TECHNICAL SPECIFICATION OF MEDICAL EQUIPMENT FOR CRITICAL CARE BLOCK UNDER PM-ABHIM

HEALTHCARE TECHNOLOGY DIVISION, NHSRC

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MOTORIZED ICU BED		
Version no.:		01
Date:		September 2023
Done By:		HCT/NHSRC
NAME AND CODING		
GMDN Name		Basic electric hospital bed
GMDN Code		34870
GENERAL		
1. USE		
1.1	Clinical Purposes	ICU beds are special hospital beds designed for ICUs to take care of critical patients and can be operated electro-mechanically. ICU beds facilitate comfortable transfer to and fro and has a provision of bedside diagnostic including X-ray investigations. Thus, they provide safety, comfort and convenience to the patients and caregivers alike.
1.2	Used by clinical department/ward	ICU (Intensive Care Unit)
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical Characteristics	1. Should have fully motorised 4 sections and sectional mattress. 2. Should have 4 separate electrically operating function through embedded control panel/handheld wired remote control for Height adjustment (Hi-Low), Back rest, Knee rest and Trendelenburg/Reverse Trendelenburg. 3. The bed frame should be made of Stainless-steel SS (304)with epoxy coating. 4. Should have ABS/polymer moulded head and foot boardpanels detachable. 5. Should have ABS/polymer moulded swing down safety siderailing on both sides. 6. Should have a provision for carrying out whole body X-ray at the bedside. 7. Should have digital/analog indicators for angle display.

		8. Should have one touch key provision on control panel for CPR position and manual CPR option in case of automatic system failure. 9. Bed position adjustments should have: i) Back Rest angular movement in range from 0-70 degree or more. ii) Knee rest angular movement in range from 0-45 degree or more. iii) Trendelenburg and Reverse Trendelenburg: 0-12 degree or more. 10. Should have a therapeutic Weight bearing up to 150-200 Kg 11. Should have heavy duty casters made up of Stainless Steel (304) ball bearing/ABS/Polyester with dual locking arrangement. 12. Should have provision for holding IV pole on four corners. 13. High density foam mattress washable and detachable in 4 parts 14. Should have battery backup of at least 1 hour 15. Clearance between Bed Base frame and Floor surface in adjustable range from mm: 120-150 mm
2.2	User's Interface	Electro-mechanical (motorised)
2.3	Software and/ or standard of communication (wherever required)	NA
3. PHYSICAL CHARACTERISTIC		
3.1	Dimensions (in cm)	1. Length: 2100-2300 mm 2. Width: 900-1100 mm
3.2	Weight	To be specified by the Manufacturer/Supplier;
3.3	Noise	Less than 50dB;
3.4	Heat Dissipation	Not applicable
3.5	Mobility/Portability	Should be easily movable with minimal physical effort.
4. ENERGY SOURCE (electricity, UPS, solar, \gas, water, CO2 .....)		
4.1	Power inputs	220 +/- 10% VAC, 50 Hz
4.2	Power consumption	To be specified by Manufacturer/Supplier;
4.3	Battery backup	Battery backup with inbuilt charger shall be provided.
5. ACCESSORIES. SPARE PARTS AND CONSUMABLE		

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

10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 3. Satisfactory certificate for any existing installation from government hospital
10.2	Other accompanying documents	List of essential spares and accessories with their part number and cost.
11. NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any warning sign should be adequately displayed.

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

		b) Inspiratory Pressure (upto 80 cm of H20) c) Respiratory rate 1 to 80 bpm. d) Apnoea back up rate. e) CPAP/PEEP f) Pressure support. g) Fi02 h) Pause Time i) Pressure & flow Trigger j) Inspiratory flow up to 120 Lpm. 10. **Monitoring and Display of the following Parameters.** a) Airway Pressure (Peak & Mean). b) Tidal volume (Inspired & Expired). c) Minute volume (Inspired & Expired d) Respiratory mechanics. e) Spontaneous Minute Volume. f) Total Frequency. g) F102 dynamic. h) Intrinsic PEEP. i) Plateau Pressure. j) Resistance & Compliance. k) Use selector Alarms for all measured & monitored parameters. l) Occlusion Pressure. m) Pressure Flow & Volume curves. 11. **Modes of Ventilation equipped with newer modes of ventilation: -** a) Assist /control. b) Volume Control. c) Pressure control. d) Pressure support. e) SIMV with pressure support (Pressure and volume control). f) PEEP. g) Inverse ratio Ventilation. h) Non-invasive ventilator- BIPAP, CPAP. i) Apnea Ventilation, User selectable, volume & pressure control. 12. Should have built in safety alarms for Airway Pressure High & low, Minute volume, High & low, power failure, Low oxygen, High

		Respiratory Rate, Air Source in-operable. 13. Should have inbuilt exhalation filter. 14. Compressor should be of same company inbuilt/ mounted with ventilator assembly. 15. Should have compatibility with existing central pipe line. 16. **Humidifier** a) Servo controlled heated Respiratory Humidifier. b) Temperature of delivered Gas on LED display. c) Temperature should be adjustable. d) Jar should be autoclavable 17. Nebulization assembly compatible with ventilator and circuit. 18. Should have interface facility. 19. Flow Sensor-Should have life more than 1 year. 20. Expiratory Unit- Life should be more than 3yrs. 21. Data storage facility for at least 24hrs. 22. Internal rechargeable battery at least 30min. backup. 23. Should be supplied with compatible UPS.
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication (wherever required)**	In-built
3. Physical characteristics		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dba)**	N.A.
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Mobile
4. Energy source (electricity, Ups, solar, gas, water, co2)		
4.1	**Power requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	Battery backup of atleast one hour.
4.3	**Protection**	NA
4.5	**Power consumption**	As specified by manufacturer
5. Accessories, spare parts, consumables		
5.1	**Accessories (mandatory,**	a) Patient breathing circuit of silicone for Adult & Paediatric

