| Specifications of medical equipments for ERS Ambulances under National Health Mission<br>And type of ambulances | | |
|---|---|---|
| **S No** | **Medical Equipments** | **Type of Ambulance** |
| 1 | Suction pump portable electric | C and D |
| 2 | Suction Pump, foot operated | A, B, C and D |
| 3 | Suction Pump, hand operated | A, B, C and D |
| 4 | Laryngoscope | C and D |
| 5 | Flowmeter with Humidifier bottle | A, B, C and D |
| 6 | Oxygen cylinder “B” Type | A and B |
| 7 | Oxygen cylinder “D” Type | C and D |
| 8 | Bag and Mask Ventilation Device (Adult) | A, B, C and D |
| 9 | Bag and Mask Ventilation device (Child & Neonatal) | A, B, C and D |
| 10 | Trolley Stretcher- with back tilt facility and collapsible wheels | A, B, C and D |
| 11 | Canvas Stretcher folding | A and B |
| 12 | Stretcher Scoop | A and B |
| 13 | BP Instrument Aneroid | A, B, C and D |
| 14 | Stethoscope | A, B, C and D |
| 15 | Pneumatic Splints | A, B, C and D |
| 16 | Cervical Collar | A, B, C and D |
| 17 | First Aid Box | A, B, C and D |
| 18 | Spinal Board | A, B, C and D |
| 19 | Double Head Immobilizers | C and D |
| 20 | Fetal doppler | D |
| 21 | Portable hand held Glucometer | A, B, C and D |
| 22 | Nebulizer (Electric) | A, B, C and D |
| 23 | Automated External Defibrillator | A, B, C and D |
| 24 | Monitor | C and D |
| 25 | Syringe Pump | D |
| 26 | Transport Ventilator(Adult & Paediatrics) | D |
| 27 | Transport Ventilator (neonatal & Paediatrics) | D |
| 28 | (A) Intra Venous Cut Down Set and (C) Suture Kit | C and D |
| 29 | Pulse Oximeter | A, B, C and D |
| 30 | Automatic Non invasive BP(NIBP) | A and B |
| 31 | Supraglotic device (LMA) all sizes | A, B, C and D |

| | | |
|---|---|---|
| **MEDICAL DEVICE SPECIFICATION<br>(Including Information on the following where relevant/appropriate, but not limited to)** | | |
| **Suction pump portable electric** | | |
| Version no. : | | 2.0 |
| Date: | | 2016 |
| Done by : (name / institution) | | Dte. GHS |
| | | NAME AND CODING |
| GMDN name | | Suction systems |
| GMDN code | | CT1272 |
| GMDN definition | | An assembly of devices designed to evacuate fluid, tissue, gas, or other foreign materials from a body cavity or lumen by means of suction. It generally consists of a mains electricity (AC and DC powered) suction pump, tubing, plastic/glass collection container(s), a vacuum gauge, a vacuum control knob, an overflow trap, a moisture filter, and a microbial filter. The pump creates a vacuum in the suction tubing, which is inserted into the body for the removal of materials into the collection container. This system can be used in a wide variety of settings within healthcare facilities. |
| **GENERAL** | | |
| **1** | | USE |
| **1.1** | **Clinical purpose** | to aspirate fluids, secretions, or other foreign materials from a patient's airway by means of suction. |
| **1.2** | **Used by clinical department/ward** | All |
| | | TECHNICAL |
| **2** | | TECHNICAL CHARACTERISTICS |
| **2.1** | **Technical characteristics (specific to this type of device)** | 0 to - 760 mm Hg ± 10 regulable, 1/2 HP; single phase 1440 RPM motor; flutter free vacuum control knob,; Wide mouthed 2 x 2 LITRE (light weight, unbreakable and clear) with self sealing bungs and mechanical over flow safety device. |
| **2.2** | **Settings** | Manual |
| **2.3** | **User's interface** | Manual |
| **2.4** | **Software and/or standard of communication(where ever required)** | NA |
| **3** | | PHYSICAL CHARACTERISTICS |
| **3.1** | **Dimensions (metric)** | Max: 43 x 30 x 68 cms |
| **3.2** | **Weight (lbs, kg)** | Max: 2.7Kg (with jar) |
| **3.3** | **Configuration** | NA |
| **3.4** | **Noise (in dBA)** | 50 dB A ± 3 |

| | | |
|---|---|---|
| **3.5** | **heat dissipation** | Should maintain upto 36.5 deg temp and the heat disbursed through a exhaust fan |
| **3.6** | **Mobility, portability** | Yes |
| **4** | **EN** | ERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) |
| **4.1** | **Power Requirements** | 220 V, 50 Hz, 2 ± 0.5 Amps, 370 watts for AC and DC compatible with ambulance power supply with other life saving equipments running |
| **4.2** | **Battery operated** | NA |
| **4.3** | **Tolerance (to variations, shutdowns)** | Voltage corrector / stabilizer to allow operation at ± 30% of local rated voltage. Use of SMPS to correct voltage |
| **4.4** | **Protection** | Electrical protection by resettable over current breakers or replaceable fuses, fitted in both live and neutral lines |
| **4.5** | **Power consumption** | should run with other life saving equipments running parallelly in the vehicle |
| **4.6** | **Other energy supplies** | NA |
| **5** | | ACCESSORIES, SPARE PARTS, CONSUMABLES |
| **5.1** | **Accessories & Spares** | collection container & its cap, suctions tube tips, a vacuum gauge, two sets of moisture & microbial filters and control knob |
| **5.2** | **Consumables / reagents (open, closed system)** | SiliconeTubing:8 mm ID x 2 mtr (PVC), 2x2 lt jar ( one set extra) |
| **6** | ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS | |
| **6.1** | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | Complete unit to be easily washable and sterilizable using alcohol and chemical agents. |
| **7** | STANDARDS AND SAFETY | |
| **7.1** | **Certifications** | FDA(US) /CE(EU) and BIS/ISO 13485:2003; IEC 60601-1 |
| **8** | TRAINING AND INSTALLATION | |
| **8.1** | **Pre-installation requirements: nature, values, quality, tolerance** | Availability of 15 amp socket, safety and operation checks before handover. Compatible with ambulance electrical systems |
| **8.2** | **Requirements for sign-off** | Certificate of Calibration and inspection from the factory. |

| | | |
|---|---|---|
| **8.3** | **Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order)** | Training of users in operation and basic maintenance shall be provided |
| **9** | WARRANTY AND MAINTENANCE | |
| **9.1** | **Warranty** | 3 years |
| **9.2** | **Maintenance tasks** | Maintenance manual detailing complete maintaining schedule |
| **9.3** | **Service contract clauses, including prices** | Local clinical staff / authorized officer on behalf of purchaser to affirm completion of installation |
| **10** | DOCUMENTATION | |
| **10.1** | **Operating manuals, service manuals, other manuals** | Advanced maintenance tasks required shall be documented in English and/or Hindi User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams.<br>List to be provided of equipment and procedures required for local calibration and routine maintenance |
| **10.2** | **Other accompanying documents** | List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided. |
| **11** | NOTES | |
| **11.1** | **Service Support Contact details (Hierchy Wise; including a toll free/landline number)** | Any Contract (AMC/MC/add-hoc) to be declared by the manufacturer |
| **11.2** | **Recommendations or warnings** | Any recommendations for best use and supplementary warning for safety should be declared |
| **11.3** | **Temperature Range** | Should be able to operate between – 32 degrees Centigrade to + 52 degrees Centigrade |

| MEDICAL DEVICE SPECIFICATION<br>(Including Information on the following where relevant/appropriate, but not limited to) | | |
|---|---|---|
| **Suction Pump, foot operated** | | |
| Version no. : | | 2.0 |
| Date: | | 2016 |
| Done by : (name / institution) | | Dte. GHS |
| **NAME AND CODING** | | |
| GMDN name | | Emergency suction systems |
| GMDN code | | CT2180 |
| GMDN definition | | A portable assembly of devices primarily intended to be used by emergency medical services (EMS) to aspirate fluids, secretions, or other foreign materials from a patient's airway by means of suction. It typically consists of a manually-powered (foot-operated) mechanism to drive the suction pump, tubing, a collection container and control knob. The pump creates a vacuum in the suction tubing, which is used for the removal of materials into the collection container. This system is typically used during patient transport or for emergency situations. |
| **GENERAL** | | |
| | **USE** | |
| **TECHNICAL** | | |
| 2 | TECHNICAL CHARACTERISTICS | |
| 2.1 | **Technical characteristics (specific to this type of device)** | 0 to - 600 mmHg +-10mm regulable, flutter free, vacuum control knob |
| 2.2 | **Settings** | Manual |
| 2.3 | **User's interface** | Manual |
| 2.4 | **Software and/or standard of communication(where ever required)** | NA |
| 3 | **PHYSICAL CHARACTERISTICS** | |
| **3.1** | **Dimensions (metric)** | NA |
| **3.2** | **Weight (lbs, kg)** | 2.5kg max |
| **3.3** | **Configuration** | NA |
| **3.4** | **Noise (in dBA)** | NA |
| **3.5** | **heat dissipation** | NA |
| **3.6** | **Mobility, portability** | Yes |
| **4** | **ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....)** | |
| **4.1** | **Power Requirements** | NA |
| **4.2** | **Battery operated** | NA |
| **4.3** | **Tolerance (to variations, shutdowns)** | NA |
| **4.4** | **Protection** | NA |
| **4.5** | **Power consumption** | NA |
| **4.6** | **Other energy supplies** | NA |
| **5** | | ACCESSORIES, SPARE PARTS, CONSUMABLES |
| **5.1** | **Accessories & spare parts** | collection bottles, clear unbreakable jar (one set extra) |
| **5.2** | **Consumables / reagents (open, closed system)** | silicon tubing - two sets |
| **6** | | ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS |
| **6.1** | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | Complete unit to be easily washable and sterilizable using both alcohol and chemical agents. |
| **7** | | STANDARDS AND SAFETY |
| **7.1** | **Certifications** | FDA(US)/CE (EU) and BIS/ISO 13485:2003; ISO 10079-2-2014 |
| **8** | | TRAINING AND INSTALLATION |
| **8.1** | **Pre-installation requirements: nature,** | NA |

| | | |
|---|---|---|
| | **values, quality, tolerance** | |
| **8.2** | **Requirements for sign-off** | NA |
| **8.3** | **Training of staff (medical, paramedical, technicians)**<br>**OPTIONAL (Depending upon scope of work order)** | Training of users in operation and basic maintenance shall be provided |
| **9** | | WARRANTY AND MAINTENANCE |
| **9.1** | **Warranty** | 3 years |
| **9.2** | **Maintenance tasks** | Maintenance manual detailing complete maintaining schedule |
| **9.3** | **Service contract clauses, including prices** | Local clinical staff / authorized officer on behalf of purchaser to affirm completion of installation |
| **10** | | DOCUMENTATION |
| **10.1** | **Operating manuals, service manuals, other manuals** | Advanced maintenance tasks required shall be documented<br>User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams.<br>List to be provided of equipment and procedures required for local calibration and routine maintenance |
| **10.2** | **Other accompanying documents** | List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided. |
| **11** | | NOTES |
| **11.1** | **Service Support Contact details (Hierarchy Wise; including a toll free/landline number)** | NA |
| **11.2** | **Recommendations or warnings** | Any recommendations for best use and supplementary warning for safety should be declared |
| **11.3** | **Temperature Range** | Should be able to operate between – 32 degrees Centigrade to + 52 degrees Centigrade |

| MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to) | | |
|---|---|---|
| **Suction Pump, hand operated** | | |
| Version no. : | | 2.0 |
| Date: | | 2016 |
| Done by : (name / institution) | | Dte. GHS |
| **NAME AND CODING** | | |
| GMDN name | | Emergency suction systems |
| GMDN code | | CT2180 |
| GMDN definition | | A portable assembly of devices primarily intended to be used by emergency medical services (EMS) to aspirate fluids, secretions, or other foreign materials from a patient's airway by means of suction. It typically consists of a manually-powered (hand-operated) mechanism to drive the suction pump, tubing, a collection container and control knob. The pump creates a vacuum in the suction tubing, which is used for the removal of materials into the collection container. This system is typically used during patient transport or for emergency situations. |
| **GENERAL** | | |
| **1** | USE | |
| **1.1** | **Clinical purpose** | to aspirate fluids, secretions, or other foreign materials from a patient's airway by means of suction. |
| | | TECHNICAL |
| **2** | | TECHNICAL CHARACTERISTICS |
| **2.1** | **Technical characteristics (specific to this type of device)** | 0 to - 600 mmHg +-10mm regulable, flutter free, vacuum control knob |
| **2.2** | **Settings** | Manual |
| **2.3** | **User's interface** | Manual |
| **2.4** | **Software and/or standard of communication(where ever required)** | NA |
| **3** | | PHYSICAL CHARACTERISTICS |
| **3.1** | **Dimensions (metric)** | NA |
| **3.2** | **Weight (lbs, kg)** | 2.5kg max |
| **3.3** | **Configuration** | NA |
| **3.4** | **Noise (in dBA)** | NA |
| **3.5** | **heat dissipation** | NA |
| **3.6** | **Mobility, portability** | Yes |
| **4** | | ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) |
| **4.1** | **Power Requirements** | NA |
| **4.2** | **Battery operated** | NA |
| **4.3** | **Tolerance (to variations, shutdowns)** | NA |
| **4.4** | **Protection** | NA |

| | | |
|---|---|---|
| **4.5** | **Power consumption** | NA |
| **4.6** | **Other energy supplies** | NA |
| **5** | | ACCESSORIES, SPARE PARTS, CONSUMABLES |
| **5.1** | **Accessories & spare parts** | collection bottles, clear unbreakable jar (one set extra) |
| **5.2** | **Consumables / reagents (open, closed system)** | silicon tubing- two sets |
| **6** | | ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS |
| **6.1** | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | Complete unit to be easily washable and sterilizable using both alcohol and chemical agents. |
| **7** | | STANDARDS AND SAFETY |
| **7.1** | **Certifications** | FDA(US)/CE(EU) and BIS/ISO 13485:2003; ISO 10079-2-2014 |
| **8** | | TRAINING AND INSTALLATION |
| **8.1** | **Pre-installation requirements: nature, values, quality, tolerance** | NA |
| **8.2** | **Requirements for sign-off** | NA |
| **8.3** | **Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order)** | Training of users in operation and basic maintenance shall be provided |
| **9** | | WARRANTY AND MAINTENANCE |
| **9.1** | **Warranty** | 3 years |
| **9.2** | **Maintenance tasks** | maintenance manual detailing complete maintaining schedule |
| **9.3** | **Service contract clauses, including prices** | Local clinical staff / authorized officer on behalf of purchaser to affirm completion of installation |
| **10** | | DOCUMENTATION |
| **10.1** | **Operating manuals, service manuals, other manuals** | Advanced maintenance tasks required shall be documented<br>User, technical and maintenance manuals to be supplied in English/ Hindi language along with machine diagrams.<br>List to be provided of equipment and procedures required for local calibration and routine maintenance |
| **10.2** | **Other accompanying documents** | List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided. |
| **11** | | NOTES |
| **11.1** | **Service Support Contact details (Hierchy Wise; including a toll free/landline number)** | NA |
| **11.2** | **Recommendations or warnings** | Any recommendations for best use and supplementary warning for safety should be declared |
| **11.3** | **Temperature Range** | Should be able to operate between – 32 degrees Centigrade to + 52 degrees Centigrade |

| MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to) | | |
|---|---|---|
| **Laryngoscope** | | |
| Version no. : | | 2.0 |
| Date: | | 2016 |
| Done by : (name / institution) | | Dte. GHS |
| **NAME AND CODING** | | |
| GMDN name | | Laryngoscopes |
| GMDN code | | CT1723 |
| GMDN definition | | A non-sterile, portable, battery-powered device intended to provide the light source for a laryngoscope (i.e., rigid intubation type) when fitted into the laryngoscope handle produces light for airway illumination using LED technology |
| **GENERAL** | | |
| **1** | USE | |
| **1.1** | **Clinical purpose** | For viewing vocal folds and glottis. Surgical and mechanical ventilation/intubation |
| **1.2** | **Used by clinical department/ward** | O.T / ICU / NICU/ Casualty |
| **1.3** | **Overview of functional requirements** | A light source on or via the blade illuminates the larynx to allow viewing and tube passage. The unit is handheld with internal batteries and has interchangeable, rigid blades of different sizes. |
| **TECHNICAL** | | |
| **2** | TECHNICAL CHARACTERISTICS | |
| **2.1** | **Technical characteristics (specific to this type of device)** | Laryngoscope should be reusable using the latest LED technology. The main body of the handle should incorporate an excellent grip even wearing a glove. The unit should allow the blade (macintosh) to be inserted easily & should provide a positive locking mechanism when moved in to the closed position. |
| **2.2** | **Settings** | NA |
| **2.3** | **User's interface** | Manual |
| **2.4** | **Software and/or standard of communication(where ever required)** | NA |
| **3** | PHYSICAL CHARACTERISTICS | |
| **3.1** | **Dimensions (metric)** | NA |
| **3.2** | **Weight (lbs, kg)** | Light weight (upto 500 gms including blade, handle and battery) |
| **3.3** | **Configuration** | Handheld unit, single piece when in use; External material to be of rust proof metal, On/off switch to be robust and easy to use; macintosh blades to be surgical grade stainless steel; Supplied in protective, enclosable case; |
| **3.4** | **Noise (in dBA), heat dissipation** | NA |
| **3.5** | **Mobility, portability** | Yes |
| **3.6** | **Others** | storage box should be provided |
| **4** | ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) | |
| **4.1** | **Power Requirements** | Battery |

| | | |
|---|---|---|
| **4.2** | **Battery operated** | Internal batteries rechargeable<br>Battery charger , Battery compartment (if reusable's) to be sealed against liquid ingress, yet easily opened. |
| **4.3** | **Tolerance (to variations, shutdowns)** | NA |
| **4.4** | **Protection** | NA |
| **4.5** | **Power consumption** | 3V lithium battery; 2nos. |
| **4.6** | **Other energy supplies** | |
| **5** | ACCESSORIES, SPARE PARTS, CONSUMABLES | |
| **5.1** | **Accessories (mandatory, standard, optional)** | Batteries, blades of all sizes 0,1,2,3,4,5 |
| **5.2** | **Spare parts (main ones)** | Handle |
| **5.3** | **Consumables / reagents (open, closed system)** | 3LED should be given as spare |
| **6** | ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS | |
| **6.1** | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.<br>Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.<br>Liquid splash resistant<br>Blades should be autoclavable |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | Complete unit to be easily washable and sterilizable using both alcohol and chemical agents. |
| **7** | STANDARDS AND SAFETY | |
| **7.1** | **Certificates** | US FDA/European CE and BIS/ISO 13485 |
| **7.3** | **Local and/or international** | Manufacturer / supplier should have ISO certificate for quality standard. |
| **8** | TRAINING AND INSTALLATION | |
| **8.1** | **Pre-installation requirements: nature, values, quality, tolerance** | NA |
| **8.2** | **Requirements for sign-off** | NA |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | NA |
| **9** | WARRANTY AND MAINTENANCE | |
| **9.1** | **Warranty** | 3 years ; LED upto 6 months |
| **9.2** | **Maintenance tasks** | NA |
| **9.3** | **Service contract clauses, including prices** | NA |
| **10** | DOCUMENTATION | |
| **10.1** | **Operating manuals, service manuals, other manuals** | User, technical and maintenance manuals to be supplied in English language along with machine diagrams. List to be provided for procedures required for routine maintenance |
| **10.2** | **Other accompanying documents** | NA |
| **11** | NOTES | |
| **11.1** | **Service Support Contact details (Hierchy Wise; including a toll free/landline number)** | NA |
| **11.2** | **Recommendations or warnings** | Any recommendations for best use and supplementary warning for safety should be declared |
| **11.3** | **Temperature Range** | Should be able to operate between – 32 degrees Centigrade to + 52 degrees Centigrade |

| MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to) | | |
|---|---|---|
| | | **Flowmeter with Humidifier bottle** |
| Version no. : | | 2.0 |
| Date: | | 2016 |
| Done by : (name / institution) | | Dte. GHS |
| | | NAME AND CODING |
| GMDN name | | Flowmeter and associated device |
| GMDN code(s) | | CT 623 |
| GMDN definition | | NA |
| | | **GENERAL** |
| **1** | | USE |
| **1.1** | **Clinical purpose** | flow meter unit is used for regulation and accurate measuring of flow of gasses |
| **1.2** | **Used by clinical department/ward** | All |
| | | TECHNICAL |
| **2** | | TECHNICAL CHARACTERISTICS |
| **2.1** | **Technical characteristics (specific to this type of device)** | Flowmeter: chromium plated brass body, metering tube and cover made of polycarbonate body, flow adjustment by needle valve equipped with inlet filter - 100 um, flow rate 0-15 litres per minute, flush flow 60 litres per minute, flow read by the centre of the ball, inlet pressure 60psi; Humidifier bottle: lid made of ABS plastic, Jar made of unbreakable Poly carbonate, valve pressure brass chromium plated, it should be steam autoclaved/gas sterilised<br>Inlet probe compatible with Oxygen system of the ambulance |
| **2.3** | **Settings** | to manage flow of oxygen through the knob from 0 to 15 LPM |
| **2.4** | **User's interface** | Manual |
| **2.5** | **Software and/or standard of communication(where ever required)** | NA |
| **3** | | PHYSICAL CHARACTERISTICS |
| **3.1** | **Dimensions (metric)** | for 200ml |
| **3.2** | **Weight (lbs, kg)** | as per standard |
| **3.3** | **Configuration** | NA |
| **3.4** | **Noise (in dBA), heat dissipation** | NA |
| **3.5** | **Mobility, portability** | Yes |
| **4** | | ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) |
| **4.1** | **Power Requirements** | NA |
| **4.2** | **Battery operated** | NA |
| **4.3** | **Tolerance (to variations, shutdowns)** | NA |

| | | |
|---|---|---|
| **4.4** | **Protection** | NA |
| **4.5** | **Power consumption** | NA |
| **4.6** | **Other energy supplies** | NA |
| **5** | | ACCESSORIES, SPARE PARTS, CONSUMABLES |
| **5.1** | **Accessories & Spares** | Stainless steel or brass chromium needle valve and outlet flow control valve |
| **5.3** | **Consumables / reagents (open, closed system)** | Crack resistant transparent tube of 1.5 MT. length |
| **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | | |
| **6** | ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS | |
| **6.1** | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | NA |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | Complete unit to be easily washable and sterilizable using alcohol and other chemical agents |
| **7** | STANDARDS AND SAFETY | |
| **7.1** | **Certifications** | complies with NFPA standard ; |
| **8** | TRAINING AND INSTALLATION | |
| **8.1** | **Pre-installation requirements: nature, values, quality, tolerance** | availability of oxygen outlet points |
| **8.2** | **Requirements for sign-off** | NA |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | NA |
| **9** | WARRANTY AND MAINTENANCE | |
| **9.1** | **Warranty** | One year |
| **9.2** | **Maintenance tasks** | Complete unit to be easily washable and sterilizable using both alcohol and chemical agents. |
| **9.3** | **Service contract clauses, including prices** | NA |
| **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/landline number)** | NA |
| **11.2** | **Recommendations or warnings** | NA |
| **11.3** | **Temperature Range** | Should be able to operate between – 32 degrees Centigrade to + 52 degrees Centigrade |

| MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to) | | |
|---|---|---|
| | **Oxygen cylinder "B" Type** | |
| Version no. : | | 2.0 |
| Date: | | 2016 |
| Done by : (name / institution) | | Dte. GHS |
| **NAME AND CODING** | | |
| GMDN name | | Oxygen cylinder |
| GMDN code | | CT 659 |
| GMDN definition | | A container designed as a refillable cylinder used to hold compressed medical oxygen (O2) under safe conditions at high pressure (e.g., 50 - 200 Bar). It is typically filled with O2 when delivered from the gas supplier and includes a valve stem, an opening/closing valve, and will be graded according to size (capacity) and colour-coded to denote O2 content. The cylinder may be made of steel or other ferrous or non-ferrous materials and must be used together with a pressure regulator in order to release the O2 at the correct working pressure. O2 is used as an essential life support gas, for anaesthesia, and for therapeutic purposes. |
| **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 anaesthesia, and for therapeutic purposes. |
| **1.2** | **Used by clinical department/ward** | All |
| **TECHNICAL** | | |
| **2** | TECHNICAL CHARACTERISTICS | |
| **2.1** | **Technical characteristics (specific to this type of device)** | 1. Colour coded, light weight molybdenum steel oxygen cylinder for providing oxygen therapy of total capacity of 4 cu M. 2. Mounted with pressure reducer and flow-meter provision of capacity upto 15 Litres per minutes and outlet for secretion aspiration. 3. Should have membrane pressure regulator with manometer complete with flow meter (0-15 litres /minute) and humidifier bottle. 4. The cylinder should be seamless |
| **2.2** | **Settings** | flowmeter as specified earlier |
| **2.3** | **User's interface** | manual |
| **2.4** | **Software and/or standard of communication(where ever required)** | NA |
| **3** | PHYSICAL CHARACTERISTICS | |
| **3.1** | **Dimensions (metric)** | to contain capacity of 4 cu M |
| **3.2** | **Weight (lbs, kg)** | NA |
| **3.3** | **Configuration** | NA |
| **3.4** | **Noise (in dBA), heat dissipation** | NA |
| **3.5** | **Mobility, portability** | Yes; for Ambulances - to be supplied bare without trolley |
| **4** | ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) | |

| | | |
|---|---|---|
| **4.1** | **Power Requirements** | NA |
| **4.2** | **Battery operated** | NA |
| **4.3** | **Tolerance (to variations, shutdowns)** | NA |
| **4.4** | **Protection** | NA |
| **4.5** | **Power consumption** | NA |
| **5** | | ACCESSORIES, SPARE PARTS, CONSUMABLES |
| **5.1** | **Accessories & Spares** | humidifier, key and flow meter |
| **5.3** | **Consumables / reagents (open, closed system)** | NA |
| **6** | | ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS |
| **6.1** | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | NA |
| **7** | | Certificates (pre-market, sanitary, ..) |
| **7.1** | **Certifications** | Cylinder should have ISI mark and ISO certificate for quality standard or BIS equivalent; IS 3224. 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, NFPA 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 |
| **9.2** | **Maintenance tasks** | NA |
| **9.3** | **Service contract clauses, including prices** | NA |
| **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/landline number)** | NA |
| **11.2** | **Recommendations or warnings** | Colour Codes to be displayed on the cylinders |
| **11.3** | **Temperature Range** | Should be able to operate between – 32 degrees Centigrade to + 52 degrees Centigrade |

| MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to) | | |
|---|---|---|
| **Oxygen cylinder "D" Type** | | |
| Version no. : | | 2.0 |
| Date: | | 2016 |
| Done by : (name / institution) | | Dte. GHS |
| **NAME AND CODING** | | |
| GMDN name | | Medical gas cylinders |
| GMDN category Code | | CT 659 |
| GMDN definition | | A container designed as a refillable cylinder used to hold compressed medical oxygen (O2) under safe conditions at high pressure (e.g., 50 - 200 Bar). It is typically filled with O2 when delivered from the gas supplier and includes a valve stem, an opening/closing valve, and will be graded according to size (capacity) and colour-coded to denote O2 content. The cylinder should be made of molybdenum steel and must be used together with a pressure regulator in order to release the O2 at the correct working pressure. O2 is used as an essential life support gas, for anaesthesia, and for therapeutic purposes |
| **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 anaesthesia, and for therapeutic purposes. |
| **1.2** | **Used by clinical department/ward** | All |
| **TECHNICAL** | | |
| **2** | TECHNICAL CHARACTERISTICS | |
| **2.1** | **Technical characteristics (specific to this type of device)** | 1. It should be a standard „D' type molybdenum steel cylinder. 2. The capacity should be of approx 7 cu mt. at pressure of 1800 - 2000ibs/square inch. 3. A pressure regulator/flow meter capable of reducing the pressure to appropriate level to run either a ventilator or provide oxygen therapy. 4. should be seamless |
| **2.2** | **Settings** | NA |
| **2.3** | **User's interface** | manual |
| **2.4** | **Software and/or standard of communication(where ever required)** | NA |
| **3** | PHYSICAL CHARACTERISTICS | |
| **3.1** | **Dimensions (metric)** | The capacity should be of 5000 to 6000 Liters at pressure of 1800 – 2000 lbs/square inch |
| **3.2** | **Weight (lbs, kg)** | NA |
| **3.3** | **Configuration** | NA |
| **3.4** | **Noise (in dBA), heat dissipation** | NA |
| **3.5** | **Mobility, portability** | NA |
| **4** | ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) | |
| **4.1** | **Power Requirements** | NA |
| **4.2** | **Battery operated** | NA |
| **4.3** | **Tolerance (to variations, shutdowns)** | NA |

| | | |
|---|---|---|
| **4.4** | **Protection** | NA |
| **4.5** | **Power consumption** | NA |
| **5** | ACCESSORIES, SPARE PARTS, CONSUMABLES | |
| **5.1** | **Accessories & Spares** | Cylinder key |
| **5.3** | **Consumables / reagents (open, closed system)** | NA |
| **6** | ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS | |
| **6.1** | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | NA |
| **7** | Certificates (pre-market, sanitary, ..) | |
| **7.1** | **Certifications** | Cylinder should have ISI mark and ISO certificate for quality standard or BIS equivalent; IS 3224, and NFPA certificate. 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, NFPA 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 |
| **9.2** | **Maintenance tasks** | NA |
| **9.3** | **Service contract clauses, including prices** | NA |
| **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 (Hierarchy Wise; including a toll free/landline number)** | NA |
| **11.2** | **Recommendations or warnings** | Colour Codes to be displayed on the cylinders |
| **11.3** | **Temperature Range** | Should be able to operate between – 32 degrees Centigrade to + 52 degrees Centigrade |

| MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to) | | |
|---|---|---|
| **Bag and Mask Ventilation Device (Adult)** | | |
| Version no. : | | 2.0 |
| Date: | | 2016 |
| Done by : (name / institution) | | Dte. GHS |
| **NAME AND CODING** | | |
| GMDN name | | Resuscitators |
| GMDN code | | CT 1899 |
| GMDN definition | | A hand-operated device designed to provide or assist ventilation in patients who are apnoeic or exhibit inadequate respiration. It typically employs entrained ambient air and includes a large flexible chamber that is hand-ventilated, a gas reservoir, tubing, and a connector for attachment to a mask or endotracheal (ET) tube; oxygen (O2) from an O2 source may also be connected when necessary. It is used by emergency medical services (EMS) in ambulances, intensive care units (ICU), during internal patient transfer, accident and emergency (A&E), mass casualty incidents (MCI), and is generally placed strategically throughout a hospital. This is a reusable device. |
| **GENERAL** | | |
| **1** | USE | |
| **1.1** | **Clinical purpose** | to provide or assist ventilation in a patient who is apnoeic or exhibits inadequate respiration through manual pulmonary-driven pressure cycle functions. |
| **1.2** | **Used by clinical department/ward** | It is used in ambulances, intensive care units (ICU), during internal patient transfer, accident and emergency (A&E), and mass casualty incidents (MCI). |
| **TECHNICAL** | | |
| **2** | TECHNICAL CHARACTERISTICS | |
| **2.1** | **Technical characteristics** | 1. Easy Grip manual resuscitator with transparent face-mask; 2. Adult models (1500 to 2000ml bag capacity); 3.Standard 15-22 mm Swivel connector allows connections to all common masks & Endotracheal Tubes; 4. Provision to give supplemented oxygen-by-oxygen reservoir providing 100% oxygen; 5.Non-re breathing valve enabling the patient to inspire oxygen from the reservoir bag; 6. Unit should be of medical grade silicon material (mask) excluding reservoir |
| **2.2** | **Settings** | manual |
| **2.3** | **User's interface** | manual |
| **2.4** | **Software and/or standard of communication(where ever required)** | NA |
| **3** | PHYSICAL CHARACTERISTICS | |
| **3.1** | **Dimensions (metric)** | Handheld |
| **3.2** | **Weight (lbs, kg)** | light enough to be operated by hand/palm for long duration |
| **3.3** | **Configuration** | NA |
| **3.4** | **Noise (in dBA), heat dissipation** | NA |
| **3.5** | **Mobility, portability** | handheld |

| | | |
|---|---|---|
| **3.6** | **Others** | |
| **4** | ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) | |
| **4.1** | **Power Requirements** | NA |
| **4.2** | **Battery operated** | NA |
| **4.3** | **Tolerance (to variations, shutdowns)** | NA |
| **4.4** | **Protection** | NA |
| **4.5** | **Power consumption** | NA |
| **4.6** | **Other energy supplies** | NA |
| **5** | ACCESSORIES, SPARE PARTS, CONSUMABLES | |
| **5.1** | **Accessories & Spares** | Silicon bellow, Non Re-breathing Valve, |
| **5.2** | **Consumables / reagents (open, closed system)** | Adult Mask - 3,4,5 size(3 nos. of each size), 1 meter oxygen tube, Guedel Airway- 3,4,5 size (3nos. each), Oxygen Reservoir bag |
| **6** | ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS | |
| **6.1** | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | Complete unit to be easily washable and sterilizable using both alcohol and any other chemical agents. |
| **7** | STANDARDS AND SAFETY | |
| **7.1** | **Certifications** | FDA(US)/CE(EU) and BIS/ISO 13485:2003 |
| **8** | TRAINING AND INSTALLATION | |
| **8.1** | **Pre-installation requirements: nature, values, quality, tolerance** | Bag for storage |
| **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 |
| **9.2** | **Maintenance tasks** | NA |
| **9.3** | **Service contract clauses, including prices** | NA |
| **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 (Hierarchy Wise; including a toll free/landline number)** | NA |
| **11.2** | **Recommendations or warnings** | NA |
| **11.3** | **Temperature Range** | Should be able to operate between – 32 degrees Centigrade to + 52 degrees Centigrade |

| MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to) | | |
|---|---|---|
| **Bag and Mask Ventilation device (Child & Neonatal)** | | |
| Version no. : | | 2.0 |
| Date: | | 2016 |
| Done by : (name / institution) | | Dte. GHS |
| **NAME AND CODING** | | |
| GMDN name | | Resuscitators |
| GMDN code | | CT1899 |
| GMDN definition | | A hand-operated device designed to provide or assist ventilation in patients who are apnoeic or exhibit inadequate respiration. It typically employs entrained ambient air and includes a large flexible chamber that is hand-ventilated, a gas reservoir, tubing, and a connector for attachment to a mask or endotracheal (ET) tube; oxygen (O2) from an O2 source may also be connected when necessary. It is used by emergency medical services (EMS) in ambulances, intensive care units (ICU), during internal patient transfer, accident and emergency (A&E), mass casualty incidents (MCI), and is generally placed strategically throughout a hospital. This is a reusable device. |
| **GENERAL** | | |
| **1** | USE | |
| **1.1** | **Clinical purpose** | to provide or assist ventilation in a patient who is apnoeic or exhibits inadequate respiration through manual pulmonary-driven pressure cycle functions. |
| **1.2** | **Used by clinical department/ward** | It is used in ambulances, intensive care units (ICU), during internal patient transfer, accident and emergency (A&E), and mass casualty incidents (MCI). |
| **TECHNICAL** | | |
| **2** | TECHNICAL CHARACTERISTICS | |
| **2.1** | **Technical characteristics** | 1. Easy Grip manual resuscitator with transparent face-mask; 2.Child models (500 to 250ml bag capacity); 3. Standard 15-22 mm Swivel connector allows connections to all common masks Endotracheal Tubes; 4. Provision to give supplemented oxygen-by-oxygen reservoir providing 100% oxygen; 5. Non-re breathing valve enabling the patient to inspire oxygen from the reservoir bag.<br>6. Device should be made of silicon except reservoir |
| **2.2** | **Settings** | Manual |
| **2.3** | **User's interface** | Manual |
| **2.4** | **Software and/or standard of communication(where ever required)** | NA |
| **3** | PHYSICAL CHARACTERISTICS | |
| **3.1** | **Dimensions (metric)** | handheld |
| **3.2** | **Weight (lbs, kg)** | light enough to be operated by hand/palm for long duration |
| **3.3** | **Configuration** | NA |
| **3.4** | **Noise (in dBA), heat dissipation** | NA |
| **3.5** | **Mobility, portability** | handheld |
| **3.6** | **Others** | |
| **4** | ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) | |

| | | |
|---|---|---|
| **4.1** | **Power Requirements** | NA |
| **4.2** | **Battery operated** | NA |
| **4.3** | **Tolerance (to variations, shutdowns)** | NA |
| **4.4** | **Protection** | NA |
| **4.5** | **Power consumption** | NA |
| **4.6** | **Other energy supplies** | NA |
| **5** | | ACCESSORIES, SPARE PARTS, CONSUMABLES |
| **5.1** | **Accessories & Spares** | silicon bellow, Non Re - breathing Valve |
| **5.2** | **Consumables / reagents (open, closed system)** | Mask (0,1,2 sizes; 3 sets), Oxygen Reservoir bag, 1 meter oxygen tube, Guedel Airway(0,1,2 sizes; 3 sets) |
| **6** | | ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS |
| **6.1** | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | Complete unit to be easily washable and sterilizable using both alcohol and other chemical agents. |
| **7** | | STANDARDS AND SAFETY |
| **7.1** | **Certifications** | FDA(US)/CE(EU) and BIS/ISO 13485:2003 |
| **8** | | TRAINING AND INSTALLATION |
| **8.1** | **Pre-installation requirements: nature, values, quality, tolerance** | Bag for storage should be supplied |
| **8.2** | **Requirements for sign-off** | Certificate of Calibration and inspection from the factory. |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | NA |
| **9** | | WARRANTY AND MAINTENANCE |
| **9.1** | **Warranty** | 1 Year |
| **9.2** | **Maintenance tasks** | NA |
| **9.3** | **Service contract clauses, including prices** | NA |
| **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 (Hierarchy Wise; including a toll free/landline number)** | NA |
| **11.2** | **Recommendations or warnings** | NA |
| **11.3** | **Temperature Range** | Should be able to operate between – 32 degrees Centigrade to + 52 degrees Centigrade |

| MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to) | | |
|---|---|---|
| **Trolley Stretcher- with back tilt facility and collapsible wheels** | | |
| Version no. : | 2.0 | |
| Date: | 2016 | |
| Done by : (name / institution) | Dte. GHS | |
| **NAME AND CODING** | | |
| GMDN name | Ambulance stretcher, manual | |
| GMDN code(s) | CT1934 | |
| GMDN definition | A manually-operated device consisting of a platform mounted on a wheeled frame designed for use by emergency medical services (EMS) primarily to facilitate easy transport of a recumbent patient to and from ambulance vehicles (e.g., automobiles, aeroplanes, helicopters, boats). It is typically constructed of lightweight materials and has an undercarriage that opens and folds when it is removed from or pushed into the ambulance; it also usually includes locking devices that match with the locking/docking devices in the ambulance | |
| **GENERAL** | | |
| **1** | USE | |
| **1.1** | **Clinical purpose** | It is designed for use by emergency medical services (EMS) primarily to facilitate easy transport of a recumbent patient to and from ambulance vehicles |
| **TECHNICAL** | | |
| **2** | TECHNICAL CHARACTERISTICS | |
| **2.1** | **Technical characteristics (specific to this type of device)** | 1. Automatic loading stretcher cum trolley.<br>2. Built with anodized aluminium lightweight / stainless steel.<br>3. Adjustable back rest 0 dg -90 dg which allows to fix the back rest safety in any position.<br>4. Side protections completely overturn able with easy locking safety belts flap type.<br>5. Safety lever for the legs positioned near the unlocking device allowing thus the release operation for the loading, keeping the hands on the stretcher. 6. Vertical legs protected by nylon wedges.<br>7. Automatic centering device mounted on rotating wheels. This system automatically blocks the back wheels in the central position during the loading of the stretcher on the ambulance without having turn the wheels manually.<br>8. Stand for automatic loading stretcher with locking facility for quick fixing system with handle to mount the stand in very position on the stretcher.<br>9. One number of IV pole of adjustable height should be provided.<br>10. Head end of the trolley should be easily identifiable |
| **2.2** | **Settings** | NA |
| **2.3** | **User's interface** | NA |
| **2.4** | **Software and/or standard of communication(where ever required)** | NA |
| **3** | PHYSICAL CHARACTERISTICS | |
| **3.1** | **Dimensions (metric)** | Length; 190-210 cm; Width: 50-60cm; Height: 80-85cm; wheel/bearing size: 6 to 8 inch |
| **3.2** | **Weight (lbs, kg)** | Weight 35-45 kg; Loading Capacity: up to 180 kgs |

| | | |
|---|---|---|
| **3.3** | **Configuration** | NA |
| **3.4** | **Noise (in dBA), heat dissipation** | NA |
| **3.5** | **Mobility, portability** | yes on castors(functional for minimum of 3 years; suitable for rough use) compatible with rails of the ambulance |
| **4** | | ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) |
| **4.1** | **Power Requirements** | NA |
| **4.2** | **Battery operated** | NA |
| **4.3** | **Tolerance (to variations, shutdowns)** | NA |
| **4.4** | **Protection** | NA |
| **4.5** | **Power consumption** | NA |
| **4.6** | **Other energy supplies** | NA |
| **5** | | ACCESSORIES, SPARE PARTS, CONSUMABLES |
| **5.1** | **Accessories (mandatory, standard, optional)** | Stand for loading stretcher- removable |
| **5.2** | **Spare parts (main ones)** | Castors, Safety lever; anti static mattress (at least 2.5" thick, stain proof, suitable for rough use, tear resistant, high density material) with 3 years warranty |
| **5.3** | **Consumables / reagents (open, closed system)** | NA |
| **5.4** | **Others** | |
| **6** | | ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS |
| **6.1** | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | NA |
| **7** | | STANDARDS AND SAFETY |
| **7.1** | **Certificates (pre-market, sanitary, ..)Performance and safety standards (specific to the device type);Local and/or international** | FDA(US)/CE(EU) and BIS/ISO 13485:2003 |
| **8** | | TRAINING AND INSTALLATION |
| **8.1** | **Pre-installation requirements: nature, values, quality, tolerance** | Supplier to perform safety and operation checks before handover. |

| | | |
|---|---|---|
| **8.2** | **Requirements for sign-off** | Certificate of inspection from the factory. |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided |
| **9** | | WARRANTY AND MAINTENANCE |
| **9.1** | **Warranty** | 3 years |
| **9.2** | **Maintenance tasks** | maintenance manual detailing complete maintaining schedule |
| **9.3** | **Service contract clauses, including prices** | |
| **10** | | DOCUMENTATION |
| | | Required- along with diagrammatic maintenance manual |
| **10.1** | **Operating manuals, service manuals, other manuals** | |
| **11** | | NOTES |
| **11.1** | **Service Support Contact details (Hierarchy Wise; including a toll free/landline number)** | should provide complete contact details of sales and service departments. |
| **11.2** | **Recommendations or warnings** | Any warning should be displayed |
| **11.3** | **Temperature Range** | Should be able to operate between – 32 degrees Centigrade to + 52 degrees Centigrade |

| MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to) | | |
|---|---|---|
| **Canvas Stretcher folding** | | |
| Version no. : | | 2.0 |
| Date: | | 2016 |
| Done by : (name / institution) | | Dte. GHS |
| **NAME AND CODING** | | |
| GMDN name | | Stretchers and associated devices |
| GMDN category | | CT 674 |
| GMDN definition | | NA |
| **GENERAL** | | |
| **1** | USE | |
| **1.1** | **Clinical purpose** | It is designed for use by emergency medical services (EMS) primarily to facilitate easy transport of a recumbent patient to and from ambulance vehicles |
| **1.2** | **Used by clinical department/ward** | ALL |
| **1.4** | **Overview of functional requirements** | |
| **TECHNICAL** | | |
| **2** | TECHNICAL CHARACTERISTICS | |
| **2.1** | **Technical characteristics (specific to this type of device)** | 1.Should be lightweight stretcher frame 2. Should be easy to carry. 3. Should be rugged. 4. Should be compact & foldable. 5. Should have automatic locking, which does not fold in automatically. 6. Canvas used should be High strength light weight material. |
| **2.2** | **Settings** | NA |
| **2.3** | **User's interface** | NA |
| **2.4** | **Software and/or standard of communication(where ever required)** | NA |
| **3** | PHYSICAL CHARACTERISTICS | |
| **3.1** | **Dimensions (metric)** | Length: 200-210 cm; Width: 50-60cm; Height: 15-20cm from the base level |
| **3.2** | **Weight (lbs, kg)** | less than 6 kg |
| **3.3** | **Configuration** | NA |
| **3.4** | **Noise (in dBA), heat dissipation** | NA |
| **3.5** | **Mobility, portability** | Yes |
| **4** | ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) | |
| **4.1** | **Power Requirements** | NA |
| **4.2** | **Battery operated** | NA |
| **4.3** | **Tolerance (to variations, shutdowns)** | NA |
| **4.4** | **Protection** | NA |
| **4.5** | **Power consumption** | NA |
| **4.6** | **Other energy supplies** | NA |
| **5** | ACCESSORIES, SPARE PARTS, CONSUMABLES | |

