सत्यमेव जयते

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

**Ministry of Health & Family Welfare**
Goverment of India

# Technical Specifications of Medical Devices for **Operational Theatres**

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राष्ट्रीय स्वास्थ्य मिशन
भानु प्रताप शर्मा
सचिव
B.P. SHARMA
Secretary

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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 : 29th 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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NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

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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
29th April, 2015

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

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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

31st 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 Ameel, 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**

# SUCTION PUMP PORTABLE ELECTRIC

| | | |
|---|---|---|
| Version no. : | | 2.0 |
| Date: | | 20/5/2014 |
| Done by : (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Suction systems |
| GMDN code | | CT1272 |
| GMDN definition | | An assembly of devices designed to evacuate fluid, tissue, gas, or other foreign materials from a body cavity or lumen by means of suction. It generally consists of a mains electricity (AC and DC powered) suction pump, tubing, plastic/glass collection container(s), a vacuum gauge, a vacuum control knob, an overflow trap, a moisture filter, and a microbial filter. The pump creates a vacuum in the suction tubing, which is inserted into the body for the removal of materials into the collection container. This system can be used in a wide variety of settings within healthcare facilities. |
| **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** | All |
| **TECHNICAL** | | |
| **2 TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 0 to - 760 mm Hg ± 10 regulable, 1/2 HP; single phase 1440 RPM motor; flutter free vacuum control knob,; 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 (with jar) |
| 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, CO2 ....)** | | |
| 4.1 | **Power Requirements** | 220 V, 50 Hz, 2 ± 0.5 Amps, 370 watts for AC and DC compatible with ambulance power supply with other life saving equipments running |

| | | |
|---|---|---|
| 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 in the vehicle |
| 4.6 | **Other energy supplies** | NA |
| | **5 ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories & Spares** | collection container & its cap, suctions tube tips, a vacuum gauge, two sets of moisture & microbial filters and control knob |
| 5.2 | **Consumables / reagents (open, closed system)** | SiliconeTubing:8 mm ID x 2 mtr (PVC), 2x2 lt jar ( one set extra) |
| | **6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | |
| 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 alcohol and chemical disinfectants. |
| | **7 STANDARDS AND SAFETY** | |
| 7.1 | **Certifications** | FDA(US) /CE(EU) and BIS/ISO 13485:2003; IEC 60601-1 |
| | **8 TRAINING AND INSTALLATION** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | Avalability of 15 amp socket, safety and operation checks before handover.<br>Compatible with ambulance electrical systems |
| 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 |
| | **9 WARRANTY AND MAINTENANCE** | |
| 9.1 | **Warranty** | 3 years |
| 9.2 | **Maintenance tasks** | maintainance 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 in English and/or Hindi<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 (Hierchy 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 supplimentary warning for safety should be declared |

# SUCTION PUMP, FOOT OPERATED

| | | |
|---|---|---|
| Version no. : | | 2.0 |
| Date: | | 20/5/2014 |
| Done by : (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Emergency suction systems |
| GMDN code | | CT2180 |
| GMDN definition | | A portable assembly of devices primarily intended to be used by emergency medical services (EMS) to aspirate fluids, secretions, or other foreign materials from a patient's airway by means of suction. It typically consists of a manually-powered (foot-operated) mechanism to drive the suction pump, tubing, a collection container and control knob. The pump creates a vacuum in the suction tubing, which is used for the removal of materials into the collection container. This system is typically used during patient transport or for emergency situations. |
| **GENERAL** | | |
| **1 USE** | | |
| 1.1 | **Clinical purpose** | to aspirate fluids, secretions, or other foreign materials from a patient's airway by means of suction. |
| **TECHNICAL** | | |
| **2 TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 0 to - 600 mmHg +-10mm regulable, flutter free, vacuum control knob |
| 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)** | NA |
| 3.2 | **Weight (lbs, kg)** | 2.5kg max |
| 3.3 | **Configuration** | NA |
| 3.4 | **Noise (in dBA)** | NA |
| 3.5 | **heat dissipation** | NA |
| 3.6 | **Mobility, portability** | Yes |
| **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 & spare parts** | collection bottles, clear unbreakable jar (one set extra) |
| 5.2 | **Consumables / reagents (open, closed system)** | silicon tubing - two sets |
| | **6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | |
| 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 chemical disinfectant. |
| | **7 STANDARDS AND SAFETY** | |
| 7.1 | **Certifications** | FDA(US)/CE (EU) and BIS/ISO 13485:2003; ISO 10079-2-2014 |
| | **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** | maintainance 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 (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 |

# AUTOCLAVE HP VERTICAL(SINGLE BIN)

| | | |
|---|---|---|
| Version no. : | | 1 |
| Date: | | 5/12/2014 |
| Done by : (name / institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Autoclave HP Vertical(single bin) |
| GMDN code(s) | | NA |
| **GENERAL** | | |
| **1 USE** | | |
| 1.1 | **Clinical purpose** | An airtight vessel for heating and sometimes agitating its contents under high steam pressure; used for industrial processing, sterilizing, and cooking with moist or dry heat at high temperatures. |
| 1.2 | **Used by clinical department/ward** | Operation theatre |
| **TECHNICAL** | | |
| **2 TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1)High Grade strong stainless steel, Triple walled construction.<br>2)Positive radial self-locking safety doors.<br>3)Hydrostatically tested to withstand 2.5 times the working pressure.<br>4)Sealed with Neoprene/Silicon long-lasting and durable gasket.<br>5)Digital display for Jacket and Chamber pressure and temperature.<br>6)Outer jacket insulated to prevent heat loss;with a high grade insulation material<br>7)Mounted on 304 stainless steel frame with ground leveling flanges.<br>8)Temperature and pressure cut-off device.<br>9)Auto cut-off at low water level<br>10)Rust-proof 304 grade stainless steel.<br>11)Cylindrical construction.<br>12)Equipment should have separate steam release valve and drainage system.<br>13)Minimum of two safety valves with auto-release at 16 and 20. |
| 2.2 | **User's interface** | Manual |
| 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)** | NA |
| 3.3 | **Capacity** | 40 L,70 L,100 L |
| 3.4 | **Noise (in dBA)** | NA |

| | | |
|---|---|---|
| 3.5 | **Heat dissipation** | Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism |
| 3.6 | **Mobility, portability** | Portable |
| | **4 ENERGY SOURCE (ELECTRICITY, UPS, SOLAR, GAS, WATER, CO2 ....)** | |
| 4.1 | **Power Requirements** | Recharging unit: Input voltage- single/3-phase |
| 4.2 | **Battery operated** | No |
| 4.3 | **Tolerance (to variations, shutdowns)** | ±10% |
| 4.4 | **Pressure gauge** | 0-2.1Kgf/cm$^2$ |
| 4.5 | **Operating pressure** | from 15-20 psi |
| 4.6 | **Sterilizing pressure** | 1.2Kgf/cm(15 psi) at 121˚C |
| 4.7 | **Protection** | Should have over-charging cut-off with visual symbol. |
| 4.8 | **Power consumption** | upto 9kW |
| | **5 ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)** | 1. Automatic Pressure Control Switch -2 no.<br>2. Automatic Water Cut-off Device -2 no.<br>3. Micro Processor PID Controller with Timer & Auto Stop Facility<br>4. Digital Pressure Indicator-2 no.<br>5. Perforate basket(rust-free stainless steel)<br>6. Cord-plug-4 no.<br>7. Biological and chemical indicators-1 set |
| | **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | |
| | **6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | |
| 6.1 | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | 1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 50 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.<br>2) Sterilization not required. |
| | **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 FDA/CE/BIS approved product.<br>2. Manufacturer and Supplier should have ISO 13485 certification for quality standards.<br>3. Electrical safety conforms to the standards for electrical safety IEC 60601-General requirements(or equivalent BIS Standard)<br>4. Shall meet internationally recognised for Electromagnetic Compatibility(EMC) for electromedical equipment: 61326-1.<br>5. Certified to be compliant with IEC 61010-1,IEC 61010-2-40 for safety. |
| 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 socket;<br>2) Safety and operation check before handover; |
| 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 |
| 9.2 | **Maintenance tasks** | 1) Maintenance manual detailing;<br>2) Complete maintenance schedule; |
| 9.3 | **Service contract clauses, including prices** | 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 | **Operating manuals, service manuals, other manuals** | Should provide 2 sets(hardcopy and soft-copy) 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) Service and operation manuals (original and copy) to be provided;<br>4) Advanced maintenance tasks documentation;<br>5) 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 |

