# TECHNICAL SPECIFICATIONS OF MEDICAL EQUIPMENT SUB DISTRICT HOSPITAL AND DISTRICT HOSPITAL

**HEALTHCARE TECHNOLOGY DIVISION**

**NATIONAL HEALTH SYSTEMS RESOURCE CENTRE**

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| 109. | Shoulder Abduction Ladder |
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| 114. | OT LIGHT-SHADOWLESS LAMP CEILING TYPE MINOR |
| 115. | OT LIGHT-SHADOWLESS LAMP CEILING TYPE MAJOR |
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| 117. | Auditory Brainstem Response Machine |
| 118. | 200 mA X-ray Machine (Mobile) |
| 119. | Defibrillator with TCP and AED |
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| 122. | Flame Photometer |
| 123. | ECMO Machine |
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| 126. | Spirometer |
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| 129. | Wheel Chair |
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| **Miscellaneous Equipment** | |

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| 135. | Tuning fork |
| 136. | Goinometer |
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| 139. | Head Lamp |
| 140. | Tongue depressor |
| 141. | External fixator |
| 142. | Finger Exerciser web |
| 143. | X-Ray View Box |
| 144. | Spirometer |

| Vein Finder | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done by: (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | |
| GMDN code(s) | | |
| **GENERAL** | | |
| **1. Use** | | |
| 1.1 | **Clinical purpose** | A Vein Finder is a medical device that projects a real-time image of a patient's veins onto their skin's surface. It helps healthcare professionals locate veins accurately, facilitating procedures such as venipuncture, IV insertion, and blood draws. |
| 1.2 | **Used by clinical department/ ward** | All Departments |
| **TECHNICAL** | | |
| **2. Technical characteristics** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1. Should be a lightweight portable and handheld non-contact type device to prevent contamination and heating etc.<br>2. Should use harmless near infrared (wavelengths from 800 to 2,500 nm) light source.<br>3. Should have multiple modes like Universal, Inverse mode, fine detail mode, resize mode and max bright mode for viewing, based on different skin tones and body characteristics of patients.<br>4. Should have a minimum brightness of 6 lumens and availability of filter to show a colour image for better contrast.<br>5. It should have the ability to visualize vessels up to 10mm deep or better.<br>6. Direct projection on surface of skin and should not require secondary monitor to interfere with technique.<br>7. Vein-imaging devices should offer an image that provides for the same accuracy and reliability of image regardless of the rotation of the device/technique for use on the patient.<br>8. Should have rechargeable battery for back up to mains.<br>9. Should be compatible for adults, neonatal and pediatrics. |

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| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/or standard of communication (wherever required)** | NA |
| | **3. Physical Characteristics** | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | Light weight |
| 3.3 | **Noise (in dba)** | NA |
| 3.4 | **Heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Portable |
| | **4. Energy source (electricity, Ups, solar, gas, water, co2 )** | |
| 4.1 | **Power requirements** | Rechargeable Battery |
| 4.2 | **Battery operated** | Rechargeable battery |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | NA |
| | **5. Accessories, spare parts, consumables** | |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)** | Should be supplied with good quality protective case. |
| | **6. Environmental and departmental considerations** | |
| 6.1 | **Atmosphere / ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, cleaning, Disinfection & sterility issues** | To be specified by manufacturer |
| | **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards. |
| | **8. Training and Installation** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | NA |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over |
| 8.3 | **Training of staff** | Training of users in operation and basic maintenance shall be |

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| | **(medical, paramedical, technicians)** | provided. |
| **9. Warranty and Maintenance** | | |
| 9.1 | **Warranty** | 03 years<br>Preventive maintenance visits at least once in each quarter. |
| **10. Documentation** | | |
| 10.1 | **Operating manuals, service manuals, other manuals** | Should provide 2 sets (hard copy and soft copy) of:<br>User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. |
| 10.2 | **Other accompanying documents** | NA |
| **11. Notes** | | |
| 11.1 | **Service support contact details (hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| **11.2** | **Recommendations or warnings** | Any warning sign should be adequately displayed. |

| Deep Vein Thrombosis (DVT) Pump | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done by: (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | |
| GMDN code(s) | | |
| **GENERAL** | | |
| **1. Use** | | |
| 1.1 | **Clinical purpose** | Deep Vein Thrombosis Pump is a pneumatic compression device that non-invasively increases blood circulation in the limbs of the body. |
| 1.2 | **Used by clinical department/ ward** | Obstetric ICU |
| **TECHNICAL** | | |
| **2. Technical characteristics** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1. Should be light – weight, portable and sturdy with a strong hanging hook which can be fitted on to the bedside/ trolley side.<br>2. Should have a large and easy to read display and audible/ visible alarm system for pressure faults and low battery power.<br>3. Should have a pressure regulator dial with a pressure range adjustable between 40-100 mm Hg.<br>4. The device should have appropriate connectors/ tubings and should allow a single leg mode option also.<br>5. Should have appropriately designed garments for calf/thigh and foot compression with clear labeling.<br>6. Garments should be made of polyfoam with inside cotton lining with Velcro closure for easy patient compliance.<br>7. Should have a single tubing connection between the garment and the pump for quick connection.<br>8. Should have an illuminated on/off power switch. And operation should be noise and vibration free. |
| 2.2 | **User's interface** | LCD display |
| 2.3 | **Software and/or standard of communication (wherever required)** | NA |

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| **3. Physical Characteristics** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | Light weight |
| 3.3 | **Noise (in dba)** | N.A. |
| 3.4 | **Heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Portable |
| **4. Energy source** | | |
| 4.1 | **Power requirements** | 220 V AC +/- 10%, 50 Hz |
| 4.2 | **Battery operated** | Li-ion type batteries with backup to mains |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | To be specified by manufacturer |
| **5. Accessories, spare parts, consumables** | | |
| 5.1 | **Accessories (mandatory, standard, optional);Spare parts (main ones); Consumables / reagents (open, closed system)** | Each unit should be supplied with reusable cuffs:-<br>a) Normal adult calf cuffs- Two Pairs.<br>b) Extra- large calf cuffs- Two pairs.<br>c) Whole leg (thigh & calf cuffs) for normal adults- One Pair. |
| **6. Environmental and departmental considerations** | | |
| 6.1 | **Atmosphere / ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, cleaning, Disinfection & sterility issues** | To be specified by manufacturer. |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. Training and Installation** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. Warranty and Maintenance** | | |
| 9.1 | **Warranty** | 03 years including all spares.<br>Preventive maintenance visits at least once in each quarter. |
| **10. Documentation** | | |

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| 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 should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided. |
| 10.2 | **Other accompanying documents** | NA |
| **11. Notes** | | |
| 11.1 | **Service support contact details (hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| **11.2** | **Recommendations or warnings** | Any warning sign should be adequately displayed. |

| Flash Autoclave | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done by: (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | |
| GMDN code(s) | | |
| **GENERAL** | | |
| **1. Use** | | |
| 1.1 | **Clinical purpose** | Flash autoclave is used for routine sterilization of the instruments, also more suitable for emergency sterilization. This is widely used for various uses in the medical industries especially for eye, dental and laboratories for various sterilization purposes. |
| 1.2 | **Used by clinical department/ ward** | Operation Theatre |
| **TECHNICAL** | | |
| **2. Technical characteristics** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1. Outer case of the unit should be made up of stainless steel (MS-304) and the unit should be based on microprocessor automatic system from adding water to sterilization and dry cycle.<br>2. Chamber capacity should be atleast 25 L or more.<br>3. Machine should perform pre and post vacuum functions.<br>4. Machine should have program selector to perform leakage, helix, prior preset test and the facility of internal water tank with auto chamber fill.<br>5. Machine should have emergency reset buttons and selectable dry time 0-60 min and have auto cut off feature for voltage surge protection.<br>6. Should have a low water indicator feature to indicate water status and to avoid overheating and digital display of temperature.<br>7. It should have a high vacuum ejector to ensure effective air removal for effective steam penetration and efficient post sterilization drying.<br>8. Pressure auto door lock feature as a safety feature to avoid opening of the door when the processor is on. |

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| | | 9. USB port to print temperature, pressure and time of cycles. |
| 2.2 | **User's interface** | Automatic |
| 2.3 | **Software and/or standard of communication (wherever required)** | NA |
| | **3. Physical Characteristics** | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dba)** | Noiseless |
| 3.4 | **Heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Stationary |
| | **4. Energy source (electricity, Ups, solar, gas, water, co2 )** | |
| 4.1 | **Power requirements** | 220 V AC +/- 10%, 50 Hz |
| 4.2 | **Battery operated** | NA |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | As specified by manufacturer |
| | **5. Accessories, spare parts, consumables** | |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)** | NA |
| | **6. Environmental and departmental considerations** | |
| 6.1 | **Atmosphere / ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, cleaning, Disinfection & sterility issues** | To be specified by manufacturer |
| | **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| | **8. Training and Installation** | |
| 8.1 | **Pre-installation requirements: nature,** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |

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| | **values, quality, tolerance** | |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. Warranty and Maintenance** | | |
| 9.1 | **Warranty** | 03 years including all spares.<br>Preventive maintenance visits at least once in each quarter. |
| **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 should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided.<br>3. Satisfactory certificate for any existing installation from government hospital |
| 10.2 | **Other accompanying documents** | NA |
| **11. Notes** | | |
| 11.1 | **Service support contact details (hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| **11.2** | **Recommendations or warnings** | Any warning sign should be adequately displayed. |

| Pneumatic Drill Set | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done by: (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | |
| GMDN code(s) | | |
| **GENERAL** | | |
| **1. Use** | | |
| 1.1 | **Clinical purpose** | Pneumatic drill devices are used by an orthopedic surgeon to make holes in bones for fixing immobilization screws, wires, plates, implants and fitting prosthetic devices etc. |
| 1.2 | **Used by clinical department/ ward** | Orthopedics OT |
| **TECHNICAL** | | |
| **2. Technical characteristics** | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1. Cannulated Pneumatic Drill Handpiece should be compatible with existing attachments:<br>• Cannulation with 3.2 mm diameter<br>• Operating pressure: 6 - 7 bars (maximum 10 bars)<br>• Variable Speed from 0-900 rpm<br>• Should have separate forward and reverse triggers.<br>• Safety Device to cut off air supply to drill on handpiece.<br>• Handpiece should be compatible with radiolucent drive.<br>• Instant change between clockwise and counterclockwise rotation<br>• Offers reliable protection of soft tissues with oscillating drill attachment.<br>• Fully Autoclavable<br>• All Attachments can be fitted on a single handpiece.<br>• The reverse trigger automatically locks when the oscillating saw and the reduction drive attachments are attached to handpiece.<br>2. Adapter for Lubrication:<br>• For oiling of hand piece<br>• Autoclavable<br>• Should be made of Stainless Steel<br>3. Double Air Hose:<br>• Length 5 meters. |

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| | | • Autoclavable<br>• Should have cocentric inlet and outlet pipes.<br><br>4. Radiolucent Drive:<br><br>• Precise aiming and drilling under image intensifier control for locking intramedullary nails.<br>• Drill Bit diameter 2.0 to 4.5 mm, Length 100 to 150 mm, Usable length 80 to 120 mm<br>• Reduced exposure to x-rays<br><br>5. Jacob's Chuck attachment:<br><br>• Chuck capacity up to 0 to 6.5 mm<br>• Cannulation of 3.2 mm diameter<br>• Maximum Speed of 900rpm<br>• Torque of 4-5 Nm<br><br>6. Quick Coupling attachment:<br><br>• Cannulation 3.2 mm<br>• Maximum Speed: 900 rpm<br>• Torque of 4-5 Nm<br><br>7. Reduction Drive for Intramedullary / Acetabular Reaming with reverse option<br><br>• Reaming Speed of 300-350 rpm<br>• Reaming Torque of 12-14 Nm<br>• Option of attachment with reverse rotation<br><br>8. Quick Coupling for K-wire<br><br>• Continuous adjustment facility for wire diameter from 0.6 to 3.2 mm<br>• Speed up to 900 rpm<br><br>9. Oscillating Saw attachment with key<br><br>• It can operate on an oscillating frequency of 0 to 14,000 osc/min.<br>• Attachment can be locked in 8 different positions<br><br>10. Quick Coupling for drill bits<br><br>• Speed: 0–900 rpm<br>• Torque: 0–4.7 Nm<br>• Cannulation: 1.3 mm<br><br>11. Quick coupling for triple reamers<br><br>12. Oscillating Saw Blades (All Sizes) |

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| | | • For Trauma 6<br>• For Joint replacement<br><br>13. Aluminium case for Pneumatic Drill system, Perforated, Autoclavable |
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/or standard of communication (wherever required)** | NA |
| **3. Physical Characteristics** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dba)** | Less than 60 dB |
| 3.4 | **Heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Portable |
| **4. Energy source** | | |
| 4.1 | **Power requirements** | Air compressor based |
| 4.2 | **Battery operated** | NA |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | NA |
| **5. Accessories, spare parts, consumables** | | |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)** | Various sizes of reamers |
| **6. Environmental and departmental considerations** | | |
| 6.1 | **Atmosphere / ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, cleaning, Disinfection & sterility issues** | To be specified by manufacturer |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards. |
| **8. Training and Installation** | | |
| 8.1 | **Pre-installation** | To be specified by manufacturer |

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| | **requirements: nature, values, quality, tolerance** | |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. Warranty and Maintenance** | | |
| 9.1 | **Warranty** | 03 years including all spares. |
| **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 should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided.<br>3. Satisfactory certificate for any existing installation from government hospital |
| 10.2 | **Other accompanying documents** | NA |
| **11. Notes** | | |
| 11.1 | **Service support contact details (hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| **11.2** | **Recommendations or warnings** | Any warning sign should be adequately displayed. |

| Ultrasound Therapy | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done by: (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | |
| GMDN code(s) | | |
| **GENERAL** | | |
| **1. Use** | | |
| 1.1 | **Clinical purpose** | Ultrasound therapy uses sound waves to penetrate soft tissues and is used by therapists to treat pain conditions and promote tissue healing. |
| 1.2 | **Used by clinical department/ ward** | Physiotherapy department |
| **TECHNICAL** | | |
| **2. Technical characteristics** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1. The unit should have a LCD Screen and should deliver therapeutic ultrasound.<br>2. The unit should have variable frequency selector option for clinical supplication.<br>3. The unit should have pulse and continuous modes of ultrasound.<br>4. The unit should have variable duty cycles (10%, 20%, 50%, 100% etc.).<br>6. It should have predefined treatment protocols.<br>7. The ultrasound probe should be waterproof, sturdy and sensitive for effective skin penetration. |
| 2.2 | **User's interface** | LCD display |
| 2.3 | **Software and/or standard of communication (wherever required)** | Inbuilt |
| **3. Physical Characteristics** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dba)** | NA |
| 3.4 | **Heat dissipation** | NA |

| | | |
|---|---|---|
| 3.5 | **Mobility, portability** | Portable |
| | **4. Energy source** | |
| 4.1 | **Power requirements** | 220 V AC +/- 10%, 50 Hz |
| 4.2 | **Battery operated** | NA |
| 4.3 | **Power consumption** | To be specified by manufacturer |
| | **5. Accessories, spare parts, consumables** | |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)** | 1. Ultrasound Head<br>2. Movable trolley |
| | **6. Environmental and departmental considerations** | |
| 6.1 | **Atmosphere / ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity up to 90% in ideal circumstances. |
| 6.2 | **User's care, cleaning, Disinfection & sterility issues** | To be specified by manufacturer |
| | **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| | **8. Training and Installation** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before handover |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation in basic maintenance shall be provided |
| | **9. Warranty and Maintenance** | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter |
| | **10. Documentation** | |
| 10.1 | **Operating manuals, service manuals, other manuals** | Should provide 2 sets of<br>1.User manual should be provided in English/ Hindi language along with the machine diagram<br>2. Service and operation manual should be provided. |
| 10.2 | **Other accompanying documents** | NA |
| | **11. Notes** | |
| 11.1 | **Service support contact details (hierchy Wise; including a toll free/landline** | Contact details of manufacturer, supplier and local service agent to be provided. |

| | | |
|---|---|---|
| | **number)** | |
| **11.2** | **Recommendations or warnings** | Any warning sign should be adequately displayed. |

| Transcutaneous Electric Nerve Stimulator (TENS) | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done by: (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | |
| GMDN code(s) | | |
| **GENERAL** | | |
| **1. Use** | | |
| 1.1 | **Clinical purpose** | Transcutaneous Electric Nerve Stimulator (TENS) is used to provide a degree of symptomatic pain relief by exciting sensory nerves and thereby stimulating either the pain gate mechanism and/or the opioid system. |
| 1.2 | **Used by clinical department/ ward** | Physiotherapy Department |
| **TECHNICAL** | | |
| **2. Technical characteristics** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1. It should be advanced microprocessor based and should have minimum 4 channels. All channels should be independent.<br>2. It should be compact, lightweight with a digital display of patient parameters.<br>3. It should have automatic intensity control to make it safe to operate.<br>4. It should have independent intensity control and a display of output current for each channel.<br>5. It should have a digital display of output current of each channel and treatment time.<br>6. The machine should produce output only after intensity of all channels are set to Zero.<br>8. Output current -0-60 mA<br>9. Output voltage 0-100V<br>10. Frequency 1-200 Hz<br>11. Pulse width 75-360 sec<br>12. Treatment time- 5,10,15,20 minutes. |

| | | |
|---|---|---|
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/or standard of communication(where ver required)** | NA |
| | **3. Physical Characteristics** | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | Light weight |
| 3.3 | **Noise (in dba)** | N.A. |
| 3.4 | **Heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Portable |
| | **4. Energy source (electricity, Ups, solar, gas, water, co2 )** | |
| 4.1 | **Power requirements** | 220 V AC +/- 10%, 50 Hz |
| 4.2 | **Battery operated** | Yes |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | To be specified by manufacturer |
| | **5. Accessories, spare parts, consumables** | |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)** | Stimulation needles of various sizes |
| | **6. Environmental and departmental considerations** | |
| 6.1 | **Atmosphere / ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, cleaning, Disinfection & sterility issues** | To be specified by manufacturer. |
| | **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| | **8. Training and Installation** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over |
| 8.3 | **Training of staff** | Training of users in operation and basic maintenance shall be |

| | | |
|---|---|---|
| | **(medical, paramedical, technicians)** | provided. |
| **9. Warranty and Maintenance** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter |
| **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 should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided. |
| 10.2 | **Other accompanying documents** | NA |
| **11. Notes** | | |
| 11.1 | **Service support contact details (hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| **11.2** | **Recommendations or warnings** | Any warning sign should be adequately displayed. |

| ACT Machine | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done by: (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | |
| GMDN code(s) | | |
| **GENERAL** | | |
| **1. Use** | | |
| 1.1 | **Clinical purpose** | The ACT machine is a medical device used to perform Activated clotting time (ACT) test. The ACT test is commonly used to monitor the effectiveness of anticoagulation therapy, particularly with heparin, during medical procedures like surgeries, angioplasties and dialysis. |
| 1.2 | **Used by clinical department/ ward** | Cardiac Care Unit, OT, Dialysis Services |
| **TECHNICAL** | | |
| **2. Technical characteristics** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1. It should be a compact & portable device for bed-side testing with LED/LCD display for displaying results.<br>2. System should be microprocessor controlled designed to determine coagulation end points in whole blood, Citrated blood and plasma samples.<br>3. It should have an inbuilt mechanism to heat the cartridge.<br>3. Range 37±2 Degree c.<br>5. It should be capable of displaying two reports at one time.<br>6. Measurement range 0-1500 sec.<br>8. Data transfer capability: Printer option available facility to store view multiple patient data.<br>9. One Button Operation- Easy to Use.<br>11. Dual well testing method.<br>12. Accepts actalyte ACT tubes with celite, glass bead activator, MAX ACT tubes with blended activator; all international technidyne Hemochron tubes.<br>13. Desirable: Rate of Actual Clot Formation (CR, Clot Rate:<br>Thrombin Activity, Low Molecular Weight Heparin Management). |

| | | |
|---|---|---|
| 2.2 | **User's interface** | LCD/LED display |
| 2.3 | **Software and/or standard of communication (wherever required)** | In-built |
| | **3. Physical Characteristics** | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dba)** | N.A. |
| 3.4 | **Heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Portable |
| | **4. Energy source (electricity, Ups, solar, gas, water, co2 )** | |
| 4.1 | **Power requirements** | 220 V AC +/- 10%, 50 Hz |
| 4.2 | **Battery operated** | Rechargeable battery |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | As specified by manufacturer |
| | **5. Accessories, spare parts, consumables** | |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)** | NA |
| | **6. Environmental and departmental considerations** | |
| 6.1 | **Atmosphere / ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, cleaning, Disinfection & sterility issues** | To be specified by manufacturer. |
| | **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| | **8. Training and Installation** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over |
| 8.3 | **Training of staff** | Training of users in operation and basic maintenance shall be |

| | | |
|---|---|---|
| | **(medical, paramedical, technicians)** | provided. |
| **9. Warranty and Maintenance** | | |
| 9.1 | **Warranty** | 03 years including all spares.<br>Preventive maintenance visits at least once in each quarter. |
| **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 should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided. |
| 10.2 | **Other accompanying documents** | List of essential spares and accessories, with their part number and cost. |
| **11. Notes** | | |
| 11.1 | **Service support contact details (hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| **11.2** | **Recommendations or warnings** | Any warning sign should be adequately displayed. |

| Hemodialysis Machine | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done by: (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | |
| GMDN code(s) | | |
| **GENERAL** | | |
| **1. Use** | | |
| 1.1 | **Clinical purpose** | Hemodialysis machine is used in dialysis procedure that filters a patient blood to remove excess water and waste products when the kidney is damaged, dysfunctional or missing. |
| 1.2 | **Used by clinical department/ ward** | Dialysis Services |
| **TECHNICAL** | | |
| **2. Technical characteristics** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1. The hemodialysis machine should have a blood pump to achieve a unidirectional flow up to 400ml/min.<br>2. It should have a heparin pump, arterial line and venous line pressure monitors and functional air bubble detector.<br>3. Mixing proportion of unit with bicarbonate dialysis facility<br>4. Dialysate delivery should be from 300 to 500 ml/min or more.<br>5. It should have conductivity meter and functional blood leak detector<br>6. Dialysate temperature regulator with temperature of 35 to 39 deg C<br>7. Built-in device for measurement and monitor of effective urea clearance (K) and dialysis dose (Kt/V) automatically during treatment.<br>7. Volumetric UF control<br>8. Safety devices functioning alarms, venous blood camp<br>9. Dialysate filter<br>**Desirable Features:**<br>1. Online blood volume monitor |

| | | |
|---|---|---|
| | | 2. Online urea clearance<br>3. Sodium profiling of dialysate<br>4. Single needle dialysis facility<br>5. Hemodiafiltration<br>6. Optical detector |
| 2.2 | **User's interface** | LCD display |
| 2.3 | **Software and/or standard of communication (wherever required)** | In-built |
| **3. Physical Characteristics** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dba)** | N.A. |
| 3.4 | **Heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Mobile |
| **4. Energy source (electricity, Ups, solar, gas, water, co2 )** | | |
| 4.1 | **Power requirements** | 220 V AC +/- 10%, 50 Hz |
| 4.2 | **Battery operated** | UPS with at least 2-hour battery backup |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | As specified by manufacturer |
| **5. Accessories, spare parts, consumables** | | |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)** | All consumables required for installation and standardization of system to be given free of cost. |
| **6. Environmental and departmental considerations** | | |
| 6.1 | **Atmosphere / ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, cleaning, Disinfection & sterility issues** | To be specified by manufacturer. |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |

| | | |
|---|---|---|
| **8. Training and Installation** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. Warranty and Maintenance** | | |
| 9.1 | **Warranty** | 03 years including all spares.<br>Preventive maintenance visits at least once in each quarter. |
| **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 should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided. |
| 10.2 | **Other accompanying documents** | List of essential spares and accessories, with their part number and cost. |
| **11. Notes** | | |
| 11.1 | **Service support contact details (hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| **11.2** | **Recommendations or warnings** | Any warning sign should be adequately displayed. |

| DIALYZER REPROCESSING SYSTEM | | |
|---|---|---|
| Version no. : | | 01 |
| Date: | | August 2023 |
| Done by : (name. Institution) | | HCT/NHSRC |
| NAME AND CODING | | |
| GMDN name | | |
| GMDN code(s) | | |
| GENERAL | | |
| 1. USE | | |
| 1.1 | Clinical purpose | Dialyzer preprocessor is a system which cleans the dialyzer for reuse on the same patient after completion of one dialysis cycle. |
| 1.2 | Used by clinical department/ward | Dialysis Unit |
| TECHNICAL | | |
| 2. TECHNICAL CHARACTERISTICS | | |
| 2.1 | Technical characteristics (specific to this type of device) | • Fully automatic reprocessing and disinfecting cycles.<br>• Should be able to clean both high flux and low flux dialyzers and hemodialysis filters.<br>• Should be safe for cellulose based and synthetic membranes.<br>• Should be compatible with sterilant available in open market.<br>• High standardization in cleaning, fiber bundle volume measuring, leak testing and chemical disinfecting<br>• Should have LCD Screen and menu guided operations.<br>• Water requirements - flow 3 litres/ minute and pressure 35-50 psi.<br>• It should have regulators and pressure gauges to monitor pressures.<br>• Safety Alarms, Audible & Visible Alarms. |
| 2.2 | User's interface | Manual |
| 2.3 | Software and/ or standard of communication (wherever required) | NA |
| 3. PHYSICAL CHARACTERISTICS | | |
| 3.1 | Dimensions(metric) | NA |
| 3.2 | Weight (lbs, kg) | NA |
| 3.3 | Noise (in dBA) | NA |
| 3.4 | Heat dissipation | NA |

| | | |
|---|---|---|
| 3.5 | Mobility, portability | Fixed |
| 4. ENERGY SOURCE | | |
| 4.1 | Power requirements | 220+/-10% V, 50/60 Hz |
| 4.2 | Battery operated | Yes, with battery backup |
| 4.3 | Protection | NA |
| 4.4 | Power consumption | NA |
| 5. ACCESSORIES, SPARE PARTS, CONSUMABLES | | |
| 5.1 | Accessories, (mandatory, standard, optional);<br>Spare parts (main ones);<br>Consumables/reagents (open, closed system) | NA |
| 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS | | |
| 6.1 | Atmosphere/Ambience (air conditioning, humidity, dust …) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | To be specified by manufacturer. |
| 7. STANDARDS AND SAFETY | | |
| 7.1 | Certificates (pre-market, sanitary,);<br>Performance and safety standards (specific to the device type); Local and/or international | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| 8. TRAINING AND INSTALLATION | | |
| 8.1 | Pre- installation requirements: nature, values, quality, tolerance | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up. |
| 8.2 | Requirements for sign-off | Supplier to perform safety and operation checks before hand over. |
| 8.3 | Training of staff (medical, paramedical, technicians) | Training of users in operation and basic maintenance shall be provided. |
| 9. WARRANTY AND MAINTENANCE | | |
| 9.1 | Warranty | • 03 years<br>• Preventive Maintenance visits at least once in each quarter |
| 10. DOCUMENTATION | | |

| | | |
|---|---|---|
| 10.1 | Operating manuals, set manuals, other manuals | Should provide 2 sets (hard copy and soft copy) of: User manuals should be supplied in English/Hindi language along with machine diagrams. |
| 10.2 | Other accompanying documents | NA |
| 11. Notes | | |
| 11.1 | Service Support Contact details (Hierarchy Wise; including a toll free/landline number) | Contact details of manufacturer and supplier should be provided. |
| 11.2 | Recommendations or warnings | Any warning sign should be displayed adequately. |

| Arthroscopy System | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done by: (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | |
| GMDN code(s) | | |
| **GENERAL** | | |
| **1. Use** | | |
| 1.1 | **Clinical purpose** | For examination or to perform surgical procedure of joint through small incision using the arthroscope. |
| 1.2 | **Used by clinical department/ ward** | Orthopedics Department |
| **TECHNICAL** | | |
| **2. Technical characteristics** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1. Wide Angle orward-Oblique Telescope 30 deg., enlarged view, diameter 4 mm, length 18 cm, autoclavable, fiber optic light transmission incorporated.<br><br>2. Arthroscope Sheath, diameter 6 mm, working length 12 cm, with 2 rotatable stopcocks and automatic lock-in coupling mechanism, autoclavable, for use with Hopkins Telescope 30deg., diameter 4mm, length 18cm, coupling between the telescope and sheath should be possible in absolutely any position.<br><br>3. Blunt Obturator, Autoclavable; for use with arthroscope sheath diameter 6 mm, working length 12 cm.<br><br>4. Hook and Retractor, graduated, Autoclavable; diameter 3.5mm, working length 8.5 cm. length of hook 2 mm.<br><br>5. Suction Punch Autoclavable, shaft diameter 4.8 mm, working length 13 cm.<br><br>6. Through cut punch, Autoclavable, cutting width 2.7 mm, shaft diameter 3.5 mm, working length 13 cm; should have an ergonomic handle and flat construction of jaws.<br><br>7. Through cut punch, Autoclavable, angled 15 deg. upwards, cutting width 2.7 mm, shaft diameter 3.5 mm, working length 13 cm; should have an ergonomic handle and flat construction of jaws.<br><br>8. Through cut punch, Autoclavable, angled 90 deg.left, cutting width 2.7 mm, shaft diameter 3.5 mm, working length 13 cm; should have an ergonomic handle and flat construction of jaws. |

| | | |
|---|---|---|
| | | 9. Through cut punch, Autoclavable, angled 90 deg. right, cutting width 2.7 mm, shaft diameter 3.5 mm, working length 13 cm; should have an ergonomic handle and flat construction of jaws.<br><br>10. Autoclavable Scissors, straight, shaft diameter 3.5 mm, working length 13 cm. Scissors with two piece design having a handle and working attachment will be preferable.<br><br>11. Autoclavable Biopsy Forceps, straight, shaft diameter 3.5 mm, sorking length 13 cm. Biopsy Forceps with two-piece design having a handle with ratchet and working attachment will be preferable.<br><br>12. Autoclavable Biopsy Forceps, straight, shaft diameter 3.5 mm, working length 13 cm. Biopsy Forceps with two piece design having a handle with ratchet and working attachment will be preferable<br><br>13. Cleaning adaptor for Hand Instruments<br><br>14. Camera Specifications:<br>Digital single chip camera-color system PAL with camera head.<br>Special features:<br>• High horizontal image resolution of more than 450 lines<br>• Integrated optical par focal zoom lens through which the image can be zoomed in or out without changing the focus.<br>• Automatic exposure control (1/50 s- 1/10000 s PAL)<br>• Automatic white balance with memory function for 2 settings<br>• RGB - video output<br>• Integrated universal power supply.<br>• Can be adapted directly to an operating microscope.<br>• Integrated Title Generator.<br>Camera system compatible with Communication Computer system for remote controlled operation of the various features of the camera along with other equipment so as to function as an integral part of the digitally controlled Operating Room under the command of the operating Surgeon.<br>Camera System having an Autoclavable Camera Head and Programmable buttons on the camera head itself will be highly desirable.<br><br>15. Light Source:<br>Halogen (15V, 250 W) light source having optimum light power with color temperature around 3400K. Compact and light in design with manual light intensity control preferably in steps. The light source should have an in-built infra-red filter for heat and a system for over-heating protection. The light source should also have automatic backup operation in case of lamp failure.<br><br>16. Fiber Optic Light Cable for Cold Light Fountains with Straight Connector; diameter 3.5 mm, length 180 cm.<br><br>17. Hardcopy devices:<br>a) Printer to take print out of the images from monitor screen. |

| | | |
|---|---|---|
| | | b) CD/DVD writer to record the procedure video for records and documentation |
| 2.2 | **User's interface** | Arthroscopic Camera |
| 2.3 | **Software and/or standard of communication (wherever required)** | NA |
| **3. Physical Characteristics** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dba)** | N.A. |
| 3.4 | **Heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Portable |
| **4. Energy source (electricity, Ups, solar, gas, water, co2 )** | | |
| 4.1 | **Power requirements** | 220 V AC +/- 10%, 50 Hz |
| 4.2 | **Battery operated** | |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | As specified by manufacturer |
| **5. Accessories, spare parts, consumables** | | |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)** | 1. Shaver System Should be supplied with 2 pieces of single use shaver blades of each of the diameter for knee and shoulder<br>2. Arthroscopy Fluid Management System should be supplied with disposable tube sets for inflow only (30pcs)<br>3. Arthroscopy Fluid Management System should be supplied with disposable Tube sets for inflow and outflow (30pcs.). |
| **6. Environmental and departmental considerations** | | |
| 6.1 | **Atmosphere / ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, cleaning, Disinfection & sterility issues** | To be specified by manufacturer. |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. Training and Installation** | | |
| 8.1 | **Pre-installation requirements: nature,** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up. |

| | | |
|---|---|---|
| | **values, quality, tolerance** | |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. Warranty and Maintenance** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter |
| **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 should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided. |
| 10.2 | **Other accompanying documents** | List of essential spares and accessories, with their part number 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. |
| **11.2** | **Recommendations or warnings** | Any warning sign should be adequately displayed. |

| Electric Cautery | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done by: (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | - |
| GMDN code(s) | | - |
| **GENERAL** | | |
| **1. Use** | | |
| 1.1 | **Clinical purpose** | Electrocautery, also known as thermal cautery, refers to a process in which a direct or alternating current is passed through a resistant metal wire electrode, generating heat. The heated electrode is then applied to living tissue to achieve hemostasis or varying degrees of tissue destruction. |
| 1.2 | **Used by clinical department/ ward** | Operation Theatre |
| **TECHNICAL** | | |
| **2. Technical characteristics** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1. The unit should be microprocessor controlled electrosurgery unit with a LCD/LED digital display having a touch screen preferably. The display visual indicator for the actual power being delivered.<br>2. The unit should have precise monopolar and bipolar modes for fine and microsurgery applications and should be capable of using very less voltage for precise applications.<br>3. The unit should have a universal socket for bipolar, monopolar for neutral output socket along with multifunctional socket for vessel ceiling based on plug and play mechanism, also having the facility to upgrade additional socket if required.<br>4. The unit should have continuous patient monitoring with return electrode (neutral electrode).<br>5. The unit should have a heat dissipation unit with an internal air-cooling system.<br>6. Automatic control of output power. Unit should have bipolar auto start functions.<br>7. Should have facility to program latest surgical procedures intended for.<br>8. Neonatal safety systema and neutral electrode safety system for pediatric applications. |

| | | |
|---|---|---|
| | | 9. It should have an on/off switch with indicator light. Should have facility for self-check of the unit after every time switching on.<br>10. It should have a reusable vessel sealing feature for open surgery.<br>11. The unit should be supplied with all standard accessories for optimum functional use. |
| 2.2 | **User's interface** | LCD Display |
| 2.3 | **Software and/or standard of communication (wherever required)** | NA |
| **3. Physical Characteristics** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dba)** | N.A. |
| 3.4 | **Heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Portable |
| **4. Energy source (electricity, Ups, solar, gas, water, co2 )** | | |
| 4.1 | **Power requirements** | 220 V AC +/- 10%, 50 Hz |
| 4.2 | **Battery operated** | NA |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | As specified by manufacturer |
| 4.5 | **Other energy supplies** | NA |
| **5. Accessories, spare parts, consumables** | | |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)** | 1. Insulated needles/electrodes of various shapes and sizes, at least two sets should be provided along with cautery machine:<br>(a) Long sharp-tipped electrode used for treating small lesions.<br>(b) Slightly thicker and angled electrode with a sharp tip.<br>(c) Wire-loops (tungsten wires of 0.004, 0.007 and 0.009 inch in diameter).<br>(d) Ball electrodes<br>2. Bipolar forceps<br>3. Neutral silicon plate<br>4. Electrode protector stand<br>5. Necessary Cables for the system<br>6. Two pedal/single pedal foot switch. |

| | | |
|---|---|---|
| | | 7. Reusable vessel sealing for open surgery |
| **6. Environmental and departmental considerations** | | |
| 6.1 | **Atmosphere / ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, cleaning, Disinfection & sterility issues** | Disinfection required |
| **7. Standards and Safety** | | |
| 7.1 | **Certificates (pre-market, sanitary, ..); performance and safety standards (specific to the device type); local and/or international** | • Should be BIS and CDSCO approved.<br>• Should conform USFDA/ European CE, in case of non-availability of BIS Standards.<br>• Should conform to ISO 13485 quality standards.<br>• Should conform to IEC 60601-1-General requirements of Electrical Safety Standards |
| **8. Training and Installation** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. Warranty and Maintenance** | | |
| 9.1 | **Warranty** | 03 years including all spares.<br>Preventive maintenance visits at least once in each quarter. |
| **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 should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided.<br>3. Satisfactory certificate for any existing installation from government hospital |
| 10.2 | **Other accompanying documents** | NA |
| **11. Notes** | | |
| 11.1 | **Service support contact details (hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| **11.2** | **Recommendations or warnings** | Any warning sign should be adequately displayed. |

| RTERIAL BLOOD GAS ANALYZER | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name/institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Blood gas analyser IVD, laboratory |
| GMDN code(s) | | 56661 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | An electrically powered laboratory instrument intended to be used for the quantitative in vitro measurement of blood pH, partial pressure of oxygen (pO2) and partial pressure of carbon dioxide (pCO2), and the calculation of other blood gas parameters [e.g., bicarbonate (HCO3-), base excess, arterial-alveolar gradient] in a clinical specimen. |
| 1.2 | **Clinical department/ward** | Clinical Diagnostic Laboratory |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics** | • Essential Measured parameters; pH, pCO2, pO2, tHb, Barometric Pressure, Na+, K+, Ca++, Cl-. All these parameters should be measured simultaneously.<br>• Should have minimum 15 calculated parameters including SaO2, Bi carbonate (HCO3), Standard HCO3, Base Excess of Blood (BE), Base Excess of extra cellular fluid.<br>• Sample volume-less than 100ul.<br>• Should have minimum process time (less than 5 min).<br>• Warm up time should be less than 30 minutes.<br>• Maintenance free electrodes<br>• Fully automatic liquid calibration of all parameters at user-defined intervals.<br>• Should be with numeric keypad, graphic / LCD display, and inbuilt printer. Should have interface for PC compatibility.<br>• QC should be based on test parameters.<br>• Automatic result processing, test ordering and provision for bi-directional LIS interface should be available.<br>• Automatic data archiving and customizable layout.<br>• Should have provision for data backup. |
| 2.2 | **User's interface** | LCD/Graphical Display |
| 2.3 | **Software and/or standard of communication** | In-built |

| | | |
|---|---|---|
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dBA)** | Noise pressure level: ≤60 dB |
| 3.4 | **heat dissipation** | Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism |
| 3.5 | **Mobility, portability** | Portable |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 )** | | |
| 4.1 | **Power Requirements** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | Yes at least 30 minutes backup |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | To be specified by manufacturer. |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | **Accessories (mandatory, standard, optional) Spare parts (main ones) Consumables/reagents (open, closed system)** | • Reagents for minimum 200 tests should be provided along with the machine.<br>• Electrodes for all the parameters specified -01 set.<br>• Quality control tools/reagents for minimum 200 tests or as per requirement. |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| 6.1 | **Atmosphere/Ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements forsign-off** | Supplier to perform installation, safety, and operation checks before handover. |

| | | |
|---|---|---|
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| **10. DOCUMENTATION** | | |
| 10.1 | **Manuals** | Should provide 2 sets (hardcopy) of: -<br>1) User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams.<br>2) List of equipment and procedures required for local calibration and routine maintenance.<br>3) Certificate of calibration and inspection; |
| 10.2 | **Other accompanying documents** | List of important spares and accessories, with their part numbers and cost. |
| **11. NOTES** | | |
| 11.1 | **Other information** | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | **Recommendations or Warnings** | Any recommendations for best use and supplementary warning for safety should be declared. |

| AUTOCLAVE HORIZONTAL | | |
|---|---|---|
| Version no. : | | 01 |
| Date: | | August 2023 |
| 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 underhigh steam pressure; used for sterilizing, with moist or dry heat at high temperatures. |
| 1.2 | Used by clinical department/ward | Sterilization services as per the requirement |
| **TECHNICAL** | | |
| **2 TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical Specifications | 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 frames 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 drainagesystem.<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 (whereever required)** | NA |
| 3 | **3 PHYSICAL CHARACTERICSTICS** | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |

| | | |
|---|---|---|
| 3.3 | **Noise (in dBA)** | NA |
| 3.4 | **Heat dissipation** | Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism |
| 3.5 | **Mobility, portability** | Portable |
| | **4 ENERGY SOURCE** | |
| 4.1 | **Power Requirements** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | No |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | To be specified by manufacturer |
| | **5 ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory, standard,optional); Spare parts (main ones); Consumables / reagents (open, closedsystem)** | 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 ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterilityissues** | To be specified by manufacturer. |
| | **7 STANDARDS AND SAFETY** | |
| 7.1 | **Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the devicetype);Local and/or international** | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| | **8 TRAINING AND INSTALLATION** | |
| 8.1 | **Pre-installation requirements: nature,values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign- off** | Supplier to perform safety and operation check before hand over. |

| | | |
|---|---|---|
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9 WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| **10 DOCUMENTATION** | | |
| 10.1 | **Operating manuals, service manuals, othermanuals** | 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) Service and operation manuals (original and copy) to be provided. |
| 10.2 | **Other accompanying documents** | NA |
| **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 beprovided. |
| 11.2 | **Recommendations or warnings** | Any warning signs would be adequately displayed |

| BLOOD CULTURE ANALYSER IVD | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done By: | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN Name | | Blood culture analyzer IVD |
| GMDN Code | | 56739 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical Purpose | An electrically powered automated laboratoryinstrument intended to be used for the qualitative and/orquantitative in vitro determination of microorganism growth in a blood culture preparation or other clinical specimen, with or without subsequent identification of the organism. |
| 1.2 | Used by clinical department/ward | Clinical Diagnostic Laboratory |
| **TECHNICAL** | | |
| **2. Technical Characteristics** | | |
| 2.1 | Technical Characteristics(Specific to this type of device) | • Fully automated modular system capable of culturing blood, sterile body fluids for bacteriaand fungi.<br>• Capacity: Minimum 25 bottle positions.<br>• System should have optimized recovery of organism with continuous agitation.<br>• System should be based on sensitive fluorescence/colorimetric technology for interpretation of results.<br>• The system should be modular with the possibility of expansion on requirement.<br>• The culture media must have strong resin based antibiotic removal devices to minimize chances of false negatives due to high antibiotics in specimens.<br>• The system should be capable of processing both adult and pediatric samples.<br>• QC should be based on test parameters.<br>• Provision for bi-directional LIS interface should be available.<br>• The system should have sample accession facilityusing bar code/ QR code reader.<br>• Should have PC interface facility. |
| 2.2 | Software and/or standard of communication (wherever required) | Within the warranty period needs to cover free of cost upgradation and re-installation |

| | | |
|---|---|---|
| **3. PHYSICAL CHARACTERISTIC** | | |
| 3.1 | Dimensions (in mm) | NA |
| 3.2 | Weight | NA |
| 3.3 | Noise | NA |
| 3.4 | Heat Dissipation | Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism. |
| 3.5 | Mobility/Portability | Stationary Lab Installation |
| **4. ENERGY SOURCE** | | |
| 4.1 | Power input | 220VAC +/- 10%, 50 Hz. |
| 4.2 | Power consumption | To be specified by manufacturer. |
| **5. ACCESSORIES, SPARE PARTS AND CONSUMABLE** | | |
| 5.1 | Accessories, (mandatory, Standard, operational); Spare parts (main ones) Consumable/reagents (open, closed system) | The system should be supplied in a complete system with all accessories, hardware's like computer, printer etcand the required software. |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | Atmosphere /Ambiance (air conditioning, humidity, dust ...) | Capable of operating continuouslyin ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | As indicated by Manufacturer |
| **7. STANDARDS & SAFETY** | | |
| 7.1 | Certificates (pre-market, sanitary); Performance and safety standards (specific to the device type); Local and/orinternational | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards in case of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | Pre-installation requirements: nature, values, quality, tolerance | As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up. |
| 8.2 | Requirements for sign-off | Supplier to perform installation, safety and operation checks before handover. |
| 8.3 | Training of staff (medical, paramedical, technicians) | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |

| | | |
|---|---|---|
| 9.1 | Warranty | • 03 years<br>• Preventive Maintenance visits at least once in each quarter |
| **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 should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided.<br>3. Certificate of calibration and inspection, |
| 10.2 | Other accompanyingdocuments | List of all the important spares and accessories, with their part numbers and cost needs to be submitted. |
| **11. NOTES** | | |
| 11.1 | Service Support Contact details (Hierarchy Wise; including a toll free/landline number) | Contact details of Vendor and local service agent needs to be provided |
| 11.2 | Recommendations orwarnings | Any specific recommendation or warning to be followed for ensuring optimal and safe utilization of medicaldevice needs to be mentioned. |

| COAGULATION ANALYZER | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done by: (Name/Institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| GMDNS name | | Coagulation analyzer IVD, laboratory |
| GMDNS code(s) | | 56689 |
| **GENERAL** | | |
| **1. USE** | | |
| **1.1** | **Clinical purpose** | A laboratory instrument intended to be used for the qualitative and quantitative in vitro determination of one or multiple coagulation components involved inhemostasis in a clinical specimen (e.g., performs tests such as prothrombin time (PT), partial thromboplastin time (PTT)) |
| **1.2** | **Used by clinical department/ward** | Clinical Diagnostic Laboratory |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| **2.1** | **Technical characteristics (specific to this type ofdevice)** | • Blood Coagulation analyzer should be a fully automated (It should automatically aspirate,dispense, incubate and measure) with random access.<br>• The system must be open for essential reagents.<br>• Should have option for clotting, Chromogenic,turbidimetric, fluorogenic or immune assays as well.<br>• Instrument should be able to detect automaticallypositive sample and reagent positions.<br>• Possibility of auto rerun and auto redilution of samples should be available, positive sample andreagents level detection should be provided.<br>• It should support a wide range of parameters including PT, APTT, Factor Assay, Protein C, Protein S, Fibrinogen, and Thrombin Time, ATIII,Heparin, PLG, LP(a), APCR, DDI, FDP, vWf. Factor VIII quantification.<br>• Throughput: Must perform at least 20 tests (for APTT and PT) per hour.<br>• Storage: It should have capacity of storing 1000test results in its memory. |

| | | |
|---|---|---|
| | | • System should have on-board cooling facility tomaintain the temperature of the reagents.<br>• Machine should provide patient analysis curve. The instrument should have in-built Barcode reader for identification of sample and reagents i.e. name, stability, volume, position etc.<br>• System should have software that automatically generates LJ charts for QC and have appropriate alerts.<br>• Provision for Bar Code/QR code reading should be available.<br>• The equipment should have in-built digital display unit and PC interface facility. |
| **2.2** | **User's interface** | • LCD Display<br>• Provision for bi-directional LIS interface should be available. |
| **2.3** | **Software and/ or standard of communication (wherever required)** | In built – to be provided by the manufacturer |
| **3. PHYSICAL CHARACTERISTICS** | | |
| **3.1** | **Dimensions(metric)** | NA |
| **3.2** | **Weight (lbs, kg)** | NA |
| **3.3** | **Noise (in dBA)** | NA |
| **3.4** | **Heat dissipation** | Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism. |
| **3.5** | **Mobility, portability** | Stationary lab installation |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)** | | |
| **4.1** | **Power requirements** | **Power Supply:**<br>220VAC +/- 10%, 50 Hz. |
| **4.2** | **Battery operated** | UPS of suitable kVA with at least 1 hour backup. |
| **4.3** | **Protection** | Internal electrical protection. |
| **4.4** | **Power consumption** | To be specified by manufacturer/vendor. |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| **5.1** | **Accessories, (mandatory, standard,optional);**<br>**Spare parts (main ones);**<br>**Consumables/reagents(open, closed system)** | 1. All the consumables, controls and calibrators and any other reagents or items required for conducting 500 tests should be mentioned and supplied with the equipment.<br>2. Barcode/QR code Scanner<br>3. Built-in Thermal printer or provision for external printer<br>4. Online UPS for minimum 1 hour back up |
| **BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS** | | |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |

| | | |
|---|---|---|
| **6.1** | **Atmosphere/Ambience(air conditioning, humidity, dust …)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterilityissues** | To be specified by manufacturer. |
| **7. STANDARDS AND SAFETY** | | |
| **7.1** | **Certificates (pre- market, sanitary,); Performance and safety standards (specific to the devicetype); Local and/or International** | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND INSTALLATION** | | |
| **8.1** | **Pre- installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up. |
| **8.2** | **Requirements for sign-off** | Supplier to perform installation, safety and operation checks before handover. |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| **9.1** | **Warranty** | • 3 years, including all spares and calibration.<br>• Preventive maintenance visits atleast one in each quarter |
| **10. DOCUMENTATION** | | |
| **10.1** | **Operating manuals,set manuals, other manuals** | Should provide 2 sets (hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should 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) tobe provided.<br>4. Certificate of calibration and inspection,<br>5. Satisfactory certificate for any existing installationfrom government hospital. |
| **10.2** | **Other accompanying Documents** | List of essential spares and accessories, with their part number and cost. |
| **11. Notes** | | |

| | | |
|---|---|---|
| **11.1** | **Service SupportContact details (Hierarchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and localservice agent to be provided. |
| **11.2** | **Recommendations or warnings** | Any warning sign should be adequately displayed. |

| C- ARM | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name / institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | C-ARM System (HF) |
| GMDN code | | NA |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | C-arm machine is a device used by a physician/surgeon to guide surgicalinstruments while watching the instrument being driven on a live x-ray machine |
| 1.2 | **Used by clinical department/ward** | OT and Screening labs |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | High End C-Arm with large LCD display. 1K X 1K High resolution imaging chain with progressive scan CCD camera, 9" Image Intensifier and dedicated computer-based acquisition system.<br>The movements should be smooth having very simple positioningmechanism.<br>**X-RAY GENERATOR:**<br>High Frequency 50 KHz X-Ray Generator with power output 5KW or moreshould be provided.<br>Following modes should be provided:<br>o Radiography<br>o Fluoroscopy selection of continuous, single pulse, multi pulse should bethere.<br>o KV Range (Rad./Fluoro): 40 to 120KVP in 1KV/Step.<br>o Radiographic mA Range: more than 100mA<br>o Fluoroscopy mA output: Up to 5mA (Normal Fluoroscopy)<br>o Up to 20mA (Boosted fluoroscopy)<br>o mAs output: 0.1 - 200mAs or more<br>**X-RAY TUBE:**<br>o Dual focus Rotating Anode X-Ray Tube of focal spot 0.3mm (small) &0.6mm (large) to be provided.<br>o Anode heat storage capacity should be more than 250KHU.<br>o Iris Collimator should be provided. |

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| | | **CONTROL PANEL:**<br>A very compact, soft touch control panel (A.P.R) with 20 X 3 (column x rows)<br>L.C.D display on which KV, mAs, fluoro time, FmA, I.I ZOOM, Error inter lock for KV, filament, thermal are displayed on wide angle LCD. Console panel has following functions & indications.<br>o Anatomical programming for radiography of 4 body parts (up to 8 programmes).<br>o Selection of Continuous/multi pulse/single pulse fluoroscopy.<br>o Machine ON/OFF switch.<br>o Collimator 's position adjustment.<br>o I.I magnification (I.I field) selection switch.<br>o "Emergency Flouro".<br>o Flouro and Radio mode selection.<br>o In built radio timer that enables to select mAS from 0.1 to 300 in 25steps for radiography.<br>o Fluoroscopy timer (Five-minute cumulative timer with buzzer that activates after the completion of 300seconds of exposure and to reinitiate the exposure reset switch is provided.)<br>o ABS (Automatic brightness Stabilization) selection for hands free operation.<br>o KV and mAs increase and decrease switches.<br>o X-Ray on switch with indicators.<br>o Switches for up/down movement of "C".<br>o Emergency OFF Switch on the control panel<br>**STAND:**<br>o Up/Down movement (Noise free Actuator movement): At least 430mm<br>o Horizontal Movement: At least 210 mm.<br>o Arc Orbital: 90º + 30º (120º)<br>o Wig wag: ± 12.5º (25º)<br>o Rotation: ± 360º (with I.I. Safety lock)<br>o Focus Screen Distance: 950mm or more<br>o C Depth: 600mm or more<br>o Locks: Locks for all the movements.<br>o Foot lock: Control Stand foot lock.<br>o A steering wheel for easy steering & movement should be available. High resolution Imaging Chain:<br>o 9 Inches, Triple Field Image Intensifier should be provided..<br>o CCD Camera with a progressive scan sensor of 2/3" of 1K x1K Medical Grade<br>o The acquisition should be made at 14 bits. |

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| | | **MEMORY SYSTEM:**<br>PC based memory system with the following features should be provided: -<br>o Image processing software with Real time image capturing, storage, and display in 1kX1k format.<br>o Boosted Fluoroscopy (CINE) up to 30 FPS with real time recording on Hard Disk Drive.<br>o More than 1000 image storage capacity in 1kX1K format<br>o Dicom 3.0 Ready<br>o Dicom CD/DVD<br>o Connectivity with PACS and HIS<br>o Length and angle Measurements with Annotation<br>o Pre-Programming for Image setting for different operating Modes.<br>o Image Flipping and Image rotation<br>o WW/WL adjustments<br>o Recursive Filters for image smoothening<br>o Programmable Motion Detection facility<br>o Gamma Curve adjustments for optimum image quality.<br>o Image Zoom with Pan<br>o Image Inversion<br>**MONITORS:**<br>02 Nos. Medical Grade Monochrome high brightness, High contrast 19" LCD Monitors should be provided. High-end monitor trolley with foldable monitors, actuator assisted height adjustable movement of monitors to facilitate viewing of images at most convenient eye level position, specially designed integrated keyboard having feather touch keys and touch pad should be provided instead of double unit keyboard and mouse, 5" wheels for better mobility. |
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/or standard of communication (Wherever required)** | In-built |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dBA)** | Noise-free system |
| 3.4 | **Heat dissipation** | Heat Dissipation: Should maintain nominal Temp and the heat should bedisbursed through a cooling mechanism |
| 3.5 | **Mobility, portability** | Mobile |
| **4. ENERGY SOURCE** | | |

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| 4.1 | **Power Requirements** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | No |
| 4.4 | **Protection** | NA |
| 4.5 | **Power consumption** | To be specified by manufacturer. |
| | **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts(main ones); Consumables / reagents (open, closed system)** | Machine should be supplied with following transducers:-<br>I. 5 No. BARC Approved whole body lead aprons with all attachments. |
| | **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | |
| | **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | |
| 6.1 | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer. |
| | **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 CDSCO and AERB approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| | **8. TRAINING AND INSTALLATION** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform installation, safety and operation check before hand over. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| | **9. WARRANTY AND MAINTENANCE** | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each |

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| | | quarter |
| **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) Service and operation manuals (original and copied) be provided.<br>3) Advanced maintenance tasks documentation. |
| 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. |
| 11.2 | **Recommendations or warnings** | Any warning signs should be adequately displayed |

| CT Scan (64 Slice) | | |
|---|---|---|
| Version no.: | | 02 |
| Date: | | August 2023 |
| Done by: (Name/Institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| GMDNS name | | Radiographic Units |
| GMDNS code(s) | | |
| **GENERAL** | | |
| **1. USE** | | |
| **1.1** | **Clinical purpose** | Computed Tomography scanners are used for a wide variety of diagnostic procedures, including spine and head injuries, lesions, and abdominal and pelvic malignancies; to examine the cerebral ventricles, the chest wall, and the large blood vessels; and to assess musculoskeletal degeneration. |
| **1.2** | **Used by clinical department/ward** | Radiology Department |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| **2.1** | **Technical characteristics (specific to this type ofdevice)** | **Gantry**<br><br>1. Should incorporate low Voltage Slip Rings<br><br>2. Minimum scan time for a 360° rotation should be less than or<br><br>equal to 0.35 sec. (350 mili sec.)<br><br>3. Should have minimum tilt of 30 degrees on either side and remote tilt should be available as standard<br><br>4. Gantry should be provided with remote/user control panels on either side for positioning of the patient<br><br>5. The sub millimetre slice @0.63 mm or less in 64 row 64 slice acquisitions should be available. The system should be in position to perform 64 slices/rotation for general, cardiac and vascular applications<br><br>6. Should have 3D positioning laser lights<br><br>7. The scan FOV in acquisition mode be at least 50 cm with intermediate steps for scanning different anatomies |

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| | | 8. Gantry aperture should be at least 70 cm. in diameter<br><br>9. Integrated Display Panel-Gantry front showing current scan parameters such as kV, mA, ECG trace etc. for easy set up for ECG gated studies.<br><br>**X-Ray Generator**<br><br>1. Should be compact and in-built in the gantry<br><br>2. Should be high frequency having at least 70 kW output or more<br><br>3. The mA range available should be between 20 to 600 or more, with increment steps of not more than 10 mA.<br><br>4. Tube Voltage: 80-140 kV<br><br>**X-Ray Tube**<br><br>1. The X-ray tube should be dual focus with heat storage capacity of 6 MHU or more, with effective storage of at least 15 MHU.<br><br>2. Peak heat dissipation rate of anode should be at least 750 KHU/min<br><br>3. X-ray tube cooler unit should be inside the gantry<br><br>4. Focal spots, and type of X-ray tube should be specified as per IEC Recommendations.<br><br>5. Filter and beam limiting devices should be quoted as standard.<br><br>**Detectors**<br><br>1. These should be of solid state type<br><br>2. 64 Slice acquisition per rotation should be possible with the detectors, in 0.63 mm mode.<br><br>3. The system should have at least 64 'physical rows' of the detectors.Number of elements in each row should be specified<br><br>4. The Z-axis coverage of at least 38 mm / rotation should be possible for standard and cardiac scans<br><br>5. Fan-angle of X-rays and the geometry should be specified |

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| | | 6. Detectors should not require frequent calibration<br><br>**Patient Table**<br><br>1. Should have minimum weight bearing capacity of 200 kilograms<br><br>2. The minimum table top height should not be more than 35 cms from floor level for easy transport of trauma patients<br><br>3. Table top width to be at least 42 cms<br><br>4. The range of metal free scannable range should be at least 150 cm.<br><br>5. The vertical range (max. Ht. - min. Ht.) 55 cm<br><br>6. Remote controlled UP/DOWN and FWD/BWD movement.<br><br>7. Pitch to be freely selectable in automatic/manual mode: 0.15-1.5<br><br>8. Reproducing accuracy of the Table: 1mm<br><br>**Spiral CT capabilities**<br><br>1. Minimum slice thickness should be 0.63 mm or less and maximum 10 mm or more.<br><br>2. Pitch factor (volume pitch): Variable between 0.5 to 1.5 or more and should be user selectable.<br><br>3. Spiral length: 150cm or more.<br><br>4. Single continuous 'spiral-on time' should be minimum 100 seconds or more.<br><br>5. Bolus triggered spiral acquisition should be possible.<br><br>6. True isotropic volume acquisition and sub-millimetre resolution of at-least 0.4 mm for all body applications.<br><br>**Topogram**<br><br>1. Length and width: specify range.<br><br>2. Scan times: specify range |