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

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

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

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

8.1	**Pre-installation requirements: nature, values, quality, tolerance**	Supplier to perform installation, safety and operation checks beforehandover.
8.2	**Requirements for sign-off**	Supplier to perform safety and operation check before hand over.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter.
10. DOCUMENTATION		
10.1	**Operating manuals, servicemanuals, other manuals**	User, technical and maintenance manuals to be supplied in English/Hindi language along with mavhine diagram.
10.2	**Other accompanying documents**	List of important spares and accessories, with their part numbers and cost.
11. NOTES		
11.1	**Other information**	Contact details of manufacturer, supplier and local service agent to beprovided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed

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

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

		supplied along with machine diagrams. 2) List of equipment and procedures required for local calibration and routine maintenance. 3) Certificate of calibration to be provided by the manufacturer.
10.2	**Other accompanying documents**	List of important spares and accessories, with their part numbers and cost
11. NOTES		
11.1	**Other information**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or Warnings**	Any warning signs should be adequately displayed

LARYNGOSCOPE		
Version no. :		02
Date:		September 2023
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Laryngoscopes
GMDN code		CT 1723
GENERAL		
1. USE		
1.1	**Clinical purpose**	To view the vocal cords and glottis and to facilitate tracheal intubation.
1.2	**Used by clinical department/ward**	PICU/NICU, OT, EMR, ICU/HDU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Fiber optic Laryngoscope - preferably should be reusable using the latest LED technology. 2. The main body of the handle should incorporate an excellent grip & should feel even wearing a glove. 3. The light source should light when the blade is placed into the operating position. 4. The unit should allow the blade to be inserted easily & should provide a positive locking mechanism when moved into the closed position. 5. Should have handle with universal adapter for interchangeable blades. 6. The laryngoscope should be supplied in leather/hard case preferably high impact plastic with internal soft cushion material for easy portability and protection. 7. The blades should be re-usable and autoclavable preferably made of S/Steel (MS-304) of high quality.
2.2	**Settings**	NA
2.3	**User's interface**	Manual
2.4	**Software and/or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	Light weight

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

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

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

4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	Accessories (mandatory, standard and optional); spare parts (main ones) and Consumables/ Reagents (Open/Closed System)	NA
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust...)	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Autoclavable face mask
	7. STANDARDS AND SAFETY	
7.1	Certifications (Pre-Market, Sanitary,), Performance and Safety Standards (Specific to the device type); Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards
	8. TRAINING AND INSTALLATION	
8.1	Pre-installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order)	Training of users in operation and basic maintenance shall be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	Warranty	03 Years
	10. DOCUMENTATION	
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: • User, technical and maintenance manuals should be supplied in English/Hindi/ Regional language along with machine diagrams.
10.2	Other accompanying documents	NA
	11. NOTES	

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

BP APPARATUS (ANEROID)		
Version no. :		02
Date:		September 2023
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Sphygmomanometers
GMDN code(s)		13106
GENERAL		
1. USE		
1.1	**Clinical purpose**	Measures blood pressure non-invasively by displaying the pressure in a cuff wrapped around a patient's arm. The systolic and diastolic pressure is usually assessed by listening to Korotk off sounds generated by arterial blood flow using a stethoscope simultaneously.
1.2	**Used by clinical department/ward**	All clinical departments
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1) Should be based on non-mercurial aneroid based measurement technology. 2) Should be able to measure blood pressure in adult as well as pediatric patients. 3) Should have a dial type display, with a hook which can be attached to the blood pressure cuff. 4) Pressure measurement range should be 0 to 300 mm Hg systolic and 40 to 200mm Hg diastolic. 5) Pressure measurement accuracy of +/- 3 to 5mm Hg 6) Manual inflation of blood pressure cuff.
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA), heat dissipation**	NA
3.4	**Mobility, portability**	Yes
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Protection**	NA
4.4	**Power consumption**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		

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

OPTHALMOSCOPES – DIRECT		
Version no. :		02
Date:		September 2023
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Ophthalmoscopes, Direct
UMDNS code(s)		12817
GENERAL		
1. USE		
1.1	Clinical purpose	Handheld ophthalmoscopes designed for examining the eye (mostlythe back of the eye, the funds) by providing a non-inverted image ofthe eye. The instruments usually consist of a light source to projectthe light into the eye through the pupil, a mirror, and a wheel of lensesof varying strength to provide a magnified view of the eye and to adjust the focus of the view. They produce an upright, or unreversed, magnified image of the eye, at approximately 15 times magnification. Direct ophthalmoscopes are used mainly to detect eye conditions oreye diseases.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Available with LED/Halogen light source. 2. Magnification up to x15 from direct vision to maximum magnification. 3. Red-free, blue and polarization filters and Anti-reflection lens. 4. Should have small and large spot sizes, fixation targets, slitaperture, hemi-spot and cobalt blue filter. 5. Should be rechargeable battery with Charger / battery/ mainsoperated. 6. At least 3 apertures and fixation star. 7. Range of lenses not smaller than -30D to +20D with steps notgreater than 1D. 8. Dust free sealed optics and aspherical optical system.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication (where ever required)	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA

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

8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including for all spares and calibration work.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: User, technical and maintenance manuals should be supplied inEnglish/Hindi/Regional language along with machine diagrams.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number andcost.
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent tobe provided.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

OPTHALMOSCOPES, INDIRECT		
Version no. :		02
Date:		September 2023
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
UMDNS name		Ophthalmoscopes, Indirect
UMDNS code(s)		12818
GENERAL		
1. USE		
1.1	Clinical purpose	Head-worn ophthalmoscopes designed for examining the eye (mostly the back of the eye, the fundus) by providing an inverted image of the funds. These instruments usually consist of a light source attached toa headband to project the light into the eye through the pupil and aconverging lens placed in front of the patient's eye. They produce aninverted, or reversed, image of 2 to 5 times magnification of the entire retina, a field of view much larger than that of direct ophthalmoscopes. Indirect ophthalmoscopes are used mainly to detect eye conditions or eye diseases.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Available with LED/Halogen light source. (Desirably LED). 2. Magnification up to 5x. 3. Red-free, blue and polarization filters. 4. Should have stereo optical system with small pupil feature. 5. Should have synchronized adjustment of convergence parallax.
2.2	User's interface	Manual
2.3	Software and/ or standard of communication (where ever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Supplied in protective case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	220 +/- 10% VAC, 50 Hz

