted in both live and neutral lines                                                             |
| 4.5                                                                          | <b>Power consumption</b><br>Should be compatible with other life saving equipments running parallel                                                                                                   |
| 4.6                                                                          | <b>Other energy supplies</b><br>NA                                                                                                                                                                    |

| 5. ACCESSORIES, SPARE PARTS, CONSUMABLES         |                                                                                         |                                                                                                                                                                                                                                                  |
|--------------------------------------------------|-----------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 5.1                                              | Accessories & Spares                                                                    | With necessary accessories- nebulization mask(both adult and pediatric size), PVC tubing for nebulizer (two pair extra); cable cord                                                                                                              |
| 5.2                                              | Consumables/reagents (open, closed system)                                              | aerosol/medicinal solutions                                                                                                                                                                                                                      |
| 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS |                                                                                         |                                                                                                                                                                                                                                                  |
| 6.1                                              | Atmosphere/Ambiance (air conditioning, humidity, dust ...)                              | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.                  |
| 6.2                                              | User's care, Cleaning, Disinfection & Sterility issues                                  | The unit should be cleanable with alcohol and/or other chemical agents.                                                                                                                                                                          |
| 7. STANDARDS AND SAFETY                          |                                                                                         |                                                                                                                                                                                                                                                  |
| 7.1                                              | Certificates (pre-market, sanitary, ..)                                                 | FDA (US)/CE (EU) and BIS/ISO 13485:2003; ISO 27427-2013; IEC-60601-1.                                                                                                                                                                            |
| 8. TRAINING AND INSTALLATION                     |                                                                                         |                                                                                                                                                                                                                                                  |
| 8.1                                              | Pre-installation requirements: nature, values, quality, tolerance                       | Supplier to perform installation, safety and operation checks before handover.                                                                                                                                                                   |
| 8.2                                              | Requirements for sign-off                                                               | Certificate of calibration and inspection from the factory.                                                                                                                                                                                      |
| 8.3                                              | Training of staff (medical, paramedical, technicians)                                   | Training of users in operation and basic maintenance shall be provided.                                                                                                                                                                          |
| 9. WARRANTY AND MAINTENANCE                      |                                                                                         |                                                                                                                                                                                                                                                  |
| 9.1                                              | Warranty                                                                                | 3 Years                                                                                                                                                                                                                                          |
| 9.2                                              | Maintenance tasks                                                                       | Maintenance manual detailing complete maintaining schedule                                                                                                                                                                                       |
| 9.3                                              | Service contract clauses, including prices                                              | Local clinical staff to affirm completion of installation                                                                                                                                                                                        |
| 10. DOCUMENTATION                                |                                                                                         |                                                                                                                                                                                                                                                  |
| 10.1                                             | Operating manuals, service manuals, other manuals                                       | Advanced maintenance tasks required shall be documented<br>User, technical and maintenance manuals to be supplied in english language.<br>List to be provided of equipment and procedures required for local calibration and routine maintenance |
| 10.2                                             | Other accompanying documents                                                            | List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.                                                                                             |
| 11. NOTES                                        |                                                                                         |                                                                                                                                                                                                                                                  |
| 11.1                                             | Service Support Contact details (Hierarchy Wise; including a toll free/landline number) | Contact details of manufacturer, supplier and local service agent to be provided                                                                                                                                                                 |
| 11.2                                             | Recommendations or warnings                                                             | List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.                                                                                             |

# SYRINGE PUMP

|                                |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|--------------------------------|-------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                  |                                                             | 3.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Date:                          |                                                             | 26/2/2015                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Done by : (name / institution) |                                                             | HCT/ NHSRC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| NAME AND CODING                |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| GMDN name                      |                                                             | Syringe pump                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| GMDN code(s)                   |                                                             | CT111                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| GENERAL                        |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 1. USE                         |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 1.1                            | Clinical purpose                                            | designed to precisely drive the plunger of a syringe down its barrel to infuse a solution when it must be administered with a high degree of volume accuracy and rate consistency.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 1.2                            | Used by clinical department/ ward                           | NICU/PICU                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| TECHNICAL                      |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 2. TECHNICAL CHARACTERISTICS   |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 2.1                            | Clinical performances                                       | Should accept all internationally produced/marketed syringes and should be able to detect it automatically, Should support the Bolus supply of drug on press of single button, as per need and should be able to preset different range of Bolus supply.<br><br>Preferably the unit should be of Bottom / side loaded to avoid accidental spilling of drugs and damage to the machine.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 2.2                            | Technical characteristics (specific to this type of device) | <ol style="list-style-type: none"> <li>Flow rate programmable range at least from 0.1 to 200 ml/hr, in steps of 0.1 ml/hr; and at least from 100 to 1200 ml/hr in steps of 1 ml/hr.</li> <li>Saves last infusion rate even when the AC power is switched off.</li> <li>Bolus rate should be programmable to approx 500 ml, with infused volume display.</li> <li>Selectable occlusion pressure trigger levels selectable from 300, 500 and 900 mmHg.</li> <li>Must work on commonly available 20, 30 and 50 ml syringes</li> <li>Accuracy of <math>\pm 2\%</math> or better.</li> <li>Maximum pressure generated <math>\leq 20</math> psi.</li> <li>Automatic detection of syringe size and proper fixing.</li> <li>Anti-bolus system to reduce pressure on sudden release of occlusion.</li> <li>Pause infusion facility required.</li> <li>Self-check carried out on powering on.</li> <li>Comprehensive alarm package required including: occlusion alarm, near end of infusion pre-alarm and alarm, volume limit pre-alarm and alarm, low battery pre-alarm and alarm, AC power failure, drive disengaged, syringe loading error, maintenance required.</li> <li>Should include KVO (Keep vein open) enabling feature.</li> <li>It should be an open system compliant.</li> </ol> |

|                                                                         |                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                  |
|-------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2.3                                                                     | Settings                                                                                                 | Single loadable with one syringe of minimum 20ml.                                                                                                                                                                                                                                                                                                                |
| 2.4                                                                     | User's interface                                                                                         | Automatic                                                                                                                                                                                                                                                                                                                                                        |
| 2.5                                                                     | Software and/or standard of communication                                                                | Inbuilt                                                                                                                                                                                                                                                                                                                                                          |
| <b>3. PHYSICAL CHARACTERISTICS</b>                                      |                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                  |
| 3.1                                                                     | Dimensions (metric)                                                                                      | NA                                                                                                                                                                                                                                                                                                                                                               |
| 3.2                                                                     | Weight (lbs, kg)                                                                                         | NA                                                                                                                                                                                                                                                                                                                                                               |
| 3.3                                                                     | Configuration                                                                                            | Tamper-resistant case made of impact resistant material.<br>Securely mountable on tabletop, IV stand or bed fitting.                                                                                                                                                                                                                                             |
| 3.4                                                                     | Noise (in dBA)                                                                                           | Noise free                                                                                                                                                                                                                                                                                                                                                       |
| 3.5                                                                     | heat dissipation                                                                                         |                                                                                                                                                                                                                                                                                                                                                                  |
| 3.6                                                                     | Mobility, portability                                                                                    | Yes                                                                                                                                                                                                                                                                                                                                                              |
| <b>4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)</b> |                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                  |
| 4.1                                                                     | Voltage (value, AC or DC, monophasic or triphase)                                                        | 220 to 240V, 50 Hz                                                                                                                                                                                                                                                                                                                                               |
| 4.2                                                                     | Battery operated                                                                                         | Internal rechargeable battery having at 4 to 6 hours backup for 10ml/hr flow rate with 50ml syringe.                                                                                                                                                                                                                                                             |
| 4.3                                                                     | Tolerance (to variations, shutdowns)                                                                     | 10%                                                                                                                                                                                                                                                                                                                                                              |
| 4.4                                                                     | Protection                                                                                               | Battery powered alarm for power failure or disconnection.                                                                                                                                                                                                                                                                                                        |
| 4.5                                                                     | Power consumption                                                                                        | 25W                                                                                                                                                                                                                                                                                                                                                              |
| 4.6                                                                     | Other energy supplies                                                                                    | Na                                                                                                                                                                                                                                                                                                                                                               |
| <b>5. ACCESSORIES, SPARE PARTS, CONSUMABLES</b>                         |                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                  |
| 5.1                                                                     | Accessories (mandatory, standard, optional)                                                              | Clamp for mounting pump on IV stand.                                                                                                                                                                                                                                                                                                                             |
| 5.2                                                                     | Spare parts (main ones)                                                                                  |                                                                                                                                                                                                                                                                                                                                                                  |
| 5.3                                                                     | Consumables / reagents (open, closed system)                                                             | Battery, syringe holder, PMO lines                                                                                                                                                                                                                                                                                                                               |
| 5.4                                                                     | Others                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                  |
| <b>BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS</b>              |                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                  |
| <b>6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS</b>                 |                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                  |
| 6.1                                                                     | Atmosphere / Ambiance (air conditioning, humidity, dust ...)                                             | Operating condition:<br>– Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances.                                                                                                                                                                                                   |
| 6.2                                                                     | User's care, Cleaning, Disinfection & Sterility issues                                                   | Capable of cleaning with alcohol or chlorine wipes.                                                                                                                                                                                                                                                                                                              |
| <b>7. STANDARDS AND SAFETY</b>                                          |                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                  |
| 7.1                                                                     | Certificates (pre-market, sanitary, ...); Performance and safety standards (specific to the device type) | CE or FDA certified.<br>Manufacturer / supplier should have ISO 13485 certificate for quality standard.<br>Electrical safety conforms to standards for electrical safety IEC-60601-1, class II.<br>Shall meet IEC 60601-1-2 EMC standard requirements.<br>Certified to IEC-60601-2-24: Particular requirements for the safety of infusion pumps and controllers. |
| <b>8. TRAINING AND INSTALLATION</b>                                     |                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                  |
| 8.1                                                                     | Pre-installation requirements: nature, values, quality, tolerance                                        | Supplier to perform installation, safety and operation checks before handover.                                                                                                                                                                                                                                                                                   |
| 8.2                                                                     | Requirements for sign-off                                                                                | As per requirement                                                                                                                                                                                                                                                                                                                                               |

|                                    |                                                              |                                                                                                                                                                                        |
|------------------------------------|--------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8.3                                | <b>Training of staff (medical, paramedical, technicians)</b> | Training of users in operation and basic maintenance shall be provided.                                                                                                                |
| 8.4                                | <b>Others</b>                                                |                                                                                                                                                                                        |
| <b>9. WARRANTY AND MAINTENANCE</b> |                                                              |                                                                                                                                                                                        |
| 9.1                                | <b>Warranty</b>                                              | 3 year                                                                                                                                                                                 |
| 9.2                                | <b>Maintenance tasks</b>                                     | Advanced maintenance and calibration tasks required shall be documented.                                                                                                               |
| 9.3                                | <b>Service contract clauses, including prices</b>            | Local clinical staff to affirm completion of installation.                                                                                                                             |
| 9.4                                | <b>Others</b>                                                |                                                                                                                                                                                        |
| <b>10. DOCUMENTATION</b>           |                                                              |                                                                                                                                                                                        |
| 10.1                               | <b>Operating manuals, service manuals, other manuals</b>     | User, technical and maintenance manuals to be supplied in english language.<br>List to be provided of equipment and procedures required for local calibration and routine maintenance. |
| 10.2                               | <b>Other accompanying documents</b>                          | List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.                                   |
| <b>11. NOTES</b>                   |                                                              |                                                                                                                                                                                        |
| 11.1                               | <b>Other information</b>                                     | Contact details of manufacturer, supplier and local service agent to be provided.                                                                                                      |
| 11.2                               | <b>Recommendations or warnings</b>                           |                                                                                                                                                                                        |

# INFUSION PUMP (VOLUMETRIC)

|                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                | 2.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Date:                        | JULY 2014.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Done by : (name/institution) | HCT/NHSRC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| NAME AND CODING              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| GMDN name                    | Infusion Pump (Volumetric)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| GMDN code(s)                 | CT1821                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| GENERAL                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 1. USE                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 1.1                          | <b>Clinical purpose</b><br>An infusion pump infuses fluids, medication or nutrients into a patient's circulatory system. It is generally used intravenously, although subcutaneous, arterial and epidural infusions are occasionally used.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 1.2                          | <b>Used by clinical department/ward</b><br>NICU and PICU                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 1.3                          | <b>Overview of functional requirements</b><br>Alarms indicate if any error situations occur.<br>The drive arm infuses the medication at a steady, programmed rate.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| TECHNICAL                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 2. TECHNICAL CHARACTERISTICS |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 2.1                          | <b>Clinical performances</b><br>Should accept all internationally produced/marketed bottle and should be able to detect it automatically, Should support the Bolus supply of drug on press of single button, as per need and should be able to preset different range of Bolus supply.<br>Preferably the unit should be of Bottom/side loaded to avoid accidental spilling of drugs and damage to the machine.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 2.2                          | <b>Technical characteristics (specific to this type of device)</b> <ol style="list-style-type: none"> <li>Flow rate programmable range at least from 0.1 to 200 ml/hr, in steps of 0.1 ml/hr; and at least from 100 to 1200 ml/hr in steps of 1 ml/hr.</li> <li>Saves last infusion rate even when the AC power is switched off.</li> <li>Bolus rate should be programmable to approx. 500 ml, with infused volume display.</li> <li>Selectable occlusion pressure trigger levels selectable from 300, 500 and 900 mmHg.</li> <li>Accuracy of <math>\pm 2\%</math> or better for set parameters.</li> <li>Maximum pressure generated 20 psi.</li> <li>Pause infusion facility required.</li> <li>Self-check carried out on powering on.</li> <li>Comprehensive alarm package required including: occlusion alarm, near end of infusion pre-alarm and alarm, volume limit pre-alarm and alarm, low battery pre-alarm and alarm, AC power failure, drive disengaged.</li> <li>It should be open system .</li> </ol> |
| 2.3                          | <b>Settings</b><br>Single loadable                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |



|                                                                                    |                                                                                                         |                                                                                                                                                                |
|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2.4                                                                                | User's interface                                                                                        | Automatic                                                                                                                                                      |
| 2.5                                                                                | Software and/or standard of communication                                                               | Inbuilt                                                                                                                                                        |
| <b>3. PHYSICAL CHARACTERISTICS</b>                                                 |                                                                                                         |                                                                                                                                                                |
| 3.1                                                                                | Dimensions (metric)                                                                                     | NA                                                                                                                                                             |
| 3.2                                                                                | Weight (lbs, kg)                                                                                        | NA                                                                                                                                                             |
| 3.3                                                                                | Configuration                                                                                           | Tamper-resistant case made of impact resistant material.<br>Securely mountable on tabletop, IV stand or bed fitting.                                           |
| 3.4                                                                                | Noise (in dBA)                                                                                          | Noise free                                                                                                                                                     |
| 3.5                                                                                | heat dissipation                                                                                        |                                                                                                                                                                |
| 3.6                                                                                | Mobility, portability                                                                                   | Yes                                                                                                                                                            |
| <b>4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO<sub>2</sub> ....)</b> |                                                                                                         |                                                                                                                                                                |
| 4.1                                                                                | Voltage (value, AC or DC, monophasic or triphase)                                                       | 220V ± 10%, 50 Hz                                                                                                                                              |
| 4.2                                                                                | Battery operated                                                                                        | Internal rechargeable battery having a minimum of 2 hours backup                                                                                               |
| 4.3                                                                                | Tolerance (to variations, shutdowns)                                                                    | ± 10%                                                                                                                                                          |
| 4.4                                                                                | Protection                                                                                              | Battery powered alarm for power failure or disconnection                                                                                                       |
| 4.5                                                                                | Power consumption                                                                                       | NA                                                                                                                                                             |
| 4.6                                                                                | Other energy supplies                                                                                   | NA                                                                                                                                                             |
| <b>5. ACCESSORIES, SPARE PARTS, CONSUMABLES</b>                                    |                                                                                                         |                                                                                                                                                                |
| 5.1                                                                                | Accessories (mandatory, standard, optional)                                                             | Clamp for mounting pump on IV stand                                                                                                                            |
| 5.2                                                                                | Spare parts (main ones)                                                                                 | NA                                                                                                                                                             |
| 5.3                                                                                | Consumables/reagents (open, closed system)                                                              | NA                                                                                                                                                             |
| 5.4                                                                                | Others                                                                                                  |                                                                                                                                                                |
| <b>BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS</b>                             |                                                                                                         |                                                                                                                                                                |
| <b>6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS</b>                            |                                                                                                         |                                                                                                                                                                |
| 6.1                                                                                | Atmosphere/Ambiance (air conditioning, humidity, dust...)                                               | Operating condition:<br>– Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances. |
| 6.2                                                                                | User's care, Cleaning, Disinfection & Sterility issues                                                  | Capable of cleaning with alcohol or chlorine wipes                                                                                                             |
| <b>7. STANDARDS AND SAFETY</b>                                                     |                                                                                                         |                                                                                                                                                                |
| 7.1                                                                                | Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type) | 1) FDA (US)/CE (EU) from authorized third party and BIS/ISO 13485.<br>2) Relevant IEC-60601-Part 1 & 2, certificates by a notified agency.                     |
| <b>8. TRAINING AND INSTALLATION</b>                                                |                                                                                                         |                                                                                                                                                                |
| 8.1                                                                                | Pre-installation requirements: nature, values, quality, tolerance                                       | Supplier to perform installation, safety and operation checks before handover.                                                                                 |
| 8.2                                                                                | Requirements for sign-off                                                                               | As per requirement                                                                                                                                             |
| 8.3                                                                                | Training of staff (medical, paramedical, technicians)                                                   | Training of users in operation and basic maintenance shall be provided.                                                                                        |
| 8.4                                                                                | Others                                                                                                  |                                                                                                                                                                |

| 9. WARRANTY AND MAINTENANCE |                                                                                         |                                                                                                                                                                                                                                                                                                             |
|-----------------------------|-----------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 9.1                         | Warranty                                                                                | 3 years                                                                                                                                                                                                                                                                                                     |
| 9.2                         | Maintenance tasks                                                                       | Advanced maintenance and calibration tasks required shall be documented                                                                                                                                                                                                                                     |
| 9.3                         | Service contract clauses, including prices                                              | 1) The spare, accessories & consumables price list required for maintenance and repairs in future after guarantee/warranty period should be attached;<br>2) Free servicing during warranty period;                                                                                                          |
| 10. DOCUMENTATION           |                                                                                         |                                                                                                                                                                                                                                                                                                             |
| 10.1                        | Operating manuals, service manuals, other manuals                                       | Should provide 2 sets (hardcopy) of:-<br>1) User, technical, maintenance and service manuals to be supplied along with machine diagrams;<br>2) List of equipment and procedures required for local calibration and routine maintenance;<br>3) Certificate of calibration to be provided by the manufacture; |
| 10.2                        | Other accompanying documents                                                            | List of important spares and accessories, with their part numbers and cost;                                                                                                                                                                                                                                 |
| 11. NOTES                   |                                                                                         |                                                                                                                                                                                                                                                                                                             |
| 11.1                        | Service Support Contact details (Hierarchy Wise; including a toll free/landline number) | 1) Contact details of manufacturer, supplier and local service agent to be provided;<br>2) Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer;                                                                                                                                               |
| 11.2                        | Recommendations or warnings                                                             | Any warning signs would be adequately displayed.                                                                                                                                                                                                                                                            |