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| | | 3. Should be possible to interrupt acquisition manually once the desired anatomy is obtained.<br><br>**Data acquisition system**<br><br>1. System should have minimum 64 rows of detector capable of generating 64 slices through latest flying focal spot technology or equivalent.<br><br>2. Mention minimum acquired slice thickness in Axial & Helical mode after reconstruction.<br><br>3. Acquisition of cardiac images with ECG gating (prospective & retrospective) should be possible<br><br>4. Step and shoot technique during cardiac scanning for dose reduction, or a similar alternative technology should be available<br><br>**Image Evaluation Tools**<br><br>1. Parallel evaluation of multiple ROI in circle, irregular and polygonal forms.<br><br>2. Statistical evaluation for area/volume, S.D., Mean, Min/Max and histogram.<br><br>3. Distance and angle measurement, freely selectable positioning of co-ordinate system, grid and image annotation.<br><br>**Latest Iterative Reconstruction Technique**<br><br>1. ASIR-V/IDose4 Premium/SAFIRE or latest available with the manufacturer to be quoted as standard.<br><br>2. Model-based Iterative reconstruction technology VEO/IMR/ ADMIRE or equivalent for all imaging protocols including hardware and software.<br><br>3. Low dose protocols for paediatric and infant scanning.<br><br>**Image Reconstruction**<br><br>1. Real time reconstruction speed: 20 images per second or more 512x512 matrix.<br><br>2. Display matrix: 1024 x 1024 or more<br><br>3 Reconstructed slice thickness range should be less than one mm (<1) to 10mm. |

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| | | 4 Patient's radiation Dose must be displayed on monition and Imaging Films.<br><br>**Image Quality**<br><br>1. The high contrast resolution be more than 20 p/mm in all routine scans, including spiral and axial mode<br><br>2 The low contrast resolution should not be more than 3 mm at 0.5% |
| **2.2** | **User's interface** | Patient Communication System. An integrated intercom and automated patient instruction system (APD) should be provided. |
| **2.3** | **Software and/ or standard of communication (wherever required)** | **Workstations:**<br><br>A client server architecture-based solution (Intellispace Portal 6/ Dexus-AW server 2/ Syngo Via 30A or equivalent) with minimum concurrent 24,000 slices rendering capacity, with storage of minimum 1TB having following client hardware specifications- Workstation 2820 or equivalent CPU, dual quad core processor, 16 GB RAM, 1TB hard drive, DVD Writing with dinical grade monitor of minimum 2 MP A reputed Anti-Virus Solution for Server should be in place<br><br>The Server should be with minimum three uter (Three Hardware's) facility Fully DICOM 30 Complant and PACS Interface ready<br><br>The workstation should have following processing tools/software's<br>**Available as standard**<br>• Mult planar reconstruction (MPR),<br>• Minimum and Maximum intensity projection<br>• 30 Volume rendering<br>• 30550 Shaded Surface Display)<br>• Advance Vessel Analyses with plaque visualization,<br>• Auto Bone Removal<br>• Volume measurement,<br>• Nodule analysis. |

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| | | • Liver lesion analysis.<br>• Colonography.<br>• Perfusion CT.<br>• Image Fusion of CT, MR & PET Data<br>• Neuro DSA.<br>• Coronary tree analysis: Automated 3D processing of coronary arteries, calcium scoring, stent analysis, LV analysis<br>• Multi-modality automatic tumour tracking & Automatic measurements in RECIST, WHO, Volume & Choi criteria calculation. |
| **3. PHYSICAL CHARACTERISTICS** | | |
| **3.1** | **Dimensions(metric)** | NA |
| **3.2** | **Weight (lbs, kg)** | NA |
| **3.3** | **Noise (in dBA)** | Noise free system |
| **3.4** | **Heat dissipation** | Should maintain nominal temperature and the heatshould be disbursed through a cooling mechanism. |
| **3.5** | **Mobility, portability** | Stationary installation |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)** | | |
| **4.1** | **Power requirements** | Input voltage- 380V-440V AC, 50Hz ;3-phase |
| **4.2** | **Battery operated** | No |
| **4.3** | **Protection** | Stabilizer of appropriate capacity to be installed |
| **4.4** | **Power consumption** | To be specified by manufacturer/vendor. |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| **5.1** | **Accessories, (mandatory, standard,optional);**<br>**Spare parts (main ones);**<br>**Consumables/reagents(open, closed system)** | 1. Dry Chemistry Laser Imager (dpi 500 or more) of a reputed make: Integrated with main console and workstation<br><br>2. Colour Laser Printer (High Resolution) for colour coded images<br><br>3. UPS with half hour 'back-up' to run entire CT system, Workstations and Laser Imager<br><br>4. Dual-Head Pressure injector of reputed make (100 syringes)<br><br>5. 160 KVA Silent DG Set with AMF panel |

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| | | 6. Two LED based view boxes with adjustable illumination to view 3 films of 14"x 17" in each view box.<br><br>7. Thyroid Collars - 2 No.<br><br>8. Gonadal Shields - 2 each for male and female (Total 4)<br><br>9. Lead Apron Hanger with 2 lightweight Lead Aprons<br><br>10. Lead glass |
| **BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS** | | |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| **6.1** | **Atmosphere/Ambience(air conditioning, humidity, dust …)** | Operating Condition: Capable of operating continuously in ambient temperature of -10 to 60 deg C (minimum range) and relative humidity of upto 90% in ideal circumstances. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterilityissues** | To be specified by manufacturer. |
| **7. STANDARDS AND SAFETY** | | |
| **7.1** | **Certificates (pre- market, sanitary,); Performance and safety standards (specific to the devicetype); Local and/or international** | 1. Should be CDSCO and AERB approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards in case of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND INSTALLATION** | | |
| **8.1** | **Pre- installation requirements: nature, values, quality,tolerance** | Lead glass, door shields and as specified by manufacturer. |
| **8.2** | **Requirements for sign-off** | Certificate of calibration and inspection of parts from the manufacturer |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | Training of users on operation and basic maintenance. |
| **9. WARRANTY AND MAINTENANCE** | | |
| **9.1** | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| **10. DOCUMENTATION** | | |

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| **10.1** | **Operating manuals,set manuals, other manuals** | Should provide 2 sets (hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) tobe provided.<br>3. Certificate of calibration and inspection,<br>4. Satisfactory certificate for any existing installationfrom government hospital. |
| **10.2** | **Other accompanying documents** | List of essential spares and accessories, with their part number and cost. |
| **11. Notes** | | |
| **11.1** | **Service SupportContact details (Hierarchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and localservice agent to be provided. |
| **11.2** | **Recommendations orwarnings** | Any warning sign should be adequately displayed. |

| 20. Monitor Vital Signs/Multipara Monitor | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name/institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Patient Monitors/Monitoring Systems. |
| GMDN code(s) | | CT1444 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | Designed to continuously measure and display multiple vital physiological parameters of patients, especially those under critical care. |
| 1.2 | **Clinical department/ward** | All Departments |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics** | 1. Multichannel (up to 12 leads) ECG measurement and selectable display of upto 5 leads at a time.<br>2. Temperature probe to be reusable, external skin contact type. Temperature range at least 30 to 40 deg C, minimum gradation 0.1 deg C.<br>3. Heart rate measurement range to be at least 30 to 250 bpm, with accuracy better than ± 5 bpm and minimum gradation 1 bpm.<br>4. SpO2 measurement range at least 40-70 % and 70 to 99 %, with accuracy better than ± 1% for 40-70 range and better than ± 3% for 70-99 range and minimum gradation 1%.<br>5. Blood pressure monitoring range at least 30 to 300 mmHg, minimum gradation 1 mmHg.<br>6. Respiration rate measurement range at least 0 to 100 bpm, minimum gradation 1 bpm.<br>7. Trend display of each parameter over at least previous 24 hours to be selectable.<br>8. LCD screen for displaying all parameters.<br>9. Audio Visual alarms required: high and low levels for each parameter (operator variable settings), sensor / wire / probe disconnected, low battery. |
| 2.2 | **User's interface** | LCD display |
| 2.3 | **Software and/or standard of communication** | In-built |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | Screen size minimum: 8”X6”. |
| 3.2 | **Weight (lbs, kg)** | Light weight |
| 3.3 | **Noise (in dBA)** | <50dB. |
| 3.4 | **heat dissipation** | Should maintain nominal temperature and the heat |

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| | | should be disbursed through an exhaust cooling fan |
| 3.5 | **Mobility, portability** | Portable |
| | **4. ENERGY SOURCE** | |
| 4.1 | **Power Requirements** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | Yes |
| 4.3 | **Protection** | Electrical protection provided by fuses in both live and neutral supply lines |
| 4.4 | **Power consumption** | To be specified by manufacturer |
| | **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory, standard, optional) Spare parts (main ones) Consumables/reagents (open, closed system)** | 2 pairs, 12 lead ECG cable. 5 sets of ECG connection electrodes (if reusable type). 5 lead ECG cable. Two reusable SpO2 probes for infant use. Two reusable neonatal cuffs. Two external skin temperature probes. Two sets of spare fuses (if non-resettable fuses used). 5 tubes electrode gel (if required). |
| | **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | |
| 6.1 | **Atmosphere/Ambiance (air conditioning, humidity, dust ...)** | Operating condition: – Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90%. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer. |
| | **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| | **8. TRAINING AND INSTALLATION** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up. |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| | **9. WARRANTY AND MAINTENANCE** | |
| 9.1 | **Warranty** | • 03 years |

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| | | • Preventive Maintenance visits at least once in each quarter. |
| **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 should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided.<br>3. Satisfactory certificate for any existing installation from government hospital |
| 10.2 | **Other accompanying Documents** | List of essential spares and accessories, with their par number and cost. |
| **11. NOTES** | | |
| 11.1 | **Other information** | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | **Recommendations or Warnings** | Any recommendations for best use and supplementary warning for safety should be declared. |

| MULTIPARA MONITOR FOR ICU | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by:(name. Institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| UMDNS name | | |
| UMDNS code(s) | | |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical purpose | These systems usually include a central station monitor that receives, consolidates, and displays the information and a set of monitors that are deployed near the patient (bedside monitors) to provide the required data from each patient (ECG, respiratory rate, noninvasive blood pressure (NIBP) and invasive blood pressure (IBP) (systolic, diastolic, and mean), body temperature, (SpO2), mixed venous oxygenation (SvO2), cardiac output, (ETCO2), intracranial pressure, and airway gas concentrations). |
| 1.2 | Used by clinical department/ward | ICU, HDU, Operation Theatre |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERICSTICS** | | |

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| 2.1 | **Technical characteristics (specific to this type of device)** | 1. Should have modular Multi parameter monitor with TFT/LED/LCD/touch screen display with more than 15 inches with at least 8 wave forms and upgradable up to 14 waveforms & 22 parameter numeric on single display.<br>2. The waveforms should be user selectable.<br>3. Monitor should have in built Lithium-ion type battery for 2 Hour continuous operation.<br>4. Should have keys for quick access to main functions.<br>5. Should be able to monitor ECG (3,5,12 leads), SPO2, NIBP, 2 IBP, Respiration Rate, 2 temp, ETCO2, for adult, pediatric and neonatal patients as standard and Anesthesia gas monitoring.<br>6. Monitor must have facility for at least 2 IBP measurements simultaneously. Also should have SPV/PPV monitoring facility.<br>7. 5 Lead ECG monitoring with full range of lethal arrhythmia recognition capability and ST analysis up to 12 leads and 72hour trend facility.<br>8. Respiration, Apnea alarm, Prioritized audio-visual alarms and snap shot facility.<br>9. Transport module with display and battery backup of at least 1 hour.<br>10. Pulse Oxymeter (SPO2) with Plethysmogragh &Pulse strength indicator With Variable pitch with change in SpO2 (low perfusion motion tolerance technology).<br>11. Side-stream Capnography with display of CO2 wave form & digital values (ETCO2, FiCO2, RR).<br>12. Monitor should have provisions for automatic identification and measurement of anesthesia agents, CO2, 02, N2O and facility to measure at least S volatile agents with automatic detection.<br>13. Should be upgradable to monitor cardiac output (Thermo dilution/ PICCO), BIS/DA and NMT.<br>14. It should have provision for automatic identification and measurement and anesthetic agents, Co2, 02, N2O and facility to measure MAC.<br>15. The display setting should have at least 10 user defined setups variable as per applications for flexible use of the monitor in various clinical environments such as in OT, PACU, ICU, ER, NICU.<br>16. Monitor should have networking options with bidirectional & bed to bed communication. |

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|---|---|---|
| 2.2 | User's interface | Manual |
| 2.3 | Software and/or standard of communication (where ever required | Inbuilt |
| **3. PHYSICAL CHARACTERICSTICS** | | |
| 3.1 | Dimensions(metric) | NA |
| 3.2 | Weight (lbs, kg) | NA |
| 3.3 | Noise (in Dba) | Noise pressure level: <60 dbA. |
| 3.4 | Heat dissipation | Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism. |
| 3.5 | Mobility, portability | Portable |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)** | | |
| 4.1 | Power | 220 +/- 10% VAC, 50 Hz |
| 4.2 | Battery operated | Yes, at least 30 minutes back up. |
| 4.3 | Protection | Stabilizer to be provided for protection. |
| 4.4 | Power consumption | To be specified by manufacturer. |
| **5. ACCESSORIES, SPARE PARTS AND CONSUMABLES** | | |
| 5.1 | Accessories, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system) | 1. 20 Nos of Disposable IBP transducers with all standard accessories &6 nos of reusable adapter cable (type as requested by the end user)<br>2. Accessories for Anesthesia Gas/Co2 monitoring -25 Nos (disposable)<br>3. Reusable adult 5 lead ECG cable set —2 nos.<br>4. NIBP cuffs for standard Adult(2 Nos), Obese Adult, Child and infant —all 1 each.(5 Nos)<br>5. Temperature Probe(esophageal/ rectal)-2Nos<br>**Accessories**<br>1. Spo2 probe adult (Reusable) —2 Nos<br>2. Spo2 probe pediatric (Reusable) —2 Nos<br>3. Fore Head Spo2 Sensor —2 Nos |
| **6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| 6.1 | Atmosphere/Ambience (air conditioning, humidity, dust . ..) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | To be specified by manufacturer. |
| **7. STANDARDS AND SAFETY** | | |
| 7.1 | Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards. |

| | | |
|---|---|---|
| | international | 5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. TRAINING AND MAINTENANCE** | | |
| 8.1 | Pre- installation requirements: nature, values, quality, tolerance | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up. |
| 8.2 | Requirements for sign-off | Supplier to perform installation, safety and operation checks before handover. |
| 8.3 | Training of staff (medical, paramedical, technicians) | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| **10. DOCUMENTATION** | | |
| 10.1 | Operating manuals, set manuals, other manuals | Should provide 2 sets(hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should be supplied in English/Hindi/ Regional language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided.<br>3. Advanced maintenance tasks documentation. |
| 10.2 | Other accompanying documents | List of essential spares and accessories, with their part number 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. |
| 11.2 | Recommendations or warnings | Any warning sign would be adequately displayed. |

| CHEMILUMINESCENT IMMUNOASSAY ANALYSER IVD | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done by: (Name/institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| GMDNS name | | Chemiluminescent immunoassay analyzer IVD |
| GMDNS code(s) | | 56701 |
| **GENERAL** | | |
| **1. USE** | | |
| **1.1** | **Clinical purpose** | An automated laboratory instrument intended to be usedfor the qualitative and quantitative in vitro determination of chemical and biological markers (e.g., protein, drug, hormone, microbial toxin) in a clinical specimen. |
| **1.2** | **Used by clinical departme nt/ward** | Clinical Diagnostic Laboratory |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| **2.1** | **Technical characteristics (specific to this type ofdevice)** | • Fully Automated multi-channel analyzer based on chemiluminescence technology.<br>• The instrument should provide comprehensive process check that performs, monitors, and verifies each step throughput sample and assay processing.<br>• Continuous loading capacity of 30 or more samples.<br>• Throughput of atleast 60 test per hour or more<br>• The system should be able to read multiple barcode types or QR code.<br>• It should have capability to do the assay in continuous, random, batch & stat mode.<br>• Serum, plasma, urine, whole blood (assay-dependent) type of samples handling system.<br>• System to use latest mixing probe technology to mix the samples and reagents to have complete uniformity with clot detection facility.<br>• It should have the facility for bubble detection, check viscosity, sample level and short samples to ensure accuracy preventing erroneous results due to improper samples.<br>• It should have an ability to do on board dilution andreflex dilution for high and abnormal samples.<br>• It should have facility for automated probe cleaning or disposable tips system to avoid reagent carryover.<br>• Should have onboard liquid waste container (4 litre), direct drain optional. |

| | | |
|---|---|---|
| | | • Should be a microprocessor-controlled device withdigital display.<br>• 2-point re-calibration facility, switched mode power supply, automated instrument calibration, user friendly and intelligent software<br>• System should have software that automatically generates LJ charts for QC and have appropriate alerts.<br>• Provision for Bar Code/QR code reading should be available.<br>• The equipment should have in-built digital display unit and PC interface facility.<br>• External USB storage available |
| **2.2** | **User's interface** | • Digital display<br>• Provision for bi-directional LIS/HIS interface should be available. |
| **2.3** | **Software and/ or standard of communication (Wherever required)** | Built - in/Automatic/compatible, windows based with data processing management system with complete back up of data base for calibration, control, patient sample results on daily basis. |
| **3. PHYSICAL CHARACTERISTICS** | | |
| **3.1** | **Dimensions(metric)** | NA |
| **3.2** | **Weight (lbs, kg)** | NA |
| **3.3** | **Noise (in dBA)** | NA |
| **3.4** | **Heat dissipation** | System should have on-board cooling facility to maintain the temperature of the reagents. |
| **3.5** | **Mobility, portability** | Stationary lab Installation |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)** | | |
| **4.1** | **Power requirements** | **Power Supply:**<br>220VAC +/- 10%, 50 Hz. |
| **4.2** | **Battery operated** | Online UPS with minimum one hour back up |
| **4.3** | **Protection** | Internal electrical protection. |
| **4.4** | **Power consumption** | To be specified by vendor |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| **5.1** | **Accessories, (mandatory, standard, optional);**<br>**Spare parts (main ones);**<br>**Consumables/reagents (open, closed system)** | • External Printer to take printout of patient results andQC reports.<br>• Online UPS with minimum one hour backup |
| **BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS** | | |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |

| | | |
|---|---|---|
| **6.1** | **Atmosphere/Ambience(air conditioning, humidity, dust …)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterilityissues** | To be specified by manufacturer. |
| **7. STANDARDS AND SAFETY** | | |
| **7.1** | **Certificates (pre- market, sanitary,); Performance and safety standards (specific to the devicetype); Local and/or international** | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND INSTALLATION** | | |
| **8.1** | **Pre-installation requirements: nature, values, quality,tolerance** | As specified by manufacturer and compatible electric accessories as per standard Indian set-up. |
| **8.2** | **Requirements for sign-off** | Supplier to perform installation, safety and operationchecks before handover. |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | Satisfactory Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented. |
| **9. WARRANTY AND MAINTENANCE** | | |
| **9.1** | **Warranty** | 1. 3 years, including all spares and calibration.<br>2. Preventive maintenance visits atleast one in eachquarter |
| **10. DOCUMENTATION** | | |

| | | |
|---|---|---|
| **10.1** | **Operating manuals,set manuals, other manuals** | Should provide 2 sets (hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should besupplied in English/Hindi language along with machine diagrams.<br>2. Advanced maintenance tasks documentation.<br>3. Certificate of calibration and inspection,<br>4. Satisfactory certificate for any existing installationfrom government hospital. |
| **10.2** | **Other accompanying documents** | List of essential spares and accessories, with their part number and cost; |
| **11. Notes** | | |
| **11.1** | **Service Support Contact details (Hierarchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and localservice agent to be provided; |
| **11.2** | **Recommendations or warnings** | Any warning sign should be adequately displayed. |

| DENTAL CHAIR WITH ACCESSORIES | | |
|---|---|---|
| Version no.: | | 02 |
| Date: | | August 2023 |
| Done by: (Name/Institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| GMDN name | | Chairs, Examination/Treatment, Dentistry |
| GMDN code(s) | | |
| **GENERAL** | | |
| **1. USE** | | |
| **1.1** | **Clinical purpose** | Examination/treatment chairs designed to facilitate dental examination, treatment, and/or minor surgical procedures. Thesechairs are typically adjustable up to a height that allows the healthcare staff to perform procedures while standing; the chairsusually include head and armrests, a reclining back that may be tilted from a vertical to a horizontal or near-horizontal position, and rotating capabilities to facilitate examination and/or treatment. |
| **1.2** | **Used by clinical department/ward** | Dental Department |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| **2.1** | **Technical characteristics (specific to this type of device)** | 1. It should have double articulating headrest with seesawmovement.<br>2. It should be provided with soft cervical support.<br>3. Dental unit should have latest overhead delivery system.<br>4. It should have two 3 way syringes (Tip autoclavable, with spare tips) one on unit side and other on the assistant side.<br>5. It should have two high speed Air rotor terminals with two rotor hand pieces and accessories and one terminal for fiber optic. One for air motor/micro motor having straight and contra angle hand pieces and other for air rotor terminal with two air rotorhand pieces with two spare cartridges.<br>6. It should have LED light cure unit with minimum intensity 1200 mW/cm$^2$.<br>7. It should have infection control system with non-retraction valves (Bio system/equivalent).<br>8. All hand pieces/terminals should be kept on Autoclavable pads.8 spare autoclavable pads should be supplied.<br>9. Arm of unit should be pneumatically locked.<br>10. All air tubing of the delivery system can be disinfected internallyafter every dental procedure.<br>11. It should have one in built piezo ultrasonic scalar (max frequencyshould be 36 kHz)<br>12. Removable auxiliary tray (autoclavable) shall be |

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|---|---|---|
| | | supplied – 10 sets.<br>13. It should have integrated latest foot operated LED light (30000 - 50000 Lux).<br>14. It should have rotatable water system with removable spittoon.<br>15. It should have Medium Vacuum Suction and high suction(Motorized Suction).<br>16. Should have following multiple program<br>• Two programmable working positions.<br>• Splitting and last working position with light ON and OFFautomatically.<br>• Return to Zero position with light OFF automatically.<br>• It should have emergency stop control with luminousindication.<br>• Programmable bowl water and cup filler water.<br>17. It should have LED based X-ray viewer (For I.P.G/O.P.G films).<br>18. It should be provided with right arm.<br>19. It should have multi-functional foot control base.<br>20. It should be provided with two stools with adjustable backresttilt including an adjustable ring for foot rest<br>21. Oil free medical grade compressor of 1HP (fully imported) |
| **2.2** | **User's interface** | Manual |
| **2.3** | **Software and/ or standard of communication (wherever required)** | In built |
| **3. PHYSICAL CHARACTERISTICS** | | |
| **3.1** | **Dimensions(metric)** | NA |
| **3.2** | **Weight (lbs, kg)** | NA |
| **3.3** | **Noise (in dBA)** | Noise-free system |
| **3.4** | **Heat dissipation** | Should maintain nominal temp and the heat should be disbursedthrough a cooling mechanism |
| **3.5** | **Mobility, portability** | Stationary Installation |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)** | | |
| **4.1** | **Power requirements** | 220 +/- 10% VAC, 50 Hz |
| **4.2** | **Battery operated** | No |
| **4.3** | **Protection** | Stabilizer or inbuilt protection to voltage fluctuation/current surge. |
| **4.4** | **Power consumption** | To be specified by vendor. |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| **5.1** | **Accessories, (mandatory, standard, optional);<br>Spare parts (main** | **LED LIGHT CARE UNIT:**<br>1. Ensures up to 1200 mW/ sq.cm<br>**ULTRASONIC SCALAR:**<br>1. Piezotronics Scalar with frequency of 28000-36000 Hz |

| | | |
|---|---|---|
| | **ones); Consumables/reagents (open, closed system)** | 2. Autoclavable hand piece, Total control is Micro processor based<br>3. Hand Pieces most sleek.<br>4. The scalar supplies with: Piezotronics scalar with 4 tips.<br>**FOOT OPERATED LIGHT:**<br>1. LED light with 3 intensity with 3 axis movement.<br>2. Intensity is between 30000 - 50000 Lux<br>3. On/off Switch by sensor switch - non touch.<br>4. Step intensity control by non-touch sensor.<br>**AIR ROTOR:**<br>1. Air Rotor hand piece clean head with a speed of 350000 RPM<br>2. Supplies with<br>a. Titanium/ SS Air rotor torque hand piece.<br>b. Ultra push type non retraction valve.<br>**BRUSHLESS MICROMOTOR:**<br>1. It should have digital display of speed.<br>2. High Torque Micro motor ( Foot Controlled) with Speed rangeof 2000 -40000 RPM<br>3. It should have reverse and forward speed along.<br>4. It should have auto cut off system for over load.<br>5. It should be supplied with<br>a. Hand piece ( Autoclavable) : Speed : 40000 RPM<br>b. Straight Hand Piece (Autoclavable): Speed 40000 RPM.<br>**AIR COMPRESSOR:**<br>1. Medical grade, Oil free, Noise free at least 1 HP Compressor.<br>2. The compressor should be fitted with<br>a. Built in thermo cut off to save motor during excess of heat<br>b. auto head air release valve,<br>c. Automatic cut off<br>d. Safety release valve<br>e. Drain Valve<br>f. The inner surface of the compressor tank (at least 35 L) iscoated with Epoxy to prevent rusting. |
| **BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS** | | |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| **6.1** | **Atmosphere/Ambience (air conditioning, humidity, dust …)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer. |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standard. |
| **8. TRAINING AND INSTALLATION** | | |
| **8.1** | **Pre- installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up. |
| **8.2** | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over. |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance. |
| **9. WARRANTY AND MAINTENANCE** | | |
| **9.1** | **Warranty** | • 3 years, including all spares parts and accessories.<br>• Preventive Maintenance visits at least once in each quarter |
| **10. DOCUMENTATION** | | |
| **10.1** | **Operating manuals, set manuals, other manuals** | Should provide 2 sets (hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams;<br>2. Certificate of calibration and inspection,<br>3. Satisfactory certificate for any existing installation from government hospital. |
| **10.2** | **Other accompanying documents** | List of essential accessories, with their part number 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; |
| **11.2** | **Recommendations or warnings** | Any warning sign would be adequately displayed. |

| ISE BASED ELECTROLYTE ANALYSER IVD | | |
|---|---|---|
| Version no.: | | 02 |
| Date: | | August 2023 |
| Done by: (Name/Institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| GMDN name | | Ion-selective Analyser IVD |
| GMDN code(s) | | 56682 |
| **GENERAL** | | |
| **1. USE** | | |
| **1.1** | **Clinical purpose** | A laboratory instrument intended to be used for the quantitative measurement of electrolytes and other ions in a clinical specimen using ion-specific membranes to selectively measure electrical potential against a reference electrode to determine the target ion concentration. |
| **1.2** | **Used by clinical department/ward** | Clinical Diagnostic Laboratory |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| **2.1** | **Technical characteristics (specific to this type of device)** | • Should be able to measure sodium [Na+], potassium[K+], chloride [Cl-]) in blood.<br>• Should be based on measuring method of IonSelective Electrode (ISE) (Direct Potentiometer).<br>• Should have individual electrodes for sodium, potassium, chloride, calcium and magnesium.<br>• Should have automatic calibration.<br>• Should have a throughput of minimum 40 samplesper hour.<br>• Should have a memory of at least 100 samples.<br>• QC should be based on test parameters.<br>• The equipment should have in-built digital display unit, PC interface facility and provision for printing of reports<br>• Should have provision for barcode/ QR code reader. |
| **2.2** | **User's interface** | • Touchscreen Display<br>• Provision for bi-directional LIS interface should be available. |
| **2.3** | **Software and/ or standard of communication (wherever required** | Inbuilt-To be provided by manufacturer |
| **3. PHYSICAL CHARACTERISTICS** | | |
| **3.1** | **Dimensions(metric)** | NA |
| **3.2** | **Weight (lbs, kg)** | NA |
| **3.3** | **Noise (in dBA)** | NA |

| | | |
|---|---|---|
| **3.4** | **Heat dissipation** | Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism. |
| **3.5** | **Mobility, portability** | Stationary lab installation |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)** | | |
| **4.1** | **Power requirements** | 220VAC +/- 10%, 50 Hz. |
| **4.2** | **Battery operated** | Online UPS for minimum one hour back up |
| **4.3** | **Protection** | Internal electrical protection |
| **4.4** | **Power consumption** | To be specified by manufacturer |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| **5.1** | **Accessories, (mandatory, standard,optional); Spare parts (main ones); Consumables/reagents(open, closed system)** | 1. 2D-Barcode/QR code Scanner.<br>2. Built-in Thermal printer or provision for external printer.<br>3. All the consumables, controls and calibrators and any other reagents or items required for conducting 1000 tests should be mentioned and supplied with the equipment.<br>4. Online UPS for minimum one hour back up |
| **BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS** | | |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| **6.1** | **Atmosphere/Ambience(air conditioning, humidity, dust …)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterilityissues** | To be specified by manufacturer. |
| **7. STANDARDS AND SAFETY** | | |
| **7.1** | **Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the devicetype); Local and/or international** | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. TRAINING AND INSTALLATION** | | |
| **8.1** | **Pre-installation requirements: nature, values, quality,tolerance** | As specified by manufacturer and compatible electric accessories as per standard Indian set-up. |
| **8.2** | **Requirements for sign-off** | Supplier to perform installation, safety and operationchecks before handover. |

| | | |
|---|---|---|
| **8.3** | **Training of staff (medical, paramedical, technicians)** | Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented |
| **9. WARRANTY AND MAINTENANCE** | | |
| **9.1** | **Warranty** | 1. 3 years, including all spares and calibration.<br>2. Preventive maintenance visits at least once in each quarter |
| **10. DOCUMENTATION** | | |
| **10.1** | **Operating manuals,set manuals, other manuals** | Should provide 2 sets (hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams.<br>2. List of equipment and procedures required for local calibration and routine maintenance.<br>3. Certificate of calibration and inspection, |
| **10.2** | **Other accompanying documents** | List of essential spares and accessories, with their part number and cost. |
| **11. Notes** | | |
| **11.1** | **Service SupportContact details (Hierarchy Wise;including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| **11.2** | **Recommendations or Warnings** | Any warning sign should be adequately displayed. |

| ELECTROPHORESIS ANALYZER | | |
|---|---|---|
| Version no.: | | 02 |
| Date: | | August 2023 |
| Done By: | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN Name | | Electrophoresis analyzer IVD |
| GMDN Code | | 57837 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical Purpose | An electrically-powered automated laboratory instrumentor system intended to be used for the qualitative and quantitative in vitro determination of various molecules (e.g., DNA, RNA, proteins) in a clinical specimen based on their size, ionic charge and/or rate of migration through an electrically charged field. |
| 1.2 | Used by clinical department/ward | Clinical Diagnostic Laboratory |
| **TECHNICAL** | | |
| **2. Technical Characteristics** | | |
| 2.1 | Technical Characteristics( Specific to this type of device) | • Should be able to undertake multiparametric analysis like serum, protein, isoenzymes, immunofixation.<br>• Automated sample application and sequential processing of each step of electrophoresis with disposable applicators<br>• Gel imaging, interpretation and reporting software should be available with the system<br>• The system should use deuterium lamp with optical fibers for emission and reception.<br>• The system needs to have in built tube mixer.<br>• Should have provision for automatic recycling of Buffer and Stainer.<br>• System should have in built reading capacity.<br>• Should be capable of automatically arrange the loading of all the reagents, standardizing furtherthe electrophoretical process.<br>• The instrument should be capable of quality control measures<br>• The through put of the system should be, at least<br>i. Hemoglobin – 8 samples/ hour<br>ii. Protein – 20 samples/ hour<br>• Automatically able to manage the reagents and automatic washing cycle before the switch-off ofthe unit.<br>• Provision for bi-directional LIS interface should be available. |

| | | |
|---|---|---|
| 2.2 | Software and/or standardof communication (wherever required) | NA |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | Dimensions (in mm) | NA |
| 3.2 | Weight | NA |
| 3.3 | Noise | NA |
| 3.4 | Heat Dissipation | NA |
| 3.5 | Mobility/Portability | NA |
| **4. ENERGY SOURCE** | | |
| 4.1 | Power input | 220VAC +/- 10%, 50 Hz. |
| 4.2 | Battery Operated | Online UPS system with minimum one hour back up. |
| 4.3 | Protection | Internal electrical safety |
| 4.2 | Power consumption | As per Manufacturer/Supplier specified |
| **5. ACCESSORIES, SPARE PARTS AND CONSUMABLES** | | |
| 5.1 | Accessories, (mandatory,Standard, operational); Spare parts (main ones) Consumable/reagents (open, closed system) | 1. To be supplied with computer (minimum i5 processor,500 GB HDD and 4 GB RAM), A4 size laser printer and appropriate bar code reader<br>2. Start-up kit for at least 200 tests should be provided.<br>3. Online UPS system with minimum one hour back up |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | Atmosphere /Ambiance (air conditioning, humidity, dust ...) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterilityissues | As indicated by Manufacturer |
| **7. STANDARDS & SAFETY** | | |
| 7.1 | Certificates (pre-market, sanitary, ..);Performanceand safety standards (specific to the device type);Local and/or international | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | Pre-installation requirements: nature, values, quality, tolerance | As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up. |

| | | |
|---|---|---|
| 8.2 | Requirements for sign-off | 1. Supplier to perform installation, safety and operation checks before handover.<br>2. Lab In-Charge to affirm completion of installation. |
| 8.3 | Training of staff (medical,paramedical, technicians) | Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | 1. 3 years, including all spares and calibration.<br>2. Preventive maintenance visits atleast one in eachquarter. |
| **10. DOCUMENTATION** | | |
| 10.1 | Operating manuals, service manuals, othermanuals | Should provide 2 sets (hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams.<br>2. List of equipment and procedures required for local calibration and routine maintenance.<br>3. Certificate of calibration and inspection,<br>4. Satisfactory certificate for any existing installation from government hospital. |
| 10.2 | Other accompanying documents | List of essential spares and accessories, with their part number and cost; |
| **11. NOTES** | | |
| 11.1 | Service Support Contact details (Hierarchy Wise; including a toll free/landline number) | Contact details of Vendor and local service agent needsto be provided |
| 11.2 | Recommendations or warnings | Any specific recommendation or warning to be followed for ensuring optimal and safe utilization of medical device needs to be mentioned. |

| ELISA READER AND WASHER | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done by: (name/institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | - |
| GMDN code | | - |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | A laboratory technique that uses antibodies linked to enzymes to detect and measure the amount of a substancein a solution, such as serum. The assay uses a solid-phasetype of enzyme immunoassay to detect the presence of a ligand in a liquid sample using antibodies directed against the protein to be measured. |
| 1.2 | **Used by clinical department/ward** | Clinical Diagnostic Laboratory |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | • The device should be fully automated and easy to operate with 8 and 12 channel manifold.<br>• It should be capable to wash flat, round and V bottom plates and strips.<br>• It should have large display along with more than40-50 program storage facility.<br>• System should have calibration facility.<br>• System should have warning/alarm for full waste container and empty wash bottle.<br>• Residual volume after washing should be < 2ul.<br>• It should have specially designed peristaltic pump to dispense 50 - 400 µl.<br>• It should be supplied with waste container, wash bottle and rinse bottle of capacity 2 liters withtubings.<br>• It should have option of programming wash cycleswith capacity for storing at least 50 wash protocols.<br>• Cross wise aspiration, overflow washing and bottom washing.<br>• Bichromatic/Optics with six standard wavelengths for ELISA kits.<br>• Trichromatic Light source.<br>• Internal Printer with port for external printer.<br>• Should read ELISA Plate Horizontally A to H and vertically 1 to 12.<br>• Photometric Accuracy should be ±3%.<br>• Should have a resolution of 0.001 Abs.<br>• Print out of whole plate in Matrix Format. |

| | | |
|---|---|---|
| | | • Linear measurement range 0 to 4 Absorbance unit.<br>• 8 filter wheel capacity with Interference.<br>• Filters of 405, 450, 492, 620 nm with at least 4 extra positions within the range of 400-750 nm. |
| 2.2 | **User Interface** | Compatibility with external Printer |
| 2.3 | **Software and/or standard of communication (wherever 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 temperature and the heat should be disbursed through a cooling mechanism. |
| 3.6 | **Mobility, portability** | Stationary lab Installation. |
| | **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 )** | |
| 4.1 | **Power Requirements** | 220VAC +/- 10%, 50 Hz |
| 4.2 | **Battery operated** | Online UPS with minimum one hour back up |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | To be specified by vendor |
| | **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts(main ones); Consumables/ reagents (open, closed system)** | 1) Paper rolls for printer- 10 nos.<br>2) Online UPS for minimum one hour back up |
| | **BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS** | |
| | **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | |
| 6.1 | **Atmosphere/Ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer |
| | **7. STANDARDS AND SAFETY** | |

| | | |
|---|---|---|
| 7.1 | **Certificates (pre-market, sanitary, ...); Performance andsafety standards (specific to the device type); Local and/or international** | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform installation, safety and operation checks before handover. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | 1. 3 years, including all spares and calibration.<br>2. Preventive maintenance visits atleast one in eachquarter |
| **10. DOCUMENTATION** | | |
| 10.1 | **Operating manuals, servicemanuals, other manuals** | Should provide 2 sets (hardcopy and soft copy) of:<br>1) User, technical and maintenance manuals to be supplied inEnglish/Hindi language along with machine diagrams.<br>2) Service and operation manuals (original and copy) to beprovided.<br>3) Certificate of calibration and inspection; |
| 10.2 | **Other accompanying documents** | List of essential spare/ accessories, reagents/all other consumables along with their part number and cost should be quoted. |
| **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 tobe provided; |
| 11.2 | **Recommendations or warnings** | Any warning signs should be adequately displayed. |

| FLOW CYTOMETRY ANALYSER IVD | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done by: | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| GMDNS name | | Flow cytometry analyzer IVD |
| GMDNS code(s) | | 57839 |
| **GENERAL** | | |
| **1. USE** | | |
| **1.1** | **Clinical purpose** | An electrically powered laboratory instrument intended tobe used to count, examine and sort cells or microscopicparticles in a clinical specimen (e.g., blood, urine). |
| **1.2** | **Used by clinical department/ward** | Clinical Diagnostic Laboratory |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| **2.1** | **Technical characteristics (specific to this type of device)** | • Pre-configured flow cytometer equipped with minimumdual laser system with inbuilt cell sorting system.<br>• Capability of minimum 4 fluorescent colors and 6 parameters. For each parameter the flow cytometer should be capable of measuring area, height and width.<br>• Minimum detectable particle size should be 0.5 µm.<br>• Forward and side scatter detector.<br>• Should have single tube sample mode as well as multi tube loader capability with minimum of 24 tube loading capacity as well as 48 and 96-well plate loader.<br>• Should offer low, medium and high flow rates.<br>• Should be able to acquire at least upto 10,000 eventsper second.<br>• Fluorescence Channel 1, Channel 2, Channel 3 and Channel 4 detectors.<br>• Should have compensation capability between all fluorescence channels with online as well as post-acquisition manual and auto-compensation features.<br>• Should have digital signal processing with linear and log modes and dynamic range of atleast 5 decades.<br>• The cytometer should have bio-hazard containment system and proper waste collection and managementsystem.<br>• Dual fluorescence compensation network<br>• Double Discrimination Module for area and width measurement (DNA Analysis)<br>• Built in sort module for 3 sort mode (recovery, single |

| | | |
|---|---|---|
| | | cell and exclusion)<br>• Data management system<br>• Sorter cell cycle 200 cells per sec.<br>• Compatible computer system: PC workstation with at least Core i7 or higher, 2 TB hard drive or more, DVD/CD ROM R/VV Combo Drive, at least 23-inch LCD monitor. |
| **2.2** | **User's interface** | LCD monitor |
| **2.3** | **Software and/ or standard of communication (wherever required)** | Built - in/Automatic/compatible, window based with data processing management system with complete back up of data base for calibration, control, patient sample results on daily basis. |
| **3. PHYSICAL CHARACTERISTICS** | | |
| **3.1** | **Dimensions(metric)** | NA |
| **3.2** | **Weight (lbs, kg)** | NA |
| **3.3** | **Noise (in dBA)** | NA |
| **3.4** | **Heat dissipation** | Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism. |
| **3.5** | **Mobility, portability** | Stationary lab Installation |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)** | | |
| **4.1** | **Power requirements** | **Power Supply:**<br>220 +- 10% VAC, 50Hz |
| **4.2** | **Battery operated** | UPS of suitable rating with voltage regulation and spike protection for one hour back up |
| **4.3** | **Protection** | Internal electrical safety |
| **4.4** | **Power consumption** | To be specified by vendor |
| **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 CONSIDERATIONS** | | |
| **6.1** | **Atmosphere/Ambience(air conditioning, humidity, dust …)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterilityissues** | To be specified by manufacturer |

| | | |
|---|---|---|
| **7. STANDARDS AND SAFETY** | | |
| **7.1** | **Certificates (pre-market, sanitary,); Performance and safety standards (specific to the devicetype); Local and/or international** | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND INSTALLATION** | | |
| **8.1** | **Pre-installation requirements: nature, values, quality,tolerance** | As specified by manufacturer and compatible electric accessories as per standard Indian set-up. |
| **8.2** | **Requirements for sign-off** | 1. Supplier to perform installation, safety and operation checks before handover.<br>2. Lab In-Charge to affirm completion of installation |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | Satisfactory Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented. |
| **9. WARRANTY AND MAINTENANCE** | | |
| **9.1** | **Warranty** | • 3 years, including all spares and calibration.<br>• Preventive maintenance visits at least one ineach quarter. |
| **10. DOCUMENTATION** | | |
| **10.1** | **Operating manuals,set manuals, other manuals** | Should provide 2 sets (hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) tobe provided.<br>3. Certificate of calibration and inspection, |
| **10.2** | **Other accompanying documents** | List of essential spares and accessories, with their part number and cost; |
| **11. Notes** | | |
| **11.1** | **Service SupportContact details (Hierarchy Wise;including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| **11.2** | **Recommendations orwarnings** | Any warning sign should be adequately displayed. |

| FULLY AUTOMATED BIOCHEMISTRY ANALYSER | | |
|---|---|---|
| Version no.: | | 02 |
| Date: | | August 2023 |
| Done by: (name/institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Multichannel clinical chemistry analyser IVD, laboratory |
| GMDN code | | 56677 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | An automated laboratory instrument intended to be used forthe qualitative and quantitative in vitro determination of multiple clinical chemistry analytes in a clinical specimen. Analytes detected may include electrolytes, specific proteins, lipids and kidney, liver and/or cardiac function test analytes. |
| 1.2 | **Used by clinical department/ward** | Clinical Diagnostic Laboratory |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |

| | | |
|---|---|---|
| 2.1 | **Technical characteristics (specific to this type of device)** | 1. The equipment should be capable of all RoutineSTAT and special Biochemical tests including specific protein, therapeutics, and user defined applications in clinical sample like whole blood, serum, plasma, urine and body fluids.<br>2. Throughput: minimum 200 tests/hour.<br>3. Measurement principle: photometric analysis.<br>4. Open Ended system preferably.<br>5. Optical System should have Wavelength range from340 to 700 nm.<br>6. Should have built in Cooled reagent Compartmentwith sample volume 2- 40 µl.<br>7. Auto diagnosis of machine errors with message and correction steps.<br>8. Must have on board capacity for permanent and numbered cuvettes.<br>9. Separate probe for reagents and sample.<br>10. Laundry System with minimum 5 step washing.<br>11. Minimum carryover of not more than 0.05 ppm.<br>12. Should have external and internal probe cleaning facility.<br>13. The system should be having the facility of both auto-calibration and manual.<br>14. Should have solid state light source (LED Technology) with a split reference beam with workinglife of more than 10000 hrs.<br>15. Should have minimum 50,000 Patient Result memory Storage |
| | | 16. Online QC Tracking with Levy and Jennings Chart for upto 30 different points, SD and CV.<br>17. Provision for Bar Code/QR code reading should be available.<br>18. The equipment should have in-built digital display unit and PC interface facility. |
| 2.2 | **User's interface** | • Digital display<br>• Provision for bi-directional LIS/HIS interface should be available. |
| 2.3 | **Software and/or standard of communication (wherever required)** | Built - in/Automatic/compatible, window based with data processing management system with complete back up of data base for calibration, control, patient sample results on daily basis. |
| **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 temperature and the heat should be disbursed through a cooling mechanism. |
| 3.6 | **Mobility, portability** | Stationary lab Installation. |
| | **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 )** | |
| 4.1 | **Power Requirements** | 220VAC +/- 10%, 50 Hz. |
| 4.2 | **Battery operated** | UPS system with minimum one hour back up |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | To be specified by manufacturer |
| | **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory, standard, optional);Spare parts (main ones); Consumables/reagents(open,closed system)** | 1. Suitable Water plant/Purification System on RO or any latesttechnology.<br>2. External printer.<br>3. UPS online pure sine wave for back up of system withPC and IT peripherals for one hour.<br>4. One light source. |
| | **BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS** | |
| | **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | |
| 6.1 | **Atmosphere/Ambiance (airconditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer |
| | **7. STANDARDS AND SAFETY** | |
| 7.1 | **Certificates (pre-market, sanitary, ..); Performanceand safety standards (specific to the device type);Local and/or international** | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| | **8. TRAINING AND INSTALLATION** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up. |
| 8.2 | **Requirements for sign-off** | Supplier to perform installation, safety and operationchecks before handover. |

| | | |
|---|---|---|
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | 1. 3 years, including all spares and calibration.<br>2. Preventive maintenance visits at least one in each quarter. |
| **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 inEnglish/Hindi language along with machine diagrams.<br>2) List of equipment and procedures required for localcalibration and routine maintenance.<br>3) Certificate of calibration and inspection |
| 10.2 | **Other accompanying documents** | List of important spares and accessories, with their part numbers and cost. |
| **11. NOTES** | | |
| 11.1 | **Service Support Contact details (Hierarchy Wise; including a tollfree/landline number)** | Contact details of manufacturer, supplier and local service agent tobe provided. |
| 11.2 | **Recommendations orwarnings** | Any warning signs should be adequately displayed |

| **CELL COUNTER AUTOMATIC (5 PART)** | |
|---|---|
| Version no. : | 02 |
| Date: | August 2023 |
| Done By (Name/Institution | HCT/NHSRC |
| **NAME AND CODING** | |
| GMDN name | Haematological Cell Analyser IVD |
| GMDN code(s) | 35476 |
| **GENERAL** | |
| **1. USE** | |
| 1.1 **Clinical purpose** | An automated laboratory instrument intended to be used forthe enumeration of a haematological cell population, using technology to measure and calculate white cell, red cell and platelet parameters and indices in a clinical specimen. |
| 1.2 **Used by clinical department/ward** | Clinical Diagnostic Laboratory |
| **TECHNICAL** | |
| **2. TECHNICAL CHARACTERISTICS** | |

| | | |
|---|---|---|
| 2.1 | **Technical characteristics (specific to this type of device)** | • Five-part differential with reticulocyte count based onthe principle of flow cytometry including minimum 24 parameters with two histograms and scattergrams for RBC and PLT: BASO, WBC, LYM, MON, NEU, EOS, BAS, LYM%, MON%, NEU%, EOS%, BAS%, RBC, HCT,MCV, RDW-SD, RDW-CV, HGB, MCH, MCHC, PLT, PCT, MPV, PDW-SD, PDW-CV.<br>• Advanced, integrated self-cleaning system.<br>• Stores minimum 25,000 test results with histogramsand scattergrams.<br>• Sample Material - EDTA blood with atleast pre-diluted mode and whole blood mode.<br>• Integrates with common practice management systems including cleaning of apertures, tube systems and calibration.<br>• Should be able to perform all parameters on variable sample volume for adult and pediatric patients.<br>• Should be able to avoid micro-RBCs interference in platelet count.<br>• System must have throughput of at least 60 or more samples per hour.<br>• Should be equipped with automatic sample loading, mixing and testing. Also have manual mode andSTAT modes along with Random access for individual samples.<br>• Open system<br>• Pre-diluted mode and whole blood mode<br>• QC Mode LJ, SD, CV, QC histogram. |
| | | • Provision for bi-directional LIS interface should be available.<br>• Provision for Bar Code/QR code reading should be available.<br>• The equipment should have in-built digital display unit and PC interface facility. |
| 2.2 | User's interface | Touch screen and PC |
| 2.3 | Software and/or standard and communication (wherever required) | NA |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.4 | **Noise (in dBA)** | NA |
| 3.5 | **Heat dissipation** | Heat Dissipation: Should maintain nominal temperature and theheat should be disbursed through a cooling mechanism. |
| 3.6 | **Mobility, portability** | Stationary lab Installation. |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 )** | | |
| 4.1 | **Power Requirements** | 220 +-10% VAC, 50 HZ |

| | | |
|---|---|---|
| 4.2 | **Battery operated** | UPS System with minimum back up time of one hour. |
| 4.6 | **Protection** | N/A |
| 4.7 | **Power consumption** | As specified by the manufacturer |
| | **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory, standard, optional);Spare parts (main ones); Consumables/reagents(open,closed system)** | • 2D-Barcode/QR Code Scanner.<br>• PC, Keyboard, Printer<br>• Reagents: All the reagents required for 1000 tests should be supplied with the equipment along with one set of tri level control. |
| | **BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS** | |
| | **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | |
| 6.1 | **Atmosphere/Ambiance (airconditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer |
| | **7. STANDARDS AND SAFETY** | |
| 7.1 | **Certificates (pre-market, sanitary, ..); Performanceand safety standards (specific to the device type);Local and/or international** | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| | **8. TRAINING AND INSTALLATION** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up. |
| 8.2 | **Requirements for sign-off** | Supplier to perform installation, safety and operation checks before handover. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented. |
| | **9. WARRANTY AND MAINTENANCE** | |
| 9.1 | **Warranty** | 1. 3 years, including all spares and calibration.<br>2. Preventive maintenance visits atleast one in each quarter. |
| | **10. DOCUMENTATION** | |

| | | |
|---|---|---|
| 10.1 | **Operating manuals, servicemanuals, other manuals** | Should provide 2 sets (hardcopy and soft copy) of:<br>1) User, technical and maintenance manuals to be supplied inEnglish/Hindi language along with machine diagrams.<br>2) List of equipment and procedures required for localcalibration and routine maintenance.<br>3) Service and operation manuals (original and copy) to beprovided.<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 numbersand cost; |
| **11. NOTES** | | |
| 11.1 | **Service Support Contactdetails (Hierarchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent tobe provided. |
| 11.2 | **Recommendation s orwarnings** | Any warning signs should be adequately displayed. |

| CELL COUNTER SEMI-AUTOMATIC (3 PART) | | |
|---|---|---|
| Version no.: | | 02 |
| Date: | | August 2023 |
| Done by: (Name/Institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Haematological cell analyser IVD |
| GMDN code(s) | | 35476 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | An automated laboratory instrument intended to be used for the enumeration of a haematological cell population, using technology to measure and calculate white cell, redcell and platelet parameters and indices in a clinical specimen. |
| 1.2 | **Used by clinical department/ward** | Clinical Diagnostic Laboratory |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | • The system should have End point, kinetic, fixed time and turbidimetric mode.<br>• The system should be capable of 3 part WBC differential, estimating minimum 18 parameters with linearity (WBC, TC, RBC, Hb, hematocrit, MCV, MCH, MCHc, RDW- SD/RDW-CV, PLT, MPV, Pt Crit, PDW, PLCR optional).<br>• The system should have memory of minimum10000 patient samples.<br>• The system should have high intensity LED sourcefor Hb estimation.<br>• The system should have dual mode – flow cell and cuvette. Non-cyanide based is preferable.<br>• External keyboard.<br>• Automated standby and wake up.<br>• Auto probe cleaning and sample dilution preferable.<br>• System must have throughput of at least 60 samples per hour.<br>• QC Mode: LJ, SD, CV, QC histogram<br>• Provision for Bar Code/QR code reading should be available<br>• Built-in voltage stabilizer and test results printing facility.<br>• The equipment should have in-built digital display unit and PC interface facility |

| | | |
|---|---|---|
| 2.2 | **User's interface** | • Touch screen (Coloured)<br>• Provision for bi-directional LIS/HIS interface shouldbe available. |
| 2.3 | **Software and/or standard of communication (wherever required)** | To be provided by manufacturer |
| | **3. PHYSICAL CHARACTERISTICS** | |
| 3.1 | **Dimensions (metric)** | N/A |
| 3.2 | **Weight (lbs, kg)** | N/A |
| 3.4 | **Noise (in dBA)** | N/A |
| 3.5 | **Heat dissipation** | Heat Dissipation: Should maintain nominal temperature and theheat should be disbursed through a cooling mechanism. |
| 3.6 | **Mobility, portability** | Stationary laboratory Installation. |
| | **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 )** | |
| 4.1 | **Power Requirements** | 220 +-10% VAC, 50 HZ |
| 4.2 | **Battery operated** | UPS system with minimum 1 hour back up |
| 4.7 | **Protection** | Internal electrical protection |
| 4.8 | **Power consumption** | To be specified by vendor |
| | **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory, standard, optional);Spare parts (main ones); Consumables/reagents(open, closed system)** | • 2D-Barcode/ QR code Scanner.<br>• Built-in Thermal printer and provision for external printer.<br>• All the consumables, controls and calibrators and any other reagents or items required for conducting 1000 tests should be mentioned and supplied with the equipment.<br>• Online UPS for minimum 1 hour back up. |
| | **BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS** | |
| | **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | |
| 6.1 | **Atmosphere/Ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer |
| | **7. STANDARDS AND SAFETY** | |

| | | |
|---|---|---|
| 7.1 | **Certificates (pre-market, sanitary, ..); Performanceand safety standards (specific to the device type);Local and/or international** | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | As specified by manufacturer and compatible electrical accessories as per standard Indian set-up. |
| 8.2 | **Requirements for sign-off** | • Supplier to perform installation, safety and operation checks before handover.<br>• Lab In-Charge to affirm completion of installation |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Satisfactory Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | • 3 years, including all spares and calibration.<br>• Preventive maintenance visits atleast one in each quarter. |
| **10. DOCUMENTATION** | | |
| 10.1 | **Operating manuals, servicemanuals, other manuals** | Should provide 2 sets (hardcopy and soft copy) of:<br>1) User, technical and maintenance manuals to be supplied inEnglish/Hindi language along with machine diagrams.<br>2) List of equipment and procedures required for localcalibration and routine maintenance.<br>3) Service and operation manuals (original and copy) to beprovided.<br>4) Advanced maintenance tasks documentation.<br>5) Certificate of calibration and inspection; |
| 10.2 | **Other accompanying documents** | List of essential spare/ accessories, reagents/all other consumables along with their part number and cost shouldbe quoted |
| **11. NOTES** | | |
| 11.1 | **Service Support Contact details (Hierarchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier, and local service agent to be provided; |
| 11.2 | **Recommendations or warnings** | Any warning signs would be adequately displayed; |

| HIGH PERFORMANCE LIQUID CHROMATOGRAPHY ANALYSER | | |
|---|---|---|
| Version no.: | | 02 |
| Date: | | August 2023 |
| Done By: | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN Name | | High performance liquid chromatography analyser IVD |
| GMDN Code | | 57845 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical Purpose | An electrically powered laboratory instrument designedfor the qualitative and/or quantitative in vitro determination of chemical and biological markers in a clinical specimen. |
| 1.2 | Used by clinical department/ward | Clinical Diagnostic Laboratory |
| **TECHNICAL** | | |
| **2. Technical Characteristics** | | |

| | | |
|---|---|---|
| 2.1 | Technical Characteristics (Specific to this type of device) | • It should be able to screen and quantitate Hb A2,Hb A, Hb F, and Hb A1c hemoglobin, in addition to that it should also be able to identify prevalent abnormal hemoglobin's like Hb S, Hb D, Hb E, Hb C, Hb Q-India etc. and other rare abnormal hemoglobin.<br>• System should be able to load a minimum of 10 samples at a time.<br>• Time of analysis per sample should not be morethan 8 minutes.<br>• Should provide two level controls for Hb A2, Hb Fand Hb S and provide quality control program to help compare results with similar users.<br>• The system should have a feature of rack & sample position identification to avoid error incase of faulty barcode/QR code reader.<br>• The system should have a visible alarm system for low buffer level in mobile phase reservoirs, low level of cartridge injection and overfill of the waste tank, and a built-in calibration failure alarm.<br>• The waste tank should be sufficiently large, to reduce frequent user interference<br>• The System should be NGSP (National Glycohemoglobin Standardization Program) Certified and verifiable to IFCC reference method.<br>• The system should offer both NGSP & IFCCvalue reporting on the same patient report, control & calibrator report.<br>• QC should be based on test parameters.<br>• Provision for bi-directional LIS interface should be available. |
| | | • Provision for Bar Code/QR code reading should be available.<br>• The equipment should have in-built digital display unit and PC interface facility. |
| **2.2** | **User Interface** | Digital Display |
| **2.3** | **Software and/or standard of communication (wherever required)** | 1. Graphical and user-friendly design of the software.<br>2. Software should be able to control all modules of the HPLC system |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | Dimensions (in mm) | NA |
| 3.2 | Weight | NA |
| 3.3 | Noise | NA |