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

10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied inEnglish/Hindi/Regional language along with machine diagrams; 2. Service and operation manuals(original and Copy) to be provided; 3. Advanced maintenance tasks documentation.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number andcost;
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent tobe provided.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

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

		Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit. Internal, replaceable, rechargeable battery allows operation for at least one hour in the event of power failure.
4.3	**Protection**	NA
4.4	**Power consumption**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables/re agents (open, closed system)**	12 lead ECG cable. 2 sets of spare fuses (if non-resettable fuses are used) 5 tube electrode gel (if required)
	BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS	
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type)**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	• 03 years

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

Portable Ventilator		
Version no.:		01
Date:		September 2023
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Intensive-care ventilators
GMDN code(s)		CT2175
GENERAL		
1. Use		
1.1	**Clinical purpose**	to provide automated, alveolar ventilatory support for patients during interhospital or intrahospital transport, and in emergency situations. It is typically a compact, lightweight, rugged device with internal batteries to power it during patient transport.
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. Modes of ventilation: a) Volume controlled. b) Pressure controlled. c) Pressure support. d) Synchronized intermittent mandatory ventilation (SIMV). e) Assist/control mode. f) PEEP. 2. Alarms required: FiO2, minute volume, pressure, PEEP, apnoea, occlusion, high respiration rate, disconnection. 3. System alarms required: power failure, gas disconnection, low battery, vent inoperative, self diagnostics. 4. If alarm silencing feature is incorporated, it must be temporary and clearly displayed when activated. 5. Air and externally supplied oxygen mixture ratios fully controllable. 6. Inlet gas supply (O2) pressure range at least 35 to 65 psi. 7. Medical air compressor integral to unit, with inlet filter. 8. Visual and audible alarms Accessories and tubing should be supplied for adult, pediatric & neo-natal size requirements. 9. The following variables should be controllable by the operator: a) Tidal volume up to 100 ml. b) Pressure (inspiratory) up to 80 cm H2O.

		c) Volume (inspiratory) up to 120 l/min. d) Respiratory rate: up to 60 breaths per minute. e) SIMV Respiratory Rate: up to 40 breaths per minute. f) PEEP up to 20 cm H2O. g) Pressure support up to 45 cm H2O. h) FiO2 between 21 to 100 %. i) Inspiratory and expiratory times up to at least 2 sec and 8 sec respectively
2.2	**User's interface**	Manual and Automatic
2.3	**Software and/or standard of communication (wherever required)**	In-built
3. Physical characteristics		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dba)**	N.A.
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Mobile
4. Energy source		
4.1	**Power requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	With atleast 6 hours battery backup.
4.3	**Protection**	NA
4.5	**Power consumption**	As specified by manufacturer
5. Accessories, Spare parts, Consumables		
5.1	**Accessories (mandatory, standard, optional) Spare parts (main ones) Consumables / reagents (open, closed system)**	a) Full face mask, breathing circuit, carry bag, filters. b) Battery, leakage adapter.
6. Environmental and departmental considerations		
6.1	**Atmosphere / ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.

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

Mobile X-ray Machine (100 mA X-Ray)		
Version no.:		02
Date:		September 2023
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Radiographic Units, Mobile
GMDN code(s)		13272
GENERAL		
1. Use		
1.1	**Clinical purpose**	Mobile X-Ray unit is required to perform X-Ray studies in emergency & trauma departments & at bed side in wards & ICU.
1.2	**Used by clinical department/ ward**	Radiology Unit
TECHNICAL		
2. Technical characteristics		
2.1	**Technical characteristics (specific to this type of device)**	Compact, easily transportable mobile radiographic unit suitable for bed side X-Ray in Emergency, ward, ICU, Operation Theatre & also in the radiology department for conventional radiography. **X-ray Generator**: 1. High frequency X-Ray generator having frequency of 20 KHz or more suitable for radiography should be provided. 2. Power output of generator should be 20 KW Radiography KV range should be 40-120 KV or more. mA range (rad.): 100 mA or more. **Control**: 1. A very compact, Soft touch Control panel having following functions & indications should be provided. The panel can be supplied in floor or wall mount with spill proof design following features should be on the control panel. 2. Machine ON/OFF switch, Digital display of KV & mAs, KV & mAs increase and decrease switches. Tube focal spot selection switch, Ready and x-ray on switch with indicators. 3. Bucky selection switch. 4. Self-diagnostic programme with indicators for earth fault error, KV error, filament error & Tube's thermal overload. **X-Ray Tube:**

		1. Tube should have one number stationary anode and thermally protected 2. Anode heat storage capacity of tube should be more than 140 KHU. One number manual collimator with aluminium filter & for adjustment of exposure area.
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication (wherever required)**	In-built
3. Physical Characteristics		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dba)**	Noise free system
3.4	**Heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	**Mobility, portability**	Mobile
4. Energy source (electricity, Ups, solar, gas, water, co2)		
4.1	**Power requirements**	220 V AC +/- 10%, 50 Hz
4.2	**Battery operated**	NA
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by manufacturer.
4.5	**Other energy supplies**	NA
5. Accessories, spare parts, consumables		
5.1	**Accessories (mandatory, standard, optional);Spare parts (main ones); Consumables / reagents (open, closed system)**	Machine should be provided with following accessories: Parts : 1. Two numbers of BARC approved whole body lead aprons with all attachments. 2. One pair of 8-meter HV Cable .
6. Environmental and departmental considerations		
6.1	**Atmosphere / ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, cleaning, Disinfection & sterility issues**	1. To be specified by manufacturer
7. Standards and Safety		
7.1	**Certificates (pre-market, sanitary, ..); performance and safety**	1. Should be CDSCO and AERB approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of

	standards (specific to the device type); local and/or international	non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
8. Training and Installation		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign-off**	Supplier to perform safety and operation check before hand over.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users on operation and basic maintenance.
9. Warranty and Maintenance		
9.1	**Warranty**	03 years including all spares. Preventive maintenance visits at least once in each quarter.
10. Documentation		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 4. Advanced maintenance tasks documentation. 5. Certificate of calibration and inspection. 6. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	NA
11. Notes		
11.1	**Service support contact details (hierchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