# AUTOCLAVE HP HORIZONTAL

| | | |
|---|---|---|
| Version no. : | | 1 |
| Date: | | 5/12/2014 |
| Done by : (name / institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Autoclave HP Horizontal |
| GMDN code(s) | | NA |
| **GENERAL** | | |
| **1 USE** | | |
| 1.1 | Clinical purpose | An airtight vessel for heating and sometimes agitating its contents under high steam pressure; used for sterilizing, with moist or dry heat at high temperatures. |
| 1.2 | Used by clinical department/ward | CSSD |
| **TECHNICAL** | | |
| **2 TECHNICAL CHARACTERISTICS** | | |
| 2.1 | | 1) High Grade strong stainless steel, Triple walled construction.<br>2) Positive radial self-locking safety doors.<br>3) Hydrostatically tested to withstand 2.5 times the working pressure.<br>4) Sealed with Neoprene/Silicon long-lasting and durable gasket.<br>5) Digital display for Jacket and Chamber pressure and temperature.<br>6) Outer jacket insulated to prevent heat loss;with a high grade insulation material<br>7) Mounted on 304 stainless steel frame with ground leveling flanges.<br>8) Temperature and pressure cut-off device.<br>9) Auto cut-off at low water level<br>10) Rust-proof 304 grade stainless steel.<br>11) Cylindrical construction.<br>12) Equipment should have separate steam release valve and drainage system.<br>13) Minimum of two safety valves with auto-release at 16 and 20. |
| 2.2 | **User's interface** | Manual |
| 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)** | NA |

| | | |
|---|---|---|
| 3.3 | **Capacity** | 100 lts;150 lts;250 lts |
| 3.4 | **Noise (in dBA)** | NA |
| 3.5 | **Heat dissipation** | Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through a cooling mechanism |
| 3.6 | **Mobility, portability** | Portable |
| | **4 ENERGY SOURCE (ELECTRICITY, UPS, SOLAR, GAS, WATER, CO2 ....)** | |
| 4.1 | **Power Requirements** | Recharging unit: Input voltage- 440V AC, 50Hz ,3-phase |
| 4.2 | **Battery operated** | No |
| 4.3 | **Tolerance (to variations, shutdowns)** | NA |
| 4.4 | **Protection** | Should have over-charging cut-off with visual symbol. |
| 4.5 | **Operating Temperature** | 121 deg c to 134 deg c |
| 4.6 | **Operating Pressure** | Should have operating pressure between 1.2 to 2.1 kg/cm2; 10-20 psi |
| 4.7 | **Power consumption** | upto 18kW |
| | **5 ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)** | 1. Automatic Pressure Control Switch -2 no.<br>2. Automatic Water Cut-off Device -2 no.<br>3. Micro Processor PID Controller with Timer & Auto Stop Facility<br>4. Digital Pressure Indicator-2 no.<br>5. Perforate basket(rust-free stainless steel)<br>6. Cord-plug-4 no.<br>7. Biological and chemical indicators-1 set |
| | **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | |
| | **6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | |
| 6.1 | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | 1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 50 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.<br>2) Sterilization not required. |
| | **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 FDA/CE/BIS approved product.<br>2. Manufacturer and Supplier should have ISO 13485 certification for quality standards.<br>3. Electrical safety conforms to the standards for electrical safety IEC 60601-General requirements(or equivalent BIS Standard)<br>4. Shall meet internationally recognised for Electromagnetic Compatibility (EMC) for electromedical equipment: 61326-1.<br>5. Certified to be compliant with IEC 61010-1,IEC 61010-2-40 for safety.<br>6. Vessel pressure testing |
| 7.2 | **Local and/or international** | Manufacturer / supplier should have ISO 13485 certificate for quality standard. |
| | **8 TRAINING AND INSTALLATION** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | 1) Availability of 15 amp socket;<br>2) Safety and operation check before handover; |

| | | |
|---|---|---|
| 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;on site |
| 9.2 | **Maintenance tasks** | 1)Maintenance manual detailing;<br>2)Complete maintenance schedule; |
| 9.3 | **Service contract clauses, including prices** | 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 | **Operating manuals, service manuals, other manuals** | Should provide 2 sets(hardcopy and soft-copy) 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) Service and operation manuals (original and copy) to be provided;<br>4) Advanced maintenance tasks documentation;<br>5) 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 |

# AUTOCLAVE HP VERTICAL(2 BIN)

| | | |
|---|---|---|
| Version no. : | | 1 |
| Date: | | 5/12/2014 |
| Done by : (name / institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Autoclave HP Vertical(2 bin) |
| GMDN code | | NA |
| **GENERAL** | | |
| **1 USE** | | |
| 1.1 | **Clinical purpose** | An airtight vessel for heating and sometimes agitating its contents under high steam pressure; used for sterilizing, with moist or dry heat at high temperatures. |
| 1.2 | **Used by clinical department/ward** | Operation theatre |
| **TECHNICAL** | | |
| **2 TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1) High Grade strong stainless steel SS 304, Triple walled construction.<br>2) Positive radial self-locking safety doors.<br>3) Hydrostatically tested to withstand 2.5 times the working pressure.<br>4) Sealed with Neoprene/Silicon long-lasting and durable gasket.<br>5) Analog display for Jacket and Chamber pressure and temperature.<br>6) Outer jacket of mild steel insulated to prevent heat loss.<br>7) Mounted on tubular Mild steel frame with ground leveling flanges.<br>8) Internal joints should be argon arc welded.<br>9) Should have 2 bins for loading. |
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/ or standard of communication(where ever required)** | NA |
| **3 PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | 400 mm x 600 mm to 400 mm x 1100 mm |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Capacity** | 75 lt to 138 lt |
| 3.4 | **Noise (in dBA)** | NA |
| 3.5 | **Heat dissipation** | Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through a cooling mechanism |
| 3.6 | **Mobility, portability** | Portable |

| | | |
|---|---|---|
| **4 ENERGY SOURCE (ELECTRICITY, UPS, SOLAR, GAS, WATER, CO2 ....)** | | |
| 4.1 | **Power Requirements** | Input voltage- 220V-240V AC, 50Hz,3-phase |
| 4.2 | **Battery operated** | No |
| 4.3 | **Tolerance (to variations, shutdowns)** | ±10% |
| 4.4 | **Pressure gauge** | 0-2.1Kgf/cm$^2$ |
| 4.5 | **Operating pressure** | from 15-20 psi |
| 4.6 | **Sterilizing pressure** | 1.2Kgf/cm(15 psi) at 121˚C |
| 4.7 | **Protection** | Should have over-charging cut-off with visual symbol. |
| 4.8 | **Power consumption** | 16kW |
| **5 ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)** | 1) Pressure control switch-2 no.<br>2) Low water level cut-off device-2 no.<br>3) Digital timer-2 no.<br>4) Vacuum breaker-2 no.<br>5) Gaskets-2 no. |
| **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | | |
| **6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | 1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 50 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.<br>2) Sterilization not required. |
| **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 FDA/CE/BIS approved product.<br>2. Manufacturer and Supplier should have ISO 13485 certification for quality standards.<br>3. Electrical safety conforms to the standards for electrical safety IEC 60601-General requirements(or equivalent BIS Standard)<br>4. Shall meet internationally recognised for Electromagnetic Compatibility(EMC) for electromedical equipment: 61326-1.<br>5. Certified to be compliant with IEC 61010-1,IEC 61010-2-40 for safety. |
| 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 socket;<br>2) Safety and operation check before handover; |
| 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 |
| 9.2 | **Maintenance tasks** | 1) Maintenance manual detailing;<br>2) Complete maintenance schedule; |
| 9.3 | **Service contract clauses, including prices** | 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 | **Operating manuals, service manuals, other manuals** | Should provide 2 sets(hardcopy and soft-copy) 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) Service and operation manuals (original and copy) to be provided;<br>4) Advanced maintenance tasks documentation;<br>5) 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 |

# BOWL STERILIZER (BIG)

| | | |
|---|---|---|
| Version no. : | | 1 |
| Date: | | 5/12/2014 |
| Done by : (name / institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Bowl Sterilizer(big) |
| GMDN code | | NA |
| **GENERAL** | | |
| **1 USE** | | |
| 1.1 | **Clinical purpose** | Used for the purpose of sterilizing various medical instruments. |
| 1.2 | **Used by clinical department/ward** | Operation theatre |
| **TECHNICAL** | | |
| **2 TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1) Constructed of high grade stainless steel.<br>2) For steam sterilization/disinfection of utensils, bowls etc.<br>3) Low water cut off device<br>4) Fitted with thermostat<br>5) With perforated inner chamber<br>6) Water outlet with angle iron painted stand.<br>7) Sterilizer tank is made of stainless steel SS 304<br>8) The perforated Tray of SS 304 is provided for keeping the Bowls of different size for sterilization.<br>9) Three SS heaters of 1.5 KW each for sterilization<br>10) Outer Cabinet is heavy gauge SS 304<br>11) Double walled with glass wool insulation.<br>12) Digital PID temperature controller for controlling the temperature.<br>13) Digital time controller housed in Temperature controller cabinet used for exposure time control.<br>14) Level Control give audible signal for maximum water level |
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/ or standard of communication(where ever required)** | NA |
| **3 PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | 21.60 cm x 22.00 cm x 8.55 cm to 33.5 cm x 21.5 cm x 23.5 cm |
| 3.2 | **Weight (lbs, kg)** | 500 g to 3kg |
| 3.3 | **Configuration** | NA |

| | | |
|---|---|---|
| 3.4 | **Noise (in dBA)** | NA |
| 3.5 | **Heat dissipation** | Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism |
| 3.6 | **Mobility, portability** | Portable |
| | **4 ENERGY SOURCE (ELECTRICITY, UPS, SOLAR, GAS, WATER, CO2 ....)** | |
| 4.1 | **Power Requirements** | Recharging unit: Input voltage- 220V-240V AC, 50Hz |
| 4.2 | **Battery operated** | Yes |
| 4.3 | **Tolerance (to variations, shutdowns)** | NA |
| 4.4 | **Protection** | Should have over-charging cut-off with visual symbol. |
| 4.5 | **Power consumption** | 5kW |
| | **5 ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)** | NA |
| | **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | |
| | **6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | |
| 6.1 | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | 1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 50 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.<br>2) Sterilization not required. |
| | **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 FDA/CE/BIS approved product.<br>2. Manufacturer and Supplier should have ISO 13485 certification for quality standards.<br>3. Electrical safety conforms to the standards for electrical safety IEC 60601-General requirements(or equivalent BIS Standard)<br>4. Shall meet internationally recognised for Electromagnetic Compatibility(EMI/EMC) for electromedical equipment: 61326-1.<br>5. Certified to be compliant with IEC 61010-1,IEC 61010-2-40 for safety. |
| 7.2 | **Local and/or international** | Manufacturer / supplier should have ISO 13485 certificate for quality standard. |
| | **8. TRAINING AND INSTALLATION** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | 1)Availability of 5 amp socket;<br>2)Safety and operation check before handover; |
| 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 |
| 9.2 | **Maintenance tasks** | 1) Maintenance manual detailing;<br>2) Complete maintenance schedule; |
| 9.3 | **Service contract clauses, including prices** | 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 | **Operating manuals, service manuals, other manuals** | Should provide 2 sets(hardcopy and soft-copy) 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) Service and operation manuals (original and copy) to be provided;<br>4) Advanced maintenance tasks documentation;<br>5) 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 |