# SUCTION PUMP PORTABLE ELECTRIC

|                                                                              |                                                                 |                                                                                                                                                                                                                                                   |
|------------------------------------------------------------------------------|-----------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                                                                |                                                                 | 1.0                                                                                                                                                                                                                                               |
| Date:                                                                        |                                                                 | SEPT 2014                                                                                                                                                                                                                                         |
| Done by : (name/institution)                                                 |                                                                 | HCT/NHSRC                                                                                                                                                                                                                                         |
| NAME AND CODING                                                              |                                                                 |                                                                                                                                                                                                                                                   |
| GMDN name                                                                    |                                                                 | Suction systems                                                                                                                                                                                                                                   |
| GMDN code                                                                    |                                                                 | CT1272                                                                                                                                                                                                                                            |
| GENERAL                                                                      |                                                                 |                                                                                                                                                                                                                                                   |
| 1. USE                                                                       |                                                                 |                                                                                                                                                                                                                                                   |
| 1.1                                                                          | Clinical purpose                                                | To aspirate fluids, secretions, or other foreign materials from a patient's airway by means of suction.                                                                                                                                           |
| 1.2                                                                          | Used by clinical department/ ward                               | NICU & PICU                                                                                                                                                                                                                                       |
| TECHNICAL                                                                    |                                                                 |                                                                                                                                                                                                                                                   |
| 2. TECHNICAL CHARACTERISTICS                                                 |                                                                 |                                                                                                                                                                                                                                                   |
| 2.1                                                                          | Technical characteristics (specific to this type of device)     | 0 to - 760 mm Hg ± 10 regulable, 1/2 HP;<br>single phase 1440 RPM motor;<br>flutter free vacuum control knob, ;<br>Wide mouthed 2 x 2 LITRE (light weight, unbreakable and clear) with self sealing bungs and mechanical over flow safety device. |
| 2.2                                                                          | Settings                                                        | Manual                                                                                                                                                                                                                                            |
| 2.3                                                                          | User's interface                                                | Manual                                                                                                                                                                                                                                            |
| 2.4                                                                          | Software and/or standard of communication (where ever required) | NA                                                                                                                                                                                                                                                |
| 3. PHYSICAL CHARACTERISTICS                                                  |                                                                 |                                                                                                                                                                                                                                                   |
| 3.1                                                                          | Dimensions (metric)                                             | Max: 43 x 30 x 68 cms                                                                                                                                                                                                                             |
| 3.2                                                                          | Weight (lbs, kg)                                                | Max: 27Kg                                                                                                                                                                                                                                         |
| 3.3                                                                          | Configuration                                                   | NA                                                                                                                                                                                                                                                |
| 3.4                                                                          | Noise (in dBA)                                                  | 50 dB A ± 3                                                                                                                                                                                                                                       |
| 3.5                                                                          | heat dissipation                                                | Should maintain upto 36.5 deg temp and the heat disbursed through a exhaust fan                                                                                                                                                                   |
| 3.6                                                                          | Mobility, portability                                           | Yes                                                                                                                                                                                                                                               |
| 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO <sub>2</sub> ....) |                                                                 |                                                                                                                                                                                                                                                   |
| 4.1                                                                          | Power Requirements                                              | 220 V, 50 Hz, 2 ± 0.5 Amps, 370 watts for AC                                                                                                                                                                                                      |
| 4.2                                                                          | Battery operated                                                | NA                                                                                                                                                                                                                                                |
| 4.3                                                                          | Tolerance (to variations, shutdowns)                            | Voltage corrector/stabilizer to allow operation at ± 30% of local rated voltage. Use of SMPS to correct voltage.                                                                                                                                  |
| 4.4                                                                          | Protection                                                      | Electrical protection by resettable overcurrent breakers or replaceable fuses, fitted in both live and neutral lines.                                                                                                                             |

|                                                         |                                                                                                     |                                                                                                                                                                                                                                                                                      |
|---------------------------------------------------------|-----------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4.5                                                     | Power consumption                                                                                   | should run with other life saving equipments running parallelly.                                                                                                                                                                                                                     |
| 4.6                                                     | Other energy supplies                                                                               | NA                                                                                                                                                                                                                                                                                   |
| <b>5. ACCESSORIES, SPARE PARTS, CONSUMABLES</b>         |                                                                                                     |                                                                                                                                                                                                                                                                                      |
| 5.1                                                     | Accessories & Spares                                                                                | collection container & its cap, suction tube tips, a vacuum gauge, two sets of moisture & microbial filters and control knob.                                                                                                                                                        |
| 5.2                                                     | Consumables/reagents (open, closed system)                                                          | Silicone Tubing: 8 mm ID x 2 mtr (PVC), 2x2 Lt jar (one set extra)                                                                                                                                                                                                                   |
| <b>6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS</b> |                                                                                                     |                                                                                                                                                                                                                                                                                      |
| 6.1                                                     | Atmosphere/Ambiance (air conditioning, humidity, dust...)                                           | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.<br>Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.                                                   |
| 6.2                                                     | User's care, Cleaning, Disinfection & Sterility issues                                              | Complete unit to be easily washable and sterilizable using alcohol and other chemical agents.                                                                                                                                                                                        |
| <b>7. STANDARDS AND SAFETY</b>                          |                                                                                                     |                                                                                                                                                                                                                                                                                      |
| 7.1                                                     | Certifications                                                                                      | FDA/CE and BIS/ISO 13485:2003;<br>IEC 60601-1-8; IEC 60601-1-SER-Ed 1.0-2011; IEC/TRF 60601-1-8-Ed 4.0-2010                                                                                                                                                                          |
| <b>8. TRAINING AND INSTALLATION</b>                     |                                                                                                     |                                                                                                                                                                                                                                                                                      |
| 8.1                                                     | Pre-installation requirements: nature, values, quality, tolerance                                   | Availability of 15 amp socket, safety and operation checks before handover.                                                                                                                                                                                                          |
| 8.2                                                     | Requirements for sign-off                                                                           | Certificate of Calibration and inspection from the factory.                                                                                                                                                                                                                          |
| 8.3                                                     | Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order) | Training of users in operation and basic maintenance shall be provided.                                                                                                                                                                                                              |
| <b>9. WARRANTY AND MAINTENANCE</b>                      |                                                                                                     |                                                                                                                                                                                                                                                                                      |
| 9.1                                                     | Warranty                                                                                            | 3 years                                                                                                                                                                                                                                                                              |
| 9.2                                                     | Maintenance tasks                                                                                   | Maintenance manual detailing complete maintaining schedule.                                                                                                                                                                                                                          |
| 9.3                                                     | Service contract clauses, including prices                                                          | Local clinical staff/authorized officer on behalf of purchaser to affirm completion of installation.                                                                                                                                                                                 |
| <b>10. DOCUMENTATION</b>                                |                                                                                                     |                                                                                                                                                                                                                                                                                      |
| 10                                                      | Operating manuals, service manuals, other manuals                                                   | Advanced maintenance tasks required shall be documented.<br>User, technical and maintenance manuals to be supplied in english/hindi language along with machine diagrams.<br>List to be provided of equipment and procedures required for local calibration and routine maintenance. |
| 10                                                      | Other accompanying documents                                                                        | List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.                                                                                                                                 |
| <b>11. NOTES</b>                                        |                                                                                                     |                                                                                                                                                                                                                                                                                      |
| 11                                                      | Service Support Contact details (Hierarchy Wise; including a toll free/landline number)             | Any Contract (AMC/MC/add-hoc) to be declared by the manufacturer.                                                                                                                                                                                                                    |
| 11                                                      | Recommendations or warnings                                                                         | Any recommendations for best use and supplementary warning for safety should be declared.                                                                                                                                                                                            |

# SUCTION PUMP, FOOT OPERATED

|                                                                              |                                                                                                                                                       |
|------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                                                                | 1.0                                                                                                                                                   |
| Date:                                                                        | SEPT 2014.                                                                                                                                            |
| Done by : (name/institution)                                                 | HCT/NHSRC                                                                                                                                             |
| NAME AND CODING                                                              |                                                                                                                                                       |
| GMDN name                                                                    | Emergency suction systems                                                                                                                             |
| GMDN code                                                                    | CT2180                                                                                                                                                |
| GENERAL                                                                      |                                                                                                                                                       |
| 1. USE                                                                       |                                                                                                                                                       |
| 1.1                                                                          | <b>Clinical purpose</b><br>To aspirate fluids, secretions, or other foreign materials from a patient's airway by means of suction.                    |
| TECHNICAL                                                                    |                                                                                                                                                       |
| 2. TECHNICAL CHARACTERISTICS                                                 |                                                                                                                                                       |
| 2.1                                                                          | <b>Technical characteristics (specific to this type of device)</b><br>Giving vacuum more than 550 mm Hg, with 200 ml/stroke; oil free diaphragm pump. |
| 2.2                                                                          | <b>Settings</b><br>Manual                                                                                                                             |
| 2.3                                                                          | <b>User's interface</b><br>Manual                                                                                                                     |
| 2.4                                                                          | <b>Software and/or standard of communication (where ever required)</b><br>NA                                                                          |
| 3. PHYSICAL CHARACTERISTICS                                                  |                                                                                                                                                       |
| 3.1                                                                          | <b>Dimensions (metric)</b><br>Max spec: 32 x 17 x 30 cms                                                                                              |
| 3.2                                                                          | <b>Weight (lbs, kg)</b><br>2.5kg max                                                                                                                  |
| 3.3                                                                          | <b>Configuration</b><br>NA                                                                                                                            |
| 3.4                                                                          | <b>Noise (in dBA)</b><br>NA                                                                                                                           |
| 3.5                                                                          | <b>heat dissipation</b><br>NA                                                                                                                         |
| 3.6                                                                          | <b>Mobility, portability</b><br>Yes                                                                                                                   |
| 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO <sub>2</sub> ....) |                                                                                                                                                       |
| 4.1                                                                          | <b>Power Requirements</b><br>NA                                                                                                                       |
| 4.2                                                                          | <b>Battery operated</b><br>NA                                                                                                                         |
| 4.3                                                                          | <b>Tolerance (to variations, shutdowns)</b><br>NA                                                                                                     |
| 4.4                                                                          | <b>Protection</b><br>NA                                                                                                                               |
| 4.5                                                                          | <b>Power consumption</b><br>NA                                                                                                                        |
| 4.6                                                                          | <b>Other energy supplies</b><br>NA                                                                                                                    |
| 5. ACCESSORIES, SPARE PARTS, CONSUMABLES                                     |                                                                                                                                                       |
| 5.1                                                                          | <b>Accessories &amp; spare parts</b><br>Collection bottles, clear unbreakable jar (one set extra)                                                     |
| 5.2                                                                          | <b>Consumables/reagents (open, closed system)</b><br>Microbial filter, silicon tubing (one set extra)                                                 |

| 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS |                                                                                                     |                                                                                                                                                                                                                                                                                    |
|--------------------------------------------------|-----------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 6.1                                              | Atmosphere/Ambiance (air conditioning, humidity, dust...)                                           | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.<br>Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.                                                 |
| 6.2                                              | User's care, Cleaning, Disinfection & Sterility issues                                              | Complete unit to be easily washable and sterilizable using both alcohol and chemical agents.                                                                                                                                                                                       |
| 7. STANDARDS AND SAFETY                          |                                                                                                     |                                                                                                                                                                                                                                                                                    |
| 7.1                                              | Certifications                                                                                      | FDA/CE and BIS/ISO 13485:2003; ISO 10079-2-1999                                                                                                                                                                                                                                    |
| 8. TRAINING AND INSTALLATION                     |                                                                                                     |                                                                                                                                                                                                                                                                                    |
| 8.1                                              | Pre-installation requirements: nature, values, quality, tolerance                                   | NA                                                                                                                                                                                                                                                                                 |
| 8.2                                              | Requirements for sign-off                                                                           | NA                                                                                                                                                                                                                                                                                 |
| 8.3                                              | Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order) | Training of users in operation and basic maintenance shall be provided                                                                                                                                                                                                             |
| 9. WARRANTY AND MAINTENANCE                      |                                                                                                     |                                                                                                                                                                                                                                                                                    |
| 9.1                                              | Warranty                                                                                            | 3 years                                                                                                                                                                                                                                                                            |
| 9.2                                              | Maintenance tasks                                                                                   | maintenance manual detailing complete maintaining schedule                                                                                                                                                                                                                         |
| 9.3                                              | Service contract clauses, including prices                                                          | Local clinical staff/authorized officer on behalf of purchaser to affirm completion of installation                                                                                                                                                                                |
| 10. DOCUMENTATION                                |                                                                                                     |                                                                                                                                                                                                                                                                                    |
| 10.1                                             | Operating manuals, service manuals, other manuals                                                   | Advanced maintenance tasks required shall be documented<br>User, technical and maintenance manuals to be supplied in english/hindi language along with machine diagrams.<br>List to be provided of equipment and procedures required for local calibration and routine maintenance |
| 10.2                                             | Other accompanying documents                                                                        | List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.                                                                                                                               |
| 11. NOTES                                        |                                                                                                     |                                                                                                                                                                                                                                                                                    |
| 11.1                                             | Service Support Contact details (Hierarchy Wise; including a toll free/landline number)             | NA                                                                                                                                                                                                                                                                                 |
| 11.2                                             | Recommendations or warnings                                                                         | Any recommendations for best use and supplementary warning for safety should be declared                                                                                                                                                                                           |

# SELF INFLATING RESERVOIR BAG

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|--------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                  | 2.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Date:                          | 27/2/2015                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Done by : (name / institution) | HCT/ NHSRC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| NAME AND CODING                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| GMDN name                      | Manual pulmonary resuscitator, reusable                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| GMDN code(s)                   | CT1911                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| GENERAL                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 1. USE                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 1.1                            | <b>Clinical purpose</b><br>To provide or assist ventilation in a patient who is apnoeic or exhibits inadequate respiration through manual pulmonar-driven pressure cycle functions.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 1.2                            | <b>Used by clinical department/ ward</b><br>It is used in ambulances, intensive care units (ICU), during internal patient transfer, accident and emergency (A&E), and mass casualty incidents (MCI).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| TECHNICAL                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 2. TECHNICAL CHARACTERISTICS   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 2.1                            | <b>Technical characteristics</b> <ol style="list-style-type: none"> <li>1. Manual resuscitator with transparent face-mask.</li> <li>2. Child models (750ml, 500ml and 260ml bag capacity).</li> <li>3. Standard 15/22 mm Swivel connector allows connections to all common masks Endotracheal Tubes both for adults and infants.</li> <li>4. Provision to give supplemented oxygen-by-oxygen reservoir providing 100% oxygen.</li> <li>5. Non-re breathing valve enabling the patient to inspire oxygen from the reservoir bag.</li> <li>6. Should be suitable for single hand operate.</li> <li>7. Should be easy to dissemble for cleaning and disinfection.</li> <li>8. Should have pressure release valve at 40cm H<sub>2</sub>O.</li> <li>9. Should have silicone oxygen tube 2m length.</li> <li>10 It should be up-to 40 times autoclavable including bag and washers.</li> <li>11. The bag should be of silicone material.</li> <li>12. Self Inflating Resuscitator bag should be of medical grade silicone rubber.</li> <li>13. The reservoir should be a PVC bag of 600ml capacity for 260ml &amp; 500ml bag capacity and 1000ml for 750ml bag capacity.</li> </ol> |
| 2.2                            | <b>Settings</b><br>NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 2.3                            | <b>User's interface</b><br>manual                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 2.4                            | <b>Software and/or standard of communication(whenever required)</b><br>NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |

| 3. PHYSICAL CHARACTERISTICS                                      |                                                                                                                                     |                                                                                                                                                                                                                                                                        |
|------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3.1                                                              | Dimensions (metric)                                                                                                                 | handheld                                                                                                                                                                                                                                                               |
| 3.2                                                              | Weight (lbs, kg)                                                                                                                    | light enough to be operated by hand/palm for long duration.                                                                                                                                                                                                            |
| 3.3                                                              | Configuration                                                                                                                       | NA                                                                                                                                                                                                                                                                     |
| 3.4                                                              | Noise (in dBA), heat dissipation                                                                                                    | NA                                                                                                                                                                                                                                                                     |
| 3.5                                                              | Mobility, portability                                                                                                               | hanheld                                                                                                                                                                                                                                                                |
| 3.6                                                              | Others                                                                                                                              |                                                                                                                                                                                                                                                                        |
| 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) |                                                                                                                                     |                                                                                                                                                                                                                                                                        |
| 4.1                                                              | Power Requirements                                                                                                                  | NA                                                                                                                                                                                                                                                                     |
| 4.2                                                              | Battery operated                                                                                                                    | NA                                                                                                                                                                                                                                                                     |
| 4.3                                                              | Tolerance (to variations, shutdowns)                                                                                                | NA                                                                                                                                                                                                                                                                     |
| 4.4                                                              | Protection                                                                                                                          | NA                                                                                                                                                                                                                                                                     |
| 4.5                                                              | Power consumption                                                                                                                   | NA                                                                                                                                                                                                                                                                     |
| 4.6                                                              | Other energy supplies                                                                                                               | NA                                                                                                                                                                                                                                                                     |
| 5. ACCESSORIES, SPARE PARTS, CONSUMABLES                         |                                                                                                                                     |                                                                                                                                                                                                                                                                        |
| 5.1                                                              | Accessories (mandatory, standard, optional)                                                                                         | Silicon bellow,<br>Non Rebreathing Valve,<br>2 meter oxygen tube,<br>Guedel Airway,                                                                                                                                                                                    |
| 5.2                                                              | Spare parts (main ones)                                                                                                             | Oxygen Reservoir bag                                                                                                                                                                                                                                                   |
| 5.3                                                              | Consumables / reagents (open, closed system)                                                                                        | Neonatal Mask of 3 sizes viz 0, 1 and 2                                                                                                                                                                                                                                |
| 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS                 |                                                                                                                                     |                                                                                                                                                                                                                                                                        |
| 6.1                                                              | Atmosphere / Ambiance (air conditioning, humidity, dust ...)                                                                        | Operating condition: <ul style="list-style-type: none"> <li>– Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances.</li> <li>– an ambient air velocity is less than 0.3 m/s.</li> </ul> |
| 6.2                                                              | User's care, Cleaning, Disinfection & Sterility issues                                                                              | Complete unit to be easily washable and sterilizable using both alcohol and chlorine agents.                                                                                                                                                                           |
| 7. STANDARDS AND SAFETY                                          |                                                                                                                                     |                                                                                                                                                                                                                                                                        |
| 7.1                                                              | Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international | ISO 13485;Manufacturer / supplier should have ISO certificate for quality standard.<br>Should be FDA (US) / CE (EU) approved product or BIS certified<br>Should meet ISO 10651-4 standard requirement                                                                  |
| 8. TRAINING AND INSTALLATION                                     |                                                                                                                                     |                                                                                                                                                                                                                                                                        |
| 8.1                                                              | Pre-installation requirements: nature, values, quality, tolerance                                                                   | Supplier to perform installation, safety and operation checks before handover.                                                                                                                                                                                         |
| 8.2                                                              | Requirements for sign-off                                                                                                           | Certificate of Calibration and inspection from the factory.                                                                                                                                                                                                            |
| 8.3                                                              | Training of staff (medical, paramedical, technicians)                                                                               | Training of users in operation and basic maintenance shall be provided                                                                                                                                                                                                 |
| 9. WARRANTY AND MAINTENANCE                                      |                                                                                                                                     |                                                                                                                                                                                                                                                                        |
| 9.1                                                              | Warranty                                                                                                                            | 1 year.                                                                                                                                                                                                                                                                |
| 9.2                                                              | Maintenance tasks                                                                                                                   | maintenance manual detailing complete maintaining schedule                                                                                                                                                                                                             |
| 9.3                                                              | Service contract clauses, including prices                                                                                          |                                                                                                                                                                                                                                                                        |
| 9.4                                                              | Others                                                                                                                              |                                                                                                                                                                                                                                                                        |



| 10. DOCUMENTATION |                                                                                         |                   |
|-------------------|-----------------------------------------------------------------------------------------|-------------------|
| 10.1              | Operating manuals, service manuals, other manuals                                       | Required          |
| 10.2              | Other accompanying documents                                                            | Demonstration CDs |
| 10.3              | Recommendations for maintenance                                                         | NA                |
| 11. NOTES         |                                                                                         |                   |
| 11.1              | Service Support Contact details (Hierarchy Wise; including a toll free/landline number) | NA                |
| 11.2              | Recommendations or warnings                                                             | NA                |