| | | |
|---|---|---|
| 3.4 | Heat Dissipation | Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism. |
| 3.5 | Mobility/Portability | Stationary lab Installation |
| **4. ENERGY SOURCE** | | |
| 4.1 | Power input | 220VAC +/- 10%, 50 Hz. |
| 4.2 | Battery Operated | Online UPS with minimum one-hour backup. |
| 4.3 | Protection | Internal Electrical Protection |
| 4.4 | Power consumption | As per Manufacturer/Supplier specified |
| **5. ACCESSORIES, SPARE PARTS AND CONSUMABLE** | | |
| 5.1 | Accessories, (mandatory, Standard, operational); Spare parts (main ones) Consumable/reagents (open, closed system) | 1. Equipment should be provided with Online UPS withat least one-hour backup.<br>2. Basic required repair tools and spare parts for regular maintenance needs to be provided.<br>3. Color Laser Jet Printer with Scanner<br>4. A Computer system with latest configuration (i5 processor with 3.2 GHz processor, 8 Gb RAM, 1 Tb harddisc, or better) and with operating system compatible with the dedicated software should be provided along with the system.<br>5. All consumables including controls, calibrators, regents etc. required for testing of 100 HbA1C & 100Hb Variants analysis. |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | Atmosphere /Ambiance (air conditioning, humidity, dust ...) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | To be specified by manufacturer |
| **7. STANDARDS & SAFETY** | | |
| 7.1 | Certificates (pre-market,sanitary); Performance and safety standards (specific to the device type); Local and/or international | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | Pre-installation requirements: nature, values, quality, tolerance | As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up. |

| | | |
|---|---|---|
| 8.2 | Requirements for sign-off | 1. Supplier to perform installation, safety and operation checks before handover.<br>2. Lab In-Charge to affirm completion of installation. |
| 8.3 | Training of staff (medical, paramedical, technicians) | Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | 1. 3 years, including all spares and calibration.<br>2. Preventive maintenance visits atleast one in eachquarter |
| **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 should 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. Advanced maintenance tasks documentation.<br>4. Certificate of calibration and inspection. |
| 10.2 | Other accompanying documents | List of essential spares and accessories, with their part number and cost. |
| **11. NOTES** | | |
| 11.1 | Service Support Contact details (Hierarchy Wise; including a toll free/landline number) | Contact details of Vendor and local service agent needsto be provided |
| 11.2 | Recommendations orwarnings | Any warning sign should be adequately displayed |

| INFUSION PUMP | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name/institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Infusion Pump (Volumetric) |
| GMDN code(s) | | CT 1821 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | An infusion pump infuses fluids, medication or nutrients into a patient's circulatory system. It is generally used intravenously, although subcutaneous, arterial and epidural infusions are occasionally used. |
| 1.2 | **Clinical department/ward** | Emergency, Operation Theatre, Critical care |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics** | 1. Flow rate programmable range at least from 0.1 to 200 ml/hr, in steps of 0.1 ml/hr; and at least from 100 to 1200 ml/hr in steps of 1 ml/hr.<br>2. Saves last infusion rate even when the AC power is switched off.<br>3. Bolus rate should be programmable to approx. 500 ml, with infused volume display.<br>4. Selectable occlusion pressure trigger levels selectable from 300, 500 and 900 mmHg.<br>5. Accuracy of ±2% or better for set parameters.<br>6. Maximum pressure generated 20 psi.<br>7. Pause infusion facility required.<br>8. Self-check carried out on powering on.<br>9. Comprehensive alarm package required including: occlusion alarm, near end of infusion pre-alarm and alarm, volume limit pre-alarm and alarm, low battery pre-alarm and alarm, AC power failure, drive disengaged.<br>10. It should be open system |
| 2.2 | **User's interface** | Automatic |
| 2.3 | **Software and/or standard of communication** | Inbuilt |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dBA)** | Noise free |
| 3.4 | **heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Yes |
| **4. ENERGY SOURCE** | | |

| | | |
|---|---|---|
| 4.1 | **Power Requirements** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | Internal rechargeable battery having a minimum of 2 hours backup |
| 4.3 | **Protection** | Battery powered alarm for power failure or disconnection |
| 4.4 | **Power consumption** | As specified by manufacturer |
| | **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory, standard, optional)**<br>**Spare parts (main ones)**<br>**Consumables/reagents (open, closed system)** | Clamp for mounting pump on IV stand |
| | **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | |
| 6.1 | **Atmosphere/Ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of up to 90%. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | Easy to clean and maintain. |
| | **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| | **8. TRAINING AND INSTALLATION** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements forsign-off** | Supplier to perform safety and operation check before hand over |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| | **9. WARRANTY AND MAINTENANCE** | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter |
| | **10. DOCUMENTATION** | |
| 10.1 | **Manuals** | Should provide 2 sets (hardcopy) of: -<br>1) User, technical, maintenance and service manuals to be supplied along with machine diagrams.<br>2) List of equipment and procedures required for local |

| | | |
|---|---|---|
| | | calibration and routine maintenance.<br>3) Certificate of calibration to be provided by the manufacturer. |
| 10.2 | **Other accompanying documents** | List of important spares and accessories, with their part numbers and cost |
| **11. NOTES** | | |
| 11.1 | **Other information** | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | **Recommendations or Warnings** | Any warning signs should be adequately displayed |

| MAMMOGRAPHY | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name / institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Mammography |
| GMDN code | | NA |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | A mammography is a screening tool used to detect and diagnose breastcancer |
| 1.2 | **Used by clinical department/ward** | Radiology/Oncology Department |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | **X-RAY GENERATOR**<br>- High Frequency 40KHz or more X-Ray Generator should be provided.<br>- Power of generator should be more than 5KW.<br>- Maximum mA output should be more than 190mA<br>- KV Range should be 22 to 35KV in steps of increment of 0.5 KV each.<br>- mAs Range for large filament should be from 1 mAs to 700 mAs or more.<br>- 1 No. High Voltage Cable should be provided.<br>**X-RAY TUBE**<br>- Rotating Anode X-Ray Tube having dual focus, dual angle should beprovided.<br>- Focal Spots:<br>Small Focus = 0.1 mm² Large Focus = 0.3 mm²<br>- Anode Heat Storage Capacity 300KHU<br>- Tube Assembly Heat capacity should be at least 1.5MHU<br>**CONTROL PANEL**<br>- Micro Processor controlled Feather Touch Control Panel with LCDdisplay should be provided.<br>- KV Range should be 22 to 35 KV in steps of increment of 0.5 KV each.<br>- mAs Range should be from 1 mAs to 700 mAs or more.<br>- Technique selection: Manual Two Point Technique (i.e. KV, mAs) shouldbe possible.<br>- Anatomic Program (APR) for small, medium & Large breasts should beprovided.<br>- more than 2 Film Screen Combinations should be provided. |

| | | |
|---|---|---|
| | | - Breast Compression: Automatic compression with digital display of compression force should be provided. (Provision should be given for the release of compression paddle on power failure) the Switch for activation & release. Adjustable compression force should be available. Automatic Compression release after Exposure completion should be available.<br>- Compression Paddles for Normal & Magnification Mode (Spot Compression) should be provided<br>- Magnification Device: 1.5X and 1.8 X should be provided<br>- 18 x 24 cm Bucky, Motor operated Oscillating Grid of Size 18 X 26 cm, 5:1, 30 lines/cm focal distance 60 to 70 cm should be provided.<br>- Molybdenum Filter & Aluminum Filter Changer.<br>- Light Beam collimator with Halogen Lamp with Auto shut off facility after 1 minute should be provided.<br>- 18 X 24cm collimation plate should be provided.<br>- Cone for Localization & Radiation protection should be provided.<br>- Switches for up/down movement of gantry, placed conveniently on both sides of gantry should be provided.<br>- Separate foot control for gantry movements should also be available for hands free operation.<br>- Hand Switch with Retractable cord for initiation of exposure should be provided. |
| 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 | **Noise (in dBA)** | Noise-free system |
| 3.4 | **Heat dissipation** | Heat Dissipation: Should maintain nominal temperature and the heat should bedisbursed through a cooling mechanism |
| 3.5 | **Mobility, portability** | Stationary Installation |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ...)** | | |
| 4.1 | **Power Requirements** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | No |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | To be specified by manufacturer. |

| | | |
|---|---|---|
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts(main ones); Consumables / reagents (open, closed system)** | Machine should be supplied with following :-<br>I. 2 No. BARC Approved whole body lead aprons with all attachments.<br>II. Free standing fully Transparent Lead Glass Screen for operator protectionshould be provided.<br>III. Film marking device & Alpha Numeric identification system should beprovided. |
| **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | | |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer |
| **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 CDSCO and AERB approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform installation, safety and operation check before hand over. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| **10. DOCUMENTATION** | | |

| | | |
|---|---|---|
| 10.1 | **Operating manuals, servicemanuals, 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) Service and operation manuals (original and copy) to be provided.<br>3) Advanced maintenance tasks documentation. |
| 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 beprovided. |
| 11.2 | **Recommendations orwarnings** | Any warning signs would be adequately displayed |

| Phototherapy Unit | | |
|---|---|---|
| Version | | 02 |
| Date: | | August 2023 |
| Done by : (name / institution) | | HCT/ NHSRC |
| NAME AND CODING | | |
| GMDN name | | |
| GMDN code(s) | | |
| GENERAL | | |
| 1. USE | | |
| 1.1 | Clinical purpose | Emits in the main radiation spectrum in the range between 400 nm and 550 nm for reducing the concentration of Bilirubin |
| 1.2 | Used by clinical department/ward | NICU/PICU/SNCU |
| TECHNICAL | | |
| 2. TECHNICAL CHARACTERISTICS | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1. Phototherapy should be based on LED technology, which after filtering should provide, a light of wavelength approximately 450 to 470 nm with peak wavelength of 450-460nm range.<br>2. Irradiance to be minimum 35 µW/cm2/nm at 40 cm height and UV should not exceed 10-4 W/m2 in 180nm to 400nm.<br>3. Digital Hour meter showing total exposure time for current patient to be clearly visible by operator.<br>4. Effective light field >700 cm2.<br>5. Lamp life should be minimum 20000 hours for LED and should have timer to indicate its usage.<br>6. Over temperature safety cut out to be included.<br>7. Up, down and tilting of head should be possible.<br>8. The unit should be mounted with castor wheels with brakes.<br>9. Variation in intensity over 5-6 hours < 10%.<br>10. The irradiance ratio (min to max) shall be greater than 40 % on mattress.<br>11. Green indicator light shall be provided to indicate that equipment is ready for normal use.<br>12. Interruption and a restoration of the power supply do not change preset values. LED heat can be reduced by natural cooling.<br>13. LED should be protected from free fall.<br>14. It should not topple at a 10 deg inclined angle.<br>15. The temperature of baby bed and metal surfaces should not exceed 40deg C and 43 deg C for other accessible surfaces.<br>16. There should be intuitive method to indicate the light surface is at the appropriate treatment distance.<br>17. Mobile stand with movable castors and height adjustment facility along with easy swiveling of source box. Unit can be used along |

| | | |
|---|---|---|
| | | with Infant care trolley, Radiant Warmer and Incubator. |
| 2.2 | User's interface | Manual |
| 2.3 | Software and/or standard of communication (wherever required) | In-built |
| | 3. PHYSICAL CHARACTERISTICS | |
| 3.1 | Dimensions (metric) | NA |
| 3.2 | Weight (lbs, kg) | NA |
| 3.3 | Noise (in dBA), | Noise: <60dBA |
| 3.4 | Heat dissipation | Should maintain nominal temperature of the body surface of the equipment. |
| 3.5 | Mobility, portability | Mobile |
| | 4. ENERGY SOURCE | |
| 4.1 | Power Requirements | 220 V +/- 10% AC, 50 Hz |
| 4.2 | Battery operated | NA |
| 4.3 | Power consumption | To be specified by manufacturer |
| | 5. ACCESSORIES, SPARE PARTS, CONSUMABLES | |
| 5.1 | Accessories (mandatory, standard, optional);<br>Spare parts (main ones);<br>Consumables / reagents (open, closed system) | Complete set of replacement tubes to allow 3 months' continuous operation.<br>Two replacement sets of fuses, if replaceable type used. |
| | 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS | |
| 6.1 | Atmosphere / Ambiance (air conditioning, humidity, dust ...) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | To be specified by manufacturer. |
| | 7. STANDARDS AND SAFETY | |
| 7.1 | Certificates (pre-market, sanitary, ..) | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |

| | | |
|---|---|---|
| 8. TRAINING AND INSTALLATION | | |
| 8.1 | Pre-installation requirements: nature, values, quality, tolerance | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up. |
| 8.2 | Requirements for sign-off | Supplier to perform safety and operation check before handover. |
| 8.3 | Training of staff (medical, paramedical, technicians) | Training of users in operation and basic maintenance shall be provided. |
| 9. WARRANTY AND MAINTENANCE | | |
| 9.1 | Warranty | • 03 years<br>• Preventive Maintenance visits at least once in each quarter |
| 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. Service and operation manuals (original and copy) to be provided.<br>3. Satisfactory certificate for any existing installation from government hospital |
| 10.2 | Other accompanying documents | List of essential spares and accessories, with their part number and cost. |
| 11. NOTES | | |
| 11.1 | Service Support Contact details (Hierarchy wise; including a toll free/landline number) | Contact details of manufacture, supplier and local service agent to be provided. |
| 11.2 | Recommendations or warnings | Any warning sign should be adequately displayed. |

| ULTRASOUND MACHINE | | |
|---|---|---|
| Version | | 02 |
| Date: | | August 2023 |
| Done by : (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Ultrasound system |
| GMDN code(s) | | NA |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | Diagnostic sonography (ultrasonography) is an ultrasound-based diagnosticimaging technique used for visualizing internal body structures including tendons, muscles, joints, vessels and internal organs for possible pathology or lesions. The practice of examining pregnant women using ultrasound is called obstetric sonography, and is widely used |
| 1.2 | **Used by clinical department/ward** | Radiology laboratories |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | **Ultrasound scanner with integrated trolley with probe, soft touchalphanumeric key board with track ball:**<br>1. With panel switches & control's easily operable.<br>2. Integrated high resolution Monitor(17").<br>3. Probes & Gel holder-conveniently placed (2 each).<br>**Following transducers are to be supplied:**<br>1. A-2.0-5.0 MHz Multi frequency Convex Transducer-One.<br>2. B-5.0-12.0 MHz Multi frequency Linear transducer-one.<br>3. C-5.0-8.0 MHz or more Endo Cavitary probe-one.<br>**(+/- 1 MHz to be allowed for each):**<br>a) All probes should be electronic transducers and multi-frequency preferably three frequencies and should give aperture & depths ofscanning.<br>b) Controls for Depth, gain compensation, body markers with transducersposition.<br>c) Real-time continuous dynamic focus.<br>d) Auto annotation facility anywhere on image.<br>e) Image display in B, B/M&M Model(2B&2D).<br>f) Zoom facility minimum five times or more.<br>g) Inbuilt cine memory.<br>h) Unite should be capable of measuring BPD, CRL, FL & AC and other GAparameters.<br>i) Facility for image magnification, inversion, changing, scan, |

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| | | direction,freeze facility.<br>j) 8 step STC/GTC should be available.<br>k) Frame rate minimum 50 FPS, hard disk capacity of 200GB or more.<br>l) Caliper with trackball for the measurement of distances circumferences, area volume etc. should be possible to make different measurement onsingle image.<br>m) Alphanumeric key board, panel switches & foot controls.<br>n) Patient reports for Obs/Gynae including fetal growth trend, includingHistogram facility for Tissue texture & Trend graph for IUGR cases, Urology and orthopedics.<br>o) Give the gain adjustable/Range & its steps.<br>p) Calculations needed, Velocity, Heart rate, Volume addl. modes.<br>q) Dicom 3.0 compatible.<br>r) Review of stored images is desirable.<br>s) Channels: 1000 or more.<br>t) Depth: 25 to 30 cm.<br>u) Dynamic range: 170dB & above.<br>v) Cine loop preview for minimum 60 secs or more.<br>w) Minimum 2 active ports should be there |
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/or standard of communication(whe rever required)** | NA |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dBA),** | NA |
| 3.4 | **Heat dissipation** | Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through a cooling mechanism. |
| 3.5 | **Mobility, portability** | Mobile |
| **4. ENERGY SOURCE** (electricity, UPS, solar, gas, water, CO2 ) | | |
| 4.1 | **Power Requirements** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | No |
| 4.3 | **Protection** | NA |
| 4.4 | **Power Consumption** | To be specified by manufacturer |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | **Accessories (mandatory, standard, optional);** | The system should be supplied with the following accessories:<br>1. B & W thermal printer with 50 rolls.<br>2. Two KVA online suitable UPS. |

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| | **Spare parts (main ones);**<br>**Consumables / reagents (open, closed system)** | |
| **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | | |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.<br>Machine to be installed only when PC-PNDT registration is obtained by health care facility. |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | 03 Years<br>Preventive Maintenance visits at least once in each quarter. |
| **10. Documentation** | | |
| **10.1** | **Operating manuals, set manuals, other manuals** | Should provide 2 sets (hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams.<br>2. Advanced maintenance tasks documentation.<br>3. Certificate of calibration and inspection.<br>4. Satisfactory certificate for any existing installation from government hospital. |
| **10.2** | **Other accompanying documents** | List of essential spares and accessories, with their part number 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. |
| **11.2** | **Recommendations or warnings** | Any warning sign should be adequately displayed. |

| | | |
|---|---|---|
| **RADIANT WARMER** | | |
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | |
| GMDN code(s) | | |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | Infant Radiant warmer is an electrically powered device with a radiant heating source intended to maintain the thermal balance of an infant by direct radiant of energy in the infrared region of the electromagnetic spectrum. |
| 1.2 | **Used by clinical department/ ward** | Neonatal ICU/ SNCU |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1. It should be microcontroller chip based radiant warmer with manual and servo options.<br>2. It should have the facility to display skin set, skin observed temperature in degree C and heat power separately.<br>3. Should have user friendly touch panel control.<br>4. It should have ceramic or quartz infrared or calrod heater.<br>5. It should have audiovisual alarm facility for overheating beyond set temperature range.<br>6. It should have alarm facility for patient temperature less than or greater than the required temperature i.e. above or below the set range. Machine should sense the skin probe failure and cut off the heater.<br>7. The warmer head should be rotatable in different direction, so as to allow taking X-ray.<br>8. It should have an alarm for probe failure, power failure, system failure and heater failure.<br>9. Observation light of 90 to 100 foot candles or 1000 Lux ( color temperature range 3700K to 5100K) should be provided for inspection<br>10. Battery backup for Power failure indication during power fail.<br>11. The desired temperature range from 25 to 40 degree C and settable temperature can be from 32 to 38 degC. |

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| | | 12. The resolution should be 0.1 degree C and accuracy should be 0.2 °C.<br>13 Should have a facility to lock the keyboard to avoid unwanted user modification of the set parameters.<br>14. The height of the warmer should be adjustable for different types of bed.<br>15. It should have separate bassinet trolley, bed should be tiltable and have provision for x-ray cassette holder, Mattress foam density should be minimum 25 kg/cm3, transparent collapsible side walls easily detachable for cleaning. Mattress size should be minimum 20"X30".<br>16. Should have a Feather Touch operation with large digital display and comprehensive alarms. Control Panel should be liquid proof and allow easy and hygienic disinfection.<br>17. Manual Mode can adjust Heater Output 10 -100 %, with 10% increment, an auditory and visual alarm shall be given at least every 15 min.<br>18. In manual mode, heater cut off / switch off, if the maximum irradiance at any point of the mattress area exceeds a total irradiance level of 10 mW/ cm2 (between 10 to 30 minutes).<br>19. Bed should be about 80 - 100 cms from the Floor and 80-90cms from the heat source.<br>20. Should have lockable castor wheels.<br>21. Green indicator light shall be provided to indicate that warmer is ready for normal use.<br>22. Markings on the bassinet and X-Ray cassette holder is mandatory to enable proper positioning of the baby while doing the X-Ray.<br>23. The size of the drop-down sides should be such that it is 5" above the mattress surface and should be at least 6mm thick; clear and transparent.<br>24. If there is more than 60% heater output for 10 minutes it should cutoff with alarm.<br>25. For the purpose of cable management there should be at least two number of tubing ports (edges covered by silicon rings) on the side walls. The height of the side walls should be minimum 110mm over the mattress.<br>26. X-Ray cassette tray should be at least 750X350mm and should adopt up to 20mm thick X-Ray cassette.<br>27. The bay bed should be crevice free for ease of cleaning, infection control.<br>28. The mattress used should be of biocompatible material.<br>29. Thermistor based skin temperature probe should be small in size not more than 10mm diameter and 3-4mm thick to fix the probe firmly on the infant. Baby contact |

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| | | material should be biocompatible as per ISO 10993 standard requirement. It should be insulated on one side and have well conducting non-rusting, non-reacting metallic surface on the other side. Probe wire should be pliable, thin and soft. The attachment site of the probe with the wire should also be pliable and non-stiff. |
| 2.2 | **Settings** | 1. Should have Manual mode and Baby (Servo) mode settings.<br>2. Mode of operation should be clearly displayed.<br>3. In servo mode baby set temperature should be 32 to 38 deg C. |
| 2.3 | **User's interface** | Manual and Servo controlled temperature regulation. |
| 2.4 | **Software and/or standard of communication (where ever required)** | LED Display and inbuilt software; Interruption and restoration of the power supply does not change the preset values. |
| 2.5 | **Others** | 1. Device shall not overbalance when placed in any transport position of normal use on a 10° inclined plane from the horizontal plane.<br>2. Transformers of device shall be protected against overheating in the event of short circuit or overload of any output winding.<br>3. Patient leakage current should be less than 100 µA in normal condition.<br>4. Temperature on the baby mattress should not exceed 43 deg C when the warmer is operating under steady temperature condition.<br>5. Temperature of HEATER GUARDS should not exceed 85 °C in normal use.<br>6. The Temperature differences on the mattress shall not exceed 2 °C. |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.4 | **Noise (in dBA)** | Sound level of the alarm shall not exceed 80 dBA |
| 3.5 | **Heat dissipation** | Should maintain nominal temperature and the heat disbursed through a exhaust fan, so that effect of UV light is not disturbed. |
| 3.6 | **Mobility, portability** | Mobile |
| **4. ENERGY SOURCE** | | |
| 4.1 | **Power Requirements** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | NA |
| 4.4 | **Power consumption** | To be specified by manufacturer |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |

| | | |
|---|---|---|
| 5.1 | **Accessories (mandatory, standard, optional)**<br>**Spare parts (main ones)**<br>**Consumables / reagents (open, closed system)** | Should have standard IV pole (sturdy; on rusting; medical grade stainless steel; adjustable to a max height of 6 feet from the ground level), monitor tray (12X10 inches;270 deg swivel; fixed at level of warmer display) and storage trays.<br>Skin temperature probes,<br>Thermal reflector to fix the skin probe on baby. |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer. |
| **7. STANDARDS AND SAFETY** | | |
| 7.1 | **Performance and safety standards (specific to the device type); Certificates (pre-market, sanitary, ...); Local and/or international** | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform installation, safety and operation checks before handover. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter |
| **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 should 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. Satisfactory certificate for any existing installation from government hospital. |
| 10.2 | **Other accompanying documents** | List of essential spares and accessories, with their part number and cost |

| 11. NOTES | | |
|---|---|---|
| 11.1 | **Service Support Contact details (Hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | **Recommendations or warnings** | Any warning/ precautions to be declared |

| TRANSPORT INCUBATOR | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Infant Incubator |
| GMDN code(s) | | CT1482 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | Designed to provide an enclosed controlled environment to maintain appropriate temperature and humidity levels mainly for premature infants andother newborns who cannot effectively regulate their body temperature. |
| 1.2 | **Used by clinical department/ ward** | NICU and PICU |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1. Visual and audible alarms for:<br>(i) Patient and air high/low temperature alarm.<br>(ii) Air circulation / probe / system / power failure alarm.<br>2. Heater power indicator<br>3. Air velocity: minimum 0.30m/sec<br>4. Oxygen input flow rate 5 to15 liters/min or oxygen concentration range25 to 70%.<br>5. Maximum CO2 concentration inside incubator 0.2%.<br>6. Internal noise level < 60 dB.<br>7. Mode of operation should be properly displayed.<br>8. Green indicator light should be provided for its ready to be in normal use.<br>9. Infants straps should be provided to restrict the baby movement.<br>10. Skin temperature probe should be small in size not more than 10mmdiameter and 4mm in height to fix the probe firmly on the infant. Babycontact material should be biocompatible. |

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| | | 11. Infant bed should be drawable. Mattress foam density should be minimum 25kg./cm3 and infant bed mattress cover should be biocompatible material.<br>12. Examination light should be provided for inspection.<br>13. Should have heater power indicator.<br>14. Warmup time 30-40 minutes and shall not differ by more than 20%.<br>15. Shall be equipped with a thermal cut-out. It shall be so arranged that the heater is disconnected, and an auditory and visual warning is given at an incubator temperature which does not exceed 40 deg C.<br>16. Should have elbow operate-able ports and head access door.<br>17. It should not topple over at 10 deg inclined plane.<br>18. Patient skin temperature range: 35 deg C to 37.5 deg C override up-to 38 deg C.<br>19. Air temperature range: 30 deg C to 39 deg C; Temperature resolution ± 0.1 deg C; Temperature accuracy ± 0.2 deg C. |
| 2.2 | **User's interface** | Display allows easy viewing in all ambient light levels |
| 2.3 | **Software and/or standard of communication** | In built |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dBA)** | <60 dBA |
| 3.4 | **Heat dissipation** | Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism. |
| 3.5 | **Mobility, portability** | Mobile |
| **4. ENERGY SOURCE** | | |
| 4.1 | **Power Supply** | 220 ± 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit. Electrical protection by resettable over-current breakers or replaceable fuses, fitted in both live and neutral lines. Battery backup of 2 hours for equipment operation. The battery should be protected from overcharging. |
| 4.4 | **Protection** | Internal, replaceable, rechargeable battery allows operation for at least two hours in the event of power failure |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | **Accessories (mandatory,** | With washable and removable straps and binders |

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| | **standard, optional)** | |
| 5.2 | **Spare parts (main ones)** | Two extra sets of all sensors |
| 5.3 | **Consumables/reagents ( open, closed system** | Two extra sets of filters, two extra set of fuses ( if replaceable fuses used) |
| | **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | |
| 6.1 | **Atmosphere / Ambiance (air conditioning , humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer. |
| | **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| | **8. TRAINING AND INSTALLATION** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided |
| | **9. WARRANTY AND MAINTENANCE** | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter |

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| **10. DOCUMENTATION** | | |
| 10.1 | **Operating manuals, service manuals, other manuals** | User, technical and maintenance manuals to be supplied in English/Hindi language. |
| 10.2 | **Other accompanying documents** | List of important spares and accessories, with their part numbers and cost |
| **11. NOTES** | | |
| 11.1 | **Other information** | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | **Recommendations or warnings** | Any recommendations for best use and supplementary warning for safetyshould be declared |

| TRANSPORT VENTILATOR (NEONATAL AND PAEDIATRIC) | | |
|---|---|---|
| Version no. : | | 2.0 |
| Date: | | August 2023 |
| Done by : (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | - |
| GMDN code(s) | | - |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | To provide automated, alveolar ventilatory support for patients duringinterhospital or intrahospital transport, and in emergency situations. |
| 1.2 | **Used by clinical department/ ward** | Emergency /Critical Care |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1. Mountable transport ventilator (Neonate/Paediatric).<br>2. Invasive Modes (CMV and SIMV) and Non-invasive Mode (CPAP).<br>3. Pressure controlled - Pressure upto 15mmHg.<br>4. Respiration Rate upto 40.<br>5. There should be two FiO2 setting range between 21% and 100%. Setting100% FiO2 should be mandatory.<br>6. PEEP 0-20 cm of water.<br>7. Trigger sensitivity - Pressure.<br>8. The associated cylinder (to be supplied along with the machines) shouldbe such that it could be locally filled.<br>9. Oxygen Cylinder connector (to be supplied along with the machines)should be compatible with ventilator.<br>10. Audio and visual alarm for disconnection and high pressure.<br>11. The device should be capable of operation in various environments such asEmergency, Ambulance, Aircraft, Hospital and MRI.<br>12. The device should be MRI conditioned up to 3 Tesla. |
| 2.3 | **User's interface** | Automatic |
| 2.4 | **Software and/or standard of communication (where ever required)** | Inbuilt |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions** | NA |

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|---|---|---|
| | **(metric)** | |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dBA)** | Should have audio visual alarm for disconnection and high pressure. |
| 3.4 | **Mobility, portability** | Mobile |
| | **4. ENERGY SOURCE** | |
| 4.1 | **Power Requirements** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | With at least 6 hours battery backup |
| 4.4 | **Protection** | NA |
| 4.5 | **Power consumption** | To be specified by manufacturer. |
| | **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories & Spares Consumables / reagents (open, closed system)** | Full face mask, 4 reusable breathing circuit of silicone material (2 for pediatric and 2 for neonates), carry bag, ventilator connecting tubes. |
| | **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | |
| 6.1 | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer. |
| | **7. STANDARDS AND SAFETY** | |
| 7.1 | **Certifications** | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| | **8. TRAINING AND INSTALLATION** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up. |
| 8.2 | **Requirements for sign-off** | Supplier to perform installation, safety and operation checks before handover. |

| | | |
|---|---|---|
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| **10. DOCUMENTATION** | | |
| 10.1 | **Operating manuals, service manuals, other manuals** | User and maintenance manuals to be supplied in English/Hindi language.<br>Service and operation manual to be provided.<br>Advance maintenance task should be documented and provided. |
| 10.2 | **Other accompanying documents** | List of important spares and accessories, with their part numbers and cost. |
| **11. NOTES** | | |
| 11.1 | **Service Suppor Contact details (Hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to beprovided. |
| 11.2 | **Recommendatic s or warnings** | Any warning signs would be adequately displayed. |

| 300 mA X-Ray | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name/institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | **300 mA HF X-Ray machine** |
| GMDN code | | NA |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | Medical x-rays are used to generate images of tissues and structures inside the body. |
| 1.2 | **Used by clinical department/ward** | Radiology |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | High Frequency X-Ray machine suitable for general Radiography.<br>**X-Ray Generator**<br>• High Frequency X-Ray generator having Frequency of 40 KHz moresuitable for Radiography should be provided.<br>• Power output of generator should be 25 KW or more.<br>• Radiography KV range should be 40 to 110 KV or more.<br>• mA range (Rad.) : 300mA or more • Exposure time (Rad.): 1 ms to 2 sec.<br>with maximum numbers of steps.<br>**Control:**<br>• A very compact, Soft Touch Control Panel having following functions & indications should be provided. The panel can be supplied in floor or wallmount with Spill Proof design Following features should be available on the control panel.<br>• Machine ON/OFF switch • Digital Display of KV& mAs.• K V & mAs increase<br>and decrease switches.<br>• Tube focal spot selection switch.• Ready and x-ray on switch ith<br>indicators.<br>• Bucky Selection switch.<br>• Self-diagnostic Programme with Indicators for Earth fault error, KV error,filament error & Tube's Thermal Overload.<br>**X-Ray Tube**<br>• One No Dual focus Rotating Anode X-ray tube thermally protected having focal spot:<br>• 1mm or less small Focus, 2mm or less large Focus. |

| | | |
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| | | • Anode heat storage capacity of tube should be more than 140 KHU.<br>• One no manual collimator with aluminum filter & for adjustment of exposure area.<br>Column Stand:<br>• It should have floor to ceiling stand with vertical counter balanced travel.<br>• It should have 360 deg. Rotation.<br>• It should be provided one vertical bucky stand with machine.<br>• Table.<br>• Five position manual tilt table having bucky grid ration of 8:1 with 85 lines per inches should be provided.<br>• The bucky tray should accept cassette of 8”x10”, 10”x12” and 14”x17” size. |
| 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)** | NA |
| 3.3 | **Noise (in dBA)** | Noise-free system |
| 3.4 | **Heat dissipation** | Heat Dissipation: Should maintain nominal temperature and the heat should bedisbursed through an cooling mechanism |
| 3.5 | **Mobility, portability** | Certified Room Installation |
| **4. ENERGY SOURCE** | | |
| 4.1 | **Power Requirements** | Input voltage- 380V-440V AC, 50Hz ;3-phase |
| 4.2 | **Battery operated** | No |
| 4.3 | **Protection** | Stabilizer of appropriate capacity to be installed. |
| 4.4 | **Power consumption** | To be specified by manufacturer |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts(main ones); Consumables/ reagents (open, closed system)** | Machine should be supplied with following transducers:<br>I. 2 No. BARC Approved whole body lead aprons with all attachments.<br>II. One Pair of 8 meter H. V. Cable. |
| **BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS** | | |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |

| | | |
|---|---|---|
| 6.1 | **Atmosphere/Ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer |
| | **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 CDSCO and AERB approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| | **8. TRAINING AND INSTALLATION** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users on operation and basic maintenance. |
| | **9. WARRANTY AND MAINTENANCE** | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| | **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) Service and operation manuals (original and copy) to be provided.<br>3) Advanced maintenance tasks documentation.<br>4) Certificate of calibration and inspection.<br>5) Satisfactory certificate for any existing installation from government hospital. |
| 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. |
| 11.2 | **Recommendations orwarnings** | Any warning signs would be adequately displayed. |

| 100 mA X-Ray (Mobile) | | |
|---|---|---|
| Version no.: | | 02 |
| Date: | | August 2023 |
| Done by: (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | |
| GMDN code(s) | | |
| **GENERAL** | | |
| **1. Use** | | |
| 1.1 | **Clinical purpose** | Mobile X-Ray unit is required to perform X-Ray studies in emergency & trauma departments & at bed side in wards & ICU. |
| 1.2 | **Used by clinical department/ ward** | Radiology Unit |
| **TECHNICAL** | | |
| **2. Technical characteristics** | | |

| | | |
|---|---|---|
| 2.1 | **Technical characteristics (specific to this type of device)** | Compact, easily transportable mobile radiographic unit suitable for bed side X-Ray in Emergency, ward, ICU, Operation Theatre & also in the radiology department for conventional radiography.<br><br>**X-ray Generator**:<br><br>1. High frequency X-Ray generator having frequency of 20 KHz or more suitable for radiography should be provided.<br><br>2. Power output of generator should be 20 KW Radiography KV range should be 40-120 KV or more. mA range (rad.): 100 mA or more.<br><br>**Control**:<br><br>1. A very compact, Soft touch Control panel having following functions & indications should be provided. The panel can be supplied in floor or wall mount with spill proof design following features should be on the control panel.<br><br>2. Machine ON/OFF switch, Digital display of KV & mAs, KV & mAs increase and decrease switches. Tube focal spot selection switch, Ready and x-ray on switch with indicators.<br><br>3. Bucky selection switch.<br><br>4. Self-diagnostic programme with indicators for earth fault error, KV error, filament error & Tube's thermal overload.<br><br>**X-Ray Tube:**<br><br>1. Tube should have one number stationary anode and thermally protected<br><br>2. Anode heat storage capacity of tube should be more than 140 KHU. One number manual collimator with aluminium filter & for adjustment of exposure area. |
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/or standard of communication (wherever required)** | In-built |
| **3. Physical Characteristics** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dba)** | Noise free system |
| 3.4 | **Heat dissipation** | Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism. |

| | | |
|---|---|---|
| | | |
| 3.5 | **Mobility, portability** | Mobile |
| **4. Energy source (electricity, Ups, solar, gas, water, co2 )** | | |
| 4.1 | **Power requirements** | 220 V AC +/- 10%, 50 Hz |
| 4.2 | **Battery operated** | NA |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | To be specified by manufacturer. |
| 4.5 | **Other energy supplies** | NA |
| **5. Accessories, spare parts, consumables** | | |
| 5.1 | **Accessories (mandatory, standard, optional);Spare parts (main ones); Consumables / reagents (open, closed system)** | Machine should be provided with following accessories:<br><br>Parts :<br>1. Two numbers of BARC approved whole body lead aprons with all attachments.<br>2. One pair of 8-meter HV Cable<br>. |
| **6. Environmental and departmental considerations** | | |
| 6.1 | **Atmosphere / ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, cleaning, Disinfection & sterility issues** | 1. To be specified by manufacturer |
| **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 CDSCO and AERB approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. Training and Installation** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users on operation and basic maintenance. |
| **9. Warranty and Maintenance** | | |
| 9.1 | **Warranty** | 03 years including all spares.<br>Preventive maintenance visits at least once in each quarter. |
| **10. Documentation** | | |
| 10.1 | **Operating manuals, service manuals, other** | Should provide 2 sets (hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should be supplied in |

| | | |
|---|---|---|
| | **manuals** | English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided.<br>4. Advanced maintenance tasks documentation.<br>5. Certificate of calibration and inspection.<br>6. Satisfactory certificate for any existing installation from government hospital. |
| 10.2 | **Other accompanying documents** | NA |
| **11. Notes** | | |
| 11.1 | **Service support contact details (hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| **11.2** | **Recommendations or warnings** | Any warning sign should be adequately displayed. |

| A SCAN BIOMETER WITH B SCAN | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done by: (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | |
| GMDN code(s) | | |
| **GENERAL** | | |
| **1. Use** | | |
| 1.1 | **Clinical purpose** | A Scan is used to measure the length of the eye for calculation of intra-ocular lens power. B-scan ultrasonography is commonly used to provide a cross sectional image of the internal structure of the eye. |
| 1.2 | **Used by clinical department/ ward** | Ophthalmology |
| **TECHNICAL** | | |
| **2. Technical characteristics** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | **A Scan Specifications:**<br>1. 10/11 MHz Biometry probe with applicator and clinical accuracy of +/- 0.1 mm.<br>2. Ability to measure axial length between 15 and 39 mm.<br>3. Gain should be 98dB or more with an adjustable range of 0-55dB.<br>4. Should have measurement memory of 10 per eye.<br>5. Should have facility for upto five different users to configure the system to their individual settings.<br>6. Should have five IOL calculations formulas: Holladay, SRK II, SRK T, Binkhorst II,Hoffer Q and an optional Haigis formula.<br>7. Should have the post refractive K adjustment software for patients who have undergone refractive procedure.<br>8. Should have the facility for inputs and store White to White data of patients.<br>9. Should have auto, manual and super auto modes.<br>10. Should have large 1024 x 600 WSVGA display LED for easy viewing and adjustable screen brightness.<br>11. Should have age compensation mode for accurate measurements.<br>12. Should have programmable velocity for each segment.<br>13. Should have post-refractive K adjustment software.<br>**B Scan Specification:** |

| | | |
|---|---|---|
| | | 1. Probe frequency should be more than10 MHz.<br>2. Scanning angle should be minimum 53 deg or better.<br>3. Resolution: axial equal or less than 0.2 mm and lateral equal or less than 0.4 mm.<br>4. Total gain should be 98Db or more and adjustable.<br>5. It should have zoom facility, selectable in 06 steps or more.<br>6. TGC should be adjustable in 06 point manually.<br>7. It should have variable delay depth of 0-15 mm.<br>8. It should have multi-group of electronic callipers for distance measurement.<br>9. Various area measurement.<br>10. Post processing: 04 group of curves (linear, logarithmic, exponential, s curve)<br>11. Gray scale: 256 levels |
| 2.2 | **User's interface** | LCD/LED display |
| 2.3 | **Software and/or standard of communication (wherever required)** | In built |
| **3. Physical characteristics** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dba)** | N.A. |
| 3.4 | **Heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Portable |
| **4. Energy source** | | |
| 4.1 | **Power requirements** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | Compatible online UPS with at least 30 minutes backup. |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | As specified by manufacturer |
| **5. Accessories, spare parts, consumables** | | |
| 5.1 | **Accessories (mandatory, standard, optional)**<br>**Spare parts (main ones)**<br>**Consumables / reagents (open, closed system)** | Printer roll, dust cover and spare fuses. |
| **6. Environmental and departmental considerations** | | |
| 6.1 | **Atmosphere / ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |

| | | |
|---|---|---|
| 6.2 | **User's care, cleaning, Disinfection & sterility issues** | Easy to clean and maintain. |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. Training and installation** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. Warranty and maintenance** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| **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 should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided.<br>3. Satisfactory certificate for any existing installation from government hospital |
| 10.2 | **Other accompanying documents** | List of essential spares and accessories, with their part number and cost. |
| **11. Notes** | | |
| 11.1 | **Service support contact details (hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | **Recommendations and Warnings** | Any warning sign should be adequately displayed. |

| APPLATION TONOMETER | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (Name/Institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| UMDNS name | | Ophthalmic tonometer's, Applanation |
| UMDNS code(s) | | |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical purpose | Ophthalmic tonometer's designed to determine intraocular pressure by measuring the force required to flatten the cornea apex by a fixed amount. These instruments are typically small and reusable instruments and are attached to a slit lamp; the tono meter includes a tip to be applied to the cornea and a manually controlled spring that applies a variable force on the cornea through the tip. |
| 1.2 | Used by clinical department/ward | Ophthalmology Department |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1. Range of Measurement 0-80 mmHg<br>2. Movement of Light Circle 1.53 x 2 = 3.06mm<br>3. Prism Diameter 7mm<br>4. Prism Range of Movement 3mm<br>5. Should be compatible with all models of slit lamps. |
| 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) | NA |
| 3.3 | Noise (in dBA) | Noise Free System |
| 3.4 | Heat dissipation | Should maintain nominal temperature and the heat should disbursedthrough a cooling mechanism. |
| 3.5 | Mobility, portability | Portable |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)** | | |
| 4.1 | Power requirements | 220 +/- 10% VAC, 50 Hz |
| 4.2 | Battery operated | No |
| 4.3 | Protection | NA |
| 4.4 | Power consumption | To be specified by service provider |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |

| | | |
|---|---|---|
| 5.1 | Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system) | 1. Calibration Bar,<br>2. Prism<br>3. Tonometer Mount base to fix with optics. |
| **BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS** | | |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| 6.1 | Atmosphere/Ambiance (air conditioning, humidity, dust …) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | To be specified by manufacturer. |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards. |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | Pre- installation requirements: nature, values, quality, tolerance | NA |
| 8.2 | Requirements for sign-off | Supplier to perform installation, safety and operation checksbefore handover. |
| 8.3 | Training of staff (medical, paramedical, technicians) | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | 03 years |
| **10. DOCUMENTATION** | | |
| 10.1 | Operating manuals, set manuals, other manuals | Should provide 2 sets(hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should be supplied inEnglish/Hindi/Regional language along with machine diagrams. |
| 10.2 | Other accompanying documents | NA |
| **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 tobe provided. |
| 11.2 | Recommendations or warnings | Any warning sign would be adequately displayed. |

| AUTO REFRACTOMETER | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (Name/Institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| UMDNS name | | Refractometers |
| UMDNS code(s) | | 15169 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical purpose | Measuring instruments used to determine the ratio of the velocity of light in a vacuum to the velocity of light in another medium (i.e., indexof refraction). |
| 1.2 | Used by clinical department/ward | Ophthalmology Department |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1. Should have in the system.<br>2. Should have refractive measurement sphere from -25 to +22D insteps of 0.25D.<br>3. Should have refractive measurement cylinder from -10 to +10D insteps of 0.25D.<br>4. Should have refractive measurement axis angle from 1 to 180º insteps of 1º.<br>5. Should have at least 0, 12 and 13.5 vertex distance.<br>6. Should measure a minimum pupil diameter of 2.5mm.<br>7. Should have at least 5 inches LCD/LED display.<br>8. Should have vertically adjustable chin rest of at least ±25mm.<br>9. Should have motorized table. |
| 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) | NA |
| 3.3 | Noise (in dBA) | NA |
| 3.4 | Heat dissipation | NA |
| 3.5 | Mobility, portability | NA |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)** | | |

| | | |
|---|---|---|
| 4.1 | Power requirements | 220 +/- 10% VAC, 50 Hz |
| 4.2 | Battery operated | No |
| 4.3 | Protection | NA |
| 4.4 | Power consumption | To be specified by service provider |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents(open, closed system) | Calibrating Device – 1 No. |
| **BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS** | | |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| 6.1 | Atmosphere/Ambiance(air conditioning, humidity, dust …) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterilityissues | To be specified by manufacturer. |
| **7. STANDARDS AND SAFETY** | | |
| 7.1 | Certificates (pre-market, sanitary,..); Performanceand safety standards (specific to the device type); Local and/or international | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | Pre- installation requirements: nature, values, quality, tolerance | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up. |
| 8.2 | Requirements for sign-off | Supplier to perform installation, safety and operation checks before handover. |

| | | |
|---|---|---|
| 8.3 | Training of staff (medical, paramedical, technicians) | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | • 03 years<br>• Preventive Maintenance visits at least once in each quarter |
| **10. DOCUMENTATION** | | |
| 10.1 | Operating manuals, set manuals, other manuals | Should provide 2 sets (hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should be supplied inEnglish/Hindi/Regional language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided.<br>3. Advanced maintenance tasks documentation.<br>4. Satisfactory certificate for any existing installation from governmenthospital. |
| 10.2 | Other accompanying documents | List of essential spares and accessories, with their part number and cost; |
| **11. Notes** | | |
| 11.1 | Service Support Contactdetails (Hierarchy Wise; including a toll free/ landline number) | Contact details of manufacturer, supplier and local service agentto be provided. |
| 11.2 | Recommendations or warnings | Any warning sign would be adequately displayed. |

| Baby Weighing Scale | | |
|---|---|---|
| Version no.: | | 2.0 |
| Date: | | August 2023 |
| Done by: (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Infant Scale, Electronic |
| GMDN code(s) | | 35324 |
| **GENERAL** | | |
| **1. Use** | | |
| 1.1 | **Clinical purpose** | It is used to measure the weight of an infant, particularly a newborn, or to monitor weight changes, e.g., during critical care procedures. |
| 1.2 | **Used by clinical department/ ward** | Midwifery Led Care Unit/NICU/SNCU/PICU |
| **TECHNICAL** | | |
| **2. Technical characteristics** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | • Tabletop, light and portable.<br>• Should have easy to read LCD/LED display.<br>• Weight displays up to 2 decimal point in Kgs/gms.<br>• Weighing pan should be skin friendly, non-toxic durable material suitable for weighing newborn babies and the construction should not allow the baby to slip from the tray<br>• The Tray should be made of ABS/ Acrylic and must be devoid of any sharp edges.<br>• Easy to clean baby tray.<br>• Zero weight adjustment facility.<br>• Quick, clear digital read outs.<br>• Measurement does not change with position of baby on the pan.<br>• Provision to measure the height of the baby in its laying position.<br>• Accuracy: 5 gm, resolution: 1g, Measuring limit: 10 gm to 20 kg.<br>• Built in rechargeable battery/ AC mains. |
| 2.2 | **User's interface** | LCD/LED display |

| | | |
|---|---|---|
| 2.3 | **Software and/or standard of communication(where ver required)** | NA |
| | **3. Physical Characteristics** | |
| 3.1 | **Dimensions (metric)** | Base: 300mm x 265mm x 85mm ± 20%, Pan: 510mm x 300mm x 85mm (minimum). |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dba)** | N.A. |
| 3.4 | **Heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Portable |
| | **4. Energy source (electricity, Ups, solar, gas, water, co2 )** | |
| 4.1 | **Power requirements** | 220 V AC +/- 10%, 50 Hz |
| 4.2 | **Battery operated** | Built in rechargeable battery /AC mains |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | NA |
| 4.5 | **Other energy supplies** | NA |
| | **5. Accessories, spare parts, consumables** | |
| 5.1 | **Accessories (mandatory, standard, optional);Spare parts (main ones); Consumables / reagents (open, closed system)** | NA |
| | **6. Environmental and departmental considerations** | |
| 6.1 | **Atmosphere / ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, cleaning, Disinfection & sterility issues** | To be specified by manufacturer. |
| | **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| | **8. Training and Installation** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over. |
| 8.3 | **Training of staff** | Training of users in operation and basic maintenance shall be |

| | | |
|---|---|---|
| | **(medical, paramedical, technicians)** | provided |
| **9. Warranty and Maintenance** | | |
| 9.1 | **Warranty** | 03 years including all spares.<br>Preventive maintenance visits at least once in each quarter. |
| **10. Documentation** | | |
| 10.1 | **Operating manuals, service manuals, other manuals** | Should provide 2 sets (hard copy and soft copy) of:<br>User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. |
| 10.2 | **Other accompanying documents** | NA |
| **11. Notes** | | |
| 11.1 | **Service support contact details (hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer and supplier to be provided. |
| **11.2** | **Recommendations or warnings** | Any warning sign should be adequately displayed. |

| BLOOD WARMER | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done by: (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | - |
| GMDN code(s) | | - |
| **GENERAL** | | |
| **1. Use** | | |
| 1.1 | **Clinical purpose** | A blood warmer is used to warm blood or other fluids, minimizing the risk of hypothermia. |
| 1.2 | **Used by clinical department/ ward** | Emergency, ICU |
| **TECHNICAL** | | |
| **2. Technical characteristics** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1. Should be able to warm blood at a temperature range of 37˚C – 40˚C with control knob.<br>2. Should be able to maintain or warm blood/fluid at a flow rate of 2.5 L/min.<br>3. It should have digital temperature display of fluid.<br>4. Should use inbuilt water tank /dry heat technology / counter current heat exchanger technology to warm the infused fluid/blood.<br>5. Should be able to attach to IV set.<br>6. Should have a digital display of temperature.<br>7. Audio visual alarms for disconnections and over temperature must be present.<br>8. Should be compatible for both adult and Paediatric patients. |
| 2.3 | **User's interface** | NA |
| 2.4 | **Software and/or standard of communication (wherever required)** | NA |
| **3. Physical characteristics** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | Light weight |
| 3.3 | **Noise (in dba)** | NA |
| 3.4 | **Heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Portable |

| | | |
|---|---|---|
| **4. Energy source** | | |
| 4.1 | **Power requirements** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | NA |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | As specified by manufacturer |
| **5. Accessories, spare parts, consumables** | | |
| 5.1 | **Accessories (mandatory, standard, optional)**<br>**Spare parts (main ones)**<br>**Consumables / reagents (open, closed system)** | At least 80 disposable tubing set for adults and 20 for paediatrics should be supplied. |
| **6. Environmental and departmental considerations** | | |
| 6.1 | **Atmosphere / ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, cleaning, Disinfection & sterility issues** | Easy to clean and maintain |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards in case of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. Training and installation** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. Warranty and maintenance** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| **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 should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided. |

| | | |
|---|---|---|
| | | 3. Satisfactory certificate for any existing installation from government hospital |
| 10.2 | **Other accompanying documents** | List of essential spares and accessories, with their part number and cost. |
| **11. Notes** | | |
| 11.1 | **Service support contact details (hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | **Recommendations and Warnings** | Any warning sign should be adequately displayed. |

| BOWL STERILIZER | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name / institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Bowl Sterilizer |
| 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 ofdifferent 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 temperature controller for controlling the temperature.<br>13) Digital time controller housed in Temperature controller cabinet usedfor 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(whereever required)** | NA |
| **3 PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dBA)** | NA |
| 3.4 | **Heat dissipation** | Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism |
| 3.5 | **Mobility, portability** | Stationary |
| **4 ENERGY SOURCE (ELECTRICITY, UPS, SOLAR, GAS, WATER, CO2 )** | | |

| | | |
|---|---|---|
| 4.1 | **Power Requirements** | 230 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | Yes |
| 4.3 | **Power consumption** | To be specified by manufacturer |
| **5 ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | **Accessories (mandatory, standard,optional); Spare parts (main ones); Consumables / reagents (open, closedsystem)** | NA |
| **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | | |
| **6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | **Atmosphere / Ambiance (air conditioning, humidity,dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer |
| **7 STANDARDS AND SAFETY** | | |
| 7.1 | **Certificates (pre- market, sanitary, ..); Performance and safety standards (specific to the device type);Local and/or international** | Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users on operation and basic maintenance. |
| **9 WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter |
| **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) Service and operation manuals (original and copy) to be provided.<br>3) Advanced maintenance tasks documentation. |
| 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. |
| 11.2 | **Recommendations or warnings** | Any warning signs would be adequately displayed |

| BP APPARATUS (ANEROID) | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Sphygmomanometers |
| GMDN code(s) | | |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | Measures blood pressure non-invasively by displaying the pressure in a cuff wrapped around a patient's arm. The systolic and diastolic pressure is usually assessed by listening to Korotk off sounds generated by arterial blood flow using a stethoscope simultaneously. |
| 1.2 | **Used by clinical department/ward** | All clinical departments |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1) Should be based on non-mercurial aneroid based measurement technology .<br>2) Should be able to measure blood pressure in adult as well as pediatric patients.<br>3) Should have a dial type display, with a hook which can be attached to the blood pressure cuff.<br>4) Pressure measurement range should be 0 to 300 mm Hg systolic and 40 to 200mm Hg diastolic.<br>5) Pressure measurement accuracy of +/- 3 to 5mm Hg<br>6) Manual inflation of blood pressure cuff. |
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/or standard of communication (wherever required)** | NA |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dBA), heat dissipation** | NA |
| 3.4 | **Mobility, portability** | Yes |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 )** | | |
| 4.1 | **Power Requirements** | NA |
| 4.2 | **Battery operated** | NA |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | NA |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |

| | | |
|---|---|---|
| 5.1 | **Accessories (mandatory, standard, optional)**<br>**Spare parts (main ones)**<br>**Consumables / reagents(open, closed system)** | Adult arm cuffs of size medium & large and pediatric size, inflation bulb, tubing.<br>Dial mano meter. |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | **Atmosphere / Ambiance(air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterilityissues** | NA |
| **7. STANDARDS AND SAFETY** | | |
| 7.1 | **Certificates (pre-market, sanitary, ...); Performanceand safety standards (specific to the device type); Local and/or international** | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards. |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | NA |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | NA |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | 1 years |
| **10. DOCUMENTATION** | | |
| 10.1 | **Operating manuals, service manuals, other manuals** | User manuals to be supplied in English languagealong with machine diagrams. |
| 10.2 | **Other accompanying documents** | NA |
| **11. NOTES** | | |
| 11.1 | **Service Support Contactdetails (Hierchy Wise; including a toll free/ landline number)** | NA |
| 11.2 | **Recommendations orwarnings** | NA |

| Sphygmomanometer (Digital) | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Automatic-inflation electronic sphygmomanometer, portable, arm/wrist |
| GMDN code(s) | | 45617 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | Digital Sphygmomanometers are automated, providing blood pressure reading without needing someone to operate the cuff or listen to blood flow sounds |
| 1.2 | **Used by clinical department/ward** | All clinical departments |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1) Should be able to measure blood pressure and pulse rate in adult patients.<br>2) Should be based on oscillometric measurement technology, using dynamic linear deflation method.<br>3) Should have backlit digital display with easy to view readings in dim light.<br>4) Pressure measurement range should be 60 to 250 mm Hg systolic, and 40 to 200mm Hg diastolic.<br>5) Pressure display accuracy of +/- 2 to 3 mm Hg<br>6) Pulse rate measurement range of 40 to 220 per minute<br>7) Pulse measurement accuracy of within +/- 5%<br>8) Single button operation for start and stop functions with auto-inflation of blood pressure cuff.<br>9) The device should have rechargeable battery. |
| 2.2 | **User's interface** | Digital Display |
| 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)** | NA |
| 3.4 | **Noise (in dBA), heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Portable |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 )** | | |
| 4.1 | **Power Requirements** | NA |
| 4.2 | **Battery operated** | YES |

| | | |
|---|---|---|
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | NA |
| | **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory,standard, optional)** | Adult arm cuffs of size small, medium, large & extra-large and inflation bulb, tubing<br>• Battery Charger |
| | **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | |
| 6.1 | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | Easy to clean |
| | **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards. |
| | **8. TRAINING AND INSTALLATION** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | NA |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| | **9. WARRANTY AND MAINTENANCE** | |
| 9.1 | **Warranty** | 01 Year |
| | **10. DOCUMENTATION** | |
| 10.1 | **Operating manuals, service manuals, other manuals** | Should provide 2 sets (hard copy and soft copy) of:<br>User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. |
| 10.2 | **Other accompanying documents** | NA |
| | **11. NOTES** | |
| 11.1 | **Service Support Contact details (Hierchy Wise; including a toll free/ landline number)** | Contact details of manufacturer and supplier to be provided. |
| 11.2 | **Recommendations or warnings** | Any warning sign should be adequately displayed. |

| CRYOSURGERY UNIT ($CO_2$, $N_2O$) | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by: (Name/Institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| UMDNS name | | Cryosurgical Units, Ophthalmic |
| UMDNS code(s) | | 11068 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical purpose | Cryosurgical units are designed for applying extreme cold to eye tissues to destroy abnormal cells. These units usually consist of a hollow probe(cryo probe) that circulates a cryogenic substance (e.g. liquid nitrogen) to form an ice crystal ball around the cells, which freezes the cells of thetissues with which it comes into contact. Ophthalmic cryosurgical units are used mainly to treat eye tumors (e.g., retinoblastoma), to relieveingrown eyelashes (trichiasis), for cryo extraction of intra capsular cataracts, and/or to repair retinal detachment. |
| 1.2 | Used by clinical department/ward | Ophthalmology - Operating theater, Operating room. |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1. Cryogen shall be $CO_2$ and $N_2O$.<br>2. Cryosurgical unit capable of achieving temperatures at the cryo tipbelow -79°C (-110.2°F) for $CO_2$, -89°C (-128.2°F) for $N_2O$.<br>3. Should have Active and Passive defrosting system.<br>4. Cryosurgical procedures require several different probe designs. Special probes are used based on the surgical procedures. Cryosurgical units with multiple probe tips can enable physicians to perform a number of specialized procedures. Should be supplied with all kinds of probes required for ophthalmology and all cryo probes must be autoclavable.<br>5. Operating pressure 400 to 850 psi.<br>6. The unit shall have a trigger mechanism to control the freeze/thaw cycle (active defrost preferred but not essential), removable circular,closed design cryo tips with flat surfaces or with a cone extrusionnot exceeding 5 mm, insulated cryo shaft of length 170 mm to 200 mm, hose assembly (high pressure) with cylinder connector,pressure gauge and relief valve, and exhaust port to which a hose can be connected to safely vent the exhaust gas.<br>7. Due to the adverse effects of chronic exposure to waste anesthetic gases, nitrous oxide units should have scavenging ability. |