# BOWL STERILIZER (SMALL)

| | | |
|---|---|---|
| Version no. : | | 1 |
| Date: | | 5/12/2014 |
| Done by : (name / institution) | | HCT/NHSRC |
| NAME AND CODING | | |
| GMDN name | | Bowl sterilizer(small) |
| GMDN code | | NA |
| **GENERAL** | | |
| **1 USE** | | |
| 1.1 | **Clinical purpose** | Used for the purpose of sterilizing various medical instruments. |
| 1.2 | **Used by clinical department/ward** | Operation theatre |
| **TECHNICAL** | | |
| **2 TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1) Constructed of high grade stainless steel 304<br>2) For steam sterilization/disinfection of utensils, bowls etc.<br>3) Low water cut off device<br>4) Fitted with thermostat<br>5) With perforated inner chamber<br>6) Water outlet with angle iron painted stand.<br>7) Sterilizer tank is made of stainless steel SS 304<br>8) The perforated Tray of SS 304 is provided for keeping the Bowls of different size for sterilization.<br>9) Three SS heaters of 1.5 KW each for sterilization<br>10) Outer Cabinet is heavy gauge SS 304<br>11) Double walled with glass wool insulation.<br>12) Digital PID temperature controller for controlling the temperature.<br>13) Digital time controller housed in Temperature controller cabinet used for exposure time control.<br>14) Level Control give audible signal for maximum water level. |
| 2.2 | **User's interface** | Manual |
| 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)** | NA |
| 3.3 | **Configuration** | NA |

| | | |
|---|---|---|
| 3.4 | **Noise (in dBA)** | NA |
| 3.5 | **Heat dissipation** | Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through a cooling mechanism |
| 3.6 | **Mobility, portability** | Portable |
| | **4 ENERGY SOURCE (ELECTRICITY, UPS, SOLAR, GAS, WATER, CO2 ....)** | |
| 4.1 | **Power Requirements** | Recharging unit: Input voltage- 220V-240V AC, 50Hz |
| 4.2 | **Battery operated** | Yes |
| 4.3 | **Tolerance (to variations, shutdowns)** | NA |
| 4.4 | **Protection** | Should have over-charging cut-off with visual symbol. |
| 4.5 | **Power consumption** | 3kW |
| | **5 ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)** | NA |
| | **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | |
| | **6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | |
| 6.1 | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | 1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 50 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.<br>2) Sterilization not required. |
| | **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 FDA/CE/BIS approved product.<br>2. Manufacturer and Supplier should have ISO 13485 certification for quality standards.<br>3. Electrical safety conforms to the standards for electrical safety IEC 60601-General requirements(or equivalent BIS Standard)<br>5. Shall meet internationally recognised for Electromagnetic Compatibility(EMI/EMC) for electromedical equipment: 61326-1.<br>6. Certified to be compliant with IEC 61010-1,IEC 61010-2-40 for safety. |
| 7.2 | **Local and/or international** | Manufacturer / supplier should have ISO 13485 certificate for quality standard. |
| | **8 TRAINING AND INSTALLATION** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | 1) Availability of 5 amp socket;<br>2) Safety and operation check before handover; |
| 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 |
| 9.2 | **Maintenance tasks** | 1) Maintenance manual detailing;<br>2) Complete maintenance schedule; |
| 9.3 | **Service contract clauses, including prices** | 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 | **Operating manuals, service manuals, other manuals** | Should provide 2 sets(hardcopy and soft-copy) 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) Service and operation manuals (original and copy) to be provided;<br>4) Advanced maintenance tasks documentation;<br>5) 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 |

# OPERATION TABLE ORTHOPEDIC

| | | |
|---|---|---|
| Version no. : | | 2 |
| Date: | | 9/2/2015 |
| Done by : (name / institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Operation table orthopedic |
| GMDN code | | NA |
| **GENERAL** | | |
| **1 USE** | | |
| 1.1 | **Clinical purpose** | An operating table, sometimes called operating room table, is the table on which the patient lies during a surgical operation.This surgical equipment is usually found inside the surgery room of a hospital. |
| 1.2 | **Used by clinical department/ward** | Operation theatre |
| **TECHNICAL** | | |
| **2 TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1) Should have OT Table type base made of high quality 304 stainless steel with double table, split leg type and can take x ray photography.<br>2) Should have imported Y type sealing ring with good sealing performance and durability.<br>3) Should have a Rotary brake device hich is easy for moving opreating table.<br>4) Base is stainless steel.<br>5) Leg board is separated & dischargeable.<br>6) Double-decked can do X- Ray.<br>7) Inclining forward ≥30°<br>8) Inclining backward ≥25°<br>9) Inclining leftward≥20°<br>10) Inclining rightward≥20°<br>11) Back board folding upward ≥45˚ Fold downward ≥90°<br>12) Head Board folding upward ≥80°Folding downward ≥10°<br>13) Leg board Folding downward ≥90°.<br>14) Fold outward ≥90°.<br>15) Waist board elevation ≥120°.<br>16) The table top must be made of durable radiolucent bakelite material capable of withstanding exposure to frequent C-Arm imaging, without diminishing the image clarity |
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/or standard of communication(where ever required)** | NA |

| | | |
|---|---|---|
| | **3** | |
| 3.1 | **Dimensions (metric)** | Max: Length:2050 ±50 mm<br>Width:480 ±20 mm<br>Height:750-950 ±50 mm |
| 3.2 | **Weight (lbs, kg)** | Max: 150 Kg (excluding battery) |
| 3.3 | **Configuration** | NA |
| 3.4 | **Noise (in dBA)** | NA |
| 3.5 | **Heat dissipation** | Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism |
| 3.6 | **Mobility, portability** | NA |
| | **4 ENERGY SOURCE (ELECTRICITY, UPS, SOLAR, GAS, WATER, CO2 ....)** | |
| 4.1 | **Power Requirements** | Recharging unit: Input voltage- 220V-240V AC, 50Hz,24 VDC |
| 4.2 | **Battery operated** | Yes |
| 4.3 | **Tolerance (to variations, shutdowns)** | NA |
| 4.4 | **Protection** | Should have over-charging cut-off with visual symbol. |
| 4.5 | **Power consumption** | NA |
| | **5 ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)** | 1) Shoulder support (1 pair)<br>2) Waist Support (1 pair)<br>3) Arm rest (1 pair)<br>4) Leg holder (1 pair)<br>5) Screen Frame (1 Piece)<br>6) Foot Plate (1 Pair) |
| | **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | |
| | **6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | |
| 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.<br>2) Sterilization not required. |
| | **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 FDA/CE/BIS approved product.<br>2. The generator must be CF isolated applied device and defibilltor production must be available.<br>3. Safety<br>IEC 60601-1:- Medical electrical equipment-Part 1: General requirement for basic saftey and essential. performation-Edition 3.1;<br>IEC 60601-2-46:- Medical electrical equipment-Part 2-46: Particular requirements for the basic saftey and Essential Performance-Collateral Standard: Usability-Edition 2.0<br>IEC 60601-1-6: Medical Electrical Eequipment-Part 1-6: General Requirements for Basic Safety and Essential Performance-Collateral Standard Usability-Edition 2.0<br>4. EMI/EMC<br>IEC 60601-1-2: Medical Electrical Equipment Part 1-2: General Requirements for Basic Saftey and Essential Performance-Collateral Standard:Electromagnetic Compatiblity-Requirements and Test-Edition 3.0<br>5. QMS:- ISO 13485 |

| | | |
|---|---|---|
| 7.2 | **Local and/or international**<br>**Manufacturer / supplier should have ISO 13485 certificate for quality standard.** | |
| **8 TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | 1) Availability of 5 amp socket;<br>2) Safety and operation check before handover; |
| 8.2 | **Requirements for sign-off** | Certificate of calibration and inspection from the manufacturer |
| 8.3 | **Training of staff (medical, paramedical, technicians)**<br>**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**<br>**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 | **Operating manuals, service manuals, other manuals** | Should provide 2 sets (hardcopy and soft-copy) 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) Service and operation manuals (original and copy) to be provided;<br>4) Advanced maintenance tasks documentation;<br>5) Certificate of calibration and inspection |
| 10.2 | **Other accompanying documents**<br>**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 |