# LARYNGOSCOPE

|                              |                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|------------------------------|-----------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                |                                                                 | 2.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Date:                        |                                                                 | SEPT 2014                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Done by : (name/institution) |                                                                 | HCT/NHSRC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| NAME AND CODING              |                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| GMDN name                    |                                                                 | Laryngoscopes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| GMDN code(s)                 |                                                                 | CT 1723                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| GENERAL                      |                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 1. USE                       |                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 1.1                          | Clinical purpose                                                | For viewing vocal folds and glottis. Surgical and mechanical ventilation/intubation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 1.2                          | Used by clinical department/ward                                | PICU/NICU                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| TECHNICAL                    |                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 2. TECHNICAL CHARACTERISTICS |                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 2.1                          | Technical characteristics (specific to this type of device)     | <p>Fiber optic Laryngoscope - preferably should be single patient use to ensure no infection to the patients, should comprise of disposable handle and reusable light source using the latest LED technology.</p> <p>The main body of the handle should incorporate an excellent grip &amp; should feel even wearing a glove.</p> <p>There should be a freely moving light intensifier of light from the light source through to the tip of the fiber optic blade to prevent any possibility of cross contamination.</p> <p>The unit should allow the blade to be inserted easily &amp; should provide a positive locking mechanism when moved in to the closed position.</p> <p>The patient contact material should be biocompatible.</p> |
| 2.2                          | Settings                                                        | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 2.3                          | User's interface                                                | Manual                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 2.4                          | Software and/or standard of communication (where ever required) | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 3. PHYSICAL CHARACTERISTICS  |                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 3.1                          | Dimensions (metric)                                             | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 3.2                          | Weight (lbs, kg)                                                | Light weight                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 3.3                          | Configuration                                                   | <ol style="list-style-type: none"> <li>1. Handheld unit, single piece when in use.</li> <li>2. On/off switch to be robust and easy to use.</li> <li>3. External material to be non-ferrous.</li> <li>4. Blades to be surgical grade stainless steel.</li> <li>5. Supplied in protective, reclosable container.</li> </ol>                                                                                                                                                                                                                                                                                                                                                                                                                  |

|                                                                                    |                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                 |
|------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3.4                                                                                | Noise (in dBA), heat dissipation                                                                                                    | NA                                                                                                                                                                                                                                                                                                                              |
| 3.5                                                                                | Mobility, portability                                                                                                               | Yes                                                                                                                                                                                                                                                                                                                             |
| 3.6                                                                                | Others                                                                                                                              | storage box should be provided                                                                                                                                                                                                                                                                                                  |
| <b>4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO<sub>2</sub> ....)</b> |                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                 |
| 4.1                                                                                | Power Requirements                                                                                                                  | independent of external source                                                                                                                                                                                                                                                                                                  |
| 4.2                                                                                | Battery operated                                                                                                                    | Internal batteries, rechargeable preferred/Penlight battery AA size, Battery charger (if rechargeables), Battery compartment (if reusables) to be sealed against liquid ingress, yet easily opened.                                                                                                                             |
| 4.3                                                                                | Tolerance (to variations, shutdowns)                                                                                                | NA                                                                                                                                                                                                                                                                                                                              |
| 4.4                                                                                | Protection                                                                                                                          | NA                                                                                                                                                                                                                                                                                                                              |
| 4.5                                                                                | Power consumption                                                                                                                   | 3V lithium battery                                                                                                                                                                                                                                                                                                              |
| 4.6                                                                                | Other energy supplies                                                                                                               |                                                                                                                                                                                                                                                                                                                                 |
| <b>5. ACCESSORIES, SPARE PARTS, CONSUMABLES</b>                                    |                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                 |
| 5.1                                                                                | Accessories (mandatory, standard, optional)                                                                                         | Batteries, light source, blades of various neonatal sizes                                                                                                                                                                                                                                                                       |
| 5.2                                                                                | Spare parts (main ones)                                                                                                             | Handle                                                                                                                                                                                                                                                                                                                          |
| 5.3                                                                                | Consumables/reagents (open, closed system)                                                                                          | 5 LED should be given as spare                                                                                                                                                                                                                                                                                                  |
| <b>6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS</b>                            |                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                 |
| 6.1                                                                                | Atmosphere/Ambiance (air conditioning, humidity, dust...)                                                                           | Operating condition: <ul style="list-style-type: none"> <li>– Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances.</li> <li>– An ambient air velocity is less than 0.3 m/s.</li> </ul> Liquid splash resistant<br>Blades should be autoclavable |
| 6.2                                                                                | User's care, Cleaning, Disinfection & Sterility issues                                                                              | Should be autoclavable                                                                                                                                                                                                                                                                                                          |
| <b>7. STANDARDS AND SAFETY</b>                                                     |                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                 |
| 7.2                                                                                | Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international | ISO7376 standard; Manufacturer/supplier should have ISO certificate for quality standard.<br>The lithium battery should comply to IEC 62133 or its equivalent.<br>The device should meet IEC 60601-1, IEC 60601-2 standard requirements.<br>Should be FDA/CE approved product.                                                  |
| <b>8. TRAINING AND INSTALLATION</b>                                                |                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                 |
| 8.1                                                                                | Pre-installation requirements: nature, values, quality, tolerance                                                                   | NA                                                                                                                                                                                                                                                                                                                              |
| 8.2                                                                                | Requirements for sign-off                                                                                                           | NA                                                                                                                                                                                                                                                                                                                              |
| 8.3                                                                                | Training of staff (medical, paramedical, technicians)                                                                               | Training of users in operation and basic maintenance shall be provided.                                                                                                                                                                                                                                                         |
| <b>9. WARRANTY AND MAINTENANCE</b>                                                 |                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                 |
| 9.1                                                                                | Warranty                                                                                                                            | 3 years; LED upto 6 months                                                                                                                                                                                                                                                                                                      |
| 9.2                                                                                | Maintenance tasks                                                                                                                   | Autoclave                                                                                                                                                                                                                                                                                                                       |
| 9.3                                                                                | Service contract clauses, including prices                                                                                          | NA                                                                                                                                                                                                                                                                                                                              |

| 10. DOCUMENTATION |                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-------------------|------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10                | <b>Operating manuals, service manuals, other manuals</b>                                       | <p>User, technical and maintenance manuals to be supplied in english language.</p> <p>Certificate of calibration and inspection to be provided.</p> <p>List to be provided of equipment and procedures required for local calibration and routine maintenance</p> <p>List to be provided of important spares and accessories, with their part numbers and cost.</p> <p>Contact details of manufacturer, supplier and local service agent to be provided</p> |
| 10                | <b>Other accompanying documents</b>                                                            | service manuals                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 11. NOTES         |                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 11                | <b>Service Support Contact details (Hierarchy Wise; including a toll free/landline number)</b> | Any Contract (AMC/MC/add-hoc) to be declared by the manufacturer                                                                                                                                                                                                                                                                                                                                                                                            |
| 11                | <b>Recommendations or warnings</b>                                                             | Any recommendations for best use and supplementary warning for safety should be declared                                                                                                                                                                                                                                                                                                                                                                    |

# OXYGEN HOOD

|                                                                  |                                                                |                                                                                                                                                                                                                                                          |
|------------------------------------------------------------------|----------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                                                    |                                                                | 2.0                                                                                                                                                                                                                                                      |
| Date:                                                            |                                                                | 26/2/2015                                                                                                                                                                                                                                                |
| Done by : (name / institution)                                   |                                                                | HCT/ NHSRC                                                                                                                                                                                                                                               |
| NAME AND CODING                                                  |                                                                |                                                                                                                                                                                                                                                          |
| GMDN name                                                        |                                                                | Oxygen administration enclosures                                                                                                                                                                                                                         |
| GMDN code(s)                                                     |                                                                | CT 1098                                                                                                                                                                                                                                                  |
| GENERAL                                                          |                                                                |                                                                                                                                                                                                                                                          |
| 1. USE                                                           |                                                                |                                                                                                                                                                                                                                                          |
| 1.1                                                              | Clinical purpose                                               | To provide an enriched environment of oxygen (O2) to increase the patient's O2 uptake.                                                                                                                                                                   |
| 1.2                                                              | Used by clinical department/ ward                              | SNCU/NICU                                                                                                                                                                                                                                                |
| TECHNICAL                                                        |                                                                |                                                                                                                                                                                                                                                          |
| 2. TECHNICAL CHARACTERISTICS                                     |                                                                |                                                                                                                                                                                                                                                          |
| 2.1                                                              | Technical characteristics (specific to this type of device)    | Transparent Polycarbonate unbreakable single molded.<br>Silicon rubber Neck Port adjustment enabled to minimize the wastage of oxygen<br>Silicon rubber Neck port adjustment to ensures use in Neonate/Infant/ Pediatric patients.<br>Oxygen inlet Port. |
| 2.3                                                              | Settings                                                       | N.A.                                                                                                                                                                                                                                                     |
| 2.4                                                              | User's interface                                               | N.A.                                                                                                                                                                                                                                                     |
| 2.5                                                              | Software and/or standard of communication(where ever required) | N.A.                                                                                                                                                                                                                                                     |
| 3. PHYSICAL CHARACTERISTICS                                      |                                                                |                                                                                                                                                                                                                                                          |
| 3.1                                                              | Dimensions (metric)                                            | Appropriate to comfortably fit all size babies up to 5 years of age.                                                                                                                                                                                     |
| 3.2                                                              | Weight (lbs, kg)                                               | extremely light weight                                                                                                                                                                                                                                   |
| 3.3                                                              | Configuration                                                  | NA                                                                                                                                                                                                                                                       |
| 3.4                                                              | Noise (in dBA)                                                 | N.A.                                                                                                                                                                                                                                                     |
| 3.5                                                              | heat dissipation                                               | NA                                                                                                                                                                                                                                                       |
| 3.6                                                              | Mobility, portability                                          | portable                                                                                                                                                                                                                                                 |
| 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) |                                                                |                                                                                                                                                                                                                                                          |
| 4.1                                                              | Power Requirements                                             | N.A.                                                                                                                                                                                                                                                     |
| 4.2                                                              | Battery operated                                               | N.A.                                                                                                                                                                                                                                                     |
| 4.3                                                              | Tolerance (to variations, shutdowns)                           | N.A.                                                                                                                                                                                                                                                     |
| 4.4                                                              | Protection                                                     | N.A.                                                                                                                                                                                                                                                     |
| 4.5                                                              | Power consumption                                              | N.A.                                                                                                                                                                                                                                                     |
| 4.6                                                              | Other energy supplies                                          | N.A.                                                                                                                                                                                                                                                     |

| 5. ACCESSORIES, SPARE PARTS, CONSUMABLES         |                                                                                         |                                                                                                                                                                                                                                                    |
|--------------------------------------------------|-----------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 5.1                                              | Accessories (mandatory, standard, optional)                                             | NA                                                                                                                                                                                                                                                 |
| 5.2                                              | Spare parts (main ones)                                                                 | NA                                                                                                                                                                                                                                                 |
| 5.3                                              | Consumables / reagents (open, closed system)                                            | tubing                                                                                                                                                                                                                                             |
| 5.4                                              | Others                                                                                  |                                                                                                                                                                                                                                                    |
| 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS |                                                                                         |                                                                                                                                                                                                                                                    |
| 6.1                                              | Atmosphere / Ambiance (air conditioning, humidity, dust ...)                            | Operating condition:<br>– Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances.                                                                                     |
| 6.2                                              | User's care, Cleaning, Disinfection & Sterility issues                                  | Complete unit to be easily washable and sterilizable using both alcohol and chlorine agents.                                                                                                                                                       |
| 7. STANDARDS AND SAFETY                          |                                                                                         |                                                                                                                                                                                                                                                    |
| 7.1                                              | Certificates (pre-market, sanitary, ...)                                                | ISO 15001-2010<br>Should be CE or FDA approved<br>The company should be ISO 13485 certified                                                                                                                                                        |
| 7.2                                              | Performance and safety standards (specific to the device type)                          | NA                                                                                                                                                                                                                                                 |
| 8. TRAINING AND INSTALLATION                     |                                                                                         |                                                                                                                                                                                                                                                    |
| 8.1                                              | Pre-installation requirements: nature, values, quality, tolerance                       | NA                                                                                                                                                                                                                                                 |
| 8.2                                              | Requirements for sign-off                                                               | Confirmation in no crack, no leak in hood structure                                                                                                                                                                                                |
| 8.3                                              | Training of staff (medical, paramedical, technicians)                                   | NA                                                                                                                                                                                                                                                 |
| 8.4                                              | Others                                                                                  | NA                                                                                                                                                                                                                                                 |
| 9. WARRANTY AND MAINTENANCE                      |                                                                                         |                                                                                                                                                                                                                                                    |
| 9.1                                              | Warranty                                                                                | 1 year                                                                                                                                                                                                                                             |
| 9.2                                              | Maintenance tasks                                                                       | NA                                                                                                                                                                                                                                                 |
| 9.3                                              | Service contract clauses, including prices                                              | NA                                                                                                                                                                                                                                                 |
| 9.4                                              | Others                                                                                  | NA                                                                                                                                                                                                                                                 |
| 10. DOCUMENTATION                                |                                                                                         |                                                                                                                                                                                                                                                    |
| 10.1                                             | Operating manuals, service manuals, other manuals                                       | Advanced maintenance tasks required shall be documented.<br>User, technical and maintenance manuals to be supplied in english language.<br>List to be provided of equipment and procedures required for local calibration and routine maintenance. |
| 10.2                                             | Other accompanying documents                                                            | List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.                                                                                               |
| 11. NOTES                                        |                                                                                         |                                                                                                                                                                                                                                                    |
| 11.1                                             | Service Support Contact details (Hierarchy Wise; including a toll free/landline number) | NA                                                                                                                                                                                                                                                 |
| 11.2                                             | Recommendations or warnings                                                             | NA                                                                                                                                                                                                                                                 |

# OXYGEN CONCENTRATOR

|                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                                                                      | 1.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Date:                                                                              | SEPT 2014.                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Done by : (name/institution)                                                       | HCT/NHSRC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>NAME AND CODING</b>                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| GMDN name                                                                          | <b>Oxygenators</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| GMDN code(s)                                                                       | CT1608                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>GENERAL</b>                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>1. USE</b>                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 1.1                                                                                | <b>Clinical purpose</b><br>to concentrate oxygen (O <sub>2</sub> ) from ambient air and deliver the concentrated O <sub>2</sub> , typically through an attached nasal cannula, to a patient requiring oxygen therapy.                                                                                                                                                                                                                                                                    |
| 1.2                                                                                | <b>Used by clinical department/ward</b><br>SNCU/NICU                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>TECHNICAL</b>                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>2. TECHNICAL CHARACTERISTICS</b>                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 2.1                                                                                | <b>Technical characteristics (specific to this type of device)</b><br>1. Flow rate: 0~5 LPM, purity > 93%.<br>2. O <sub>2</sub> delivery pressure: 0.03 to 0.07 Mpa (4.35 - 10.15 PSI).<br>3. Atomising pellet (ml/min.) > 0.5, uninterrupted flow of oxygen.<br>4. Oxygen monitoring system (optional).<br>5. Low pressure alarm, high pressure alarm and power failure alarm.<br>6. Unit capable for supplying oxygen to two outlets simultaneously using two independent flow meters. |
| 2.2                                                                                | <b>Settings</b><br>Should be capable of providing minimum 12 hours of continuous operation.                                                                                                                                                                                                                                                                                                                                                                                              |
| 2.3                                                                                | <b>User's interface</b><br>Front panel access to reset switch.                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 2.4                                                                                | <b>Software and/or standard of communication (where ever required)</b><br>NA                                                                                                                                                                                                                                                                                                                                                                                                             |
| 2.5                                                                                | <b>Others</b><br>                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>3. PHYSICAL CHARACTERISTICS</b>                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 3.1                                                                                | <b>Dimensions (metric)</b><br>Max spec: 640 mm (H) x 410 mm (W) x 410 mm (D).                                                                                                                                                                                                                                                                                                                                                                                                            |
| 3.2                                                                                | <b>Weight (lbs, kg)</b><br>Max 30 kg.                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 3.3                                                                                | <b>Configuration</b><br>NA                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 3.4                                                                                | <b>Noise (in dBA)</b><br><50 db                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 3.5                                                                                | <b>heat dissipation</b><br>Heat desipated using an internal exhaust, so that a maximum of 36.5 degree C is maintained.                                                                                                                                                                                                                                                                                                                                                                   |
| 3.6                                                                                | <b>Mobility, portability</b><br>Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO<sub>2</sub> ....)</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 4.1                                                                                | <b>Power Requirements</b><br>230 +/- 10% VAC, 50 Hz, 2 amps.                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 4.2                                                                                | <b>Battery operated</b><br>NA                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 4.3                                                                                | <b>Tolerance (to variations, shutdowns)</b><br>fuse controlled variation, automatic switch over from AC to DC and vice versa.                                                                                                                                                                                                                                                                                                                                                            |

|                                                         |                                                                                                         |                                                                                                                                                                                                                                 |
|---------------------------------------------------------|---------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4.4                                                     | Protection                                                                                              | OVP, earth leakage protection                                                                                                                                                                                                   |
| 4.5                                                     | Power consumption                                                                                       | <500 Watts                                                                                                                                                                                                                      |
| 4.6                                                     | Other energy supplies                                                                                   |                                                                                                                                                                                                                                 |
| <b>5. ACCESSORIES, SPARE PARTS, CONSUMABLES</b>         |                                                                                                         |                                                                                                                                                                                                                                 |
| 5.1                                                     | Accessories (mandatory, standard, optional)                                                             | Humidifier Bottles-4nos, power cord-1 no.                                                                                                                                                                                       |
| 5.2                                                     | Spare parts (main ones)                                                                                 |                                                                                                                                                                                                                                 |
| 5.3                                                     | Consumables/reagents (open, closed system)                                                              | Nasal Cannula with extension tubing-2 nos; Gross particle cabinet filter, compressor intake filter and bacterial filter of 0.8-1.0 micron; geolite crystal.                                                                     |
| <b>6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS</b> |                                                                                                         |                                                                                                                                                                                                                                 |
| 6.1                                                     | Atmosphere/Ambiance (air conditioning, humidity, dust...)                                               | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%. |
| 6.2                                                     | User's care, Cleaning, Disinfection & Sterility issues                                                  | Complete unit to be easily washable and sterilizable using both alcohol and chlorine agents.                                                                                                                                    |
| <b>7. STANDARDS AND SAFETY</b>                          |                                                                                                         |                                                                                                                                                                                                                                 |
| 7.1                                                     | Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type) | CE or FDA approved and company should be ISO 13485 certified; and shall meet IEC 60601-1, IEC 60601-1-2 standard requirements; and comply with ISO 15001-2010.                                                                  |
| <b>8. TRAINING AND INSTALLATION</b>                     |                                                                                                         |                                                                                                                                                                                                                                 |
| 8.1                                                     | Pre-installation requirements: nature, values, quality, tolerance                                       | Availability of 5 amp/15 Amp. Electrical socket (2 nos) for each warmer.                                                                                                                                                        |
| 8.2                                                     | Requirements for sign-off                                                                               | Certificate of Calibration and inspection from the factory.                                                                                                                                                                     |
| 8.3                                                     | Training of staff (medical, paramedical, technicians)                                                   | user training manual required.                                                                                                                                                                                                  |
| 8.4                                                     | Others                                                                                                  | List of important spare parts and accessories with their part number and costing.                                                                                                                                               |
| <b>9. WARRANTY AND MAINTENANCE</b>                      |                                                                                                         |                                                                                                                                                                                                                                 |
| 9.1                                                     | Warranty                                                                                                | 3 years                                                                                                                                                                                                                         |
| 9.2                                                     | Maintenance tasks                                                                                       | Maintenance manual detailing complete maintaining schedule.                                                                                                                                                                     |
| 9.3                                                     | Service contract clauses, including prices                                                              | warranty of one year with free servicing (min. 3) during warranty.                                                                                                                                                              |
| 9.4                                                     | Others                                                                                                  | The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee/warranty period should be attached.                                                         |
| <b>10. DOCUMENTATION</b>                                |                                                                                                         |                                                                                                                                                                                                                                 |
| 10.1                                                    | Operating manuals, service manuals, other manuals                                                       | Yes                                                                                                                                                                                                                             |
| 10.2                                                    | Other accompanying documents                                                                            | to be supplied.                                                                                                                                                                                                                 |
| 10.3                                                    | Recommendations for maintenance                                                                         | User/Technical/Maintenance manuals to be supplied in English.                                                                                                                                                                   |
| 10.4                                                    | Others                                                                                                  |                                                                                                                                                                                                                                 |
| <b>11. NOTES</b>                                        |                                                                                                         |                                                                                                                                                                                                                                 |
| 11.1                                                    | Service Support Contact details (Hierarchy Wise; including a toll free/landline number)                 | Any Contract (AMC/MC/add-hoc) to be declared by the manufacturer.                                                                                                                                                               |
| 11.2                                                    | Recommendations or warnings                                                                             | Any recommendations for best use and supplementary warning for safety should be declared.                                                                                                                                       |