| | | |
|---|---|---|
| **5.1** | **Accessories (mandatory, standard, optional)** | None |
| **5.2** | **Spare parts (main ones)** | None |
| **5.3** | **Consumables / reagents (open, closed system)** | None |
| **6** | ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS | |
| **6.1** | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | NA |
| **7** | STANDARDS AND SAFETY | |
| **7.1** | **Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international** | ISO 13485 |
| **8** | TRAINING AND INSTALLATION | |
| **8.1** | **Pre-installation requirements: nature, values, quality, tolerance** | Supplier to perform safety and operation checks before handover. |
| **8.2** | **Requirements for sign-off** | Certificate of inspection from the factory. |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided |
| **9** | WARRANTY AND MAINTENANCE | |
| **9.1** | **Warranty** | 1 years |
| **9.2** | **Maintenance tasks** | Maintenance manual detailing complete maintaining schedule |
| **9.3** | **Service contract clauses, including prices** | |
| **10** | DOCUMENTATION | |
| **10.1** | **Operating manuals, service manuals, other manuals** | Advanced maintenance tasks required shall be documented<br>User, technical and maintenance manuals to be supplied in English language along with machine diagrams.<br>List to be provided for procedures required for routine maintenance |
| **10.2** | **Other accompanying documents** | |
| **11** | NOTES | |
| **11.1** | **Service Support Contact details (Hierarchy Wise; including a toll free/landline number)** | NA |
| **11.2** | **Recommendations or warnings** | Any recommendations for best use and supplementary warning for safety should be declared |
| **11.3** | **Temperature Range** | Should be able to operate between – 32 degrees Centigrade to + 52 degrees Centigrade |

| MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to) | | |
|---|---|---|
| | **Stretcher Scoop** | |
| Version no. : | | 2.0 |
| Date: | | 2016 |
| Done by : (name / institution) | | Dte. GHS |
| **NAME AND CODING** | | |
| GMDN name | | Stretchers and associated devices |
| GMDN code(s) | | CT 674 |
| GMDN definition | | NA |
| | | GENERAL |
| **1** | USE | |
| **1.1** | **Clinical purpose** | It is most frequently used to lift supine patients from the ground, either due to unconsciousness or in order to maintain stability in the case of trauma, especially spinal injury, where it is used as an intermediate step between the ground and a restraining device such as a long spine board or vacuum mattress. |
| **1.2** | **Used by clinical department/ward** | Emergency |
| **TECHNICAL** | | |
| **2** | TECHNICAL CHARACTERISTICS | |
| **2.1** | **Technical characteristics (specific to this type of device)** | 1. The equipment shall be lightweight aluminium stretcher, which folds into two and separates for application and removal, locking adjustable length with latches-with nylon-straps 2. Narrow foot end frame for handling in confined areas |
| **2.3** | **Settings** | NA |
| **2.4** | **User's interface** | manual |
| **2.5** | **Software and/or standard of communication(where ever required)** | NA |
| **3** | PHYSICAL CHARACTERISTICS | |
| **3.1** | **Dimensions (metric)** | Length: 160 to 200 cms; Width: 42 cm (Minimum); |
| **3.2** | **Weight (lbs, kg)** | Weight: < 10 kg; Load capacity -120 kg (Min) |
| **3.3** | **Configuration** | NA |
| **3.4** | **Noise (in dBA), heat dissipation** | NA |
| **3.5** | **Mobility, portability** | Yes |
| **4** | ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) | |
| **4.1** | **Power Requirements** | NA |
| **4.2** | **Battery operated** | NA |
| **4.3** | **Tolerance (to variations, shutdowns)** | NA |
| **4.4** | **Protection** | NA |
| **4.5** | **Power consumption** | NA |
| **4.6** | **Other energy supplies** | NA |
| **5** | ACCESSORIES, SPARE PARTS, CONSUMABLES | |
| **5.1** | **Accessories (mandatory, standard, optional)** | NA |
| **5.2** | **Spare parts (main ones)** | NA |

| | | |
|---|---|---|
| **5.3** | **Consumables / reagents (open, closed system)** | NA |
| **6** | ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS | |
| **6.1** | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | NA |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | NA |
| **7** | STANDARDS AND SAFETY | |
| **7.1** | **Certifications** | ISO 13485/BIS and European CE/US FDA |
| **8** | TRAINING AND INSTALLATION | |
| **8.1** | **Pre-installation requirements: nature, values, quality, tolerance** | Supplier to perform safety and operation checks before handover. |
| **8.2** | **Requirements for sign-off** | Certificate of inspection from the factory. |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided |
| **9** | WARRANTY AND MAINTENANCE | |
| **9.1** | **Warranty** | 5 years |
| **9.2** | **Maintenance tasks** | maintenance manual detailing complete maintaining schedule |
| **9.3** | **Service contract clauses, including prices** | |
| **10** | DOCUMENTATION | |
| **10.1** | **Operating manuals, service manuals, other manuals** | Advanced maintenance tasks required shall be documented<br>User, technical and maintenance manuals to be supplied in english language along with machine diagrams.<br>List to be provided for procedures required for routine maintenance |
| **10.2** | **Other accompanying documents** | List to be provided 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)** | NA |
| **11.2** | **Recommendations or warnings** | Any recommendations for best use and supplimentary warning for safety should be declared |
| **11.3** | **Temperature Range** | Should be able to operate between – 32 degrees Centigrade to + 52 degrees Centigrade |

| MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to) | | |
|---|---|---|
| **BP Instrument Aneroid** | | |
| Version no. : | | 2.0 |
| Date: | | 2016 |
| Done by : (name / institution) | | Dte. GHS |
| | | NAME AND CODING |
| GMDN name | | Sphygmomanometers |
| GMDN code(s) | | CT1677 |
| GMDN definition | | A device designed to measure blood pressure consisting of an inflatable cuff that fits around a limb (arm or thigh), an inflation bulb for controlling the air pressure within the cuff, an aneroid manometer, and tubing. The aneroid manometer consists of a metal bellows, which expands as the pressure in the cuff increases, and a mechanical amplifier that transmits this expansion through a lever to an indicator needle, which rotates around a circular, calibrated scale. The manometer may be mounted to a wall, placed on a table, or hand held (portable); blood pressure measurement is taken in conjunction with a stethoscope. |
| **GENERAL** | | |
| **1** | | USE |
| **1.1** | **Clinical purpose** | to measure non invasive blood pressure |
| **1.2** | **Used by clinical department/ward** | All |
| **1.4** | **Overview of functional requirements** | |
| | | TECHNICAL |
| **2** | | TECHNICAL CHARACTERISTICS |
| **2.1** | **Technical characteristics (specific to this type of device)** | Scale 0-300 mm hg. Air release at closed lap with maximum 4mmHg/Minute. Manual setting of deflation possible upto 2/3mm Hg/sec. From 260mmHg. To 15mm Hg in a maximum deflation time of 10 seconds. Gauge's background in white colour. Graduated scale for ever/ 2mmhg, every 10 units and every 20 units. Nylon straps cuff with pouch, latex bulb with completely chromium plated valve with regulation of vent-hole air by screw valve. Additional provision of panel dial with standard size (diameter) of the dial |
| **2.2** | **Settings** | The cuff is inflated just to fit in the limb for which an inflation bulb is used to control the air pressure within the cuff. |
| **2.3** | **User's interface** | manual |
| **2.4** | **Software and/or standard of communication(where ever required)** | NA |
| **3** | | PHYSICAL CHARACTERISTICS |
| **3.1** | **Dimensions (metric)** | The rubber tubes used should have an internal diameter of 3 ± 0.5mm and the external diameter should not be less than 8mm; The dial mano meter with minimum diameter of 160 mm |
| **3.2** | **Weight (lbs, kg)** | NA |
| **3.3** | **Configuration** | NA |
| **3.4** | **Noise (in dBA), heat dissipation** | NA |

| | | |
|---|---|---|
| **3.5** | **Mobility, portability** | Yes |
| **4** | | ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) |
| **4.1** | **Power Requirements** | NA |
| **4.2** | **Battery operated** | NA |
| **4.3** | **Tolerance (to variations, shutdowns)** | NA |
| **4.4** | **Protection** | NA |
| **4.5** | **Power consumption** | NA |
| **4.6** | **Other energy supplies** | NA |
| **5** | | ACCESSORIES, SPARE PARTS, CONSUMABLES |
| **5.1** | **Accessories (mandatory, standard, optional)** | one extra pair of adult( both medium & large size of adult) and paediatric arm cuffs size, inflation bulb and tubing(one extra pair) |
| **5.2** | **Spare parts (main ones)** | dial manometer |
| | | NA |
| **5.3** | **Consumables / reagents (open, closed system)** | |
| **6** | | ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS |
| **6.1** | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | The unit should be cleanable with alcohol |
| **7** | | STANDARDS AND SAFETY |
| **7.1** | **Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international** | ISO 13485 certified company and the instrument should have ISI mark. The parts shall be made of natural or artificial rubber. |
| **8** | | TRAINING AND INSTALLATION |
| **8.1** | **Pre-installation requirements: nature, values, quality, tolerance** | Supplier to perform safety and operation checks before handover. |
| **8.2** | **Requirements for sign-off** | Certificate of inspection from the factory. |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided |
| **9** | | WARRANTY AND MAINTENANCE |
| **9.1** | **Warranty** | 1 years |
| **9.2** | **Maintenance tasks** | Maintenance manual detailing complete maintaining schedule |
| **9.3** | **Service contract clauses, including prices** | |
| **10** | | DOCUMENTATION |
| **10.1** | **Operating manuals, service manuals, other manuals** | User, technical and maintenance manuals to be supplied in english language along with machine diagrams.<br>List to be provided for procedures required for routine maintenance |
| **10.2** | **Other accompanying documents** | |
| **11** | | NOTES |

| | | |
|---|---|---|
| **11.1** | **Service Support Contact details (Hierarchy Wise; including a toll free/landline number)** | NA |
| **11.2** | **Recommendations or warnings** | Any recommendations for best use and supplementary warning for safety should be declared |
| **11.3** | **Temperature Range** | Should be able to operate between – 32 degrees Centigrade to + 52 degrees Centigrade |

| **MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to)** | |
|---|---|
| **Stethoscope** | |
| Version no. : | 2.0 |
| Date: | 2016 |
| Done by : (name / institution) | Dte. GHS |
| | NAME AND CODING |
| GMDN name | Stethoscopes |
| GMDN code(s) | CT1930 |
| GMDN definition | A mechanical listening device designed for listening to sounds from the heart, lungs, and/or gastrointestinal tract. It typically comprises a membrane at the listening head connected by a split "Y" tube to the headgear with ear olives that are placed into the users ears. |

| **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 |
| | | TECHNICAL |
| **2** | | TECHNICAL CHARACTERISTICS |
| **2.1** | **Technical characteristics (specific to this type of device)** | 1. Stethoscope should amplify sounds below 100Hz and attenuate sounds above 200Hz.<br>2. Designed to transmit low frequency sounds in the range of 30-1000Hz.<br>3. Provide amplifications of between 10 to 15 dB, with the best performance in the frequency range of human auscultation sounds (30 Hz)<br>4. Ear pieces made of soft gel or rubber. High quality flexible diaphragm made of plastic or epoxy fibreglass compound, capable of good contact with skin. Tube made of thick PVC or latex rubber. Dual head (with bell) made of stainless steel (aluminium not acceptable). No air leakage between examiner's air and diaphragm of the stethoscope.<br>5. Good performance and characteristics in the following areas:<br>a. Loudness- the perceived amplitude of the sound<br>b. clarity- the ability to distinguish diagnostic cardiac sounds such as vulvular clicks c. Ergonomics- the ease of use.<br>6. Elimination of noise artifacts or external noise interference. |
| **2.2** | **Settings** | NA |
| **2.3** | **User's interface** | manual |
| **2.4** | **Software and/or standard of communication(where ever required)** | NA |
| **2.5** | **Others** | NA |

| | | |
|---|---|---|
| **3** | | PHYSICAL CHARACTERISTICS |
| **3.1** | **Dimensions (metric)** | Diaphragm approx: 20 mm, length between 54.1cm to 78.7 cm. |
| **3.2** | **Weight (lbs, kg)** | 70gm to 240gm |
| **3.3** | **Configuration** | NA |
| **3.4** | **Noise (in dBA)** | NA |
| **3.5** | **heat dissipation** | NA |
| **3.6** | **Mobility, portability** | Portable |
| **4** | | ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) |
| **4.1** | **Power Requirements** | NA |
| **4.2** | **Battery operated** | NA |
| **4.3** | **Tolerance (to variations, shutdowns)** | NA |
| **4.4** | **Protection** | NA |
| **4.5** | **Power consumption** | NA |
| **4.6** | **Other energy supplies** | NA |
| **5** | | ACCESSORIES, SPARE PARTS, CONSUMABLES |
| **5.1** | **Accessories& Spares** | 1 x spare set of earpiece, 1 x spare diaphram, |
| **5.2** | **Consumables / reagents (open, closed system)** | NA |
| **5.3** | **Others** | NA |
| **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | | |
| **6** | ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS | |
| **6.1** | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | The unit should be cleanable with alcohol |
| **6.3** | **Others** | NA |
| **7** | STANDARDS AND SAFETY | |
| **7.1** | **Certifications** | by ISO 9001 certified manufacturer and the device should comply to IS 3391 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 |
| **8.4** | **Others** | NA |
| **9** | WARRANTY AND MAINTENANCE | |
| **9.1** | **Warranty** | 1 year |

| | | |
|---|---|---|
| **9.2** | **Maintenance tasks** | NA |
| **9.3** | **Service contract clauses, including prices** | NA |
| **9.4** | **Others** | NA |
| **10** | DOCUMENTATION | |
| **10.1** | **Operating manuals, service manuals, other manuals** | NA |
| **10.2** | **Other accompanying documents** | NA |
| **10.3** | **Recommendations for maintenance** | NA |
| **10.4** | **Others** | NA |
| **11** | NOTES | |
| **11.1** | **Service Support Contact details (Hierarchy Wise; including a toll free/landline number)** | NA |
| **11.2** | **Recommendations or warnings** | NA |
| **11.3** | **Temperature Range** | Should be able to operate between – 32 degrees Centigrade to + 52 degrees Centigrade |