| | | |
|---|---|---|
| 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 | Noise (in dBA) | NA |
| 3.4 | Heat dissipation | NA |
| 3.5 | Mobility, portability | Portable |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, $CO_2$ ….)** | | |
| 4.1 | Power requirements | NA |
| 4.2 | Battery operated | NA |
| 4.3 | Protection | NA |
| 4.4 | Power consumption | NA |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | Accessories, (mandatory, standard,optional); Spare parts (main ones); Consumables/reagents (open, closed system) | 1. Cryo probes to according the specific use (Preferably 3 sizes (1.5mm, 2 mm, 3 mm)).<br>2. Integral timer and temperature indicator.<br>3. Should be supplied with rolling cart.<br>4. Should be supplied with unfilled cylinder for $N_2O$ or $CO_2$. |
| **BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS** | | |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| 6.1 | Atmosphere/Ambiance(air conditioning, humidity, dust …) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | To be specified by manufacturer |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards. |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | Pre- installation requirements: nature, values, quality, tolerance | NA |
| 8.2 | Requirements for sign-off | Supplier to perform installation, safetyand operation checks before handover. |
| 8.3 | Training of staff (medical, paramedical, technicians) | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | • 03 years<br>• Preventive Maintenance visits at least once in each quarter |
| **10. DOCUMENTATION** | | |
| 10.1 | Operating manuals, setmanuals, other manuals | Should provide 2 sets (hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should be supplied inEnglish/Hindi/Regional language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided.<br>3. Advanced maintenance tasks documentation. |
| 10.2 | Other accompanying documents | List of essential spares and accessories, with their part number andcost; |
| **11. Notes** | | |
| 11.1 | Service Support Contactdetails (Hierarchy Wise; including a toll free/ landline number) | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | Recommendations or warnings | Any warning sign would be adequately displayed. |

| CRYOSURGERY UNIT (LIQUID NITROGEN) | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by: (Name/Institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| UMDNS name | | Cryosurgical Units, Ophthalmic |
| UMDNS code(s) | | 11068 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical purpose | Cryosurgical units designed for applying extreme cold to eye tissues to destroy abnormal cells. These units usually consist of a hollow probe (cryo probe) that circulates a cryogenic substance (e.g. liquid nitrogen) to form an ice crystal ball around the cells, which freezes the cells of the tissues with which it comes into contact. Ophthalmic cryosurgical units are used mainly to treat eye tumors (e.g., retinoblastoma), to relieveingrown eyelashes (trichiasis), for cryo extraction of intra capsular cataracts, and/or to repair retinal detachment. |
| 1.2 | Used by clinical department/ward | Ophthalmology - Operating theater, Operating room. |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1. Cryogen shall be Liquid Nitrogen.<br>2. Cryosurgical unit capable of achieving temperatures at the cryo tipbelow --196°C (-320.8°F).<br>3. Should have Active and Passive defrosting system.<br>4. Cryosurgical procedures require several different probe designs. Special probes are used based on the surgical procedures. Cryosurgical units with multiple probe tips can enable physicians to perform a number of specialized procedures. Should be suppliedwith all kinds of probes required for ophthalmology and all cryo probes must be autoclavable.<br>5. Operating pressure 400 to 850 psi.<br>6. The unit shall have a trigger mechanism to control the freeze/thaw cycle (active defrost preferred but not essential), removable circular, closed design cryo tips with flat surfaces or with a cone extrusionnot exceeding 5 mm, insulated cryo shaft of length 170 mm to 200 mm, hose assembly (high pressure) with cylinder connector, pressure gauge and relief valve, and exhaust port to which a hose can be connected to safely vent the exhaust gas. |
| 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 | Noise (in dBA) | NA |
| 3.4 | Heat dissipation | NA |
| 3.5 | Mobility, portability | Portable |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, $CO_2$ ….)** | | |
| 4.1 | Power requirements | NA |
| 4.2 | Battery operated | NA |
| 4.3 | Protection | NA |
| 4.4 | Power consumption | NA |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | Accessories, (mandatory, standard,optional); Spare parts (main ones); Consumables/reagents (open, closed system) | 1. Cryo probes to according the specific use (Preferably 3 sizes (1.5mm, 2 mm, 3 mm)).<br>2. Integral timer and temperature indicator.<br>3. Should be supplied with rolling cart.<br>4. Should be supplied with unfilled cylinder for $N_2O$ or $CO_2$. |
| **BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS** | | |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| 6.1 | Atmosphere/Ambiance (air conditioning, humidity, dust …) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | To be specified by manufacturer |
| **7. STANDARDS AND SAFETY** | | |
| 7.1 | Certificates (pre-market, sanitary,..); Performanceand safety standards (specific to the device type); Local and/or international | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards. |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | Pre- installation requirements: nature, values, quality, tolerance | NA |

| | | |
|---|---|---|
| 8.2 | Requirements for sign-off | Supplier to perform installation, safety and operation checks before handover. |
| 8.3 | Training of staff (medical, paramedical, technicians) | Training of users in operation and basic maintenance shall be provided.Advanced maintenance tasks required shall be documented. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| **10. DOCUMENTATION** | | |
| 10.1 | Operating manuals, set manuals, other manuals | Should provide 2 sets (hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams;<br>2. Service and operation manuals (original and Copy) to be provided.<br>3. Advanced maintenance tasks documentation. |
| 10.2 | Other accompanying documents | List of essential spares and accessories, with their part number andcost; |
| **11. Notes** | | |
| 11.1 | Service Support Contact details (Hierarchy Wise; including a toll free/ landline number) | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | Recommendations or warnings | Any warning sign would be adequately displayed. |

| DEFIBRILLATOR | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | - |
| GMDN code(s) | | - |
| **GENERL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | To detect cardiac arrhythmias in a sudden cardiac arrest patient, and then audibly/visually instructs an operator to enable it to activate defibrillation of theheart through application of electrical shocks to the chest surface. |
| 1.2 | **Used by clinical department/ward** | Emergency/ICU/Cardiac care |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1. Unit should be lightweight compact and portable.<br>2. Unit should have facility for Automatic External Defibrillation and manualdefibrillation.<br>3. Should be able to deliver shock from 50-200 joules in biphasic mode viametal chest pads.<br>4. Should having design protection to avoid passage of current to the user.<br>5. The whole system should have an inbuilt recorder. |
| 2.2 | **User's interface** | The monitor should have a color display with a three channel display. |
| 2.3 | **Software and/or standard of communication(where ever required)** | Inbuilt |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | Compact |
| 3.2 | **Weight (lbs, kg)** | Light weight |
| 3.4 | **Noise (in dBA), heat dissipation** | <60dBA; adjustable heart rate alarm as well as paddles & ECG cable disconnection alarms. |
| 3.5 | **Mobility, portability** | Yes |
| **4. ENERGY SOURCE** | | |
| 4.1 | **Power Requirements** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | Rechargeable battery backup of approximately 5 hours. |

| | | |
|---|---|---|
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | As specified by manufacturer. |
| | **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory, standard, optional)**<br>**Spare parts (main ones)**<br>**Consumables / reagents(open, closed system)** | Chest paddles<br>ECG cable; Recording paper rolls; Disposable pads; |
| | **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | |
| 6.1 | **Atmosphere / Ambiance(air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterilityissues** | To be specified by manufacturer. |
| | **7. STANDARDS AND SAFETY** | |
| 7.1 | **Certifications** | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| | **8. TRAINING AND INSTALLATION** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over. |
| 8.3 | **Training of staff (medical,paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| | **9. WARRANTY AND MAINTENANCE** | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| | **10. DOCUMENTATION** | |
| 10.1 | **Operating manuals, service manuals, other manuals** | 1. User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams.<br>2. Advanced maintenance tasks required shall be documented. |

| | | |
|---|---|---|
| 10.2 | **Other accompanying documents** | List of important spares and accessories, with their part numbersand cost. |
| **11. NOTES** | | |
| 11.1 | **Service Support Contactdetails (Hierchy Wise; including a toll free/ landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | **Recommendations orwarnings** | Any warning sign should be displayed adequately. |

| SUCTION MACHINE-FOOT & ELECTRIC OPERATED | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by: (name/institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | |
| GMDN code | | |
| **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 | Emergency, ICU, OT, HDU |
| **TECHNICAL** | | |
| 2. TECHNICAL CHARACTERISTICS | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1.Should be designed for draining blood and other fragmented secretions in emergency settings.<br>2. Should be operable both electrically and foot operated during non-availability of electricity.<br>3. Should be fitted with oil immersed noiseless motorized vacuum pump.<br>4. Cabinet should be made of stainless steel (MS-304).<br>5. Should have two lightweight, clear glass or unbreakable polycarbonate Jar on the top having minimum capacity of 2 Ltr each fitted with rubber airtight lids and having overflow safety device.<br>6. Should have a motor of minimum ½ HP capacity single phase 1440 RPM with control knob.<br>7. Should have vacuum at least between 100 mmHg to at least 575 mm Hg ± 10 regulable with vacuum control knob.<br>8. Should be mounted on 4 castor wheels, nylon material, heavy duty, movable in all directions. |
| 2.2 | User's interface | Manual |
| 2.3 | Software and/or standard of communication (wherever required) | NA |
| 3. PHYSICAL CHARACTERISTICS | | |
| 3.1 | Dimensions (metric) | NA |
| 3.2 | Weight (lbs, kg) | Light weight |
| 3.3 | Noise (in dBA) | Noise free operation |

| | | |
|---|---|---|
| 3.4 | Heat dissipation | NA |
| 3.5 | Mobility, portability | Yes |
| | 4. ENERGY SOURCE | |
| 4.1 | Power Requirements | 220 +/- 10% VAC, 50 Hz |
| 4.2 | Battery operated | NA |
| 4.3 | Protection | NA |
| 4.3 | Power consumption | As specified by manufacturer. |
| | 5. ACCESSORIES, SPARE PARTS, CONSUMABLES | |
| 5.1 | Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system) | Collection bottles, clear unbreakable jar (one set extra) |
| | 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS | |
| 6.1 | Atmosphere/Ambiance (air conditioning, humidity, dust...) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | To be specified by manufacturer |
| | 7. STANDARDS AND SAFETY | |
| 7.1 | Certifications | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| | 8. TRAINING AND INSTALLATION | |
| 8.1 | Pre-installation requirements: nature, values, quality, tolerance | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | Requirements for sign-off | Supplier to perform installation, safety and operation checks before handover. |
| 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 | • 03 years<br>• Preventive Maintenance visits at least once in each quarter |
| | 10. DOCUMENTATION | |

| | | |
|---|---|---|
| 10.1 | Operating manuals, service manuals, other manuals | User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams. |
| 10.2 | Other accompanying documents | NA |
| 11. NOTES | | |
| 11.1 | Service Support Contact details (Hierchy Wise; including a toll free/landline number) | Contact details of manufacturer should be provided. |
| 11.2 | Recommendations or warnings | Any recommendations for best use and supplementary warning for safety should be declared. |

| NCV- EMG VEP MACHINE (Nerve Conduction Velocity, electromyograph, Visual Evoked Potential Machine) | | |
|---|---|---|
| Version no.: | | 02 |
| Date: | | August 2023 |
| Done by: (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | |
| GMDN code(s) | | |
| **GENERAL** | | |
| **1. Use** | | |
| 1.1 | **Clinical purpose** | It detects, process, and records electrical activity of nerves, neuromuscular junctions and skeletal muscles. Evoked Potential graphic recorders measure and document the brain's electrical response to visual, auditory, or somatosensory stimuli. |
| 1.2 | **Used by clinical department/ ward** | Physical Medicine and Rehabilitation Unit |
| **TECHNICAL** | | |
| **2. Technical characteristics** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1. NCV-EMG EP machine should have at least 4 Channels or more.<br>2. NCV-EMG EP machine should be based on Windows Operating System, Desktop Computer/laptop with latest configuration and high storage capacity.<br>3. Amplifiers should have at least 4 Optically Isolated Channels with 14/16/24-bit ADC, CMRR should be more than 100dB, Input Impedance should be more than 100M Ohms, Sensitivity from 1 microV/Div to 20 mV/Div and should have sweep speed in the range of 1 to 1000 ms /div .<br>4. System should have handheld electrical Stimulator with stimulus intensity dial and stimulus trigger on handle.<br>5. It should have start /stop switches provided on handle. It should stimulate with constant Electrical Current (from 0 to 100mA) up to 1 ms duration. It should be electrically isolated with independent controls.<br>6. The system should have the following Application software as standard :-<br>• Motor and Sensory nerve conduction, F -wave, H-reflex, Blink reflex, Repetitive nerve stimulation test, inching.<br>• It should have packages for doing EMG acquisition and analysis, advanced quantitative analysis of EMG (facility to record/Replay EMG on Hard Drive ).On single screen surface EMG, SP activity , interference pattern , single motor unit potential , turn/amplitude analysis should be possible. Manual/auto MUPs selection for |

| | | |
|---|---|---|
| | | analysis<br>• Somatosensory SEP, ABR, Pattern Reversal VEP, LED Goggles VEP, P-300 etc.<br>7. The system should have facility for Automatic Online Summary Report |
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/or standard of communication (wherever required)** | In-built |
| **3. Physical characteristics** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dba)** | N.A. |
| 3.4 | **Heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Portable |
| **4. Energy source** | | |
| 4.1 | **Power requirements** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | Rechargeable battery with minimum 24 hours backup |
| 4.3 | **Protection** | NA |
| 4.5 | **Power consumption** | As specified by manufacturer |
| **5. Accessories, spare parts, consumables** | | |
| 5.1 | **Accessories (mandatory, standard, optional) Spare parts (main ones) Consumables / reagents (open, closed system)** | NA |
| **6. Environmental and departmental considerations** | | |
| 6.1 | **Atmosphere / ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, cleaning, Disinfection & sterility issues** | To be specified by manufacturer. |
| **7. Standards and safety** | | |
| 7.1 | **Certificates (pre-** | 1. Should be CDSCO approved. |

| | | |
|---|---|---|
| | **market, sanitary, ..); performance and safety standards (specific to the device type); local and/or international** | 2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. Training and installation** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. Warranty and maintenance** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter |
| **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 should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided.<br>3. Satisfactory certificate for any existing installation from government hospital |
| 10.2 | **Other accompanying documents** | List of essential spares and accessories, with their part number and cost. |
| **11. Notes** | | |
| 11.1 | **Service support contact details (hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | **Recommendations and Warnings** | Any warning sign should be adequately displayed. |

| EEG - ELECTROENCEPHALOGRAPHY | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name/institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Electroencephalography |
| GMDN code(s) | | CT138 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | To record the variations of the electrical potential caused by the electricalactivity of the brain |
| 1.2 | **Used by clinical department/ward** | Radiology Services |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1) Should be a 32 Channel digital EEG Machine, where 24 Channels for acquisition and storage, 5 Polygraph Channels and 3 DC Channels.<br>2) Frequency response should be 0.05Hz to 70Hz.<br>3) Should have facility to view all channels in different montages duringacquisition and review.<br>4) Should have split screen facility to study and even carefully duringacquisition, where data storage should be on going in hard disk.<br>5) Should have split screen facility in analysis to compare the data of sametime or different times with individual selection of filters, sensitivity, montages etc.<br>6) Should have the facility for simultaneous acquisition and review of samerecord.<br>7) Should have the facility to mark pages/important events for printing inreview.<br>8) Should have user definable photic stimulator protocol execution withdisplay of photic marks on screen using LED or Xenon flash lights<br>9) Should have unlimited Montage Reformatting.<br>10) Should have HLF (15, 35, 70 Hz) and LLF (0.1, 0.3, 1.5, 3, 5 Hz) filters foreach channel as well as for all channels for display.<br>11) Should have the facility for sweep speed selection.<br>12) Should have the facility to display traces with limit trace.<br>13) Should mark and annotate standards events such as Eyes open, Eyes closed, Hyperventilation on, Hyperventilation off, Artifact, and other userdefined events of max. 50. |

| | | |
|---|---|---|
| | | 14) Should have separate sensitivity control for each channels as well as forall channels.<br>15) Should have the facility to enter patient details such as ID, Name, Referred By, Sex, Age, Patient History, Address, Doctor Name etc.<br>16) Should have the facility to review of selected patient form list, to sort data according to patient name, sex, age, test date etc, review another patient while acquisition and to edit the patient details.<br>17) Should have the facility to browse page by page, Scroll in forward and reverse direction and the speed of scrolling can be different speed levels such as same acquisition speed, 2 times, 3 times , 4 times the acquisition speed.<br>18) Should have user definable protocols for acquisition.<br>19) EEG pages should displayed in BRAIN MAP montage and it should have the facility to view Amplitude brain map, Progressive amplitude brain map, frequency brain map, progressive frequency brain map, 4 bands frequency brain map with frequency spectrum, 5 bands frequency brain map with frequency spectrum, 4 bands frequency brain map with EEG & 5 bands frequency brain map with EEG in review mode.<br>20) Should have the facility to edit current page events, browse all the marked events. Display the page having the selected event, to store any number of marked EEG pages on another HDD.<br>21) Should have the facility for spike detection with amplitude greater than or equal to the specified amplitude and within specified duration.<br>22) Should have the facility to print all marked EEG pages/Brain map pages in queue.<br>23) Should have Acquisition Hot keys for Sensitivity for all traces, Eyes open, Eyes close, Hyperventilation ON, Hyperventilation OFF, Mark page, Artifact, Annotated event, Toggle pause/Release pause, Snap shot mode, photic stimulation etc.<br>24) Should have Review Hot Keys for page mode, scroll mode, flip mode, next page, increase speed, mark page for printing, forward direction, reverse direction, previous page, decrease speed etc.<br>25) Photic frequency should be 1-30 Hz, Stimulating time 1-16 sec and pause time 1-16 sec.<br>26) CMRR should be greater than 100 db and input impedance should be greater than 10 M Ohms.<br>27) Should have a high resolution low light video camera.<br>28) Should have infra red camera for night VEEG recording facilities.<br>29) Should have facility to upgrade EEG to sleep system in |

| | | |
|---|---|---|
| | | future.<br>30) Should be supplied all necessary accessories including EEG Disc Electrode. |
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/or standard of communication (where ever required)** | 1) Convenient and quick USB interface.<br>2) Should have an efficient data base management including Hospital details, Reference doctors list, standard comments for summary report etc.<br>3) Should have the facility to edit and print summary report, EEG page and Brain map page.<br>4) Inbuilt software. |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | Light weight |
| 3.4 | **Noise (in dBA)** | NA |
| 3.5 | **Heat dissipation** | NA |
| 3.6 | **Mobility, portability** | Portable |
| **4. ENERGY SOURCE** | | |
| 4.1 | **Power Requirements** | 220 VAC ± 10%, 50Hz; |
| 4.2 | **Battery operated** | Battery powered, silence able alarm for power failure.<br>Battery charger to be integral to mains power supply, and to charge batteryduring mains power operation of unit.<br>Internal, replaceable, rechargeable battery allows operation for at least onehour in the event of power failure. |
| 4.4 | **Protection** | NA |
| 4.5 | **Power consumption** | As specified by manufacturer. |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | **Accessories (mandatory, standard, optional)**<br>**Spare Parts (Main ones)**<br>**Consumables/reagents (open, closed system)** | 2 Two sets of electrodes<br>Two sets of spare fuses (if non-resettable fuses used).<br>5 tubes/box of elefix EEG paste. |
| **BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS** | | |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | **Atmosphere/Ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection &** | To be specified by manufacturer. |

| | | |
|---|---|---|
| | **Sterility issues** | |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standard. |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform installation, safety and operation checks before handover. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users on operation and basic maintenance. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| **10. DOCUMENTATION** | | |
| 10.1 | **Operating manuals, service manuals, other manuals** | Should provide 2 sets(hardcopy) of:-<br>User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams; |
| 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 (Hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | **Recommendations or warnings** | Any warning signs would be adequately displayed. |

| ERYTHROCYTE SEDIMENTATION RATE (ESR) ANALYSER | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done By: | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN Name | | Erythrocyte Sedimentation rate (ESR) analyser IVD |
| GMDN Code | | 56691 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical Purpose | An electrically powered automated laboratory instrument intended to be used to determine the erythrocyte sedimentation rate (ESR) of red blood cells in an anticoagulated whole blood specimen. |
| 1.2 | Used by clinical department/ward | Clinical Diagnostic Laboratory |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical Characteristics (Specific to this type of device) | • The instrument should carry out automated ESR analysis directly from closed ESR tubes or EDTA vacutainers using the principle of sedimentation of red blood cells (Westergren Method).<br>• Should be able to load minimum 10 samples at a time. Both batch and continuous.<br>• Measuring range in mm: 1-140 using optical sensor.<br>• Throughput should be at least 60 samples/hr.<br>• ESR controls should have long shelf life (minimum 6 months).<br>• Should have an inbuilt Bar code Reader and printer.<br>• Should have auto mixing facility as per ICSH & CLSI requirements.<br>• Have provision for internal temperature correction at 18°C or 37° C<br>• Should have feature of haemocrit HCT correction<br>• Should offer random access testing<br>• Data storage capacity: upto 1000 test results.<br>• Internal Quality Control Management with minimum two level of controls should be provided.<br>• Should have facility for calibration and should comply with National/International quality standards<br>• Provision for bi-directional LIS interface should be available.<br>• Provision for Bar Code/QR code reading should be available. |

| | | |
|---|---|---|
| | | • The equipment should have in-built digital display unit and PC interface facility. |
| **2.2** | **User's Interface** | Microcontroller based LCD/LED Display Unit |
| **2.3** | **Software and/or standard of communication (Wherever required)** | All software installations or updates should be done free of cost during warranty period. |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | Dimensions (in mm) | NA |
| 3.2 | Weight | NA |
| 3.3 | Noise | NA |
| 3.5 | Heat Dissipation | NA |
| 3.6 | Mobility/Portability | Stationary Lab Installation |
| **4. ENERGY SOURCE** | | |
| 4.1 | Power input | 220VAC +/- 10%, 50 Hz. |
| 4.2 | Battery Operated | Yes |
| 4.3 | Protection | Internal Electrical Safety |
| 4.2 | Power consumption | As per Manufacturer/Supplier specified |
| **5. ACCESSORIES, SPARE PARTS AND CONSUMABLES** | | |
| 5.1 | Accessories, (mandatory, Standard, operational); Spare parts (main ones) Consumable/reagents (Open, closed system) | 1. Reagents and consumables to carry out minimum 200 tests<br>2. One additional set of RS 232 cables<br>3. Other Standard accessories. |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | Atmosphere /Ambiance (air conditioning, humidity, dust ...) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | To be specified by manufacturer. |
| **7. STANDARDS & SAFETY** | | |

| | | |
|---|---|---|
| 7.1 | Certificates (pre-market, sanitary, ..);Performance and safety standards (specific to the device type);Local and/or international | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | Pre-installation requirements: nature, values, quality, tolerance | As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up. |
| 8.2 | Requirements for sign-off | 1. Supplier to perform installation, safety and operation checks before handover.<br>2. Lab In-Charge to affirm completion of installation |
| 8.3 | Training of staff (medical, paramedical, technicians) | Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | **1.** 3 years, including all spares and calibration.<br>2. Preventive maintenance visits atleast one in each quarter |
| **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 should 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,<br>6. Satisfactory certificate for any existing installation from government hospital. |
| **10.2** | **Other accompanying documents** | List of all the important spares and accessories, with their part numbers and cost needs to be submitted. |
| **11. NOTES** | | |

| | | |
|---|---|---|
| 11.1 | Service Support Contact details (Hierarchy Wise; including a toll free/landline number) | Contact details of Vendor and local service agent needs to be provided. |
| 11.2 | Recommendations or warnings | Any specific recommendation or warning to be followed for ensuring optimal and safe utilization of medical device needs to be mentioned. |

| Examination Light/Mobile Spot Light | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (Name/Institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| GMDN name | | Mobile Examination/Treatment Room Light |
| GMDN code(s) | | 36843 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical purpose | A mobile device intended to provide light to illuminate a site of patient examination and/or treatment. |
| 1.2 | Used by clinical department/ward | Examination Room, Minor OT |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1. Should use a LED light source.<br>2. It should have variable light intensity upto 50000 Lux.<br>3. Knob or buttons for adjusting the light intensity between 20,000 to 50,000 Lux.<br>4. Lifespan of LED lamp should not be less than 30000 hours.<br>5. It should have wide field size of illumination.<br>6. Arm should be adjustable horizontally, vertically and easy to focus on all directions.<br>7. It should have an on/off switch.<br>8. The stand should be heavy, and it should have 360 deg roller wheels (Angular/SS MS-304) with locking mechanism. |
| 2.2 | User's interface | Manual |
| 2.3 | Software and/or standard of communication (wherever required) | Not required |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | Dimensions(metric) | Height should be adjustable. |
| 3.2 | Weight (lbs, kg) | NA |
| 3.3 | Noise (in dBA) | NA |
| 3.4 | Heat dissipation | NA |
| 3.5 | Mobility, portability | Mobile |
| **4. ENERGY SOURCE** | | |
| 4.1 | Power requirements | 220 +/- 10% VAC, 50 Hz |
| 4.2 | Battery operated | Yes, Minimum backup time of 02 hour |
| 4.3 | Protection | NA |
| 4.4 | Power consumption | To be specified by manufacturer |

| | | |
|---|---|---|
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system) | Not required. |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| 6.1 | Atmosphere/Ambiance (air conditioning, humidity, dust …) | NA |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | Easy to clean |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | Pre- installation requirements: nature, values, quality, tolerance | Compatible electrical accessories as per standard Indian set-up. |
| 8.2 | Requirements for sign-off | Supplier to perform safety and operation check before handover. |
| 8.3 | Training of staff (medical, paramedical, technicians) | NA |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | 03 Years |
| **10. DOCUMENTATION** | | |
| 10.1 | Operating manuals, set manuals, other manuals | One copy (hard copy and soft copy) to be provided on user manual/ operating manual and service/Technical manual. |
| 10.2 | Other accompanying documents | List of essential accessories and cost should be quoted. |
| **11. Notes** | | |
| 11.1 | Service Support Contact details (Hierarchy Wise; including a toll free/ landline number) | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | Recommendations or warnings | Any warning sign would be adequately displayed on equipment. |

| Foetal Doppler / Fetoscope | | |
|---|---|---|
| Version | | 02 |
| Date: | | August 2023 |
| Done by : (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Foetal Doppler System |
| GMDN code(s) | | 34040 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | It is used to noninvasively detect foetal heart beats using Ultrasound/Doppler technology. The heart beats are typically conveyed audibly via the measuring/display unit and attached probe which is applied to the surface of the pregnant woman's abdomen. |
| 1.2 | **Used by clinical department/ward** | Midwifery Led Care Unit/Obstetric/ANC Clinic |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | • It should measure fetal heart rate (FHR) accurately.<br>• It should have backlit digital display.<br>• The probe should be highly sensible to pick up FHR.<br>• The probe should be waterproof.<br>• Probe (transducer) with 2-5 MHz frequency attached via a cable.<br>• It should give indication for low battery.<br>• It should have built-in-speaker with volume adjustment.<br>• Built-in rechargeable Li-on battery with minimum back up of 6-8 Hrs. |
| 2.2 | **User's interface** | Backlit digital display |
| 2.3 | **Software and/or standard of communication( wherever required)** | NA |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions** | NA |

| | | |
|---|---|---|
| | **(metric)** | |
| 3.2 | **Weight (lbs, kg)** | Light weight |
| 3.3 | **Noise (in dBA),** | Noise: <60dBA |
| 3.4 | **Heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Portable, Handheld device |
| | **4. ENERGY SOURCE** | |
| 4.1 | **Power Requirements** | 220 +- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | Built-in rechargeable Li-on battery with minimum backup of 6-8 Hrs. |
| 4.3 | **Power Consumption** | To be specified by manufacturer |
| | **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory, standard, optional);**<br>**Spare parts (main ones);**<br>**Consumables / reagents (open, closed system)** | Doppler probe, battery charger, Gel for application of probe. |
| | **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | |
| | **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | |
| 6.1 | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer |
| | **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |

| | | |
|---|---|---|
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | NA |
| 8.2 | **Requirements for sign-off** | Supplier to perform installation, safety and operation check before hand over. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | Three years<br>Preventive Maintenance visits at least once in each quarter. |
| **10. Documentation** | | |
| **10.1** | **Operating manuals, set manuals, other manuals** | Should provide 2 sets (hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided. |
| **10.2** | **Other accompanying documents** | List of essential spares and accessories, with their part number 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. |
| **11.2** | **Recommendations or warnings** | Any warning sign should be adequately displayed. |

| FUNDUS CAMERA | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done by: (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Ophthalmic fundus camera |
| GMDN code(s) | | 10551 |
| **GENERAL** | | |
| **1. Use** | | |
| 1.1 | **Clinical purpose** | An electrically powered optical device intended to be used to create digital color photographic images of the ocular fundus (interior eye surface opposite the lens) through the pupil, to aid in diagnosing and monitoring retinal pathology. |
| 1.2 | **Used by clinical department/ ward** | Ophthalmology |
| **TECHNICAL** | | |
| **2. Technical characteristics** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1. Both modalities- mydriatic and non-mydriatic imaging should be available.<br>2. Digital camera should have filter for red, green and blue images with capture sequence of 1.5 to 2 seconds.<br>3. Should have fluorescent angiography and live visualization features preferably. Should have availability of compensation for ametropia.<br>4. It should have retinal image montage, HDR & colour and red free imaging facility.<br>5. Field of View should be at least 45 degrees and above.<br>6. Camera sensor resolution should be 06 megapixel or more.<br>7. Should have a focus range of - 15 D to +15D or wider.<br>8. It should be compatible with Windows PC with facility for image storage in a secondary device such as desktop or a laptop.<br>9. Supporting computer system with latest configuration should be supplied along with the device.<br>10. Image viewer and archive software should be |

| | | |
|---|---|---|
| | | provided with facility for data storage, data transfer, image archiving and image analysis.<br>11. It should be DICOM compliant and telemedicine ready. |
| 2.2 | **User's interface** | LCD Display for image |
| 2.3 | **Software and/or standard of communication (wherever required)** | In built |
| **3. Physical characteristics** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dba)** | N.A. |
| 3.4 | **Heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Table mounted product |
| **4. Energy source** | | |
| 4.1 | **Power requirements** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | Online UPS system with minimum 30-minute backup. |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | As specified by manufacturer |
| **5. Accessories, spare parts, consumables** | | |
| 5.1 | **Accessories (mandatory, standard, optional)**<br>**Spare parts (main ones)**<br>**Consumables / reagents (open, closed system)** | 1. DVD and CD writer<br>2. Should be supplied with motorised table and patient stool. |
| **6. Environmental and departmental considerations** | | |
| 6.1 | **Atmosphere / ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, cleaning, Disinfection & sterility issues** | Easy to clean and maintain. |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. Training and installation** | | |

| | | |
|---|---|---|
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. Warranty and maintenance** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| **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 should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided.<br>3. Satisfactory certificate for any existing installation from government hospital |
| 10.2 | **Other accompanying documents** | List of essential spares and accessories, with their part number and cost. |
| **11. Notes** | | |
| 11.1 | **Service support contact details (hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | **Recommendations or warnings** | Any warning sign should be adequately displayed. |

| PORTABLE HANDHELD GLUCOMETER | | |
|---|---|---|
| Version no.: | | 02 |
| Date: | | August 2023 |
| Done by : (name/institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Glucose self-testing |
| GMDN code(s) | | CT296 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | It intended to be used together for testing, either at the point-of-care or in self-testing by a layperson, for the quantitative measurement of glucose and/or ketones in a whole blood clinical specimen. |
| 1.2 | **Clinical department/ward** | All |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics** | 1. Should be open system having compatibility with any make of available glucose strips in open market.<br>2. Should have LCD display screen and auto shut off feature when not in use.<br>3. Display of the sugar reading should be in mg/dl.<br>4. Should have reading range/linearity from 20 to 700 mg/dl.<br>5. Should have a maximum reading time of less than 10 seconds<br>3. Should be supplied with autoinjector pen and disposable lancets.<br>4 Should have the feature of automatic code detection of glucose strips.<br>5. Should have a minimum memory of 100 tests |
| 2.2 | **User's interface** | LCD |
| 2.3 | **Software and/or standard of communication** | Inbuilt |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | Handheld Device |
| 3.2 | **Weight (lbs, kg)** | Handheld Device |
| 3.3 | **Noise (in dBA)** | NA |
| 3.4 | **Heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Handheld Device |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 )** | | |
| 4.1 | **Power Requirements** | Battery powered |
| 4.2 | **Battery operated** | 3-volt lithium coin cell battery or 2 x (AAA) Alkaline Batteries |

| | | |
|---|---|---|
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | NA |
| | **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory, standard, optional)**<br>**Spare parts (main ones)**<br>**Consumables/reagents (open, closed system)** | Glucose strips (able to use capillary blood samples) with availability in local market |
| | **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | |
| 6.1 | **Atmosphere/Ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity upto 90%. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer. |
| | **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards in case of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards. |
| | **8. TRAINING AND INSTALLATION** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | NA |
| 8.2 | **Requirements forsign-off** | NA |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | User training should be provided. |
| | **9. WARRANTY AND MAINTENANCE** | |
| 9.1 | **Warranty** | 01 Years |
| | **10. DOCUMENTATION** | |
| 10.1 | **Operating manuals, service manuals, other manuals** | User, technical and maintenance manuals should be supplied along with machine diagrams |
| 10.2 | **Other accompanying documents** | NA |
| | **11. NOTES** | |
| 11.1 | **Other information** | Contact details of manufacturer and supplier should be provided. |

| | | |
|---|---|---|
| 11.2 | **Recommendations or Warnings** | NA |

| **BED FOR INTENSIVE CARE UNIT (ICU BED-MOTARISED)** | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done By: | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN Name | | Basic electric hospital bed |
| GMDN Code | | 34870 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical Purposes | ICU beds are special hospital beds designed for ICUs to take care of critical patients and can be operated electro-mechanically. ICU beds facilitates comfortable transfer to and fro and has a provision of bedside diagnostic including X-ray investigations. Thus, they provide safety, comfort and convenience to the patients and caregivers alike. |
| 1.2 | Used by clinical department/ward | ICU (Intensive Care Unit) |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical Characteristics | I. Should have fully motorised 4 sections and sectional mattress;<br>II. Should have 4 separate electrically operating function through embedded control panel/handheld wired remote control for Height adjustment (Hi-Low), Back rest, Knee rest and Trendelenburg/Reverse Trendelenburg;<br>III. The bed frame should be made of Stainless-steel SS (304)with epoxy coating.<br>IV. Should have ABS/polymer moulded head and foot board panels detachable.<br>V. Should have ABS/polymer moulded swing down safety side railing on both sides.<br>VI. Should have a provision for carrying out whole body X-ray at the bedside.<br>VII. Should have digital/analog indicators for angle display. |

| | | |
|---|---|---|
| | | VIII. Should have one touch key provision on control panel for CPR position and manual CPR option in case of automatic system failure.<br>IX. Bed position adjustments should have:<br>Back Rest angular movement in range from 0-70o (degree) or more;<br>Knee rest angular movement in range from 0-45o (degree) or more;<br>Trendelenburg and Reverse Trendelenburg: 0-12o (degree) or more;<br>X. Should have a therapeutic Weight bearing up to 150-200 Kg<br>XI. Should have heavy duty casters made up of Stainless Steel (304) ball bearing/ABS/Polyester with dual locking arrangement.<br>XII. Should have provision for holding IV pole on four corners.<br>XII. High density foam mattress washable and detachable in 4 parts<br>XIII. Should have battery backup of at least 1 hour<br>XIV. Clearance between Bed Base frame and Floor surface in adjustable range from mm: 120-150 mm |
| 2.2 | User's Interface | Electro-mechanical (motorised) |
| 2.3 | Software and/ or standard of communication (wherever required) | NA |
| **3. PHYSICAL CHARACTERISTIC** | | |
| 3.1 | Dimensions (in cm) | 1. Length: 2100-2300 mm<br>2. Width: 900-1100 mm |
| 3.2 | Weight | To be specified by the Manufacturer/Supplier; |
| 3.3 | Noise | Less than 50dB; |
| 3.4 | Heat Dissipation | Not applicable |
| 3.5 | Mobility/Portability | Should be easily movable with minimal physical effort. |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2.....)** | | |
| 4.1 | Power inputs | 220 +/- 10% VAC, 50 Hz |
| 4.2 | Power consumption | To be specified by Manufacturer/Supplier; |
| 4.3 | Battery backup | Battery backup with inbuilt charger shall be provided. |
| **5. ACCESSORIES. SPARE PARTS AND CONSUMABLE** | | |

| | | |
|---|---|---|
| 5.1 | Accessories, (mandatory, Standard, operational);<br>Spare parts (main ones)<br>Consumable/reagents (open, closed system) | I. Should be provided with IV rods;<br>II. Mattress as per the specs specified in Section (2.1)<br>III. Side rails<br>IV. X-ray cassette tray, Urine bottle holder and drainage bottle holder |
| **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | | |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | Atmosphere /Ambiance (air conditioning, humidity, dust ...) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | Easy to clean and disinfect. |
| **7. STANDARDS & SAFETY** | | |
| 7.1 | Certificates (pre-market, sanitary); Performance and safety standards (specific to the device type); Local and/or international | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | Pre-installation requirements: nature, values,<br>quality, tolerance | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up. |
| 8.2 | Requirements for sign-off | Supplier to perform safety and operation check before hand over. |
| 8.3 | Training of staff (medical, paramedical,<br>technicians) | Training of User on operation and basic maintenance. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | 3 years including all spare parts and accessories. |

| | | |
|---|---|---|
| **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 should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided.<br>3. Satisfactory certificate for any existing installation from government hospital |
| 10.2 | Other accompanying documents | List of essential spares and accessories with their part number 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. |
| 11.2 | Recommendations or warnings | Any warning sign should be adequately displayed. |

| IRRADIANCE METER | | |
|---|---|---|
| Version no. : | | 01 |
| Date: | | August 2023 |
| Done by : (name/institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Blue light radiometer |
| GMDN code(s) | | NA |
| **GENERAL** | | |
| 1.1 | **Clinical purpose** | Used for checking radiance of phototherapy units. |
| 1.2 | **Used by clinical department/ward** | New born stabilization unit, SNCU. |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1. Hand-held, Band-pass filter with max transmission 425-475 nm.<br>2. Light detector sensitivity range: 0-2000 µW/cm²/nm.<br>3. Measurement range: 0-100 µW/cm²/nm.<br>4. Minimal graduation: 1µW/cm²/nm.<br>5. Accuracy: ± 10%.<br>6. LED or LCD display.<br>7. Should be able to zero between measurements.<br>8. Fast measurement response- <5 sec.<br>9. Memory storage: required.<br>10. UV and IR should be blocked.<br>11. Hold function for recording previous value. |
| 2.2 | **User's interface** | Digital display |
| 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 | **Noise (in dBA)** | NA |
| 3.4 | **heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Mobile |
| **4. ENERGY SOURCE** | | |
| 4.1 | **Power Requirements** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | Rechargeable lithium ion battery/2xAA Alkaline battery |
| 4.4 | **Protection** | Should be provided with fuse while using mains for charging. |

| | | |
|---|---|---|
| 4.5 | **Power consumption** | As specified by manufacturer |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | **Accessories (mandatory, standard, optional)**<br>**Spare parts (main ones)**<br>**Consumables/ Reagents ( open, closed system)** | Charger<br>No spares |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | **Atmosphere/Ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | NA |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | User training on complete operation should be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter |
| **10. DOCUMENTATION** | | |
| 10.1 | **Operating manuals, servicemanuals, other manuals** | Operator & service manual with machine diagram should be provided. |

| | | |
|---|---|---|
| 10.2 | **Other accompanying documents** | NA |
| **11. NOTES** | | |
| 11.1 | **Service Support Contact details (Hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer and supplier should be provided. |
| 11.2 | **Recommendations orwarnings** | NA |

| KERATOMETER | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (Name/Institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| UMDNS name | | Ophthalmometers |
| UMDNS code(s) | | 12811 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical purpose | Ophthalmic measuring instruments designed for objectively determining the curvature of the anterior corneal surface and the refraction of the eye (e.g., diopter, cylinder axis) by projecting illuminated images onto the patient's cornea. The instruments usually consist of light sources, a pair of objects to be projected onto the cornea, a telescope with prisms and lenses for reflecting and observing images, a device for adjusting the positions of the reflected images, and the software appropriate to calculate the corneal curvatureand the refractive power. Ophthalmometers are used mainly for preassessment for refractive corneal surgery and for contact lens fitting. |
| 1.2 | Used by clinical department/ward | Ophthalmology Department |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1. Should have (15x / 10x) eye piece.<br>2. Should measure corneal refractive power measuring range from36 to 52 D in steps of 0.25D steps.<br>3. Should measure corneal radius of curvature measuring range from 6.5 to 9.4 mm in steps of 0.05mm.<br>4. Should have high accuracy of measurements.<br>5. Should have dust cover and spare bulb.<br>6. Should be supplied with motorized table.<br>7. Should have well illuminated circular mires with + sign. |
| 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) | NA |
| 3.3 | Noise (in dBA) | NA |
| 3.4 | Heat dissipation | NA |
| 3.5 | Mobility, portability | NA |

| | | |
|---|---|---|
| **4. ENERGY SOURCE** | | |
| 4.1 | Power requirements | 220 +/- 10% VAC, 50 Hz |
| 4.2 | Battery operated | No |
| 4.3 | Protection | NA |
| 4.4 | Power consumption | To be specified by service provider |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | Accessories, (mandatory,standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system) | 1. Lamp (12v 10w): 5 No<br>2. Calibrating Device – 1 No |
| **BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS** | | |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| 6.1 | Atmosphere/Ambiance (air conditioning, humidity, dust …) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | To be specified by manufacturer. |
| **7. STANDARDS AND SAFETY** | | |
| 7.1 | Certificates (pre-market, sanitary,..); Performanceand safety standards (specific to the device type); Local and/or international | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | Pre- installation requirements: nature, values, quality, tolerance | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | Requirements for sign-off | Supplier to perform installation, safety and operation checks before handover. |
| 8.3 | Training of staff (medical, paramedical, technicians) | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | 03 years |
| **10. DOCUMENTATION** | | |
| 10.1 | Operating manuals, set manuals, other manuals | Should provide 2 sets (hard copy and soft copy) of: User, technical and maintenance manuals should be |

| | | |
|---|---|---|
| | | supplied in English/Hindi/Regional language along with machine diagrams. |
| 10.2 | Other accompanying documents | List of essential spares and accessories, with their part number 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 tobe provided. |
| 11.2 | Recommendations or warnings | Any warning sign would be adequately displayed. |

| TABLE FOR OBSTETRIC LABOUR (LDR) | | |
|---|---|---|
| Version no.: | | 02 |
| Date: | | August 2023 |
| Done By: | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN Name | | Birthing Bed/Table, Powered |
| GMDN Code | | 15732 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical Purpose | Table for Obstetric labour (LDR) is specifically designed to support the motherduring all stages of giving birth that includes labour, delivery and recovery.<br><br>The bed should convert quickly from a practical labour bed to a delivery platformand back to a comfortable recovery bed. At any stage, it can be rapidly adjustedto any positions to cater for emergency situations. |
| 1.2 | Used by clinical department/ward | Labour Room Complex (As per Labour room standard Guideline) |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |

| | | |
|---|---|---|
| 2.1 | Technical Characteristics (Specific to this type of device) | 1. The LDR bed should be electro-mechanically controlled.<br>2. It should have three sections and seamless joint in each part with minimal gap between sectional mattresses and the seat-section should have a large perinealcut.<br>3. Mattresses cover should be non-slippery, washable and waterproof.<br>4. The foam density of the mattresses should be of minimum 60 kg/m3 and thickness of minimum 3-4 inches.<br>5. The mattress should be fixed with high grade adhesive velcro tape for proper fixing on the bed top.<br>6. Removable SS (304)/ABS head and leg bows with padded panel.<br>7. The unit should have provision for trendelenburg and reverse trendelenburg positions (minimum 15 degree or more) and reclinable adjustable back rest angle of 60 degree or more. All positions should be achievable by both mechanically and electronically.<br>8. Should have control device for back and height adjustments through remote control as well as manually operable.<br>9. Pre-fitted SS-304 grade adjustable/collapsible side rails.<br>10. Push grip handle (grab bars) with soft cushion padding on both sides of the bed.<br>11. Should have foot support for nursing staff.<br>12. Frame should be of epoxy powder coated steel.<br>13. Should be easy to clean, sterilize (especially blood stains) and maintain.<br>14. Should have catheter bag holder which can be attached on either side of bed.<br>15. Should have infusion rods (made of SS-304 grade) which have adjustable heights, quick release and attachable to all corners of the bed.<br>16. Should have retractable foot section (section can be telescoped under) so as to convert bed into table.<br>17. To and fro motion of the leg section should be very smooth.<br>18. Should be able to hold minimum 150 Kg of load.<br>19. Caster: Should have minimum 100mm or more heavy duty roller wheels with ball bearing and with central & directional locking mechanism.<br>20. Should have rectangular sliding/detachable SS-304 tray at perineal part of table. |
| 2.2 | User's Interface | Electro-mechanical. |
| **3. PHYSICAL CHARACTERISTICS** | | |

| | | |
|---|---|---|
| 3.1 | Dimensions (in mm) | Overall approximate size 1880 -2160 mm (L) * 900 - 1010 mm (W) * 550 mm to 880 mm (H) (With option of manual adjustable height of the bed) |
| 3.2 | Weight | To be specified by the Manufacturer/Supplier |
| 3.3 | Noise | Less than 50 db. |
| 3.4 | Heat Dissipation | Not applicable |
| 3.5 | Mobility/Portability | Area Specified above (Labour room) |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)** | | |
| 4.1 | Power input | 220-240V AC,50 Hz fitted with Indian plug |
| 4.2 | Battery backup | 1. Battery backup of minimum 30 minutes operation time with inbuilt battery charger shall be provided. The handset shall have indications for power onand battery charge.<br>2. Should have facility to operate manually in case of power failure. |
| 4.3 | Power consumption | To be specified by the Manufacturer/Supplier |
| **5. ACCESSORIES, SPARE PARTS AND CONSUMABLES** | | |
| 5.1 | Accessories, (mandatory,Standard, operational); Spare parts (main ones) Consumable/reagents (open, closed system) | 1. All consumables required for installation and standardization of the systemshould be provided free of cost.<br>2. Minimum 60 mm thick kg/$m^3$ high density foam mattress washable andwaterproof and detachable in three parts.<br>3. Should be provided with extra one pair of leg rest.<br>4. Should be provided with minimum four infusion rods (SS 304) with hookfor hanging IV fluids. |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| 6.1 | Atmosphere /Ambiance(air conditioning, humidity, dust ...) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterility Issues | Parts of the Device that are designed to come into contact with the patient or the operator should be compatible with medical grade disinfectant solution. |
| **7. STANDARDS & SAFETY** | | |

| | | |
|---|---|---|
| 7.1 | Certificates (pre-market, sanitary,..);Performa nceand safety standards (specific to the device type);Local and/or international | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | Pre-installation requirements: nature,values, quality, tolerance | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | Requirements for sign-off | Supplier to perform safety and operation check before hand over. |
| 8.3 | Training of staff (medical,paramedical, technicians) | 1. Hands on training to be provided to healthcare professional on using theequipment, day to day maintenance/cleaning.<br>2. Hand on training for in-house (Biomedical engineers) for preventive andCorrective maintenance. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | 03 years all spares parts, battery and other accessories. |
| **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/Regional language along with machine diagrams.<br>2. List of equipment and procedures required for local calibration and routinemaintenance.<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 | ISO Certification on quality of stainless steel used; |
| **11. NOTES** | | |

| | | |
|---|---|---|
| 11.1 | Service Support Contactdetails (Hierarchy Wise; including a toll free/landline number) | 1. Contact details of manufacturer, supplier and local service agent to beprovided.<br>2. Manufacturer/ Supplier of medical services should provide price quote for spare part of medical device or supply items, against requisition/Purchase order from Biomedical engineers /technicians. |
| 11.2 | Recommendations and Warnings | Any warning sign needs to be clearly mentioned. |

| LARYNGOSCOPE | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Laryngoscopes |
| GMDN code | | - |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | To view the vocal cords and glottis and to facilitate tracheal intubation. |
| 1.2 | **Used by clinical department/ward** | PICU/NICU, OT, EMR, ICU/HDU |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1. Fiber optic Laryngoscope - preferably should be reusable using the latest LED technology.<br>2. The main body of the handle should incorporate an excellent grip & should feel even wearing a glove.<br>3. The light source should light when the blade is placed into the operating position.<br>4. The unit should allow the blade to be inserted easily & should provide a positive locking mechanism when moved into the closed position.<br>5. Should have handle with universal adapter for interchangeable blades.<br>6. The laryngoscope should be supplied in leather/hard case preferably high impact plastic with internal soft cushion material for easy portability and protection.<br>7. The blades should be re-usable and autoclavable preferably made of S/Steel (MS-304) of high quality. |
| 2.2 | **Settings** | NA |
| 2.3 | **User's interface** | Manual |
| 2.4 | **Software and/or standard of communication (wherever required)** | NA |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | Light weight |

| | | |
|---|---|---|
| 3.4 | **Noise (in dBA), heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Portable |
| | **4. ENERGY SOURCE** | |
| 4.1 | **Power Requirements** | NA |
| 4.2 | **Battery operated** | Yes |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | NA |
| | **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory, standard, optional)**<br>**Spare parts (main ones)**<br>**Consumables / reagents (open, closed system)** | Batteries, blades of various neonatal sizes<br>Handle<br>5 LED should be given as spare |
| | **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | |
| 6.1 | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | Should be autoclavable |
| | **7. STANDARDS AND SAFETY** | |
| 7.1 | **Certificates** | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards. |
| | **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,** | NA |

| | | |
|---|---|---|
| | **technicians)** | |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | 03 years |
| **10. DOCUMENTATION** | | |
| 10.1 | **Operating manuals, service manuals, other manuals** | Should provide 2 sets (hard copy and soft copy) of:<br>User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. |
| 10.2 | **Other accompanying documents** | NA |
| **11. NOTES** | | |
| 11.1 | **Service Support Contact details (Hierchy Wise; including a toll free/ landline number)** | Contact details of manufacturer and supplier should be provided.. |
| 11.2 | **Recommendations or warnings** | Any recommendations for best use and supplementary warning for safety should be declared |

| Manual Vacuum Aspirator | | |
|---|---|---|
| Version no. : | | 01 |
| Date: | | August 2023 |
| Done by : (Name/Institution) | | HCT/NHSRC |
| NAME AND CODING | | |
| GMDN name | | NA |
| GMDN code(s) | | NA |
| GENERAL | | |
| 1. USE | | |
| 1.1 | Clinical purpose | A non-sterile, manual, syringe-like device intended to be used in conjunction with an intrauterine cannula (not included) to aspirate fluid from the uterus for treatment of incomplete abortion, first trimester abortion, and/or for menstrual regulation; it may also be intended for endometrial biopsy. |
| 1.2 | Used by clinical department/ward | Gynecology |
| TECHNICAL | | |
| 2. TECHNICAL CHARACTERISTICS | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1. It should be double valve type manually operated vacuum aspirator.<br>2. Valve should have double locking system.<br>3. It should have 60 ml calibrated barrel and plunger cum piston rod with ergonomic handle to withstand autoclave at 120 deg C and more.<br>4. Vacuum capacity should be above 650 mm/hg.<br>5. Cannula adapter size should be from 4mm-12mm. |
| 2.2 | User's interface | Manual |
| 2.3 | Software and/or standard of communication (where ever required | Not required |
| 3. PHYSICAL CHARACTERISTICS | | |
| 3.1 | Dimensions(metric) | NA |
| 3.2 | Weight (lbs, kg) | NA |
| 3.3 | Noise (in dBA) | NA |
| 3.4 | Heat dissipation | NA |
| 3.5 | Mobility, portability | Portable |
| 4. ENERGY SOURCE | | |
| 4.1 | Power requirements | NA |
| 4.2 | Battery operated | NA |
| 4.3 | Protection | NA |
| 4.4 | Power consumption | NA |
| 5. ACCESSORIES, SPARE PARTS, CONSUMABLES | | |

| | | |
|---|---|---|
| 5.1 | Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system) | Collar stop clip |
| 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS | | |
| 6.1 | Atmosphere/Ambiance (air conditioning, humidity, dust …) | NA |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | As specified by manufacturer |
| 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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards. |
| 8. TRAINING AND INSTALLATION | | |
| 8.1 | Pre- installation requirements: nature, values, quality, tolerance | NA |
| 8.2 | Requirements for sign-off | NA |
| 8.3 | Training of staff (medical, paramedical, technicians) | NA |
| 9. WARRANTY AND MAINTENANCE | | |
| 9.1 | Warranty | 03 Years |
| 10. DOCUMENTATION | | |
| 10.1 | Operating manuals, set manuals, other manuals | One copy (hard copy and soft copy) to be provided on user manual/ operating manual. |
| 10.2 | Other accompanying documents | NA |
| 11. Notes | | |
| 11.1 | Service Support Contact details (Hierarchy Wise; including a toll free/ landline number) | Contact details of manufacturer, supplier should be provided |

| | | |
|---|---|---|
| 11.2 | Recommendations or warnings | NA |

| BINOCULAR MICROSCOPE | | |
|---|---|---|
| Version no.: | | 02 |
| Date: | | August 2023 |
| Done by: (name/Institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| GMDNS name | | NA |
| GMDNS code(s) | | NA |
| **GENERAL** | | |
| **1. USE** | | |
| **1.1** | **Clinical purpose** | A microscope is a laboratory instrument used to examine objects that are too small to be seen by the naked eye. Microscopic analysis of specimens helps diagnose diseases by looking at cellular morphology and presence of infectious agents and other microscopic structures. Binocular microscope is a microscope that lets the viewer use both eyes as it has 2 eye lenses. |
| **1.2** | **Used by clinical department/ward** | Clinical Diagnostic Laboratory |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| **2.1** | **Technical characteristics (specific to this type of device)** | • Body-Single mold sturdy stand inclined Binocular body 30 °, 360º rotatable head without adjusting screws with inter-pupillary distance of 50-75mm.<br>• It should have LED light source with rechargeable battery system.<br>• Eyepieces-Paired high quality 10X/20mm wide angle anti fungus field eyepiece. one with pointer. Diopter adjustment must be present on both eye pieces.<br>• Objectives-Parfocal, antifungal coated 4x, 10x, 40x and 100x having numerical aperture 0.1, 0.25, 0.60-0.65 and 1.25-1.65 respectively. Oil immersion objective (40x and 100x) should be spring loaded. All objectives should be plan achromatic, antifungal coated infinity and color corrected. Objective should be well centered even if their position on turret is changed.<br>• Mechanical stag- ceramic coated surface with vernier scale on X-Y axis and slide holder.<br>• Condenser, numerical aperture (NA) 1.25 focusable with rack and pinion arrangement incorporating spherical lens and iris diaphragm. It should have filter holder and swing in/out blue filter.<br>• Should have inbuilt protective safety device which can withstand fluctuations of voltage from 140 V-280V. |

| | | |
|---|---|---|
| | | • LED illumination 3W with intensity control knob > 10,000 Hrs bulb lifespan with battery backup of 1 hrs and charging indication.<br>• Focusing knob should have coaxial coarse and fine focusing knobs. Fine focusing movements should have sensitivity of 2 micron or less, coarse focus with torque adjustment, focusing stop for slide safety should be there. |
| **2.2** | **User's interface** | Manual |
| **2.3** | **Software and/ or standard of communication (wherever required)** | NA |
| **3. PHYSICAL CHARACTERISTICS** | | |
| **3.1** | **Dimensions(metric)** | NA |
| **3.2** | **Weight (lbs, kg)** | NA |
| **3.3** | **Noise (in dBA)** | NA |
| **3.4** | **Heat dissipation** | NA |
| **3.5** | **Mobility, portability** | Stationary lab Installation |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)** | | |
| **4.1** | **Power requirements** | **Power Supply:**<br>220VAC +/- 10%, 50 Hz. |
| **4.2** | **Battery operated** | No |
| **4.3** | **Protection** | NA |
| **4.4** | **Power consumption** | To be specified by manufacturer/vendor |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| **5.1** | **Accessories, (mandatory, standard, optional);<br>Spare parts (main ones);<br>Consumables/reagents (open, closed system)** | Should be provided with wooden storage box, dust cover, immersion oil. |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| **6.1** | **Atmosphere/Ambience (air conditioning, humidity, dust …)** | Operating Condition: Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of up to 90% in ideal circumstances. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer. |
| **7. STANDARDS AND SAFETY** | | |
| **7.1** | **Certificates (pre-market, sanitary,);<br>Performance and safety standards (specific to the device type); Local and/or** | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General |

| | | |
|---|---|---|
| | **international** | requirements of electrical safety standards. |
| **8. TRAINING AND INSTALLATION** | | |
| **8.1** | **Pre- installation requirements: nature, values, quality, tolerance** | As specified by manufacturer and compatible electric accessories as per standard Indian set-up. |
| **8.2** | **Requirements for sign-off** | 1. Supplier to perform installation, safety and operation checks before handover.<br>2. Lab In-Charge to affirm completion of installation |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | Satisfactory Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented. |
| **9. WARRANTY AND MAINTENANCE** | | |
| **9.1** | **Warranty** | 1. 3 years, including all spares and calibration.<br>2. Preventive maintenance visits atleast one in each quarter |
| **10. DOCUMENTATION** | | |
| **10.1** | **Operating manuals, set manuals, other manuals** | Should provide 2 sets (hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should 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,<br>6. Satisfactory certificate for any existing installation from government hospital. |
| **10.2** | **Other accompanying documents** | List of essential spares and accessories, with their part number 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; |
| **11.2** | **Recommendations or warnings** | Any warning sign should be adequately displayed. |

| MORTUARY TABLE | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (Name/Institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| UMDNS name | | Autopsy Tables |
| UMDNS code(s) | | 5246 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical purpose | These tables are used for post-mortem examination and fordemonstration purposes. |
| 1.2 | Used by clinical department/ward | Postmortem Department |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical Characteristics | 1. Elevating with stainless steel dissection board (straight table, not L type), Approx Dimension:100”L x 40”W. Integrated sink should also have same length and width.<br>2. Elevating height 32” to 40’ up and down pedestal control. All thick gauge heavy duty anti corrosion stainless (SS 304) construction.<br>3. Table top and integrated sink fabricate of minimum 14 gauge stainless steel, anti corrosion pedestal of minimum 11” gauge stainless steel with satin finish. Minimum 1/2” removable perforatedgrid plate with 3/8” diameter hole on 2” centers (4 each).<br>4. Large double wall Sink with regular removable sprinkle system, Handy spray, rinse facility. Faucets stainless steel. Hand shower:heavy duty chrome plated hand piece durable minimum 8’ long flexible hose Hand piece with hose drop in deck. Concealed pressure control hot and cold water mixture/swing spout/tap. Hydroaspirator with reverse flow having built in vacuum breaker. Access panel 2 outlet curved molded sides of table (Stainless Steel).<br>5. (L) 70”X30” (W) for dissection of internal organs. Extension should have independent fixed pedestal and not attached to autopsy table as pedestal is fixed. The edger should be curved, molded andraised. Electrical outlets should be water splash proof.<br>6. Table should be able to mount in position that allow surgeon to move around the table.<br>7. Table should have engraved scale for cadaver measurement in centimeters and inches.<br>8. Rivets or bolts on table should not enable bacterial or microorganismgrowth or accumulation. |
| 2.2 | User's interface | Table should be height adjustable. |