Portable Ultrasound		
Version		02
Date:		September 2023
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. USE		
1.1	**Clinical purpose**	An assembly of devices designed for extracorporeal and / or intracorporeal (endosonography or endoscopic) imaging procedures involving the heart and blood vessels. Included are software packages that support a variety of static or real-time cardiac specific imaging applications used to diagnose anatomical defects of the heart, determine blood flow characteristics and functional anatomical problems associated with myocardial infarction.
1.2	**Used by clinical department/ward**	Radiology
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. A typical configuration for a cardiac ultrasound system consists of a scanner and software, several single- or multi frequency transducers, a TEE probe, color Doppler, M-mode, CFM, cardiac analysis software. 2. Phased array transducers required. 3. Following transducers are to be supplied: • A-2.0-5.0 MHz Multi frequency Convex Transducer-One. • B-5.0-12.0 MHz Multi frequency Linear transducer-One. • C-5.0-8.0 MHz or more Endo Cavitory probe-One. 4. Transesophageal Echocardiogram - TEE scanning capability. 5. Penetration depth of at least 30 cm. 6. Digital and caliper measurement functions required for both distance and area. 7. Alphanumeric annotation to be possible. 8. Measurement accuracy to be better than 2% over 10cm distance. 9. Doppler display to indicate blood flow both numerically and in colour.

		10. System that is DICOM compatible for communication efficiency. 3D or 2D image for cardiac studies in adults, children and infants 11. ZOOM in real time at least 4X and ZOOM for frozen image at least 20X. 12. Equipment dynamic range, at least, 180 dB.
2.2	**User's interface**	Patient Communication system: An integrated intercom and automated patient instruction system API should be provided.
2.3	**Software and/or standard of communication (wherever required)**	The hardware and software included should allow the following application: Cardiac and stress echo; tissue differentiation to clearly show the walls of the left ventricle and regional wall motion abnormalities. Left ventricle wall abnormalities software; abdominal; obstetrical and gynecological; peripheral and deep vascular.
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA),**	Noise free system
3.4	**Heat dissipation**	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through a cooling mechanism.
3.5	**Mobility, portability**	Mobile
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)		
4.1	**Power Requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	3 Hours
4.3	**Protection**	NA
4.4	**Power Consumption**	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional);** **Spare parts (main ones);** **Consumables / reagents (open, closed system)**	All probes required for frequency range stated. It is recommended include the type of transducers and the minimum transducers with harmonics.
BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.

6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up. PCPNDT Act clearance.
8.2	**Requirements for sign-off**	Supplier to perform safety and operation check before hand over.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	03 Years Preventive Maintenance visits at least once in each quarter.
	10. Documentation	
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Advanced maintenance tasks documentation. 3. Certificate of calibration and inspection. 4. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost.
	11. Notes	
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

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

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

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

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

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

9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in eachquarter.
	10. DOCUMENTATION	
10.1	**Manuals**	Should provide 2 sets (hardcopy) of: - 1) User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams. 2) List of equipment and procedures required for localcalibration and routine maintenance. 3) Certificate of calibration and inspection;
10.2	**Other accompanying Documents**	List of important spares and accessories, with their part numbers and cost.
	11. NOTES	
11.1	**Other information**	Contact details of manufacturer, supplier and local serviceagent to be provided.
11.2	**Recommendations or Warnings**	Any recommendations for best use and supplementary warning for safety should be declared.

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

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

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

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

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

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

PATIENT STRETCHER		
Version no. :		02
Date:		September 2023
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		-
GMDN code		-
GENERAL		
1. USE		
1.1	**Clinical purpose**	A patient trolley is a bed on wheels for moving patient in hspitals.
1.2	**Used by clinical department/ward**	All Departments
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Overall Dimension: 1985 mm (L) x 610 mm (W) x 810 mm (H). (Specific to this type of 2. Frame work: • Vertical member- Thickness of tube Cut size diameter of tubing pipe- 18 Gauge 31.75mm • Horizontal member - 18 Gauge 31.75mm 3. Removable stretcher made of curved CRCA Sheet 20 SWG supported on tubular frame having steel supports under the sheet. 4. Wheels: 4 Nos. swivel caster wheels are fitted in front and rear side of the wheel 150mm diameter x 38mm with plug diameter 32.5mm fitted with thrust bearing and solid rubber wheels with sleeve 21mm thick fork 10 SWG zinc plated. King pin is 14.5mm; length of plug is 65mm inclusive of collar. 5. Handle should be made of SS-304. 6. All the steel components should be pre-treated for de-greasing. de-rusting and phosphating. After proper pre-treatment, the steel components should be epoxy powder coated and oven baked at temp. Above 200 °C to provide scratch resistance surface coating film thickness 45-50 microns
2.2	**Settings**	NA
2.3	**User's interface**	NA
2.4	**Software and/or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA

3.4	**Noise (in dBA), heat dissipation**	NA
3.5	**Mobility, portability**	Mobile
	4. ENERGY SOURCE	
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Protection**	NA
4.4	**Power consumption**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables / reagents (open, closed system)**	NA
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	NA
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Easy to clean and maintain.
	7. STANDARDS AND SAFETY	
7.1	**Certificates**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	NA
8.3	**Training of staff (medical, paramedical, technicians)**	NA

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

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

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

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

4.3	**Protection**	NA
4.4	**Power consumption**	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables/reagents (open, closed system)**	Glucose strips (able to use capillary blood samples) with availability in local market
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity upto 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards in case of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	NA
8.3	**Training of staff (medical, paramedical, technicians)**	User training should be provided.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	01 Years
	10. DOCUMENTATION	
10.1	**Operating manuals, service manuals, other manuals**	User, technical and maintenance manuals should be supplied along with machine diagrams
10.2	**Other accompanying Documents**	NA
	11. NOTES	
11.1	**Other information**	Contact details of manufacturer and supplier should be provided.
11.2	**Recommendations or Warnings**	NA