| MEDICAL DEVICE SPECIFICATION<br>(Including Information on the following where relevant/appropriate, but not limited to) | | |
|---|---|---|
| **Pneumatic Splints** | | |
| Version no. : | | 2.0 |
| Date: | | 2016 |
| Done by : (name / institution) | | Dte. GHS |
| **NAME AND CODING** | | |
| GMDN name | | Splints |
| GMDN code(s) | | CT665 |
| GMDN definition | | A non-sterile sleeve intended to be placed around an arm or leg and inflated to immobilize and protect the limb. It is typically used by emergency medical services (EMS) as a temporary measure in emergencies, e.g., accidents and motor vehicle crashes, to stabilize the limb for transport to a hospital. This is a reusable device |
| **GENERAL** | | |
| **1** | USE | |
| **1.1** | **Clinical purpose** | to immobilize the limb for transport to a hospital |
| **1.2** | **Used by clinical department/ward** | Emergency Services |
| **1.3** | **Overview of functional requirements** | |
| **TECHNICAL** | | |
| **2** | TECHNICAL CHARACTERISTICS | |
| **2.1** | **Technical characteristics (specific to this type of device)** | 1.X-ray should be possible through the splints (Radio-transparency);<br>2.Inflatory tubes' extension with dosing damp makes dosing easy and quick after inflation;<br>3.Fixing of splint is by zipper or belt;<br>4.Distal end left open to expose toes;<br>5.Should be washable and reusable<br>6. Weather Proof<br>7. Material: Neoprene rubber |
| **2.3** | **Settings** | Fixing of splint is by zipper or belt |
| **2.4** | **User's interface** | Manual |
| **2.5** | **Software and/or standard of communication(where ever required)** | NA |
| **3** | PHYSICAL CHARACTERISTICS | |
| **3.1** | **Dimensions (metric)** | set of 6 adult sizes with carrying case:1.Hand & Wrist 2.Half arm 3.Full arm 4. Foot and ankle 5. Half leg 6. Full leg |
| **3.2** | **Weight (lbs, kg)** | Light |
| **3.3** | **Configuration** | NA |
| **3.4** | **Noise (in dBA), heat dissipation** | NA |

| | | |
|---|---|---|
| **3.5** | **Mobility, portability** | Yes |
| **4** | ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) | |
| **4.1** | **Power Requirements** | NA |
| **4.2** | **Battery operated** | NA |
| **4.3** | **Tolerance (to variations, shutdowns)** | NA |
| **4.4** | **Protection** | NA |
| **4.5** | **Power consumption** | NA |
| **5** | ACCESSORIES, SPARE PARTS, CONSUMABLES | |
| **5.1** | **Accessories (mandatory, standard, optional)** | Inflatory tubes' extension |
| **5.2** | **Spare parts (main ones)** | NA |
| **5.3** | **Consumables / reagents (open, closed system)** | NA |
| **5.4** | **Others** | NA |
| **6** | ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS | |
| **6.1** | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | Should be washable and reusable |
| 6.3 | **Others** | Should be washable and reusable |
| **7** | STANDARDS AND SAFETY | |
| **7.1** | **Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international** | ISO 9001 certified manufacturer |
| **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 |
| **8.4** | **Others** | NA |
| **9** | WARRANTY AND MAINTENANCE | |
| **9.1** | **Warranty** | 1 year |
| **9.2** | **Maintenance tasks** | NA |
| **9.3** | **Service contract clauses, including prices** | NA |
| **9.4** | **Others** | NA |
| **10** | DOCUMENTATION | |
| **10.1** | **Operating manuals, service manuals, other manuals** | NA |

| | | |
|---|---|---|
| **10.2** | **Other accompanying documents** | NA |
| **10.3** | **Recommendations for maintenance** | NA |
| **10.4** | **Others** | NA |
| **11** | NOTES | |
| **11.1** | **Service Support Contact details (Hierarchy Wise; including a toll free/landline number)** | NA |
| **11.2** | **Recommendations or warnings** | NA |
| **11.3** | **Temperature Range** | Should be able to operate between – 32 degrees Centigrade to + 52 degrees Centigrade |

| MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to) | | |
|---|---|---|
| **Cervical Collar** | | |
| Version no. : | | 2.0 |
| Date: | | 2016 |
| Done by : (name / institution) | | Dte. GHS |
| | | NAME AND CODING |
| GMDN name | | Disability-assistive products |
| GMDN code(s) | | CT1000 |
| GMDN definition | | A padded device that is worn around the neck and used to support or immobilize the cervical spine to treat deformities, fractures, sprains, or strains (often to treat whiplash resulting from an automobile accident). This device will provide support to the head while limiting movement of the cervical vertebrae. It is available in a variety of sizes. This is a reusable device. |
| **GENERAL** | | |
| **1** | | USE |
| **1.1** | **Clinical purpose** | used to support or immobilize the cervical spine to treat deformities, fractures, sprains, or strains |
| **1.2** | **Used by clinical department/ward** | Trauma care; musculo-skeletal support |
| | | TECHNICAL |
| **2** | | TECHNICAL CHARACTERISTICS |
| **2.1** | **Technical characteristics (specific to this type of device)** | 1. Should be adjustable to 4 different sizes.<br>2. Should be pre-moulded chin support, locking dips and rear ventilation panel, enlarged trachea opening<br>3. Should be high-density polyethylene and foam padding with one piece design enables efficient storage where space is limited.<br>4. Should be X-ray lucent and easy to clean and disinfect. |
| **2.3** | **Settings** | Size adjustment |
| **2.4** | **User's interface** | Manual |
| **2.5** | **Software and/or standard of communication(where ever required)** | NA |
| **3** | | PHYSICAL CHARACTERISTICS |
| **3.1** | **Dimensions (metric)** | NA |
| **3.2** | **Weight (lbs, kg)** | As light as possible |
| **3.3** | **Configuration** | NA |
| **3.4** | **Noise (in dBA), heat dissipation** | NA |
| **3.5** | **Mobility, portability** | NA |
| **4** | | ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) |
| **4.1** | **Power Requirements** | NA |

| | | |
|---|---|---|
| **4.2** | **Battery operated** | NA |
| **4.3** | **Tolerance (to variations, shutdowns)** | NA |
| **4.4** | **Protection** | NA |
| **4.5** | **Power consumption** | NA |
| **4.6** | **Other energy supplies** | NA |
| **5** | ACCESSORIES, SPARE PARTS, CONSUMABLES | |
| **5.1** | **Accessories (mandatory, standard, optional)** | NA |
| **5.2** | **Spare parts (main ones)** | NA |
| **5.3** | **Consumables / reagents (open, closed system)** | NA |
| **6** | ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS | |
| **6.1** | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | 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** | ISO 9001 |
| **8** | TRAINING AND INSTALLATION | |
| **8.1** | **Pre-installation requirements: nature, values, quality, tolerance** | Supplier to perform safety and operation checks before handover. |
| **8.2** | **Requirements for sign-off** | |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | |
| **9** | WARRANTY AND MAINTENANCE | |
| **9.1** | **Warranty** | 1 years |
| **9.2** | **Maintenance tasks** | NA |
| **9.3** | **Service contract clauses, including prices** | NA |
| **9.4** | **Others** | |
| **10** | DOCUMENTATION | |
| **10.1** | **Operating manuals, service manuals, other manuals** | NA |
| **10.2** | **Other accompanying documents** | NA |
| **10.3** | **Recommendations for maintenance** | NA |
| **10.4** | **Others** | |
| **11** | NOTES | |

| | | |
|---|---|---|
| **11.1** | **Service Support Contact details (Hierchy Wise; including a toll free/landline number)** | NA |
| **11.2** | **Recommendations or warnings** | NA |
| **11.3** | **Temperature Range** | Should be able to operate between – 32 degrees Centigrade to + 52 degrees Centigrade |

| **MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to)** | | |
|---|---|---|
| | **First Aid Box** | |
| Version no. : | 2.0 | |
| Date: | 2016 | |
| Done by : (name / institution) | Dte. GHS | |
| **NAME AND CODING** | | |
| GMDN name | Emergency/First aid kits | |
| GMDN code(s) | CT1279 | |
| GMDN definition | Light Weight, portable bag made of strong, damage, dust and water resistant material such as polyester, nylon or fabric designed to transport medical devices, instruments, supplies and consumables relevant to life support for trauma and emergency patients to be carried personally by clinical staff/ assistant/ attendant to places which cannot be directly accessed by vehicles. The bag typically has internal spaces configured to accommodate the instruments, equipment, medicines and devices for life support including the care of airway, breathing, circulation and management of deformity/ disability-- which may include airway devices such as ambu bag, guedel airway, vials of Injectable medicines, IV fluids and cannulae for field use, stethoscope, sphygmomanometer, torch, cervical collar and splints, specified for variety of users including physicians, nurses, rescue workers, paramedics and first air workers. This is a reusable devices which should be possible to be cleaned by use of appropriate chemicals including alcohol/spirit wipes. It should be easy to handle with mechanism of closure. | |
| **GENERAL** | | |
| **1** | USE | |
| **1.1** | **Clinical purpose** | Transport of medical equipment, devices and supplies to places where vehicles cannot get sufficiently close to the patient. |
| **1.2** | **Used by clinical department/ward** | Trauma care; musculo-skeletal support |
| **TECHNICAL** | | |
| **2** | TECHNICAL CHARACTERISTICS | |
| **2.1** | **Technical characteristics (specific to this type of device)** | The bag should be possible to carry via a shoulder strap and also by handles and as a back pack to suit the convenience of the user. It should be resistant to wear and tear. It should be waterproof. There should be space for multiple colour coded pouches which should be possible to arrange as relevant to Airway, Breathing, Circulation, Disability management and carrying essential Injectable medicine vials or fluid. It should not have less than 4 external pockets and not less than 5 detachable colour coded compartments / pouches with transparent windows to enable user to see the contents without opening them. The bags should also have space to safely store used needles, blades etc. |
| **2.3** | **Settings** | NA |

| | | |
|---|---|---|
| **2.4** | **User's interface** | NA |
| **2.5** | **Software and/or standard of communication(where ever required)** | NA |
| **3** | PHYSICAL CHARACTERISTICS | |
| **3.1** | **Dimensions (metric)** | Pre-packed kits as convenient as long as it contains the specified first aid items. |
| **3.2** | **Weight (lbs, kg)** | Less than 3kg, should sustain minimum 10kg. wt. equipment, medicines and accessories |
| **3.3** | **Configuration** | NA |
| **3.4** | **Noise (in dBA), heat dissipation** | NA |
| **3.5** | **Mobility, portability** | Yes |
| **4** | | ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) |
| **4.1** | **Power Requirements** | NA |
| **4.2** | **Battery operated** | NA |
| **4.3** | **Tolerance (to variations, shutdowns)** | NA |
| **4.4** | **Protection** | NA |
| **4.5** | **Power consumption** | NA |
| **4.6** | **Other energy supplies** | NA |
| **5** | | ACCESSORIES, SPARE PARTS, CONSUMABLES |
| **5.1** | **Accessories (mandatory, standard, optional)** | NA |
| **5.2** | **Spare parts (main ones)** | NA |
| **5.3** | **Consumables / reagents (open, closed system)** | NA |
| **6** | | ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS |
| **6.1** | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | 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** | ISO 9001 supplier |
| **8** | | TRAINING AND INSTALLATION |
| **8.1** | **Pre-installation requirements: nature, values, quality, tolerance** | Supplier to perform safety and operation checks before handover. |
| **8.2** | **Requirements for sign-off** | |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | |
| **9** | | WARRANTY AND MAINTENANCE |
| **9.1** | **Warranty** | NA |
| **9.2** | **Maintenance tasks** | NA |
| **9.3** | **Service contract clauses, including prices** | NA |
| **9.4** | **Others** | |
| **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 (Hierarchy Wise; including a toll free/landline number)** | NA |
| **11.2** | **Recommendations or warnings** | NA |
| **11.3** | **Temperature Range** | Should be able to operate between – 32 degrees Centigrade to + 52 degrees Centigrade |

| MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to) | | |
|---|---|---|
| **Spinal Board** | | |
| Version no. : | | 2.0 |
| Date: | | 2016 |
| Done by : (name / institution) | | Dte. GHS |
| **NAME AND CODING** | | |
| GMDN name | | Stretchers and associated devices |
| GMDN code(s) | | CT674 |
| GMDN definition | | A flat, stiff device intended to be placed under a patient (the patient is usually strapped to this device) to ensure spinal immobilization when a spinal injury is suspected. This device is often used in combination with a head/neck immobilizing device that is also typically fixed or strapped to it. It is typically used after serious accidents and for transport of the patient on a stretcher. It is typically made of x-ray translucent/non-ferromagnetically active materials that allow x-ray and magnetic resonance imaging (MRI) and comes in various sizes. This is a reusable device. |
| **GENERAL** | | |
| **1** | | USE |
| **1.1** | **Clinical purpose** | It is placed under a patient to ensure spinal immobilization when a spinal injury is suspected. |
| **1.2** | **Used by clinical department/ward** | Emergency/Trauma Care |
| | | TECHNICAL |
| **2** | | TECHNICAL CHARACTERISTICS |
| **2.1** | **Technical characteristics (specific to this type of device)** | 1. Should be in plastic material of high strength and waterproof.<br>2. It should be supplied with 3 belts with rapid unhooking buckle in all three belts.<br>3. Should have radio transparency to make radiologic examinations/x-rays without removing the patient from the board. |
| **2.3** | **Settings** | NA |
| **2.4** | **User's interface** | Manual |
| **2.5** | **Software and/or standard of communication(where ever required)** | NA |
| **3** | | PHYSICAL CHARACTERISTICS |
| **3.1** | **Dimensions (metric)** | Length: 180 - 190cm; Breadth: 40 - 48cm ; Height: 5 to 7cm |
| **3.2** | **Weight (lbs, kg)** | Weight: <8 kg; load: upto 120kgs. |
| **3.3** | **Configuration** | NA |
| **3.4** | **Noise (in dBA), heat dissipation** | NA |
| **3.5** | **Mobility, portability** | Yes |
| **4** | | ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) |

| | | |
|---|---|---|
| **4.1** | **Power Requirements** | NA |
| **4.2** | **Battery operated** | NA |
| **4.3** | **Tolerance (to variations, shutdowns)** | NA |
| **4.4** | **Protection** | NA |
| **4.5** | **Power consumption** | NA |
| **4.6** | **Other energy supplies** | NA |
| **5** | | ACCESSORIES, SPARE PARTS, CONSUMABLES |
| **5.1** | **Accessories (mandatory, standard, optional)** | NA |
| **5.2** | **Spare parts (main ones)** | NA |
| **5.3** | **Consumables / reagents (open, closed system)** | NA |
| **6** | ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS | |
| **6.1** | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | 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** | ISO 9001; FDA/CE |
| **8** | TRAINING AND INSTALLATION | |
| **8.1** | **Pre-installation requirements: nature, values, quality, tolerance** | Supplier to perform safety and operation checks before handover. |
| **8.2** | **Requirements for sign-off** | |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | |
| **9** | WARRANTY AND MAINTENANCE | |
| **9.1** | **Warranty** | 1 year |
| **9.2** | **Maintenance tasks** | NA |
| **9.3** | **Service contract clauses, including prices** | NA |
| **9.4** | **Others** | |
| **10** | DOCUMENTATION | |
| **10.1** | **Operating manuals, service manuals, other manuals** | NA |
| **10.2** | **Other accompanying documents** | NA |
| **10.3** | **Recommendations for maintenance** | NA |
| **10.4** | **Others** | |
| **11** | NOTES | |