# RADIANT WARMER

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                  | 3.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Date:                          | 26/2/2015                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Done by : (name / institution) | HCT/ NHSRC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| NAME AND CODING                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| GMDN name                      | Infant warmer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| GMDN code(s)                   | CT1452                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| GENERAL                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 1. USE                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 1.1                            | <p><b>Clinical purpose</b></p> <p>Infant Radiant warmer is an electrically powered device with a radiant heating source intended to maintain the thermal balance of an infant by direct radiant of energy in the infrared region of the electromagnetic spectrum.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 1.2                            | <p><b>Used by clinical department/ ward</b></p> <p>Neonatal ICU/ SNCU</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| TECHNICAL                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 2. TECHNICAL CHARACTERISTICS   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 2.1                            | <p><b>Technical characteristics (specific to this type of device)</b></p> <ol style="list-style-type: none"> <li>1. It should be microcontroller based radiant warmer with manual and servo options.</li> <li>2. It should have facility to display skin set, skin observed temperature in degree C and heat power separately.</li> <li>3. Should have user friendly touch panel control.</li> <li>4. It should have ceramic or quartz infrared or calrod heater.</li> <li>5. It should have audiovisual alarm facility for overheating beyond set temperature range.</li> <li>6. It should have alarm facility for patient temperature less than or greater than the required temperature i.e. above or below the set range. Machine should sense the skin probe failure and cut off the heater.</li> <li>7. Warmer head should be rotatable in different direction, so as to allow taking X-ray.</li> <li>8. It should have alarm for probe failure, power failure, system failure and heater failure.</li> <li>9. Observation light of 90 to 100 foot candles or 1000 Lux ( color temperature range 3700K to 5100K) could be provided for inspection</li> <li>10. Battery back up for Power failure indication during power fail.</li> <li>11. The desired temperature range from 25 to 40 degree C and settable temperature can be from 32 to 38 degC.</li> <li>12. The resolution should be 0.1 degree C and accuracy should be 0.2 °C.</li> <li>13. Should have a facility to lock the keyboard to avoid unwanted user modification of the set parameters.</li> <li>14. The height of the warmer should be adjustable for different types of bed.</li> </ol> |

|     |                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----|---------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|     |                                                                     | <p>15. It should have separate bassinet trolley, bed should be tiltable and have provision for x-ray cassette holder, Mattress foam density should be minimum 25 kg/cm<sup>3</sup>, transparent collapsible side walls easily detachable for cleaning. Mattress size should be minimum 20"X30".</p> <p>16. Should have a Feather Touch operation with large digital display and comprehensive alarms. Control Panel should be liquid proof and allow easy and hygienic disinfection.</p> <p>17. Manual Mode can adjust Heater Output 10 -100 %, with 10% increment, an auditory and visual alarm shall be given at least every 15 min.</p> <p>18. In manual mode, heater cut off / switch off , if the maximum irradiance at any point of the mattress area exceeds a total irradiance level of 10 mW/cm<sup>2</sup> (between 10 to 30 minutes).</p> <p>19. Bed should be about 80 - 100 cms from the Floor and 80-90cms from the heat source.</p> <p>20. Should have lockable castor wheels.</p> <p>21. Green indicator light shall be provided to indicate that warmer is ready for normal use.</p> <p>22. Markings on the bassinet and X-Ray cassette holder is mandatory to enable proper positioning of the baby while doing the X-Ray.</p> <p>23. The size of the drop down sides should be such that it is 5" above the mattress surface and should be atleast 6mm thick; clear and transparent.</p> <p>24. If there is more than 60% heater output for 10 minutes it should cutoff with alarm.</p> <p>25. For the purpose of cable management there should be at least two number of tubing ports (edges covered by silicon rings) on the side walls. The height of the side walls should be minimum 110mm over the mattress.</p> <p>26. X-Ray cassette tray should be at least 750X350mm and should adopt up to 20mm thick X-Ray cassette.</p> <p>27. The bay bed should be crevice free for ease of cleaning, infection control.</p> <p>28. The mattress used should be of biocompatible material.</p> <p>29. Thermistor based skin temperature probe should be small in size not more than 10mm diameter and 3-4mm thick to fix the probe firmly on the infant. Baby contact material should be biocompatible as per ISO 10993 standard requirement. It should be insulated on one side and have well conducting non-rusting, non reacting metallic surface on the other side. Probe wire should be pliable, thin and soft. The attachment site of the probe with the wire should also be pliable and non stiff.</p> |
| 2.2 | <b>Settings</b>                                                     | <p>1. Should have Manual mode and Baby (Servo) mode settings.</p> <p>2. Mode of operation should be clearly displayed.</p> <p>3. In servo mode baby set temperature should be 32 to 38 deg C.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 2.3 | <b>User's interface</b>                                             | Manual and Servo controlled temperature regulation.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 2.4 | <b>Software and/or standard of communication(whenever required)</b> | LED Display and inbuilt software; Interruption and restoration of the power supply does not change the preset values.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 2.5 | <b>Others</b>                                                       | <p>1. Device shall not overbalance when placed in any transport position of normal use on a 10° inclined plane from the horizontal plane.</p> <p>2. Transformers of device shall be protected against overheating in the event of short circuit or overload of any output winding.</p> <p>3. Patient leakage current should be less than 100 µA in normal condition.</p> <p>4. Temperature on the baby mattress should not exceed 43 deg C when the warmer is operating under steady temperature condition.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

|                                                                                    |                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                    |                                                                                                                                             | <p>5. Temperature of HEATER GUARDS should not exceed 85 °C in normal use.</p> <p>6. The Temperature differences on the mattress shall not exceed 2 °C.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>3. PHYSICAL CHARACTERISTICS</b>                                                 |                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 3.1                                                                                | <b>Dimensions (metric)</b>                                                                                                                  | specifications upto: 2000 mm (Height) X 900mm (Width) X 1100 mm (Length).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 3.2                                                                                | <b>Weight (lbs, kg)</b>                                                                                                                     | maximum spec: 150kg.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 3.3                                                                                | <b>Configuration</b>                                                                                                                        | Atleast 60 degree angle adjustment must be possible in the heat source and it should provide shielding to the infant in case of breakage of tubes/bulbs, All surfaces to be made of corrosion resistant material.                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 3.4                                                                                | <b>Noise (in dBA)</b>                                                                                                                       | Auditory alarm shall have a sound level of at least 65 dBA at a distance of 3 m from the front of the infant radiant warmer, and the sound level of the alarm shall not exceed 80 dBA on the mattress.                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 3.5                                                                                | <b>heat dissipation</b>                                                                                                                     | Should maintain upto 36.5 deg temp and the heat disbursed through a exhaust fan , so that effect of UV light is not disturbed.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 3.6                                                                                | <b>Mobility, portability</b>                                                                                                                | Yes, on castors (2 of the castors should have breaks; casotor size can be atleast 4inch).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO<sub>2</sub> ....)</b> |                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 4.1                                                                                | <b>Power Requirements</b>                                                                                                                   | 220 to 240V, 50 Hz                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 4.2                                                                                | <b>Battery operated</b>                                                                                                                     | Power failure indication during power fail.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 4.3                                                                                | <b>Tolerance (to variations, shutdowns)</b>                                                                                                 | ± 10% of input                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 4.4                                                                                | <b>Protection</b>                                                                                                                           | OVP, earth leakage protection.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 4.5                                                                                | <b>Power consumption</b>                                                                                                                    | maximum 800 Watt                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 4.6                                                                                | <b>Other energy supplies</b>                                                                                                                | Solar Heating - desirable ; not essential                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>5. ACCESSORIES, SPARE PARTS, CONSUMABLES</b>                                    |                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 5.1                                                                                | <b>Accessories (mandatory, standard, optional)</b>                                                                                          | Should have standard IV pole(sturdy;non rusting; medical grade stainless steel;adjustable to a max height of 6 feet from the ground level), monitor tray(12X10 inches;270 deg swivel;fixed at level of warmer display) and storage trays.                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 5.2                                                                                | <b>Spare parts (main ones)</b>                                                                                                              | Skin temperature probes,                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 5.3                                                                                | <b>Consumables / reagents (open, closed system)</b>                                                                                         | Thermal refelctor to fix the skin probe on baby.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS</b>                             |                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 6.1                                                                                | <b>Atmosphere / Ambiance (air conditioning, humidity, dust ...)</b>                                                                         | <p>Operating condition:</p> <ul style="list-style-type: none"> <li>– Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances.</li> <li>– an ambient air velocity is less than 0.3 m/s.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                        |
| 6.2                                                                                | <b>User's care, Cleaning, Disinfection &amp; Sterility issues</b>                                                                           | Complete unit to be easily washable and sterilizable using both alcohol and chlorine agents.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>7. STANDARDS AND SAFETY</b>                                                     |                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 7.1                                                                                | <b>Performance and safety standards (specific to the device type); Certificates (pre-market, sanitary, ...); Local and/or international</b> | <p>Should be FDA / (CE of class IIb) approved product. Shall meet IEC-60601-1-2:2007 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Or Equivalent BIS). Shall meet IEC 60601-2-21: 2009 Medical Electrical Equipment – Part 2-21: Particular Requirement for the basic safety and essential performance of infant radiant warmers . should meet IEC 60601-1:2005 standard requirements.</p> <p>Baby contact material should be biocompatible as per ISO 10993 standard requirement.</p> <p>Manufacturer should be ISO 13485 certified.</p> |

| 8. TRAINING AND INSTALLATION |                                                                                              |                                                                                                                                                                           |
|------------------------------|----------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8.1                          | <b>Pre-installation requirements: nature, values, quality, tolerance</b>                     | Availability of 5 amp/15 Amp. Electrical socket (2 nos) for each warmer.                                                                                                  |
| 8.2                          | <b>Requirements for sign-off</b>                                                             | Certificate of Calibration and inspection from the factory.                                                                                                               |
| 8.3                          | <b>Training of staff (medical, paramedical, technicians)</b>                                 | user training manual required                                                                                                                                             |
| 8.4                          | <b>Others</b>                                                                                | List of important spare parts and accessories with their part number and costing.                                                                                         |
| 9. WARRANTY AND MAINTENANCE  |                                                                                              |                                                                                                                                                                           |
| 9.1                          | <b>Warranty</b>                                                                              | nickel chrome wire filament and tube of quartz should have a life time warranty; equipment - 3 years.                                                                     |
| 9.2                          | <b>Maintenance tasks</b>                                                                     | maintainance manual detailing complete maintaining schedule                                                                                                               |
| 9.3                          | <b>Service contract clauses, including prices</b>                                            | warranty of one year with free servicing ( min. 3) during warranty                                                                                                        |
| 9.4                          | <b>Others</b>                                                                                | The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee / warranty period should be attached. |
| 10. DOCUMENTATION            |                                                                                              |                                                                                                                                                                           |
| 10.1                         | <b>Operating manuals, service manuals, other manuals</b>                                     | to be supplied                                                                                                                                                            |
| 10.2                         | <b>Other accompanying documents</b>                                                          | User/Technical/Maintenance manuals to be supplied in English                                                                                                              |
| 11. NOTES                    |                                                                                              |                                                                                                                                                                           |
| 11.1                         | <b>Service Support Contact details (Hierchy Wise; including a toll free/landline number)</b> | should provide complete contact details of sales and service departments.                                                                                                 |
| 11.2                         | <b>Recommendations or warnings</b>                                                           | Any warning/ precautions to be declared                                                                                                                                   |

# PHOTOTHERAPY

|                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                       | 3.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Date:                               | 26/2/2015                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Done by : (name / institution)      | HCT/ NHSRC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>NAME AND CODING</b>              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| GMDN name                           | Phototherapy units/systems                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| GMDN code(s)                        | CT 2066                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>GENERAL</b>                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>1. USE</b>                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 1.1                                 | <b>Clinical purpose</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 1.2                                 | <b>Used by clinical department/ ward</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 1.3                                 | <b>Overview of functional requirements</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>TECHNICAL</b>                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>2. TECHNICAL CHARACTERISTICS</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 2.1                                 | <b>Technical characteristics (specific to this type of device)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|                                     | <ol style="list-style-type: none"> <li>1. Phototherapy should be based on LED technology, which after filtering should provide, a light of wavelength approximately 450 to 470 nm with peak wavelength of 450-460nm range.</li> <li>2. Irradiance to be minimum 35 <math>\mu\text{W}/\text{cm}^2/\text{nm}</math> at 40 cm height and UV should not exceed 10-4 W/m<sup>2</sup> in 180nm to 400nm.</li> <li>3. Digital Hour meter showing total exposure time for current patient to be clearly visible by operator.</li> <li>4. Effective light field &gt;700 cm<sup>2</sup>.</li> <li>5. Lamp life should be minimum 20000 hours for LED and should have timer to indicate its usage.</li> <li>6. Over temperature safety cut out to be included.</li> <li>7. Up, down and tilting of head should be possible.</li> <li>8. The unit should be mounted with castor wheels with brakes.</li> <li>9. Variation in intensity over 5-6 hours &lt; 10%.</li> <li>10. The irradiance ratio (min to max) shall be greater than 40 % on mattress.</li> <li>11. Green indicator light shall be provided to indicate that equipment is ready for normal use.</li> <li>12. Interruption and a restoration of the power supply do not change preset values. LED heat can be reduced by natural cooling.</li> <li>13. LED should be protected from free fall.</li> <li>14. It should not topple on 10 deg inclined angle.</li> <li>15. The temperature of baby bed and metal surfaces should not exceed 40deg C and 43 deg C for other accesible surfaces.</li> </ol> |

|                                                                                    |                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                              |
|------------------------------------------------------------------------------------|------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                    |                                                                        | <p>16. There should be intuitive method to indicate the light surface is at the appropriate treatment distance.</p> <p>17. Mobile stand with movable castors and height adjustment facility along with easy swivelling of source box. Unit can be used along with Infant care trolley, Radiant Warmer and Incubator.</p>                                                                                     |
| 2.2                                                                                | <b>Settings</b>                                                        | UP/DOWN adjustment of Over Head Unit; The phototherapy unit should be able to provide effective treatment for beds and incubators of varying heights (generally 1.0 to 1.6m). Adjustment of light intensity may be provided.                                                                                                                                                                                 |
| 2.3                                                                                | <b>User's interface</b>                                                | Manual                                                                                                                                                                                                                                                                                                                                                                                                       |
| 2.4                                                                                | <b>Software and/or standard of communication (where ever required)</b> | LED Display and inbuilt software                                                                                                                                                                                                                                                                                                                                                                             |
| 2.5                                                                                | <b>Others</b>                                                          |                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>3. PHYSICAL CHARACTERISTICS</b>                                                 |                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                              |
| 3.1                                                                                | <b>Dimensions (metric)</b>                                             | minimum spec: 1650mm Height X 750mm Width X 500mm Length                                                                                                                                                                                                                                                                                                                                                     |
| 3.2                                                                                | <b>Weight (lbs, kg)</b>                                                | <20 kg                                                                                                                                                                                                                                                                                                                                                                                                       |
| 3.3                                                                                | <b>Configuration</b>                                                   | <p>Clear cabinet for observation of infant.</p> <p>Infant bassinette to be an integral unit which should be detachable.</p> <p>Unit to provide shielding of infant in the event of bulb breakage.</p> <p>Bulb mount to have angle adjustment of at least 30 degrees.</p> <p>All surfaces to be made of corrosion resistant materials.</p> <p>Light unit tilting facility and height adjustment facility.</p> |
| 3.4                                                                                | <b>Noise (in dBA)</b>                                                  | <60dBA                                                                                                                                                                                                                                                                                                                                                                                                       |
| 3.5                                                                                | <b>heat dissipation</b>                                                | The temperature of baby bed and metal surfaces should not exceed 40deg C and 43 deg C for other accesible surfaces.                                                                                                                                                                                                                                                                                          |
| 3.6                                                                                | <b>Mobility, portability</b>                                           | Minimum 3 castors and atleast 2 with brakes                                                                                                                                                                                                                                                                                                                                                                  |
| <b>4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO<sub>2</sub> ....)</b> |                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                              |
| 4.1                                                                                | <b>Power Requirements</b>                                              | 220 to 240V, 50 Hz                                                                                                                                                                                                                                                                                                                                                                                           |
| 4.2                                                                                | <b>Battery operated</b>                                                | NA                                                                                                                                                                                                                                                                                                                                                                                                           |
| 4.3                                                                                | <b>Tolerance (to variations, shutdowns)</b>                            | ± 10% of input AC                                                                                                                                                                                                                                                                                                                                                                                            |
| 4.4                                                                                | <b>Protection</b>                                                      | Electrical protection by resettable overcurrent breakers or replaceable fuses, fitted in both live and neutral lines.                                                                                                                                                                                                                                                                                        |
| 4.5                                                                                | <b>Power consumption</b>                                               | Should not be more than 160 W                                                                                                                                                                                                                                                                                                                                                                                |
| 4.6                                                                                | <b>Other energy supplies</b>                                           | Mains cable to be at least 2.5m length                                                                                                                                                                                                                                                                                                                                                                       |
| <b>5. ACCESSORIES, SPARE PARTS, CONSUMABLES</b>                                    |                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                              |
| 5.1                                                                                | <b>Accessories (mandatory, standard, optional)</b>                     | <p>Complete set of replacement tubes to allow 3 months' continuous operation</p> <p>Two replacement sets of fuses, if replaceable type used.</p>                                                                                                                                                                                                                                                             |
| 5.2                                                                                | <b>Spare parts (main ones)</b>                                         | No spares required                                                                                                                                                                                                                                                                                                                                                                                           |
| 5.3                                                                                | <b>Consumables / reagents (open, closed system)</b>                    | Total 500 nos. Infant eye masks of both available sizes (term and pre term babies).                                                                                                                                                                                                                                                                                                                          |
| <b>6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS</b>                             |                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                              |
| 6.1                                                                                | <b>Atmosphere / Ambiance (air conditioning, humidity, dust ...)</b>    | Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90% in ideal circumstances.                                                                                                                                                                                                                                                                        |
| 6.2                                                                                | <b>User's care, Cleaning, Disinfection &amp; Sterility issues</b>      | Complete unit to be easily washable and sterilizable using both alcohol and chlorine agents.                                                                                                                                                                                                                                                                                                                 |

| 7. STANDARDS AND SAFETY      |                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 7.1                          | <b>Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international</b> | <p>Should be FDA / CE approved product</p> <p>Shall meet IEC-60601-1-2:2007 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Or Equivalent BIS)</p> <p>Should meet IEC 60601-1:2005 standard requirements</p> <p>Shall meet IEC 60601-2-50: 2009 Medical Electrical Equipment – Part 2-50: Particular Requirement for the basic safety and essential performance of infant phototherapy equipment;</p> <p>Manufacturer should be ISO 13485 certified</p> |
| 8. TRAINING AND INSTALLATION |                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 8.1                          | <b>Pre-installation requirements: nature, values, quality, tolerance</b>                                                                   | Supplier to perform installation, safety and operation checks before handover.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 8.2                          | <b>Requirements for sign-off</b>                                                                                                           | Certificate of Calibration and inspection from the factory.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 8.3                          | <b>Training of staff (medical, paramedical, technicians)</b>                                                                               | Training of users in operation and basic maintenance shall be provided                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 8.4                          | <b>Others</b>                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 9. WARRANTY AND MAINTENANCE  |                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 9.1                          | <b>Warranty</b>                                                                                                                            | 3 years for the machine and 20,000 hours for LEDs                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 9.2                          | <b>Maintenance tasks</b>                                                                                                                   | Maintenance manual detailing complete maintaining schedule                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 9.3                          | <b>Service contract clauses, including prices</b>                                                                                          | Local clinical staff to affirm completion of installation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 9.4                          | <b>Others</b>                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 10. DOCUMENTATION            |                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 10.1                         | <b>Operating manuals, service manuals, other manuals</b>                                                                                   | <p>Advanced maintenance tasks required shall be documented</p> <p>User, technical and maintenance manuals to be supplied in english language.</p> <p>List to be provided of equipment and procedures required for local calibration and routine maintenance</p>                                                                                                                                                                                                                                                                                                                                  |
| 10.2                         | <b>Other accompanying documents</b>                                                                                                        | List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 11. NOTES                    |                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 11.1                         | <b>Service Support Contact details (Hierarchy Wise; including a toll free/landline number)</b>                                             | Contact details of manufacturer, supplier and local service agent to be provided                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 11.2                         | <b>Recommendations or warnings</b>                                                                                                         | List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.                                                                                                                                                                                                                                                                                                                                                                                                                                             |