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

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

(ICU BED- MECHANICAL, HANDLE OPERATED)		
Version no.:		01
Date:		September 2023
Done By:		HCT/NHSRC
NAME AND CODING		
GMDN Name		Hydraulic Hospital Bed
GMDN Code		34871
GENERAL		
1. USE		
1.1	Clinical Purposes	ICU beds are special hospital beds designed for ICUs totake care of critical patients. ICU beds facilitates comfortable transfer to and fro and has a provision of bedside diagnostic including X-ray investigations. Thus, they provide safety, comfort and convenience to the patients and caregivers alike.
1.2	Used by clinical department/ward	ICU (Intensive Care Unit)
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical Characteristics	1. Should have 4 sections and sectional mattress with perforated top. 2. Should have 4 separate mechanical operating function (Screw Lever mechanism) for Height adjustment (Hi- Low), Back rest, Knee rest and Trendelenburg/Reverse Trendelenburg. 3. Should have PPE head and foot board fixed/ detachable on the bed frame; 4 PPE side boards with 360-degree swivel mechanism/push button mechanism for operation. 4. Should have four section lying surface, three made of robust materials and having microbe free material & joined by corrosion resistant joineries. 5. The bed frame should be made of stainless-steel SS (304) with epoxy coating and should be easy to disinfect and maintain. 6. The bed should be radiolucent for using portable X-rays and supporting accessories like attaching urine bags and bed pans. 7. Should have indicator for correct height to operate Trendelenburg/Reverse Trendelenburg. 8. Clearance between Bed Base frame and Floor surfaceshould be having adjustable range in mm: 120-150 mm. 9. Should have Back Rest angular movement in range from 0-70^{o} (degree) and Knee rest angular movementin range from 0-

		45^{o} (degree). 10.Should have Ergonomically designed detachable plastic/Stainless steel handles having outward locking mechanism. Handles are self-locking with a knob with aNylon grip. 11. Should have a therapeutic Weight bearing up to 150-200 Kg. 12. Should have heavy duty roller casters made up of Stainless Steel (304) ball bearing/ABS/Polyester with dual locking arrangement. 13. High density foam mattress washable and detachable in 4 parts.
2.2	User's Interface	Manual
2.3	Software and/ or standard of communication (wherever required)	NA
3. PHYSICAL CHARACTERISTIC		
3.1	Dimensions (in cm)	NA
3.2	Weight	To be specified by the Manufacturer/Supplier;
3.3	Noise	NA
3.4	Heat Dissipation	Not applicable
3.5	Mobility/Portability	Should be easily movable with minimal physical effort.
4. ENERGY SOURCE		
4.1	Power inputs	NA
4.2	Power consumption	NA
4.3	Battery backup	NA
5. ACCESSORIES. SPARE PARTS AND CONSUMABLES		
5.1	Accessories,(mandatory, Standard, operational); Spare parts (main ones) Consumable/reagents (open, closed system)	1. Should be provided with Saline Stand made of StainlessSteel SS (304) grade. 2. Telescopic Saline Stand with two hooks with a provisionto fix on all four corners of the beds and also in the middle of the bed on either side. 3. Mattress with cross sectional thickness of (100mm-250mm) with rexin cover as per the specs specified in Section (2.1) 4. Oxygen Cylinder holder should be provided detachable handles of plastic/SS (304) material/ABSwith a Nylon grip.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		

6.1	Atmosphere /Ambiance (air conditioning, humidity, dust ...)	NA
6.2	User's care, Cleaning, Disinfection & Sterility issues	Easy to clean and disinfect.
7. STANDARDS & SAFETY		
7.1	Certificates (pre-market, sanitary); Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	Supplier to perform safety and operation check before hand over.
8.3	Training of staff (medical, paramedical, technicians)	Training of User on operation and basic maintenance.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years including all spare parts and accessories.
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 3. Satisfactory certificate for any existing installation from government hospital
10.2	Other accompanying documents	List of essential spares and accessories with their part number and cost.
11. NOTES		

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

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

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

9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter.
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 3. Satisfactory certificate for any existing installation from government hospital
10.2	**Other accompanying Documents**	List of essential spares and accessories, with their par number and cost.
11. NOTES		
11.1	**Other information**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or Warnings**	Any recommendations for best use and supplementary warning for safety should be declared.

OT TABLE		
Version no.:		02
Date:		September 2023
Done by: (name / institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Operation table
GMDN code		NA
GENERAL		
1 USE		
1.1	**Clinical purpose**	An operating table, sometimes called operating room table, is the table on which the patient lies during a surgical operation. This surgical equipment is usually found inside the surgery room of a hospital.
1.2	**Used by clinical department/ward**	Operation theatre
TECHNICAL		
2 TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific tothis type of device)**	1) Should have OT Table type base made of high quality304 stainless steel with double table, split leg type and can take x ray photography. 2) Should have imported Y type sealing ring with good sealing performance and durability. 3) Should have a Rotary brake device which is easy for moving operating table. 4) Base is stainless steel. 5) Leg board is separated & dischargeable. 6) Inclining forward ≥30° 7) Inclining backward ≥25° 8) Inclining leftward≥20° 9) Inclining rightward≥20° 10) Back board folding upward ≥45˚ Fold downward ≥90° 11) Headboard folding upward ≥80°Folding downward ≥10° 12) Leg board Folding downward ≥90°. 13) Fold outward ≥90°. 14) Waist board elevation ≥120°. 15) The table top must be made of durable radiolucent Bakelite material capable of withstanding exposure to frequent C-Arm imaging, without diminishing the Image clarity
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA

3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	NA
	4 ENERGY SOURCE	
4.1	**Power Requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	Yes
4.3	**Protection**	NA
4.4	**Power consumption**	As specified by manufacturer
	5 ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)**	1) Shoulder support (1 pair) 2) Waist Support (1 pair) 3) Arm rest (1 pair) 4) Leg holder (1 pair) 5) Screen Frame (1 Piece) 6) Foot Plate (1 Pair)
	BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS	
	6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection &Sterility issues**	To be specified by manufacturer.
	7 STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards in case of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
	8 TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.
8.2	**Requirements for sign-off**	Supplier to perform safety and operation check before hand over.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users on operation and basic maintenance;
	9 WARRANTY AND MAINTENANCE	
9.1	**Warranty**	03 years
	10 DOCUMENTATION	