| | | |
|---|---|---|
| **11.1** | **Service Support Contact details (Hierchy Wise; including a toll free/landline number)** | NA |
| **11.2** | **Recommendations or warnings** | NA |
| **11.3** | **Temperature Range** | Should be able to operate between – 32 degrees Centigrade to + 52 degrees Centigrade |

| **MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to)** | |
|---|---|
| **Double Head Immobilizers** | |
| Version no. : | 2.0 |
| Date: | 2016 |
| Done by : (name / institution) | Dte. GHS |
| | NAME AND CODING |
| GMDN name | Immobilizers |
| GMDN code(s) | CT1818 |
| GMDN definition | A rigid device, usually made of polymer materials, used to temporarily render the head/neck of a patient immovable to ensure immobilization when a head and/or spinal injury is suspected. It is used in conjunction with serious accidents and for transport of the patient on a stretcher and possibly in conjunction with a spinal board to which this device and the patient are strapped. It is typically made of x-ray translucent/non-ferromagnetically active materials that allow x-ray and magnetic resonance imaging (MRI) and comes in various sizes. This is a reusable device after appropriate cleaning. |

| **GENERAL** | | |
|---|---|---|
| **1** | USE | |
| **1.1** | **Clinical purpose** | used to temporarily render the head/neck of a patient immovable to ensure immobilization when a head and/or spinal injury is suspected. |
| **1.2** | **Used by clinical department/ward** | Emergency |
| | | TECHNICAL |
| **2** | | TECHNICAL CHARACTERISTICS |
| **2.1** | **Technical characteristics (specific to this type of device)** | 1.Should be of two adult sizes (large and medium) and one paediatric size.<br>2. Should be with padded belts for the fixing.<br>3. It should be covered by a liquid proof material.<br>4. Should be high density plastic material |
| **2.2** | **Settings** | NA |
| **2.3** | **User's interface** | Manual |
| **2.4** | **Software and/or standard of communication(where ever required)** | NA |
| **3** | | PHYSICAL CHARACTERISTICS |
| **3.1** | **Dimensions (metric)** | standard |
| **3.2** | **Weight (lbs, kg)** | standard |
| **3.3** | **Configuration** | NA |
| **3.4** | **Noise (in dBA), heat dissipation** | NA |

| | | |
|---|---|---|
| **3.5** | **Mobility, portability** | Yes |
| **4** | | ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) |
| **4.1** | **Power Requirements** | NA |
| **4.2** | **Battery operated** | NA |
| **4.3** | **Tolerance (to variations, shutdowns)** | NA |
| **4.4** | **Protection** | NA |
| **4.5** | **Power consumption** | NA |
| **4.6** | **Other energy supplies** | NA |
| **5** | | ACCESSORIES, SPARE PARTS, CONSUMABLES |
| **5.1** | **Accessories (mandatory, standard, optional)** | NA |
| **5.2** | **Spare parts (main ones)** | NA |
| **5.3** | **Consumables / reagents (open, closed system)** | NA |
| **6** | | ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS |
| **6.1** | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | 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** | ISO 9001 manufacturer |
| **8** | | TRAINING AND INSTALLATION |
| **8.1** | **Pre-installation requirements: nature, values, quality, tolerance** | Supplier to perform safety and operation checks before handover. |
| **8.2** | **Requirements for sign-off** | |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | |
| **9** | | WARRANTY AND MAINTENANCE |
| **9.1** | **Warranty** | 1 year |
| **9.2** | **Maintenance tasks** | NA |
| **9.3** | **Service contract clauses, including prices** | NA |
| **9.4** | **Others** | |
| **10** | | DOCUMENTATION |
| **10.1** | **Operating manuals, service manuals, other manuals** | NA |
| **10.2** | **Other accompanying documents** | NA |
| **10.3** | **Recommendations for maintenance** | NA |

| | | |
|---|---|---|
| **10.4** | **Others** | |
| **11** | | NOTES |
| **11.1** | **Service Support Contact details (Hierchy Wise; including a toll free/landline number)** | NA |
| **11.2** | **Recommendations or warnings** | NA |
| **11.3** | **Temperature Range** | Should be able to operate between – 32 degrees Centigrade to + 52 degrees Centigrade |

| **MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to)** | | |
|---|---|---|
| **Fetal doppler** | | |
| Version no. : | | 2.0 |
| Date: | | 2016 |
| Done by : (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Foetal Doppler system |
| GMDN code(s) | | CT 2000 |
| GMDN definition | | A portable, hand-held, battery-powered device assembly consisting of a measuring and display unit and an attached probe or interchangeable probes designed 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. The device aids in determining foetal viability. |
| **GENERAL** | | |
| **1** | USE | |
| **1.1** | **Clinical purpose** | to non-invasively detect foetal heart beats from the surface of the pregnant women's abdomen. |
| **1.2** | **Used by clinical department/ward** | Emergency/Gynae deptt. |
| **1.3** | **Overview of functional requirements** | |
| **TECHNICAL** | | |
| **2** | TECHNICAL CHARACTERISTICS | |
| **2.1** | **Technical characteristics (specific to this type of device)** | Water proof probes of 2MHz, 3MHz and 5 MHz frequency, Ultra sound Intensity ‹10mw/cm2, Auto Shut Off Facility to save Battery Power, Built-in Speaker, Volume Control Facility and Audio Output for Ear Phone, Heart Rate Range should be from 50 to 210 bpm with accuracy of + /-2%, Should be Water Proof Body |
| **2.2** | **Settings** | setting of ultrasound intensity |
| **2.3** | **User's interface** | LCD/LED display |
| **2.4** | **Software and/or standard of communication(where ever required)** | inbuilt |
| **3** | PHYSICAL CHARACTERISTICS | |
| **3.1** | **Dimensions (metric)** | handheld |
| **3.2** | **Weight (lbs, kg)** | 500 gm |
| **3.3** | **Configuration** | |

| | | |
|---|---|---|
| **3.4** | **Noise (in dBA),** | Noise: <60dBA |
| **3.5** | heat dissipation | |
| **3.6** | **Mobility, portability** | Yes |
| **4** | ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) | |
| **4.1** | **Power Requirements** | Rechargeable battery |
| **4.2** | **Battery operated** | Rechargeable battery |
| **4.3** | **Tolerance (to variations, shutdowns)** | ± 10% of input AC |
| **4.4** | **Protection** | Electrical protection by resettable overcurrent breakers or replaceable fuses, fitted in both live and neutral lines |
| **4.5** | **Power consumption** | |
| **4.6** | **Other energy supplies** | NA |
| **5** | ACCESSORIES, SPARE PARTS, CONSUMABLES | |
| **5.1** | **Accessories (mandatory, standard, optional)** | Doppler probe, rechargeable battery, battery charger |
| **5.2** | **Spare parts (main ones)** | |
| **5.3** | **Consumables / reagents (open, closed system)** | Rechargeable battery |
| **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | | |
| **6** | ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS | |
| **6.1** | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | The unit should be cleanable with alcohol |
| **7** | STANDARDS AND SAFETY | |
| **7.1** | **Certificates (pre-market, sanitary, ..)** | US FDA/European CE and BIS/ISO 13485 |
| **7.2** | **Performance and safety standards (specific to the device type)** | Shall meet IEC-60601- part 1 and 2 |
| **7.3** | **Local and/or international** | NA |
| **8** | TRAINING AND INSTALLATION | |
| **8.1** | **Pre-installation requirements: nature, values, quality, tolerance** | Supplier to perform installation, safety and operation checks before handover. |
| **8.2** | **Requirements for sign-off** | Certificate of Calibration and inspection from the factory. |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided |
| **9** | WARRANTY AND MAINTENANCE | |
| **9.1** | **Warranty** | three years (including probe and battery) |
| **9.2** | **Maintenance tasks** | maintenance manual detailing complete maintaining schedule |
| **9.3** | **Service contract clauses, including prices** | Local clinical staff to affirm completion of installation |
| **10** | DOCUMENTATION | |

| | | |
|---|---|---|
| **10.1** | **Operating manuals, service manuals, other manuals** | Advanced maintenance tasks required shall be documented<br>User, technical and maintenance manuals to be supplied in english language.<br>List to be provided of equipment and procedures required for local calibration and routine maintenance |
| **10.2** | **Other accompanying documents** | List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided. |
| **11** | NOTES | |
| **11.1** | **Service Support Contact details (Hierchy Wise; including a toll free/landline number)** | AMC/CAMC Details to be provided |
| **11.2** | **Recommendations or warnings** | List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided. |
| **11.3** | **Temperature Range** | Should be able to operate between – 32 degrees Centigrade to + 52 degrees Centigrade |

| MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to) | | |
|---|---|---|
| **Portable hand held Glucometer** | | |
| Version no. : | | 2.0 |
| Date: | | 2016 |
| Done by : (name / institution) | | Dte. GHS |
| **NAME AND CODING** | | |
| GMDN name | | Glucose self-testing |
| GMDN code(s) | | CT296 |
| GMDN definition | | A collection of devices including a portable, battery-powered, semi-automated or automated instrument (self-testing meter), reagents, test strips and/or other associated materials and accessories [e.g., control solutions, lancets] intended to be used together for testing, either at the point-of-care or in self testing by a lay person, for the quantitative measurement of glucose and/or ketones in a whole blood clinical specimen. Measured glucose values are used to manage blood glucose levels, primarily by persons with diabetes mellitus |
| **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** | **Used by clinical department/ward** | All |
| **TECHNICAL** | | |
| **2** | TECHNICAL CHARACTERISTICS | |
| **2.1** | **Technical characteristics (specific to this type of device)** | Should have reading range/linearity from 30 to 600 mg/dl; Should have a maximum reading time of less than 10 seconds; Should use a minimum blood sample less than 1.5µl; Should have a minimum memory of 50 tests; accuracy +/-10% and reproducibility +/-5%; Packing of strips should be such that there are not more than 50 strips/pack. The strips should be readily available throughout the country |
| **2.2** | **Settings** | Should have automatic code detection facility , display of sugar in Mg/dl and NOT in millimoles. |
| **2.3** | **User's interface** | LCD display |
| **2.4** | **Software and/or standard of communication(where ever required)** | inbuilt; .Should have facility to ensure accuracy of measurements |
| **3** | PHYSICAL CHARACTERISTICS | |
| **3.1** | **Dimensions (metric)** | handheld device |
| **3.2** | **Weight (lbs, kg)** | handheld device |
| **3.3** | **Configuration** | Should use electrochemical technology |
| **3.4** | **Noise (in dBA), heat dissipation** | NA |
| **3.5** | **Mobility, portability** | handheld |
| **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** | **Tolerance (to variations, shutdowns)** | NA |

| | | |
|---|---|---|
| **4.4** | **Protection** | NA |
| **4.5** | **Power consumption** | NA |
| **4.6** | **Other energy supplies** | NA |
| **5** | ACCESSORIES, SPARE PARTS, CONSUMABLES | |
| **5.1** | **Accessories & Spare parts** | NA |
| **5.2** | **Consumables / reagents (open, closed system)** | glucose strips(able to use capillary blood samples) with availability in local market, shelf life of strips should be 12 months, the cost of strips for the next five years should be declared (for cost comparison) |
| **BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS** | | |
| **6** | ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS | |
| **6.1** | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | The unit should be cleanable with alcohol |
| **7** | STANDARDS AND SAFETY | |
| **7.1** | **Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international** | FDA US) /CE(EU) and BIS/ISO 13485:2003; ISO 15197: 2013 compliant |
| **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)** | required |
| **9** | WARRANTY AND MAINTENANCE | |
| **9.1** | **Warranty** | 2 years; shelf life of minimum 12 months for strips from the date of manufacture; strips should work minimum 3 months from opening of pack |
| **9.2** | **Maintenance tasks** | Should require no routine maintenance |
| **9.3** | **Service contract clauses, including prices** | Should have life time replacement offer |
| **10** | DOCUMENTATION | |
| **10.1** | **Operating manuals, service manuals, other manuals** | Required |
| **10.3** | **Recommendations for maintenance** | to be provided during installation |
| **11** | NOTES | |
| **11.1** | **Service Support Contact details (Hierchy Wise; including a toll free/landline number)** | should provide complete contact details of sales and service departments. |
| **11.2** | **Recommendations or warnings** | NA |
| **11.3** | **Temperature Range** | Should be able to operate between – 32 degrees Centigrade to + 52 degrees Centigrade |

| MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to) | | |
|---|---|---|
| **Nebulizer (Electric)** | | |
| Version no. : | | 2.0 |
| Date: | | 2016 |
| Done by : (name / institution) | | Dte. GHS |
| **NAME AND CODING** | | |
| GMDN name | | Nebulising systems |
| GMDN code(s) | | CT1097 |
| GMDN definition | | An assembly of devices designed to generate warmed aerosolized medication/fluids (finely dispersed airborne droplets in a liquid phase) intended to be inhaled by a patient with a respiratory disorder [e.g., chronic obstructive pulmonary disease (COPD), cystic fibrosis (CF)]. It will typically consist of an electrically-powered generator, a reservoir, a heating element, and a hand-held nebulising chamber where the nebulisation of the medicine usually takes place. |
| **GENERAL** | | |
| **1** | USE | |
| **1.1** | **Clinical purpose** | Designed to generate aerosolized medication/fluids (finely dispersed airborne droplets in a liquid phase) intended to be inhaled by a patient with a respiratory disorder. |
| **1.2** | **Used by clinical department/ward** | All |
| | | TECHNICAL |
| **2** | | TECHNICAL CHARACTERISTICS |
| **2.1** | **Technical characteristics (specific to this type of device)** | medicine cup capacity of minimum 5 ml |
| **2.2** | **Settings** | manual |
| **2.3** | **User's interface** | manual |
| **2.4** | **Software and/or standard of communication(where ever required)** | NA |
| **3** | | PHYSICAL CHARACTERISTICS |
| **3.1** | **Dimensions (metric)** | should be compact |
| **3.2** | **Weight (lbs, kg)** | <2kg. |
| **3.3** | **Configuration** | |
| **3.4** | **Noise (in dBA), heat dissipation** | <60dBA |
| **3.5** | **Mobility, portability** | Yes |
| **4** | | ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) |
| **4.1** | **Power Requirements** | 220 V AC + 10%, 50Hz power supply; 5A plug |
| **4.2** | **Battery operated** | NA |