# DEHUMIDIFIER

| | | |
|---|---|---|
| Version no. : | | 1 |
| Date: | | 10/2/2015 |
| Done by : (name / institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Dehumidifier |
| GMDN code | | NA |
| **GENERAL** | | |
| **1 USE** | | |
| 1.1 | **Clinical purpose** | Control Moisture level in hospitals |
| 1.2 | **Used by clinical department/ward** | Operation theatre/Labour Room/Diagnostic Laboratory |
| **TECHNICAL** | | |
| **2 TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1) Type of Dehumidifier: Desiccant type<br>2) Requirement of dehumidified air: 170 CMH.<br>3) CNC fabricated unit with powder coated finish.<br>4) Eco-Dry rotor and totally self-contained.<br>5) The desiccant rotor shall be of fluted honeycomb type<br>6) The dehumidifier shall have differential air pressure switch to control reactivation air flow.<br>7) The Dehumidifier shall have high temperature thermostat cut out.<br>8) The Dehumidifier shall have additional cooling thermostat as a safety measure<br>9) The Dehumidifier shall have electrical interlocking of fan, motor, heaters and rotor drive as a safety measure.<br>10) The dehumidifier shall have PTFE bonded silicon bulb seal designed to minimize air leakage. |
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/ or standard of communication (where ever required)** | NA |
| **3 PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | 676mm X470 mm X 390 mm (H)± 10% |
| 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** | NA |

| | | |
|---|---|---|
| **4 ENERGY SOURCE (ELECTRICITY, UPS, SOLAR, GAS, WATER, CO2 ....)** | | |
| 4.1 | **Power Requirements** | 220V, 50 Hz |
| 4.2 | **Battery operated** | NA |
| 4.3 | **Tolerance (to variations, shutdowns)** | ± 10% |
| 4.4 | **Protection** | NA |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)** | NA |
| **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | | |
| **6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | NA |
| 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.<br>2) Sterilization not required. |
| **7 STANDARDS AND SAFETY** | | |
| 7.1 | **Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type);Local and/or international** | IEC 60335-2-40 ed5.0 |
| 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** | NA |
| 8.2 | **Requirements for sign-off** | NA |
| 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** | 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 | **Operating manuals, service manuals, other manuals** | Should provide 2 sets (hardcopy and soft-copy) 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) Service and operation manuals (original and copy) to be provided;<br>4) Advanced maintenance tasks documentation;<br>5) 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** | NA |

# ELECTROSURGICAL UNIT

| | | |
|---|---|---|
| Version no. : | | 1 |
| Date: | | 9/2/2015 |
| Done by : (name / institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Electrosurgical Unit |
| GMDN code | | NA |
| **GENERAL** | | |
| **1 USE** | | |
| 1.1 | **Clinical purpose** | Diathermy uses an electric current to produce heat deep inside a targeted tissue. It can reach areas as deep as two inches from the skin's surface. The diathermy machine does not apply heat directly to the body. Instead, the current from the machine allows the body to generate heat from within the targeted tissue. |
| 1.2 | **Used by clinical department/ward** | Operation theatre |
| **TECHNICAL** | | |
| **2 TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1) Facility for Monopolar, Bipolar and underwater cutting.<br>2) Monopolar cutting and coagulation<br>3) Micro-processor based technology<br>4) Monopolar cut in minimum 3 modes<br>5) Bipolar-coagulation in 3 or more modes ( forced coagulation, spray coagulation and soft coagulation)<br>6) Blending of cutting and coagulation -in minimum 2 levels<br>7) Automatic cut-off technology with self check on every start.<br>8) Foot and hand switch<br>9) Automonitoring and display of set parameters<br>10) Touch-controlled interface to set parameters<br>11) 4 or more programmable memory<br>12) Simultaneous use of Monopolar and Bipolar Coagulation.<br>13) Output Power of 300 Watt(Minimum)<br>14) Monopolar Cutting and Coagulation power adjustable from 0-300 Watt<br>15) Bipolar Coagulation power adjustable from 0-50 W, Micro Power Range- 0.1 to 9.9 Watt increment of 0.1 Watt, Macro Power range from 1-50 Watt increment of 1 Watt<br>16) Audio-Visual Alarm for disconnection of Neutral Plate |
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/ or standard of communication(where ever required)** | In-built |
| **3 PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |

| | | |
|---|---|---|
| 3.2 | **Weight (lbs, kg)** | Max: 10kg |
| 3.3 | **Configuration** | NA |
| 3.4 | **Noise (in dBA)** | NA |
| 3.5 | **Heat dissipation** | Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism |
| 3.6 | **Mobility, portability** | Portable |
| | **4 ENERGY SOURCE (ELECTRICITY, UPS, SOLAR, GAS, WATER, CO2 ....)** | |
| 4.1 | **Power Requirements** | Recharging unit: Input voltage- 220V-240V AC, 50Hz |
| 4.2 | **Battery operated** | No |
| 4.3 | **Tolerance (to variations, shutdowns)** | ±10% |
| 4.4 | **Protection** | Should have over-charging cut-off with visual symbol. |
| 4.5 | **Power consumption** | 60W |
| | **5 ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)** | 1. Power cord :1pc<br>2. Electrode lever:1pc<br>3. Electrode:2sets<br>4. Collective electric bulb: 2pcs switch<br>5. Trolley;Foot switch<br>6. Reusable electrode handle with cutting/coagulation switch<br>7. Disposable REM plate<br>8. Cable for electrode handle<br>9. Neutral plate for adults and pediatric. |
| | **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | |
| | **6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | |
| 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.<br>2) Sterilization not required. |
| | **7 STANDARDS AND SAFETY** | |
| 7.1 | **Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type);Local and/or international** | 1. Shall meet internationally recognised IEC 60601-1-1 standard(General Requirements)<br>2. Shall meet internationally recognised IEC 60601-2-2 standard(Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories)<br>3. Shall meet internationally recognised IEC 60601-1-6 standard(MEDICAL ELECTRICAL EQUIPMENT - PART 1-6: GENERAL REQUIREMENTS FOR SAFETY - COLLATERAL STANDARD:USABILITY)<br>4. Shall meet internationally recognised IEC 60601-1-8 standard(MEDICAL ELECTRICAL EQUIPMENT - PART 1-: GENERAL REQUIREMENTS FOR SAFETY - COLLATERAL STANDARD:GENERAL REQUIREMENTS, TESTS AND GUIDANCE FOR ALARM SYSTEMS IN MEDICAL ELECTRICAL EQUIPMENT AND MEDICAL ELECTRICAL SYSTEMS)<br>5. Shall meet internationally recognised IEC 60601-1-2 standard(MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR SAFETY 2. COLLATERAL STANDARD: ELECTROMAGNETIC COMPATIBILITY - REQUIREMENTS AND TESTS)<br>6. Shall meet internationally recognised IEC 62304 standard(Medical device software – Software life cycle processes) |

| | | |
|---|---|---|
| 7.2 | **Local and/or international** | Manufacturer / supplier should have ISO 13485 certificate for quality standard. |
| | **8 TRAINING AND INSTALLATION** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | 1) Availability of 5 amp socket;<br>2) Safety and operation check before handover; |
| 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 |
| 9.2 | **Maintenance tasks** | 1) Maintenance manual detailing;<br>2) Complete maintenance schedule; |
| 9.3 | **Service contract clauses, including prices** | 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 | **Operating manuals, service manuals, other manuals** | Should provide 2 sets (hardcopy and soft-copy) 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) Service and operation manuals (original and copy) to be provided;<br>4) Advanced maintenance tasks documentation;<br>5) 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 |

# ETHYLENE OXIDE STERILIZER

| | | |
|---|---|---|
| Version no. : | | 1 |
| Date: | | 5/12/2014 |
| Done by : (name / institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Ethylene Oxide Sterilizer |
| GMDN code | | NA |
| **GENERAL** | | |
| **1 USE** | | |
| 1.1 | **Clinical purpose** | (EO or EtO) gas is commonly used to sterilize objects sensitive to temperatures greater than 60 °C and / or radiation such as plastics, optics and electrics. Ethylene oxide treatment is generally carried out between 30 °C and 60 °C with relative humidity above 30% and a gas concentration between 200 and 800 mg/l, and typically lasts for at least three hours. |
| 1.2 | **Used by clinical department/ward** | |
| **TECHNICAL** | | |
| **2 TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1. Interior made of 304 stainless steel mirror sterilization,anti-corrosion.<br>2. Equipped with a thermal barrier layer.<br>3. Double protective doors, insulation, sealing and leak-proof.<br>4. Sterilization process automatic computer control, LCD/digital panel display.<br>5. anti-leak vacuum pumping system.<br>6. automatic humidification system<br>7. automatic heating system<br>8. Auto exhaust system should be sound proof.<br>9. Efficiency and prevent environmental pollution discharge residual heating air purification system<br>10. Audio-visual alarm system for temperature,pressure and leakage.<br>11. Exhaust pipeline to be above the top floor of the building ; copper pipeline<br>12. Temperature accuracy: ± 1 °C<br>13. Vacuum pressure: -7 ~-70Kpa<br>14. Composition of gases (90% Ethylene oxide and 10% carbon dioxide or 100% Ethylene Oxide)<br>15. Operating temperature to be settable at 35 degree celsius and 55 degree celsius. |
| 2.2 | **User's interface** | Software,Automatic (stages to be displayed or recordable for printing) |
| 2.3 | **Software and/ or standard of communication(where ever required)** | NA |