10.1	**Operating manuals, service manuals, othermanuals**	Should provide 2 sets (hardcopy and soft-copy) of:- 1) User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams. 2) Service and operation manuals (original and copy) to be provided. 3) Advanced maintenance tasks documentation.
10.2	**Other accompanying documents**	List of important spares and accessories, with their part numbers and cost;
11 NOTES		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning signs would be adequately displayed

OT LIGHT (SHADOWLESS LAMP CEILING TYPE MAJOR)		
Version no.:		02
Date:		September 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Shadowless lamp ceiling type major
GMDN code(s)		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	Luminescence shadow less lamp adopts light sources different positions for focus to eliminate shadows of different parts of medical workers.
1.2	**Clinical department/ward**	Operation Theater
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics**	1) Double dome 2) Intensity Control in 9 steps for individual domes 3) Height Adjustment :600mm 4) Action Radius :1850mm 5) Possible Movements: Radial, Angular & Axial 6) Colour Temperature :4500K and above 7) LED technology: minimum 40,000 hours lamp life 8) Intensity, brightness, contrast and power switch to be made available on handle/wall-check. 9) Focal distance(d1+d2) =0.8 to 1.2 m 10) Temperature rises on the keep of surgeries to be less than 10° 11) CR± approx. 95 or more 12) 360° rotation for both arms
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**heat dissipation**	Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through an cooling mechanism
3.5	**Mobility, portability**	Stationary
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)		
4.1	**Power Requirements**	220 +/- 10% VAC, 50 Hz

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

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

ANAESTHESIA WORKSTATION		
Version no.:		02
Date:		September 2023
Done by:(Name/Institution)		HCT/NHSRC
NAME AND CODING		
UMDNS name		
UMDNS code(s)		
GENERAL		
1 USE		
1.1	Clinical purpose	Devices that continuously or intermittently administer a mixture of gases (e.g., oxygen, nitrous oxide, the vapor of a volatile liquid such as halogenated hydrocarbon), varying the proportion of gases in order to control an individual's level of consciousness. These devices are also designed to facilitate spontaneous, controlled, or assisted ventilation with these gas mixtures. An anesthesia unit is typically comprised of four basic subunits: a gas supply and controlcircuit, breathing and ventilation circuit, a scavenging system to help prevent the escape of exhaled gases, and a set of function and breathing circuit monitors (e.g., inspired oxygen concentration, breathing circuit integrity).
1.2	Used by clinical department/ward	Operation Theatre
TECHNICAL		
2 TECHNICAL SPECIFICATIONS		
2.1	Technical characteristics (Specific to thistype of device)	Flow Management: 1. Should be compact, ergonomic and easy to use. 2. Machine should provide electronic gas mixing. 3. Multi color TFT display of at least 15"size, with virtual meters forO2, N2O or Air. 4. Dual flow sensing capability at inhalation and exhalation ports. 5. Should have backup02control which provides an independentfresh gas source and flow meter control in case of electronic failure. 6. Gas regulators (flow control valves) shall be of modulardesign/ graphic display. 7. All pipeline connections should have diameter-indexed safety systems (DISSs) or another means of preventing connection of dangerous gases. 8. System should permit connection of atleast two yokes, one dedicated to 02 cylinder to meet clinical needs during failure ofpipeline supply. All cylinder yokes (regardless of the gas forwhich they are

		intended) should include pin-index safety systems to prevent connection of dangerous gases. 9. Hypoxic guard to ensure minimum 25% 02 across all 02-N2O mixtures and Oxygen failure warning. **Breathing System:** 1. Latex free fully autoclavable/ disposable with minimal flowof 250 ml of 02. 2. Sensor should not require daily maintenance. 3. Bag to vent switch shall be bi stable and automaticallybegins mechanical ventilation in the ventilator position. 4. Adjustable pressure limiting valve shall be flow and pressure compensated. **Vaporizers:** 1. Provision to mount following selectable vaporizers such asDesflurane, halothane, isoflurane, sevoflurane with interlocking facility to allow use of only one vaporizer at a time. 2. All the vaporizers should be temperature, pressure andflow compensated vaporizers and maintenance free. **Ventilation:** 1. The workstation should have an integrated anesthesia ventilator system. 2. It should have the following Ventilation modes Manual/spontaneous, VCV, PCV, SIMV or pressure support,advanced modes. 3. Tidal volume: A control adjusts the volume of individualbreaths within range of 20-1,500 cc. 4. Minute volume: A control adjusts the total inspiratory volume- per-minute delivery from the bellows shall be >20L/min. 5. The respiratory frequency can be set within range of 5-60 breaths per minute. 6. Inspiratory flow: The flow range of gas that the ventilatoris capable of delivering to the patient shall be 0-180 L/min. 7. Pressure limit shall be adjustable and <70 preferred cmH2O. Unit should have PEEP of 0-20 cm H2O. 8. The workstation should be capable of delivery of low flow anesthesia. **Anesthesia Monitoring Specifications:** 1. Monitoring of vital parameters: ECG, NIBP, SPO2, andInvasive Blood Pressure. 2. Twin temperature measurement with skin