| | | |
|---|---|---|
| 2.3 | Software and/ or standard of Communication (wherever required) | Not required |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | Dimensions(metric) | As mentioned in technical characteristics |
| 3.2 | Weight (lbs, kg) | NA |
| 3.3 | Noise (in dBA) | Less than 50 dbA. |
| 3.4 | Heat dissipation | Not applicable |
| 3.5 | Mobility, portability | Fixed. |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)** | | |
| 4.1 | Power requirements | 220 +/- 10% VAC, 50 Hz. |
| 4.2 | Battery operated | Not required |
| 4.3 | Protection | NA |
| 4.4 | Power consumption | As specified by manufacturer |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | Accessories, (mandatory, standard, optional);<br>Spare parts (main ones);<br>Consumables/reagents (open, closed system) | Organ cutting table, sprinkle system with wrist control water tap, neckrest, body support sheet and head rest. |
| **BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS** | | |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| 6.1 | Atmosphere/Ambience (air conditioning, humidity, dust …) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | Should be compatible with Medical grade disinfectant solutions like Cidex or hydrogen peroxide solution. |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |

| | | |
|---|---|---|
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | Pre- installation requirements: | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | Requirements for sign-off | Supplier to perform safety and operation check before hand over. |
| 8.3 | Training of staff (medical, paramedical, technicians) | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | 3 years, including all spares parts and accessories. |
| **10. DOCUMENTATION** | | |
| 10.1 | Operating manuals, set manuals, other manuals | One copy (hardcopy and softcopy) to be provided on user manual/operating manual and service/Technical manual. |
| 10.2 | Other accompanying documents | 1. Certification on quality of stainless steel. Compliance with autopsytable standards or regulation.<br>2. Document illustrating frequency of calibration or preventive maintenance by manufacturer. |
| **11. Notes** | | |
| 11.1 | Service Support Contact details (Hierarchy Wise; including a toll free/ landline number) | 1. Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | Recommendations or warnings | Any warning sign would be adequately displayed on autopsy table. |

| Nd YAG Laser | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done by: (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | |
| GMDN code(s) | | |
| **GENERAL** | | |
| **1. Use** | | |
| 1.1 | **Clinical purpose** | Nd YAG lasers are most commonly used to treat posterior capsular opacification (PCO) after cataract surgery and to create a peripheral iridotomy in patients with narrow angles or angle-closure glaucoma |
| 1.2 | **Used by clinical department/ ward** | Eye OT |
| **TECHNICAL** | | |
| **2. Technical characteristics** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1. Laser Type: Neodymium Yttrium Aluminium Garnet<br>2. Should have Wavelength of 1064 nm.<br>3. Should have following mode of Operation: Q-Switched (CQ-Crystal)<br>4. Energy Output: Maximum of 45 mJ in Triple pulse mode. Nominally 1 mJ maximum in single pulse mode<br>5. Energy Adjustment: Continuously variable across full energy range<br>6. Burst Mode: 1.2 or 3 pulse each burst with the separation between pulses of 20 ms<br>7. YAG Offset Focus: Continuously variable from Anterior (-) 500 um to Posterior (+) 500um. In steps of 0, +/-150, 250, 500 um<br>8. Pulse width: 4ns +/- 2ns<br>9. Repetition Rate: 2.5Hz for single pulse<br>10. Spot Size: 8µm-10µ<br>11. Cone Angle: 160<br>12. Focal length: 107mm<br>13. Energy Display accuracy: Better than+/-20% of actual<br>14. Aiming Beam:630-670nm (Red) laser Diode, 4 Point<br>15. Mode of Operation: Continuous wave (CW)<br>16. Should have monocular assistant eye piece. |
| 2.3 | **User's interface** | Manual |
| 2.4 | **Software and/or standard of communication (wherever required)** | NA |

| | | |
|---|---|---|
| **3. Physical Characteristics** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dba)** | N.A. |
| 3.4 | **Heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Tabletop |
| **4. Energy source** | | |
| 4.1 | **Power requirements** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | UPS: with at least 30 minutes battery back up |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | As specified by manufacturer |
| **5. Accessories, spare parts, consumables** | | |
| 5.1 | **Accessories (mandatory, standard, optional)**<br>**Spare parts (main ones)**<br>**Consumables / reagents (open, closed system)** | 1. Should be supplied with slit lamp (5 step magnification 5, 8, 12, 20 , 32x)<br>2. Eye piece of at least 10X/12.5X to be supplied.<br>3. Should be supplied with motorised table.<br>4. Should provide protective goggles for Nd-Yag Laser<br>5. Should provide contact lens for iridotomy and capsulotomy. |
| **6. Environmental and departmental considerations** | | |
| 6.1 | **Atmosphere / ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, cleaning, Disinfection & sterility issues** | To be specified by manufacturer. |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. Training and installation** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up. |
| 8.2 | **Requirements for sign-off** | Supplier to perform installation, safety and operation checks before handover. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. Warranty and maintenance** | | |

| | | |
|---|---|---|
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter |
| **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 should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided.<br>3. Satisfactory certificate for any existing installation from government hospital |
| 10.2 | **Other accompanying documents** | List of essential spares and accessories, with their part number and cost. |
| **11. Notes** | | |
| 11.1 | **Service support contact details (hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | **Recommendations and Warnings** | Any warning sign should be adequately displayed. |

| ULTRASONIC NEBULIZER | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name/institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Aerosol Generators |
| GMDN code(s) | | |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | Devices designed to produce ( i.e. generate) gaseous suspensions of extremely small particles of a liquid or solid. These generators typically include a micro-ultrasonic or pneumatic pumping mechanism capable of creating a fine-particle liquid mist appropriate for delivery to the patient's airways and/or lung disposition |
| 1.2 | **Used by clinical department/ward** | All |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.2 | **Technical characteristics (specific to this type of device)** | 1) Should be light weight, portable, compact and easy to use.<br>2) Frequency of ultrasonic generator should be greater than 1.5 MHz<br>3) Speed nebulization rate control (minimum, medium, maximum).<br>4) Should have a nebulisation capacity of 0.3 ml/min.<br>5) Transducer element should have life of at least 5000 hours.<br>6) Medication cup capacity should have capacity of maximum 8ml.Should uses water as ultrasonic conduction medium, no gel is required.<br>7) Should provide silent operation.<br>8) Should have a built-in timer and shuts off after 10 minutes use. |
| 2.3 | **User's interface** | Manual |
| 2.4 | **Software and/or standard of communication** | Inbuilt |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dBA)** | NA |
| 3.4 | **heat dissipation** | Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism. |
| 3.5 | **Mobility, portability** | Portable |
| **4. ENERGY SOURCE** | | |

| | | |
|---|---|---|
| 4.1 | **Power Requirements** | 220V ± 10%, 50 Hz |
| 4.2 | **Battery operated** | Internal rechargeable battery through AC mains |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | As specified by manufacturer |
| | **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory, standard, optional)**<br>**Spare parts (main ones)**<br>**Consumables/reagents (open,closed system)** | Should be provided with a complete nebulization kit of 10 no.s including adult. |
| | **BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS** | |
| | **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | |
| 6.1 | **Atmosphere/Ambiance (air conditioning, humidity, dust...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer. |
| | **7. STANDARDS AND SAFETY** | |
| 7.1 | **Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type)** | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| | **8. TRAINING AND INSTALLATION** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up. |
| 8.2 | **Requirements for sign-off** | Supplier to perform installation, safety and operation checks before handover.<br>Local clinical staff to affirm completion of installation. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| | **9. WARRANTY AND MAINTENANCE** | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter |

| | | |
|---|---|---|
| **10. DOCUMENTATION** | | |
| 10.1 | **Operating manuals, servicemanuals, other manuals** | Should provide 2 sets (hardcopy) of:-<br>1) User, technical, maintenance and service manuals to be supplied alongwith machine diagrams<br>2) List of equipment and procedures required for local calibration androutine maintenance<br>3) Certificate of calibration to be provided by the manufacture |
| 10.2 | **Other accompanying documents** | List of important spares and accessories, with their part numbers and cost |
| **11. NOTES** | | |
| 11.1 | **Service Support Contact details (Hierchy Wise; including a toll free/landline number)** | 1) Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | **Recommendations orwarnings** | Any warning signs would be adequately displayed. |

| NAAT MACHINE | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done by: | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| GMDNS name | | NA |
| GMDNS code(s) | | NA |
| **GENERAL** | | |
| **1. USE** | | |
| **1.1** | **Clinical purpose** | It is intended for amplification and real-time detection of target nucleic acid of human pathogens in a clinical specimens using polymerase chain reaction (PCR) principle. |
| **1.2** | **Used by clinical department/ward** | Clinical Diagnostic laboratory |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| **2.1** | **Technical characteristics (specific to this type of device)** | • The System should be based on rapid Real Time PCR Technology with complete automated workflow including extraction, amplification, detection and result interpretation with minimal hands-on time and able to do rapid on-demand molecular tests as required by national guidelines/health programs.<br>• The System should be based on Single use disposable Cartridge/chip capable of performing RNA/DNA extraction, reverse transcription and realtime PCR.<br>• The tests cartridge should include built-in internal controls for all test steps to ensure accurate test performance and for identification ofmicroorganisms.<br>• The system should be able to perform on-demand and random access.<br>• The system should be easily connected to LIS/HIS.<br>• The system should not require special (lab or PCR)environment to operate effectively.<br>**Reaction site thermal controls:**<br>1. Each Active Module should have Solid State heater and forced air cooling.<br>2. Reaction chamber thermistors calibrated to ± 1.0°C using National Institute of Standards and Technology (NIST)-traceable standards<br>3. The System should have 4-16 active |

| | | |
|---|---|---|
| | | modules which are independently used and controlled for any test cartridge. |
| **2.2** | **User's interface** | Automatic |
| **2.3** | **Software and/ or standard of communication (wherever required)** | Built - in/Automatic/compatible, window based with data processing management system with complete back up of data base for calibration, control, patient sample results on daily basis. |
| **3. PHYSICAL CHARACTERISTICS** | | |
| **3.1** | **Dimensions(metric)** | NA |
| **3.2** | **Weight (lbs, kg)** | NA |
| **3.3** | **Noise (in dBA)** | NA |
| **3.4** | **Heat dissipation** | Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through a coolingmechanism. |
| **3.5** | **Mobility, portability** | Stationary lab Installation |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)** | | |
| **4.1** | **Power requirements** | 220VAC +/- 10%, 50 Hz. |
| **4.2** | **Battery operated** | No |
| **4.3** | **Protection** | NA |
| **4.4** | **Power consumption** | To be specified by vendor |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| **5.1** | **Accessories, (mandatory, standard,optional); Spare parts (main ones); Consumables/reagents (open, closed system)** | Laptop/Desktop (if required to control the system) withsoftware. |
| **BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS** | | |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| **6.1** | **Atmosphere/Ambience(air conditioning, humidity, dust …)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer . |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |

| | | |
|---|---|---|
| **8. TRAINING AND INSTALLATION** | | |
| **8.1** | **Pre- installation requirements: nature, values, quality, tolerance** | As specified by manufacturer and compatible electrical accessories as per standard Indian set-up. |
| **8.2** | **Requirements for sign-Off** | 1.Supplier to perform installation, safety and operation checks before handover.<br>2. Lab In-Charge to affirm completion of installation |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | Satisfactory Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented. |
| **9. WARRANTY AND MAINTENANCE** | | |
| **9.1** | **Warranty** | 1. 3 years, including all spares and calibration.<br>2. Preventive maintenance visits at least one ineach quarter |
| **10. DOCUMENTATION** | | |
| **10.1** | **Operating manuals,set manuals, other manuals** | Should provide 2 sets (hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machinediagrams;<br>2. List of equipment and procedures required for localcalibration and routine maintenance;<br>3. Service and operation manuals (original and Copy) tobe provided;<br>4. Advanced maintenance tasks documentation;<br>5. Certificate of calibration and inspection,<br>6. Satisfactory certificate for any existing installationfrom government hospital. |
| **10.2** | **Other accompanying documents** | List of essential spares and accessories, with their partnumber and cost; |
| **11. Notes** | | |
| **11.1** | **Service Support Contact details (Hierarchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and localservice agent to be provided; |
| **11.2** | **Recommendations or warnings** | Any warning sign should be adequately displayed. |

| OPTICAL COHERENCE TOMOGRAPHY (OCT ) | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done by: (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Ophthalmic spectral-domain optical coherence tomography system |
| GMDN code(s) | | 58850 |
| **GENERAL** | | |
| **1. Use** | | |
| 1.1 | **Clinical purpose** | *Optical Coherence Tomography* (*OCT*) is a non-invasive diagnostic instrument used for imaging the retina. |
| 1.2 | **Used by clinical department/ ward** | Ophthalmology |
| **TECHNICAL** | | |
| **2. Technical characteristics** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1. The spectral domain OCT should have confocal Optics and it should be possible to perform both Anterior segment and Posterior segment OCT.<br>2. The system should have simultaneous Infrared fundus and OCT imaging.<br>3. The axial resolution of the system should be 03 microns and transverse resolution 12 microns or better.<br>4. The OCT system should have real time eye tracking facility for precise alignment of blood vessels from fundus image to the corresponding OCT scan and minimize internal eye motion related artifacts.<br>5. Should have eye tracking while taking single line scan as well as high density volume scan.<br>6. Should have a field of view 30 deg or better.<br>7. The system should have Enhanced depth imaging to view Choroidal layer.<br>8. It should be possible to perform volume section scan for detailed analysis of lesions.<br>9. The system should have Retinal Nerve fibre layer thickness analysis and posterior pole asymmetry analysis for Glaucoma assessment.<br>10. The OCT system should have in-built segmentation |

| | | |
|---|---|---|
| | | software for delineation of layers of retina, (Nerve Fibre Layer) NFL or Retinal pigment epithelium (RPE).<br>11. It should be possible to view irido corneal angles of either side.<br>12. It should be possible measure corneal thickness in the anterior segment OCT mode. |
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/or standard of communication (wherever required)** | In built |
| **3. Physical characteristics** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dba)** | N.A. |
| 3.4 | **Heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Portable |
| **4. Energy source** | | |
| 4.1 | **Power requirements** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | Online UPS with minimum one-hour back-up. |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | As specified by manufacturer. |
| **5. Accessories, spare parts, consumables** | | |
| 5.1 | **Accessories (mandatory, standard, optional)**<br>**Spare parts (main ones)**<br>**Consumables / reagents (open, closed system)** | PC Networking |
| **6. Environmental and departmental considerations** | | |
| 6.1 | **Atmosphere / ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, cleaning, Disinfection & sterility issues** | Easy to clean and maintain |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |

| | | |
|---|---|---|
| **8. Training and installation** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. Warranty and maintenance** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| **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 should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided.<br>3. Satisfactory certificate for any existing installation from government hospital |
| 10.2 | **Other accompanying documents** | List of essential spares and accessories, with their part number and cost. |
| **11. Notes** | | |
| 11.1 | **Service support contact details (hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | **Recommendations or warnings** | Any warning sign should be adequately displayed. |

| OPTHALMOSCOPES - DIRECT | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by: (Name/Institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| UMDNS name | | Ophthalmoscopes, Direct |
| UMDNS code(s) | | |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical purpose | Hand held ophthalmoscopes designed for examining the eye (mostlythe back of the eye, the funds) by providing a non inverted image ofthe eye. The instruments usually consist of a light source to projectthe light into the eye through the pupil, a mirror, and a wheel of lensesof varying strength to provide a magnified view of the eye and to adjust the focus of the view. They produce an upright, or un reversed, magnified image of the eye, at approximately 15 times magnification. Direct ophthalmoscopes are used mainly to detect eye conditions oreye diseases. |
| 1.2 | Used by clinical department/ward | Ophthalmology Department |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1. Available with LED/Halogen light source.<br>2. Magnification up to x15 from direct vision to maximum magnification.<br>3. Red-free, blue and polarization filters and Anti-reflection lens.<br>4. Should have small and large spot sizes, fixation targets, slitaperture, hemi-spot and cobalt blue filter.<br>5. Should be rechargeable battery with Charger / battery/ mainsoperated.<br>6. At least 3 apertures and fixation star.<br>7. Range of lenses not smaller than -30D to +20D with steps notgreater than 1D.<br>8. Dust free sealed optics and aspherical optical system. |
| 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 | Noise (in dBA) | NA |
| 3.4 | Heat dissipation | NA |

| | | |
|---|---|---|
| 3.5 | Mobility, portability | Supplied in protective case for clean storage and safe transport. |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)** | | |
| 4.1 | Power requirements | 220 +/- 10% VAC, 50 Hz |
| 4.2 | Battery operated | Internal batteries, rechargeable preferred compatible with both 2.5 V and 3.5 V batteries or handles provided; Led display indicating the charging status. |
| 4.3 | Protection | Yes |
| 4.4 | Power consumption | To be specified by Vendor |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system) | Bulb – 2 nos |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| 6.1 | Atmosphere/ambiance (air conditioning, humidity, dust …) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | To be specified by manufacturer. |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | Pre- installation requirements: nature, values, quality, tolerance | NA |
| 8.2 | Requirements for sign-off | Supplier to perform installation, safety and operation checksbefore handover. |

| | | |
|---|---|---|
| 8.3 | Training of staff (medical, paramedical, technicians) | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | 3 years, including for all spares and calibration work. |
| **10. DOCUMENTATION** | | |
| 10.1 | Operating manuals, set manuals, other manuals | Should provide 2 sets(hard copy and soft copy) of:<br>User, technical and maintenance manuals should be supplied inEnglish/Hindi/Regional language along with machine diagrams. |
| 10.2 | Other accompanying documents | List of essential spares and accessories, with their part number andcost. |
| **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 tobe provided. |
| 11.2 | Recommendations or warnings | Any warning sign would be adequately displayed. |

| OPTHALMOSCOPES, INDIRECT | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by: (Name/Institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| UMDNS name | | Ophthalmoscopes, Indirect |
| UMDNS code(s) | | |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical purpose | Head-worn ophthalmoscopes designed for examining the eye (mostly the back of the eye, the fundus) by providing an inverted image of the funds. These instruments usually consist of a light source attached toa headband to project the light into the eye through the pupil and aconverging lens placed in front of the patient's eye. They produce aninverted, or reversed, image of 2 to 5 times magnification of the entire retina, a field of view much larger than that of direct ophthalmoscopes. Indirect ophthalmoscopes are used mainly to detect eye conditions or eye diseases. |
| 1.2 | Used by clinical department/ward | Ophthalmology Department |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1. Available with LED/Halogen light source. (Desirably LED).<br>2. Magnification up to 5x.<br>3. Red-free, blue and polarization filters.<br>4. Should have stereo optical system with small pupil feature.<br>5. Should have synchronized adjustment of convergence parallax. |
| 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 | Noise (in dBA) | NA |
| 3.4 | Heat dissipation | NA |
| 3.5 | Mobility, portability | Supplied in protective case for clean storage and safe transport. |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)** | | |
| 4.1 | Power requirements | 220 +/- 10% VAC, 50 Hz |

| | | |
|---|---|---|
| 4.2 | Battery operated | Internal batteries, rechargeable preferred compatible with both 2.5 V and 3.5 V batteries or handles provided; Led display indicating the charging status. |
| 4.3 | Protection | Yes |
| 4.4 | Power consumption | To be specified by Vendor |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | Accessories, (mandatory, standard,optional); Spare parts (main ones); Consumables/reagents (open, closed system) | a. Three pencils,<br>b. Funds chart,<br>c. Sclera depressor,<br>d. 20D condensing lens with anti reflecting coating.<br>e. Bulb – 2 nos, Bulb holder, Bulb cover. |
| **BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS** | | |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| 6.1 | Atmosphere/Ambiance (air conditioning, humidity, dust …) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | To be specified by manufacturer |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | Pre- installation requirements: nature, values, quality, tolerance | NA |
| 8.2 | Requirements for sign-off | Supplier to perform installation, safety and operation checks beforehandover. |
| 8.3 | Training of staff (medical, paramedical, technicians) | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | 3 years, including for all spares |

| | | |
|---|---|---|
| 10.1 | Operating manuals, set manuals, other manuals | Should provide 2 sets(hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should be supplied inEnglish/Hindi/Regional language along with machine diagrams;<br>2. Service and operation manuals(original and Copy) to be provided;<br>3. Advanced maintenance tasks documentation. |
| 10.2 | Other accompanying documents | List of essential spares and accessories, with their part number andcost; |
| **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 tobe provided. |
| 11.2 | Recommendations or warnings | Any warning sign would be adequately displayed. |

| OT TABLE | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name / institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Operation 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 tothis type of device)** | 1) Should have OT Table type base made of high quality304 stainless steel with double table, split leg type andcan take x ray photography.<br>2) Should have imported Y type sealing ring with goodsealing performance and durability.<br>3) Should have a Rotary brake device which is easy for moving operating table.<br>4) Base is stainless steel.<br>5) Leg board is separated & dischargeable.<br>6) Inclining forward ≥30°<br>7) Inclining backward ≥25°<br>8) Inclining leftward≥20°<br>9) Inclining rightward≥20°<br>10) Back board folding upward ≥45˚ Fold downward ≥90°<br>11) Head Board folding upward ≥80°Folding downward ≥10°<br>12) Leg board Folding downward ≥90°.<br>13) Fold outward ≥90°.<br>14) Waist board elevation ≥120°.<br>15) The table top must be made of durable radiolucent Bakelite material capable of withstanding exposure to frequent C-Arm imaging, without diminishing the imageclarity |
| 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 | **Noise (in dBA)** | NA |
| 3.4 | **Heat dissipation** | NA |
| 3.5 | **Mobility, portability** | NA |
| | **4 ENERGY SOURCE** | |
| 4.1 | **Power Requirements** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | Yes |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | As specified by manufacturer |
| | **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 ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection &Sterility issues** | To be specified by manufacturer. |
| | **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| | **8 TRAINING AND INSTALLATION** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up. |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users on operation and basic maintenance; |
| | **9 WARRANTY AND MAINTENANCE** | |
| 9.1 | **Warranty** | 03 years |
| | **10 DOCUMENTATION** | |

| | | |
|---|---|---|
| 10.1 | **Operating manuals, servicemanuals, other manuals** | Should provide 2 sets (hardcopy and soft-copy) of:-<br>1) User, technical and maintenance manuals to be suppliedin English/Hindi language along with machine diagrams;<br>2) Service and operation manuals (original and copy) to beprovided.<br>3) Advanced maintenance tasks documentation. |
| 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 serviceagent to be provided. |
| 11.2 | **Recommendations or warnings** | Any warning signs would be adequately displayed |

| OTOSCOPE | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (Name/Institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| GMDN name | | Otoscope |
| GMDN code(s) | | |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical purpose | An otoscope is a tool which is used to examine structures of the ear, particularly the external auditory canal, tympanic membrane and middle ear. |
| 1.2 | Used by clinical department/ward | ENT department. |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1. At least 2.5 V Xenon or halogen light source.<br>2. Should be convenient pocket type otoscope.<br>3. Swivelling viewing with at least 3X magnification.<br>4. Should be able to detach the otoscope head.<br>5. Should provide no reflections and obstructions.<br>6. Should provide detachable accessories of various sizes.<br>7. Should have in built rechargeable battery. Recharge should be possible with direct mains supply. |
| 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) | NA |
| 3.3 | Noise (in dBA) | NA |
| 3.4 | Heat dissipation | NA |
| 3.5 | Mobility, portability | Portable |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)** | | |
| 4.1 | Power requirements | 220 +- 10% VAC, 50 Hz |
| 4.2 | Battery operated | Should have built in rechargeable battery |
| 4.3 | Protection | NA |
| 4.4 | Power consumption | To be specified by manufacturer |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |

| | | |
|---|---|---|
| 5.1 | Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system) | Set of plastic specula, varying diameters between 2.0 and 5.0 mm Two spare bulbs<br>At least n. 10 reusable (autoclavable) otoscope specula for each one stem) of the following measure: 2, 3 and 5 mm. |
| **BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS** | | |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| 6.1 | Atmosphere/Ambiance (air conditioning, humidity, dust …) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | To be specified by manufacturer. |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | Pre- installation requirements: nature, values, quality, tolerance | NA |
| 8.2 | Requirements for sign-off | Supplier to perform installation, safety and operation check before handover. |
| 8.3 | Training of staff (medical, paramedical, technicians) | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | 03 years, including all spares and calibration. |
| **10. DOCUMENTATION** | | |
| 10.1 | Operating manuals, set manuals, other manuals | Should provide 2 sets (hard copy and soft copy) of:<br>User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. |
| 10.2 | Other accompanying documents | List of essential accessories and cost should be quoted. |
| **11. Notes** | | |
| 11.1 | Service Support Contact details (Hierarchy Wise; including a toll free/ landline number) | Contact details of manufacturer and supplier to be provided |
| 11.2 | Recommendations or warnings | Any warning sign would be adequately displayed on equipment. |

| PHACOMACHINE | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (Name/Institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| UMDNS name | | Phaco emulsification Units, Cataract Extraction |
| UMDNS code(s) | | |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical purpose | Ophthalmic surgery units designed for removal of cataractous lensesby the insertion of a probe that cuts and emulsifies the lenses using ultrasonic waves (phacoemulsification). These units consist of a hollow probe (i.e., a phaco probe) that includes an irrigation sleeve, an oscillating tip that converts electric energy into ultrasonic waves,and a channel for aspiration of lens fragments; the units also includea vacuum pump and controls for the output levels, irrigation rate, and mode of operation. Phacoemulsification units are used in ophthalmic offices for cataract extraction surgery. |
| 1.2 | Used by clinical department/ward | Ophthalmology Department |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical characteristics (specific to this type of device) | **1. OPERATIONAL MODES:**<br>i. System should have following operation modes: Irrigation, Ultrasound, Irrigation/Aspiration (I/A) system, Diathermy and Vitrectomy.<br>**2. ULTRA SOUND SYSTEM:**<br>i. Hand Piece type: Piezoelectric, made up of Titanium.<br>ii. Frequency: 25-80 kHz.<br>iii. It should be autoclavable.<br>**3. IRRIGATION/ASPIRATION (I/A)SYSTEM:**<br>i. System should have dual pump (Peristaltic and Venturi) usercan switch between the two pumps during surgery with Max.Vacuum (peristaltic: 500 mmHg) with 1 mmHg pump increment.<br>ii. Reflux method: Gravity / Pump reversal.<br>iii. Tubing shall be re usable.<br>iv. I/A Hand pieces shall be autoclavable with port diameter of 0.2-0.5 mm.<br>v. Collection container size shall be 1-60 cc.<br>**4. ANTERIOR VITRECTOMY:**<br>i. Guillotine type hand piece with variable speed shall bepreferred.<br>ii. Hand piece shall be re usable and autoclavable.<br>iii. Control Panel or linear cut rate control by foot pedal. |
| 2.2 | User's interface | Manual |

| | | |
|---|---|---|
| 2.3 | Software and/or standard of communication(where ever required) | As Applicable. |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | Dimensions(metric) | NA |
| 3.2 | Weight (lbs, kg) | NA |
| 3.3 | Noise (in dBA) | Noise Free System |
| 3.4 | Heat dissipation | Should maintain nominal temperature and the heat should disbursedthrough a cooling mechanism. |
| 3.5 | Mobility, portability | Portable |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, $CO_2$ ….)** | | |
| 4.1 | Power requirements | 220 +/- 10% VAC, 50 Hz |
| 4.2 | Battery operated | An UPS with 30 minutes back up shall be provided. |
| 4.3 | Protection | Stabilizer to be provided. |
| 4.4 | Power consumption | To be specified by manufacturer. |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents(open, closed system) | 1. Phaco hand piece – 1no<br>2. Phaco tips -4 nos<br>3. Anterior vitrectomy packs including cutters and other disposables – 25 nos<br>4. Cassettes and disposables – 12 nos. |
| **BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS** | | |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| 6.1 | Atmosphere/Ambiance(air conditioning, humidity, dust …) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning,Disinfection & Sterilityissues | Sterilization is required for hand piece, tips and forceps. |
| **7. STANDARDS AND SAFETY** | | |
| 7.1 | Certificates (pre-market,sanitary,..); Performanceand safety standards (specific to the device type); Local and/or international | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | Pre- installation requirements: nature, values, quality, tolerance | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up. |

| | | |
|---|---|---|
| 8.2 | Requirements for sign-off | Supplier to perform installation, safety and operation checksbefore handover. |
| 8.3 | Training of staff (medical, paramedical, technicians) | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | 3 years, including for all spares and calibration work. |
| **10. DOCUMENTATION** | | |
| 10.1 | Operating manuals, set manuals, other manuals | Should provide 2 sets (hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should be supplied inEnglish/Hindi/Regional language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided.<br>3. Advanced maintenance tasks documentation.<br>4. Satisfactory certificate for any existing installation from governmenthospital. |
| 10.2 | Other accompanying documents | List of essential spares and accessories, with their part number andcost; |
| **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 tobe provided. |
| 11.2 | Recommendations or warnings | Any warning sign would be adequately displayed. |

| PULSE OXIMETER-TABLE TOP | | |
|---|---|---|
| Version no.: | | 02 |
| Date: | | August 2023 |
| Done by: (name / institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Pulse oximeter |
| GMDN code(s) | | 45607 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | It is used for the transcutaneous measurement and display of haemoglobin oxygen saturation (SpO2). The signals are produced by light-emitting diodes (LEDs) and received by a photodetector. The device displays the SpO2 values and may also measure and display pulse rate. |
| 1.2 | **Used by clinical department/ward** | All Departments |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | • Should be a portable, light weight, desktop model with adult, pediatric and neonatal finger probes.<br>• Should have digital display with parameters: SpO2, pulse rate, plethysmograph waveform, alarm message and battery state indication.<br>• SpO2 detection range to include: 70–100%<br>• SpO2 resolution: 1% or less<br>• Accuracy of SpO2 should be within +/-3%<br>• SpO2 probes should be reusable.<br>• Pulse rate range detection range to include: 30-240 beats per minute (bpm).<br>• Pulse rate accuracy: within ± 3 bpm.<br>• Pulse rate resolution: 1 bpm or less<br>• Audio and visual alarms required: high and low SpO2 and pulse rate (operator variable settings), sensor disconnected, sensor failure, low battery. |

| | | |
|---|---|---|
| | | • Suitable for detection in low perfusion conditions.<br>• Should have a minimum of 02 hours back-up time.<br>• Should have trend data of at least 36 hrs. |
| 2.2 | **User's interface** | Digital display and easily accessible buttons to operate the machine. |
| 2.3 | **Software and/or standard of communication (wherever required)** | In built. |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | Light weight |
| 3.3 | **Noise (in dBA)** | <60dBA |
| 3.4 | **Heat dissipation** | Should be dispersed through exhaust. |
| 3.5 | **Mobility, Portability** | Mobile |
| **4. ENERGY SOURCE** | | |
| 4.1 | **Power Requirements** | 220 V +/- 10% AC, 50 Hz |
| 4.2 | **Battery operated** | Yes, with minimum backup time of 02 hour |
| 4.3 | **Power consumption** | To be specified by manufacturer |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | **Accessories & Spares parts; Consumables / reagents (open, closed system)** | Two reusable probes each for adult, pediatric and infant use |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer |

| | | |
|---|---|---|
| **7. STANDARDS AND SAFETY** | | |
| 7.1 | **Certifications** | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards in case of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | Electrical accessories as per standard Indian set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform installation, safety and operation checks before handover. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| **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 should 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. Satisfactory certificate for any existing installation from government hospital. |
| 10.2 | **Other accompanying documents** | NA |
| **11. NOTES** | | |
| 11.1 | **Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |

| | | |
|---|---|---|
| 11.2 | **Recommendations or warnings** | Any recommendations for best use and supplementary warning for safety should be displayed. |

| RT-PCR SYSTEM | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done By: | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN Name | | NA |
| GMDN Code | | NA |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical Purpose | RT-PCR is a laboratory technique combining reverse transcription of RNA into DNA (in this context called complementary DNA or cDNA) and amplification of specific DNA targets using polymerase chain reaction (PCR). This is achieved by monitoring the amplification reaction using fluorescence a technique called real-time PCR or quantitative PCR (qPCR). Combined RT-PCR and qPCR are routinely used for analysis of gene expression and quantification of viral RNA in research and clinical settings. |
| 1.2 | Used by clinical department/ward | Clinical Diagnostic Laboratory |
| **TECHNICAL** | | |
| **2. Technical Characteristics** | | |
| 2.1 | Technical Characteristics (Specific to this type of device) | • Tabletop model.<br>• Open system to accommodate TaqMan, SYBRgreen and all other fluorescent dye-based chemistries.<br>• The system should be flexible to use micro well plates, individual PCR tubes and PCR tube strips.<br>• Peltier based atleast 48 well block/Rotor or bettersystem.<br>• It should have excellent thermal (Temperature range: 4 to 99 deg C; Temperature accuracy: ± 0.25 Deg C) and optical performance.<br>• Sensitivity: Detection of 1 copy of template anddifferences as small as 1.5-fold in target.<br>• It should have a fast ramp rate for heating andcooling.<br>• The system should be easily calibrated with new dyes without any change filter or hardware. (Should have pre-calibrated for minimum 7 dyes).<br>• CCD camera with halogen/LED/Photodiode/CMOS and at least sixexcitation and six emission filters to perform |

| | | |
|---|---|---|
| | | multiplex assays.<br>• Option for melt curve analysis using highresolution software.<br>• The system should facilitate for calibration ofmultiple dyes at installation.<br>• It should have 5 channels (5plex) for optical detection: Green channel (Excitation: 470 ± 10 nm, Detection: 510 ± 5 nm), Yellow channel (Excitation: 530 ± 5 nm, Detection: 557 ± 5 nm), Orange channel (Excitation: 585 ± 5 nm, Detection: 610 ± 5 nm), Red channel (Excitation: 625 ± 5 nm, Detection: 660 ± 10 nm), and crimson channel (Excitation: 680 ± 5 nm, Detection: 712 high pass nm). In addition, the software should allow creation of new excitation/detection wavelength combinations, as per requirement.<br>• There should be enough excitation and emission filters to cover majority of dyes.<br>• The system should be flexible and compatible with reagents, chemistries and plastic ware from third party vendors.<br>• The system should have online UPS system with minimum 2-hour backup.<br>• HRM analysis should be supported by thermal resolution of 0.02°C, high data-acquisition rates, and appropriate HRM software.<br>• It should support multiple PCR tube formats and strips as per standards.<br>• It should have digital display.<br>• It should have a small footprint (Width: <40 cm; Height: <30 cm; Depth: <45 cm and Depth (door open): <55 cm).<br>• Software: Software should be latest, compatible with window OS system and should be compliant or matching with the hardware.<br>• Should be able to generate reports and analysis reports in both excel or pdf format.<br>• A quick and automated temperature accuracy testing provision should be available. |
| **2.2** | **Software and/or standard of communication (wherever required)** | 1. Unlimited user licenses and individual user management provision should be available for the software.<br><br>2. Analysis workstation should be of latest configuration with a color printer. |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | Dimensions (in mm) | As per the manufacturer |
| 3.2 | Weight | As per the manufacturer |
| 3.3 | Noise | NA |

| | | |
|---|---|---|
| 3.4 | Heat Dissipation | Should maintain nominal temperature and the heatshould be disbursed through a cooling mechanism. |
| 3.5 | Mobility/Portability | Portable |
| **4. ENERGY SOURCE** | | |
| 4.1 | Power input | 220 + - 10% VAC, 50 Hz |
| 4.2 | Battery Backup | Should be compatible with online UPS (2KV). |
| 4.3 | Protection | Internal electrical safety |
| 4.4 | Power consumption | As per Manufacturer/Supplier specified |
| **5. ACCESSORIES, SPARE PARTS AND CONSUMABLE** | | |
| 5.1 | Accessories, (mandatory, Standard, operational); Spare parts (main ones) Consumable/reagents (open, closed system) | 1. A laptop with latest configuration and with operating system compatible with the dedicated softwareshould be provided along with the system.<br>2. The system should come with –<br>a. RT-PCR instrument,<br>b. Rotors stand/holder,<br>c. USB and RS-232 serial cable<br>d. PCR tubes (1000 Nos.) and strip tubes with caps(1000 Nos.).<br>e. Dyes should be provided with the system.<br>f. Reagents for 500 reactions should be providedwith the instrument. |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | Atmosphere /Ambiance (air conditioning, humidity, dust ...) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | As per manufacturer's recommendation |
| **7. STANDARDS & SAFETY** | | |
| 7.1 | Certificates (pre-market, sanitary, ..);Performance and safety standards (specific to the device type);Local and/or international | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | Pre-installation requirements: nature, values, quality, tolerance | As indicated by manufacturer and compatible electricalaccessories as per standard Indian set-up. |
| 8.2 | Requirements for sign-off | 1. Supplier to perform installation, safety and operationchecks before handover.<br>2. Lab In-Charge to affirm completion of installation |

| | | |
|---|---|---|
| 8.3 | Training of staff (medical, paramedical, technicians) | Satisfactory training of users in operation and basic maintenance shall be provided on installation and duringPreventive Maintenance visits and shall be documented. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | 1. 3 years<br>2. Preventive maintenance visits at least one in each quarter. |
| **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 should be supplied in English/Hindi language along with machine diagrams.<br>2. List of equipment and procedures required for localcalibration and routine maintenance.<br>3. Service and operation manuals (original and Copy) tobe provided.<br>4. Advanced maintenance tasks documentation.<br>5. Certificate of calibration and inspection,<br>6. Satisfactory certificate for any existing installation fromgovernment hospital. |
| 10.2 | Other accompanying documents | List of essential spares and accessories, with their partnumber and cost. |
| **11. NOTES** | | |
| 11.1 | Service Support Contact details (Hierarchy Wise; including a toll free/landline number) | Contact details of manufacturer, supplier and localservice agent to be provided. |
| 11.2 | Recommendations or warnings | Any warning signs should be adequately displayed. |

| Shoulder Wheel | | |
|---|---|---|
| Version no. : | | 01 |
| Date: | | August 2023 |
| Done by : (Name/Institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| GMDNS name | | NA |
| GMDNS code(s) | | NA |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical purpose | The wheel allows carrying out a shoulder exercise safely and decrease the pain in shoulder and arms. |
| 1.2 | Used by clinical department/ward | Physiotherapy |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical characteristics(specific to this type of device) | 1. Shoulder wheel is a metal drum fitted with adjustable bars made of Stainless Steel.<br>2. The wheel should be wall mounted<br>3. Adjustment bar to raise up and release down as per the height requirements fitted on a laminated board frame.<br>4. The wheel should provide 360-degree revolution bidirectionally. |
| 2.2 | User's interface | Manual |
| 2.3 | Software and/or standard of communication (wherever required | Not required |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | Dimensions(metric) | NA |
| 3.2 | Weight (lbs, kg) | NA |
| 3.3 | Noise (in dBA) | NA |
| 3.4 | Heat dissipation | NA |
| 3.5 | Mobility, portability | Fixed |
| **4. ENERGY SOURCE** | | |
| 4.1 | Power requirements | NA |
| 4.2 | Battery operated | NA |
| 4.3 | Power consumption | NA |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | Accessories, (mandatory,standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system) | Not required. |
| **BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS** | | |

| | | |
|---|---|---|
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| 6.1 | Atmosphere/Ambiance(air conditioning, humidity, dust …) | NA |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | Should be easy to clean and disinfectable |
| **7. STANDARDS AND SAFETY** | | |
| 7.1 | Certificates (pre-market,sanitary,); Performanceand safety standards (specific to the device type); Local and/or international | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards. |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | Pre- installation requirements: nature, values, quality, tolerance | NA |
| 8.2 | Requirements for sign-off | Supplier to perform safety and operation check before handover. |
| 8.3 | Training of staff (medical, paramedical, technicians) | NA |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | 03 year. |
| **10. DOCUMENTATION** | | |
| 10.1 | Operating manuals, setmanuals, other manuals | NA |
| 10.2 | Other accompanying documents | NA |
| **11. Notes** | | |
| 11.1 | Service Support Contactdetails (Hierarchy Wise; including a toll free/ landline number) | Contact details of manufacturer and supplier to be provided. |
| 11.2 | Recommendations or warnings | NA |

| SLIT LAMP | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by: (Name/Institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| UMDNS name | | Slit Lamp |
| UMDNS code(s) | | |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical purpose | Ophthalmic diagnostic instruments designed for examining the eye (mostly the anterior part of the eye) using an illumination system combined with a binocular microscope. The instruments usually consist of illumination sources with a mechanism that provides aslit beam of light into the eye with different types of illumination (e.g., direct or indirect, focal or diffuse, background illumination), a binocular microscope for viewing the magnified slit image, and a control component for adjusting the focus of the microscope and the slit (e.g., slit rotation, slit width); some also have refraction mirrors to direct light to a camera mounted above the microscope. Slit lamps provide a magnified view of eye structures (e.g., eyelid, sclera, iris, crystalline lens and cornea); some instruments can also examine the retina using specific lenses. Slit lamps are used mainly in the diagnosis of eye conditions. |
| 1.2 | Used by clinical department/ward | Ophthalmology Department |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1. Should have LED with adjustable and good illumination.<br>2. Should have facility for applanation tonometer if required.<br>3. Type of microscope: Binocular<br>4. Should have 3 step magnification and total magnification is greater than 10x.<br>5. Should have slit width ≥ 0-10 mm, adjustable.<br>6. Should have slit length ≥ 0-10 mm, adjustable.<br>7. Should have standard filters: Minimum: blue, green (red-free), heat absorption. A broader selection of filters increases the functionality of the slit lamp.<br>8. Rotation is between 0-180°.<br>9. Should be supplied with motorized table.<br>10. Should have a longitudinal movement of at least 90mm<br>11. Should have a lateral movement of at least 95mm.<br>12. Should have a vertical movement of at least 30mm.<br>13. Should have a chin rest vertical movement of at least |

| | | |
|---|---|---|
| | | 55mm. |
| 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 | Noise (in dBA) | Noiseless operation |
| 3.4 | Heat dissipation | NA |
| 3.5 | Mobility, portability | Stationary |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)** | | |
| 4.1 | Power requirements | 220 +/- 10% VAC, 50 Hz |
| 4.2 | Battery operated | Should be supplied with suitable online UPS with at least half an hour backup. |
| 4.3 | Protection | NA |
| 4.4 | Power consumption | To be specified by manufacturer. |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | Accessories, (mandatory, standard,optional); Spare parts (main ones); Consumables/reagents (open, closed system) | 1. Focusing Test rod & dust cover;<br>2. Slit lamp dust cover,<br>3. Rack, manual and motorized guard,<br>4. 90D/70D Lens |
| **BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS** | | |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |

| | | |
|---|---|---|
| 6.1 | Atmosphere/Ambiance (air conditioning, humidity, dust …) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | To be specified by manufacturer. |
| **7. STANDARDS AND SAFETY** | | |
| 7.1 | Certificates (pre-market, sanitary,..); Performanceand safety standards (specific to the device type); Local and/or international | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | Pre- installation requirements: nature, values, quality, tolerance | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | Requirements for sign-off | Supplier to perform installation, safety and operation checks beforehandover. |
| 8.3 | Training of staff (medical, paramedical, technicians) | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| **10. DOCUMENTATION** | | |
| 10.1 | Operating manuals, set manuals, other manuals | Should provide 2 sets (hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should be supplied inEnglish/Hindi/Regional language along with machine diagrams.<br>2. Advanced maintenance tasks documentation.<br>3. Certificate of calibration and inspection,<br>4. Satisfactory certificate for any existing installation from governmenthospital. |
| 10.2 | Other accompanying documents | List of essential spares and accessories, with their part number 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 tobe provided. |
| | 11 .2 | Recommendations or warnings | Any warning sign would be adequately displayed. |

| STADIOMETER | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done by: (Name/Institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| GMDN name | | NA |
| GMDN code(s) | | NA |
| **GENERAL** | | |
| **1. USE** | | |
| **1.1** | **Clinical purpose** | A stadiometer is a device used to measure body height in vertical position. |
| **1.2** | **Used by clinical department/ward** | OPD |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| **2.1** | **Technical characteristics (specific to this type of device)** | 1. Should have adjustable measuring range to accommodate tall person (minimum 200 cm) with graduation marks on either side in cm/mm and inches/ft metrics.<br>2. It should be light weight, portable with a sturdy base capable to accommodate weight upto 200 Kg.<br>3. It should be made of high-quality material stainless steel (SS-304)/wood or moulded unbreakable plastic/Fibre material with an adjustable head rod.<br>4. Should be portable, light weight and easy to carry.<br>5. Durable resistant to effects of excess humidity and high temperature and water resistant. |
| **2.2** | **User's interface** | Manual |
| **2.3** | **Software and/ or standard of communication (wherever required)** | NA |
| **3. PHYSICAL CHARACTERISTICS** | | |
| **3.1** | **Dimensions(metric)** | In accordance with measuring length mentioned in technical characteristics |
| **3.2** | **Weight (lbs, kg)** | Light weight |
| **3.3** | **Noise (in dBA)** | NA |
| **3.4** | **Heat dissipation** | NA |
| **3.5** | **Mobility, portability** | Portable |
| **4. ENERGY SOURCE** | | |

| | | |
|---|---|---|
| **4.1** | **Power requirements** | NA |
| **4.2** | **Battery operated** | NA |
| **4.3** | **Protection** | NA |
| **4.4** | **Power consumption** | NA |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| **5.1** | **Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)** | Should be supplied with carry bag or carry case |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| **6.1** | **Atmosphere/Ambience (air conditioning, humidity, dust …)** | Durable resistant to effects of excess humidity and high temperature. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | Should be easily disinfected by using normal hospital grade *cleaning* solution. |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards in case of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards. |
| **8. TRAINING AND INSTALLATION** | | |
| **8.1** | **Pre- installation requirements: nature, values, quality, tolerance** | NA |
| **8.2** | **Requirements for sign-off** | NA |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | NA |
| **9. WARRANTY AND MAINTENANCE** | | |
| **9.1** | **Warranty** | 3 years |
| **10. DOCUMENTATION** | | |
| **10.1** | **Operating manuals, set manuals, other manuals** | Should provide 2 sets (hard copy and soft copy) of: User, technical and maintenance manuals in English/Hindi language along with machine diagrams. |
| **10.2** | **Other accompanying documents** | NA |
| **11. Notes** | | |
| **11.1** | **Service Support Contact details (Hierarchy Wise; including a toll free/landline number)** | Contact details of manufacturer and supplier should be provided. |

| | | |
|---|---|---|
| **11.2** | **Recommendations or warnings** | NA |

| **RETINOSCOPE** | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by: (Name/Institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| UMDNS name | | Retinoscopes |
| UMDNS code(s) | | |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical purpose | Retinoscopy is a technique to obtain an objective measurement of the refractive error of a patient's eyes. The examiner uses a retinoscopeto shine light into the patient's eye and observes the reflection (reflex) of the patient's retina. |
| 1.2 | Used by clinical department/ward | Ophthalmology Department |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1. Available with LED light source.<br>2. Should be interchangeable to plane mirror and concave mirrormode by sleeve movement.<br>3. Should have an external focusing sleeve which is easy to grip.<br>4. Should have crossed-linear polarizing filter.<br>5. Should allow one-hand operation for streak focus.<br>6. Available with 360º streak rotation.<br>7. Should have 100% dust proof housing and multi-coated optics. |
| 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) | NA |
| 3.3 | Noise (in dBA) | <50 dB |
| 3.4 | Heat dissipation | NA. |
| 3.5 | Mobility, portability | Portable |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)** | | |
| 4.1 | Power requirements | 220 +/- 10% VAC, 50 Hz |
| 4.2 | Battery operated | Yes, should be rechargeable battery with Charger. |
| 4.3 | Protection | Yes |
| 4.4 | Power consumption | To be specified by Vendor |

| | | |
|---|---|---|
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | Accessories, (mandatory, standard,optional); Spare parts (main ones); Consumables/reagents (open, closed system) | 1. Should have a carrying case.<br>2. Bulb – 2 nos<br>3. Rechargeable battery – 1 no |
| **BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS** | | |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| 6.1 | Atmosphere/Ambiance(air conditioning, humidity, dust …) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterilityissues | To be specified by manufacturer. |
| **7. STANDARDS AND SAFETY** | | |
| 7.1 | Certificates (pre-market, sanitary,..); Performanceand safety standards (specific to the device type); Local and/or international | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | Pre- installation requirements: nature, values, quality, tolerance | NA |
| 8.2 | Requirements for sign-off | Supplier to perform installation, safety and operation checks beforehandover. |
| 8.3 | Training of staff (medical, paramedical,technicians) | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | 3 years |
| **10. DOCUMENTATION** | | |
| 10.1 | Operating manuals, setmanuals, other manuals | Should provide 2 sets(hard copy and soft copy) of:<br>User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams. |
| 10.2 | Other accompanying documents | List of essential spares and accessories, with their part number andcost; |
| **11. Notes** | | |
| 11.1 | Service Support Contactdetails (Hierarchy Wise; including a toll free/ landline number) | Contact details of manufacturer, supplier and local service agent tobe provided. |
| 11.2 | Recommendations or warnings | Any warning sign would be adequately displayed. |

| Stethoscope | | |
|---|---|---|
| Version no.: | | 02 |
| Date: | | August 2023 |
| Done by : (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Stethoscopes, Mechanical |
| GMDN code(s) | | 13755 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | Listening to sounds from the heart, lungs, and/or gastrointestinal tract. |
| 1.2 | **Used by clinical department/ward** | All |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics(specific to this type of device)** | 1. Should have single lumen binaural.<br>2. Latex free Polyvinyl chloride (PVC) stethoscope tubing, soft and should not harden/crack.<br>3. Tube should be impervious to outside noises.<br>4. Earpieces (02) should be with soft sealing ear tips and easy to stay fixed in ears.<br>5. Earpiece material: Soft PVC/Silicone preferably.<br>6. Should have good quality and highly sensitive fixed/floating diaphragm.<br>7. Dual head: Cup/ bell for low frequency sounds, sensitive membrane for skin contact. |
| 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)** | Tube length - 55 cm minimum |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dBA)** | NA |
| 3.4 | **heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Portable |
| **4. ENERGY SOURCE** | | |
| 4.1 | **Power Requirements** | NA |
| 4.2 | **Battery operated** | NA |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | NA |
| 4.5 | **Other energy supplies** | NA |

| | | |
|---|---|---|
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | **Accessories& Spares Consumables / reagents (open, closed system)** | 1 x spare set of earpiece, 1 x spare diaphragm. |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | NA |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | NA |
| **7. STANDARDS AND SAFETY** | | |
| 7.1 | **Certifications** | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards. |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | NA |
| 8.2 | **Requirements for sign-off** | NA |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | NA |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | 1 year |
| **10. DOCUMENTATION** | | |
| 10.1 | **Operating manuals, service manuals, other manuals** | NA |
| 10.2 | **Other accompanying documents** | NA |
| 10.3 | **Recommendations for maintenance** | NA |
| **11. NOTES** | | |
| 11.1 | **Service Support Contact details (Hierchy Wise; including a toll free/ landlir number)** | NA |
| 11.2 | **Recommendations or warnings** | NA |

| SYRINGE PUMP | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Syringe pump |
| GMDN code(s) | | CT111 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | Designed to precisely drive the plunger of a syringe down its barrel to infusea solution when it must be administered with a high degree of volume accuracy and rate consistency. |
| 1.2 | **Used by clinical department/ward** | NICU/PICU/Critical Care |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1. Flow rate programmable range at least from 0.1 to 200 ml/hr, in steps of 0.1 ml/hr; and at least from 100 to 1200 ml/hr in steps of 1 ml/hr.<br>2. Saves last infusion rate even when the AC power is switched off.<br>3. Bolus rate should be programmable to approx 500 ml, with infusedvolume display.<br>4. Selectable occlusion pressure trigger levels selectable from 300, 500 and900 mmHg.<br>5. Must work on commonly available 20, 30 and 50 ml syringes.<br>6. Accuracy of ±2% or better.<br>7. Maximum pressure generated ≤ 20 psi.<br>8. Automatic detection of syringe size and proper fixing.<br>9. Anti-bolus system to reduce pressure on sudden release of occlusion.<br>10. Pause infusion facility required.<br>11. Self-check carried out on powering on.<br>12. Comprehensive alarm package required including: occlusion alarm, nearend of infusion pre-alarm and alarm, volume limit pre-alarm and alarm, low battery pre-alarm and alarm, AC power failure, drive disengaged, syringe loading error, maintenance required.<br>13. Should include KVO (Keep vein open) enabling feature.<br>14. It should be an open system compliant. |
| 2.2 | **User's interface** | Automatic |

| | | |
|---|---|---|
| 2.3 | **Software and/or standard of communication** | Inbuilt |
| | **3. PHYSICAL CHARACTERISTICS** | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dBA)** | Noise free |
| 3.4 | **Heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Portable |
| | **4. ENERGY SOURCE** | |
| 4.1 | **Voltage (value, AC or DC, monophase or triphase)** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | Internal rechargeable battery having atleast 4 to 6 hours backup for 10ml/hr flowrate with 50ml syringe. |
| 4.3 | **Protection** | Battery powered alarm for power failure or disconnection. |
| 4.4 | **Power consumption** | As specified by manufacturer. |
| | **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory, standard, optional) Spare parts (main ones) Consumables / reagents(open, closed system)** | Clamp for mounting pump on IV stand.<br><br>Battery, syringe holder, PMO lines |
| | **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | |
| | **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | |
| 6.1 | **Atmosphere / Ambiance (airconditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer |
| | **7. STANDARDS AND SAFETY** | |
| 7.1 | **Certificates (pre-market, sanitary, ..); Performance andsafety standards (specific to the device type)** | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| | **8. TRAINING AND INSTALLATION** | |
| 8.1 | **Pre-installation requirements:nature, values, quality, tolerance** | Supplier to perform installation, safety and operation checks beforehandover. |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over. |

| | | |
|---|---|---|
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| **10. DOCUMENTATION** | | |
| 10.1 | **Operating manuals, servicemanuals, other manuals** | User, technical and maintenance manuals to be supplied in English/Hindi language along with mavhine diagram. |
| 10.2 | **Other accompanying documents** | List of important spares and accessories, with their part numbers and cost. |
| **11. NOTES** | | |
| 11.1 | **Other information** | Contact details of manufacturer, supplier and local service agent to beprovided. |
| 11.2 | **Recommendations or warnings** | Any warning sign should be adequately displayed |

| THERMOMETER | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name / institution) | | HCT,NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Intermittent Electronic Patient Thermometer |
| GMDN code(s) | | 14035 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | A hand-held non-mercury digital thermometer (battery-powered, electronic instrument) is used to measure a patient's body temperature. |
| 1.2 | **Used by clinical department/ward** | All |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | • Range of temperature measurement 32 deg C- 42 deg C (89.60F-109.40F)<br>• Accuracy of temperature ± 0.1degC or ± 0.2 F.<br>• Should have digital display with temperature showing in both Centigrade and Fahrenheit interchangeable mode using a button.<br>• Beep sound when final steady temperature arrived during test.<br>• Buzzer alert function for indicating low (< 35 deg C /95 deg F) for hypothermia and high (> 42 deg C/ 106 deg F) temperature for hyperthermia.<br>• Takes 60-90 seconds to measure temperature.<br>• Can be used in the armpit/axilla, orally and rectally.<br>• Should have auto shut down feature for remaining idle for more than 1 minute. |
| 2.2 | **User's interface** | Digital display |
| 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 | **Noise (in dBA)** | NA |
| 3.4 | **Heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Portable |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ..... )** | | |

| | | |
|---|---|---|
| 4.1 | **Power Requirements** | NA |
| 4.2 | **Battery operated** | Yes |
| 4.3 | **Protection** | NA |
| 4.4 | **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 ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer. |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards. |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | NA |
| 8.2 | **Requirements for sign-off** | NA |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | NA |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | One year |
| **10. DOCUMENTATION** | | |
| 10 | **Operating manuals, service manuals, other manuals** | User manual should be provided. |
| **11. NOTES** | | |

| | | |
|---|---|---|
| 11.1 | **Service Support Contact details (Hierarchy Wise; including a toll free/landlinenumber)** | NA |
| 11.2 | **Recommendations or warnings** | NA |

| BILIRUBINOMETER | | |
|---|---|---|
| Version no. : | | 01 |
| Date: | | August 2023 |
| Done by : (name / institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Bilirubinometer |
| GMDN code(s) | | CT834 |
| **GENERAL** | | |
| **1 USE** | | |
| 1.1 | **Clinical purpose** | Determining the concentration of bilirubin in the blood or other clinical specimen, most commonly to rapidly assess hyperbilirubinemia in neonates. |
| 1.2 | **Used by clinical department/ward** | NICU/PICU |
| **TECHNICAL** | | |
| **2 TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1) Sample volume of < 100 µL required, automatic calibration facility.<br>2) Total bilirubin concentration measurable (at least) in range of 0 to 30 mg/dl.<br>3) Time for total concentration measurement: ≤ 5 seconds.<br>4) Should have filters: 455 and 575 nm (± 2%).<br>5) Should have error rate less than 5%.<br>6) Should have resolution- 0.1 mg/dl.<br>7) Automatic correction for Hemoglobin.<br>8) Measuring cell: Direct Hematocrit capillary readings.<br>9) heparinized hematocrit glass capillary. |
| 2.2 | **User's interface** | Manual interface.<br>Backlit display with easy viewing in all ambient light levels. |
| 2.3 | **Software and/or standard of communication(where ever required)** | Inbuilt software.<br>Convenient and quick USB interface. |
| **3 PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dBA)** | <60dB |
| 3.4 | **Heat dissipation** | Heat Dissipation:<br>Should maintain nominal temperature and the heat should be disbursed through ancooling mechanism. |
| 3.5 | **Mobility, portability** | Portable |
| **4 ENERGY SOURCE (Electricity, Ups, Solar, Gas, Water, Co2 )** | | |