| | | |
|---|---|---|
| **3 PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | Max: 450 mm x 450 mm x 1200 mm |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Configuration** | NA |
| 3.4 | **Noise (in dBA)** | Noise-free system |
| 3.5 | **Heat dissipation** | Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism |
| 3.6 | **Mobility, portability** | Portable |
| **4 ENERGY SOURCE (ELECTRICITY, UPS, SOLAR, GAS, WATER, CO2 ....)** | | |
| 4.1 | **Power Requirements** | Recharging unit: Input voltage- 220V-240V AC, 50Hz Single-phase |
| 4.2 | **Battery operated** | Yes |
| 4.3 | **Tolerance (to variations, shutdowns)** | NA |
| 4.4 | **Protection** | Should have over-charging cut-off with visual symbol. |
| 4.5 | **Power consumption** | Can be operated on UPS |
| **5 ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)** | Should have a detector to be installed in sterilizer room. |
| **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | | |
| **6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | 1) Operating condition: Capable of operating continuously in ambient temperature of 5 to 50 deg C and relative humidity of 15 to 80% 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.<br>2) Sterilization not required. |
| **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 FDA/CE/BIS approved product.<br>2. Manufacturer and Supplier should have ISO 13485 certification for quality standards.<br>3. Electrical safety conforms to the standards for electrical safety IEC 60601-General requirements(or equivalent BIS Standard)<br>5. Shall meet internationally recognised for Electromagnetic Compatibility(EMI/EMC) for electromedical equipment: 61326-1.<br>6. Certified to be compliant with IEC 61010-1,IEC 61010-2-40 for safety. |
| 7.2 | **Local and/or international** | Manufacturer / supplier should have ISO 13485 certificate for quality standard. |
| **8 TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | 1) Availability of 5 amp socket;<br>2) Safety and operation check before handover;<br>3) To be installed in a separate room. |

| | | |
|---|---|---|
| 8.2 | **Requirements for sign-off** | Certificate of calibration and inspection of parts 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 |
| 9.2 | **Maintenance tasks** | 1) Maintenance manual detailing;<br>2) Complete maintenance schedule; |
| 9.3 | **Service contract clauses, including prices** | 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 | **Operating manuals, service manuals, other manuals** | Should provide 2 sets(hardcopy and soft-copy) 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) Service and operation manuals (original and copy) to be provided;<br>4) Advanced maintenance tasks documentation;<br>5) Certificate of calibration and inspection |
| 10.2 | **Other accompanying documents** | List of essential 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 |

# FLASH STERILIZER WITH TROLLEY

| | | |
|---|---|---|
| Version no. : | | 1 |
| Date: | | 5/12/2014 |
| Done by : (name / institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Flash Sterilizer with trolley |
| GMDN code | | NA |
| **GENERAL** | | |
| **1 USE** | | |
| 1.1 | **Clinical purpose** | Used for sterilization of unwrapped equipment at 132°C for three to ten minutes using steam. |
| 1.2 | **Used by clinical department/ward** | Operation Theatre |
| **TECHNICAL** | | |
| **2 TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1) 18-23 litres table-top model.<br>2) No utility connection other than drainage and electricity.<br>3) In-built dryer.<br>4) Constructed of 304 or 316 stainless steel<br>5) Automatic cycle control with printer |
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/ or standard of communication (where ever required)** | Stages should be displayable. |
| **3 PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | As per capacity |
| 3.2 | **Weight (lbs, kg)** | Max:900 gm |
| 3.3 | **Capacity** | 18 to 20 litre |
| 3.4 | **Noise (in dBA)** | Noise-free |
| 3.5 | **Heat dissipation** | Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism |
| 3.6 | **Mobility, portability** | Table with castors and brakes |
| **4 ENERGY SOURCE (ELECTRICITY, UPS, SOLAR, GAS, WATER, CO2 ....)** | | |
| 4.1 | **Power Requirements** | Recharging unit: Input voltage- 220V-240V AC, 50Hz |
| 4.2 | **Battery operated** | Yes |
| 4.3 | **Tolerance (to variations, shutdowns)** | NA |
| 4.4 | **Protection** | Should have over-charging cut-off with visual symbol. |
| 4.5 | **Power consumption** | 3 to 4 kW |

| | | |
|---|---|---|
| **5 ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)** | 1. Trays-2 nos |
| **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | | |
| **6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 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.<br>2) Sterilization not required. |
| **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 FDA/CE/BIS approved product.<br>2. Manufacturer and Supplier should have ISO 13485 certification for quality standards.<br>3. Electrical safety conforms to the standards for electrical safety IEC 60601-General requirements(or equivalent BIS Standard)<br>4. Shall meet internationally recognised for Electromagnetic Compatibility(EMC) for electromedical equipment: 61326-1.<br>5. Certified to be compliant with IEC 61010-1,IEC 61010-2-40 for safety. |
| 7.2 | **Local and/or international** | Manufacturer / supplier should have ISO 13485 certificate for quality standard. |
| **8 TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | 1) Availability of 15 amp socket;<br>2) Safety and operation check before handover; |
| 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 |
| 9.2 | **Maintenance tasks** | 1) Maintenance manual detailing;<br>2) Complete maintenance schedule; |
| 9.3 | **Service contract clauses, including prices** | 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 | **Operating manuals, service manuals, other manuals** | Should provide 2 sets (hardcopy and soft-copy) 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) Service and operation manuals (original and copy) to be provided;<br>4) Advanced maintenance tasks documentation;<br>5) 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 |

# OPERATION TABLE HYDRAULIC MAJOR

| | | |
|---|---|---|
| Version no. : | | 1 |
| Date: | | 5/12/2014 |
| Done by : (name / institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Operation Table Hydraulic Major |
| GMDN code(s) | | NA |
| **GENERAL** | | |
| **1 USE** | | |
| 1.1 | **Clinical purpose** | An operating table, sometimes called operating room table, is the table on which the patient lies during a surgical operation. This surgical equipment is usually found inside the surgery room of a hospital. |
| 1.2 | **Used by clinical department/ward** | Operation theatre |
| **TECHNICAL** | | |
| **2 TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1) Should be a manually controlled operating table, working range from floor level: 800-1040mm.<br>2) Should be adjustable to all essential positions.<br>3) Should be equipped with movement controls at side of the table.<br>4) Should have Frame and bottom made of Stainless Steel 304 material.<br>5) Should have reinforced three section stainless steel top.<br>6) Height should be adjustable by oil pump, foot step control.<br>7) Should have detachable head rest which can be easily adjustable to any desired position, above or below table top.<br>8) Table top can be rotated 360° through base.<br>9) Trendelenburg: ≥25°-30°<br>10) Reversed Trendelenburg: ≥30°<br>11) Head Section Raised from the Horizontal: ≥20°-30°<br>12) Head Section Lowered from the Horizontal: ≥28°-30°<br>13) Back Section Raised from the Horizontal: ≥60°-70 °<br>14) Leg Section Lowered from the Horizontal: ≥40°-50°<br>15) Kidney Position should be achievable by breaking the table.<br>16) Table-top should be radio-lucent. |
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/ or standard of communication(where ever required)** | NA |

| | | |
|---|---|---|
| **3 PHYSICAL CHARACTERISTICS** | | |
| 3.1 | Dimensions (metric) | Table top dimension (1900 mm x 525 mm) ± 15%<br>Table elevation: (700mm -1000 mm) ± 10% |
| 3.2 | Weight (lbs, kg) | Should be able to bear patient having weight upto 160 kg |
| 3.3 | Configuration | NA |
| 3.4 | Noise (in dBA) | NA |
| 3.5 | Heat dissipation | Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism |
| 3.6 | Mobility, portability | Not portable |
| **4 ENERGY SOURCE (ELECTRICITY, UPS, SOLAR, GAS, WATER, CO2 ....)** | | |
| 4.1 | Power Requirements | Recharging unit: Input voltage - 220V-240V AC,50 Hz |
| 4.2 | Battery operated | Yes |
| 4.3 | Tolerance (to variations, shutdowns) | NA |
| 4.4 | Protection | Should have over-charging cut-off with visual symbol. |
| 4.5 | Power consumption | NA |
| **5 ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system) | 1) S. S. Arm Rest 1 No<br>2) Anaesthetic Screen 1 No.<br>3) Lithotomy Leg Holders with Stirr-Ups 1 Set<br>4) Leather Wristlets 1 Set<br>5) Padded Leg Rest (Gutter Type)-2 nos<br>6) Anti static mattress-2 nos<br>7) Side rails-2 nos |
| **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | | |
| **6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 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.<br>2) Sterilization not required. |
| **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 FDA/CE/BIS approved product.<br>2. Electrical safety confoms to the standards for electrical safety IEC 60601-General requirements(or equivalent BIS standard) and IEC 60601-2-46 for usability.<br>3. Shall meet internationally recognised IEC 60601-1-2 for Electromagnetic Compatibility(EMC) and Electromagnetic Interference(EMI) |
| 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 socket;<br>2) Safety and operation check before handover; |

| | | |
|---|---|---|
| 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 |
| 9.2 | Maintenance tasks | 1) Maintenance manual detailing;<br>2) Complete maintenance schedule; |
| 9.3 | Service contract clauses, including prices | 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 | Operating manuals, service manuals, other manuals | Should provide 2 sets(hardcopy and soft-copy) 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) Service and operation manuals (original and copy) to be provided;<br>4) Advanced maintenance tasks documentation;<br>5) 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 |