		and coretemperature probes — Two sets with each monitor. 3. Automatic identification and measurement of anestheticagents EtCO2, 02, and N2O and MAC value. FiO2 measurement. 3. Facility to store snapshots during critical events forwaveform review at a later stage. 4. Audio visual and graded alarming system. **Display of Ventilator:** Mode of ventilation to be displayed, Respiratory rate, flow,pressure also to be displayed.
2.2	User Interface	Manual
2.3	Software and/ or standard of communication (where ever Required)	Inbuilt
3 PHYSICAL CHARACTERICSTICS		
3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise pressure level: <60 dbA.
3.4	Heat dissipation	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	Mobility, portability	Portable
4. ENERGY SOURCE		
4.1	Power	220 +/- 10% VAC, 50 Hz
4.2	Battery operated	Yes, at least 30 minutes back up.
4.3	Protection	Stabilizer to be provided for protection.
4.4	Power consumption	To be specified by service provider.
5. ACCESSORIES, SPARE PARTS AND CONSUMABLES		
5.1	Accessories, standard, optional); Spare parts (main ones); Consumables/re-agents (open, closed system)	1. Circle absorber — 01 No. 2. Vaporizer Halothene — 01 No. 3. Vaporizer Desflurane — 01 No. 4. Vaporizer isoflurane — 01 No. 5. Vaporizer sevoflurane — 01 No. 6. Adult and Pediatric autoclavable silicone breathing circuits —2each. 7. Reusable IBP cable -04. 8. Humidifiers — 1 No 9. Disposable transducer — 100 10. Temperature Probe Skin reusable — 02. 12. Temperature core reusable -04 (02-Adults, 02-paediatrics) 13. Depth of anesthesia sensors — 50 14. Accessories for neuromuscular transmission monitor - 01 set. 15. Standard accessories to make all parameters working -

		01 set. 16. Disposable adult and pediatric circuit — 50 each. 17. HME Filters — 1000 nos 18. Vital parameter accessories (ECG Leads — 5 sets, NIBPCuffs all sizes) -01 set. 19. Spo2 probes both adult and pediatric 2in no should be suppliedwith each machine. 20. EtCo2 sampling line and connector should be supplied 25 no each with apparatus.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust. ..)	Capable of operating continuously in ambient temperature of -10to 60 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by manufacturer.
7 STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance andsafety standards (specific to the device type); Local and/or International	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase ofnon-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements ofelectrical safety standards.
8 TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	To be specified by manufacturer and compatible electricalaccessories as per Indian standard set-up
8.2	Requirements forsign-off	Supplier to perform safety and operation check before hand over.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shallbe provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	• 03 years • Preventive Maintenance visits at least once in each quarter
10 DOCUMENTATION		

10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be suppliedin English/Hindi/ Regional language along with machine diagrams. 2. Service and operation manuals (original and Copy) to beprovided. 3. Advanced maintenance tasks documentation. 4. Satisfactory certificate for any existing installationfrom government hospital.
10.2	Other accompanying Documents	List of essential spares and accessories, with their part number and cost.
11 NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agentto be provided.
11.2	Recommendations or Warnings	Any warning sign would be adequately displayed.

SURGICAL DIATHERMY (ELECTROSURGICAL UNIT)		
Version no.:		02
Date:		September 2023
Done by: (name. Institution)		HCT/NHSRC
NAME AND CODING		
UMDNS name		Electrosurgical Unit
UMDNS code(s)		NA
GENERAL		
1. USE		
1.1	Clinical purpose	Diathermy uses an electric current to produce heat deep inside a targeted tissue. It can reach areas as deep as two inches from the skin's surface. The diathermy machine does not apply heat directly to the body. Instead, the current from the machine allows the body to generate heat from within the targeted tissue
1.2	Used by clinical department/ward	OT
TECHNICAL		
2. TECHNICAL CHARACTERICSTICS		
2.1	Technical characteristics (Specific to this type of device)	1) Facility for Monopolar, Bipolar and underwater cutting. 2) Monopolar cutting and coagulation 3) Micro-processor-based technology 4) Monopolar cut in minimum 3 modes 5) Bipolar coagulation in 3 or more modes (forced coagulation, spray coagulation and soft coagulation) 6) Blending of cutting and coagulation -in minimum 2 levels 7) Automatic cut-off technology with self check on every start. 8) Foot and hand switch 9) Auto monitoring and display of set parameters 10) Touch-controlled interface to set parameters 11) 4 or more programmable memory 12) Simultaneous use of Monopolar and Bipolar Coagulation. 13) Output Power of 300 Watt(Minimum) 14) Monopolar Cutting and Coagulation power adjustable from 0-300 Watt 15) Bipolar Coagulation power adjustable from 0-50 W, Micro Power Range- 0.1-to-9.9-Watt increment of 0.1 Watt, Macro Power range from 1-50 Watt increment of 1 Watt 16) Audio-Visual Alarm for disconnection of Neutral Plate
2.2	User's interface	Manual
2.3	Software and/ or standard of communication (where ever required)	Inbuilt
3. PHYSICAL CHARACTERICSTICS		
3.1	Dimensions(metric)	NA

3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise pressure level: <60 dbA.
3.4	Heat dissipation	NA
3.5	Mobility, portability	Portable
4. ENERGY SOURCE		
4.1	Power	220 +/- 10% VAC, 50 Hz
4.2	Battery operated	NA
4.3	Protection	NA
4.4	Power consumption	To be specified by Manufacturer
5. ACCESSORIES, SPARE PARTS AND CONSUMABLES		
5.1	Accessories, standard, optional); Spare parts (main ones); Consumables/re- agents (open, closed system)	1) Power cord :1pc 2) Electrode lever:1pc 3) Electrode:2sets 4) Collective electric bulb: 2pcs switch 5) Trolley: Foot switch 6) Reusable electrode handle withcutting/coagulation switch 7) Disposable REM plate 8) Cable for electrode handle 9) Neutral plate for adults and pediatric
6 ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust…)	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirementsof electrical safety standards.
8. TRAINING AND MAINTENANCE		
8.1	Pre- installation requirements:	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenanceshall be provided.

9. WARRANTY AND MAINTENANCE		
9.1	Warranty	• 03 years • Preventive Maintenance visits at least once ineach quarter
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: 1) User, technical and maintenance manuals shouldbe supplied in English/Hindi/ Regional language along with machine diagrams. 2) Advanced maintenance tasks documentation. 3) Satisfactory certificate for any existinginstallation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their partnumber and cost;
11. NOTES		
11.1	Service Support Contact details	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

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

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

10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 3. Satisfactory certificate for any existing installation from government hospital
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	**Service support contact details (hierchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations and Warnings**	Any warning sign should be adequately displayed.