| | | |
|---|---|---|
| 4.1 | **Power Requirements** | 220VAC ± 10%, 50 Hz; |
| 4.2 | **Battery operated** | Yes (optional) |
| 4.4 | **Protection** | NA |
| 4.5 | **Power consumption** | As specified by manufacturer |
| **5 ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | **Accessories (mandatory, standard, optional)**<br>**Spare parts (main ones)**<br>**Consumables / reagents (open, closed system)** | Hard and splash-proof case to be supplied.<br>1) Spare/replaceable fuses - 2 sets.<br>2) Reagents and capillary tubes sufficient for minimum 100 tests.<br>3) Reagents and consumables per test should be declared.<br>4) Capillary tubes, haemo fluorometric reagents (e.g., aqueous cyanide saltwith stabilizers, if applicable).<br>5) Price of all Consumables to be mentioned. |
| **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | | |
| **6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | **Atmosphere / Ambiance (airconditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer. |
| **7 STANDARDS AND SAFETY** | | |
| 7.1 | **Certificates (pre-market, sanitary, ..); Performance andsafety standards (specific to the device type);Local and/orinternational** | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8 TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up. |
| 8.2 | **Requirements for sign-off** | Supplier to perform installation, safety and operation checks beforehandover. |
| 8.3 | **Training of staff (medical,paramedical, technicians)** | Training of users on operation and basic maintenance. |
| **9 WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | 3 years |
| **10 DOCUMENTATIONS** | | |

| | | |
|---|---|---|
| 10.1 | **Operating manuals, servicemanuals, other manuals** | Should provide 2 sets(hardcopy) of:-<br>1) User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams.<br>2) 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(Hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to beprovided. |

| ANAESTHESIA MACHINE | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by: (name. Institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| UMDNS name | | Anesthesia Units |
| UMDNS code(s) | | 10134 |
| **GENERAL** | | |
| **1 USE** | | |
| 1.1 | Clinical purpose | Anesthesia machine is used for delivering anesthesia agents to the patients during surgery. |
| 1.2 | Used by clinical department/ward | Operation Theatre |
| **TECHNICAL** | | |
| **2 TECHNICAL CHARACTERICSTICS** | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1. Should be portable stainless steel, with large antistatic sturdy castor wheels fitted with brakes.<br>2. Anesthesia machine should be with 3 gas supply system (02, N2O and Air) with pipeline connections and reserve cylinder yokes.<br>3. All pipeline connections should have diameter-indexed safety systems (DISSs) or another means of preventing connection of dangerous gases.<br>4. System should permit connection of at least two yokes, one dedicated to 02 cylinder to meet clinical needs during failure of pipeline supply. All cylinder yokes (regardless of the gas for which they are intended) should include pin-index safety systems to prevent connection of dangerous gases.<br>5. Provision to mount following selectable vaporizers such as Desflurane, halothane, isoflurane, sevoflurane with interlocking facility to allow use of only one vaporizer at a time. All the vaporizers should be maintenance free.<br>6. It should have following Ventilation modes Manual / spontaneous, VCV.<br>7. Tidal volume: A control adjusts the volume of individual breaths within range of 50-1,200 cc. Minute volume: A control adjusts the total inspiratory volume-per-minute delivery from the bellows shall be >20 L/min. The respiratory frequency can be set within range of 5-60 breaths per minute.<br>8. Inspiratory flow: The flow range of gas that the ventilator is capable of delivering to the patient shall be 0-120 L/min.<br>9. Pressure limit shall be adjustable and <70 preferred cm |

| | | |
|---|---|---|
| | | H2O.<br>10. Unit should have PEEP of 0-20 cm H2O.<br>11. Unit can able perform to ensure proper functioning of Pre-use vent, gas supply, ongoing system.<br>12. It should have active or passive scavenging system.<br>13. It should provide facility to monitor of Airway pressure along with High-pressure alarm, Sub atmospheric pressure alarm, continuing pressure alarm and low pressure/apnea.<br>14. System should also provide facility to monitor of expiratory volume/ flow along with Apnea alarm.<br>15. It should have 3 (caution, advisory, alarm) prioritized alarms for ventilator failure, low oxygen supply pressure, inadequate volume delivery, disconnecting alarm and power supply failure.<br>16. Should have dual cascade type flow meter for 02, N2O and Air calibrated in multiple scale.<br>17. Should have adjustable pressure limiting valve, breathing circuit<br>pressure measuring device.<br>18. Should have a bag/ ventilator select valve integrated on to absorber.<br>19. Should be able to use low flow anesthesia technique and facility to attach oxygen sensor.<br>20. Should have CO2 absorbent chamber canister.<br>21. Integrated physiological monitoring is preferred. |
| 2.2 | User's interface | Manual |
| 2.3 | Software and/ or standard of communication(where ever required | Inbuilt |
| **3 PHYSICAL CHARACTERICSTICS** | | |
| 3.1 | Dimensions(metric) | NA |
| 3.2 | Weight (lbs, kg) | NA |
| 3.3 | Noise (in dBA) | Noise pressure level: <60 dbA. |
| 3.4 | Heat dissipation | Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism. |
| 3.5 | Mobility, portability | NA |
| **4. ENERGY SOURCE** | | |
| 4.1 | Power | 220 +/- 10% VAC, 50 Hz |
| 4.2 | Battery operated | Yes, at least 30 minutes back up. |
| 4.3 | Protection | Stabilizer to be provided for protection. |
| 4.4 | Power consumption | To be specified by manufacturer |
| **5 ACCESSORIES, SPARE PARTS AND CONSUMABLES** | | |

| | | |
|---|---|---|
| 5.1 | Accessories, standard, optional); Spare parts (main ones); Consumables/re- agents (open, closed system) | 1. Should have a provision for mount monitors on top of the machine. The table top made up of stainless steel/ chemical resistant fiber<br>2. Standard bains circuit: 2 nos. with each unit<br>3. Humidifier — 1 no<br>4. Vaporizer Halothene — 01 No.<br>S. Vaporizer Desflurane — 01 No.<br>6. Vaporizer isoflurane — 01 No.<br>7. Vaporizer sevoflurane — 01 No.<br>8. Reservoir bag (2liters): 3 nos. with each machine<br>9. Connectors for bains circuit: 5 nos with each machine.<br>10. AMBU bag: 1 no. with each machine. Pressure regulated valve with 5 meter hose and connector (conversion kit) for oxygen should be provided with each machine. Should be supplied with driver gas hoses with necessary attachments (color coded). |
| **6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| 6.1 | Atmosphere/Ambience (air conditioning, humidity, dust …) | Should be capable to withstand operation in extreme and ambient temperature ( -10 deg C to 60 deg C). Capable to work in relative humidity up to 90% |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | To be specified by manufacturer |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND MAINTENANCE** | | |
| 8.1 | Pre- installation requirements: | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up. |
| 8.2 | Requirements for sign-off | Supplier to perform installation, safety and operation checks before handover. |
| 8.3 | Training of staff (medical, paramedical, technicians) | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | • 03 years<br>• Preventive Maintenance visits at least once in each quarter |
| **10. DOCUMENTATION** | | |

| | | |
|---|---|---|
| 10.1 | Operating manuals, set manuals, other manuals | Should provide 2 sets(hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should be supplied in English/Hindi/ Regional language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided.<br>3. Advanced maintenance tasks documentation;,<br>4. Satisfactory certificate for any existing installation from government hospital. |
| 10.2 | Other accompanying Documents | List of essential spares and accessories, with their part number and cost; |
| **11. NOTES** | | |
| 11.1 | Service Support Contact details | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | Recommendations or warnings | Any warning sign would be adequately displayed. |

| ANAESTHESIA WORKSTATION | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by:(name. Institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| UMDNS name | | |
| UMDNS code(s) | | |
| **GENERAL** | | |
| **1 USE** | | |
| 1.1 | Clinical purpose | Devices that continuously or intermittently administer a mixture of gases (e.g., oxygen, nitrous oxide, the vapor of a volatile liquid such as halogenated hydrocarbon), varying the proportion of gases in order to control an individual's level of consciousness. These devices are also designed to facilitate spontaneous, controlled, or assisted ventilation with these gas mixtures. An anesthesia unit is typically comprised of four basic subunits: a gas supply and control circuit, breathing and ventilation circuit, a scavenging system to help prevent the escape of exhaled gases, and a set of function and breathing circuit monitors (e.g., inspired oxygen concentration, breathing circuit integrity). |
| 1.2 | Used by clinical department/ward | Operation Theatre |
| **TECHNICAL** | | |
| **2 TECHNICAL SPECIFICATIONS** | | |

| | | |
|---|---|---|
| 2.1 | Technical characteristics (specific to this type of device) | Flow Management:<br>1. Should be compact, ergonomic and easy to use.<br>2. Machine should provide electronic gas mixing.<br>3. Multi color TFT display of at least 15"size, with virtual meters for O2, N2O or Air.<br>4. Dual flow sensing capability at inhalation and exhalation ports.<br>5. Should have backup 02 control which provides an independent fresh gas source and flow meter control in case of electronic failure.<br>6. Gas regulators (flow control valves) shall be of modular design/ graphic display.<br>7. All pipeline connections should have diameter-indexed safety systems (DISSs) or another means of preventing connection of dangerous gases.<br>8. System should permit connection of at least two yokes, one dedicated to 02 cylinder to meet clinical needs during failure of pipeline supply. All cylinder yokes (regardless of the gas for which they are intended) should include pin-index safety systems to prevent connection of dangerous gases.<br>i. Hypoxic guard to ensure minimum 25% 02 across all 02-N2O mixtures and Oxygen failure warning.<br>Breathing System:<br>1. Latex free fully autoclavable/ disposable with minimal flow of 250 ml of 02.<br>2. Sensor should not require daily maintenance.<br>3. Bag to vent switch shall be bi stable and automatically begins mechanical ventilation in the ventilator position.<br>4. Adjustable pressure limiting valve shall be flow and pressure compensated.<br>Vaporizers:<br>1. Provision to mount following selectable vaporizers such as Desflurane, halothane, isoflurane, sevoflurane with interlocking facility to allow use of only one vaporizer at a time.<br>2. All the vaporizers should be temperature, pressure and flow compensated vaporizers and maintenance free.<br>Ventilation:<br>1. The work station should have integrated anesthesia ventilator system.<br>2. It should have following Ventilation modes Manual/spontaneous, VCV, PCV, SIMV or pressure support, advanced modes.<br>3. Tidal volume: A control adjusts the volume of individual breaths within range of 20-1,500 cc. |

4. Minute volume: A control adjusts the total inspiratory volume- per-minute delivery from the bellows shall be >20 L/min.
5. The respiratory frequency can be set within range of 5-60 breaths per minute.
6. Inspiratory flow: The flow range of gas that the ventilator is capable of delivering to the patient shall be 0-180 L/min.
7. Pressure limit shall be adjustable and <70 preferred cm H2O. Unit should have PEEP of 0-20 cm H2O.
8. The workstation should be capable of delivery of low flow anesthesia.

**Anesthesia Monitoring Specifications:**

1. Monitoring of vital parameters: ECG, NIBP, SPO2, and Invasive Blood Pressure.
2. Twin temperature measurement with skin and core temperature

probes — Two sets with each monitor.

3. Automatic identification and measurement of anesthetic agents EtCO2, 02, and N2O and MAC value. FiO2 measurement.
3. Facility to store snapshots during critical events for waveform review at a later stage.
4. Audio visual and graded alarming system.

**Display of Ventilator:**

Mode of ventilation to be displayed, Respiratory rate, flow, pressure also to be displayed.

| | | |
|---|---|---|
| 2.2 | User's interface | Manual |
| 2.3 | Software and/ or standard of communication(where ever required | Inbuilt |
| **3 PHYSICAL CHARACTERICSTICS** | | |
| 3.1 | Dimensions(metric) | NA |
| 3.2 | Weight (lbs, kg) | NA |
| 3.3 | Noise (in dBA) | Noise pressure level: <60 dbA. |
| 3.4 | Heat dissipation | Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism. |
| 3.5 | Mobility, portability | Portable |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)** | | |
| 4.1 | Power | 220 +/- 10% VAC, 50 Hz |
| 4.2 | Battery operated | Yes, at least 30 minutes back up. |
| 4.3 | Protection | Stabilizer tobe provided for protection. |
| 4.4 | Power consumption | To be specified by service provider. |
| **5 ACCESSORIES, SPARE PARTS AND CONSUMABLES** | | |

| | | |
|---|---|---|
| 5.1 | Accessories,<br><br>standard, optional); Spare parts (main ones); Consumables/re-agents (open, closed system) | 1. Circle absorber — 01 No.<br>2. Vaporizer Halothene — 01 No.<br>3. Vaporizer Desflurane — 01 No.<br>4. Vaporizer isoflurane — 01 No.<br>5. Vaporizer sevoflurane — 01 No.<br>6. Adult and Pediatric autoclavable silicone breathing circuits —2 each.<br>7. Reusable IBP cable -04.<br>8. Humidifiers — 1 No<br>9. Disposable transducer — 100<br>10. Temperature Probe Skin reusable — 02.<br>12. Temperature core reusable -04 (02-Adults, 02-paediatrics)<br>13. Depth of anesthesia sensors — 50<br>14. Accessories for neuromuscular transmission monitor -01 set.<br>15. Standard accessories to make all parameters working -01 set.<br>16. Disposable adult and pediatric circuit — 50 each.<br>17. HME Filters — 1000 nos<br>18. Vital parameter accessories (ECG Leads — 5 sets, NIBP Cuffs all sizes) -01 set.<br>19. Spo2 probes both adult and pediatric 2 in no should be supplied with each machine.<br>20. EtCo2 sampling line and connector should be supplied 25 no each with apparatus. |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | Atmosphere/Ambience (air conditioning, humidity, dust . ..) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | To be specified by manufacturer. |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8 TRAINING AND INSTALLATION** | | |

| | | |
|---|---|---|
| 8.1 | Pre- installation requirements: nature, values, quality, tolerance | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | Requirements for sign-off | Supplier to perform safety and operation check before hand over. |
| 8.3 | Training of staff (medical, paramedical,technicians) | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | • 03 years<br>• Preventive Maintenance visits at least once in each quarter |
| **10 DOCUMENTATION** | | |
| 10.1 | Operating manuals, set manuals, other manuals | Should provide 2 sets(hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should be supplied in English/Hindi/ Regional language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided.<br>3. Advanced maintenance tasks documentation.<br>4. Satisfactory certificate for any existing installation from government hospital. |
| 10.2 | Other accompanying Documents | List of essential spares and accessories, with their part number 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. |
| 11.2 | Recommendations or Warnings | Any warning sign would be adequately displayed. |

| BUBBLE CONTINUOUS POSITIVE AIRWAY PRESSURE (BUBBLE CPAP) UNIT | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done By: | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN Name | | Neonatal CPAP Unit |
| GMDN Code | | 61197 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical Purpose | This device is designed to apply Continuous Positive Airway Pressure to non-intubated neonatal and infant patients. It is commonly used in spontaneously breathing patients who require short-term mechanical assistance. |
| 1.2 | Used by clinical department/ ward | NICU, PICU |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical Characteristics | A. **BCPAP machine should have the following components:**<br>1. CPAP generator<br>2. Servo humidifier including reusable chamber, temperature probe, heater wire with adaptor<br>3. Air-oxygen blender<br>4. Single equipment mounting stand with swivel brake casters (four)<br>5. Reusable circuits<br>6. Nasal interface including nasal prongs, and masks of different sizes<br>7. Head bonnet of different sizes<br><br>B. **CPAP generator**<br>1. Capable to deliver nasal/ nasopharyngeal CPAP and heated humidified high gas flow through nasal canulae/ mask (>2 LPM).<br>2. Circuits (reusable) should be compatible with different nasal interfaces<br>3. CPAP range: 1 – 10 cm of $H_2O$<br>4. Accuracy: ±1 cm of $H_2O$.<br>5. Gas flow range: 1 – 12 LPM.<br>6. Pressure release valve: safety valve mechanism to release excessive pressure.<br>7. Reservoir (Bubble chamber) capacity: >300 ml.<br>8. Generator tube: graduations in the tube should be clearly readable from a distance of 6 feet, and it should be snugly fitting into the chamber and the chamber should be transparent for checking water level. |

| | | |
|---|---|---|
| | | 9. Equipment mounting stand: should be supplied with a stand with clamps for mounting blender, bubble chamber and humidifier.<br><br>C. **Servo controlled humidifier**<br>1. Capable of working with both CPAP and Heated Humidified High Flow Nasal Cannula (HHHFNC)<br>2. Should be capable of supplying fully saturated gas at $37^0$C.<br>3. Flow resistance <20 cm $H_2O$/ L/ sec (Ins R <12, Exp R <8)<br>4. Temperature range: $31^0$C – $40^0$C<br>5. Temperature control: ± $2^0$C<br>6. Digital display of temperature: $5^0$C – 80°C<br>7. Range of working room temperature: $20^0$C – $30^0$C<br>8. Capable of ambient humidity compensation<br>9. Should be compatible with both reusable & disposable chambers and circuits.<br>10. Must have water level indicator in the chamber (both types).<br>11. Minimum warm up time: <30 min<br><br>D. **Air-oxygen blender**<br>1. Oxygen concentration range should be 21 – 100%.<br>2. Number of ports should be two (02).<br>3. Accuracy: ±3% full scale<br>4. Weight: should be less than 2 kilograms<br>5. Gas supply pressure: 30 – 75 PSIG<br>6. Primary outlet flow range: 1 – 15 L/ min<br>7. Auxiliary outlet flow range: 1 – 15 L/ min<br>8. External calibration should be done at least once in six months.<br>9. It should be supplied with air & oxygen hose at least 5 metres in length with suitable adaptors |
| 2.2 | User's Interface | User interface to be easy to operate, numbers and displays to be clearly visible.<br>1. Display easily readable in low ambient light and sunlight.<br>2. Pressure [$cmH_2O$].<br>3. $FiO_2$%.<br>4. Flow rate<br>5. Air leak %<br>6. Respiration rate<br>7. Temperature |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | Dimensions (in cm) | To be specified by manufacturer |
| 3.2 | Weight | To be specified by manufacturer |
| 3.3 | Noise | Noise level to be less than 35dbA at mid pressure range. Alarm: 65dbA |
| 3.4 | Alarm | Should have audio and visual alarm as per critical parameters as per 2.2 |

| | | |
|---|---|---|
| 3.5 | Mobility/Portability | Should be a lightweight portable, reliable and sturdy equipment with mechanical strength to withstand rough handling. |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)** | | |
| 4.1 | Power input | 220 +/- 10% VAC, 50 Hz |
| 4.2 | Power consumption | To be specified by manufacturer |
| 4.3 | Battery backup | At-least one hour battery backup. |
| **5. ACCESSORIES. SPARE PARTS AND CONSUMABLE** | | |
| 5.1 | Accessories, (mandatory, Standard, operational); Spare parts (main ones) Consumable/reagents (open, closed system) | 1. Equipment mounting stand (stainless steel) with clamps and hanger<br>2. Reusable patient circuit for all modes including Heated Humidified High Flow Nasal Cannula (HHHFNC).<br>3. Servo controlled humidifier with digital temperature display<br>4. Heater wire for servo humidifier for reusable circuits, Heater wire adaptor for servo humidifier<br>5. Temperature/ flow probe for servo humidifier<br>6. Reusable humidifier chamber<br>7. Nasal interface (disposable kit)<br>8. Nasal mask CPAP (small, medium, large)<br>9. Nasal prongs for CPAP (Hudson) – (Size '0', Size '1', Size '2', Size '3')<br>10. Infant bonnet (17 cm – 22 cm, 22 cm – 25 cm, 25 cm – 29 cm, 29 cm – 36 cm)<br>11. Oxygen analyzer compatible with Bubble CPAP machine<br>12. Air-oxygen blender<br>13. Hose for $O_2$ connection (for wall connection)<br>14. Hose for compressed air (for wall connection)<br>15. CPAP generator/ bubble chamber (Reusable vs. Disposable) |
| **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | | |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | Atmosphere /Ambiance (air conditioning, humidity, dust ...) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | To be specified by manufacturer |
| **7. STANDARDS & SAFETY** | | |
| 7.1 | Certificates (pre-market, sanitary); Performance and safety standards (specific to the device type); Local and/or international | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | Pre-installation requirements: nature, values, quality, tolerance | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |

| | | |
|---|---|---|
| 8.2 | Requirements for sign-off | Supplier to perform safety and operation check before hand over. |
| 8.3 | Training of staff (medical, paramedical, technicians) | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | • 03 years including all spare parts and accessories.<br>• Preventive Maintenance visits at least once in each quarter |
| **10. DOCUMENTATION** | | |
| 10.1 | Operating manuals, service manuals, other manuals | Supplier should provide 2 sets(hardcopy) of: -<br>1. User, technical, maintenance and service manuals to be supplied along with machine diagrams.<br>2. List of equipment and procedures required for local calibration and routine maintenance.<br>3. Certificate of calibration and inspection. |
| 10.2 | Other accompanying documents | NA |
| **11. NOTES** | | |
| 11.1 | Service Support Contact details (Hierarchy Wise; including a toll free/landline number) | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | Recommendations or warnings | Any warning signs should be adequately displayed. |

| BI-LEVEL POSITIVE AIRWAY PRESSURE (BiPAP) UNIT (ADULT/PEDIATRIC) | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done By: | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN Name | | Bi-Level Positive Airway Pressure Unit (BiPAP Unit) |
| GMDN Code | | 60712 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical Purpose | A BiPAP (bi-level positive airway pressure), device is a form of non-invasive ventilation (NIV) therapy used to facilitate breathing. This helps in providing positive pressure ventilation both in inspiration and expiration phase. The machine is connected with a tube to the face mask worn over nose & mouth by the patient.<br>BiPAP is helpful in a variety of clinical conditions that make breathing difficult, such as chronic obstructive pulmonary disorder (COPD, obstructive sleep apnoea, obesity hypoventilation syndrome (Pickwickian Syndrome), Amyotrophic Lateral Sclerosis (ALS), Muscular dystrophy. |
| 1.2 | Used by clinical department/ward | ICU, PICU, Emergency, HDU, General Ward |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical Characteristics | 1. Should have Real-time display – LCD display shows actual pressure, leakrate and patient breathing parameters such as breath rate, I/E ratio, minute volume and tidal volume, On board Filter Clean Reminder, etc<br>2. BIPAP (Bi-level Positive Airway Pressure) should be complete unit with allstandard accessories<br>3. The device should allow adjustment of transitions in and out of IPAP andEPAP<br>4. IPAP: approx. 3 to 25 cm H2O, EPAP: approx. 3 to 25 cm H2O<br>5. Breath rate: approx.0 to 30 BPM with spontaneous for time mode ormanual override<br>6. Timed inspiration: approx. 0.5 to 3.0s<br>7. Should have ramp function to lower the pressure at initial phase andslowly increase to allow pressure.<br>8. Should have automatic leakage compensation.<br>9. Should have customizable and the sensitivity of the trigger should beadjustable.<br>10. Should have operating mode of CPAP, Spontaneous, timed, PAC/PC (Pressure Assisted Control/Pressure Control). |

| | | |
|---|---|---|
| | | 11. Should provide with carry bag. |
| 2.2 | User's Interface | Display easily readable in low ambient light and sunlight:<br>a. Inspiratory and Expiratory pressure;<br>b. Inspiratory and Expiratory time;<br>c. FiO2%;<br>d. Mean Airway Pressure (MAP);<br>e. Air leak%. |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | Dimensions (in cm) | NA |
| 3.2 | Weight | Should be light weight. |
| 3.3 | Noise | Less than 35dbA at mid pressure range. Alarm: 65dbA |
| 3.4 | Heat Dissipation | Should not get heated when operated. |
| 3.5 | Mobility/Portability | Should be a lightweight portable, reliable and sturdy equipment with mechanical strength to withstand rough handling. |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ..... )** | | |
| 4.1 | Power input | 220 +/- 10% VAC, 50 Hz<br>Automatic switch from AC power electric-line mode to battery operatingmode and vice versa. |
| 4.2 | Power consumption | To be specified by manufacturer. |
| 4.3 | Battery backup | At-least one hour battery backup. |
| **5. ACCESSORIES. SPARE PARTS AND CONSUMABLE** | | |
| 5.1 | Accessories, (mandatory, Standard, operational);<br>Spare parts (main ones)<br>Consumable/reagents (open, closed system) | 1. Reusable nasal mask for adult and pediatric use with tubing; withstands highlevel disinfection and sterilization.<br>2. Humidifier accessory, if not integrated in-built.<br>3. Connectors for air and oxygen outlets.<br>4. Mains power cable to have length ≥2.<br>5. Inlet bacteria filter, if applicable and Expiratory filters high efficiency. |
| **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | | |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | Atmosphere /Ambiance (air conditioning, humidity, dust ...) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | To be specified by manufacturer |
| **7. STANDARDS & SAFETY** | | |
| 7.1 | Certificates (pre-market, sanitary);<br>Performance and safety standards | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. |

| | | |
|---|---|---|
| | (specific to the device type);Local and/or international | 4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | Pre-installation requirements: nature, values, quality, tolerance | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | Requirements for sign-off | Supplier to perform installation and safety and operations check for the device before handover. |
| 8.3 | Training of staff (medical, paramedical, technicians) | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | • 03 years<br>• Preventive Maintenance visits at least once in each quarter |
| **10. DOCUMENTATION** | | |
| 10.1 | Operating manuals, service manuals, other manuals | Supplier should provide 2 sets(hardcopy) of: -<br>1. User, technical, maintenance and service manuals to be supplied along withmachine diagrams.<br>2. List of equipment and procedures required for local calibration and routinemaintenance.<br>3. Certificate of calibration and inspection. |
| 10.2 | Other accompanying documents | NA |
| **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 beprovided. |
| 11.2 | Recommendations or warnings | Any warning signs would be adequately displayed. |

| DENTAL X-RAY | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by: (Name/Institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| UMDNS name | | Radiographic Units, Dental, Extra oral |
| UMDNS code(s) | | 18427 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical purpose | Dental radiographic units in which the dental film is placed inan external film cassette. These units are designed for imaging the maxillofacial region using a rotating x-ray beam (panoramic radiography), which produces a single image of the dental arch as a fixed elliptical shape; and/or to obtain images of the complete skull (cephalometric radiography) or of a region of interest from various angles. Some extra oral units can produce multilayered transverse images of the maxillary and mandibular jaws (cross- sectional tomography). |
| 1.2 | Used by clinical department/ward | Dental Department |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1. It should be digital.<br>2. Suitable for Adult and Pediatrics.<br>3. Minimum total filtration shall be 2.5 mm Al.<br>4. Heat capacity shall be ≥20,000 HU.<br>5. Focal spot size should be 0.6 mm.<br>6. Constant potential; high-frequency required.<br>7. Automatic Exposure Control (AEC) is required which is used to control the length of x-ray exposure. The exposure timer controls the length of the x-ray exposure; typical exposure times are 0.1 to 5 seconds for cephalometric radiography and 5 to 20 seconds for panoramic radiography. Patient selection Switches (Thin, Normal and Obese)<br>8. Feather touch keypad and length of exposure cable should be5 to 6 meters.<br>9. Ease of operation as all the functions can be selected from the remote control as well as timer.<br>10. An excellent output of 60 kV to 80 kV, 0 mAs to 15 mAs.<br>11. Exposure time shall be ≤ 15 sec<br>12. Audible and Visual indication of “X-Ray On” (Radiation indications).<br>13. Should provide compatible voltage stabilizer (Built in/External).<br>14. Source to Image Distance(SID) 400-500 mm<br>15. Magnification : 1.2-1.5x |

| | | |
|---|---|---|
| 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 | Noise (in dBA) | Noise-free system |
| 3.4 | Heat dissipation | Should maintain nominal temp and the heat should be disbursed through a cooling mechanism |
| 3.5 | Mobility, portability | Stationary Installation |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)** | | |
| 4.1 | Power requirements | 220 +/- 10% VAC, 50 Hz |
| 4.2 | Battery operated | No |
| 4.3 | Protection | High voltage protection for X-ray tube. |
| 4.4 | Power consumption | To be specified by vendor. |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system) | Machine should be provided with following items,<br>1. Two numbers of BARC approved whole body lead aprons with allattachments and thyroid color. |
| **BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS** | | |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| 6.1 | Atmosphere/Ambience(air conditioning, humidity, dust …) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterilityissues | To be specified by manufacturer |
| **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 CDSCO and AERB approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | Pre- installation requirements: (nature,values, quality) | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | Requirements for sign-off | Supplier to perform safety and operation check before hand over. |
| 8.3 | Training of staff (medical, paramedical, technicians) | Training of users on operation and basic maintenance. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| **10. DOCUMENTATION** | | |
| 10.1 | Operating manuals, set manuals, other manuals | Should provide 2 sets (hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided.<br>3. Advanced maintenance tasks documentation.<br>4. Satisfactory certificate for any existing installation from government hospital. |
| 10.2 | Other accompanying documents | List of essential spares and accessories, with their part number and cost. |
| **11. Notes** | | |
| 11.1 | Service Support Contactdetails (Hierarchy Wise; including a toll free/ landline number) | Contact details of manufacturer, supplier and local service agent tobe provided. |
| 11.2 | Recommendations orwarnings | Any warning sign would be adequately displayed. |

| ECG MACHINE – 12 CHANNEL | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name/institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Electrocardiographs, multichannel |
| GMDN code(s) | | |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | Continuously detect, measure and display a patients echocardiogram (ECG) through leads and sensors attached to the patient. |
| 1.2 | **Used by clinical department/ward** | Radiology Department |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.2 | **Technical characteristics (specific to this type of device)** | 1) Simultaneous 6 Channel ECG recording with 12 lead simultaneous acquisition.<br>2) Should have a digital display of 6 channel ECG and should have three modes (Automatic, Manual and rhythm).<br>3) Heart rate measurement range to be at least 30 bpm to 250 bpm, with accuracy better than ± 5bpm.<br>4) Heart rate trend display of at least previous 24 hours.<br>5) Arrhythmia detection facility required; minimum gradation of 1 bpm. |
| 2.3 | **User's interface** | Manual |

| | | |
|---|---|---|
| 2.4 | **Software and/or standard of communication** | Inbuilt |
| | **3. PHYSICAL CHARACTERISTICS** | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dBA)** | NA |
| 3.4 | **heat dissipation** | Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism. |
| 3.5 | **Mobility, portability** | Stationary |
| | **4. ENERGY SOURCE** | |
| 4.1 | **Power Requirements** | 220V ± 10%, 50 Hz |
| 4.2 | **Battery operated** | Battery powered, silence able alarm for power failure.<br>Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit.<br>Internal, replaceable, rechargeable battery allows operation for at least one hour in the event of power failure. |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | NA |
| | **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory, standard, optional)**<br>**Spare parts (main ones)**<br>**Consumables/re agents (open, closed system)** | 12 lead ECG cable.<br>2 sets of spare fuses (if non-resettable fuses are used)<br>5 tube electrode gel (if required) |
| | **BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS** | |
| | **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | |
| 6.1 | **Atmosphere/Ambianc e (air conditioning, humidity, dust...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer. |
| | **7. STANDARDS AND SAFETY** | |
| 7.1 | **Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type)** | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |

| | | |
|---|---|---|
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform installation, safety and operation checks before handover. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter |
| **10. DOCUMENTATION** | | |
| 10.1 | **Operating manuals, servicemanuals, other manuals** | Should provide 2 sets (hardcopy) of:-<br>1) User, technical, maintenance and service manuals to be supplied alongwith machine diagrams.<br>2) List of equipment and procedures required for local calibration androutine maintenance.<br>3) Certificate of calibration to be provided by the manufacture |
| 10.2 | **Other accompanying documents** | List of important spares and accessories, with their part numbers and cost |
| **11. NOTES** | | |
| 11.1 | **Service Support Contact details (Hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | **Recommendations or warnings** | Any warning signs would be adequately displayed. |

| ECG MACHINE – 3 CHANNEL | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name/institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Electrocardiographs, multichannel |
| GMDN code(s) | | 11411 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | Continuously detect, measure and display a patients echocardiogram (ECG) through leads and sensors attached to the patient. |
| 1.2 | **Used by clinical department/ ward** | All |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.2 | **Technical characteristics (specific to this type of device)** | 1) Simultaneous 3 Channel ECG recording with 12 lead simultaneous acquisition.<br>2) Should have a digital display of 3 channel ECG and should have three modes (Automatic, Manual and rhythm).<br>3) Heart rate measurement range to be at least 30 bpm to 250 bpm, with accuracy better than ± 5bpm.<br>4) Heart rate trend display of at least previous 24 hours.<br>5) Arrhythmia detection facility required; minimum gradation of 1 bpm. |
| 2.3 | **User's interface** | Manual |
| 2.4 | **Software and/or standard of communication** | Inbuilt |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dBA)** | < 60dB |
| 3.4 | **Heat dissipation** | Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism. |
| 3.5 | **Mobility, portability** | Portable. |
| **4. ENERGY SOURCE** | | |
| 4.1 | **Power Requirements** | 220V ± 10%, 50 Hz |
| 4.2 | **Battery operated** | Battery powered, silence able alarm for power failure.<br>Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit.<br>Internal, replaceable, rechargeable battery allows operation for at least one hour in the event of power failure. |

| | | |
|---|---|---|
| | | |
| 4.4 | **Power consumption** | To be specified by manufacturer |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | **Accessories (mandatory, standard, optional)**<br>**Spare parts (main ones)**<br>**Consumables/reagents (open, closed system)** | 3 lead ECG cable.<br>100 sets of ECG connection electrodes (if disposable type).<br>5 sets of ECG connection electrodes (if reusable type). |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | **Atmosphere/Ambiance (air conditioning, humidity, dust...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer |
| **7. STANDARDS AND SAFETY** | | |
| 7.1 | **Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type)** | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up. |
| 8.2 | **Requirements for sign-off** | Supplier to perform installation, safety and operation checks before handover. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| **10. DOCUMENTATION** | | |
| 10.1 | **Operating manuals, service manuals, other manuals** | Should provide 2 sets (hardcopy) of: -<br>1) User, technical, maintenance and service manuals should be supplied in English/Hindi/Regional 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) Satisfactory certificate for any existing installation from government hospital |
| 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 (Hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | **Recommendations or warnings** | Any warning signs would be adequately displayed. |

| CPAP | | |
|---|---|---|
| Version no.: | | 02 |
| Date: | | August 2023 |
| Done by: (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | |
| GMDN code(s) | | |
| **GENERAL** | | |
| **1. Use** | | |
| 1.1 | **Clinical purpose** | It is used to deliver air or a mixture of air and oxygen (O2) at high flow rates through tubing to a nasal or oral-nasal mask which is affixed to the patient's face. CPAP units are commonly used to treat patients with obstructive sleep apnea (OSA) or sleep apnea/hypopnea syndrome (SAHS). |
| 1.2 | **Used by clinical department/ ward** | NICU & PICU |
| **TECHNICAL** | | |
| **2. Technical characteristics** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1) Device should be able to deliver CPAP of 1 to 10 cmH2O increments of 1cm, using an underwater bubble system.<br>2) The device should have an in-built air oxygen blender to deliver FiO2 21% to 100% (+/- 2 %) with an adjustable flow in the range of 0 -15 L/min (+/-0.5 L/min).<br>3) Should have a heated wire servo-controlled humidifier with display temperature near patient end of the circuit; to be supplied with 2 reusable infant water chamber.<br>4) Should be supplied with 2 reusable heated wire silicone tubing circuit for infant/Newborn.<br>5) Should be able to deliver CPAP using available patient interfaces nasal prongs/nasopharyngeal prongs.<br>6) For devices based on underwater bubble systems the water chamber should be reusable; to be supplied with 2 reusable water chamber.<br>7) Should be provided pressure release valve at 15cmH2O to 17cm H2O. |
| 2.2 | **User's interface** | 1. For a flow driving system a pressure display is required<br>2. Audio visual alarm for low pressure, high pressure, power failure and low O2. |

| | | |
|---|---|---|
| 2.3 | **Software and/or standard of communication (wherever required)** | NA |
| **3. Physical Characteristics** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dba)** | Noiseless |
| 3.4 | **Heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Portable |
| **4. Energy source (electricity, Ups, solar, gas, water, co2 )** | | |
| 4.1 | **Power requirements** | 220 V AC +/- 10%, 50 Hz |
| 4.2 | **Battery operated** | Minimum 6 hours battery back up |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | As specified by manufacturer |
| **5. Accessories, spare parts, consumables** | | |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)** | 1) Each device should be provided with 30 nasal prongs (At least three sizes suitable for neonates weighing <1000grms, 1000-1500grms & >1500grms)<br>2) Air and O2 hose of 3m length each along with the appropriate socket |
| **6. Environmental and departmental considerations** | | |
| 6.1 | **Atmosphere / ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, cleaning, Disinfection & sterility issues** | To be specified by manufacturer |
| **7. Standards and Safety** | | |
| 7.1 | **Certificates (pre-market, sanitary, ..); performance and safety standards (specific to the device type); local and/or international** | • Should be BIS and CDSCO approved.<br>• Should conform USFDA/ European CE, in case of non-availability of BIS Standards.<br>• Should conform to ISO 13485 quality standards.<br>• Should conform to IEC 60601-1-General requirements of Electrical Safety Standards |
| **8. Training and Installation** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over |
| 8.3 | **Training of staff (medical, paramedical,** | Training of users in operation and basic maintenance shall be provided. |

| | | |
|---|---|---|
| | **technicians)** | |
| **9. Warranty and Maintenance** | | |
| 9.1 | **Warranty** | 03 years including all spares.<br>Preventive maintenance visits at least once in each quarter. |
| **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 should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided.<br>3. Satisfactory certificate for any existing installation from government hospital |
| 10.2 | **Other accompanying documents** | NA |
| **11. Notes** | | |
| 11.1 | **Service support contact details (hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| **11.2** | **Recommendations or warnings** | Any warning sign should be adequately displayed. |

| AMBU BAG | | |
|---|---|---|
| Version No: | | 02 |
| Date: | | August 2023 |
| Done by: (Name/Institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | NA |
| GMDN code | | NA |
| **GENERAL** | | |
| 1. USE | | |
| 1.1 | Clinical purpose | An Ambu bag, is a handheld tool used to provide ventilation (positive pressure) who is not breathing or who is breathing inadequately. It consists of a self-inflating bag, one-way valve, mask, and an oxygen reservoir. |
| 1.2 | Used by clinical department/Ward | Emergency department, Operation Theatre, Ambulance, Resuscitation kit. |
| **TECHNICAL** | | |
| 2. TECHNICAL CHARACTERISTICS | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1. Bag should be made up of silicone, latex free, double layered rubber and should retain sensitivity, resistant to rough use.<br>2. Inlet end of the bag should have separate port for oxygen supplement.<br>3. Outer port should be such that re-breathing valve or non-return valve can be attached.<br>4. Should be supplied with oxygen reservoir bag and should deliver tidal volume of 250/500/750 & 1000 ml.<br>5. Should be autoclavable.<br>6. Should be provided with a carry case. |
| 2.2 | User's interface | Manual |
| 2.3 | Software and/or standard of communication (wherever required) | NA |
| 3. PHYSICAL CHARACTERISTICS | | |
| 3.1 | Dimensions (metric) | NA |
| 3.2 | Weight (lbs, kg) | NA |
| 3.3 | Noise (in dBA) | NA |
| 3.4 | Heat dissipation | NA |
| 3.5 | Mobility, portability | NA |
| 4. ENERGY SOURCE | | |
| 4.1 | Power Requirements | NA |

| | | |
|---|---|---|
| 4.2 | Battery operated | NA |
| 4.3 | Protection | NA |
| 4.4 | Power consumption | NA |
| | 5. ACCESSORIES, SPARE PARTS, CONSUMABLES | |
| 5.1 | Accessories (mandatory, standard and optional); spare parts (main ones) and Consumables/ Reagents (Open/Closed System) | NA |
| | 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS | |
| 6.1 | Atmosphere/Ambiance (air conditioning, humidity, dust...) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | Autoclavable face mask |
| | 7. STANDARDS AND SAFETY | |
| 7.1 | Certifications (Pre-Market, Sanitary,), Performance and Safety Standards (Specific to the device type); Local and/or international | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards |
| | 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 | 03 Years |
| | 10. DOCUMENTATION | |
| 10.1 | Operating manuals, service manuals, other manuals | Should provide 2 sets (hard copy and soft copy) of:<br>• User, technical and maintenance manuals should be supplied in English/Hindi/ Regional language along with machine diagrams. |
| 10.2 | Other accompanying documents | NA |
| | 11. NOTES | |

| | | |
|---|---|---|
| 11.1 | Service Support Contact details (Hierarchy Wise; including a toll free/landline number) | Contact details of manufacturer and supplier should be provided. |
| 11.2 | Recommendations or warnings | NA |

| WEIGHING SCALE | | |
|---|---|---|
| Version no.: | | 02 |
| Date: | | August 2023 |
| Done by: (name / institution) | | HCT/ NHSRC |
| NAME AND CODING | | |
| GMDN name | | |
| GMDN code(s) | | |
| GENERAL | | |
| 1. USE | | |
| 1.1 | Clinical purpose | Weighing scale is used to measure body mass. |
| 1.2 | Used by clinical department/ ward | OPD |
| TECHNICAL | | |
| 2. TECHNICAL CHARACTERISTICS | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1. Should be made of sturdy mechanical structure to support/withstand heavy workload in public health centre.<br>2. Platform size 350 x 350 mm (Tolerance +/- 10%)<br>3. Measuring capacity should be at least 150 kg with accuracy up to 100 gms.<br>4. The display should be LCD/LED with four digits. The size of display should be minimum height 24 mm for clear visibility.<br>5. The scale should operate on electricity as well as on inbuilt re-chargeable batteries.<br>6. The reading should get locked automatically at stable weight and there should be an indication for the same.<br>7. The scale should have readings in SI system (Kgs and Gms).<br>8. The scale should have auto off feature when not in use.<br>9. It should be able to record weight in less than 05 seconds.<br>10. Built in rechargeable battery. |
| 2.2 | User's interface | LCD/ LED display. |
| 2.3 | Software and/or standard of communication (wherever required) | NA |
| 3. PHYSICAL CHARACTERISTICS | | |
| 3.1 | Dimensions (metric) | NA |
| 3.2 | Weight (lbs, kg) | NA |
| 3.3 | Configuration | N.A. |
| 3.4 | Noise (in dBA) | N.A. |
| 3.5 | Heat dissipation | NA |
| 3.6 | Mobility, portability | Portable |

| | | |
|---|---|---|
| 4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO2 ) | | |
| 4.1 | Power Requirements | 220 V AC +/- 10%, 50 Hz |
| 4.2 | Battery operated | Rechargeable battery |
| 4.3 | Protection | NA |
| 4.4 | Power consumption | NA |
| 4.5 | Other energy supplies | NA |
| 5. ACCESSORIES, SPARE PARTS, CONSUMABLES | | |
| 5.1 | Accessories (mandatory, standard, optional), Spare parts (main ones), Consumables / reagents (open, closed system) | NA |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | Atmosphere / Ambiance (air conditioning, humidity, dust ...) | NA |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | Easy to clean |
| 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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| 8. TRAINING AND INSTALLATION | | |
| 8.1 | Pre-installation requirements: nature, values, quality, tolerance | NA |
| 8.2 | Requirements for sign-off | NA |
| 8.3 | Training of staff (medical, paramedical, technicians) | NA |
| 9. WARRANTY AND MAINTENANCE | | |
| 9.1 | Warranty | • 03 years<br>• Preventive Maintenance visits at least once in each quarter |
| 10. DOCUMENTATION | | |
| 10.1 | Operating manuals, service manuals, other manuals | NA |
| 10.2 | Other accompanying documents | NA |
| 11. NOTES | | |

| | | |
|---|---|---|
| 11.1 | Service Support Contact details (Hierchy Wise; including a toll free/landline number) | Contact details of the manufacturer should be provided. |
| 11.2 | Recommendations or warnings | Any warning sign should be displayed adequately. |

| DIGITAL WEIGHING SCALE FOR ORGANS | | |
|---|---|---|
| Version no.: | | 02 |
| Date: | | August 2023 |
| Done by: (name / institution) | | HCT/ NHSRC |
| NAME AND CODING | | |
| GMDN name | | |
| GMDN code(s) | | |
| GENERAL | | |
| 1. USE | | |
| 1.1 | Clinical purpose | To measure weight of organs during Autopsy |
| 1.2 | Used by clinical department/ ward | Post-Mortem Department |
| TECHNICAL | | |
| 2. TECHNICAL CHARACTERISTICS | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1. Should be made up of stainless steel 304 grade.<br>2. Should have a platform of 350 mm x 350 mm approx (14" x 14"), easy to clean and anti-staining.<br>3. Should be able to measure weight upto 15 kg with accuracy of about 2 gm.<br>4. Should have a digital display<br>5. Should have rechargeable battery back-up pack provided for usage in power failure |
| 2.2 | User's interface | LCD/ LED display. |
| 2.3 | Software and/or standard of communication (wherever required) | NA |
| 3. PHYSICAL CHARACTERISTICS | | |
| 3.1 | Dimensions (metric) | NA |
| 3.2 | Weight (lbs, kg) | NA |
| 3.3 | Configuration | N.A. |
| 3.4 | Noise (in dBA) | N.A. |
| 3.5 | Heat dissipation | NA |
| 3.6 | Mobility, portability | Portable |
| 4. ENERGY SOURCE (Electricity, UPS, Solar, Gas, Water, CO2 ) | | |
| 4.1 | Power Requirements | 220 V AC +/- 10%, 50 Hz |
| 4.2 | Battery operated | Rechargeable battery |
| 4.3 | Protection | NA |
| 4.4 | Power consumption | NA |
| 4.5 | Other energy supplies | NA |
| 5. ACCESSORIES, SPARE PARTS, CONSUMABLES | | |
| 5.1 | Accessories (mandatory, standard, optional), Spare parts (main ones), Consumables / | NA |

| | | |
|---|---|---|
| | reagents (open, closed system) | |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | Atmosphere / Ambiance (air conditioning, humidity, dust ...) | NA |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | Easy to clean |
| 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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| 8. TRAINING AND INSTALLATION | | |
| 8.1 | Pre-installation requirements: nature, values, quality, tolerance | NA |
| 8.2 | Requirements for sign-off | NA |
| 8.3 | Training of staff (medical, paramedical, technicians) | NA |
| 9. WARRANTY AND MAINTENANCE | | |
| 9.1 | Warranty | • 03 years<br>• Preventive Maintenance visits at least once in each quarter |
| 10. DOCUMENTATION | | |
| 10.1 | Operating manuals, service manuals, other manuals | NA |
| 10.2 | Other accompanying documents | NA |
| 11. NOTES | | |
| 11.1 | Service Support Contact details (Hierchy Wise; including a toll free/landline number) | Contact details of the manufacturer should be provided. |
| 11.2 | Recommendations or warnings | Any warning sign should be displayed adequately. |

| INFANTOMETER | | |
|---|---|---|
| Version no. : | | 01 |
| Date: | | August 2023 |
| Done by : (name. Institution) | | HCT/NHSRC |
| NAME AND CODING | | |
| GMDN name | | NA |
| GMDN code(s) | | NA |
| GENERAL | | |
| 1. USE | | |
| 1.1 | Clinical purpose | An Infantometer is used to measure an infant's length from heel to head |
| 1.2 | Used by clinical department/ward | Neonatal Intensive Care Unit (NICU) |
| TECHNICAL | | |
| 2. TECHNICAL CHARACTERISTICS | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1. The Infantometer should be compact and light weight.<br>2. It should have graduation in both mm and cm.<br>3. It should be made of good-quality, skin friendly, durable material.<br>4. Should be foldable for easy carrying and space saving.<br>5. Should have integrated head positioner and easy to move leg positioner.<br>6. Should have smooth, rounded surfaces to prevent bumps and jolts during measuring and make cleaning easy.<br>7. Measuring Range should be upto 100 cm or more. |
| 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) | In accordance with measuring range mentioned in technical characteristics. |
| 3.2 | Weight (lbs, kg) | Light weight |
| 3.3 | Noise (in dBA) | NA |
| 3.4 | Heat dissipation | NA |
| 3.5 | Mobility, portability | Portable |
| 4. ENERGY SOURCE | | |
| 4.1 | Power requirements | NA |
| 4.2 | Battery operated | NA |

| | | |
|---|---|---|
| 4.3 | Protection | NA |
| 4.4 | Power consumption | NA |
| 5. ACCESSORIES, SPARE PARTS, CONSUMABLES | | |
| 5.1 | Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system) | NA |
| 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS | | |
| 6.1 | Atmosphere/Ambience (air conditioning, humidity, dust …) | Durable resistant to effects of excess humidity and high temperature. |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | Should be easily disinfected by using normal hospital grade cleaning solution. |
| 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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE Standards in case of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards. |
| 8. TRAINING AND INSTALLATION | | |
| 8.1 | Pre- installation requirements: nature, values, quality, tolerance | NA |
| 8.2 | Requirements for sign-off | NA |
| 8.3 | Training of staff (medical, paramedical, technicians) | NA |
| 9. WARRANTY AND MAINTENANCE | | |
| 9.1 | Warranty | 03 Years |
| 10. DOCUMENTATION | | |
| 10.1 | Operating manuals, set manuals, other manuals | Should provide 2 sets (hard copy and soft copy) of:<br><br>User manuals should be supplied in English/Hindi language along with machine diagrams. |
| 10.2 | Other accompanying documents | NA |
| 11. Notes | | |
| 11.1 | Service Support Contact details (Hierarchy Wise; including a toll free/landline number) | Contact details of manufacturer and supplier to be provided. |
| 11.2 | Recommendations or | NA |

| | | |
|---|---|---|
| | warnings | |

| OXYGEN HOOD NEONATAL | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | |
| GMDN code(s) | | |
| GENERAL | | |
| 1. USE | | |
| 1.1 | Clinical purpose | To provide an enriched environment of oxygen (O2) to increase the patient's O2 uptake. |
| 1.2 | Used by clinical department/ ward | SNCU/NICU |
| TECHNICAL | | |
| 2. TECHNICAL CHARACTERISTICS | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1. Transparent polycarbonate unbreakable single molded.<br>2. Silicon rubber neck port adjustment enabled to minimize the wastage of oxygen.<br>3. Silicon rubber neck port adjustment to ensure use in Neonate/Infant/ Pediatric patients.<br>4. Oxygen inlet Port.<br>5. Diameter of the hood should be minimum 20cms |
| 2.3 | Settings | N.A. |
| 2.4 | User's interface | N.A. |
| 2.5 | Software and/or standard of communication (where ever required) | N.A. |
| 3. PHYSICAL CHARACTERISTICS | | |
| 3.1 | Dimensions (metric) | Appropriate to comfortably fit all size babies up to 5 years of age. |
| 3.2 | Weight (lbs, kg) | Light weight |
| 3.3 | Configuration | NA |
| 3.4 | Noise (in dBA) | N.A. |
| 3.5 | heat dissipation | NA |
| 3.6 | Mobility, portability | Portable |
| 4. ENERGY SOURCE | | |
| 4.1 | Power Requirements | N.A. |
| 4.2 | Battery operated | N.A. |
| 4.3 | Protection | N.A. |
| 4.4 | Power consumption | N.A. |
| 4.5 | Other energy supplies | N.A. |

| | | |
|---|---|---|
| 5. ACCESSORIES, SPARE PARTS, CONSUMABLES | | |
| 5.1 | Accessories (mandatory, standard, optional), Spare parts (main ones), Consumables / reagents (open, closed system) | NA |
| 6**. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | Atmosphere / Ambiance (air conditioning, humidity, dust ...) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | To be specified by manufacturer |
| 7. STANDARDS AND SAFETY | | |
| 7.1 | Certificates (pre-market, sanitary, ...) | 1.Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards. |
| 7.2 | Performance and safety standards (specific to the device type) | NA |
| 8. TRAINING AND INSTALLATION | | |
| 8.1 | Pre-installation requirements: nature, values, quality, tolerance | NA |
| 8.2 | Requirements for sign-off | Confirmation in no crack, no leak in hood structure |
| 8.3 | Training of staff (medical, paramedical, technicians) | NA |
| 9. WARRANTY AND MAINTENANCE | | |
| 9.1 | Warranty | 03 years |
| 10. DOCUMENTATION | | |
| 10.1 | Operating manuals, service manuals, other manuals | User and technical manuals to be supplied in English/Hindi language. |
| 10.2 | Other accompanying documents | NA |
| 11. NOTES | | |
| 11.1 | Service Support Contact details (Hierchy Wise; including a toll | Contact details of manufacturer and supplier should be provided. |

| | | |
|---|---|---|
| | free/landline number) | |
| 11.2 | Recommendations or warnings | NA |

| CTG Machine | |
|---|---|
| Version no.: | 01 |
| Date: | August 2023 |
| Done by: (name / institution) | HCT/ NHSRC |
| **NAME AND CODING** | |
| GMDN name | |
| GMDN code(s) | |
| **GENERAL** | |
| **1. Use** | |
| 1.1 **Clinical purpose** | For recording and analysing the Fetal Heart Rate (FHR) and contractions of uterus during antepartum and intrapartum period. |
| 1.2 **Used by clinical department/ ward** | Obs & Gynaecology OPD & OT, LDR Complex |
| **TECHNICAL** | |
| **2. Technical characteristics** | |
| 2.1 **Technical characteristics (specific to this type of device)** | 1. LCD Screen for Foetal Heart Rate, Uterine Contractions & Foetal Movement.<br>2. LCD Screen should be tiltable, rotatable and can be fixed at any angle from 0-90 degree<br>3. It should have display modes of Trend mode, Number mode & Graph Mode.<br>4. It should have alarm functions in all movement with facility to adjust alarm sounds.<br>5. It should have Automatic track & hold facility.<br>6. The probe should be highly sensitive to pick up FHR and waterproof within the range of 2 to 5 MHz frequency.<br>8. It should have Foetal Heart Rate & Uterine Pressure recording system.<br>9. It should have automatic & manual foetal movement detection.<br>10. It should have inbuilt thermal recorder.<br>11. It should have Twin Foetal Monitoring system (Capability to pick up the FHR of the twins separately). |

| | | |
|---|---|---|
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/or standard of communication (wherever required)** | In-built |
| | **3. Physical characteristics** | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dba)** | N.A. |
| 3.4 | **Heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Portable |
| | **4. Energy source (electricity, Ups, solar, gas, water, co2 )** | |
| 4.1 | **Power requirements** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | Battery with minimum 1 hr backup. |
| 4.3 | **Protection** | NA |
| 4.5 | **Power consumption** | As specified by manufacturer |
| | **5. Accessories, spare parts, consumables** | |
| 5.1 | **Accessories (mandatory, standard, optional) Spare parts (main ones) Consumables / reagents (open, closed system)** | • US probe/FHR probe - 2 nos.<br>• Toco Probe - 1 no.<br>• Print paper - 10 rolls<br>• Power adapter & Cord - 1 no.<br>• Ultrasound Gel - 4 no.<br>• Probe Belt - 3 sets |
| | **6. Environmental and departmental considerations** | |
| 6.1 | **Atmosphere / ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, cleaning, Disinfection & sterility issues** | To be specified by manufacturer. |
| | **7. Standards and safety** | |
| 7.1 | **Certificates (pre-market, sanitary, ..); performance and safety standards (specific to the device type); local and/or** | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |

| | | |
|---|---|---|
| | **international** | |
| **8. Training and installation** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. Warranty and maintenance** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| **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 should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided.<br>3. Satisfactory certificate for any existing installation from government hospital |
| 10.2 | **Other accompanying documents** | List of essential spares and accessories, with their part number and cost. |
| **11. Notes** | | |
| 11.1 | **Service support contact details (hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | **Recommendations and Warnings** | Any warning sign should be adequately displayed. |

| Color Doppler Ultrasound | | |
|---|---|---|
| Version | | 02 |
| Date: | | August 2023 |
| Done by : (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | |
| GMDN code(s) | | |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | Doppler ultrasound uses sound waves to detect the movement of blood in vessels. It is used in pregnancy to study blood circulation in the baby, uterus and placenta. |
| 1.2 | **Used by clinical department/ward** | Radiology laboratories |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | The system should be with full Digital Technology & should be capable of whole-body sonography & other application for adult & paediatrics (Infants & Neonates) which includes abdominal, Obs/Gyn, Endovascular, Peripheral vascular, transcranial, transvaginal, transrectal & small parts.<br>1) The system should incorporate facility for high resolution 2D, 3D, M mode, PW color imaging, Power Doppler Angio Imaging Modes.<br>2) The system should have more than 20000 Digital Channels & on the site to higher number of channels (preferable).<br>3) The system should have 256 Grey shade or more.<br>4) The system should have capability of triplex display in real time with all probes.<br>5) The system should have a very high frame rate of 700 frames per second or more.<br>6) The system should have Harmonic imaging for hard to image patients. The system shall support Tissue Harmonic Imaging capability on phased, linear, 3D and curved array transducers.<br>7) The system should have advance image processing algorithms to analyze between targets & artifacts so as to sharpen target anatomy, reduce the sparkle & artifacts to improve image quality.<br>8) The system shall offer Harmonic Imaging in Power Doppler Imaging mode for improved sensitivity and specificity in differentiating blood/ agent from tissue.<br>9) The system should have facility for Zoom(Real-time and Frozen-image) & manipulation of image through pre-processing and post-processing with cine loop viewing image of all modes.<br>10) System should have disc of atleast 500 GB or more.<br>11) The system should have facility of digital storage & retrieval of |

| | | |
|---|---|---|
| | | B/W & color image data(Both frozen & cine loops) on built in as well as ramble media(CD, DVD)USB port.<br>12) The system should have automatic real time quantification of Doppler parameter like velocity, frequency, time heart rate stop, flow volume, plasticity index, resistivity index, peak velocity, average value, point value, area & diameter flow volume etc.<br>13) The system should have high dynamic range of 170 dB with scanning depth of 30 cm or more.<br>14)All transducers(minimum 3) should be broad bandwidth, Frequency range 2 to 12 MHz or more with universal ports for transducer interchange. Two active ports and one parking probe is required.<br>15) System should have 19" HD display with tilt and swivel Facility along with alphanumeric keyboard with illuminating keys and status function.<br>16) Dicom 3.0 compatible.<br>17)Review of stored images is desirable |
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/or standard of communication(whe rever required)** | In-built |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dBA),** | Noise Free system |
| 3.4 | **Heat dissipation** | Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism. |
| 3.5 | **Mobility, portability** | Room Installation |
| **4. ENERGY SOURCE** | | |
| 4.1 | **Power Requirements** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | No |
| 4.3 | **Protection** | NA |
| 4.4 | **Power Consumption** | To be specified by manufacturer |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | **Accessories (mandatory, standard, optional);**<br>**Spare parts (main ones);**<br>**Consumables / reagents (open, closed system)** | Machine should be supplied with following:<br>I. Broad band convex array transducer with multi-frequency range of 2 to 5 MHz or wider range-1 No.<br>II. Broad band transvaginal/transrectal probe with multi-frequency range between 5 to 8 MHz or wider range-1 No.<br>III. Linear probe Transducer 5 to 12 MHz or more.<br>The system should have following devices:<br>a) Laser color printer for color image printing |