# TRANSPORT INCUBATOR

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|--------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                  | 2.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Date:                          | 26/2/2015                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Done by : (name / institution) | HCT/ NHSRC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| NAME AND CODING                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| GMDN name                      | infant incubator                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| GMDN code(s)                   | CT1482                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| GENERAL                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 1. USE                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 1.1                            | <b>Clinical purpose</b><br>designed to provide an enclosed controlled environment to maintain appropriate temperature and humidity levels mainly for premature infants and other newborns who cannot effectively regulate their body temperature.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 1.2                            | <b>Used by clinical department/ ward</b><br>NICU and PICU                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 1.3                            | <b>Overview of functional requirements</b><br>Control of air temperature and infant skin temperature.<br>Clear, hard cabinet for infant viewing.<br>Easy access control panel, with light touch operation switches.<br>Facility to elevate base, adjustable range.<br>Self-test functions are performed.<br>Built for transport of infants between wards or health facilities, including by vehicle.<br>Must have skin temperature display.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| TECHNICAL                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 2. TECHNICAL CHARACTERISTICS   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 2.1                            | <b>Technical characteristics (specific to this type of device)</b> <ol style="list-style-type: none"> <li>Visual and audible alarms for:               <ol style="list-style-type: none"> <li>Patient and air high/low temperature alarm.</li> <li>Air circulation / probe / system / power failure alarm.</li> </ol> </li> <li>Heater power indicator</li> <li>Air velocity: minimum 0.30m/sec</li> <li>Oxygen input flow rate 5 to 15 liters/min or oxygen concentration range 25 to 70%.</li> <li>Maximum CO<sub>2</sub> concentration inside incubator 0.2%.</li> <li>Internal noise level &lt; 60 dB.</li> <li>Mode of operation should be properly displayed.</li> <li>Green indicator light should be provided for its ready to be in normal use.</li> <li>Infants straps should be provided to restrict the baby movement.</li> <li>skin temperature probe should be small in size not more than 10mm diameter and 4mm in height to fix the probe firmly on the infant. Baby contact material should be biocompatible as per ISO 10993 standard requirement.</li> </ol> |



|                                    |                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|------------------------------------|--------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                    |                                                  | <p>11. Infant bed should be drawable. Mattress foam density should be minimum 25kg./cm<sup>3</sup> and infant bed mattress cover should be biocompatible material.</p> <p>12. Examination light should be provided for inspection.</p> <p>13. Should have heater power indicator.</p> <p>14. Warmup time 30-40 minutes and shall not differ by more than 20%.</p> <p>15. Shall be equipped with a thermal cut-out. It shall be so arranged that the heater is disconnected and an auditory and visual warning is given at an incubator temperature which does not exceed 40 deg C.</p>                                                                                               |
|                                    |                                                  | <p>16. Should have elbow operate-able ports and head access door.</p> <p>17. It should not topple over at 10 deg inclined plane.</p> <p>18. Patient skin temperature range: 35 deg C to 37.5 deg C. over ride up-to 38 deg C.</p> <p>19. Air temperature range: 30 deg C to 39 deg C; Temperature resolution <math>\pm</math> 0.1 deg C; Temperature accuracy <math>\pm</math> 0.2 deg C.</p>                                                                                                                                                                                                                                                                                        |
| 2.2                                | <b>Settings</b>                                  | <p>Patient skin temperature range: 35 deg C to 37.5 deg C. over ride upto 38 deg C.</p> <p>Air temperature range: 30 deg C to 39 deg C.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 2.3                                | <b>User's interface</b>                          | Display allows easy viewing in all ambient light levels                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 2.4                                | <b>Software and/or standard of communication</b> | in built                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 2.5                                | <b>Others</b>                                    | <p>1. Temperature on the baby mattress should not exceed 40 deg C and 43 deg for other materials</p> <p>2. Uniformity of temperature on the horizontal mattress shall not exceed 1.5 deg C and in tilted mattress not exceed 2 deg C.</p> <p>3. The overshoot temperature shall not exceed 2 deg C.</p> <p>4. The stability of temperature during steady temperature shall not differ from the average temperature by more than 1 deg C.</p>                                                                                                                                                                                                                                         |
| <b>3. PHYSICAL CHARACTERISTICS</b> |                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 3.1                                | <b>Dimensions (metric)</b>                       | Baby bed should be at-least 60X30cm and the canopy should be at-least 80X40 cm.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 3.2                                | <b>Weight (lbs, kg)</b>                          | not exceeding 40kg. (without cylinders).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 3.3                                | <b>Configuration</b>                             | <p>Oxygen port with tubing, also mount for oxygen cylinder of 5 liters size. Accommodates shelves, suction unit and I/V poles.</p> <p>Double-walled cabinet with at least two hand ports.</p> <p>Should have collapsible trolley with lockable castors.</p> <p>Mounted on mobile base, lowest height setting of which is at least 80 cm high.</p> <p>Minimum castor diameter 12cm.</p> <p>At least two castors must be fitted with brake facility.</p> <p>Castors must be made of conductive material such as Static dissipative Polyurethane and rotate (swivel) freely around the vertical axis.</p> <p>The canopy and infant bed should be crevice free for ease of cleaning.</p> |
| 3.4                                | <b>Noise (in dBA)</b>                            | <60dBA; Alarm Audible sound level should be at-least 65dBA at 3meter distance from the device.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 3.5                                | <b>heat dissipation</b>                          | Should maintain up-to 37 deg temp.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 3.6                                | <b>Mobility, portability</b>                     | Yes, on castors                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |

| 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO <sub>2</sub> ....) |                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                |
|------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4.1                                                                          | Voltage (value, AC or DC, monophasic or triphase)                                                                                   | 220VAC $\pm$ 10% , 50 Hz                                                                                                                                                                                                                                                                                                                       |
| 4.2                                                                          | Battery operated                                                                                                                    | Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit. Electrical protection by resettable over-current breakers or replaceable fuses, fitted in both live and neutral lines. Battery backup of 2 hours for equipment operation. The battery should be protected from overcharging. |
| 4.3                                                                          | Tolerance (to variations, shutdowns)                                                                                                | Voltage corrector / stabilizer to allow operation at $\pm$ 10% of rated voltage.                                                                                                                                                                                                                                                               |
| 4.4                                                                          | Protection                                                                                                                          | Internal, replaceable, rechargeable battery allows operation for at least two hours in the event of power failure                                                                                                                                                                                                                              |
| 4.5                                                                          | Power consumption                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                |
| 4.6                                                                          | Other energy supplies                                                                                                               | Mains cable to be at least 3m length                                                                                                                                                                                                                                                                                                           |
| 5. ACCESSORIES, SPARE PARTS, CONSUMABLES                                     |                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                |
| 5.1                                                                          | Accessories (mandatory, standard, optional)                                                                                         | With washable and removable straps and binders                                                                                                                                                                                                                                                                                                 |
| 5.2                                                                          | Spare parts (main ones)                                                                                                             | Two extra sets of all sensors                                                                                                                                                                                                                                                                                                                  |
| 5.3                                                                          | Consumables / reagents (open, closed system)                                                                                        | Two extra sets of filters, two extra set of fuses ( if replaceable fuses used)                                                                                                                                                                                                                                                                 |
| 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS                             |                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                |
| 6.1                                                                          | Atmosphere / Ambiance (air conditioning, humidity, dust ...)                                                                        | Operating condition: <ul style="list-style-type: none"> <li>– Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances.</li> <li>– an ambient air velocity is less than 0.3 m/s.</li> </ul>                                                                         |
| 6.2                                                                          | User's care, Cleaning, Disinfection & Sterility issues                                                                              | Unit layout to enable easy cleaning and sterilization of all surfaces, with no unreachable fluid traps. The case is to be cleanable with alcohol or chlorine wipes                                                                                                                                                                             |
| 6.3                                                                          | Others                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                |
| 7. STANDARDS AND SAFETY                                                      |                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                |
| 7.1                                                                          | Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international | <ol style="list-style-type: none"> <li>1) FDA (US) /CE (EU) from authorized third party and BIS/ISO 13485</li> <li>2) Relevant IEC-60601-Part 1 &amp; 2, certificates by a notified agency</li> </ol>                                                                                                                                          |
| 8. TRAINING AND INSTALLATION                                                 |                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                |
| 8.1                                                                          | Pre-installation requirements: nature, values, quality, tolerance                                                                   | Supplier to perform installation, safety and operation checks before handover.                                                                                                                                                                                                                                                                 |
| 8.2                                                                          | Requirements for sign-off                                                                                                           | Certificate of Calibration and inspection from the factory.                                                                                                                                                                                                                                                                                    |
| 8.3                                                                          | Training of staff (medical, paramedical, technicians)                                                                               | Training of users in operation and basic maintenance shall be provided                                                                                                                                                                                                                                                                         |
| 9. WARRANTY AND MAINTENANCE                                                  |                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                |
| 9.1                                                                          | Warranty                                                                                                                            | 3 years excluding battery and consumables                                                                                                                                                                                                                                                                                                      |
| 9.2                                                                          | Maintenance tasks                                                                                                                   | Advanced maintenance tasks required shall be documented                                                                                                                                                                                                                                                                                        |
| 9.3                                                                          | Service contract clauses, including prices                                                                                          | Local clinical staff to affirm completion of installation                                                                                                                                                                                                                                                                                      |

| 10. DOCUMENTATION |                                                          |                                                                                                                                                                                                                                                                                                                                                  |
|-------------------|----------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10                | <b>Operating manuals, service manuals, other manuals</b> | User, technical and maintenance manuals to be supplied in english language.<br>Certificate of calibration and inspection to be provided.<br>List to be provided of equipment and procedures required for local calibration and routine maintenance<br>List to be provided of important spares and accessories, with their part numbers and cost. |
| 10                | <b>Other accompanying documents</b>                      | User/Technical/Maintenance manuals to be supplied in English                                                                                                                                                                                                                                                                                     |
| 11. NOTES         |                                                          |                                                                                                                                                                                                                                                                                                                                                  |
| 11                | <b>Other information</b>                                 | Any Contract (AMC/MC/add-hoc) to be declared by the manufacturer                                                                                                                                                                                                                                                                                 |
| 11                | <b>Recommendations or warnings</b>                       | Any recommendations for best use and supplementary warning for safety should be declared                                                                                                                                                                                                                                                         |

# THERMOMETER; DIGITAL

|                                                                  |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                         |
|------------------------------------------------------------------|----------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                                                    |                                                                | 2                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Date:                                                            |                                                                | 26/2/2015                                                                                                                                                                                                                                                                                                                                                                                                               |
| Done by : (name / institution)                                   |                                                                | HCT,NHSRC                                                                                                                                                                                                                                                                                                                                                                                                               |
| NAME AND CODING                                                  |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                         |
| GMDN name                                                        |                                                                | Electronic Patient Thermometers                                                                                                                                                                                                                                                                                                                                                                                         |
| GMDN code(s)                                                     |                                                                | CT1954                                                                                                                                                                                                                                                                                                                                                                                                                  |
| GENERAL                                                          |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 1. USE                                                           |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 1.1                                                              | Clinical purpose                                               | to measure body temperature                                                                                                                                                                                                                                                                                                                                                                                             |
| 1.2                                                              | Used by clinical department/ward                               | All                                                                                                                                                                                                                                                                                                                                                                                                                     |
| TECHNICAL                                                        |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 2. TECHNICAL CHARACTERISTICS                                     |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 2.1                                                              | Technical characteristics (specific to this type of device)    | 1. Range of temperature measurement 320C- 420 (89.60F-109.40F).<br>2. Can be calibrated in both centigrade and Fahrenheit, but if only one option is available, then Fahrenheit is preferable.<br>3. Buzzer signal function.<br>4. Takes 60-90 seconds to measure temperature.<br>5. Can be used in the armpit/axilla, orally and rectally.<br>6. Accuracy of temperature $\pm 0.1\text{degC}$ and $\pm 0.2\text{ F}$ . |
| 2.2                                                              | User's interface                                               | LCD display                                                                                                                                                                                                                                                                                                                                                                                                             |
| 2.3                                                              | Software and/or standard of communication(where ever required) | inbuilt                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 3. PHYSICAL CHARACTERISTICS                                      |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 3.1                                                              | Dimensions (metric)                                            | NA                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 3.2                                                              | Weight (lbs, kg)                                               | NA                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 3.3                                                              | Configuration                                                  | NA                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 3.4                                                              | Noise (in dBA)                                                 | NA                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 3.5                                                              | Heat dissipation                                               | NA                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 3.6                                                              | Mobility, portability                                          | Portable                                                                                                                                                                                                                                                                                                                                                                                                                |
| 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 4.1                                                              | Power Requirements                                             | As per device                                                                                                                                                                                                                                                                                                                                                                                                           |
| 4.2                                                              | Battery operated                                               | yes                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 4.3                                                              | Tolerance (to variations, shutdowns)                           | NA                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 4.4                                                              | Protection                                                     | NA                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 4.5                                                              | Power consumption                                              | As per device                                                                                                                                                                                                                                                                                                                                                                                                           |

| 5. ACCESSORIES, SPARE PARTS, CONSUMABLES            |                                                                                                                                     |                                                                                                                                                                                                                                |
|-----------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 5.1                                                 | Accessories (mandatory, standard, optional)                                                                                         | NA                                                                                                                                                                                                                             |
| 5.2                                                 | Spare parts (main ones)                                                                                                             | NA                                                                                                                                                                                                                             |
| 5.3                                                 | Consumables / reagents (open, closed system)                                                                                        | Batteries                                                                                                                                                                                                                      |
| BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS |                                                                                                                                     |                                                                                                                                                                                                                                |
| 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS    |                                                                                                                                     |                                                                                                                                                                                                                                |
| 6.1                                                 | Atmosphere / Ambiance (air conditioning, humidity, dust ...)                                                                        | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%. |
| 6.2                                                 | User's care, Cleaning, Disinfection & Sterility issues                                                                              | Complete unit to be easily washable and sterilizable using both alcohol and chlorine agents.                                                                                                                                   |
| 7. STANDARDS AND SAFETY                             |                                                                                                                                     |                                                                                                                                                                                                                                |
| 7.1                                                 | Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international | ISO:13485 Manufacturer                                                                                                                                                                                                         |
| 8. TRAINING AND INSTALLATION                        |                                                                                                                                     |                                                                                                                                                                                                                                |
| 8.1                                                 | Pre-installation requirements: nature, values, quality, tolerance                                                                   | Supplier to perform operation checks before handover.                                                                                                                                                                          |
| 8.2                                                 | Requirements for sign-off                                                                                                           | Certificate of inspection from the factory.                                                                                                                                                                                    |
| 8.3                                                 | Training of staff (medical, paramedical, technicians)                                                                               | NA                                                                                                                                                                                                                             |
| 9. WARRANTY AND MAINTENANCE                         |                                                                                                                                     |                                                                                                                                                                                                                                |
| 9.1                                                 | Warranty                                                                                                                            | One year                                                                                                                                                                                                                       |
| 9.2                                                 | Maintenance tasks                                                                                                                   | NA                                                                                                                                                                                                                             |
| 9.3                                                 | Service contract clauses, including prices                                                                                          | NA                                                                                                                                                                                                                             |
| 10. DOCUMENTATION                                   |                                                                                                                                     |                                                                                                                                                                                                                                |
| 10                                                  | Operating manuals, service manuals, other manuals                                                                                   | Required                                                                                                                                                                                                                       |
| 11. NOTES                                           |                                                                                                                                     |                                                                                                                                                                                                                                |
| 11                                                  | Service Support Contact details (Hierarchy Wise; including a toll free/landline number)                                             |                                                                                                                                                                                                                                |
| 11                                                  | Recommendations or warnings                                                                                                         | NA                                                                                                                                                                                                                             |

# BP INSTRUMENT ANEROID

|                                                                              |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|------------------------------------------------------------------------------|----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                                                                |                                                                | 1.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Date:                                                                        |                                                                | SEPT 2014.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Done by : (name/institution)                                                 |                                                                | HCT/NHSRC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| NAME AND CODING                                                              |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| GMDN name                                                                    |                                                                | Sphygmomanometers                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| GMDN code(s)                                                                 |                                                                | CT1677                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| GENERAL                                                                      |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 1. USE                                                                       |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 1.1                                                                          | Clinical purpose                                               | To measure non invasive blood pressure.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 1.2                                                                          | Used by clinical department/ward                               | All                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 1.4                                                                          | Overview of functional requirements                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| TECHNICAL                                                                    |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 2. TECHNICAL CHARACTERISTICS                                                 |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 2.1                                                                          | Technical characteristics (specific to this type of device)    | Corrosion resistant shock proof body, chrome plated metal/stainless steel pressure control valve, scale 0-300 mm hg.<br>Air release at closed lap with maximum 4mmHg/Minute. Manual setting of deflation possible upto 2/3mm Hg/sec. From 260mmHg.<br>To 15mm Hg in a maxium deflation time of 10 seconds.<br>Gauge's background in white colour.<br>Graduated scale for ever/2mmhg, every 10 units and every 20 units.<br>Nylon straps cuff with pouch, latex bulb with completely chromium plated valve with regulation of vent-hole air by screw valve. |
| 2.2                                                                          | Settings                                                       | The cuff is inflated just to fit in the limb for which an inflation bulb is used to control the air pressure within the cuff.                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 2.3                                                                          | User's interface                                               | Manual                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 2.4                                                                          | Software and/or standard of communication(where ever required) | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 3. PHYSICAL CHARACTERISTICS                                                  |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 3.1                                                                          | Dimensions (metric)                                            | The rubber tubes used should have an internal diameter of $3 \pm 0.5$ mm and the external diameter should not be less than 8mm; The dial mano meter with minimum diameter of 160 mm.                                                                                                                                                                                                                                                                                                                                                                       |
| 3.2                                                                          | Weight (lbs, kg)                                               | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 3.3                                                                          | Configuration                                                  | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 3.4                                                                          | Noise (in dBA), heat dissipation                               | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 3.5                                                                          | Mobility, portability                                          | Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO <sub>2</sub> ....) |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 4.1                                                                          | Power Requirements                                             | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

|                                                        |                                                                                                                                     |                                                                                                                                                                                                                                 |
|--------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4.2                                                    | Battery operated                                                                                                                    | NA                                                                                                                                                                                                                              |
| 4.3                                                    | Tolerance (to variations, shutdowns)                                                                                                | NA                                                                                                                                                                                                                              |
| 4.4                                                    | Protection                                                                                                                          | NA                                                                                                                                                                                                                              |
| 4.5                                                    | Power consumption                                                                                                                   | NA                                                                                                                                                                                                                              |
| 4.6                                                    | Other energy supplies                                                                                                               | NA                                                                                                                                                                                                                              |
| <b>5. ACCESSORIES, SPARE PARTS, CONSUMABLES</b>        |                                                                                                                                     |                                                                                                                                                                                                                                 |
| 5.1                                                    | Accessories (mandatory, standard, optional)                                                                                         | Adult arm cuffs of size medium & large and paediatric size, inflation bulb, tubing.                                                                                                                                             |
| 5.2                                                    | Spare parts (main ones)                                                                                                             | Dial mano meter                                                                                                                                                                                                                 |
| 5.3                                                    | Consumables/reagents (open, closed system)                                                                                          | NA                                                                                                                                                                                                                              |
| <b>6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS</b> |                                                                                                                                     |                                                                                                                                                                                                                                 |
| 6.1                                                    | Atmosphere/Ambiance (air conditioning, humidity, dust ...)                                                                          | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%. |
| 6.2                                                    | User's care, Cleaning, Disinfection & Sterility issues                                                                              | NA                                                                                                                                                                                                                              |
| <b>7. STANDARDS AND SAFETY</b>                         |                                                                                                                                     |                                                                                                                                                                                                                                 |
| 7.1                                                    | Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international | ISO 13485;                                                                                                                                                                                                                      |
| <b>8. TRAINING AND INSTALLATION</b>                    |                                                                                                                                     |                                                                                                                                                                                                                                 |
| 8.1                                                    | Pre-installation requirements: nature, values, quality, tolerance                                                                   | Supplier to perform safety and operation checks before handover.                                                                                                                                                                |
| 8.2                                                    | Requirements for sign-off                                                                                                           | Certificate of inspection from the factory.                                                                                                                                                                                     |
| 8.3                                                    | Training of staff (medical, paramedical, technicians)                                                                               | Training of users in operation and basic maintenance shall be provided.                                                                                                                                                         |
| <b>9. WARRANTY AND MAINTENANCE</b>                     |                                                                                                                                     |                                                                                                                                                                                                                                 |
| 9.1                                                    | Warranty                                                                                                                            | 1 years                                                                                                                                                                                                                         |
| 9.2                                                    | Maintenance tasks                                                                                                                   | Maintainance manual detailing complete maintaining schedule.                                                                                                                                                                    |
| 9.3                                                    | Service contract clauses, including prices                                                                                          |                                                                                                                                                                                                                                 |
| <b>10. DOCUMENTATION</b>                               |                                                                                                                                     |                                                                                                                                                                                                                                 |
| 10.1                                                   | Operating manuals, service manuals, other manuals                                                                                   | Should be supplied in english.                                                                                                                                                                                                  |
| 10.2                                                   | Other accompanying documents                                                                                                        | NA                                                                                                                                                                                                                              |
| <b>11. NOTES</b>                                       |                                                                                                                                     |                                                                                                                                                                                                                                 |
| 11.1                                                   | Service Support Contact details (Hierchy Wise; including a toll free/landline number)                                               | NA                                                                                                                                                                                                                              |
| 11.2                                                   | Recommendations or warnings                                                                                                         | Any recommendations for best use and supplimentary warning for safety should be declared.                                                                                                                                       |