# SHADOWLESS LAMP CEILING TYPE MAJOR

| | | |
|---|---|---|
| Version no. : | | 2 |
| Date: | | 9/2/2015 |
| Done by : (name / institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Shadowless lamp ceiling type major |
| GMDN code | | NA |
| **GENERAL** | | |
| **1 USE** | | |
| 1.1 | Clinical purpose | Luminescence shadow less lamp adopts light sources different positions for focus to eliminate shadows of different parts of medical workers. |
| 1.2 | Used by clinical department/ward | Operation theatre |
| **TECHNICAL** | | |
| **2 TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1) Double dome<br>2) Intensity Control in 9 steps for indiviual domes<br>3) Height Adjustment :600mm<br>4) Action Radius :1850mm<br>5) Possible Movements :Radial, Angular & Axial<br>6) Colour Temperature :4500K and above<br>7) LED technology: minimum 40,000 hours lamp life<br>8) Intensity,brightness,contrast and power switch to be made available on handle/wall-check.<br>9) Focal distance(d1+d2)=0.8 to 1.2 m<br>10) Temperature rise on the keep of surgeries to be less than 10°<br>11) CR± approx. 95 or more<br>12) 360° rotation for both arms |
| 2.2 | User's interface | Manual |
| 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) | NA |
| 3.3 | Configuration | NA |
| 3.4 | Noise (in dBA) | NA |

| | | |
|---|---|---|
| 3.5 | Heat dissipation | Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism |
| 3.6 | Mobility, portability | Handheld device |
| **4 ENERGY SOURCE (ELECTRICITY, UPS, SOLAR, GAS, WATER, CO2 ....)** | | |
| 4.1 | Power Requirements | Recharging unit: Input voltage- 220V-240V AC, 50Hz |
| 4.2 | Battery operated | Yes |
| 4.3 | Tolerance (to variations, shutdowns) | Voltage:±10%,Frequency:±2% |
| 4.4 | Protection | Should have over-charging cut-off with visual symbol. |
| 4.5 | Power consumption | NA |
| **5 ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system) | NA |
| **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | | |
| **6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 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.<br>2) Sterilization not required. |
| **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 FDA/CE/BIS and ISO 13485 approved product.<br>2. Electrical safety conforms to the standards for electrical safety IEC 60601-1General requirements(or equivalent BIS Standard)<br>3. Shall meet internationally recognised for Electromagnetic Compatibility(EMC)and Electromagnetic Interference(EMI) for electromedical equipment:IEC 60601-1-2<br>4. Certified to be compliant with IEC 60601-2-4 for usability. |
| 7.2 | Local and/or international | Manufacturer / supplier should have ISO 13485 certificate for quality standard. |
| **8 TRAINING AND INSTALLATION** | | |
| 8.1 | Pre-installation requirements: nature, values, quality, tolerance | 1) Availability of 5 amp socket;<br>2) Safety and operation check before handover; |
| 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 |
| 9.2 | Maintenance tasks | 1) Maintenance manual detailing;<br>2) Complete maintenance schedule; |

| | | |
|---|---|---|
| 9.3 | Service contract clauses, including prices | 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 | Operating manuals, service manuals, other manuals | Should provide 2 sets(hardcopy and soft-copy) 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) Service and operation manuals (original and copy) to be provided;<br>4) Advanced maintenance tasks documentation;<br>5) 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 |

# STERILIZER(BIG INSTRUMENTS)

| | | |
|---|---|---|
| Version no. : | | 1 |
| Date: | | 5/12/2014 |
| Done by : (name / institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Sterilizer(Big instruments) |
| GMDN code | | NA |
| **GENERAL** | | |
| **1 USE** | | |
| 1.1 | **Clinical purpose** | A sterilizer is a pressure chamber used to sterilize equipment and supplies by subjecting them to high pressure saturated steam at 121 °C for around 15–20 minutes depending on the size of the load and the contents |
| 1.2 | **Used by clinical department/ward** | Operation theatre |
| **TECHNICAL** | | |
| **2 TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1) Should have seamless shell & lever operated Lid fitted with full proof mechanism control excessive steam escape and restricts condensate within the shell.<br>2) Synchronized maneuverability of lid, due to statistically perforated tray for flushing & entry of water.<br>3) SS 304/316 deep drawn seamless construction<br>4) Thermostatically controlled<br>5) Drainage plug at the bottom |
| 2.2 | **User's interface** | Manual |
| 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)** | NA |
| 3.3 | **Capacity** | 4.5-7.5 L |
| 3.4 | **Noise (in dBA)** | NA |
| 3.5 | **Heat dissipation** | Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism |
| 3.6 | **Mobility, portability** | Portable |
| **4 ENERGY SOURCE (ELECTRICITY, UPS, SOLAR, GAS, WATER, CO2 ....)** | | |
| 4.1 | **Power Requirements** | Recharging unit: Input voltage- 220V-240V AC, 50Hz |
| 4.2 | **Battery operated** | Yes |

| | | |
|---|---|---|
| 4.3 | **Tolerance (to variations, shutdowns)** | NA |
| 4.4 | **Protection** | Should have over-charging cut-off with visual symbol. |
| 4.5 | **Power consumption** | NA |
| | **5 ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)** | NA |
| | **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | |
| | **6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | |
| 6.1 | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | 1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 50 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.<br>2) Sterilization not required. |
| | **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 FDA/CE/BIS approved product.<br>2. Manufacturer and Supplier should have ISO 13485 certification for quality standards.<br>3. Electrical safety conforms to the standards for electrical safety IEC 60601-General requirements(or equivalent BIS Standard)<br>4. Shall meet internationally recognised for Electromagnetic Compatibility(EMC) for electromedical equipment: 61326-1.<br>5. Certified to be compliant with IEC 61010-1,IEC 61010-2-40 for safety. |
| 7.2 | **Local and/or international** | Manufacturer / supplier should have ISO 13485 certificate for quality standard. |
| | **8 TRAINING AND INSTALLATION** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | 1) Availability of 5 amp socket;<br>2) Safety and operation check before handover; |
| 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 |
| 9.2 | **Maintenance tasks** | 1) Maintenance manual detailing;<br>2) Complete maintenance schedule; |

| | | |
|---|---|---|
| 9.3 | **Service contract clauses, including prices** | 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 | **Operating manuals, service manuals, other manuals** | Should provide 2 sets(hardcopy and soft-copy) 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) Service and operation manuals (original and copy) to be provided;<br>4) Advanced maintenance tasks documentation;<br>5) 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 |

# GYNAE- EXAMINATION TABLE

| | | |
|---|---|---|
| Version no. : | | 1 |
| Date: | | 5/2/2015 |
| Done by : (name / institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Table for examination |
| GMDN code | | NA |
| **GENERAL** | | |
| **1 USE** | | |
| 1.1 | **Clinical purpose** | A portable, collapsible chair/table for performing an OB/GYN examination or procedure, comprising a collapsible chair structure having a seat, a back rest, a pair of armrests and a pair of substantially planar leg rests, said chair being moveable between a collapsed condition for storage and/or transport and an examination position in which it enables a patient to be seated in a position suitable for an OB/GYN examination or procedure, said chair when in said examination position. |
| 1.2 | **Used by clinical department/ward** | Examination room |
| **TECHNICAL** | | |
| **2 TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1) Should have Head side adjustment 75° up on ratchet<br>2) MS tubular construction<br>3) Perineal cut-out<br>4) Should be Mounted on PVC shoe<br>5) Pre-treated and powder coated<br>6) In built sliding side stool<br>7) Adjustable Lithotomy Rods with rexine covered padded crutches<br>8) U-Cut at leg end |
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/ or standard of communication (where ever required)** | NA |
| **3 PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | 1830 mm L X 610 mm W X 760 mm H(minimun) |
| 3.2 | **Weight (lbs, kg)** | Should be able to support patient weight upto 160kg |
| 3.3 | **Configuration** | NA |
| 3.4 | **Noise (in dBA)** | NA |
| 3.5 | **Heat dissipation** | NA |
| 3.6 | **Mobility, portability** | NA |

| | | |
|---|---|---|
| **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 |
| **5 ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)** | 1). Mattress 50 mm with U Cut thick should be tear proof covered with non pinching Rexine, seamless joint, washable and water-proof |
| **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | | |
| **6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | NA |
| 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.<br>2) Sterilization not required. |
| **7 STANDARDS AND SAFETY** | | |
| 7.1 | **Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type);Local and/or international** | NA |
| 7.2 | **Local and/or international** | 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** | NA |
| 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** | 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 | **Operating manuals, service manuals, other manuals** | Should provide 2 sets(hardcopy and soft-copy) 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) Service and operation manuals (original and copy) to be provided;<br>4) Advanced maintenance tasks documentation;<br>5) 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** | NA |