| | | |
|---|---|---|
| **4.3** | **Tolerance (to variations, shutdowns)** | ± 10% of input AC |
| **4.4** | **Protection** | Electrical protection by resettable overcurrent breakers or replaceable fuses, fitted in both live and neutral lines |
| **4.5** | **Power consumption** | Should be compatible with ambulances power sources with other equipments running |
| **4.6** | **Other energy supplies** | NA |
| **5** | | ACCESSORIES, SPARE PARTS, CONSUMABLES |
| **5.1** | **Accessories & Spares** | With necessary accessories- nebulisation mask(both adult and paediatric size), PVC tubing for nebulizer (two pair extra); cable cord |
| **5.2** | **Consumables / reagents (open, closed system)** | aerosol/medicinal solutions |
| **6** | | ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS |
| **6.1** | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | The unit should be cleanable with alcohol |
| **7** | | STANDARDS AND SAFETY |
| **7.1** | **Certificates (pre-market, sanitary, ..)** | FDA (US)/CE (EU) and BIS/ISO 13485:2003; ISO 27427-2013; IEC-60601-1 |
| **8** | | TRAINING AND INSTALLATION |
| **8.1** | **Pre-installation requirements: nature, values, quality, tolerance** | Supplier to perform installation, safety and operation checks before handover. |
| **8.2** | **Requirements for sign-off** | Certificate of Calibration and inspection from the factory. |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided |
| **9** | | WARRANTY AND MAINTENANCE |
| **9.1** | **Warranty** | 3 Years |
| **9.2** | **Maintenance tasks** | Maintenance manual detailing complete maintaining schedule |
| **9.3** | **Service contract clauses, including prices** | Local clinical staff to affirm completion of installation |
| **10** | | DOCUMENTATION |
| **10.1** | **Operating manuals, service manuals, other manuals** | Advanced maintenance tasks required shall be documented<br>User, technical and maintenance manuals to be supplied in english language.<br>List to be provided of equipment and procedures required for local calibration and routine maintenance |
| **10.2** | **Other accompanying documents** | List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided. |
| **11** | | NOTES |
| **11.1** | **Service Support Contact details (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** | List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided. |
| **11.3** | **Temperature Range** | Should be able to operate between – 32 degrees Centigrade to + 52 degrees Centigrade |

| MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to) | | |
|---|---|---|
| **Automated External Defibrillator** | | |
| Version no. : | | 2.0 |
| Date: | | 2016 |
| Done by : (name / institution) | | Dte. GHS |
| **NAME AND CODING** | | |
| GMDN name | | Automated external defibrillators |
| GMDN code(s) | | CT269 |
| GMDN definition | | A portable electronic device designed to automatically detect cardiac arrhythmias (ventricular fibrillation/ pulseless ventricular tachycardia) in a sudden cardiac arrest (SCA) patient, after which it audibly/visually instructs an operator to enable it to activate defibrillation of the heart through application of electrical shocks to the chest surface. The device is intended to be operated by healthcare professionals (e.g., paramedics, medical staff) in healthcare settings. It also includes internal rechargeable batteries that must be charged when not in use. |
| **GENERAL** | | |
| **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 the heart 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. Defibrillator should be bi-phasic<br>2. Should work on Automated external defirilation mode. Manual selection maximum upto 150J to 200J<br>3. Should be capable of doing syncronised cardioversion<br>4. Can be operated from mains as well as battery<br>5. Should defibrilate through pads<br>6. Should have charging time of less than 10 seconds for maximum energy with charging indicator<br>7. Should have two inbuilt battery capable of usage for atleast 120 minutes and/or 30 discharge<br>8. Detailed audio visual message guide responder through use of the defibrillator<br>9. Color Coding for different buttons |
| **2.2** | **Settings** | Automatic |
| **2.3** | **User's interface** | Should have display- LCD |
| **2.4** | **Software and/or standard of communication(where ever required)** | inbuilt |
| **3** | PHYSICAL CHARACTERISTICS | |
| **3.1** | **Dimensions (metric)** | compact |
| **3.2** | **Weight (lbs, kg)** | <5kg |
| **3.3** | **Configuration** | |
| **3.4** | **Noise (in dBA), heat dissipation** | Audio Visual message incase pads not applied properly |
| **3.5** | **Mobility, portability** | Yes |
| **4** | ENERGY SOURCE | |

| | | |
|---|---|---|
| **4.1** | **Power Requirements** | 220 to 240V, 50 Hz |
| **4.2** | **Battery operated** | Should have a battery capable of usage for at least 120 minutes and/or 30 discharge |
| **4.3** | **Tolerance (to variations, shutdowns)** | ± 10% of input AC |
| **4.4** | **Protection** | Electrical protection by resettable overcurrent breakers or replaceable fuses, fitted in both live and neutral lines |
| **4.5** | **Power consumption** | - |
| **5** | ACCESSORIES, SPARE PARTS, CONSUMABLES | |
| **5.1** | **Accessories & Spares** | 2 nos of patient cable, 2 sets each adult and paediatrics pads |
| **5.3** | **Consumables / reagents (open, closed system)** | - |
| **6** | ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS | |
| **6.1** | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | The unit should be cleanable with alcohol |
| **7** | STANDARDS AND SAFETY | |
| **7.1** | **Certifications** | FDA (US) /CE (EU) and BIS/ISO 13485:2003; IEC-60601-1-2 |
| **8** | TRAINING AND INSTALLATION | |
| **8.1** | **Pre-installation requirements: nature, values, quality, tolerance** | Supplier to perform installation, safety and operation checks before handover. |
| **8.2** | **Requirements for sign-off** | Certificate of Calibration and inspection from the factory. |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | NA |
| **9** | WARRANTY AND MAINTENANCE | |
| **9.1** | **Warranty** | 3 years |
| **9.2** | **Maintenance tasks** | maintenance manual detailing complete maintaining schedule |
| **9.3** | **Service contract clauses, including prices** | Local clinical staff to affirm completion of installation |
| **10** | DOCUMENTATION | |
| **10.1** | **Operating manuals, service manuals, other manuals** | Advanced maintenance tasks required shall be documented<br>User, technical and maintenance manuals to be supplied in english language.<br>List to be provided of equipment and procedures required for local calibration and routine maintenance |
| **10.2** | **Other accompanying documents** | List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided. |
| **11** | NOTES | |
| **11.1** | **Service Support Contact details (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** | List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided. |
| **11.3** | **Temperature Range** | Should be able to operate between – 32 degrees Centigrade to + 52 degrees Centigrade |

| MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to) | | |
|---|---|---|
| | **Monitor** | |
| Version no. : | | 2.0 |
| Date: | | 2016 |
| Done by : (name / institution) | | Dte. GHS |
| **NAME AND CODING** | | |
| GMDN name | | Patient monitors/monitoring systems |
| GMDN code(s) | | CT1444 |
| GMDN category | | Anaesthetic and respiratory devices , Electro mechanical medical devices |
| GMDN definition | | A device assembly designed to continuously measure and display multiple vital physiological parameters of patients, especially those under critical care. It is typically capable of monitoring parameters such as electrocardiogram (ECG), respiration rate, heart rate, blood pressure, body temperature, and haemoglobin oxygen saturation (SpO2). |
| **GENERAL** | | |
| **1** | USE | |
| **1.1** | **Clinical purpose** | Designed to continuously measure and display multiple vital physiological parameters |
| **1.2** | **Used by clinical department/ward** | All |
| **TECHNICAL** | | |
| **2** | TECHNICAL CHARACTERISTICS | |
| **2.1** | **Technical characteristics (specific to this type of device)** | 1. Should have facility for printing ECG at 25mm/sec and 50mm/sec speed.<br>2. Should have facility for charging from both 12V DC & 220V AC.<br>3. Should be supplied with<br>i. Pulse oximeter probe (adult and paediatric)<br>ii. ECG cable -12 lead<br>iii. Temperature probe<br>iv. NIBP (non-invasive blood pressure) cuffs<br>All probes should be supplied in 2 pairs, should be re-usable and should include adult, pediatric & neonatal size cuff/leads. The material of the probe should be such that it is non-breakable<br>4. Capable of saving data for minimum of 24 hrs<br>5. Prices for consumables should be offered in financial bid<br>6. The monitor should have facility for transmission of data from ambulance to a receiving station (desirable and NOT Mandatory, to be quoted separately)<br>7. Material of probe should be non-biodegradable<br>8. Should also have wall mounting facility available |
| **2.2** | **Settings** | User operated 1mV ECG test marker function required |
| **2.3** | **User's interface** | Manual |
| **2.4** | **Software and/or standard of communication** | Audio Visual alarms required: high and low levels for each parameter (operator variable settings), sensor / wire / probe disconnected, low battery |
| **3** | PHYSICAL CHARACTERISTICS | |
| **3.1** | **Dimensions (metric)** | Screen size minimum: 10" or more |
| **3.2** | **Weight (lbs, kg)** | <6kg. |
| **3.3** | **Configuration** | Case is to be hard and splash proof. Display must allow easy viewing in all ambient light levels.Cable connectors to be designed so as fit correct socket only |
| **3.4** | **Noise (in dBA)** | <50 dB; Lead disconnection Alarm > 65 dB |
| **3.5** | **heat dissipation** | Should maitain nominal Temp and the heat should be disbursed through a exhaust cooling fan |
| **3.6** | **Mobility, portability** | Supplied in protective case for clean storage and safe transport |

| | | |
|---|---|---|
| | | |
| **4** | ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) | |
| **4.1** | **Voltage (value, AC or DC, monophase or triphase)** | 220 to 240V, 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. Battery powered, silenceable alarm for power failure. Internal, replaceable, rechargeable battery allows operation for at least one hour in the event of power failure. |
| **4.3** | **Tolerance (to variations, shutdowns)** | Voltage corrector / stabilizer to allow operation at ± 30% of local rated voltage. |
| **4.4** | **Protection** | Electrical protection provided by fuses in both live and neutral supply lines |
| **4.5** | **Power consumption** | <120Watt<br>Compatible with electrical system of the ambulance; should be able to perform with other life saving equipments running |
| **4.6** | **Other energy supplies** | Mains cable |
| **5** | ACCESSORIES, SPARE PARTS, CONSUMABLES | |
| **5.1** | **Accessories & Spares** | 2 pairs, 12 lead ECG cable. 2 packs of 100 disposable ECG connection electrodes. Two sets of reusable SpO2 probes including adult, paediatric & neonatal probes. two sets of NIBP cuffs of each size(adult, paediatric and neonatal).Two external skin temperature probes |
| **5.2** | **Consumables / reagents (open, closed system)** | |
| **6** | ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS | |
| **6.1** | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | The unit should be cleanable with alcohol |
| **7** | STANDARDS AND SAFETY | |
| **7.1** | **Certifications** FDA (US) /CE | (EU) and BIS/ISO 13485:2003;<br>IEC-60601-1-2; ISO 80601-2-56-2009 (Thermometer); ISO 80601-2-61-2011 (SpO2) |
| **8** | TRAINING AND INSTALLATION | |
| **8.1** | **Pre-installation requirements: nature, values, quality, tolerance** | Supplier to perform installation, safety and operation checks before handover. |
| **8.2** | **Requirements for sign-off** | Supplier to perform installation, safety and operation checks<br>before handover 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. |
| **8.4** | **Others** | |
| **9** | WARRANTY AND MAINTENANCE | |
| **9.1** | **Warranty** | 3 years |
| **9.2** | **Maintenance tasks** | Maintenance manual detailing complete maintaining schedule |
| **9.3** | **Service contract clauses, including prices** | warranty of 3 years with free servicing ( min. 3/year) during warranty |

| | | |
|---|---|---|
| **9.4** | **Others** | The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee / warranty period should be attached |
| **10** | DOCUMENTATION | |
| **10.1** | **Operating manuals, service manuals, other manuals** | Advanced maintenance tasks required shall be documented<br>User, technical and maintenance manuals to be supplied in English language.<br>List to be provided of equipment and procedures required for local calibration and routine maintenance |
| **10.2** | **Other accompanying documents** | List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided. |
| **11** | NOTES | |
| **11.1** | **Other information** | Contact details of manufacturer, supplier and local service agent to be provided |
| **11.2** | **Recommendations or warnings** | Any warning signs would be adequately displayed |
| **11.3** | **Temperature Range** | Should be able to operate between – 32 degrees Centigrade to + 52 degrees Centigrade |

| MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to) | | |
|---|---|---|
| **Syringe Pump** | | |
| Version no. : | | 2.0 |
| Date: | | 2016 |
| Done by : (name / institution) | | HCT/ NHSRC |
| **NAME AND CODING** | | |
| GMDN name | | Syringe pump |
| GMDN code(s) | | CT111 |
| GMDN definition | | A device designed to precisely drive the plunger of a syringe down its barrel to infuse a solution when it must be administered with a high degree of volume accuracy and rate consistency. Because of the lower flow settings and flow resolution, it is especially appropriate for neonatal, infant, and critical care applications in which small volumes of concentrated drugs are to be delivered over an extended period. It can also be used to administer epidural analgesia. |
| **GENERAL** | | |
| **1** | USE | |
| **1.1** | **Clinical purpose** | designed to precisely drive the plunger of a syringe down its barrel to infuse a solution when it must be administered with a high degree of volume accuracy and rate consistency |
| **1.2** | **Used by clinical department/ward** | Intensive care unit (ICU), radiology department, orthopaedics, emergencies, ...) |
| **1.3** | **Overview of functional requirements** | A syringe containing medication is securely mounted on the drive arm.<br>Alarms indicate if any error situations occur.<br>The drive arm infuses the medication at a steady, programmed rate. |
| **TECHNICAL** | | |
| **2** | TECHNICAL CHARACTERISTICS | |
| **2** | **Technical characteristics (specific to this type of device)** | i. Flow rate programmable range at least from 1 to 100 ml/hr, in steps of 0.1 ml/hr; with bolus rate from 200 to 999 ml/hr in steps of 1 ml/hr<br>ii. Saves last infusion rate even when the AC power is switched off iii. Bolus rate should be programmable, with infused volume display.<br>iv. Must work on commonly available 5, 10, 20 and 50 ml syringes<br>v. Accuracy of ±2% or better.<br>vi. Maximum pressure generated ≤ 20 psi<br>vii. Automatic detection of syringe size and proper fixing. Must provide alarm for wrong loading of syringe viii. Anti-bolus system to reduce pressure on sudden release of occlusion.<br>ix. Pause infusion facility required<br>x. Self-check carried out on powering on xi. 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 alarm, drive disengaged alarm, syringe loading error alarm x. Should be front loading with wall mounting facility xi. water proof surface |
| **2.3** | **Settings** | NA |
| **2.4** | **User's interface** | Automatic |
| **2.5** | **Software and/or standard of communication** | Inbuilt |
| **3** | PHYSICAL CHARACTERISTICS | |
| **3.1** | **Dimensions (metric)** | max spec: 120 x 100 x 40mm |
| **3.2** | **Weight (lbs, kg)** | <500gm |
| **3.3** | **Configuration** | Tamper-resistant case made of impact resistant material Securely mountable on tabletop, IV stand or bed fitting proof water |