# PULSE OXYMETER, LINE POWERED

|                              |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|------------------------------|-------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                |                                                             | 2.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Date:                        |                                                             | SEPT 2014                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Done by : (name/institution) |                                                             | HCT/NHSRC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| NAME AND CODING              |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| GMDN name                    |                                                             | Pulse oximeter                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| GMDN code(s)                 |                                                             | CT 1446                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| GENERAL                      |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 1. USE                       |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 1.1                          | Clinical purpose                                            | Measurement and display of haemoglobin oxygen saturation (SpO <sub>2</sub> ).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 1.2                          | Used by clinical department/ward                            | All                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 1.3                          | Overview of functional requirements                         | Continuously displays patient oxygen saturation in real time using an external probe on the skin.<br>Contains adjustable alarms to alert when either saturation or heart rate is low.<br>Reusable, sterilisable probes are robust and easily connected and disconnected.<br>Operates from mains voltage or from internal rechargeable battery.                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| TECHNICAL                    |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 2. TECHNICAL CHARACTERISTICS |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 2.1                          | Technical characteristics (specific to this type of device) | <ul style="list-style-type: none"> <li>a) SpO<sub>2</sub> measurement range at least 40-70 and 70 to 99 %, minimum gradation 1%.</li> <li>b) Accuracy of SpO<sub>2</sub> better than <math>\pm 1\%</math> for range 40-70 and better than <math>\pm 3\%</math> for range 70-99.</li> <li>c) Pulse rate range at least 30 to 240 bpm, minimum gradation 1 bpm.</li> <li>d) Accuracy of pulse rate better than <math>\pm 5</math> bpm.</li> <li>e) Signal strength or quality to be visually displayed.</li> <li>f) Audiovisual alarms required: high and low SpO<sub>2</sub> and pulse rate (operator variable settings), sensor disconnected, sensor failure, low battery.</li> <li>g) TFT Screen.</li> <li>h) Plethysmograph (may be in form of bar) display is mandatory.</li> </ul> |
| 2.2                          | Settings                                                    | Should have minimum 24 hrs trend memory for SpO <sub>2</sub> & PR.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 2.3                          | User's interface                                            | Easily accessible touch button to operate the machine.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 2.4                          | Software and/or standard of communication                   | in built.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 3. PHYSICAL CHARACTERISTICS  |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 3.1                          | Dimensions (metric)                                         | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 3.2                          | Weight (lbs, kg)                                            | should be less than 5kg                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |



|                                                                         |                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3.3                                                                     | <b>Configuration</b>                                                                                                                      | Case is to be hard and splashproof.<br>Display must allow easy viewing in all ambient light levels.<br>Supplied in protective case for clean storage and safe transport.                                                                                                                                                                                                                                            |
| 3.4                                                                     | <b>Noise (in dBA)</b>                                                                                                                     | <50dBA                                                                                                                                                                                                                                                                                                                                                                                                              |
| 3.5                                                                     | <b>heat dissipation</b>                                                                                                                   | Dispersed through exhaust.                                                                                                                                                                                                                                                                                                                                                                                          |
| 3.6                                                                     | <b>Mobility, portability</b>                                                                                                              | Mobile                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)</b> |                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 4.1                                                                     | <b>Voltage (value, AC or DC, monophasic or triphase)</b>                                                                                  | 220 to 240V, 50 Hz                                                                                                                                                                                                                                                                                                                                                                                                  |
| 4.2                                                                     | <b>Battery operated</b>                                                                                                                   | Internal, replaceable, rechargeable battery allows operation for at least four hours in the event of power failure.<br>Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit.                                                                                                                                                                            |
| 4.3                                                                     | <b>Tolerance (to variations, shutdowns)</b>                                                                                               | Voltage corrector/stabilizer/UPS to allow operation at $\pm 30\%$ of local rated voltage.                                                                                                                                                                                                                                                                                                                           |
| 4.4                                                                     | <b>Protection</b>                                                                                                                         | Electrical protection by resettable circuit breakers in both live and neutral supply lines, Alarms should include Power failure.                                                                                                                                                                                                                                                                                    |
| 4.5                                                                     | <b>Power consumption</b>                                                                                                                  | 50-100 W.                                                                                                                                                                                                                                                                                                                                                                                                           |
| 4.6                                                                     | <b>Other energy supplies</b>                                                                                                              | Mains supply cable to be at least 3m in length.                                                                                                                                                                                                                                                                                                                                                                     |
| <b>5. ACCESSORIES, SPARE PARTS, CONSUMABLES</b>                         |                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 5.1                                                                     | <b>Accessories (mandatory, standard, optional)</b>                                                                                        | Two reusable probes each for adult, paediatric and infant use, Y Probes with clips for infant use and Forehead SpO2 sensors for detection of low saturation levels (less than 70%)/flex probe with provision of fixation.                                                                                                                                                                                           |
| 5.2                                                                     | <b>Spare parts (main ones)</b>                                                                                                            | Two sets of spare fuses (if non-resettable fuses used).                                                                                                                                                                                                                                                                                                                                                             |
| 5.3                                                                     | <b>Consumables/reagents (open, closed system)</b>                                                                                         | NA                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS</b>                 |                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 6.1                                                                     | <b>Atmosphere/Ambiance (air conditioning, humidity, dust ...)</b>                                                                         | Operating condition:<br>– Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances.                                                                                                                                                                                                                                                      |
| 6.2                                                                     | <b>User's care, Cleaning, Disinfection &amp; Sterility issues</b>                                                                         | Cleanable with alcohol or chlorine wipes                                                                                                                                                                                                                                                                                                                                                                            |
| <b>7. STANDARDS AND SAFETY</b>                                          |                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 7.1                                                                     | <b>Certificates (pre-market, sanitary, ..), Performance and safety standards (specific to the device type);Local and/or international</b> | Should be FDA/CE approved product ISO 80601-2-61-2011: Medical Electrical equipment- part 2-61: Particular requirements for the basic safety and essential performance of pulse oximeter.<br>Electrical safety conforms to standards for electrical safety IEC-60601-1, EMC safety conforms to IEC 60601-1-2 standard requirement.<br>Manufacturer/supplier should have ISO 13485 certificate for quality standard. |
| <b>8. TRAINING AND INSTALLATION</b>                                     |                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 8.1                                                                     | <b>Pre-installation requirements: nature, values, quality, tolerance</b>                                                                  | Electrical sockets                                                                                                                                                                                                                                                                                                                                                                                                  |
| 8.2                                                                     | <b>Requirements for sign-off</b>                                                                                                          | Supplier to perform installation, safety and operation checks before handover.<br>Local clinical staff to affirm completion of installation.                                                                                                                                                                                                                                                                        |
| 8.3                                                                     | <b>Training of staff (medical, paramedical, technicians)</b>                                                                              | Training of users in operation and basic maintenance shall be provided<br>Advanced maintenance tasks required shall be documented.                                                                                                                                                                                                                                                                                  |
| 8.4                                                                     | <b>Others</b>                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                     |

| 9. WARRANTY AND MAINTENANCE |                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------------|----------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 9.1                         | <b>Warranty</b>                                          | 3 years                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 9.2                         | <b>Maintenance tasks</b>                                 | Maintainance manual detailing complete maintaining schedule.                                                                                                                                                                                                                                                                                                                                                               |
| 9.3                         | <b>Service contract clauses, including prices</b>        | Warranty of three year with free servicing (min. 3) during warranty.                                                                                                                                                                                                                                                                                                                                                       |
| 9.4                         | <b>Others</b>                                            | The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee/warranty period should be attached.                                                                                                                                                                                                                                                    |
| 10. DOCUMENTATION           |                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 10.1                        | <b>Operating manuals, service manuals, other manuals</b> | User and maintenance manuals to be supplied in English language.<br>Certificate of calibration and inspection to be provided.<br>List to be provided of equipment and procedures required for local calibration and routine maintenance<br>List to be provided of important spares and accessories, with their part numbers and cost.<br>Contact details of manufacturer, supplier and local service agent to be provided. |
| 10.2                        | <b>Other accompanying documents</b>                      | User/Technical/Maintenance manuals to be supplied in English.                                                                                                                                                                                                                                                                                                                                                              |
| 11. NOTES                   |                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 11.1                        | <b>Other information</b>                                 | Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer                                                                                                                                                                                                                                                                                                                                                          |
| 11.2                        | <b>Recommendations or warnings</b>                       | Any recommendations for best use and supplimentary warning for safety should be declared.                                                                                                                                                                                                                                                                                                                                  |

# MONITOR

|                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                | 1.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Date:                        | SEPT 2014.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Done by : (name/institution) | HCT/NHSRC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| NAME AND CODING              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| GMDN name                    | Patient monitors/monitoring systems                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| GMDN code(s)                 | CT1444                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| GENERAL                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 1. USE                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 1.1                          | <b>Clinical purpose</b><br>Designed to continuously measure and display multiple vital physiological parameters of newborn and premature infants, especially those under critical care.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 1.2                          | <b>Used by clinical department/ward</b><br>NICU and PICU                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 1.3                          | <b>Overview of functional requirements</b><br>Operates from mains voltage or from internal rechargeable battery. Operator can set audio visual alarm levels for low or high levels of each parameter independently. Allows display of single, 3 lead ECG or simultaneous display of at least 5 waves ECG selected from up to 12 points. Display to be digital of all active parameters and trace display for at least three selectable parameters. Continuous display on screen of neonatal or infant ECG, respiration and heart rates, invasive/non-invasive blood pressure, body temperature and SpO2.                                                                                                                                                                                                                                                                                                                                    |
| TECHNICAL                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 2. TECHNICAL CHARACTERISTICS |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 2.1                          | <b>Technical characteristics (specific to this type of device)</b> <ol style="list-style-type: none"> <li>Should have facility for printing ECG at 25mm/sec and 50mm/sec speed.</li> <li>Should have facility for charging from both 12V DC &amp; 220V AC. 3a. Should be supplied with.               <ol style="list-style-type: none"> <li>Pulse oximeter probe.</li> <li>ECG cable -12 lead.</li> <li>Temperature probe.</li> <li>NIBP (non-invasive blood pressure) probe All probes should be supplied in 2 pairs, should be re-usable and should include adult, pediatric &amp; neonatal size cuff/leads. The material of the probe should be such that it is non-breakable.</li> </ol> </li> <li>Capable of saving data for min 24 hrs.</li> <li>Rates for consumables should be offered in price bid.</li> <li>Optional item to be quoted : invasive blood pressure-monitoring module complete with reusable transducer.</li> </ol> |
| 2.2                          | <b>Settings</b><br>User operated 1mV ECG test marker function required.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 2.3                          | <b>User's interface</b><br>Manual (touch screen or remote operated not mandatory).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |

|                                                                                    |                                                                          |                                                                                                                                                                                                                                                                                                                                  |
|------------------------------------------------------------------------------------|--------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2.4                                                                                | <b>Software and/or standard of communication</b>                         | Audio Visual alarms required: high and low levels for each parameter (operator variable settings), sensor/wire/probe disconnected, low battery.                                                                                                                                                                                  |
| <b>3. PHYSICAL CHARACTERISTICS</b>                                                 |                                                                          |                                                                                                                                                                                                                                                                                                                                  |
| 3.1                                                                                | <b>Dimensions (metric)</b>                                               | Screen size minimum: 10".                                                                                                                                                                                                                                                                                                        |
| 3.2                                                                                | <b>Weight (lbs, kg)</b>                                                  | <6kg.                                                                                                                                                                                                                                                                                                                            |
| 3.3                                                                                | <b>Configuration</b>                                                     | Case is to be hard and splash proof. Display must allow easy viewing in all ambient light levels. Cable connectors to be designed so as fit correct socket only.                                                                                                                                                                 |
| 3.4                                                                                | <b>Noise (in dBA)</b>                                                    | <50 dB; Lead disconnection Alarm > 65 dB.                                                                                                                                                                                                                                                                                        |
| 3.5                                                                                | <b>heat dissipation</b>                                                  | Should maintain nominal Temp and the heat should be disbursed through a exhaust cooling fan.                                                                                                                                                                                                                                     |
| 3.6                                                                                | <b>Mobility, portability</b>                                             | Supplied in protective case for clean storage and safe transport.                                                                                                                                                                                                                                                                |
| <b>4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO<sub>2</sub> ....)</b> |                                                                          |                                                                                                                                                                                                                                                                                                                                  |
| 4.1                                                                                | <b>Voltage (value, AC or DC, monophasic or triphase)</b>                 | 220 to 240V, 50 Hz.                                                                                                                                                                                                                                                                                                              |
| 4.2                                                                                | <b>Battery operated</b>                                                  | Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit. Battery powered, silenceable alarm for power failure. Internal, replaceable, rechargeable battery allows operation for at least one hour in the event of power failure. Battery backup of minimum 100 minutes. |
| 4.3                                                                                | <b>Tolerance (to variations, shutdowns)</b>                              | Voltage corrector/stabilizer to allow operation at $\pm 30\%$ of local rated voltage.                                                                                                                                                                                                                                            |
| 4.4                                                                                | <b>Protection</b>                                                        | Electrical protection provided by fuses in both live and neutral supply lines.                                                                                                                                                                                                                                                   |
| 4.5                                                                                | <b>Power consumption</b>                                                 | <120Watt.                                                                                                                                                                                                                                                                                                                        |
| 4.6                                                                                | <b>Other energy supplies</b>                                             | Mains cable.                                                                                                                                                                                                                                                                                                                     |
| <b>5. ACCESSORIES, SPARE PARTS, CONSUMABLES</b>                                    |                                                                          |                                                                                                                                                                                                                                                                                                                                  |
| 5.1                                                                                | <b>Accessories &amp; Spares</b>                                          | 2 pairs, 12 lead ECG cable. 2 packs of 100 disposable ECG connection electrodes. Two sets of reusable SpO <sub>2</sub> probes ncluding adult, pediatric & neonatal probes. two sets of NIBP cuffs of each size. Two external skin temperature probes.                                                                            |
| 5.2                                                                                | <b>Consumables/reagents (open, closed system)</b>                        |                                                                                                                                                                                                                                                                                                                                  |
| <b>6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS</b>                             |                                                                          |                                                                                                                                                                                                                                                                                                                                  |
| 6.1                                                                                | <b>Atmosphere/Ambiance (air conditioning, humidity, dust ...)</b>        | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.<br>Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.                                                                                               |
| 6.2                                                                                | <b>User's care, Cleaning, Disinfection &amp; Sterility issues</b>        | Complete unit to be easily washable and sterilizable using alcohol and other chemical agents.                                                                                                                                                                                                                                    |
| <b>7. STANDARDS AND SAFETY</b>                                                     |                                                                          |                                                                                                                                                                                                                                                                                                                                  |
| 7.1                                                                                | <b>Certifications</b>                                                    | FDA/CE and BIS/ISO 13485:2003; ; IEC-60601-1-2:2007; IEC 60601-1-8-2006; IEC 60601-1-SER-Ed 1.0-2011; IEC/TRF 60601-1-8 Ed4.0-2010; ISO 13485; ISO 80601-2-56-2009 (Thermometer); ISO 80601-2-61-2011 (SpO <sub>2</sub> )                                                                                                        |
| <b>8. TRAINING AND INSTALLATION</b>                                                |                                                                          |                                                                                                                                                                                                                                                                                                                                  |
| 8.1                                                                                | <b>Pre-installation requirements: nature, values, quality, tolerance</b> | Supplier to perform installation, safety and operation checks before handover.                                                                                                                                                                                                                                                   |
| 8.2                                                                                | <b>Requirements for sign-off</b>                                         | Supplier to perform installation, safety and operation checks before handover Local clinical staff to affirm completion of installation.                                                                                                                                                                                         |
| 8.3                                                                                | <b>Training of staff (medical, paramedical, technicians)</b>             | Training of users in operation and basic maintenance shall be provided.                                                                                                                                                                                                                                                          |

|                                    |                                                   |                                                                                                                                                                                                                                               |
|------------------------------------|---------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8.4                                | Others                                            |                                                                                                                                                                                                                                               |
| <b>9. WARRANTY AND MAINTENANCE</b> |                                                   |                                                                                                                                                                                                                                               |
| 9.1                                | Warranty                                          | 3 years                                                                                                                                                                                                                                       |
| 9.2                                | Maintenance tasks                                 | Maintenance manual detailing complete maintaining schedule                                                                                                                                                                                    |
| 9.3                                | Service contract clauses, including prices        | Warranty of 3 years with free servicing (min. 3/year) during warranty                                                                                                                                                                         |
| 9.4                                | Others                                            | The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee/warranty period should be attached                                                                        |
| <b>10. DOCUMENTATION</b>           |                                                   |                                                                                                                                                                                                                                               |
| 10.1                               | Operating manuals, service manuals, other manuals | Advanced maintenance tasks required shall be documented User, technical and maintenance manuals to be supplied in English language.<br>List to be provided of equipment and procedures required for local calibration and routine maintenance |
| 10.2                               | Other accompanying documents                      | List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.                                                                                          |
| <b>11. NOTES</b>                   |                                                   |                                                                                                                                                                                                                                               |
| 11.1                               | Other information                                 | Contact details of manufacturer, supplier and local service agent to be provided                                                                                                                                                              |
| 11.2                               | Recommendations or warnings                       | Any warning signs would be adequately displayed                                                                                                                                                                                               |

# BABY WEIGHING SCALE

|                                |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|--------------------------------|----------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                  |                                                                | 2.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Date:                          |                                                                | 26/2/2015                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Done by : (name / institution) |                                                                | HCT/ NHSRC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| NAME AND CODING                |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| GMDN name                      |                                                                | NA (Instrument)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| GMDN code(s)                   |                                                                | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| Definition                     |                                                                | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| GENERAL                        |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 1. USE                         |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 1.1                            | Clinical purpose                                               | To measure body mass of the neonate                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 1.2                            | Used by clinical department/ ward                              | NICU/SNCU                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 1.3                            | Overview of functional requirements                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| TECHNICAL                      |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 2. TECHNICAL CHARACTERISTICS   |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 2.1                            | Technical characteristics (specific to this type of device)    | <ol style="list-style-type: none"> <li>1. Table top, light and portable.</li> <li>2. Built in rechargeable battery.</li> <li>3. Easy to clean baby tray (acrylic).</li> <li>4. Zero weight adjustment facility.</li> <li>5. Quick, clear digital read outs.</li> <li>6. Measurement does not change with position of baby on the pan.</li> <li>7. Provision to measure the height of the baby in its laying position.</li> <li>8. Accuracy: 5g, resolution: 1g, limit: 10gm to 15kg.</li> </ol> |
| 2.2                            | Settings                                                       | Auto setting to 0.00 once a the machine is switched on or when no external weight has been put on.                                                                                                                                                                                                                                                                                                                                                                                              |
| 2.3                            | User's interface                                               | LCD/LED display                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 2.4                            | Software and/or standard of communication(where ever required) | in built                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 3. PHYSICAL CHARACTERISTICS    |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 3.1                            | Dimensions (metric)                                            | Base: 300mm x 265mm x 85mm $\pm$ 20%, Pan: 510mm x 300mm x 85mm (minimum).                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 3.2                            | Weight (lbs, kg)                                               | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 3.3                            | Configuration                                                  | N.A.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 3.4                            | Noise (in dBA)                                                 | N.A.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 3.5                            | heat dissipation                                               | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 3.6                            | Mobility, portability                                          | portable                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |

| 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) |                                                                                                                                     |                                                                                                                                                                                                                                                                     |
|------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4.1                                                              | Power Requirements                                                                                                                  | 230 V AC,                                                                                                                                                                                                                                                           |
| 4.2                                                              | Battery operated                                                                                                                    | 4XAA battery(rechargable) or equivalent; one hour backup.                                                                                                                                                                                                           |
| 4.3                                                              | Tolerance (to variations, shutdowns)                                                                                                | NA                                                                                                                                                                                                                                                                  |
| 4.4                                                              | Protection                                                                                                                          | NA                                                                                                                                                                                                                                                                  |
| 4.5                                                              | Power consumption                                                                                                                   | NA                                                                                                                                                                                                                                                                  |
| 4.6                                                              | Other energy supplies                                                                                                               | NA                                                                                                                                                                                                                                                                  |
| 5. ACCESSORIES, SPARE PARTS, CONSUMABLES                         |                                                                                                                                     |                                                                                                                                                                                                                                                                     |
| 5.1                                                              | Accessories (mandatory, standard, optional)                                                                                         | NA                                                                                                                                                                                                                                                                  |
| 5.2                                                              | Spare parts (main ones)                                                                                                             | NA                                                                                                                                                                                                                                                                  |
| 5.3                                                              | Consumables / reagents (open, closed system)                                                                                        | NA                                                                                                                                                                                                                                                                  |
| 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS                  |                                                                                                                                     |                                                                                                                                                                                                                                                                     |
| 6.1                                                              | Atmosphere / Ambiance (air conditioning, humidity, dust ...)                                                                        | Operating condition: <ul style="list-style-type: none"> <li>– Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances.</li> <li>– An ambient air velocity less than 0.3 m/s.</li> </ul> |
| 6.2                                                              | User's care, Cleaning, Disinfection & Sterility issues                                                                              | Complete unit to be easily washed and disinfected using both alcohol and chlorine agents.                                                                                                                                                                           |
| 7. STANDARDS AND SAFETY                                          |                                                                                                                                     |                                                                                                                                                                                                                                                                     |
| 7.1                                                              | Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international | The Scale should be as per BIS specifications. The scale should have ISI mark ie IS: 2489 Or CE/FDA certified. Should have model approval from Legal Metrology Dept., Govt. of India.                                                                               |
| 8. TRAINING AND INSTALLATION                                     |                                                                                                                                     |                                                                                                                                                                                                                                                                     |
| 8.1                                                              | Pre-installation requirements: nature, values, quality, tolerance                                                                   | NA                                                                                                                                                                                                                                                                  |
| 8.2                                                              | Requirements for sign-off                                                                                                           | NA                                                                                                                                                                                                                                                                  |
| 8.3                                                              | Training of staff (medical, paramedical, technicians)                                                                               | NA                                                                                                                                                                                                                                                                  |
| 9. WARRANTY AND MAINTENANCE                                      |                                                                                                                                     |                                                                                                                                                                                                                                                                     |
| 9.1                                                              | Warranty                                                                                                                            | one year                                                                                                                                                                                                                                                            |
| 9.2                                                              | Maintenance tasks                                                                                                                   | Callibration schedule to be provided.                                                                                                                                                                                                                               |
| 9.3                                                              | Service contract clauses, including prices                                                                                          | Any Contract (AMC/MC/add-hoc) to be declared by the manufacturer.                                                                                                                                                                                                   |
| 10. DOCUMENTATION                                                |                                                                                                                                     |                                                                                                                                                                                                                                                                     |
| 10                                                               | Operating manuals, service manuals, other manuals                                                                                   | NA                                                                                                                                                                                                                                                                  |
| 10                                                               | Other accompanying documents                                                                                                        | NA                                                                                                                                                                                                                                                                  |
| 10                                                               | Recommendations for maintenance                                                                                                     | Cautionary Note: Do not press the weighing pan with your hand. It could damage the load cell system in the weighing machine                                                                                                                                         |
| 10                                                               | Others                                                                                                                              |                                                                                                                                                                                                                                                                     |
| 11. NOTES                                                        |                                                                                                                                     |                                                                                                                                                                                                                                                                     |
| 11                                                               | Service Support Contact details (Hierchy Wise; including a toll free/landline number)                                               | Any Contract (AMC/MC/add-hoc) to be declared by the manufacturer                                                                                                                                                                                                    |
| 11                                                               | Recommendations or warnings                                                                                                         | Any Contract (AMC/MC/add-hoc) to be declared by the manufacturer                                                                                                                                                                                                    |

# IRRADIANCE METER

|                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|--------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                                                      | 2.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Date:                                                              | SEPT 2014.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Done by : (name/institution)                                       | HCT/NHSRC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| NAME AND CODING                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| GMDN name                                                          | Blue light radiometer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| GMDN code(s)                                                       | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| GENERAL                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 1. USE                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 1.1 Clinical purpose                                               | Used for checking raddiance of phototherapy units.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 1.2 Used by clinical department/ward                               | New born stablisation unit, SNCU.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| TECHNICAL                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 2. TECHNICAL CHARACTERISTICS                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 2.1 Technical characteristics (specific to this type of device)    | 1. Hand held, Band pass filter with max transmission 425-475 nm.<br>2. light detector sensitivity range: 0-2000 $\mu\text{W}/\text{cm}^2/\text{nm}$ .<br>3. Measurement range: 0-100 $\mu\text{W}/\text{cm}^2/\text{nm}$ .<br>4. Minimal graduation: 1 $\mu\text{W}/\text{cm}^2/\text{nm}$ .<br>5. Accuracy: $\pm 10\%$ .<br>6. LED or LCD display.<br>7. Should be able to zero between measurements.<br>8. Fast measurement response- <5 sec.<br>9. Memory storage: required.<br>10. UV and IR should be blocked.<br>11. Hold function. |
| 2.2 Settings                                                       | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 2.4 User's interface                                               | Digital display                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 2.5 Software and/or standard of communication(where ever required) | Built in software                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 2.6 Others                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 3. PHYSICAL CHARACTERISTICS                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 3.1 Dimensions (metric)                                            | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 3.2 Weight (lbs, kg)                                               | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 3.3 Configuration                                                  | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 3.4 Noise (in dBA)                                                 | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 3.5 heat dissipation                                               | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |



|                                                                         |                                                                                                                                     |                                                                                                                                                                                                                                 |
|-------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3.6                                                                     | Mobility, portability                                                                                                               | Mobile                                                                                                                                                                                                                          |
| <b>4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)</b> |                                                                                                                                     |                                                                                                                                                                                                                                 |
| 4.1                                                                     | Power Requirements                                                                                                                  | 220VAC/50 Hz                                                                                                                                                                                                                    |
| 4.2                                                                     | Battery operated                                                                                                                    | in built                                                                                                                                                                                                                        |
| 4.3                                                                     | Tolerance (to variations, shutdowns)                                                                                                | NA                                                                                                                                                                                                                              |
| 4.4                                                                     | Protection                                                                                                                          | Should be provided with fuse while using mains for charging.                                                                                                                                                                    |
| 4.5                                                                     | Power consumption                                                                                                                   | 30W max                                                                                                                                                                                                                         |
| 4.6                                                                     | Other energy supplies                                                                                                               | NA                                                                                                                                                                                                                              |
| <b>5. ACCESSORIES, SPARE PARTS, CONSUMABLES</b>                         |                                                                                                                                     |                                                                                                                                                                                                                                 |
| 5.1                                                                     | Accessories (mandatory, standard, optional)                                                                                         | Charger                                                                                                                                                                                                                         |
| 5.2                                                                     | Spare parts (main ones)                                                                                                             | No spares                                                                                                                                                                                                                       |
| 5.3                                                                     | Consumables/reagents (open, closed system)                                                                                          | NA                                                                                                                                                                                                                              |
| 5.4                                                                     | Others                                                                                                                              |                                                                                                                                                                                                                                 |
| <b>6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS</b>                 |                                                                                                                                     |                                                                                                                                                                                                                                 |
| 6.1                                                                     | Atmosphere/Ambiance (air conditioning, humidity, dust ...)                                                                          | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%. |
| 6.2                                                                     | User's care, Cleaning, Disinfection & Sterility issues                                                                              | NA                                                                                                                                                                                                                              |
| <b>7. STANDARDS AND SAFETY</b>                                          |                                                                                                                                     |                                                                                                                                                                                                                                 |
| 7.1                                                                     | Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international | Shall meet IEC-61010(Or Equivalent BIS) Standard Requirements. Should be FDA/CE approved product; ISO certified company.                                                                                                        |
| <b>8. TRAINING AND INSTALLATION</b>                                     |                                                                                                                                     |                                                                                                                                                                                                                                 |
| 8.1                                                                     | Pre-installation requirements: nature, values, quality, tolerance                                                                   | NA                                                                                                                                                                                                                              |
| 8.2                                                                     | Requirements for sign-off                                                                                                           | Hand-over report with end user sign.                                                                                                                                                                                            |
| 8.3                                                                     | Training of staff (medical, paramedical, technicians)                                                                               | User training on complete operation should be provided.                                                                                                                                                                         |
| 8.4                                                                     | Others                                                                                                                              |                                                                                                                                                                                                                                 |
| <b>9. WARRANTY AND MAINTENANCE</b>                                      |                                                                                                                                     |                                                                                                                                                                                                                                 |
| 9.1                                                                     | Warranty                                                                                                                            | 3 yrs                                                                                                                                                                                                                           |
| 9.2                                                                     | Maintenance tasks                                                                                                                   | Calibration to be done atleast once a year.                                                                                                                                                                                     |
| 9.3                                                                     | Service contract clauses, including prices                                                                                          | Two Preventive Maintenance annually under the warranty period.                                                                                                                                                                  |
| 9.4                                                                     | Others                                                                                                                              |                                                                                                                                                                                                                                 |
| <b>10. DOCUMENTATION</b>                                                |                                                                                                                                     |                                                                                                                                                                                                                                 |
| 10.1                                                                    | Operating manuals, service manuals, other manuals                                                                                   | Operator & service manual with circuit diagram should be provided with the machine.                                                                                                                                             |

|                  |                                                                                              |                                                                      |
|------------------|----------------------------------------------------------------------------------------------|----------------------------------------------------------------------|
| 10.2             | <b>Other accompanying documents</b>                                                          | Calbration certification to be attached with the instalation report. |
| 10.3             | <b>Recommendations for maintenance</b>                                                       | NA                                                                   |
| 10.4             | <b>Others</b>                                                                                |                                                                      |
| <b>11. NOTES</b> |                                                                                              |                                                                      |
| 11.1             | <b>Service Support Contact details (Hierchy Wise; including a toll free/landline number)</b> |                                                                      |
| 11.2             | <b>Recommendations or warnings</b>                                                           |                                                                      |

# BASINET

|                                                                  |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|------------------------------------------------------------------|----------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                                                    |                                                                | 3.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Date:                                                            |                                                                | 26/2/2015                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Done by : (name / institution)                                   |                                                                | HCT/ NHSRC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| NAME AND CODING                                                  |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| GMDN name                                                        |                                                                | Bed, Infant, general purpose                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| GMDN code(s)                                                     |                                                                | CT 1469                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| GENERAL                                                          |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 1. USE                                                           |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 1.1                                                              | Clinical purpose                                               | For care of neonate as a body positioning device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 1.2                                                              | Used by clinical department/ ward                              | NICU/SNCU, labour room, maternity ward                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| TECHNICAL                                                        |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 2. TECHNICAL CHARACTERISTICS                                     |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 2.1                                                              | Technical characteristics (specific to this type of device)    | <p>Baby Tray with mattress, along with head up/down facility, Mattress density approx 25Kg/m3 and with removable, washable, waterproof cover, mattress cover should be biocompatible and easy to clean.</p> <p>Lower Shelf which is rotatble and swivel castors (100mm) - 2 castors with brake.</p> <p>Baby tray should be of polycarbonate/acrylic material.</p> <p>It should not topple on 30 deg inclined plane.</p> <p>Baby bed should withstand upto 10kg weight.</p> <p>It should have provision for baby name identification tag/label.</p> <p>Minimum dimensions of the bassinet mattress should be 20X30" and walls both for the radiant warmer and baby bassinet.</p> |
| 2.2                                                              | Settings                                                       | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 2.3                                                              | User's interface                                               | Care giver should have a clean view of the neonate inside the basinet.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 2.4                                                              | Software and/or standard of communication(where ever required) | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 2.5                                                              | Others                                                         | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 3. PHYSICAL CHARACTERISTICS                                      |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 3.1                                                              | Dimensions (metric)                                            | 90cm-100cm height, 40cm-70cm width, 70-80cm length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 3.2                                                              | Weight (lbs, kg)                                               | net weight: 30 kgs with loading capacity to be 10 kg                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 3.3                                                              | Configuration                                                  | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 3.4                                                              | Noise (in dBA)                                                 | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 3.5                                                              | heat dissipation                                               | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 3.6                                                              | Mobility, portability                                          | yes, on castors                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 4.1                                                              | Power Requirements                                             | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 4.2                                                              | Battery operated                                               | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 4.3                                                              | Tolerance (to variations, shutdowns)                           | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |

|                                                         |                                                                                                                                     |                                                                                                                                                                                                                                                                        |
|---------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4.4                                                     | Protection                                                                                                                          | NA                                                                                                                                                                                                                                                                     |
| 4.5                                                     | Power consumption                                                                                                                   | NA                                                                                                                                                                                                                                                                     |
| 4.6                                                     | Other energy supplies                                                                                                               | NA                                                                                                                                                                                                                                                                     |
| <b>5. ACCESSORIES, SPARE PARTS, CONSUMABLES</b>         |                                                                                                                                     |                                                                                                                                                                                                                                                                        |
| 5.1                                                     | Accessories (mandatory, standard, optional)                                                                                         | mattress                                                                                                                                                                                                                                                               |
| 5.2                                                     | Spare parts (main ones)                                                                                                             | castors                                                                                                                                                                                                                                                                |
| 5.3                                                     | Consumables / reagents (open, closed system)                                                                                        | NA                                                                                                                                                                                                                                                                     |
| 5.4                                                     | Others                                                                                                                              | NA                                                                                                                                                                                                                                                                     |
| <b>6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS</b> |                                                                                                                                     |                                                                                                                                                                                                                                                                        |
| 6.1                                                     | Atmosphere / Ambiance (air conditioning, humidity, dust ...)                                                                        | Operating condition: <ul style="list-style-type: none"> <li>– Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances.</li> <li>– An ambient air velocity is less than 0.3 m/s.</li> </ul> |
| 6.2                                                     | User's care, Cleaning, Disinfection & Sterility issues                                                                              | Complete unit to be easily washable using both alcohol and chlorine agents.                                                                                                                                                                                            |
| <b>7. STANDARDS AND SAFETY</b>                          |                                                                                                                                     |                                                                                                                                                                                                                                                                        |
| 7.1                                                     | Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international | ISO 13485 and CE certified                                                                                                                                                                                                                                             |
| <b>8. TRAINING AND INSTALLATION</b>                     |                                                                                                                                     |                                                                                                                                                                                                                                                                        |
| 8.1                                                     | Pre-installation requirements: nature, values, quality, tolerance                                                                   | NA                                                                                                                                                                                                                                                                     |
| 8.2                                                     | Requirements for sign-off                                                                                                           | NA                                                                                                                                                                                                                                                                     |
| 8.3                                                     | Training of staff (medical, paramedical, technicians)                                                                               | NA                                                                                                                                                                                                                                                                     |
| 8.4                                                     | Others                                                                                                                              | NA                                                                                                                                                                                                                                                                     |
| <b>9. WARRANTY AND MAINTENANCE</b>                      |                                                                                                                                     |                                                                                                                                                                                                                                                                        |
| 9.1                                                     | Warranty                                                                                                                            | 3 year                                                                                                                                                                                                                                                                 |
| 9.2                                                     | Maintenance tasks                                                                                                                   |                                                                                                                                                                                                                                                                        |
| 9.3                                                     | Service contract clauses, including prices                                                                                          | warranty of one year with free servicing ( min. 3) during warranty.                                                                                                                                                                                                    |
| 9.4                                                     | Others                                                                                                                              |                                                                                                                                                                                                                                                                        |
| <b>10. DOCUMENTATION</b>                                |                                                                                                                                     |                                                                                                                                                                                                                                                                        |
| 10.1                                                    | Operating manuals, service manuals, other manuals                                                                                   | NA                                                                                                                                                                                                                                                                     |
| 10.2                                                    | Other accompanying documents                                                                                                        | List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.                                                                                                                   |
| 10.3                                                    | Recommendations for maintenance                                                                                                     | washing periodically                                                                                                                                                                                                                                                   |
| 10.4                                                    | Others                                                                                                                              | Na                                                                                                                                                                                                                                                                     |
| <b>11. NOTES</b>                                        |                                                                                                                                     |                                                                                                                                                                                                                                                                        |
| 11.1                                                    | Service Support Contact details (Hierarchy Wise; including a toll free/landline number)                                             |                                                                                                                                                                                                                                                                        |
| 11.2                                                    | Recommendations or warnings                                                                                                         |                                                                                                                                                                                                                                                                        |

# BREAST PUMP

|                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                                                                | 2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Date:                                                                        | 27/2/2015                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Done by : (Name / institution)                                               | HCT/NHSRC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| NAME AND CODING                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| GMDN name                                                                    | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| GMDN code(s)                                                                 | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| GENERAL                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 1. USE                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 1.1                                                                          | <b>Clinical purpose</b><br>A breast pump is a mechanical device that extracts milk from the breasts of a lactating individual. Breast pumps is an electrical devices powered by electricity or batteries.                                                                                                                                                                                                                                                                                                                                                                                 |
| 1.2                                                                          | <b>Used by clinical department/ ward</b><br>NICU and PICU                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| TECHNICAL                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 2. TECHNICAL CHARACTERISTICS                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 2.1                                                                          | <b>Technical characteristics (specific to this type of device)</b><br>1) Pumping frequency 30 to 80 Cpm and user adjustable.<br>2) Cushion inserted inside the breast cup so that it does not hurt the mother.<br>3) Suction Pressure 100 to 250 mm hb; user adjustable.<br>4) Able to express milk from both breasts simultaneously.<br>5) Collection bottles can be used for storage of milk should be autoclavable and biocompatible.<br>6) Double alternating pumps/double cycling pumps.<br>7) Should be motorized breast pump units.<br>8) Should be hospital grade and heavy duty. |
| 2.2                                                                          | <b>User's interface</b><br>Manual                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 2.3                                                                          | <b>Software and/or standard of communication(where ever required)</b><br>NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 3. PHYSICAL CHARACTERISTICS                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 3.1                                                                          | <b>Dimensions (metric)</b><br>Portable                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 3.2                                                                          | <b>Weight (lbs, kg)</b><br>Compact unit (weight less than 4 kg)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 3.3                                                                          | <b>Configuration</b><br>LCD/LED display suction timing                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 3.4                                                                          | <b>Noise (in dBA)</b><br><60db                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 3.5                                                                          | <b>Heat dissipation</b><br>NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 3.6                                                                          | <b>Mobility, portability</b><br>Yes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO <sub>2</sub> ....) |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 4.1                                                                          | <b>Power Requirements</b><br>220 V AC + 10%, 50Hz power supply; 5A plug.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

|                                                            |                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                             |
|------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4.2                                                        | Battery operated                                                                                                                   | NA                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 4.3                                                        | Tolerance (to variations, shutdowns)                                                                                               | ± 10% of input AC                                                                                                                                                                                                                                                                                                                                                                                                           |
| 4.4                                                        | Protection                                                                                                                         | Electrical protection by resettable overcurrent breakers or replaceable fuses.                                                                                                                                                                                                                                                                                                                                              |
| 4.5                                                        | Power consumption                                                                                                                  | Should be compatible with other life saving equipments running parallel.                                                                                                                                                                                                                                                                                                                                                    |
| <b>5. ACCESSORIES, SPARE PARTS, CONSUMABLES</b>            |                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 5.1                                                        | Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)                 | 1) Resuable collection bottles along-with breast cups - 10 sets.<br>2) All kinds of tubes - 12 sets (If applicable).<br>3) Diaphragm - 100Nos.<br>4) Other accessories required for optimum functioning of the equioment.                                                                                                                                                                                                   |
| <b>BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS</b> |                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS</b>     |                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 6.1                                                        | Atmosphere / Ambiance (air conditioning, humidity, dust ...)                                                                       | 1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90% in ideal circumstances.<br>2) Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.                                                                                                                     |
| 6.2                                                        | User's care, Cleaning, Disinfection & Sterility issues                                                                             | Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.                                                                                                                                                                                                                   |
| <b>7. STANDARDS AND SAFETY</b>                             |                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 7.1                                                        | Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type);Local and/or international | 1) Should be CE (EU)/FDA (US) approved product.<br>2) Manufacturer / supplier should have ISO 13485 certificate for quality standard.<br>3) Electrical safety conforms to standards for electrical safety IEC-60601-1.                                                                                                                                                                                                      |
| <b>8. TRAINING AND INSTALLATION</b>                        |                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 8.1                                                        | Pre-installation requirements: nature, values, quality, tolerance                                                                  | Supplier to perform installation, safety and operation checks before handover.                                                                                                                                                                                                                                                                                                                                              |
| 8.2                                                        | Requirements for sign-off                                                                                                          | Certificate of calibration and inspection from the factory.                                                                                                                                                                                                                                                                                                                                                                 |
| 8.3                                                        | Training of staff (medical, paramedical, technicians)                                                                              | Training of users in operation and basic maintenance shall be provided.                                                                                                                                                                                                                                                                                                                                                     |
| <b>9. WARRANTY AND MAINTENANCE</b>                         |                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 9.1                                                        | Warranty                                                                                                                           | 3 years                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 9.2                                                        | Maintenance tasks                                                                                                                  | Maintainance manual detailing complete maintaining schedule.                                                                                                                                                                                                                                                                                                                                                                |
| 9.3                                                        | Service contract clauses, including prices                                                                                         | warranty of three year with free servicing ( min. 3) during warranty.                                                                                                                                                                                                                                                                                                                                                       |
| <b>10. DOCUMENTATION</b>                                   |                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 10.1                                                       | Operating manuals, service manuals, other manuals                                                                                  | User and maintenance manuals to be supplied in English language.<br>Certificate of calibration and inspection to be provided.<br>List to be provided of equipment and procedures required for local calibration and routine maintenance.<br>List to be provided of important spares and accessories, with their part numbers and cost.<br>Contact details of manufacturer, supplier and local service agent to be provided. |

|                  |                                                                                                |                                                                                   |
|------------------|------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| 10.2             | <b>Recommendations for maintenance</b>                                                         | User/Technical/Maintenance manuals to be supplied in English.                     |
| <b>11. NOTES</b> |                                                                                                |                                                                                   |
| 11.1             | <b>Service Support Contact details (Hierarchy Wise; including a toll free/landline number)</b> | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2             | <b>Recommendations or warnings</b>                                                             | Any warning signs would be adequately displayed.                                  |