# TABLE FOR OBSTETRIC LABOUR

| | | |
|---|---|---|
| Version no. : | | 1 |
| Date: | | 5/2/2015 |
| Done by : (name / institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Table for Obstetric labour |
| GMDN code | | NA |
| **GENERAL** | | |
| **1 USE** | | |
| 1.1 | **Clinical purpose** | Delivery Bed finds extensive usage in hospitals and nursing homes. These are specifically designed to support the mother during all stages of giving birth that include labor, delivery and recovery. Manufactured using quality raw material, these beds are widely known for their sturdy construction. |
| 1.2 | **Used by clinical department/ward** | Operation theatre/Labour Room |
| **TECHNICAL** | | |
| **2 TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1) Tubular frame mounted on PVC shoes<br>2) Three sections, with top made of SS 304 grade<br>3) Trendelburg and CPR position instantly available with the help of penumatic gas spring mechanism along with manual over-ride<br>4) Back rest manually adjustable on ratchets mechanism<br>5) Leg end section should slide completely under the main section<br>6) Lithotomy Rods should be height adjustable covered with soft Rubber and Rexine<br>7) U-Cut in the middle section<br>8) Head and side safety railing along with hand grips made of SS |
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/ or standard of communication (where ever required)** | NA |
| **3 PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | 74"L×35"W×26"H adjustable to 36" |
| 3.2 | **Weight (lbs, kg)** | should be able to support patient weight upto 160kg |
| 3.3 | **Configuration** | NA |
| 3.4 | **Noise (in dBA)** | NA |
| 3.5 | **Heat dissipation** | NA |
| 3.6 | **Mobility, portability** | NA |

| | | |
|---|---|---|
| **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 |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)** | 1). Mattress 50 mm with U Cut thick should be tear proof covered with non pinching Rexine,seamless joint,washable and water-proof |
| **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | | |
| **6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | NA |
| 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.<br>2) Sterilization not required. |
| **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 US FDA/EU CE approved product. |
| 7.2 | **Local and/or international** | 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** | NA |
| 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** | 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 | **Operating manuals, service manuals, other manuals** | Should provide 2 sets(hardcopy and soft-copy) 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) Service and operation manuals (original and copy) to be provided;<br>4) Advanced maintenance tasks documentation;<br>5) 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** | NA |

# FOCUS LAMP ORDINARY- FOR EXAMINATION

| | | |
|---|---|---|
| Version no. : | | 1 |
| Date: | | 5/12/2014 |
| Done by : (name / institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Focus Lamp Ordinary |
| GMDN code | | NA |
| **GENERAL** | | |
| **1 USE** | | |
| 1.1 | Clinical purpose | Widely used in examination and operation lighting in surgical dept, ENT dept, dept of stomatology, orthopedic dept, dept of ophthalmology, dept of dermatology and OPD, Facial features section, operation illumination, flow examination, gynecology examination etc.Perfect for specialties that require very focused light in specific areas like OB/GYN etc. |
| 1.2 | Used by clinical department/ward | Operation theatre |
| **TECHNICAL** | | |
| **2 TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1) LED light<br>2) Illumination(lx) should be LED<br>3) Minimum 40,000 Lux<br>4) Height Adjustment(mm): <=440<br>5) Radial and axial movement of the lamp |
| 2.2 | User's interface | Manual |
| 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) | NA |
| 3.3 | Configuration | NA |
| 3.4 | Noise (in dBA) | NA |
| 3.5 | Heat dissipation | Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism |
| 3.6 | Mobility, portability | Portable |
| **4 ENERGY SOURCE (ELECTRICITY, UPS, SOLAR, GAS, WATER, CO2 ....)** | | |
| 4.1 | Power Requirements | Recharging unit: Input voltage- 220V-240V AC, 50Hz |
| 4.2 | Battery operated | Yes |
| 4.3 | Tolerance (to variations, shutdowns) | NA |

| | | |
|---|---|---|
| 4.4 | Protection | Should have over-charging cut-off with visual symbol. |
| 4.5 | Power consumption | NA |
| | **5 ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system) | NA |
| | **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | |
| | **6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | |
| 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.<br>2) Sterilization not required. |
| | **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 FDA/CE/BIS and ISO 13485 approved product.<br>2. Electrical safety conforms to the standards for electrical safety IEC 60601-1General requirements(or equivalent BIS Standard)<br>3. Shall meet internationally recognised for Electromagnetic Compatibility(EMC)and Electromagnetic Interference(EMI) for electromedical equipment:IEC 60601-1-2<br>4. Certified to be compliant with IEC 60601-2-4 for usability. |
| 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 socket;<br>2) Safety and operation check before handover; |
| 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 |
| 9.2 | Maintenance tasks | 1) Maintenance manual detailing;<br>2) Complete maintenance schedule; |
| 9.3 | Service contract clauses, including prices | 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 | Operating manuals, service manuals, other manuals | Should provide 2 sets(hardcopy and soft-copy) 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) Service and operation manuals (original and copy) to be provided;<br>4) Advanced maintenance tasks documentation;<br>5) 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 |

# OPERATION TABLE ELECTRO-HYDRAULIC(ELECTRICAL WITH MANUAL OVERSIDE)

| | | |
|---|---|---|
| Version no. : | | 1 |
| Date: | | 5/12/2014 |
| Done by : (name / institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Electro- hydraulic table |
| GMDN code | | NA |
| **GENERAL** | | |
| **1 USE** | | |
| 1.1 | Clinical purpose | An operating table, sometimes called operating room table, is the table on which the patient lies during a surgical operation.This surgical equipment is usually found inside the surgery room of a hospital. |
| 1.2 | Used by clinical department/ward | Operation theatre |
| **TECHNICAL** | | |
| **2 TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1) Should be manually controlled operating table,working range from floor level:700 -1000 or more ±10%<br>2) Should be adjustable to all essential positions.<br>3) Should be equipped with movement controls at side of the table.<br>4) Should have frame and bottom made of 304 grade Stainless Steel material.<br>5) Should have reinforced five section stainless steel top.<br>6) Height should be adjustable by oil pump,foot step control.<br>7) Should have detachable head rest which can be easily adjustable to any desired position,above or below the table top.<br>8) Table top can be rotated 360° through base.<br>9) Head section raised from the Horizontal:20°-30°<br>10) Durable and leak-proof hydraulic pump.<br>11) Head section lowered from horizontal:28°-30°<br>12) Back section raised from the horizontal:60°-70°<br>13) Trendelenburg:25-30˚<br>14) Reverse Trendelenburg:≥30°<br>15) Leg section lowered from the Horizontal:40°-50°<br>16) Kidney-position should be acheivable by breaking the table.<br>17) Table-top should be radio-lucent.<br>18) Should have handset for position selection by in-built stand-by control. |
| 2.2 | User's interface | Manual |

| | | |
|---|---|---|
| 2.3 | Software and/ or standard of communication(where ever required) | NA |
| | **3 PHYSICAL CHARACTERISTICS** | |
| 3.1 | Dimensions (metric) | 1910 x 530 mm |
| 3.2 | Weight (lbs, kg) | Should be able to bear patient weight |
| 3.3 | Configuration | NA |
| 3.4 | Noise (in dBA) | NA |
| 3.5 | Heat dissipation | Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism |
| 3.6 | Mobility, portability | Not portable |
| | **4 ENERGY SOURCE (ELECTRICITY, UPS, SOLAR, GAS, WATER, CO2 ....)** | |
| 4.1 | Power Requirements | Recharging unit: Input voltage- 220V-240V AC, 50Hz |
| 4.2 | Battery operated | Yes |
| 4.3 | Tolerance (to variations, shutdowns) | NA |
| 4.4 | Protection | Should have over-charging cut-off with visual symbol. |
| 4.5 | Power consumption | NA |
| | **5 ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system) | 1) S.S Arm Rest: 2 no.<br>2) Anaesthetic Screen: 1 no.<br>3) Lithotomy Leg Holders with Stirr-Ups:1 set<br>4) Leather Wristlets:1 set<br>5) Padded Leg Rest(Gutter type)<br>6) Anti static mattress<br>7) Side rails |
| | **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | |
| | **6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | |
| 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.<br>2) Sterilization not required. |
| | **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 FDA/CE/BIS approved product.<br>2. All mechanical tests.<br>2. Electrical safety conforms to the standards for electrical safety IEC 60601-General requirements( or equivalent BIS standard) and IEC 60601-2-46 for usability.<br>3. Certified to be compliant with IEC 60601-2-2 Medical Electrical Equipment Part 2-2 :Particular requirements for the safety of High frequency Surgical Equipment if applicable or equivalent |
| 7.2 | Local and/or international | Manufacturer / supplier should have ISO 13485 certificate for quality standard. |

| | | |
|---|---|---|
| **8 TRAINING AND INSTALLATION** | | |
| 8.1 | Pre-installation requirements: nature, values, quality, tolerance | 1) Availability of 5 amp socket;<br>2) Safety and operation check before handover; |
| 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 |
| 9.2 | Maintenance tasks | 1) Maintenance manual detailing;<br>2) Complete maintenance schedule; |
| 9.3 | Service contract clauses, including prices | 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 | Operating manuals, service manuals, other manuals | Should provide 2 sets(hardcopy and soft-copy) 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) Service and operation manuals (original and copy) to be provided;<br>4) Advanced maintenance tasks documentation;<br>5) 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 |