| | | |
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| | | b) B/W Thermal printer of latest model<br>c) Glazed thermal paper rolls 50 no. & 5 rim of Glossy paper sheet.<br>d) Online Ups for power back up of minimum 30 minutes<br>e) 50 nos. of CDs to be supplied |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer. |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up. |
| 8.2 | **Requirements for sign-off** | Supplier to perform installation, safety and operation checks before handover. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users on operation and basic maintenance should be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| **10. Documentation** | | |
| **10.1** | **Operating manuals, set manuals, other manuals** | Should provide 2 sets (hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided.<br>3. Advanced maintenance tasks documentation.<br>4. Satisfactory certificate for any existing installation from government hospital. |
| **10.2** | **Other accompanying documents** | List of essential spares and accessories, with their part number 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. |
| **11.2** | **Recommendations or warnings** | Any warning sign should be adequately displayed. |

| SURGICAL DIATHERMY (ELECTROSURGICAL UNIT) | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by: (name. Institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| UMDNS name | | Electrosurgical Unit |
| UMDNS code(s) | | 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.<br>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 | OT |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERICSTICS** | | |
| 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) Auto monitoring 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 | Inbuilt |
| **3. PHYSICAL CHARACTERICSTICS** | | |
| 3.1 | Dimensions(metric) | NA |

| | | |
|---|---|---|
| 3.2 | Weight (lbs, kg) | NA |
| 3.3 | Noise (in dBA) | Noise pressure level: <60 dbA. |
| 3.4 | Heat dissipation | NA |
| 3.5 | Mobility, portability | Portable |
| **4. ENERGY SOURCE** | | |
| 4.1 | Power | 220 +/- 10% VAC, 50 Hz |
| 4.2 | Battery operated | NA |
| 4.3 | Protection | NA |
| 4.4 | Power consumption | To be specified by Manufacturer |
| **5. ACCESSORIES, SPARE PARTS AND CONSUMABLES** | | |
| 5.1 | Accessories, standard, optional); Spare parts (main ones); Consumables/re- agents (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 |
| **6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| 6.1 | Atmosphere/Ambience (air conditioning, humidity, dust …) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | To be specified by manufacturer |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. TRAINING AND MAINTENANCE** | | |
| 8.1 | Pre- installation requirements: | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | Requirements for sign-off | Supplier to perform installation, safety and operation checks before handover. |

| | | |
|---|---|---|
| 8.3 | Training of staff(medical, paramedical, technicians) | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | • 03 years<br>• Preventive Maintenance visits at least once in each quarter |
| **10. DOCUMENTATION** | | |
| 10.1 | Operating manuals, set manuals, other manuals | Should provide 2 sets(hard copy and soft copy) of:<br>1) User, technical and maintenance manuals should be supplied in English/Hindi/ Regional language along with machine diagrams.<br>2) Advanced maintenance tasks documentation;<br>3) Satisfactory certificate for any existing installation from government hospital. |
| 10.2 | Other accompanying documents | List of essential spares and accessories, with their part number and cost; |
| **11. NOTES** | | |
| 11.1 | Service Support Contact details | Contact details of manufacturer, supplier and local service agent to be provided; |
| 11.2 | Recommendations or warnings | Any warning sign would be adequately displayed. |

| OXYGEN CYLINDER "D" TYPE | | |
|---|---|---|
| Version no.: | | 02 |
| Date: | | August 2023 |
| Done by : (name/institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Medical gas cylinders |
| GMDN code(s) | | CT 659 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | A container designed as a refillable cylinder used to hold compressed medical oxygen (O2) under safe conditions at high pressure; O2 is used as an essential life support gas, for anesthesia, and for therapeutic purposes. |
| 1.2 | **Clinical department/ward** | All Departments |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics** | 1. The high pressure seamless steel cylinder should conform to the standard IS 7285 (Part II) 2004<br>2. Casing should be made up of high-pressure resistant SS approved by PESO as per Gas Cylinder Rules 2016.<br>3. The water capacity should be 47L. The hydrostatic test pressure should be 250 bar.<br>4. Maximum working pressure is 150 bars.<br>5. Outer casing diameter should be approximately 232 mm. Minimum wall thickness should be 5.2 mm.<br>6. TARE weight should be approximately 50 Kg. The length of the cylinder should be approximately 1370 mm.<br>7. The cylinder should have a neck ring, bull nose valve and PESO filling permission.<br>3. A pressure regulator/flow meter capable of reducing the pressure to an appropriate level to run either a ventilator or provide oxygen therapy.<br>4. Should be seamless. |
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/or standard of communication** | NA |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dBA)** | NA |
| 3.4 | **heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Trolley for mobility |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 )** | | |

| | | |
|---|---|---|
| 4.1 | **Power Requirements** | NA |
| 4.2 | **Battery operated** | NA |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | NA |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | **Accessories (mandatory, standard, optional) Spare parts (main ones) Consumables/reagents (open, closed system)** | Humidifier, key and flow meter |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| 6.1 | **Atmosphere/Ambiance (air conditioning, humidity, dust ...)** | Capable of being operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90%. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | NA |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Cylinder should have explosive safety certificate and should be provided along with each cylinder during installation |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | NA |
| 8.2 | **Requirements for sign-off** | Certificate of Calibration, PESO certificate and inspection from the factory. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | 10 years warranty |
| **10. DOCUMENTATION** | | |
| 10.1 | **Manuals** | NA |
| 10.2 | **Other accompanying documents** | NA |
| **11. NOTES** | | |

| | | |
|---|---|---|
| 11.1 | **Other information** | NA |
| 11.2 | **Recommendations or Warnings** | Color Codes to be displayed on the cylinders. |

| Mechanical Ventilator (ICU) | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done by: (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | |
| GMDN code(s) | | |
| **GENERAL** | | |
| **1. Use** | | |
| 1.1 | **Clinical purpose** | Mechanical ventilators are life support devices that move gas (e.g., air and/or oxygen) to and from a patient's lungs. These devices may provide temporary or permanent respiration for patients who cannot breathe on their own, or who require assistance maintaining adequate ventilation. It can be used in two modes Invasive (Tube Inside trachea) and Non invasive (through face mask/nasal tube) ventilation. |
| 1.2 | **Used by clinical department/ ward** | ICU |
| **TECHNICAL** | | |
| **2. Technical characteristics** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1. Should have facility for Invasive and Non-Invasive ventilation.<br>2. Microprocessor Control suitable for Pediatric and adult ventilation.<br>3. Electromagnetic Compatible Hinged arm holder for holding the circuit.<br>4. Should have built in touch colour screen TFT display of minimum 10” or more for display of waveforms and Monitored value.<br>5. Should have inbuilt facility to upgrade with EtcO2.<br>6. **Facility to Measure and display: -**<br>a) Status indicator for ventilator mode.<br>b) Battery indication.<br>c) Pressure Vs time Vs volume Vs time, flow Vs time 3 curves/ waveforms.<br>d) Alarm setting.<br>7. Automatic compliance and leakage compensation for circuit and ET Tube.<br>8. Should have facility of logbook, for events and alarms with date & time.<br>9. **Should have following settings.**<br>a) Tidal volume (Minimum at least 50ml, Maximum up to 2000ml)<br>b) Inspiratory Pressure (upto 80 cm of H20) |

| | | |
|---|---|---|
| | | c) Respiratory rate 1 to 80 bpm.<br>d) Apnoea back up rate.<br>e) CPAP/PEEP<br>f) Pressure support.<br>g) Fi02<br>h) Pause Time<br>i) Pressure & flow Trigger<br>j) Inspiratory flow up to 120 Lpm.<br>10. **Monitoring and Display of the following Parameters.**<br>a) Airway Pressure (Peak & Mean).<br>b) Tidal volume (Inspired & Expired).<br>c) Minute volume (Inspired & Expired<br>d) Respiratory mechanics.<br>e) Spontaneous Minute Volume.<br>f) Total Frequency.<br>g) F102 dynamic.<br>h) Intrinsic PEEP.<br>i) Plateau Pressure.<br>j) Resistance & Compliance.<br>k) Use selector Alarms for all measured & monitored parameters.<br>l) Occlusion Pressure.<br>m) Pressure Flow & Volume curves.<br>11. **Modes of Ventilation equipped with newer modes of ventilation: -**<br>a) Assist /control.<br>b) Volume Control.<br>c) Pressure control.<br>d) Pressure support.<br>e) SIMV with pressure support (Pressure and volume control).<br>f) PEEP.<br>g) Inverse ratio Ventilation.<br>h) Non-invasive ventilator- BIPAP, CPAP.<br>i) Apnea Ventilation, User selectable, volume & pressure control.<br>12. Should have built in safety alarms for Airway Pressure High & low, Minute volume, High & low, power failure, Low oxygen, High Respiratory Rate, Air Source in-operable.<br>13. Should have inbuilt exhalation filter. |

| | | |
|---|---|---|
| | | 14. Compressor should be of same company inbuilt/ mounted with ventilator assembly.<br>15. Should have compatibility with existing central pipe line.<br>16. **Humidifier**<br>a) Servo controlled heated Respiratory Humidifier.<br>b) Temperature of delivered Gas on LED display.<br>c) Temperature should be adjustable.<br>d) Jar should be autoclavable<br>17. Nebulization assembly compatible with ventilator and circuit.<br>18. Should have interface facility.<br>19. Flow Sensor-Should have life more than 1 year.<br>20. Expiratory Unit- Life should be more than 3yrs.<br>21. Data storage facility for at least 24hrs.<br>22. Internal rechargeable battery at least 30min. backup.<br>23. Should be supplied with compatible UPS. |
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/or standard of communication (wherever required)** | In-built |
| **3. Physical characteristics** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dba)** | N.A. |
| 3.4 | **Heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Mobile |
| **4. Energy source (electricity, Ups, solar, gas, water, co2 )** | | |
| 4.1 | **Power requirements** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | Battery backup of atleast one hour. |
| 4.3 | **Protection** | NA |
| 4.5 | **Power consumption** | As specified by manufacturer |
| **5. Accessories, spare parts, consumables** | | |
| 5.1 | **Accessories (mandatory, standard, optional)** | a) Patient breathing circuit of silicone for Adult & Paediatric (reusable).<br>b) Non-invasive ventilator mask reusable for adult (3sizes) and |

| | | |
|---|---|---|
| | **Spare parts (main ones) Consumables / reagents (open, closed system)** | paediatric according to age- 4 set each.<br>c) ET tube cuff pressure monitor and HME filter - 10. |
| **6. Environmental and departmental considerations** | | |
| 6.1 | **Atmosphere / ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, cleaning, Disinfection & sterility issues** | To be specified by manufacturer |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. Training and installation** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. Warranty and maintenance** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter |
| **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 should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided.<br>3. Satisfactory certificate for any existing installation from government hospital |
| 10.2 | **Other accompanying documents** | List of essential spares and accessories, with their part number and cost. |
| **11. Notes** | | |

| | | |
|---|---|---|
| 11.1 | **Service support contact details (hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | **Recommendations and Warnings** | Any warning sign should be adequately displayed. |

| OT LIGHT -SHADOWLESS LAMP CEILING MOBILE | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name/institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Shadowless lamp standing model |
| GMDN code(s) | | 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 | **Clinical department/ward** | Operation Theatre |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics** | 1) Dome Head :515mm Dia<br>2) LED lights-2 nos<br>3) Lockable castors stand with minor dome<br>3) Light intensity at 1 mt. :1,00,000 Lux<br>4) Intensity Control: Continuous<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) Temperature Rise in field :3°-6° c from ambient temperature<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** | NA |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dBA)** | NA |
| 3.4 | **heat dissipation** | Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism |
| 3.5 | **Mobility, portability** | Mobile |
| **4. ENERGY SOURCE** | | |

| | | |
|---|---|---|
| 4.1 | **Power Requirements** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | Yes |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | As specified by manufacturer |
| | **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory, standard, optional)**<br>**Spare parts (main ones)**<br>**Consumables/reagents (open, closed system)** | NA |
| | **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | |
| 6.1 | **Atmosphere/Ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | Easy to clean and maintain. |
| | **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| | **8. TRAINING AND INSTALLATION** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up. |
| 8.2 | **Requirements forsign-off** | Supplier to perform installation, safety and operation checks before handover. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users on operation and basic maintenance. |
| | **9. WARRANTY AND MAINTENANCE** | |
| 9.1 | **Warranty** | 03 years warranty |
| | **10. DOCUMENTATION** | |
| 10.1 | **Operating manuals, set manuals, other manuals** | Should provide 2 sets (hardcopy and soft-copy) of: -<br>User, technical and maintenance manuals to be supplied in English/ Hindi language along with machine diagrams. |

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| | | |
| 10.2 | **Other accompanying documents** | List of important spares and accessories, with their part numbers and cost |
| **11. NOTES** | | |
| 11.1 | **Other information** | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | **Recommendations or Warnings** | Any warning signs should be adequately displayed |

| ECG MACHINE – 6 CHANNEL | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name/institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Electrocardiographs, multichannel |
| GMDN code(s) | | 11411 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | Continuously detect, measure and display a patients echocardiogram (ECG) through leads and sensors attached to the patient. |
| 1.2 | **Used by clinical department/ ward** | All |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.2 | **Technical characteristics (specific to this type of device)** | 1) Simultaneous 6 Channel ECG recording with 12 lead simultaneous acquisition.<br>2) Should have a digital display of 6 channel ECG and should have three modes (Automatic, Manual and rhythm).<br>3) Heart rate measurement range to be at least 30 bpm to 250 bpm, with accuracy better than ± 5bpm.<br>4) Heart rate trend display of at least previous 24 hours.<br>5) Arrhythmia detection facility required; minimum gradation of 1 bpm. |
| 2.3 | **User's interface** | Manual |
| 2.4 | **Software and/or standard of communication** | Inbuilt |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | Less than 5 Kgs |
| 3.3 | **Noise (in dBA)** | < 50dB |
| 3.4 | **Heat dissipation** | Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism. |
| 3.5 | **Mobility, portability** | Portable. |
| **4. ENERGY SOURCE** | | |
| 4.1 | **Power Requirements** | 220V ± 10%, 50 Hz |
| 4.2 | **Battery operated** | Battery powered, silence able alarm for power failure.<br>Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit. |

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| | | Internal, replaceable, rechargeable battery allows operation for at least one hour in the event of power failure. |
| 4.3 | **Protection** | Voltage corrector/stabilizer to allow operation at ± 30% of local rated voltage. |
| 4.4 | **Power consumption** | To be specified by manufacturer |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | **Accessories (mandatory, standard, optional)**<br>**Spare parts (main ones)**<br>**Consumables/reagents (open, closed system)** | 6 lead ECG cable.<br>100 sets of ECG connection electrodes (if disposable type).<br>5 sets of ECG connection electrodes (if reusable type).<br>2 sets of spare fuses (if non-resettable fuses are used)<br>5 tube electrode gel (if required) |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | **Atmosphere/Ambiance (air conditioning, humidity, dust...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer |
| **7. STANDARDS AND SAFETY** | | |
| 7.1 | **Certificates (pre-market, sanitary, ..);**<br>**Performance and safety standards (specific to the device type)** | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up. |
| 8.2 | **Requirements for sign-off** | Supplier to perform installation, safety and operation checks before handover. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| **10. DOCUMENTATION** | | |

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| 10.1 | **Operating manuals, service manuals, other manuals** | Should provide 2 sets (hardcopy) of: -<br>1) User, technical, maintenance and service manuals should be supplied in English/Hindi/Regional 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) Satisfactory certificate for any existing installation from government hospital |
| 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 (Hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | **Recommendations or warnings** | Any warning signs would be adequately displayed. |

| HYSTEROSCOPY SET | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done by: (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | |
| GMDN code(s) | | |
| **GENERAL** | | |
| **1. Use** | | |
| 1.1 | **Clinical purpose** | Hysteroscopy is a procedure to examine the inside of the uterus. Hysteroscope is used for this process which is a narrow telescope with light and camera at the end. |
| 1.2 | **Used by clinical department/ ward** | Gynaecology Department |
| **TECHNICAL** | | |
| **2. Technical characteristics** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | **Hysteroscopy set should consist of following:**<br>• CCD camera system.<br>• Resectoscope<br>• Monitor<br>• Light Source with Light Guide Cable<br>• Fluid Management System<br>• Mobile Trolley<br>**1. Hysteroscopy set with accessories:**<br>• Hysteroscope Forward-Oblique Telescope 30° (Diameter more than 2 mm).<br>• Diagnostic sheath must not exceed 3mm when assembled for continuous flow<br>• Therapeutic sheath should not exceed 4.5 mm when assembled for continuous flow with 5 fr (French Gauge- 1 fr = 0.33 mm) working channel<br>• Semi- rigid 5 Fr biopsy forceps and Semi-rigid 5 Fr grasping forceps for removing IUCDs<br>• System should be Autoclavable.<br>• Dedicated protection tube for telescope should be available.<br>**2. Resectoscope:**<br>Connecting tube for inflow and outflow for the above 4 mm hysteroscope telescope complete with continuous irrigation double sheath system, i.e outer flow and rotating inner tube with ceramic insulation distal tip complete set |

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| | | of electrodes and 2 set of HF cables.<br>**3. CCD High Resolution Camera System:**<br>**Camera Head:**<br>• Should be waterproof with a high resolution interline rugged CCD system and compatible with Fiber optic endoscope.<br>• High Quality Image by 10 Bit DSP (Digital Signal Processor)<br>• Signal Noise — 50 dB or less<br>• Brightness — 1.8 (3 Lux) or more<br>**Camera Control Unit:**<br>• Auto Gain Control<br>• White Balance — Automatically adjusted by the Button<br>• Should have facility for Brightness Control<br>**4.Monitor:**<br>• Should be supplied with 15 inch or more medical grade Monitor.<br>• It should have USB port for capturing videos and stills in external USB drive.<br>**5. Light Source with Light Guide Cable:**<br>• LED light source suitable for performing Hysteroscopy.<br>• Light Guide Cable.<br>**6. Fluid Management System:**<br>• The pump must be indicated to provide liquid distension of the uterus during diagnostic and operative hysteroscopy. The volume differential between the irrigation fluid flowing into and out of the uterus must be monitored.<br>• The pump must be electronically pressure controlled<br>• Nominal pressure must be able to preset between 10 and 160 mmHg.<br>• Flow must be able to maintain between 0 and 500 ml/min.<br>• Intrauterine pressure must be maintained and displayed as well as the pre-set pressure and flowrate.<br>• Intrauterine pressure must be displayed as well by large numeric as symbolic.<br>• Overpressure must be displayed visually and by acoustic and rapid deficit alarm.<br>• The graphic user interface of the pump should be a touchscreen/Digitally controlled. |

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| | | • Device should operate with a completely non-contact pressure measurement of the irrigation-medium due to closed system.<br>• Patient safety must be given by accurate pressure monitoring and several alarms.<br>• Tubing set must be able to set-up two irrigation bags and must have either inflow and outflow tubing or inflow tubing only.<br>• Tubing set for inflow only must be re-usable and must not exceed 20 autoclave cycles<br>• Tubing set coming with inflow and outflow tubing should be DEHP-free and single-use.<br>**7. CO2 Electronic Insufflator 30L/M and above flow rate:**<br>1. Electronic CO2 insufflators with pin index connection<br>2. Should have an adjustable flow rate of 0 to 30 ltr. per minute or above and a pressure range adjustable between 0-30 mm Hg.<br>3. Preset and actual value for Pressure and flow should be displayed together on the front panel in digital display.<br>4. Constant monitoring of intra-abdominal pressure; any overpressure is released immediately with back flow with acoustic alarm.<br>5. Unit should have in-built heater to warm up and preheat the CO2 gas.<br>6. Should be able to select either central supply (4.5Kg/cm2) input pressure from central supply as well as direct connection to high pressure CO2 cylinder and should indicate the right inlet pressure of CO2 gas supply by bar graph on front panel of machine.<br>7. Unit should produce immediately acoustic alarm in case of sudden blockage in the gas outlet tube or wrongly placed Veress Needle.<br>8. Provided with Silicon autoclave tubing with luer attachment.<br>9. Should have internal heater to initially heat the CO2 gas to a level to make it from liquid to gas.<br>10. Should have external integrated heater to deliver CO2 gas at body temperature.<br>**8. Mobile Trolley:**<br>• A mobile trolley to accommodate all the items to be |

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| | | used for performing Office Hysteroscopy.<br>• Should be having strong wheels. |
| 2.3 | **User's interface** | Manual |
| 2.4 | **Software and/or standard of communication (wherever required)** | NA |
| | **3. Physical characteristics** | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dba)** | N.A. |
| 3.4 | **Heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Portable |
| | **4. Energy source (electricity, Ups, solar, gas, water, co2 )** | |
| 4.1 | **Power requirements** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | NA |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | As specified by manufacturer |
| | **5. Accessories, spare parts, consumables** | |
| 5.1 | **Accessories (mandatory, standard, optional)**<br>**Spare parts (main ones)**<br>**Consumables / reagents (open, closed system)** | NA |
| | **6. Environmental and departmental considerations** | |
| 6.1 | **Atmosphere / ambiance (air conditioning, humidity, dust ...)** | Should be rugged and capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90% |
| 6.2 | **User's care, cleaning, Disinfection & sterility issues** | To be specified by manufacturer. |
| | **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |

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| **8. Training and installation** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. Warranty and maintenance** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter |
| **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 should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided.<br>3. Satisfactory certificate for any existing installation from government hospital |
| 10.2 | **Other accompanying documents** | List of essential spares and accessories, with their part number and cost. |
| **11. Notes** | | |
| 11.1 | **Service support contact details (hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | **Recommendations and Warnings** | Any warning sign should be adequately displayed. |

| 500 mA X-Ray | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name/institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | |
| GMDN code | | NA |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | Medical x-rays are used to generate images of tissues and structures inside the body. |
| 1.2 | **Used by clinical department/ ward** | Radiology |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | High Frequency X-Ray machine suitable for general Radiography.<br>**X-Ray Generator**<br>• High Frequency X-Ray generator having Frequency of 50 KHz or more should be provided.<br>• Power output of generator should be 50 KW.<br>• Radiography KV range should be 40 to 125 KV.<br>• mA range (Rad.): 500mA or more<br>• Exposure time (Rad.): 1 ms to 3 sec.<br>• mAs Range (Rad.): 1 to 200mAs.<br>**Control:**<br>• A very compact, Soft Touch Control Panel having following functions & indications should be provided. The panel can be supplied in floor or wall mount with Spill Proof design.<br><br>Following features should be available on the control panel.<br>• Machine ON/OFF switch<br>• Digital Display of KV& mAs.<br>• K V & mAs increase and decrease switches.<br>• Tube focal spot selection switch.<br>• Ready and x-ray on switch with indicators.<br>• Bucky Selection switch.<br>• Self-diagnostic Programme with Indicators for Earth fault error, KV error, filament error & Tube's Thermal Overload.<br>• Anatomical Programming Radiography (i.e. APR) should have Preprogrammed parameters of human Anatomy Up to 216 programs which helps the user to select exposure parameters based on body part, examination view and size of the patient.<br><br>**X-Ray Tube**<br>A dual action hand switch with retractable cord should be provided for Radiation Protection of Operator. There should be provision for a cordless Exposure switch also. |

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| | | There should be provision of auto shut off of Control if no key is pressed for 10Min.<br>• Two Nos. Dual focus Rotating Anode X-Ray tube thermally protected.<br>• Anode heat storage capacity of tube should be more than 140KHU.<br>• Two Pair of 8-meter H.V. Cable.<br>• Two Nos. Collimator with auto shut off facility should be provided.<br><br>**HV TANK:**<br>A very compact H.V. Tank filled with high dielectric transformer oil should be provided. The H.V. Tank should contain H.V. transformer, Filament Transformers, H.V. Rectifiers & H.V. Cable receptacles.<br><br>**TUBE STAND:**<br>Floor to Ceiling Stand with Counter Balanced Tube Head (Rotatable ±180 Degree), 360 Degree Rotatable; mounted on Floor Ceiling Rails for convenient movements should be provided.<br><br>**TABLE:**<br>- Motorized table should have motorized bucky consisting of bucky grid of size 17 ¼" x 18 7/8" ratio 8:1, 85 lines/inch. Spot Film Device (semi-automatic) capable of doing all routine spot filming (4 on 1, 2 on 1, 1 on 1) for use with 8" x 10", 10" x 12", 14" x 14" cassettes. Grid size 15" x 15", 6:1 ratio, 103 lines per inch. Compression movement of spot film device is motorized. The fluoroscopic parameters (fluoro KV, fluoro mA and fluoro time) should be digitally displayed on the SFD. Control of fluoro KV should be available on SFD.<br><br>**VERTICAL BUCKY STAND:**<br>• Vertical Bucky Stand with oscillating Grid of Ratio 8:1, 85 lines/inch is provided.<br>• The Bucky moves up & down & is equipped with a stainless-steel cassette tray.<br>• The stand is floor-mounted type & can accommodate cassettes up to 14" X 17". The Bucky is tilted in 6 steps of 15-degree Angle each for various Radiographs. |
| 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)** | NA |
| 3.3 | **Noise (in dBA)** | Noise-free system |

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| 3.4 | **Heat dissipation** | Should maintain nominal temperature and the heat should be disbursed through an cooling mechanism. |
| 3.5 | **Mobility, portability** | Stationary Installation |
| | **4. ENERGY SOURCE** | |
| 4.1 | **Power Requirements** | Input voltage- 380V-440V AC, 50Hz ;3-phase |
| 4.2 | **Battery operated** | No |
| 4.3 | **Protection** | Stabilizer of appropriate capacity to be installed. |
| 4.4 | **Power consumption** | To be certified by manufacturer. |
| | **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)** | Machine should be supplied with following:<br>III. 2 No. BARC Approved whole body lead aprons with all attachments.<br>IV. One Pair of 8 meter H. V. Cable. |
| | **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | |
| 6.1 | **Atmosphere/Ambiance (air conditioning, humidity,**<br>**dust ...)** | Should be rugged and capable to withstand operation in extreme and ambient temperature ( -10 deg C to 60 deg C). Capable to work in relative humidity up to 90% |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer. |
| | **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 CDSCO and AERB approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| | **8. TRAINING AND INSTALLATION** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | 1) Availability of three phase uniform power supply.<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** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| | **10. DOCUMENTATION** | |

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| 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) Service and operation manuals (original and copy) to be provided.<br>3) Advanced maintenance tasks documentation.<br>4) Satisfactory certificate for any existing installation from government hospital. |
| 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. |
| 11.2 | **Recommendations or warnings** | Any warning signs would be adequately displayed. |

| MRI System-1.5 Tesla | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name/institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | |
| GMDN code | | NA |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | MRI is primarily used to identify diseases of the central nervous system, brain, and spine and to detect musculoskeletal disorders. It is also used to view cartilage, tendons, and ligaments. MRI can also be used to image the eyes and the sinuses. MRI can be used to help diagnose infectious diseases; to detect metastatic liver disease; to display heart-wall structure; to stage prostate, bladder, and uterine cancer MRI can also be used as a functional imaging tool. |
| 1.2 | **Used by clinical department/ ward** | Radiology |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | **MAGNET**<br><br>1. Whole Body 1.5Tesla Magnetic Resonance Imaging System optimized for higher performance in Whole Body and Vascular examinations with superconducting magnet, high performance gradients and digital Radio Frequency System.<br>2. 1.5T active shielded super conductive magnet should be short and non-claustrophobic.<br>3. It should have at least 70 cm patient bore with flared opening.<br>4. Magnet length should be less than 200cm.<br>5. The homogeneity of magnet should be less than 3.5 ppm over 45cm DSV.<br>6. The magnet should be well ventilated and illuminated with a built-in 2-way intercom for communication with patient.<br>7. It should have a built in cryo-cooler such that helium consumption does not exceed 0.01 lit/hour.<br>8. Emergency Rundown Control at both operator console room and Gantary Room is a must.<br>9. Fringe Field 0.5 Gauss line radius is essential.<br>10. Front Panel of gantry should display table and patient position.<br><br>**SHIM SYSTEM**<br><br>1. High performance, highly stable shim system with global and localized automated shimming for high homogeneity magnetic field for imaging and spectroscopy.<br>2. Auto shim should be available to shim the magnet with patient |

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| | | in position.<br>**Gradient System:**<br>**1.** Actively shielded gradient system.<br>2. The gradient should be actively shielded with each axis having independently a slew rate of at least 200 T/m/s and a peak amplitude of 33mT/m.<br>3. The system should have efficient and adequate Eddy current compensation.<br>4. Effective cooling system for gradient coil and power supply<br>5. Duty Cycle- 100% the gradient power amplifier.<br>6. Usable over 45 cm of FOV in all directions.<br>**RF SYSTEM**<br>1. A fully digital RF system capable of transmitting power of at least 15kw.<br>2. It should also have at least 32 independent RF receiver channels with each having bandwidth of 1 MHz or more along with necessary hardware to support quadrature ICP array/Matrix coils. The highest receiver channels available with the vendor should be quoted.<br>3. It should support Parallel acquisition techniques with a factor of up to 4 in 2D.<br>4. Should allow remote selection of coils and/or coil elements.<br><br>**PATIENT TABLE**<br>1. The table should be fully motorized, computer-controlled table movements in vertical and horizontal directions.<br>2. A CCTV system with colour LCD display to observe the patient should be provided:<br>Moving table angiography should be possible.<br>3. There should be a handheld alarm for patients<br>4. Light Localizer for patient positioning<br>5. Physiological signals display like ECG, Pulse and SPO2<br>6. Patient load bearing capacity, minimum 200 Kg.<br><br>**MEASUREMENT SYSTEM**<br>1. Largest Field of View should be at least 45 cm in all axis.<br>2. The measurement matrix should be from 128x128 to 1024x1024.<br>3. Minimum 2D slice thickness mm should be equal to or less than 0.5<br>4. Minimum 3D slice thickness mm should be equal to or less than 0.1<br>**COIL SYSTEM**<br>1. The main body coil integrated to the magnet must be Quadrature/CP. In addition to this following coils should be provided:<br>i. Multichannel Head coils with at least 12 channel for high resolution brain imaging.<br>ii. Neuro-vascular Coil with 16 or more channels or Head / Neck Coil combined, capable of high-resolution neuro-vascular imaging<br>iii. 18 Channel Spine Array/Matrix Coils for thoracic and lumbar spine imaging. |

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| | | iv. Body Array/Matrix coil with at least 40 cm z axis coverage for imaging of abdomen, angiograms and heart with 32 channel.<br>v. Suitable Cardiac Coil<br>vi. Dedicated 8 channel extremity coil.<br>vii. Bilateral Breast Coil with at least 4 channel with fully functional spectroscopy.<br>vi. Dedicated 8 channel extremity coil.<br>vii. Bilateral Breast Coil with at least 4 channel with fully functional spectroscopy.<br>viii. Dedicated Shoulder Coil with atleast 8 channels<br>ix. Dedicated Knee Coil with atleast 8 channels<br>x. General purpose flexible coil with small and large size<br>2. Coil Storage Cart from manufacturer.<br>3. The system should continuously monitor the RF coils used during scanning to detect failure modes. RF coils should not require either set up time or coil tuning; Multi coil connection for up to 2 or more coils simultaneous scanning without patient repositioning.<br><br>**APPLICATION SEQUENCES**<br>1. The system should have basic sequences package with Spin Echo, Inversion Recovery, Turbo Spin Echo with high turbo factor of 256 or more, Gradient Echo with ETL of 255 or more, FLAIR.<br>2. Single slice, multiple single slice, multiple slice, multiple stacks, radial stacks and 3D acquisitions for all applications.<br>3. Single and Multi-shot EPI imaging techniques with ETL factor of 255 or more<br>4. Fat suppression for high quality images both STIR and SPIR.<br>5. The system should acquire motion artifact free images in T2 studies of brain in restless patients<br>6. Dynamic study for pre and post contrast scans and time intensity studies<br>7. MR angio Imaging: Should have 20/30 TOF, 20/30 PC , MTS and TONE, ceMRA, Facilities for Accelerated time resolved vascular imaging with applications like Treats/Tracks/Tricks sequences.<br>8. Fat and water excitation package. Di-usion Weighted Imaging, with at least b value of 5000 or more.<br>9. Bolus chasing with automatic and manual triggering from uro mode to 3D acquisition mode with moving table facility.<br>10. Non contrast enhanced peripheral angiography for arterial flow with Native/Trance/Inhance sequences<br>11. Whole body screening imaging studies for metastasis<br>12. High resolution Abdominal and Liver imaging in breathold and free breathing modes with respirator triggered volume acquisitions.<br>13. The system should have basic and advanced MRCP packages including free breathing and 3D techniques.<br>14. The system should have facility for flow quantification of CSF, Vessel flow and hepatobiliary system.<br>15. The system should have Hydrogen, Single Voxel spectroscopy, Multivoxel, Multislice & Multiangle 2D, 3D Spectroscopy and Chemical shift imaging in 2D/3D. The complete |

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| | | processing/post-processing software including color metabolite maps should be available on the main console. Complete prostate spectroscopy hardware and applications should be provided.<br>16. Advanced Cardiac Applications:<br>VCG gating, Morphology/wall motion; Cine perfusion imaging; Myocardial viability imaging; Arrhythmia rejection techniques, Advanced Cardiac Ventricular Measurement Analysis; Cine Cardiac Tagging Techniques; Coronary artery techniques; real time interactive imaging, 20/30 fast eld echo/balanced/steady state techniques and evaluation package on workstation<br>17. Advanced Breast imaging Package.<br>18. Perfusion imaging of brain (including PASL and CASL)<br>19. Susceptibility weighted imaging with phase information.<br>20. Multi Direction DWl and DTI with minimum of 32 directions (Complete package including quantification and tractography software). Prospective motion correction enabled software preferred.<br>21. High resolution imaging for inner ear<br><br>**SAFETY FEATURES**<br>1. The magnet system should include an Emergency Ramp Down unit (ERDU) for fast reduction of the magnetic eld with Ramp Down time below 3 minutes<br>2. The magnet should have quench bands that contain the fringe elds to a specied value in the event of a magnet quench<br>3. Real time SAR calculation should be performed by software to ensure that RF power levels comply with regulatory guidelines and are displayed on each image.<br>4. The system shall have manual override of the motor drive for quick removal of the patients from the magnet bore.<br>5. Temperature sensor (built in) for magnet refrigeration efficiency must be provided. |
| 2.2 | **User's interface** | 1. The main Host computer should have a 19 inches or more high resolution LCD TFT color monitor with 1024 x 1024 matrix display<br>2. The system should have image storage capacity of 100 GB for at least 2,00,000 images in 256x256 matrix.<br>3. The reconstruction speed should be at least 1300 or more for full FOV 256 matrix.<br>4. The main console should have facility for music system for patient in the magnet room. The system should have DVD / CD / flash drive archiving facility. The system should be provided with auto DVD writer.<br>5. Two-way intercom system for patient communication.<br>6. MRI System should be DICOM ready in all parameters with no additional requirement of license for connectivity to any PACS/ HIS and Radiotherapy treatment planning system. |
| 2.3 | **Software and/or standard of communication (wherever required)** | 1. A workstation with same user interface as of main console is required with the availability of all necessary software including:<br>i. Basic post-processing software including MIP, MPR, surface reconstruction and volume rendering technique.<br>ii. Advanced post-processing offered applications perfusion quantification, advanced diffusion and DTI, processing of 2D/ |

| | | |
|---|---|---|
| | | 3D CSI data, with color metabolite mapping, quantification of CSF flow data, vascular analysis package.<br>2. It should have at least 19-inch color monitor, with hard disk of at<br>least 120 GB for at least 250,000 image storage in 256 matrix, and 4 GB RAM capacity or more, with self-playing DVD/CD archiving facility.<br>3. Separate viewing station should be provided. |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dBA)** | Maximum 120 dBA |
| 3.4 | **Heat dissipation** | Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism. |
| 3.5 | **Mobility, portability** | Stationary Installation |
| **4. ENERGY SOURCE** | | |
| 4.1 | **Power Requirements** | Input voltage- 380V-440V AC, 50Hz ;3-phase |
| 4.2 | **Battery operated** | No |
| 4.3 | **Protection** | Stabilizer of appropriate capacity to be installed. |
| 4.4 | **Power consumption** | To be certified by manufacturer. |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)** | 1. Dual Head MRI Compatible Pressure Injector with 100 sets of syringes.<br>2. Water Chiller for Cold Head I Gradients..<br>3. 2 non-ferromagnetic patient transfer trolley should be provided.<br>4. Fire Fighting System, Detectors and 6 Fire Extinguishers - MR compatible / MR safe<br>5. Handheld metal detectors and two metal detector doors to be installed at the entrance point as will be intimated.<br>6. Closed circuit CCD camera<br>7. Phantoms for image quality audits.<br>8. MRI compatible Anesthesia machine (for pediatric and adult use) with dual vaporizers<br>9. Suction and O2 pipeline and manifold to be provided inside the RF enclosure.<br>10. Suitable RF Enclosure<br>11. UPS for entire system for backup of 30 minutes.<br>12. DG set |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | **Atmosphere/Ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |

| | | |
|---|---|---|
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer. |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | Turnkey Project only space to be provided. |
| 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** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| **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.<br>6) Satisfactory certificate for any existing installation from government hospital. |
| 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. |
| 11.2 | **Recommendations or warnings** | Any warning signs would be adequately displayed. |

| Shoulder Pulley | | |
|---|---|---|
| Version no. : | | 01 |
| Date: | | August 2023 |
| Done by : (Name/Institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| GMDNS name | | NA |
| GMDNS code(s) | | NA |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical purpose | Shoulder pulleys help to stretch the shoulder in various directions to improve mobility and function of the shoulders. |
| 1.2 | Used by clinical department/ward | Physiotherapy |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1. Wall mountable unit and the set should include mounting hardware.<br>2. Construction: Tubular stainless-steel tube is fitted with two<br>close hooks to fix pulleys.<br>3. Pulleys: Two, Nylon pulleys with hooks to fix.<br>4. Grip Handles: Two, spring steel wire handles with grips.<br>5. Rope/Cord: Durable interwoven Nylon cord of suitable length. |
| 2.2 | User's interface | Manual |
| 2.3 | Software and/or standard of communication (wherever required | NA |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | Dimensions(metric) | NA |
| 3.2 | Weight (lbs, kg) | NA |
| 3.3 | Noise (in dBA) | NA |
| 3.4 | Heat dissipation | NA |
| 3.5 | Mobility, portability | Fixed |
| **4. ENERGY SOURCE** | | |
| 4.1 | Power requirements | NA |
| 4.2 | Battery operated | NA |
| 4.3 | Power consumption | NA |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |

| | | |
|---|---|---|
| 5.1 | Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system) | Not required. |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| 6.1 | Atmosphere/Ambiance(air conditioning, humidity, dust …) | NA |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | Should be easy to clean. |
| **7. STANDARDS AND SAFETY** | | |
| 7.1 | Certificates (pre-market, sanitary,); Performanceand safety standards (specific to the device type); Local and/or international | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards. |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | Pre- installation requirements: nature, values, quality, tolerance | NA |
| 8.2 | Requirements for sign-off | NA |
| 8.3 | Training of staff (medical, paramedical, technicians) | NA |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | NA |
| **10. DOCUMENTATION** | | |
| 10.1 | Operating manuals, set manuals, other manuals | NA |
| 10.2 | Other accompanying documents | NA |
| **11. Notes** | | |
| 11.1 | Service Support Contact details (Hierarchy Wise; including a toll free/ landline number) | Contact details of manufacturer to be provided. |
| 11.2 | Recommendations orwarnings | NA |

| Shoulder Abduction Ladder | | |
|---|---|---|
| Version no. : | | 01 |
| Date: | | August 2023 |
| Done by : (Name/Institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| GMDNS name | | NA |
| GMDNS code(s) | | NA |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical purpose | It is used to offer progressive motion exercises for the shoulder, elbow and wrist joints of the patients. |
| 1.2 | Used by clinical department/ward | Physiotherapy |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1. Wall mounted ladder used for shoulder/finger exercise.<br>2. Should be made up of polished wood/high quality fiber plastic.<br>3. The ladder should have minimum 30 steps.<br>4. Height of the step: 36-38 mm.<br>5. Each step should be numbered to give feed-back to the patient and to keep record of progress. |
| 2.2 | User's interface | Manual |
| 2.3 | Software and/or standard of communication (wherever required | NA |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | Dimensions(metric) | NA |
| 3.2 | Weight (lbs, kg) | NA |
| 3.3 | Noise (in dBA) | NA |
| 3.4 | Heat dissipation | NA |
| 3.5 | Mobility, portability | Fixed |
| **4. ENERGY SOURCE** | | |
| 4.1 | Power requirements | NA |
| 4.2 | Battery operated | NA |
| 4.3 | Power consumption | NA |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system) | Not required. |

| | | |
|---|---|---|
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| 6.1 | Atmosphere/Ambiance(air conditioning, humidity, dust …) | NA |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | Should be easy to clean. |
| **7. STANDARDS AND SAFETY** | | |
| 7.1 | Certificates (pre-market, sanitary,); Performanceand safety standards (specific to the device type); Local and/or international | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards in case of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards. |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | Pre- installation requirements: nature, values, quality, tolerance | NA |
| 8.2 | Requirements for sign-off | NA |
| 8.3 | Training of staff (medical, paramedical, technicians) | NA |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | NA |
| **10. DOCUMENTATION** | | |
| 10.1 | Operating manuals, set manuals, other manuals | NA |
| 10.2 | Other accompanying documents | NA |
| **11. Notes** | | |
| 11.1 | Service Support Contact details (Hierarchy Wise; including a toll free/ landline number) | Contact details of manufacturer tobe provided. |
| 11.2 | Recommendations or warnings | NA |

| EXERCISE TABLE | | |
|---|---|---|
| Version no.: | | 02 |
| Date: | | August 2023 |
| Done by : (name/institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Exercise Plinth/Couch |
| GMDN code(s) | | NA |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | Tables are designed for the treatment of diseases using therapeutic exercises and massage. It may be used for all purpose related to PMR department. |
| 1.2 | **Clinical department/ward** | Physical Therapy Department |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics** | 1. Made up of solid wood. Should have 4 legs<br>2. Plinth size: high and low<br>3. Top 19mm thickness ply.<br>4. 4 inch cushioned with rexin cover legs cross section 8 x 10cm.<br>L*B*H*(to be specified as per the requirements) |
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/or standard of communication** | NA |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dBA)** | NA |
| 3.4 | **Heat dissipation** | NA |
| 3.5 | **Mobility, portability** | NA |
| **4. ENERGY SOURCE** | | |
| 4.1 | **Power Requirements** | NA |
| 4.2 | **Battery operated** | NA |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | NA |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | **Accessories (mandatory, standard, optional)**<br>**Spare parts (main ones)**<br>**Consumables/reagents (open, closed system)** | Exercise plinth High and exercise plinth Low |

| | | |
|---|---|---|
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| 6.1 | **Atmosphere/Ambiance (air conditioning, humidity, dust ...)** | **NA** |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | NA |
| **7. STANDARDS AND SAFETY** | | |
| 7.1 | **Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international** | Should conform to ISO 13485 quality standards. |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | NA |
| 8.2 | **Requirements forsign-off** | NA |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | NA |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | NA |
| **10. DOCUMENTATION** | | |
| 10.1 | **Manuals** | NA |
| 10.2 | **Other accompanying Documents** | NA |
| **11. NOTES** | | |
| 11.1 | **Other information** | NA |
| 11.2 | **Recommendations or Warnings** | NA |

| INTERFERENTIAL THERAPY UNIT | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name/institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Interferential Therapy Unit |
| GMDN code(s) | | 11248 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | Therapeutic ultrasound units convert electrical energy to high- frequency (i.e., 1 or 3 megahertz [MHz]) sound waves that penetrate tissues to produce pain relief and facilitate tissue healing through thermal and non-thermal physiologic reactions |
| 1.2 | **Clinical department/ward** | Physical Therapy Department |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics** | 1. Dual output Channels and isolated between channels<br>2. Should have 0-30 operation programs<br>3. Symmetrical Balanced Sine Wave<br>4. Output Current:0-100 mA<br>5. Interference Frequency 2-160 Hz<br>6. Output Frequency 4000Hz (with ±1% tolerance) fixed on Channel 1<br>7. Modulating Frequency 4002 4160Hz (with ±1% tolerance) adjustable on Channel 21<br>8. Treatment Timer Continuous, 15, 30, 45 or 60 minutes<br>9. 2pole/4pole multi vector mode<br>10. Patient safety fuse/Auto cut-out |
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/or standard of communication** | Inbuilt |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dBA)** | Noise pressure level (< or = 60)dBA |
| 3.4 | **heat dissipation** | Should maintain a nominal temp and the heat should be disbursed through a cooling mechanism. |
| 3.5 | **Mobility, portability** | Portable |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 )** | | |
| 4.1 | **Power Requirements** | 220 +/- 10% VAC, 50 Hz |

| | | |
|---|---|---|
| 4.2 | **Battery operated** | NA |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | To be specified by the manufacturer |
| | **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory, standard, optional)**<br>**Spare parts (main ones)**<br>**Consumables/reagents (open, closed system)** | 1. one set patient wire IFT<br>2. Two set fixation straps<br>3. One gel bottle<br>4. One power cable<br>5. One operating manual<br>6. Big and small rubber electrode |
| | **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | |
| 6.1 | **Atmosphere/Ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90%. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer. |
| | **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| | **8. TRAINING AND INSTALLATION** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements forsign-off** | Supplier to perform installation, safety and operation checks before handover. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users on operation and basic maintenance. |
| | **9. WARRANTY AND MAINTENANCE** | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| | **10. DOCUMENTATION** | |

| | | |
|---|---|---|
| 10.1 | **Manuals** | Should provide 2 sets (hard copy and soft copy) of:<br>User, technical and maintenance manuals should be supplie in English/Hindi/Regional language along with machine diagrams. |
| 10.2 | **Other accompanying documents** | List of important spares and accessories, with their part numbers and cost |
| **11. NOTES** | | |
| 11.1 | **Other information** | Contact details of manufacturer, supplier, and local service agent to be provided. |
| 11.2 | **Recommendations or Warnings** | Any warning sign should be adequately displayed. |

| Washer Disinfector | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done by: (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | |
| GMDN code(s) | | |
| **GENERAL** | | |
| **1. Use** | | |
| 1.1 | **Clinical purpose** | A washer disinfector is used for the automated cleaning and disinfection of instruments in practices. |
| 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 minimum capacity of 45 ltrs.<br>2. Washer Disinfector, single door, suitable for cleaning and disinfection of surgical instruments, anesthetic equipment, suction bottles, general circulation goods, dental tray and glassware with a fully closed process.<br>3. The washer disinfector, fully automatic, should have an advanced micro-processor which controls all services, programming and static functions. For safety reasons the service and programming functions should be coded.<br>4. The door should be provided with interlocking system. The chamber should be equipped with minimum four spray arms which ensure good water penetration from all directions.<br>5. Various attachments should be provided to suit the load to be washed. Suitable dosage of detergent to be preset with the dosing pump.<br>6. The wash chamber, the inside door, the pipework system and the circulation arms should be made up of stainless steel. |
| 2.2 | **User's interface** | Automatic |
| 2.3 | **Software and/or standard of communication (wherever required)** | NA |
| **3. Physical characteristics** | | |
| 3.1 | **Dimensions** | Chamber dimension should suit the capacity. |

| | | |
|---|---|---|
| | **(metric)** | |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dba)** | The provision of a double wall with insulation in between enables the Washer Disinfector to run with minimum sound and heat emission. |
| 3.4 | **Heat dissipation** | The provision of a double wall with insulation in between enables the Washer Disinfector to run with minimum sound and heat emission. |
| 3.5 | **Mobility, portability** | NA |
| **4. Energy source (electricity, Ups, solar, gas, water, co2 )** | | |
| 4.1 | **Power requirements** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | NA |
| 4.3 | **Protection** | NA |
| 4.5 | **Power consumption** | As specified by manufacturer |
| **5. Accessories, spare parts, consumables** | | |
| 5.1 | **Accessories (mandatory, standard, optional) Spare parts (main ones) Consumables / reagents (open, closed system)** | Consumables equivalent for 100 cycles. |
| **6. Environmental and departmental considerations** | | |
| 6.1 | **Atmosphere / ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, cleaning, Disinfection & sterility issues** | To be specified by manufacturer |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. Training and installation** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |

| | | |
|---|---|---|
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. Warranty and maintenance** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter |
| **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 should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided.<br>3. Satisfactory certificate for any existing installation from government hospital |
| 10.2 | **Other accompanying documents** | List of essential spares and accessories, with their part number and cost. |
| **11. Notes** | | |
| 11.1 | **Service support contact details (hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | **Recommendations and Warnings** | Any warning sign should be adequately displayed. |

| OPERATING MICROSCOPE (ENT) | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name/institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Microscopes, light, operating, Otorhinolaryngology |
| GMDN code(s) | | 12849 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | Operating light microscopes designed to magnify minute structures (e.g., nerves, vessels) in the performance of delicate ear, nose, and/or throat (ENT) surgical procedures, which require high magnification and adjustable focusing ENT operating microscopes typically consist of a stereo microscope (standard or modified) and a mobile floor stand or wall or ceiling mount. |
| 1.2 | **Clinical department/ward** | ENT department |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics** | 1. Should be mobile floor stand on four caster wheels for easy handling and absolute stability with brake.<br>2. Should have apochromatic optics and should have LED Light Source with bright natural Light.<br>3. Should have Manual Fine Focusing<br>4. Should have Focal Distance of Objective Lens (F 200 mm)<br>5. Should have three step magnification: 5x, 10x & 20x and should have total magnification from at least 0.6x to 1.6x<br>6. Additional objective lenses of 250mm and 300 mm and 400mm should be supplied.<br>7. Eye pieces should be minimum 10x or 12.5x or 15x paired super wide field with eye guards.<br>8. Should have universal coupling.<br>9. Should have 90-degree binocular with converging optics<br>10. Should have cold light coaxial illumination by fiber light guide<br>11. Should have tools free design for stand-by bulb change over and for failed bulb replacement<br>12. Should have heat absorbing and UV filters.<br>13. Should have in-built green and cobalt blue filters.<br>14. Should have counter balanced arm mechanism.<br>15. Should have a minimum vertical stroke of 400mm |
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/or standard of communication** | NA |

| | | |
|---|---|---|
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dBA)** | <50dB |
| 3.4 | **heat dissipation** | Heat dissipation should maintain nominal temperature and the heat should be disbursed through an exhaust cooling fan. |
| 3.5 | **Mobility, portability** | Mobile floor, stand or wall or ceiling mount. |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 )** | | |
| 4.1 | **Power Requirements** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | Battery operated light source. |
| 4.3 | **Protection** | Voltage corrector/stabilizer to allow operation at ± 30% of local rated voltage. |
| 4.4 | **Power consumption** | To be specified by manufacturer |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | **Accessories (mandatory, standard, optional)**<br>**Spare parts (main ones)**<br>**Consumables/reagents (open, closed system)** | 1. Beam splitter with 'C' Mount.<br>2. Motorized with foot control<br>3. Objective lens 250 mm, 300 mm, 400 mm.<br>4. Monocular assitoscope.<br>5. Binocular assitoscope<br>6. Battery operated light source. |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| 6.1 | **Atmosphere/Ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer. |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up. |

| | | |
|---|---|---|
| 8.2 | **Requirements forsign-off** | Supplier to perform installation, safety and operation checks before handover.<br>Local clinical staff to affirm completion of installation. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| **10. DOCUMENTATION** | | |
| 10.1 | **Manuals** | Should provide 2 sets (hardcopy) of: -<br>1. User, technical, maintenance and service manuals to be supplied along with machine diagrams.<br>2. List of equipment and procedures required for local calibration and routine maintenance.<br>3. Certificate of inspection and calibration.<br>4. Satisfactory certificate for any existing installation from government hospital. |
| 10.2 | **Other accompanying documents** | List of important spares and accessories, with their part numbers and cost |
| **11. NOTES** | | |
| 11.1 | **Other information** | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | **Recommendations or Warnings** | Any warning signs should be adequately displayed |

| OT LIGHT-SHADOWLESS LAMP CEILING TYPE MINOR | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name/institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Shadowless lamp ceiling type minor |
| GMDN code(s) | | 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 | **Clinical department/ward** | Operation Theatre |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics** | 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 rises on the keep of surgeries to be less than 10°<br>12) CR± approx. 95 or more 13) 360° rotation for both arms |
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/or standard of communication** | NA |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dBA)** | NA |
| 3.4 | **heat dissipation** | Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through an cooling mechanism |
| 3.5 | **Mobility, portability** | Ceiling Type |
| **4. ENERGY SOURCE** | | |

| | | |
|---|---|---|
| 4.1 | **Power Requirements** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | Yes |
| 4.3 | **Protection** | Should have over-charging cut-off with visual symbol. |
| 4.4 | **Power consumption** | As specified by manufacturer. |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | **Accessories (mandatory, standard, optional)**<br>**Spare parts (main ones)**<br>**Consumables/reagents (open, closed system)** | NA |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| 6.1 | **Atmosphere/Ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | Easy to clean and maintain. |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up. |
| 8.2 | **Requirements forsign-off** | Supplier to perform installation, safety and operation checks before handover. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users on operation and basic maintenance. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | 03 years |
| **10. DOCUMENTATION** | | |
| 10.1 | **Manuals** | Should provide 2 sets (hardcopy and soft-copy) of:-<br>User, technical and maintenance manuals to be supplied in English/ Hindi language along with machine diagrams. |

| | | |
|---|---|---|
| 10.2 | **Other accompanying documents** | List of important spares and accessories, with their part numbers and cost. |
| **11. NOTES** | | |
| 11.1 | **Other information** | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | **Recommendations or Warnings** | Any warning signs should be adequately displayed |

| OT LIGHT - SHADOWLESS LAMP CEILING TYPE MAJOR | | |
|---|---|---|
| Version no.: | | 02 |
| Date: | | August 2023 |
| Done by : (name/institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Shadowless lamp ceiling type major |
| GMDN code(s) | | 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 | **Clinical department/ward** | Operation Theater |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics** | 1) Double dome<br>2) Intensity Control in 9 steps for individual 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 rises 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** | NA |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dBA)** | NA |
| 3.4 | **heat dissipation** | Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through an cooling mechanism |
| 3.5 | **Mobility, portability** | Stationary |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 )** | | |
| 4.1 | **Power Requirements** | 220 +/- 10% VAC, 50 Hz |

| | | |
|---|---|---|
| 4.2 | **Battery operated** | Yes |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | As specified by manufacturer |
| | **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory, standard, optional)**<br>**Spare parts (main ones)**<br>**Consumables/reagents (open, closed system)** | NA |
| | **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | |
| 6.1 | **Atmosphere/Ambiance (air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90%. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | Easy to clean and maintain. |
| | **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| | **8. TRAINING AND INSTALLATION** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up. |
| 8.2 | **Requirements forsign-off** | Supplier to perform installation, safety and operation checks before handover. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance should be provided |
| | **9. WARRANTY AND MAINTENANCE** | |
| 9.1 | **Warranty** | 3 years |
| | **10. DOCUMENTATION** | |
| 10.1 | **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. |
| 10.2 | **Other accompanying documents** | List of important spares and accessories, with their part numbers and cost |
| | **11. NOTES** | |

| | | |
|---|---|---|
| 11.1 | **Other information** | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | **Recommendations or Warnings** | Any warning signs should be adequately displayed |

| Turbidometer | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done by : (name.institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| GMDN name | | |
| GMDN code(s) | | |
| **GENERAL** | | |
| **1. USE** | | |
| **1.1** | **Clinical purpose** | The turbidimeter is an instrument used for measuring the turbidity of a liquid by determining the degree to which particles suspended in the solution decrease the intensity of light lost as a beam is passed through it. |
| **1.2** | **Used by clinical department/ward** | Clinical Lab |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| **2.1** | **Technical characteristics (specific to this type of device)** | 1. Material should be of high-grade SS (MS-304)<br>2. Should be benchtop type with LED/LCD display.<br>3. Suitable for measurement even for colored samples.<br>4. Range- 0-1000 NTU in four ranges minimum.<br>5. Resolution should be 0.01 NTU or better.<br>6. Accuracy: +/- 2 percent of full scale 1 and 1000 NTU<br>7. The detector should be photodiode.<br>8. Should have tungsten lamp light source. The lamp life should be minimum for 1 Lakh readings.<br>9. Measuring modes – Normal, Average & Continuous. The range selection should be automatic.<br>10. Should be operable in both electric and re-chargeable batteries mode. |
| **2.2** | **User's interface** | Manual |
| **2.3** | **Software and/ or standard of communication (wherever required** | NA |
| **3. PHYSICAL CHARACTERISTICS** | | |
| **3.1** | **Dimensions(metric)** | NA |
| **3.2** | **Weight (lbs, kg)** | NA |
| **3.3** | **Noise (in dBA)** | Noise-free system |
| **3.4** | **Heat dissipation** | Should maintain nominal temp and the heat should be disbursed through a cooling mechanism |
| **3.5** | **Mobility, portability** | Tabletop |
| **4. ENERGY SOURCE** | | |

| | | |
|---|---|---|
| **4.1** | **Power requirements** | 220 +/- 10% VAC, 50 Hz |
| **4.2** | **Battery operated** | Yes |
| **4.3** | **Protection** | NA |
| **4.4** | **Power consumption** | To be specified by manufacturer |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| **5.1** | **Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)** | Should be supplied with cuvettes and cuvettes stand. |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| **6.1** | **Atmosphere/Ambience (air conditioning, humidity, dust …)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards in case of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND INSTALLATION** | | |
| **8.1** | **Pre- installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up. |
| **8.2** | **Requirements for sign-off** | Supplier to perform installation, safety and operation checks before handover.<br>Local clinical staff to affirm completion of installation. |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| **9.1** | **Warranty** | 3 years, including all spares and calibration.<br>Preventive maintenance visits atleast one in each quarter |
| **10. DOCUMENTATION** | | |

| | | |
|---|---|---|
| **10.1** | **Operating manuals, set manuals, other manuals** | Should provide 2 sets (hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams;<br>2. Service and operation manuals (original and Copy) to be provided;<br>3. Advanced maintenance tasks documentation;<br>4. Certificate of calibration and inspection,<br>5. Satisfactory certificate for any existing installation from government hospital. |
| **10.2** | **Other accompanying documents** | List of essential spares and accessories, with their part number 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; |
| **11.2** | **Recommendations or warnings** | Any warning sign would be adequately displayed. |