| | | |
|---|---|---|
| **3.4** | **Noise (in dBA)** | <50 dB |
| **3.5** | **heat dissipation** | NA |
| **3.6** | **Mobility, portability** | Yes |
| **4** | ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) | |
| **4.1** | **Voltage (value, AC or DC, monophase or triphase)** | 220 to 240V, 50 Hz |
| **4.2** | **Battery operated** | Internal rechargeable battery having at least 5 hours backup for 10ml/hr flow rate with 50ml syringe |
| **4.3** | **Tolerance (to variations, shutdowns)** | Voltage corrector / stabilizer to allow operation at ± 30% of local rated voltage. |
| **4.4** | **Protection** | Battery powered alarm for power failure or disconnection; Electrical protection provided by fuses in both live and neutral supply lines; |
| **4.5** | **Power consumption** | Should easily run in an ambulance with other life saving equipments |
| **4.6** | **Other energy supplies** | NA |
| **5** | ACCESSORIES, SPARE PARTS, CONSUMABLES | |
| **5.1** | **Accessories & Spares** | Clamp for mounting pump on IV stand |
| **5.2** | **Consumables / reagents (open, closed system)** | Battery, syringe holder |
| **6** | ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS | |
| **6.1** | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.<br>Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.<br>Enclosure to protect against water ingress; |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | The unit should be cleanable with alcohol |
| **7** | STANDARDS AND SAFETY | |
| **7.1** | **Certifications** | FDA (US) /CE (EU) and BIS/ISO 13485:2003; IEC-60601-1 including particular requirements for the safety of infusion pumps and controllers; |
| **8** | TRAINING AND INSTALLATION | |
| **8.1** | **Pre-installation requirements: nature, values, quality, tolerance** | Supplier to perform installation, safety and operation checks before handover. |
| **8.2** | **Requirements for sign-off** | As per requirement |
| **8.3** | **Training of staff (medical, paramedical, technicians)** | Training of users in operation and basic maintenance shall be provided |
| **9** | WARRANTY AND MAINTENANCE | |
| **9.1** | **Warranty** | 3 years |
| **9.2** | **Maintenance tasks** | Advanced maintenance and calibration tasks required shall be documented |
| **9.3** | **Service contract clauses, including prices** | Local clinical staff to affirm completion of installation |
| **10** | DOCUMENTATION | |
| **10.1** | **Operating manuals, service manuals, other manuals** | User, technical and maintenance manuals to be supplied in english language.<br>List to be provided of equipment and procedures required for local calibration and routine maintenance |
| **10.2** | **Other accompanying documents** | List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided. |
| **11** | NOTES | |

| | | |
|---|---|---|
| **11.1** | **Other information** | Contact details of manufacturer, supplier and local service agent to be provided |
| **11.2** | **Recommendations or warnings** | NA |
| **11.3** | **Temperature Range** | Should be able to operate between – 32 degrees Centigrade to + 52 degrees Centigrade |

| **MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to)** | | |
|---|---|---|
| **Transport Ventilator(Adult & Pediatrics)** | | |
| Version no. : | | 2.0 |
| Date: | | 2016 |
| Done by : (name / institution) | | Dte. GHS |
| **NAME AND CODING** | | |
| GMDN name | | Transport pneumatic high-frequency ventilator |
| GMDN code(s) | | CT2175 |
| GMDN definition | | A pneumatically-powered automatic cycling machine intended to provide automated, alveolar ventilatory support for patients during inter - hospital or intra - hospital transport, and in emergency situations. It is used to assist or control alveolar ventilation using a frequency that is considerably higher than the physiological breathing rate and a tidal volume less than or equal to the anatomic dead space (percussive ventilation). It is typically a compact, lightweight, rugged device powered either by institutional gas supply or on-board compressor systems, with manually-operated user interface. It is used in conjunction with an endotracheal (ET) tube, tracheostomy cannula, or mask. |
| **GENERAL** | | |
| **1** | USE | |
| **1.1** | **Clinical purpose** | To provide automated, alveolar ventilatory support for patients during inter - hospital or intra - hospital 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 (Adult & Pediatrics)<br>2. Invasive Modes (CMV and SIMV) and Non-Invasive Mode (CPAP)<br>3. Tidal Volume: 50 - 1500 ml<br>4. Respiration Rate upto 30<br>5. Apnoeic Ventilation: 10 - 60 seconds with alarm<br>6. There should be two FiO2 settings ranging from 21% to 100%. Setting of 100% FiO2 is mandatory.<br>7. PEEP 0 - 20 cm of water<br>8. Trigger Sensitivity - Pressure<br>9. Flow Range: 1 - 120 Lts.<br>10.The associated cylinder(to be supplied along with the machines) should be such that it could be locally filled.<br>11. Oxygen Cylinder connector(to be supplied along with the machines) should be compatible with ventilator<br>12. Audio visual alarm for disconnection and high pressure |
| **2.4** | **User's interface** | Automatic |
| **2.5** | **Software and/or standard of communication(where ever required)** | inbuilt |
| **3** | PHYSICAL CHARACTERISTICS | |

| | | |
|---|---|---|
| **3.1** | **Dimensions (metric)** | NA |
| **3.2** | **Weight (lbs, kg)** | <8kgs |
| **3.3** | **Configuration** | NA |
| **3.4** | **Noise (in dBA), heat dissipation** | <60dB; Alarm > 65dB |
| **3.5** | **Mobility, portability** | Yes |
| **4** | ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) | |
| **4.1** | **Power Requirements** | 220 to 240V, 50 Hz; electricity and battery driven |
| **4.2** | **Battery operated** | Atleast 6 hours battery backup |
| **4.3** | **Tolerance (to variations, shutdowns)** | ± 10% of input |
| **4.4** | **Protection** | OVP, earth leakage protection |
| **4.5** | **Power consumption** | <140Watt |
| **5** | ACCESSORIES, SPARE PARTS, CONSUMABLES | |
| **5.1** | **Accessories & Spares** | full face mask, 4 reusable breathing circuit of silicone material (2 for adults and 2 for pediatrics), carry bag, filters |
| **5.3** | **Consumables / reagents (open, closed system)** | battery, leakage adapter |
| **6** | | ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS |
| **6.1** | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.<br>Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | The unit should be cleanable with alcohol |
| **7** | | STANDARDS AND SAFETY |
| **7.1** | **Certifications** | FDA (US) /CE (EU) and BIS/ISO 13485:2003; IEC-60601-1-2; ISO 15001-2010 (Anestheric & respiratory equipment- compatibility with oxygen) Certificate of approval for transport ventilator |
| **8** | | TRAINING AND INSTALLATION |
| **8.1** | **Pre-installation requirements: nature, values, quality, tolerance** | electrical sockets; Oxygen supply |
| **8.2** | **Requirements for sign-off** | Supplier to perform installation, safety and operation checks before handover 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 Advanced maintenance tasks required shall be documented |
| **9** | | WARRANTY AND MAINTENANCE |
| **9.1** | **Warranty** | 3 years |
| **9.2** | **Maintenance tasks** | Maintenance manual detailing complete maintaining schedule |
| **9.3** | **Service contract clauses, including prices** | warranty of three year with free servicing ( min. 3) during warranty |
| **9.4** | **Others** | The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee / warranty period should be attached |
| **10** | | DOCUMENTATION |
| **10.1** | **Operating manuals, service manuals, other manuals** | User and maintenance manuals to be supplied in English language.<br>Certificate of calibration and inspection to be provided.<br>List to be provided of equipment and procedures required for local calibration and routine maintenance List to be provided of important spares and accessories, with their part numbers and cost.<br>Contact details of manufacturer, supplier and local service agent to be provided |

| | | |
|---|---|---|
| **10.2** | **Other accompanying documents** | User/Technical/Maintenance manuals to be supplied in English |
| **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 |
| **11.3** | **Temperature Range** | Should be able to operate between – 32 degrees Centigrade to + 52 degrees Centigrade |

| MEDICAL DEVICE SPECIFICATION (Including Information on the following where relevant/appropriate, but not limited to) | | |
|---|---|---|
| **Transport Ventilator (neonatal & Pediatrics)** | | |
| Version no. : | | 2.0 |
| Date: | | 2016 |
| Done by : (name / institution) | | Dte. GHS |
| | | NAME AND CODING |
| GMDN name | | Transport pneumatic high-frequency ventilator |
| GMDN code(s) | | CT2175 |
| GMDN definition | | A pneumatically-powered automatic cycling machine intended to provide automated, alveolar ventilatory support for patients during inter - hospital or intra - hospital transport, and in emergency situations. It is used to assist or control alveolar ventilation using a frequency that is considerably higher than the physiological breathing rate and a tidal volume less than or equal to the anatomic dead space (percussive ventilation). It is typically a compact, lightweight, rugged device powered either by institutional gas supply or on-board compressor systems, with manually-operated user interface. It is used in conjunction with an endotracheal (ET) tube, tracheostomy, cannula, or mask. |
| | | |
| | | GENERAL |
| **1** | USE | |
| **1.1** | **Clinical purpose** | To provide automated, alveolar ventilatory support for patients during inter - hospital or intra - hospital 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/ mins<br>5. There should be two FiO2 setting range between 21% and 100%. Setting 100% 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) should be 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 |
| **2.3** | **User's interface** | Automatic |
| **2.4** | **Software and/or standard of communication(where ever required)** | inbuilt |
| **3** | | PHYSICAL CHARACTERISTICS |
| **3.1** | **Dimensions (metric)** | NA |

| | | |
|---|---|---|
| **3.2** | **Weight (lbs, kg)** | <8kgs |
| **3.3** | **Configuration** | NA |
| **3.4** | **Noise (in dBA), heat dissipation** | Should have audio visual alarm for disconnection and high pressure |
| **3.5** | **Mobility, portability** | Yes |
| **4** | | ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ....) |
| **4.1** | **Power Requirements** | 220 to 240V, 50 Hz; electricity and battery driven |
| **4.2** | **Battery operated** | with at least 6 hours battery backup |
| **4.3** | **Tolerance (to variations, shutdowns)** | ± 10% of input |
| **4.4** | **Protection** | OVP, earth leakage protection |
| **4.5** | **Power consumption** | <140Watt |
| **5** | | ACCESSORIES, SPARE PARTS, CONSUMABLES |
| **5.1** | **Accessories & Spares** | full face mask, 4 reusable breathing circuit of silicone material(2 for pediatiric and 2 for neonates), carry bag, ventilator connecting tubes |
| **5.3** | **Consumables / reagents (open, closed system)** | battery, leakage adapter |
| **6** | | ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS |
| **6.1** | **Atmosphere / Ambiance (air conditioning, humidity, dust ...)** | Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.<br>Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%. |
| **6.2** | **User's care, Cleaning, Disinfection & Sterility issues** | The unit should be cleanable with alcohol |
| **7** | | STANDARDS AND SAFETY |
| **7.1** | **Certifications** | FDA (US) /CE (EU) and BIS/ISO 13485:2003; IEC-60601-1-2; ISO 15001-2010 (Anaesthetic & respiratory equipment- compatibility with oxygen)<br>Certificate of approval for transport ventilator |
| **8** | | TRAINING AND INSTALLATION |
| **8.1** | **Pre-installation requirements: nature, values, quality, tolerance** | electrical sockets; Oxygen supply |
| **8.2** | **Requirements for sign-off** | Supplier to perform installation, safety and operation checks before handover 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 Advanced maintenance tasks required shall be documented |
| **9** | | WARRANTY AND MAINTENANCE |
| **9.1** | **Warranty** | 3 years |
| **9.2** | **Maintenance tasks** | Maintenance manual detailing complete maintaining schedule |

| | | |
|---|---|---|
| **9.3** | **Service contract clauses, including prices** | warranty of three year with free servicing ( min. 3) during warranty |
| **9.4** | **Others** | The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee / warranty period should be attached |
| **10** | | DOCUMENTATION |
| **10.1** | **Operating manuals, service manuals, other manuals** | User and maintenance manuals to be supplied in English language.<br>Certificate of calibration and inspection to be provided.<br>List to be provided of equipment and procedures required for local calibration and routine maintenance List to be provided of important spares and accessories, with their part numbers and cost.<br>Contact details of manufacturer, supplier and local service agent to be provided |
| **10.2** | **Other accompanying documents** | User/Technical/Maintenance manuals to be supplied in English |
| **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 |
| **11.3** | **Temperature Range** | Should be able to operate between – 32 degrees Centigrade to + 52 degrees Centigrade |

| **(A) Intra Venous Cut Down Set** | | | |
|---|---|---|---|
| **S.No** | **Description of items** | **Qty** | **Technical Specifications** |
| 1 | Forceps, Artery, curved, 145mm | 3 | Material: Stainless Steel<br>Rusting Prevention Procedure: Passivated<br>Ultrasonic Cleaned: Yes<br>Dull Polished: Yes<br>Tests Performed: Boil test, performance test, shape test<br>Packing: Individually packed<br>QC Passed: Yes |
| 2 | Forceps, Artery, straight, 145mm | 3 | |
| 3 | Forceps, dissecting, straight, ½ teeth 145mm | 1 | |
| 4 | Forceps, dissecting, straight, Plain 180mm | 1 | |
| 5 | Hook, skin, Gilles, 180mm | 1 | |
| 6 | Handle for surgical blade No. 3 | 2 | |
| 7 | Needle Holder, mayo, 150mm | 1 | |
| 8 | Scissors, ligature, Spenser, 115mm | 1 | |
| 9 | Instruments Container, S.S. with cover | 1 | |
| 10 | Bowl | 1 | |
| 11 | Sponge holding instrument | 1 | |
| 12 | Suture, Nylon 3-0 | 2 | |
| 13 | Suture, Nylon 5-0 | 2 | |
| **(B) Dressing Kit** | | | |
| **S.No** | **Description of items** | **Qty** | **Technical Specifications** |
| 1 | Mayo Scissors 14cm Straight TC | 1 | Material: Stainless Steel<br>Rusting Prevention Procedure: Passivated<br>Ultrasonic Cleaned: Yes<br>Dull Polished: Yes |
| 2 | Dissecting Scissors 14cm Sharp/blunt | 1 | |
| 3 | Lister Bandage Scissors 15cm | 1 | |

| | | | |
|---|---|---|---|
| 4 | Spenser Stitch Scissors 11cm | 1 | Tests Performed: Boil test, performance test, shape test<br>Packing: Individually packed<br>QC Passed: Yes |
| 5 | Forester sponge forceps 25.5cm | 1 | |
| 6 | Dressing forceps 16cm | 2 | |
| 7 | Dressing Forceps 1:2 16cm | 2 | |
| 8 | Kelly Forceps 14cm Straight | 1 | |
| 9 | Adson forceps 12cm | 1 | |
| 10 | Lotion Bowl 04 Oz | 1 | |
| 11 | Kidney dish 08” | 1 | |

| **(C) Suture Kit** | | | |
|---|---|---|---|
| **S.No** | **Description of items** | **Qty** | **Technical Specifications** |
| 1 | Container for storage and sterilization of suturing set | 1 | Material: Stainless Steel<br>Rusting Prevention Procedure: Passivated<br>Ultrasonic Cleaned: Yes<br>Dull Polished: Yes<br>Tests Performed: Boil test, performance test, shape test<br>Packing: Individually packed<br>QC Passed: Yes |
| 2 | Lancet Handle | 1 | |
| 3 | Scissors straight Standard 13-15cm | 1 | |
| 4 | Scissors Curved (Baby Metzenbaum)13-15cm | 1 | |
| 5 | Forceps Straight | 1 | |
| 6 | Needle holder small stout | 1 | |
| 7 | Forceps Hem. Curved 14cm | 2 | |
| 8 | Dressing, Gauge, sterile, 2”X2” Pkg./2 | 1 | |
| 9 | Dressing, Gauge, sterile, 4”X4” Pkg./2 | 1 | |
| 10 | Antiseptic Wipe | 10 | |
| 11 | Suture, Nylon 3-0 | 1 | |
| 12 | Suture, Nylon 5-0 | 2 | |
| 13 | Povidone Iodine, ¾ oz | 2 | |