# EXAMINATION TREATMENT LIGHT

|                              |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|------------------------------|-------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                |                                                             | 1.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Date:                        |                                                             | JULY 2014.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Done by : (Name/institution) |                                                             | HCT/NHSRC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| NAME AND CODING              |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| GMDN name                    |                                                             | Examination/treatment light                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| GMDN code(s)                 |                                                             | CT 1268                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| GENERAL                      |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 1. USE                       |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 1.1                          | Clinical purpose                                            | Provides light to illuminate the site of examination and/or treatment of the patient.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 1.2                          | Used by clinical department/ward                            | NICU and PICU                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 1.3                          | Overview of functional requirements                         | Provides clear and cool light to operating area Minimizes shadows and distortion of colour Mounted on mobile base Single head must be easily moved by operator to direct light to required area Integral rechargeable battery for operation without mains electricity.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| TECHNICAL                    |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 2. TECHNICAL CHARACTERISTICS |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 2.1                          | Technical characteristics (specific to this type of device) | <ol style="list-style-type: none"> <li>1. Color temperature to be between 3, 000 and 5, 000 K; shadowless.</li> <li>2. Maximum illumination level at 1m distance to be at least 60, 000 lux.</li> <li>3. Color rendering index to be 93 or greater.</li> <li>4. Minimum bulb life required 1, 000 hours (incandescent type) or 20, 000 hrs (LED type).</li> <li>5. Field diameter required <math>\square</math> 16cm, field depth required <math>\square</math> 50cm.</li> <li>6. Focal length required <math>\square</math> 65 cm.</li> <li>7. Heat to light ratio to be <math>\leq 6</math> mW/m<sup>2</sup>.lx</li> <li>8. Brightness control to allow full adjustment from zero to maximum illumination.</li> <li>9. Bulb voltage and type to be clearly labeled on external body.</li> <li>10. Replacement bulbs to be locally available.</li> <li>11. Front panel to include power switch and battery state indicator.</li> <li>12. Automatic switching to battery power in the event of power failure.</li> </ol> |
| 2.2                          | Settings                                                    | Manual                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 2.3                          | User's interface                                            | Manual                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 2.4                          | Software and/or standard of communication                   | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 3. PHYSICAL CHARACTERISTICS  |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 3.1                          | Dimensions (metric)                                         | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 3.2                          | Weight (lbs, kg)                                            | Less than 30 kgs                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |



|                                                                         |                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3.3                                                                     | <b>Configuration</b>                                                                                                                       | Case is to be hard, splash-proof and corrosion resistant Movement must be easily achieved by operator of height 1.5m Light head mounting to allow vertical and rotational movement, capable of illuminating at least 1m high table Handle for movement must be easy to grasp and clean Light must remain steady on position and balanced once moved Base to have at least four fully 360 degree swivel castors, minimum diameter 75mm Whole system to be stable for all positions of light head All power supply and battery location to be within access for ease in replacement. |
| 3.4                                                                     | <b>Noise (in dBA)</b>                                                                                                                      | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 3.5                                                                     | <b>heat dissipation</b>                                                                                                                    | Should maintain cool temp and the heat disbursed through a exhaust fan.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 3.6                                                                     | <b>Mobility, portability</b>                                                                                                               | Portable on castors.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)</b> |                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 4.1                                                                     | <b>Voltage (value, AC or DC, monophasic or triphase)</b>                                                                                   | 220VAC $\pm$ 10%, 50 Hz                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 4.2                                                                     | <b>Battery operated</b>                                                                                                                    | Internal, replaceable, rechargeable battery allows operation for at least eight hours in the event of power failure Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit.                                                                                                                                                                                                                                                                                                                                              |
| 4.3                                                                     | <b>Tolerance (to variations, shutdowns)</b>                                                                                                | Voltage corrector/stabilizer to allow operation at $\pm$ 30% of local rated voltage.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 4.4                                                                     | <b>Protection</b>                                                                                                                          | Electrical protection by resettable overcurrent breakers or replaceable fuses, fitted in both live and neutral lines                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 4.5                                                                     | <b>Power consumption</b>                                                                                                                   | 100 W or below                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 4.6                                                                     | <b>Other energy supplies</b>                                                                                                               | Mains cable to be at least 3m length                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>5. ACCESSORIES, SPARE PARTS, CONSUMABLES</b>                         |                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 5.1                                                                     | <b>Accessories (mandatory, standard, optional)</b>                                                                                         | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 5.2                                                                     | <b>Spare parts (main ones)</b>                                                                                                             | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 5.3                                                                     | <b>Consumables/reagents (open, closed system)</b>                                                                                          | Two sets of spare fuses (if replaceable fuses used).<br>Ten sets of replacement bulbs (if incandescent).                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 5.4                                                                     | <b>Others</b>                                                                                                                              | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS</b>                 |                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 6.1                                                                     | <b>Atmosphere/Ambiance (air conditioning, humidity, dust ...)</b>                                                                          | Operating condition:<br>– Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances.                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 6.2                                                                     | <b>User's care, Cleaning, Disinfection &amp; Sterility issues</b>                                                                          | Unit layout to enable easy cleaning and sterilization of all surfaces.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>7. STANDARDS AND SAFETY</b>                                          |                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 7.1                                                                     | <b>Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international</b> | Should be FDA (US)/CE (EU) approved product Manufacturer/supplier should have ISO 13485 certificate for quality standard.<br>Electrical safety conforms to standards for electrical safety IEC-60601-1 Shall meet IEC-60601-1-2 (General requirements for safety - electromagnetic compatibility).                                                                                                                                                                                                                                                                                 |
| <b>8. TRAINING AND INSTALLATION</b>                                     |                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 8.1                                                                     | <b>Pre-installation requirements: nature, values, quality, tolerance</b>                                                                   | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 8.2                                                                     | <b>Requirements for sign-off</b>                                                                                                           | Supplier to perform installation, safety and operation checks before handover Local clinical staff to affirm completion of installation.                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 8.3                                                                     | <b>Training of staff (medical, paramedical, technicians)</b>                                                                               | Training of users in operation and basic maintenance shall be provided<br>Advanced maintenance tasks required shall be documented.                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 8.4                                                                     | <b>Others</b>                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

| 9. WARRANTY AND MAINTENANCE |                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-----------------------------|---------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 9.1                         | Warranty                                          | One year;                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 9.2                         | Maintenance tasks                                 | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 9.3                         | Service contract clauses, including prices        | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 9.4                         | Others                                            | NA                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 10. DOCUMENTATION           |                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 10.1                        | Operating manuals, service manuals, other manuals | <p>User, technical and maintenance manuals to be supplied in English language.</p> <p>Certificate of calibration and inspection to be provided.</p> <p>List to be provided of equipment and procedures required for local calibration and routine maintenance List to be provided of important spares and accessories, with their part numbers and cost.</p> <p>Contact details of manufacturer, supplier and local service agent to be provided</p> |
| 11. NOTES                   |                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 11.1                        | Other information                                 | Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer                                                                                                                                                                                                                                                                                                                                                                                    |
| 11.2                        | Recommendations or warnings                       | Any recommendations for best use and supplementary warning for safety should be declared                                                                                                                                                                                                                                                                                                                                                             |

# EEG-ELECTROENCEPHALOGRAPHY

|                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Version no. :                | 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Date:                        | JULY 2014.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Done by : (name/institution) | HCT/NHSRC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| NAME AND CODING              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| GMDN name                    | Electroencephalography                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| GMDN code(s)                 | CT138                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| GENERAL                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 1. USE                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 1.1                          | <b>Clinical purpose</b><br>To record the variations of the electrical potential caused by the electrical activity of the brain                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 1.2                          | <b>Used by clinical department/ward</b><br>NICU/PICU                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| TECHNICAL                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 2. TECHNICAL CHARACTERISTICS |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 2.1                          | <b>Technical characteristics (specific to this type of device)</b> <ol style="list-style-type: none"> <li>Should be a 32 Channel digital EEG Machine, where 24 Channels for acquisition and storage, 5 Polygraph Channels and 3 DC Channels.</li> <li>Frequency response should be 0.05Hz to 70Hz.</li> <li>Should have facility to view all channels in different montages during acquisition and review.</li> <li>Should have split screen facility to study and even carefully during acquisition, where data storage should be on going in hard disk.</li> <li>Should have split screen facility in analysis to compare the data of same time or different times with individual selection of filters, sensitivity, montages etc.</li> <li>Should have the facility for simultaneous acquisition and review of same record.</li> <li>Should have the facility to mark pages/important events for printing in review.</li> <li>Should have user definable photic stimulator protocol execution with display of photic marks on screen using LED or Xenon flash lights</li> <li>Should have unlimited Montage Reformatting.</li> <li>Should have HLF (15, 35, 70 Hz) and LLF (0.1, 0.3, 1.5, 3, 5 Hz) filters for each channel as well as for all channels for display.</li> <li>Should have the facility for sweep speed selection.</li> <li>Should have the facility to display traces with limit trace.</li> <li>Should mark and annotate standards events such as Eyes open, Eyes closed, Hyperventilation on, Hyperventilation off, Artifact, and other user defined events of max. 50.</li> <li>Should have separate sensitivity control for each channels as well as for all channels.</li> </ol> |

|                                    |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|------------------------------------|----------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                    |                                                                | <p>15) Should have the facility to enter patient details such as ID, Name, Referred By, Sex, Age, Patient History, Address, Doctor Name etc.</p> <p>16) Should have the facility to review of selected patient form list, to sort data according to patient name, sex, age, test date etc, review another patient while acquisition and to edit the patient details.</p> <p>17) Should have the facility to browse page by page, Scroll in forward and reverse direction and the speed of scrolling can be different speed levels such as same acquisition speed, 2 times, 3 times , 4 times the acquisition speed.</p> <p>18) Should have user definable protocols for acquisition.</p> <p>19) EEG pages should displayed in BRAIN MAP montage and it should have the facility to view Amplitude brain map, Progressive amplitude brain map, frequency brain map, progressive frequency brain map, 4 bands frequency brain map with frequency spectrum, 5 bands frequency brain map with frequency spectrum, 4 bands frequency brain map with EEG &amp; 5 bands frequency brain map with EEG in review mode.</p> <p>20) Should have the facility to edit current page events, browse all the marked events. Display the page having the selected event, to store any number of marked EEG pages on another HDD.</p> <p>21) Should have the facility for spike detection with amplitude greater than or equal to the specified amplitude and within specified duration.</p> <p>22) Should have the facility to print all marked EEG pages/Brain map pages in queue.</p> <p>23) Should have Acquisition Hot keys for Sensitivity for all traces, Eyes open, Eyes close, Hyperventilation ON, Hyperventilation OFF, Mark page, Artifact, Annotated event, Toggle pause/Release pause, Snap shot mode, photic stimulation etc.</p> <p>24) Should have Review Hot Keys for page mode, scroll mode, flip mode, next page, increase speed, mark page for printing, forward direction, reverse direction, previous page, decrease speed etc.</p> <p>25) Photic frequency should be 1-30 Hz, Stimulating time 1-16 sec and pause time 1-16 sec.</p> <p>26) CMRR should be greater than 100 db and input impedance should be greater than 10 M Ohms.</p> <p>27) Should have a high resolution low light video camera.</p> <p>28) Should have infra red camera for night VEEG recording facilities.</p> <p>29) Should have facility to upgrade EEG to sleep system in future.</p> <p>30) Should be supplied all necessary accessories including EEG Disc Electrode.</p> |
| 2.2                                | User's interface                                               | Manual                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 2.3                                | Software and/or standard of communication(where ever required) | <p>1) Convenient and quick USB interface.</p> <p>2) Should have an efficient data base management including Hospital details, Reference doctors list, standard comments for summary report etc.</p> <p>3) Should have the facility to edit and print summary report, EEG page and Brain map page.</p> <p>4) Inbuilt software.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>3. PHYSICAL CHARACTERISTICS</b> |                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 3.1                                | Dimensions (metric)                                            | Portable                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 3.2                                | Weight (lbs, kg)                                               | Portable                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 3.3                                | Configuration                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |

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|------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3.4                                                                                | Noise (in dBA)                                                                                                                      | NA                                                                                                                                                                                                                                                                                                                                                                              |
| 3.5                                                                                | Heat dissipation                                                                                                                    | NA                                                                                                                                                                                                                                                                                                                                                                              |
| 3.6                                                                                | Mobility, portability                                                                                                               | Supplied in protective case for clean storage and safe transport.                                                                                                                                                                                                                                                                                                               |
| <b>4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO<sub>2</sub> ....)</b> |                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                 |
| 4.1                                                                                | Power Requirements                                                                                                                  | Input voltage 220 VAC $\pm$ 10%, 50Hz;                                                                                                                                                                                                                                                                                                                                          |
| 4.2                                                                                | Battery operated                                                                                                                    | Battery powered, silenceable alarm for power failure.<br>Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit.<br>Internal, replaceable, rechargeable battery allows operation for at least one hour in the event of power failure.                                                                                 |
| 4.3                                                                                | Tolerance (to variations, shutdowns)                                                                                                | Voltage corrector/stabilizer to allow operation at $\pm$ 10% of local rated voltage. Use of SMPS to correct voltage.                                                                                                                                                                                                                                                            |
| 4.4                                                                                | Protection                                                                                                                          | Electrical protection, resettable over current breakers or replaceable fuses (fitted in both live and neutral lines).                                                                                                                                                                                                                                                           |
| 4.5                                                                                | Power consumption                                                                                                                   | Should run with other life saving equipments running parallelly in the NICU/ PICU.                                                                                                                                                                                                                                                                                              |
| 4.6                                                                                | Other energy supplies                                                                                                               | Mains power cable to be at least 3m length                                                                                                                                                                                                                                                                                                                                      |
| <b>5. ACCESSORIES, SPARE PARTS, CONSUMABLES</b>                                    |                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                 |
| 5.1                                                                                | Accessories (mandatory, standard, optional)                                                                                         | 2 Two sets of electrodes;                                                                                                                                                                                                                                                                                                                                                       |
| 5.2                                                                                | Spare parts (main ones)                                                                                                             | Two sets of spare fuses (if non-resettable fuses used).                                                                                                                                                                                                                                                                                                                         |
| 5.3                                                                                | Consumables/reagents (open, closed system)                                                                                          | 5 tubes/box of elefix EEG paste.                                                                                                                                                                                                                                                                                                                                                |
| <b>BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS</b>                             |                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS</b>                            |                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                 |
| 6.1                                                                                | Atmosphere/Ambiance (air conditioning, humidity, dust ...)                                                                          | 1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90% in ideal circumstances.<br>2) Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.                                                                         |
| 6.2                                                                                | User's care, Cleaning, Disinfection & Sterility issues                                                                              | Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.                                                                                                                                                                       |
| <b>7. STANDARDS AND SAFETY</b>                                                     |                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                 |
| 7.1                                                                                | Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international | 1) Should be CE (EU)/FDA (US) approved product;<br>2) Manufacturer/supplier should have ISO 13485 certificate for quality standard;<br>3) Electrical safety conforms to standards for electrical safety IEC-60601-1;<br>4) Shall meet IEC-60601-1-2 (General requirements for safety - electromagnetic compatibility);<br>5) IEC 60601-2-26:2002 and IEC 60601-2-37 applicable; |
| <b>8. TRAINING AND INSTALLATION</b>                                                |                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                 |
| 8.1                                                                                | Pre-installation requirements: nature, values, quality, tolerance                                                                   | 1) Availability of 5 Amps. electrical socket;                                                                                                                                                                                                                                                                                                                                   |
| 8.2                                                                                | Requirements for sign-off                                                                                                           | 1) Supplier to perform installation, safety and operation checks before handover;<br>2) Local clinical staff to affirm completion of installation;                                                                                                                                                                                                                              |

|                                    |                                                                                                |                                                                                                                                                                                                                                                                                                          |
|------------------------------------|------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8.3                                | <b>Training of staff (medical, paramedical, technicians)</b>                                   | 1) Training of users on operation and basic maintenance;<br>2) Advanced maintenance tasks required shall be documented;                                                                                                                                                                                  |
| <b>9. WARRANTY AND MAINTENANCE</b> |                                                                                                |                                                                                                                                                                                                                                                                                                          |
| 9.1                                | <b>Warranty</b>                                                                                | 3 years                                                                                                                                                                                                                                                                                                  |
| 9.2                                | <b>Maintenance tasks</b>                                                                       | 1) Maintenance manual detailing;<br>2) Complete maintenance schedule;                                                                                                                                                                                                                                    |
| 9.3                                | <b>Service contract clauses, including prices</b>                                              | 1) The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee/warranty period should be attached;<br>2) Free servicing (min. 2/year) during warranty period;                                                                    |
| <b>10. DOCUMENTATION</b>           |                                                                                                |                                                                                                                                                                                                                                                                                                          |
| 10.1                               | <b>Operating manuals, service manuals, other manuals</b>                                       | Should provide 2 sets(hardcopy) of:-<br>1) User, technical and maintenance manuals to be supplied in english/hindi language along with machine diagrams;<br>2) List of equipment and procedures required for local calibration and routine maintenance;<br>3) Certificate of calibration and inspection; |
| 10.2                               | <b>Other accompanying documents</b>                                                            | List of important spares and accessories, with their part numbers and cost;                                                                                                                                                                                                                              |
| <b>11. NOTES</b>                   |                                                                                                |                                                                                                                                                                                                                                                                                                          |
| 11.1                               | <b>Service Support Contact details (Hierarchy Wise; including a toll free/landline number)</b> | Contact details of manufacturer, supplier and local service agent to be provided;<br>Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer;                                                                                                                                                  |
| 11.2                               | <b>Recommendations or warnings</b>                                                             | Any warning signs would be adequately displayed.                                                                                                                                                                                                                                                         |

## NICU AND PICU EQUIPMENT LIST

| S.NO. | EQUIPMENT NAME                                     |
|-------|----------------------------------------------------|
| 1     | Direct Ophthalmoscope                              |
| 2     | Mobile X-Ray                                       |
| 3     | Bilirubinometer                                    |
| 4     | ECG unit, 3 channel, portable                      |
| 5     | LowCost Glucometer                                 |
| 6     | Blood Gas Analyzer                                 |
| 7     | Transilluminator Cold Light Source                 |
| 8     | CPAP                                               |
| 9     | Intensive Care Ventilator (Neonatal and Pediatric) |
| 10    | Transport Ventilator (Neonatal and Pediatric)      |
| 11    | Defibrillator                                      |
| 12    | Nebulizer (Electric)                               |
| 13    | Syring Pump                                        |
| 14    | Infusion Pump-Volumetric                           |
| 15    | Suction Pump, Portable, Electronic                 |
| 16    | Suction Pump, foot operated                        |
| 17    | Self inflating reservoir bag                       |
| 18    | Laryngoscope                                       |
| 19    | Oxygen Hood                                        |
| 20    | Oxygen Concentrator                                |
| 21    | Radiant Warmer                                     |
| 22    | Phototherapy Unit                                  |
| 23    | Transport Incubator                                |
| 24    | Thermometer, Digital                               |
| 25    | B.P.Instrument Aneroid                             |
| 26    | Pulse Oximeter_Line Powered                        |
| 27    | Monitor                                            |
| 28    | Electric Baby Weighing Scale                       |
| 29    | Irradiance meter                                   |
| 30    | Basinet                                            |
| 31    | Breast Pump                                        |
| 32    | Examination Treatment Light                        |
| 33    | Mobile EEG                                         |









**NATIONAL HEALTH MISSION**  
Ministry of Health and Family Welfare  
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