| Auditory Brainstem Response Machine (Brainstem Evoked Response Audiometer (BERA)) | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done by: (Name/Institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| GMDN name | | - |
| GMDN code(s) | | - |
| **GENERAL** | | |
| **1. USE** | | |
| **1.1** | **Clinical purpose** | The Brain Stem Evoked Response Audiometry (BERA) is an objective test that gives us the approximate average hearing threshold level of the subject. |
| **1.2** | **Used by clinical department/ward** | PMR Diagnostics |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| **2.1** | **Technical characteristics (specific to this type of device)** | • The system should be able to perform the Brain Stem Evoked Response Audiometry (BERA), Auditory Steady State Response (ASSR).<br>• Should have following test types: - AEP: Chirp, Click & tone burst ABR, ECochG, Cortical AEP: AMLR, LLR, & Electrical ABR for pre surgical & Post-surgical Cochlear Implant procedure, VEMP<br>• Should have ability to record under physiological and electromagnetic noises.<br>• Impedance measurement should be built in and displayed on screen. Should have facility of display multiple panels of waveforms simultaneously. Should have the facility of continuous live display of ongoing input signals.<br>• Should have stimulus polarity: Condensation, Rarefaction, Alternating. Should have absolute or stimulus relative masking types (NBN & White noise). Should have two isolated channels. Should have digital Butterworth High pass/ Low pass Filter.<br>• Signal presentation : right, left and both<br>• Should have pre-programmed auto tests. Should have facility of unlimited number of user defined test protocols.<br>• Stimulus types: CE- Chirp, Click, Pure Tone, Tone Burst, tone pip Transducer: Insert ear phones, Headphones and Bone Vibrator<br>• Intensity: 0-130dB nHL<br>• Tone Burst 10 to 130 dB on 250 to 8000 Hz<br>• Analysis time should be short: -50 to 700 ms<br>• Should be amplifier frequency response 0.2 to 10,000 Hz. |

| | | |
|---|---|---|
| | | • Should have repetition rates 0.2 to 100 depending on modality.<br>**Technical Specification for ASSR (Optional)**<br>• Stimulus - Modulated Tone, Clicks<br>• Intensity: up to 125 dB SPL<br>• Frequency response up to 5000Hz or better<br>• Should be able to test multiple frequencies simultaneously for both ears.<br>• Automatic Generation of Audiogram in SPL/ HL<br>• Phasor diagram should be generated automatically.<br>• Frequency and intensity-based phasor diagram.<br>• FFT Values should be displayed.<br>• Should have spectrum graph.<br>**Technical Specification for VEMP**<br>• It should be 2 channels.<br>• Transducer type: Ear-Tone ABR insert phone with VEMP stimulus/Position indicator.<br>• Stimuli: Click and Tone Bursts.<br>• Should have automatic test protocols for Click and Tone burst.<br>• Patient communication: Talk forward |
| **2.2** | **User's interface** | Digital Display |
| **2.3** | **Software and/ or standard of communication (wherever required)** | NA |
| **3. PHYSICAL CHARACTERISTICS** | | |
| **3.1** | **Dimensions(metric)** | NA |
| **3.2** | **Weight (lbs, kg)** | NA |
| **3.3** | **Noise (in dBA)** | NA |
| **3.4** | **Heat dissipation** | Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism |
| **3.5** | **Mobility, portability** | NA |
| **4. ENERGY SOURCE** | | |
| **4.1** | **Power requirements** | 220VAC +/- 10%, 50 Hz. |
| **4.2** | **Battery operated** | Suitable UPS with maintenance free batteries. |
| **4.3** | **Protection** | NA |
| **4.4** | **Power consumption** | To be specified by vendor. |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| **5.1** | **Accessories, (mandatory, standard, optional);**<br>**Spare parts (main ones);**<br>**Consumables/reagents (open, closed system)** | Should be supplied with following accessories:<br>1. Insert Earphone 01 no.<br>2. Electrodes 6mm cup 12 nos.<br>3. Electrodes 10 mm cup 12 nos.<br>4. Electrode linker 02 nos.<br>5. Skin preparation gel 01 no.<br>6. Conductive paste 01 no.<br>7. Infant ear tips 3.5 mm 20 nos,<br>8. Infant ear tips 4.0mm 20 nos.<br>9. Foam ear tips, 10mm 100 nos.<br>10. Disposable Electrodes25 nos. |

| | | |
|---|---|---|
| | | 11. Foam ear tips, 13mm 100 nos.<br>12. User Manual 01 no.<br>13. Ear Hug/ Halo muffin 100 Nos.<br>14. Insert adaptor for ear hug/Halo muffin – 02 sets |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| **6.1** | **Atmosphere/Ambience (air conditioning, humidity, dust …)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of up to 90% in ideal circumstances. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | As specified by manufacturer |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. TRAINING AND INSTALLATION** | | |
| **8.1** | **Pre- installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| **8.2** | **Requirements for sign-off** | Supplier to perform installation, safety and operation checks before handover. |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| **9.1** | **Warranty** | 1. 3 years, including all spares and calibration.<br>2. Preventive maintenance visits atleast one in each quarter |
| **10. DOCUMENTATION** | | |
| **10.1** | **Operating manuals, set manuals, other manuals** | Should provide 2 sets (hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided.<br>4. Satisfactory certificate for any existing installation from government hospital. |
| **10.2** | **Other accompanying documents** | List of essential spares and accessories, with their part number 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; |
| **11.2** | **Recommendations or warnings** | Any warning sign should be adequately displayed. |

| 200 mA X-Ray (Mobile) | | |
|---|---|---|
| Version no. : | | 01 |
| Date: | | August 2023 |
| Done by : (name/institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | **-** |
| GMDN code | | - |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | Mobile X-Ray unit is required to perform X-Ray studies in emergency & trauma departments & at bed side in wards & ICU. |
| 1.2 | **Used by clinical department/ ward** | Radiology |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | Compact, easily transportable mobile radiographic unit suitable for bed side X-Ray in Emergency, ward, ICU, Operation Theatre & also in the radiology department for conventional radiography.<br><br>**X-ray Generator**:<br><br>1. High frequency X-Ray generator having frequency of 20 KHz or more suitable for radiography should be provided.<br><br>2. Power output of generator should be 20 KW Radiography KV range should be 40-120 KV or more. mA range (rad.): 200 mA or more.<br><br>**Control**:<br><br>1. Compact, Soft touch Control panel having following functions & indications should be provided. The panel can be supplied in floor or wall mount with spill proof design following features should be on the control panel.<br><br>2. Machine ON/OFF switch, Digital display of KV & mAs, KV & mAs increase and decrease switches. Tube focal spot selection switch, Ready and x-ray on switch with indicators.<br><br>3. Bucky selection switch.<br><br>4. Self-diagnostic programme with indicators for earth fault error, KV error, filament error & Tube's thermal overload.<br><br>**X-Ray Tube:**<br><br>1. Tube should have one number stationary anode and thermally protected |

| | | |
|---|---|---|
| | | 2. Anode heat storage capacity of tube should be more than 140 KHU. One number manual collimator with aluminium filter & for adjustment of exposure area. |
| 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 | **Noise (in dBA)** | Noise-free system |
| 3.4 | **Heat dissipation** | Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through an cooling mechanism |
| 3.5 | **Mobility, portability** | Mobile |
| | **4. ENERGY SOURCE** | |
| 4.1 | **Power Requirements** | 220 V AC +/- 10%, 50 Hz |
| 4.2 | **Battery operated** | No |
| 4.3 | **Protection** | Stabilizer of appropriate capacity to be installed. |
| 4.4 | **Power consumption** | To be certified by manufacturer. |
| | **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)** | Machine should be supplied with following:<br>Ⅴ. 2 No. BARC Approved whole body lead aprons with all attachments.<br>Ⅵ. One Pair of 8 meter H. V. Cable. |
| | **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | |
| 6.1 | **Atmosphere/Ambiance (air conditioning, humidity, dust ...)** | Should be rugged and capable to withstand operation in extreme and ambient temperature ( -10 deg C to 60 deg C). Capable to work in relative humidity up to 90% |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer. |
| | **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 CDSCO and AERB approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| | **8. TRAINING AND INSTALLATION** | |

| | | |
|---|---|---|
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Certificate of calibration and inspection of parts from the manufacturer. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users on operation and basic maintenance. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| **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.<br>6) Satisfactory certificate for any existing installation from government hospital. |
| 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. |
| 11.2 | **Recommendations or warnings** | Any warning signs would be adequately displayed. |

| EXTERNAL DEFIBRILLATOR WITH TRANSCUTANEOUS PACING (TCP) | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | - |
| GMDN code(s) | | - |
| **GENERL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | Manual or automatic defibrillator with the facility for applying transcutaneous pacing (TCP), usually done by giving electrical stimulus to the heart (delivering pulses of electric current through the patient chest) which stimulates the heart to contract. |
| 1.2 | **Used by clinical department/ward** | Emergency/ICU/Cardiac care |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1. Defibrillator should be easy to use, having facility for AED (Automated External Defibrillation) and Manual mode defibrillation based on Biphasic technology.<br>2. It should be able to deliver shock from 1 J to 200 Joules (or more) in Manual Mode and automatic mode for pediatric & adult patients.<br>3. It should have at least 5 Lead ECG Monitoring.<br>4. Should have CPR Metronome during AED Mode operation.<br>5. It should have 7 inch (or more) diagonal color LCD/LED screen facility to view color mode display.<br>6. Should work on A.C. and D.C. and on latest rechargeable Lithium-Ion batteries with fully charged Battery capacity to monitor minimum 4 hours of operation and 100 (±20) shocks of 200 Joules discharges.<br>7. Should have in-built printer / recorder.<br>8 Should have vital sign monitoring of SpO2, NIBP.<br>9. Should have facility for external pacemaker (with Demand and Fixed/Non demand mode) and Synchronous Cardioversion. |
| 2.2 | **User's interface** | Manual and AED |
| 2.3 | **Software and/or standard of communication(wher** | Inbuilt |

| | | |
|---|---|---|
| | **e ever required)** | |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | Light weight |
| 3.4 | **Noise (in dBA), heat dissipation** | <60dBA |
| 3.5 | **Mobility, portability** | Yes |
| **4. ENERGY SOURCE** | | |
| 4.1 | **Power Requirements** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | Rechargeable battery backup of minimum 04 hours. |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | As specified by manufacturer. |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | **Accessories (mandatory, standard, optional)**<br>**Spare parts (main ones)**<br>**Consumables / reagents(open, closed system)** | Reusable Hard Paddels-1 Set<br>Multipurpose Electrode (AED cum Pacing Pads)-3 No.s Adult and 2 No.s Pediatric Pads<br>SpO2 Probe-1Adult & 1 Pediatric<br>NIBP Hose & Cuff 1Adult & 1 Pediatric |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | **Atmosphere / Ambiance(air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterilityissues** | To be specified by manufacturer. |
| **7. STANDARDS AND SAFETY** | | |
| 7.1 | **Certifications** | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over. |

| | | |
|---|---|---|
| 8.3 | **Training of staff (medical,paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| **10. DOCUMENTATION** | | |
| 10.1 | **Operating manuals, service manuals, other manuals** | 1. User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams.<br>2. Advanced maintenance tasks required shall be documented. |
| 10.2 | **Other accompanying documents** | List of important spares and accessories, with their part numbersand cost. |
| **11. NOTES** | | |
| 11.1 | **Service Support Contactdetails (Hierchy Wise; including a toll free/ landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | **Recommendations orwarnings** | Any warning sign should be displayed adequately. |

| Oxygen Therapy Equipment (High Flow Nasal Cannula) | | |
|---|---|---|
| Version no. : | | 01 |
| Date: | | August 2023 |
| Done By: | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN Name | | Professional High Flow Respiratory Unit |
| GMDN Code | | 57828 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical Purpose | **High flow nasal cannula** (**HFNC**) is an oxygen supply system capable of delivering up to 100% humidified and heated oxygen at a high flow rate required in ICU settings. |
| 1.2 | Used by clinical department/ward | ICU (Intensive Care Unit) and HDU |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical Characteristics | HFNC unit consists of a mobile trolley with tubing and oxygen hose holding set (Basket/Drawer), servo controlled auto heated humidifier with accessories and power cable. The unit should have the features for treating paediatric and adult patients in a single unit.<br>1. Ability to generate flow from room air and mix with oxygen. Adaptable to all type of oxygen source.<br>2. The mixed gas of air and oxygen should be humidified and warmed between $31^0$C – $40^0$C.<br>3. FiO2: 21 to 100 %<br>4. Flow: 2 to 60 L/min with controls to adjust the flow rate.<br>5. Controls to be easy to operate, numbers and displays to be clearly visible.<br>6. Digital display of Temperature [°C], Flow [L/min], Oxygen concentration [%].<br>7. Humidity compensation system.<br>8. Noise level to be less than 35 dB A at mid pressure range.<br>9. Trigger sensitivity range: 1-10 cmH2O, increments of 1 cmH2O or automatic.<br>10. All parts withstand high disinfection procedures<br>11. Visual and audible alarm for: High/Low FiO2; Incorrect Temperature/Humidity; System leakage or blockage, lack of water, system failure, air filter to be replaced, power failure and low battery.<br>12. Display easily readable in low ambient light and sunlight. |

| | | |
|---|---|---|
| | | 13. Displayed parameters: Gas temperature (°C), FiO2 Tidal volume; Inspiratory pressure; Inspiratory and Expiratory time; I:E ratio; Mean Airway Pressure (MAP); Air leak [%].<br>14. Machine should be installed on Mounting Tray and Pole with Castor C& IV Hook.<br>15. HNFC tubing and hose should be kink proof pliable material with option of adhesive pads to stick on skin for paediatric patients. Should have smooth bore tubing to minimise risk of kinking and should be noiseless in operation.<br>16. Should have a tracheostomy interface for use in tracheostomy patients. |
| 2.2 | User's Interface | User interface to be easy to operate, numbers and displays to be clearly visible. |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | Design | 1. Soft nasal prongs – silicone prongs for patient comfort.<br>2. Contoured nasal prongs – soft and anatomically formed nasal prongs conform to the individual patients to provide maximum patient comfort.<br>3. Should be metal free – safe to use in the MRI suite.<br>4. Universal connector – should be compatible with most heated wire breathing circuits.<br>5. Colour coded for quick and easy identification.<br>6. Secure connections – adjustable tube holder for eliminating drag and working in tandem with the lanyard and clip.<br>7. Adjustable tube replacement - detachable smooth bore tube and plug so that the tube can be comfortably placed on either side.<br>8. Split head strap design – easy to use wide elastic split strap for secure fit and patient comfort. |
| 3.2 | Dimensions (in cm) | Nasal prong of various sizes having standard diameter for use in pediatric and adult patient:<br>Small: 4mm, Medium: 5mm, Large: 6mm |
| 3.3 | Weight | To be specified by the Manufacturer |
| 3.4 | Noise | NA |
| 3.5 | Heat Dissipation | NA |
| 3.6 | Mobility/ Portability | Should be light weight and easily movable with minimal physical effort. |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)** | | |
| 4.1 | Power input | 1. Operates from AC power electric line: 220-240 V, 50 Hz. Built-in rechargeable battery<br>2. Automatic switch from AC power electric-line mode to battery operating mode and vice versa. |
| 4.2 | Power consumption | To be specified by the Manufacturer/Supplier. |
| 4.3 | Battery backup | Continuous in battery operating mode withstands at least 1 hour. |
| **5. ACCESSORIES. SPARE PARTS AND CONSUMABLE** | | |
| 5.1 | Accessories, (mandatory, Standard, | HFNC should be supplied with accessories, consumables and parts required for its proper operation, which include: |

| | | |
|---|---|---|
| | operational); Spare parts (main ones) Consumable/reagents (open, closed system) | 1. Housing and patient interface for adult and paediatric use; withstands high level disinfection and sterilization.<br>2. Flowmeter, graduated in L/min<br>3. Humidifier<br>4. Water chamber<br>5. Connectors for air and oxygen outlets<br>6. Mains power cable ≥ 2 m |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | Atmosphere /Ambiance (air conditioning, humidity, dust ...) | Capable of operating continuously in ambient temperature of -10 to 60◦C and relative humidity upto 90%. |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | As per manufacturer recommendations |
| **7. STANDARDS & SAFETY** | | |
| 7.1 | Certificates (pre-market, sanitary);Performance and safety standards (specific to the device type);Local and/or international | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | Pre-installation requirements: nature, values, quality, tolerance | HFNC system shall be installed and commissioned by qualified and skilled technician. Any prerequisites for installation to be communicated in advance. |
| 8.2 | Requirements for sign-off | 1. Compliance with quantity checklist.<br>2. Complete quality check of the product. |
| 8.3 | Training of staff (medical, paramedical, technicians) | Hands on training to be provided to the end users on using the equipment, day to day maintenance/cleaning. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | 3 years including all spare parts and accessories. |
| **10. DOCUMENTATION** | | |
| 10.1 | Operating manuals, service manuals, other | 1. Should provide two sets of hard copy and a soft copy of user, technical and maintenance manual printed in English/Hindi along with the diagrams. |

| | | |
|---|---|---|
| | manuals | 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. Certificate of calibration and inspection from the factory by the manufacturer. |
| 10.2 | Other accompanying documents | Certification on quality of material of construction. |
| **11. NOTES** | | |
| 11.1 | Service Support Contact details (Hierarchy Wise; including a toll free/landline number) | 1. Contact details of manufacturer, supplier and local service agent to be provided.<br>2. Any Contract (AMC/CMC/ad-hoc) to be declared by the manufacturer.<br>3. Purchaser may engage third party for maintenance of equipment and vendor needs to comply in all terms.<br>4. Manufacturer/ Supplier of medical services should provide price quote for spare part of medical device or supply items, against requisition/Purchase order from Biomedical engineers/technicians. |
| 11.2 | Recommendations or warnings | Any warning sign would be adequately displayed |

| ICU BED-MOTARISED WITH RESUSCITATION MODE (RESUSCITATION BED) | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done By: | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN Name | | Basic electric hospital bed |
| GMDN Code | | 34870 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | Clinical Purposes | ICU beds are special hospital beds designed for ICUs to take care of critical patients and can be operated electro-mechanically. ICU beds facilitates comfortable transfer to and fro and has a provision of bedside diagnostic including X-ray investigations. Thus, they provide safety, comfort and convenience to the patients and caregivers alike. |
| 1.2 | Used by clinical department/ward | ICU (Intensive Care Unit) |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | Technical Characteristics | I. Should have fully motorised 4 sections and sectional mattress.<br>II. Should have 4 separate electrically operating function through embedded control panel/handheld wired remote control for Height adjustment (Hi-Low), Back rest, Knee rest and Trendelenburg/Reverse Trendelenburg.<br>III. The bed frame should be made of Stainless-steel SS (304)with epoxy coating.<br>IV. Should have ABS/polymer moulded head and foot board panels detachable.<br>V. Should have ABS/polymer moulded swing down safety side railing on both sides.<br>VI. Should have a provision for carrying out whole body X-ray at the bedside.<br>VII. Should have digital/analog indicators for angle display. |

| | | |
|---|---|---|
| | | XIII. Should have one touch key provision on control panel for CPR position and manual CPR option in case of automatic system failure.<br>XIV. Bed position adjustments should have:<br>Back Rest angular movement in range from 0-70 deg or more;<br>Knee rest angular movement in range from 0-45 deg or more;<br>Trendelenburg and Reverse Trendelenburg: 0-12 deg or more;<br>XV. Should have a therapeutic Weight bearing up to 150-200 Kg<br>XVI. Should have heavy duty casters made up of Stainless Steel (304) ball bearing/ABS/Polyester with dual locking arrangement.<br>XVII. Should have provision for holding IV pole on four corners.<br>XV. High density foam mattress washable and detachable in 4 parts<br>XVI. Should have battery backup of at least 1 hour<br>XVII. Clearance between Bed Base frame and Floor surface in adjustable range from mm: 120-150 mm |
| 2.2 | User's Interface | Electro-mechanical (motorised) |
| 2.3 | Software and/ or standard of communication (wherever required) | NA |
| **3. PHYSICAL CHARACTERISTIC** | | |
| 3.1 | Dimensions (in cm) | 1. Length: 2100-2300 mm<br>2. Width: 900-1100 mm |
| 3.2 | Weight | To be specified by the Manufacturer/Supplier; |
| 3.3 | Noise | Less than 50dB; |
| 3.4 | Heat Dissipation | Not applicable |
| 3.5 | Mobility/Portability | Should be easily movable with minimal physical effort. |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2.....)** | | |
| 4.1 | Power inputs | 220 +/- 10% VAC, 50 Hz |
| 4.2 | Power consumption | To be specified by Manufacturer/Supplier; |
| 4.3 | Battery backup | Battery backup with inbuilt charger shall be provided. |
| **5. ACCESSORIES. SPARE PARTS AND CONSUMABLE** | | |

| | | |
|---|---|---|
| 5.1 | Accessories, (mandatory, Standard, operational); Spare parts (main ones) Consumable/reagents (open, closed system) | V. Should be provided with IV rods;<br>VI. Mattress as per the specs specified in Section (2.1)<br>VII. Side rails<br>VIII. X-ray cassette tray, Urine bottle holder and drainage bottle holder |
| **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | | |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | Atmosphere /Ambiance (air conditioning, humidity, dust ...) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | Easy to clean and disinfect. |
| **7. STANDARDS & SAFETY** | | |
| 7.1 | Certificates (pre-market, sanitary); Performance and safety standards (specific to the device type); Local and/or international | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | Pre-installation requirements: nature, values, quality, tolerance | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up. |
| 8.2 | Requirements for sign-off | Supplier to perform safety and operation check before hand over. |
| 8.3 | Training of staff (medical, paramedical, technicians) | Training of User on operation and basic maintenance. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | Warranty | 3 years including all spare parts and accessories. |

| | | |
|---|---|---|
| **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 should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided.<br>3. Satisfactory certificate for any existing installation from government hospital |
| 10.2 | Other accompanying documents | List of essential spares and accessories with their part number 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. |
| 11.2 | Recommendations or warnings | Any warning sign should be adequately displayed. |

| FLAME PHOTOMETER | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done by: (Name/Institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| GMDN name | | - |
| GMDN code(s) | | - |
| **GENERAL** | | |
| **1. USE** | | |
| **1.1** | **Clinical purpose** | Flame Photometer is used for the determination of metal ions in biological fluids such as blood and urine. The measurement of these metal ions aids in diagnosis of several medical conditions such as kidney disorders, dehydration, and electrolyte imbalances. |
| **1.2** | **Used by clinical department/ward** | Clinical Diagnostic Laboratory |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| **2.1** | **Technical characteristics (specific to this type of device)** | • It should have LED/LCD display.<br>• Should have adjustable knobs for gas control.<br>• Should have auto ignition system, auto detection for flame failure and automatic gas cut off feature.<br>• Measuring Range: Na+: 0 to 199.9 ppm, K+:0 to 199.9 ppm, Ca+:0-99.9 ppm, Li2+: 0 to 9.99 ppm<br>• Sensitivity- Na+: 0.1 ppm, K+: 0.1 ppm<br>• Specificity: less than 0.5% interference when concentrations are equal to test.<br>• Reproducibility: Less than 1% coefficient of variation for 20 consecutive samples using 10 ppm Na set as maximum standard.<br>• Linearity: Less than 1%<br>• Fuel supply: High-grade propane/butane mixture regulated at approximately 30 psi.<br>• Air supply: 6 L/min at 12 psi; oil and moisture free. |
| **2.2** | **User's interface** | Digital Display |
| **2.3** | **Software and/ or standard of communication (wherever required)** | NA |
| **3. PHYSICAL CHARACTERISTICS** | | |
| **3.1** | **Dimensions(metric)** | NA |
| **3.2** | **Weight (lbs, kg)** | NA |
| **3.3** | **Noise (in dBA)** | NA |
| **3.4** | **Heat dissipation** | Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism |
| **3.5** | **Mobility, portability** | Benchtop |

| | | |
|---|---|---|
| **4. ENERGY SOURCE** | | |
| **4.1** | **Power requirements** | 220VAC +/- 10%, 50 Hz. |
| **4.2** | **Battery operated** | No |
| **4.3** | **Protection** | NA |
| **4.4** | **Power consumption** | To be specified by manufacturer. |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| **5.1** | **Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)** | NA |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| **6.1** | **Atmosphere/Ambience (air conditioning, humidity, dust …)** | Operating Condition: Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of up to 90% in ideal circumstances. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | As specified by manufacturer |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND INSTALLATION** | | |
| **8.1** | **Pre- installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| **8.2** | **Requirements for sign-off** | 1. Supplier to perform installation, safety and operation checks before handover.<br>2. Lab In-Charge to affirm completion of installation. |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| **9.1** | **Warranty** | 1. 3 years, including all spares and calibration.<br>2. Preventive maintenance visits atleast one in each quarter |
| **10. DOCUMENTATION** | | |
| **10.1** | **Operating manuals, set manuals, other manuals** | Should provide 2 sets (hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams;<br>2. Service and operation manuals (original and Copy) |

| | | |
|---|---|---|
| | | to be provided;<br>3. Certificate of calibration and inspection,<br>4. Satisfactory certificate for any existing installation from government hospital. |
| **10.2** | **Other accompanying documents** | List of essential spares and accessories, with their part number 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; |
| **11.2** | **Recommendations or warnings** | Any warning sign should be adequately displayed. |

| EXTRACORPOREAL MEMBRANE OXYGENATION AND CIRCULATORY SUPPORT SYSTEM (ECMO) | | |
|---|---|---|
| Version no. : | | 01 |
| Date: | | August 2023 |
| Done by : (name/institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | - |
| GMDN code(s) | | - |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | The ECMO machine pumps blood from the patient's body to an artificial lung (oxygenator) that adds oxygen to it and removes carbon dioxide. Thus, it replaces the function of the person's own lungs. |
| 1.2 | **Used by clinical department/ ward** | |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.2 | **Technical characteristics (specific to this type of device)** | • The Extracorporeal Membrane Oxygenation and Circulatory Support System (ECMO) should be small, compact, light in weight, and movable with big lockable castor wheels.<br>• The ECMO unit should have:<br>A. Console system<br>B. Pump Drive Unit<br>C. Oxygenator<br>D. Heating cooling unit<br>**Console system with Pump Drive Unit:**<br>• The Pump Drive Unit should be centrifugal or diagonal pump.<br>• It should have an integrated bubble sensor & a separate level sensor to monitor level.<br>• It should be supplied with a Hand Crank or Backup Pump Drive Unit with backup battery pack for emergency used.<br>• Should have an adjustable arm assembly to hold its Drive Unit & also it should be able to fix it in any position.<br>• Should have battery backup for minimum 1.5 hours.<br>• Should have RPM speed 0-5000 rpm or above.<br>• Should have Flow Rate 0-8 litres per minute or above.<br>• It should have a warning Alert to the Operator that he has taken necessary clamp / valve to prevent back flow.<br>• Should be possible to set higher & lower limit for RPM along with low limit setting for LPM.<br>• It should have an integrated flow measuring sensor.<br>• In case of any error message, an acoustic alarm must be sound.<br>**Oxygenator:**<br>The Oxygenator should be for continuous use for minimum 14 days or more, for adults and Pediatric Applications.<br>**Heating Cooling Unit:** |

| | | |
|---|---|---|
| | | • The temperature setting range of water temperature should be 35 to 39 degree Centigrade or better with increments of 0.1 degree centigrade.<br>• Should have digital display for set & outlet temperature & should be capable of showing alarm indications.<br>• Water reservoir capacity should not be more than 2-4 litres<br><br>**Others:**<br>• Should have an advanced cart design maximizing safety and convenience to move the complete unit anywhere.<br>• Should have a standard I.V. pole and provision for a second one.<br>• Should have a convenient oxygen cylinder storage facility.<br>• Gas Blender should be supplied with the ECMO unit |
| 2.3 | **User's interface** | Automatic |
| 2.4 | **Software and/or standard of communication** | Inbuilt |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dBA)** | NA |
| 3.4 | **Heat dissipation** | Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism. |
| 3.5 | **Mobility, portability** | Mobile |
| **4. ENERGY SOURCE** | | |
| 4.1 | **Power Requirements** | 220V ± 10%, 50 Hz |
| 4.2 | **Battery operated** | Battery backup should be available. |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | To be specified by manufacturer |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | **Accessories (mandatory, standard, optional)**<br>**Spare parts (main ones)**<br>**Consumables/reagents (open, closed system)** | 1 Ultrasonic Gel<br>2 Insertion kit<br>3 Dilator<br>4 Tubing Clamp<br>5 Venous Canula (Femoral) of various sizes<br>6. Arterial Canula |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | | |
| 6.1 | **Atmosphere/Ambiance (air conditioning, humidity, dust...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer |
| **7. STANDARDS AND SAFETY** | | |

| | | |
|---|---|---|
| 7.1 | **Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type)** | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up. |
| 8.2 | **Requirements for sign-off** | Supplier to perform installation, safety and operation checks before handover. |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| **10. DOCUMENTATION** | | |
| 10.1 | **Operating manuals, service manuals, other manuals** | Should provide 2 sets (hardcopy) of: -<br>1. User, technical, maintenance and service manuals should be supplied in English/Hindi/Regional 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. Satisfactory certificate for any existing installation from government hospital |
| 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 (Hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | **Recommendations or warnings** | Any warning signs would be adequately displayed. |

| RESUSCITATION KIT | | |
|---|---|---|
| Version No: | | 01 |
| Date: | | August 2023 |
| Done by: (Name/Institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | - |
| GMDN code | | - |
| **GENERAL** | | |
| 1. USE | | |
| 1.1 | Clinical purpose | A neonatal self-inflating resuscitator is used to ventilate a neonate. |
| 1.2 | Used by clinical department/Ward | Emergency department, NICU, SNCU, Ambulance, Resuscitation kit. |
| **TECHNICAL** | | |
| 2. TECHNICAL CHARACTERISTICS | | |
| 2.1 | Technical characteristics (specific to this type of device) | 1. **Neonatal Resuscitation bag with mask:**<br>• size: 200–320 mL<br>• for full-term babies, preterm and low-weight infants less than 5 kg<br>• reusable<br>• self-inflating<br>• hand operated<br>• portable<br>• made of silicone or other materials specified in ISO10651-4 or equivalent.<br>• ventilation can be done with ambient air or with oxygen<br>• intake valve with optional nipple for O2 tubing, material made of polycarbonate/polysulfone or any other material fulfilling ISO 10651-4 or equivalent.<br><br>**2. Mask:**<br>• Size 0 for preterm and low-weight baby, round type, outer diameter 35–50 mm<br>• Size 1 for term baby, round type, outer diameter 50–65 mm<br>• translucent<br><br>**3. Resuscitator bag and masks supplied as a complete set along with the following:**<br>• non-rebreathing patient valve with a pressure limiting valve so that the airway pressure does not exceed 4.5 kPa (45cm H2O) and can generate an airway pressure of at least 3 kPa (30 cm H2O).<br><br>4. All parts should be made up of high strength, long life material. |

| | | |
|---|---|---|
| | | **Suction machine, Electrically Operated:**<br>• low vacuum, low flow, oil-free vacuum pump<br>• electrically powered or battery-powered with rechargeable battery<br>• maximum vacuum: 100 mmHg<br>• collection bottle (one or two): 1 L (disposable bag or collection jar); with an automatic cut off when full to prevent ingress of fluid to the pump; a filter and overflow valve incorporated to prevent cross-contamination (e.g. shatter proof material, overflow protection system); either disposable or autoclavable<br>• airline to the pump incorporating a bacterial filter<br>• tubing to the patient a minimum of 0.5 m long, a non collapsible type; all parts manufactured from high-strength, durable material that does not require specific maintenance or storage conditions and are approved by national regulatory agencies<br>• pump that can be disassembled entirely, is easy to disinfect and clean<br>• pressure gauge that displays the level of suction generated<br>• adjustment of suction delivered to the patient<br>• unit surface that is hard and corrosion resistant; pump handle/pedal that is spring loaded to return to the “up” position after each stroke<br>• mounted on a robust board with a carrying handle. |
| 2.2 | User's interface | Manual |
| 2.3 | Software and/or standard of communication (wherever required) | NA |
| | 3. PHYSICAL CHARACTERISTICS | |
| 3.1 | Dimensions (metric) | NA |
| 3.2 | Weight (lbs, kg) | NA |
| 3.3 | Noise (in dBA) | NA |
| 3.4 | Heat dissipation | NA |
| 3.5 | Mobility, portability | Yes |
| | 4. ENERGY SOURCE | |
| 4.1 | Power Requirements | Suction Pump: 220 +/- 10% VAC, 50 Hz |
| 4.2 | Battery operated | Yes |
| 4.3 | Protection | NA |
| 4.4 | Power consumption | As specified by manufacturer |
| | 5. ACCESSORIES, SPARE PARTS, CONSUMABLES | |
| 5.1 | Accessories (mandatory, standard and optional); spare parts (main ones) and Consumables/ Reagents (Open/Closed | NA |

| | | |
|---|---|---|
| | System) | |
| | 6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS | |
| 6.1 | Atmosphere/Ambiance (air conditioning, humidity, dust...) | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | User's care, Cleaning, Disinfection & Sterility issues | Esay to clean and disinfect. Cleaning instructions should be specified by manufacturer. |
| | 7. STANDARDS AND SAFETY | |
| 7.1 | Certifications (Pre-Market, Sanitary,), Performance and Safety Standards (Specific to the device type); Local and/or international | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| | 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 | 03 Years |
| | 10. DOCUMENTATION | |
| 10.1 | Operating manuals, service manuals, other manuals | Should provide 2 sets (hard copy and soft copy) of:<br>• User, technical and maintenance manuals should be supplied in English/Hindi/ Regional language along with machine diagrams. |
| 10.2 | Other accompanying documents | NA |
| | 11. NOTES | |
| 11.1 | Service Support Contact details (Hierarchy Wise; including a toll free/landline number) | Contact details of manufacturer and supplier should be provided. |
| 11.2 | Recommendations or warnings | NA |

| Haemoglobinometer | | |
|---|---|---|
| Version no. : | | 01 |
| Date: | | August 2023 |
| Done by : (Name, Institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| GMDN name | | - |
| GMDN code(s) | | - |
| **GENERAL** | | |
| **1. USE** | | |
| **1.1** | **Clinical purpose** | Haemoglobinometer is intended to be used for quantitative measurement of haemoglobin in fresh capillary or whole blood samples. |
| **1.2** | **Used by clinical department/ward** | Clinical lab, POC device |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| **2.1** | **Technical characteristics (specific to this type of device)** | 1. It should be an automated, integrated system and based on Photometry.<br>2. Open system (preferably) with direct read-out on LED/LCD display for estimation of hemoglobin.<br>2. Should have LCD display screen and auto shut off feature when not in use.<br>3. Should display results in g/dl.<br>4. Measuring Range 0 to 25 g/dl<br>6. Should have automatic calibration system for maintaining accuracy of reading (<5%CV).<br>7. Should have rechargeable batteries (3.6 V).<br>8. Should have USB connectivity interface for PC and printer.<br>9. Should be supplied with autoinjector pen and disposable lancets. |
| **2.2** | **User's interface** | Manual |
| **2.3** | **Software and/ or standard of communication (wherever required)** | NA |
| **3. PHYSICAL CHARACTERISTICS** | | |
| **3.1** | **Dimensions(metric)** | NA |
| **3.2** | **Weight (lbs, kg)** | NA |
| **3.3** | **Noise (in dBA)** | Noise-free system |
| **3.4** | **Heat dissipation** | NA |
| **3.5** | **Mobility, portability** | Portable |
| **4. ENERGY SOURCE** | | |
| **4.1** | **Power requirements** | NA |
| **4.2** | **Battery operated** | Yes |
| **4.3** | **Protection** | NA |

| | | |
|---|---|---|
| **4.4** | **Power consumption** | NA |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| **5.1** | **Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)** | Hb Strips |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| **6.1** | **Atmosphere/Ambience (air conditioning, humidity, dust …)** | Capable of operating continuously in ambient temperature -10 to 60 deg and relative humidity of upto 90% in ideal circumstances. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer. |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards. |
| **8. TRAINING AND INSTALLATION** | | |
| **8.1** | **Pre- installation requirements: nature, values, quality, tolerance** | NA |
| **8.2** | **Requirements for sign-off** | Supplier to perform safety and operation checks before handover. |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| **9.1** | **Warranty** | 01 year |
| **10. DOCUMENTATION** | | |
| **10.1** | **Operating manuals, set manuals, other manuals** | Should provide 2 sets (hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams;<br>2. Certificate of calibration and inspection, |
| **10.2** | **Other accompanying documents** | NA |
| **11. Notes** | | |
| **11.1** | **Service Support Contact details (Hierarchy Wise; including a toll free/landline number)** | Contact details of manufacturer and supplier to be provided; |

| | | |
|---|---|---|
| **11.2** | **Recommendations or warnings** | Any warning sign should be adequately displayed. |

| Spirometer | | |
|---|---|---|
| Version no.: | | 01 |
| Date: | | August 2023 |
| Done by: (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | - |
| GMDN code(s) | | - |
| **GENERAL** | | |
| **1. Use** | | |
| 1.1 | **Clinical purpose** | A spirometer is an apparatus for measuring the volume of air inspired and expired by the lungs. |
| 1.2 | **Used by clinical department/ ward** | Respiratory Medicine Department, COPD clinic, Internal Medicine |
| **TECHNICAL** | | |
| **2. Technical characteristics** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1. The spirometer should be portable and should have facility of interface with Windows OS desktop / Laptop Computer.<br>2. The microprocessor/computer should be capable of recording patient details with ABHA ID integration for ABDM compliance.<br>3. It should be able to monitor the following parameters:<br>• Spirometry & Flow Volume Parameter<br>• Maximum Ventilation Volume<br>• Pre & Post Bronchodilator comparison<br>• Lung Volumes & Sub – divisions<br>• Broncho Provocation Test.<br>4. Flow meter: –Bi-directional digital turbine or Pneumotach.<br>5. Should incorporate Electronic Barometer & temperature Sensors, for Automatic BTPS Correction.<br>6. The device should provide real time flow volume and volume – time traces on computer/microprocessor screen. |
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/or standard of communication (wherever required)** | In-built |
| **3. Physical characteristics** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |

| | | |
|---|---|---|
| 3.3 | **Noise (in dba)** | N.A. |
| 3.4 | **Heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Portable |
| | **4. Energy source (electricity, Ups, solar, gas, water, co2 )** | |
| 4.1 | **Power requirements** | 220 +/- 10% VAC, 50 Hz |
| 4.2 | **Battery operated** | UPS with power backup of at least 30 minutes |
| 4.3 | **Protection** | NA |
| 4.5 | **Power consumption** | As specified by manufacturer |
| | **5. Accessories, spare parts, consumables** | |
| 5.1 | **Accessories (mandatory, standard, optional) Spare parts (main ones) Consumables / reagents (open, closed system)** | 1. Computer interfacing package, cables and software<br>2. Disposable mouth pieces-100 |
| | **6. Environmental and departmental considerations** | |
| 6.1 | **Atmosphere / ambiance (air conditioning, humidity, dust ...)** | Should be rugged and capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90% |
| 6.2 | **User's care, cleaning, Disinfection & sterility issues** | To be specified by manufacturer. |
| | **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| | **8. Training and installation** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| | **9. Warranty and maintenance** | |
| 9.1 | **Warranty** | • 03 years |

| | | |
|---|---|---|
| | | • Preventive Maintenance visits at least once in each quarter. |
| **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 should be supplied in English/Hindi language along with machine diagrams.<br>2. Service and operation manuals (original and Copy) to be provided.<br>3. Satisfactory certificate for any existing installation from government hospital |
| 10.2 | **Other accompanying documents** | List of essential spares and accessories, with their part number and cost. |
| **11. Notes** | | |
| 11.1 | **Service support contact details (hierchy Wise; including a toll free/landline number)** | Contact details of manufacturer, supplier and local service agent to be provided. |
| 11.2 | **Recommendations and Warnings** | Any warning sign should be adequately displayed. |

| PORTABLE/MINI AUTOCLAVE (VACUUM TYPE) | | |
|---|---|---|
| Version no.: | | 02 |
| Date: | | August 2023 |
| Done by: (Name/Institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| GMDN name | | Sterilizing Units, Steam, Tabletop |
| GMDN code(s) | | 16142 |
| **GENERAL** | | |
| **1. USE** | | |
| **1.1** | **Clinical purpose** | To sterilize medical devices. |
| **1.2** | **Used by clinical department/ward** | Emergency OT |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| **2.1** | **Technical characteristics (specific to this type of device)** | 1. The autoclave should provide sterilization at 121$^{O}$ C and 134$^{O}$ C for both wrapped and unwrapped tools and also a flash cycle for rapid sterilization.<br>2. The autoclave should be equipped with a powerful vacuum pump to eject air pockets from the chamber at the beginning and at the end of cycle (Pre-vacuum and Post vacuum)<br>3. It should have minimum four sterilization programs and two test programs.<br>4. Minimum volume at least 20 liters.<br>5. It should be class B autoclave so that hollow bodied instruments, hand pieces, and turbines can be fully autoclaved. |
| **2.2** | **User's interface** | Manual |
| **2.3** | **Software and/ or standard of communication (wherever required)** | NA |
| **3. PHYSICAL CHARACTERISTICS** | | |
| **3.1** | **Dimensions(metric)** | NA |
| **3.2** | **Weight (lbs, kg)** | NA |
| **3.3** | **Noise (in dBA)** | Noise-free system |
| **3.4** | **Heat dissipation** | NA |
| **3.5** | **Mobility, portability** | NA |
| **4. ENERGY SOURCE** | | |
| **4.1** | **Power requirements** | 220 +/- 10% VAC, 50 Hz |
| **4.2** | **Battery operated** | No |
| **4.3** | **Protection** | Stabilizer or inbuilt protection to voltage fluctuation/current surge. |

| | | |
|---|---|---|
| **4.4** | **Power consumption** | To be specified by manufacturer. |
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| **5.1** | **Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)** | All accessories should be supplied to make equipment fully functional as per user requirement |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| **6.1** | **Atmosphere/Ambience (air conditioning, humidity, dust …)** | Capable to withstand operation in extreme and ambient temperature ( -10 deg C to 60 deg C). Capable to work in relative humidity up to 90%. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer. |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. TRAINING AND INSTALLATION** | | |
| **8.1** | **Pre- installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up. |
| **8.2** | **Requirements for sign-off** | Supplier to perform installation, safety and operation checks before handover. |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | Training of users on operation and basic maintenance. |
| **9. WARRANTY AND MAINTENANCE** | | |
| **9.1** | **Warranty** | • 03 years<br>• Preventive Maintenance visits at least once in each quarter. |
| **10. DOCUMENTATION** | | |
| **10.1** | **Operating manuals, set manuals, other manuals** | Should provide 2 sets (hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams.<br>2. Satisfactory certificate for any existing installation from government hospital. |
| **10.2** | **Other accompanying documents** | List of essential accessories, with their part number 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. |
| **11.2** | **Recommendations or warnings** | Any warning sign should be adequately displayed. |

| Water Bath | | |
|---|---|---|
| Version no. : | | 01 |
| Date: | | August 2023 |
| Done by : (name.institution) | | HCT/NHSRC |
| **NAME, CATEGORY AND CODING** | | |
| UMDNS name | | Baths, Water |
| UMDNS code(s) | | 15108 |
| **GENERAL** | | |
| **1. USE** | | |
| **1.1** | **Clinical purpose** | Baths used to increase, decrease, or hold constant the temperature of bodies or vessels immersed in the water. |
| **1.2** | **Used by clinical department/ward** | Clinical Lab |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| **2.1** | **Technical characteristics (specific to this type of device)** | 1. Stainless Steel, insulated double walled.<br>2. Inner wall of stainless steel.<br>3. Temperature range from ambient to 100° C complete with immersion heater.<br>4. Aluminium /SS cover.<br>5. Brass drain cock.<br>6. Digital microprocessor display to set temperature point preventing thermal runaway.<br>7. Seamless reservoir with no welds to leak or rust, see- through cover should be removable. |
| **2.2** | **User's interface** | Manual |
| **2.3** | **Software and/ or standard of communication (wherever required** | NA |
| **3. PHYSICAL CHARACTERISTICS** | | |
| **3.1** | **Dimensions(metric)** | NA |
| **3.2** | **Weight (lbs, kg)** | NA |
| **3.3** | **Noise (in dBA)** | Noise-free system |
| **3.4** | **Heat dissipation** | Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism |
| **3.5** | **Mobility, portability** | Stationary |
| **4. ENERGY SOURCE** | | |
| **4.1** | **Power requirements** | 220 +/- 10% VAC, 50 Hz |
| **4.2** | **Battery operated** | No |
| **4.3** | **Protection** | NA |

| | | |
|---|---|---|
| **4.4** | **Power consumption** | To be specified by manufacturer |
| **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 CONSIDERATIONS** | | |
| **6.1** | **Atmosphere/Ambience (air conditioning, humidity, dust …)** | 1 .Operating Condition: Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | To be specified by manufacturer. |
| **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 CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards. |
| **8. TRAINING AND INSTALLATION** | | |
| **8.1** | **Pre- installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| **8.2** | **Requirements for sign-off** | Supplier to perform installation, safety and operation checks before handover.<br>Local clinical staff to affirm completion of installation. |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| **9. WARRANTY AND MAINTENANCE** | | |
| **9.1** | **Warranty** | 03 years<br>Preventive maintenance visits atleast one in each quarter |
| **10. DOCUMENTATION** | | |
| **10.1** | **Operating manuals, set manuals, other manuals** | Should provide 2 sets(hard copy and soft copy) of:<br>1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams;<br>2. Advanced maintenance tasks documentation;<br>3. Certificate of calibration and inspection,<br>4. Satisfactory certificate for any existing installation from government hospital. |

| | | |
|---|---|---|
| **10.2** | **Other accompanying documents** | List of essential spares and accessories, with their part number 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; |
| **11.2** | **Recommendations or warnings** | Any warning sign would be adequately displayed. |

| Wheel Chair | | |
|---|---|---|
| Version no.: | | 02 |
| Date: | | August 2023 |
| Done by : (name/institution) | | HCT/NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Wheel Chairs |
| GMDN code(s) | | 14449 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | Chairs mounted on large wheels, designed for indoor (e.g., hospital, institution, home) or outdoor transportation of patients or individuals with impaired walking ability. |
| 1.2 | **Clinical department/ward** | All Department |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics** | 1. Overall size 670 mm W x 1120mm D x 920 mm H.<br>2 Should be made of 16 gauge SS 304 grade tube frames and 16 gauge SS 304 sheet for seat & back rest.<br>3. Should have a fixed arm rest.<br>4. Should have Reticulated and breathable cushion<br>5 Should have minimum 6 swivel nylon caster front wheel, 24" bicycle type rear wheel with pneumatic tyre.<br>6. Two handles are provided with the hand grips<br>7. Back wheel fixing bolt shall be covered with cup type nut.<br>8. Should have breaking system on both side<br>9. All pipes & Foot rest should be made of aluminum |
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/or standard of communication** | NA |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dBA)** | NA |
| 3.4 | **Heat dissipation** | NA |
| 3.5 | **Mobility, portability** | Mobile |
| **4. ENERGY SOURCE** | | |
| 4.1 | **Power Requirements** | NA |
| 4.2 | **Battery operated** | NA |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | NA |

| | | |
|---|---|---|
| **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | | |
| 5.1 | **Accessories (mandatory, standard, optional) Spare parts (main ones) Consumables/reagents (open, closed system)** | NA |
| **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS** | | |
| 6.1 | **Atmosphere/Ambiance (air conditioning, humidity, dust ...)** | **NA** |
| 6.2 | **User's care, Cleaning, Disinfection & Sterility issues** | Easy to clean |
| **7. STANDARDS AND SAFETY** | | |
| 7.1 | **Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international** | Should conform to ISO 13485 quality standards. |
| **8. TRAINING AND INSTALLATION** | | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | NA |
| 8.2 | **Requirements forsign-off** | NA |
| 8.3 | **Training of staff (medical, paramedical, technicians)** | NA |
| **9. WARRANTY AND MAINTENANCE** | | |
| 9.1 | **Warranty** | 03 Years |
| **10. DOCUMENTATION** | | |
| 10.1 | **Manuals** | NA |
| 10.2 | **Other accompanying Documents** | NA |
| **11. NOTES** | | |
| 11.1 | **Other information** | NA |
| 11.2 | **Recommendations or Warnings** | NA |

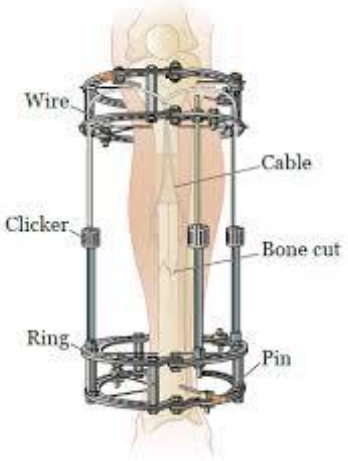
| Lower and Upper Extremity Cycle/Basic Ergometer/Static Cycle | | |
|---|---|---|
| Version no. : | | 02 |
| Date: | | August 2023 |
| Done by : (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Ergometer, Bicycle |
| GMDN code(s) | | 10383 |
| **GENERAL** | | |
| **1. USE** | | |
| 1.1 | **Clinical purpose** | Aerobic cycle exercisers designed to simulate the motions of riding a bicycle; the bicycles remain stationary while the wheels move. These exercisers are usually self-powered devices; they may use friction belts or wheels, magnets, fans, or hydraulics to increase resistance. Some stationary bicycles may include a motor to regulate speed. |
| 1.2 | **Used by clinical department/ward** | Physiotherapy Department |
| **TECHNICAL** | | |
| **2. TECHNICAL CHARACTERISTICS** | | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 1. LCD Display unit to measure heart rate, speed, distance, time and energy.<br>2. Should have a digital display showing speed, time, distance and calories used.<br>3 Body should be rugged and made up of SS-304 grade (Anti-Rust)<br>4. Should have comfortable saddle and foam fitted handle.<br>5. Should have an adjustable design to fit all heights and weights.<br>6. Should be able to bear body weight upto 100 kg.<br>7. Comfortable latex/Rubber hand grip facility for pulse oximetry.<br>8. Should have a resistance system with manual control.<br>9. Should have large adjustable softer HR seat<br>10. Should have firm, durable, broad paddle with adjustable locking strap. |
| 2.2 | **User's interface** | Manual |
| 2.3 | **Software and/or standard of communication (wherever required)** | In-built |
| **3. PHYSICAL CHARACTERISTICS** | | |
| 3.1 | **Dimensions (metric)** | NA |
| 3.2 | **Weight (lbs, kg)** | NA |
| 3.3 | **Noise (in dBA), heat dissipation** | NA |
| 3.4 | **Mobility, portability** | NA |
| **4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 )** | | |
| 4.1 | **Power Requirements** | 220 +/- 10% VAC, 50 Hz |

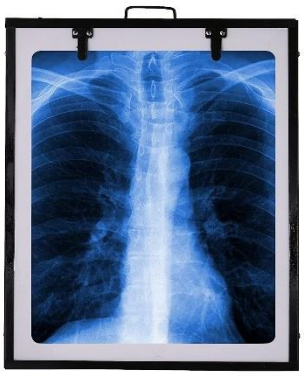
| | | |
|---|---|---|
| 4.2 | **Battery operated** | NA |
| 4.3 | **Protection** | NA |
| 4.4 | **Power consumption** | As specified by manufacturer |
| | **5. ACCESSORIES, SPARE PARTS, CONSUMABLES** | |
| 5.1 | **Accessories (mandatory,standard, optional)**<br>**Spare parts (main ones)**<br>**Consumables / reagents(open, closed system)** | NA |
| | **6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS** | |
| 6.1 | **Atmosphere / Ambiance(air conditioning, humidity, dust ...)** | Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances. |
| 6.2 | **User's care, Cleaning, Disinfection & Sterilityissues** | To be specified by manufacturer. |
| | **7. STANDARDS AND SAFETY** | |
| 7.1 | **Certificates (pre-market, sanitary, ...); Performanceand safety standards (specific to the device type); Local and/or international** | 1. Should be CDSCO approved.<br>2. Should comply with BIS standards.<br>3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.<br>4. Should conform to ISO 13485 quality standards.<br>5. Should conform to IEC 60601-1 General requirements of electrical safety standards |
| | **8. TRAINING AND INSTALLATION** | |
| 8.1 | **Pre-installation requirements: nature, values, quality, tolerance** | To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up |
| 8.2 | **Requirements for sign-off** | Supplier to perform safety and operation check before hand over. |
| 8.3 | **Training of staff (medical,paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided. |
| | **9. WARRANTY AND MAINTENANCE** | |
| 9.1 | **Warranty** | 03 years |
| | **10. DOCUMENTATION** | |
| 10.1 | **Operating manuals, service manuals, othermanuals** | User manuals to be supplied in English languagealong with machine diagrams. |
| 10.2 | **Other accompanying documents** | NA |
| | **11. NOTES** | |
| 11.1 | **Service Support Contactdetails (Hierchy Wise; including a toll free/ landline number)** | Contact details of manufacturer and supplier should be provided. |

| | | |
|---|---|---|
| 11.2 | **Recommendations or warnings** | NA |

| Sl. No. | Title | Specifications | Image of the equipment |
|---|---|---|---|
| 1. | Foetoscope | • Description: Used to listen to the heart rate of a foetus during pregnancy by placing the scope over the abdomen.<br>• Material: Standard hollow horn, should be made up of rust proof metal, with smooth lips for tight contact with the skin.<br>• Should be at least 8 inches long. |  |
| 2. | Proctoscope | • Description: Proctoscope is a short rigid single-use plastic or chromium plated metal (reusable) instrument with hollow interior and a tapering probe fitted with a handle and is used for visual examination of the lower part of rectum and anal canal<br>• Diameter: Approx. 20-30 mm<br>• Material: rust resistance, latex free material, autoclavable (for reusable) |  |
| 3. | Punctum Dilator | • Description: A surgical device with cylindrical corrugated metal handle with conical pointed tips on both sides that ophthalmic surgeons use to broaden obstructed tear ducts, looking towards to restore the tear flow and discharge the lachrymal system.<br>• Material: Made up of premium stainless steel; polished finish for aesthetic and corrosion resistance, and autoclavable. |  |

| | | | |
|---|---|---|---|
| 4. | Walking Aid for training/Reciprocal walker | • Description: Lightweight foldable frame walker fitted with soft hand grip, used to provide stability.<br>• Portability: foldable for easy storage and transportation<br>• Material/Quality: made up of stainless steel rugged tubular frame to bear weight.<br>• Distance between handgrips should be approx. 34 cms<br>• Height: should be at least 175 cm, from ground and preferably adjustable/lockable.<br>• Should have latex free handgrip with forearm support |  |
| 5. | Tuning fork | • Description: An acoustic resonator in the form of a two-pronged fork with the prongs (tines) formed from a U-shaped bar of premium quality elastic metal<br>• Material: Alloy of steel, nickel and chromium, called Elinvar<br>• Frequency: 128, 256, 512 Hz, each fork is individually tested to match the specific frequency.<br>• ISO 13485/BIS/CE Certificate |  |
| 6. | Goinometer | • Description Measuring tool used in occupational therapy and physical therapy to measure a joint's axis and range of motion.<br>• Material: made up of Stainless steel, two 180-degree scale in opposite direction, measures about 50mm x 200 length<br>• Should have ISO certification for quality standards. |  |
| 7. | Ear and Nasal Suction/Aspirator | • The ear syringe used for cleaning the ear canal and nasal aspirator is used to clear the nasal passages of infants, children, and adults.<br>• Should be made up of high-quality medical grade material.<br>• Nasal aspirator consists of a soft, flexible tube with a bulb or chamber at one end and a nozzle at the other. |  |

| | | | |
|---|---|---|---|
| 8. | Percussion Hammer/Reflex Hammer | • Description: Used to examine the reflexes of the deep muscle tender and to check the abnormalities, if any, of the nervous system.<br>• Material: Should be made of stainless steel arm with a rubber head (triangular in shape) for percussion.<br>• Length: 7.5" (Approx.) with a comfortable handle grip.<br>• Should have ISO 13485/BIS/CE/ISI/ISO:9001 |  |
| 9. | Head Lamp | • Description: Light weight, wearable head lamp using LED technology to produce intense white light for spot examination and illumination.<br>• Adjustable leather head band. Ion lithium rechargeable battery.<br>• Minimum 3.5 - 4 hours of continuous operating time.<br>• Features: Pure white light of high intensity.<br>• Light spot focalization system with multidirectional adjustment of the light. |  |
| 10. | Tongue depressor | • Description: L-Shaped tongue Spatula used to depress the tongue to allow for examination of the mouth and throat<br>• Material: made of rustproof premium quality Stainless Steel<br>• Length: 5 to 6 inches approx. with varying sizes for pediatric and adult use.<br>• Packed in set of 5 pcs, re-usable and autoclavable. |  <br>Tongue Spatula L-Shape |
| 11. | External fixator | • Description: Use in orthopedic surgery for external fixation of open fractures/ comminuted fractures externally by pins and rods.<br>• Universal Clamp, Tubular rods with Caps 6"-18" with 5 cm increment,<br>Two Pin Clamps (Twin Clamps)<br>Tube to Tube Clamp<br>3.2/3.5mm extralong drill bit<br>• Accessories: Drill Bits 1.5 mm<br>Allen Key of suitable size<br>Threaded & nonthreaded K wires/small distractor 1.5, 2mm.<br>Link joints for above wires. |  |

| | | | |
|---|---|---|---|
| | | • Should have ISO certification for quality standards. | |
| 12. | Finger Exerciser web | • Description: Use for hand strengthening and hand therapy. Excellent for physical therapy, conditioning, and rehabilitation.<br>• used to perform finger flexion, extension, opposition, and supination exercises.<br>• Material: latex-free material with high quality rubber with special agents added for durability and strength which can accommodate all hand sizes and strength levels<br>• Dimension: 14" in diameter<br>• Available in 6 resistance levels. |  |
| 13. | X-Ray View Box | • For viewing single X-ray films having dimensions of 15 x 5"x 25" (Lx D x H) with 2 nos. of 20W fluorescent tubes of 2 feet length each with necessary fittings in MS housing of 20 SWG and is duly powder coated.<br>• View box to be fitted with white acrylic sheet to reduce glare and provide uniform illumination.<br>• Grip clips/ grip rollers are to be provided to hold the film.<br>• Drip tray for wet films |  |
| 14. | Spirometer | • Description: Spirometer is used for lung exercises.<br>• Should be compact, lightweight and made up of high-quality break-resistant plastic.<br>• Should have 3 chambers for different inhalation rates consisting of 3-balls spirometer.<br>• |  |