# OPERATION TABLE HYDRAULIC MINOR

| | | |
|---|---|---|
| Version no. : | | 1 |
| Date: | | 5/12/2014 |
| Done by : (name / institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Operation table hydraulic minor |
| GMDN code(s) | | NA |
| **GENERAL** | | |
| **1 USE** | | |
| 1.1 | Clinical purpose | An operating table, sometimes called operating room table, is the table on which the patient lies during a surgical operation.This surgical equipment is usually found inside the surgery room of a hospital. |
| 1.2 | Used by clinical department/ward | Operation theatre |
| **TECHNICAL** | | |
| **2 TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1) Should have Stainless steel top 304 grade<br>2) Should have Castor wheel for easy mobility<br>3 )Head & Leg section should be detachable and interchangeable<br>4) Four section table<br>5) Durable and leak proof hydraulic pump with heavy pillar fitted in center of the table<br>6) Archived by gear mechanism<br>7) Trendelenburg: 25°-30°<br>8) Lateral tilt (Left & Right):15°-20°<br>9) Leg Section 90° |
| 2.2 | User's interface | Manual |
| 2.3 | Software and/ or standard of communication(where ever required) | NA |
| **3 PHYSICAL CHARACTERISTICS** | | |
| 3.1 | Dimensions (metric) | Table Top dimension 1900 mm x 525 mm ± 15%<br>Table elevation 700 mm – 1000 mm± 10% |
| 3.2 | Weight (lbs, kg) | Should be able to support the weight of the patient upto 160 kg. |
| 3.3 | Configuration | NA |
| 3.4 | Noise (in dBA) | NA |
| 3.5 | Heat dissipation | Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism |
| 3.6 | Mobility, portability | Not portable |

| | | |
|---|---|---|
| **4 ENERGY SOURCE (ELECTRICITY, UPS, SOLAR, GAS, WATER, CO2 ....)** | | |
| 4.1 | Power Requirements | Recharging unit: Input voltage- 220V-240V AC, 50Hz |
| 4.2 | Battery operated | Yes |
| 4.3 | Tolerance (to variations, shutdowns) | NA |
| 4.4 | Protection | Should have over-charging cut-off with visual symbol. |
| 4.5 | Power consumption | NA |
| 5 | ACCESSORIES, SPARE PARTS, CONSUMABLES | |
| 5.1 | Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system) | 1) side rail clamp,<br>2) shoulder support,<br>3) Arm support(2 nos)<br>4) IV pole<br>5) Body restraining belt<br>6) Leg supports:2 nos<br>7) Lateral supports<br>8) Anti-static mattress |
| **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | | |
| **6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 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.<br>2) Sterilization not required. |
| **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 FDA/CE/BIS approved product.<br>2. All mechanical tests.<br>3. Shall meet internationally recognised standard IEC 60601-2-46 for usability. |
| 7.2 | Local and/or international | Manufacturer / supplier should have ISO 13485 certificate for quality standard. |
| **8 TRAINING AND INSTALLATION** | | |
| 8.1 | Pre-installation requirements: nature, values, quality, tolerance | 1) Availability of 5 amp socket;<br>2) Safety and operation check before handover; |
| 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 |
| 9.2 | Maintenance tasks | 1) Maintenance manual detailing;<br>2) Complete maintenance schedule; |
| 9.3 | Service contract clauses, including prices | 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 | Operating manuals, service manuals, other manuals | Should provide 2 sets (hard copy and soft-copy) 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) Service and operation manuals (original and copy) to be provided;<br>4) Advanced maintenance tasks documentation;<br>5) 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 |

# SHADOWLESS LAMP CEILING TYPE MINOR

| | | |
|---|---|---|
| Version no. : | | 1 |
| Date: | | 5/12/2014 |
| Done by : (name / institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Shadowless lamp ceiling type minor |
| GMDN code | | NA |
| **GENERAL** | | |
| **1 USE** | | |
| 1.1 | Clinical purpose | Luminescence shadow less lamp adopts light sources different positions for focus to eliminate shadows of different parts of medical workers. |
| 1.2 | Used by clinical department/ward | Operation theatre |
| **TECHNICAL** | | |
| **2 TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1) Single dome<br>2) minor dome<br>3) Intensity Control :continuous (1,00,000 Lux)<br>4) Height Adjustment :600mm<br>5) Action Radius :1850mm<br>6) Possible Movements :Radial, Angular & Axial<br>7) Colour Temperature :4500 and above<br>8) LED technology: minimum 40,000 hours lamp life<br>9) Intensity,brightness,contrast and power switch to be made available on handle/wall-check.<br>10) Focal distance(d1+d2)=0.8 to 1.2 m<br>11) Temperature rise on the keep of surgeries to be less than 10°<br>12) CR± approx. 95 or more<br>13) 360° rotation for both arms |
| 2.2 | User's interface | Manual |
| 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) | NA |
| 3.3 | Configuration | NA |
| 3.4 | Noise (in dBA) | NA |

| | | |
|---|---|---|
| 3.5 | Heat dissipation | Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism |
| 3.6 | Mobility, portability | Portable |
| **4 ENERGY SOURCE (ELECTRICITY, UPS, SOLAR, GAS, WATER, CO2 ....)** | | |
| 4.1 | Power Requirements | Recharging unit: Input voltage- 220V-240V AC, 50Hz |
| 4.2 | Battery operated | NA |
| 4.3 | Tolerance (to variations, shutdowns) | NA |
| 4.4 | Protection | Should have over-charging cut-off with visual symbol. |
| 4.5 | Power consumption | NA |
| **5 ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system) | NA |
| **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | | |
| **6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 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.<br>2) Sterilization not required. |
| **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 FDA/CE and BIS/ ISO 13485 approved product.<br>2. Electrical safety conforms to the standards for electrical safety IEC 60601-1General requirements(or equivalent BIS Standard)<br>3. Shall meet internationally recognised for Electromagnetic Compatibility(EMC)and Electromagnetic Interference(EMI) for electromedical equipment:IEC 60601-1-2<br>4. Certified to be compliant with IEC 60601-2-4 for usability. |
| 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 socket;<br>2) Safety and operation check before handover; |
| 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 |
| 9.2 | Maintenance tasks | 1) Maintenance manual detailing;<br>2) Complete maintenance schedule; |

| | | |
|---|---|---|
| 9.3 | Service contract clauses, including prices | 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 | Operating manuals, service manuals, other manuals | Should provide 2 sets(hardcopy and soft-copy) 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) Service and operation manuals (original and copy) to be provided;<br>4) Advanced maintenance tasks documentation;<br>5) 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 |

# SHADOWLESS LAMP STANDING MODEL

| | | |
|---|---|---|
| Version no. : | | 1 |
| Date: | | 5/12/2014 |
| Done by : (name / institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Shadowless lamp standing model |
| GMDN code | | NA |
| **GENERAL** | | |
| **1 USE** | | |
| 1.1 | Clinical purpose | Luminescence shadow less lamp adopts light sources different positions for focus to eliminate shadows of different parts of medical workers. |
| 1.2 | Used by clinical department/ward | Operation theatre |
| **TECHNICAL** | | |
| **2 TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1) Dome Head :515mm Dia<br>2) LED lights-2 nos<br>3) Lockable castor stand with minor dome<br>3) Light intensity at 1 mt. :1,00,000 Lux<br>4) Intensity Control :Continupus<br>5) Height Adjustment :600 mm approx<br>6) Action Radius :1250mm<br>7) Possible Movements :Radial, Angular & Axial<br>8) Colour Temperature :4500K or above<br>9) Temp.rise in field :3°-6° c from Amb.Temp<br>10) Control Panel at the dome<br>11) CR± 95000<br>12) Lamp life:40,000 hours<br>13) Battery back-up:1 hour<br>14) Auto-power off and over-charging cut-off. |
| 2.2 | User's interface | Manual |
| 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) | NA |
| 3.3 | Configuration | NA |
| 3.4 | Noise (in dBA) | NA |
| 3.5 | Heat dissipation | Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism |
| 3.6 | Mobility, portability | Portable |

| | | |
|---|---|---|
| **4 ENERGY SOURCE (electricity, ups, solar, gas, water, $CO_2$ ....)** | | |
| 4.1 | Power Requirements | Recharging unit: Input voltage- 220V-240V AC, 50Hz |
| 4.2 | Battery operated | Yes;Rechargeable battery at the base with the frame. |
| 4.3 | Tolerance (to variations, shutdowns) | NA |
| 4.4 | Protection | Should have over-charging cut-off with visual symbol. |
| 4.5 | Power consumption | NA |
| **5 ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system) | NA |
| **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | | |
| **6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 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.<br>2) Sterilization not required. |
| **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 FDA/CE and BIS/ISO 13485 approved product.<br>2. Electrical safety conforms to the standards for electrical safety IEC 60601-1General requirements(or equivalent BIS Standard)<br>3. Shall meet internationally recognised for Electromagnetic Compatibility(EMC)and Electromagnetic Interference(EMI) for electromedical equipment:IEC 60601-1-2<br>4. Certified to be compliant with IEC 60601-2-4 for usability. |
| 7.2 | Local and/or international | Manufacturer / supplier should have ISO 13485 certificate for quality standard. |
| **8 TRAINING AND INSTALLATION** | | |
| 8.1 | Pre-installation requirements: nature, values, quality, tolerance | 1) Availability of 5 amp socket;<br>2) Safety and operation check before handover; |
| 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 |
| 9.2 | Maintenance tasks | 1) Maintenance manual detailing;<br>2) Complete maintenance schedule; |
| 9.3 | Service contract clauses, including prices | 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 | Operating manuals, service manuals, other manuals | Should provide 2 sets(hardcopy and soft-copy) 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) Service and operation manuals (original and copy) to be provided;<br>4) Advanced maintenance tasks documentation;<br>5) 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 |


NATIONAL HEALTH MISSION
Ministry of Health and Family Welfare
Government of India
website : www.nrhm.gov.in