RADIANT WARMER		
Version no. :		02
Date:		September 2023
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		
GMDN code(s)		
GENERAL		
1. USE		
1.1	**Clinical purpose**	Infant Radiant warmer is an electrically powered device with a radiant heating source intended to maintain the thermal balance of an infant by direct radiant of energy in the infrared region of the electromagnetic spectrum.
1.2	**Used by clinical department/ ward**	Neonatal ICU/ SNCU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. It should be microcontroller chip based radiant warmer with manual and servo options. 2. It should have the facility to display skin set, skin observed temperature in degree C and heat power separately. 3. Should have user friendly touch panel control. 4. It should have ceramic or quartz infrared or calrod heater. 5. It should have audiovisual alarm facility for overheating beyond set temperature range. 6. It should have an alarm facility for patient temperature less than or greater than the required temperature i.e.above or below the set range. Machine should sense the skin probe failure and cut off the heater. 7. The warmer head should be rotatable in different direction, so as to allow taking X-ray. 8. It should have an alarm for probe failure, power failure, system failure and heater failure. 9. Observation light of 90-to-100-foot candles or 1000Lux (color temperature range 3700K to 5100K) should be provided for inspection. 10. Battery backup for Power failure indication during power fail. 11. The desired temperature range from 25 to 40 degree C and settable temperature can be from 32 to 38 degC. 12. The resolution should be 0.1 degree C and accuracy

		should be 0.2 °C. 13 Should have a facility to lock the keyboard to avoid unwanted user modification of the set parameters. 14. The height of the warmer should be adjustable for different types of bed. 15. It should have separate bassinet trolley, bed should be tiltable and have provision for x-ray cassette holder, Mattress foam density should be minimum 25 kg/cm3, transparent collapsible side walls easily detachable for cleaning. Mattress size should be minimum 20"X30". 16. Should have a Feather Touch operation with large digital display and comprehensive alarms. Control Panel should be liquid proof and allow easy and hygienic disinfection. 17. Manual Mode can adjust Heater Output 10 -100 %, with 10% increment, an auditory and visual alarm shall be given at least every 15 min. 18. In manual mode, heater cut off / switch off, if the maximum irradiance at any point of the mattress area exceeds a total irradiance level of 10 mW/ cm2 (between 10 to 30 minutes). 19. Bed should be about 80 - 100 cms from the Floor and 80-90cms from the heat source. 20. Should have lockable castor wheels. 21. Green indicator light shall be provided to indicate that warmer is ready for normal use. 22. Markings on the bassinet and X-Ray cassette holder is mandatory to enable proper positioning of the baby while doing the X-Ray. 23. The size of the drop-down sides should be such that it is 5" above the mattress surface and should be at least 6mm thick; clear and transparent. 24. If there is more than 60% heater output for 10 minutes it should cutoff with alarm. 25. For the purpose of cable management there should be at least two number of tubing ports (edges covered by silicon rings) on the side walls. The height of the side walls should be minimum 110mm over the mattress. 26. X-Ray cassette tray should be at least 750X350mm and should adopt up to 20mm thick X-Ray cassette. 27. The bay bed should be crevice free for ease of cleaning, infection control. 28. The mattress used should be of biocompatible material. 29. Thermistor based skin temperature probe should be small in size not more than 10mm diameter and 3-4mm thick to fix the probe firmly on the infant. Baby contact material should be biocompatible as per ISO 10993 standard requirement. It should be insulated on one side and have

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

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

10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/landlinenumber)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations orwarnings**	Any warning/ precautions to be declared

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

		3. Sodium profiling of dialysate 4. Single needle dialysis facility 5. Hemodiafiltration 6. Optical detector
2.2	**User's interface**	LCD display
2.3	**Software and/or standard of communication (wherever required)**	In-built
3. Physical Characteristics		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dba)**	N.A.
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Mobile
4. Energy source (electricity, Ups, solar, gas, water, cO2)		
4.1	**Power requirements**	220 V AC +/- 10%, 50 Hz
4.2	**Battery operated**	UPS with at least 2-hour battery backup
4.3	**Protection**	NA
4.4	**Power consumption**	As specified by manufacturer
5. Accessories, spare parts, consumables		
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)**	All consumables required for installation and standardization of system to be given free of cost.
6. Environmental and departmental considerations		
6.1	**Atmosphere / ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, cleaning, Disinfection & sterility issues**	To be specified by manufacturer.
7. Standards and Safety		
7.1	**Certificates (pre-market, sanitary, ..); performance and safety standards (specific to the device type); local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
8. Training and Installation		

8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign-off**	Supplier to perform safety and operation check before hand over
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. Warranty and Maintenance		
9.1	**Warranty**	03 years including all spares. Preventive maintenance visits at least once in each quarter.
10. Documentation		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	**Service support contact details (hierchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

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

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

10.2	Other accompanying documents	NA
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer and supplier should be provided.
11.2	Recommendations or warnings	Any warning sign should be displayed adequately.

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

2.3	**Software and/or standard of communication (wherever required)**	NA
3. Physical Characteristics		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dba)**	Noiseless
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Portable
4. Energy source (electricity, Ups, solar, gas, water, cO2)		
4.1	**Power requirements**	220 V AC +/- 10%, 50 Hz
4.2	**Battery operated**	Minimum 6 hours battery back up
4.3	**Protection**	NA
4.4	**Power consumption**	As specified by manufacturer
5. Accessories, spare parts, consumables		
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)**	1) Each device should be provided with 30 nasal prongs (At least three sizes suitable for neonates weighing <1000grms, 1000-1500grms & >1500grms) 2) Air and O2 hose of 3m length each along with the appropriate socket
6. Environmental and departmental considerations		
6.1	**Atmosphere / ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, cleaning, Disinfection & sterility issues**	To be specified by manufacturer
7. Standards and Safety		
7.1	**Certificates (pre-market, sanitary, ..); performance and safety standards (specific to the device type); local and/or international**	• Should be BIS and CDSCO approved. • Should conform USFDA/ European CE, in case of non-availability of BIS Standards. • Should conform to ISO 13485 quality standards. • Should conform to IEC 60601-1-General requirements of Electrical Safety Standards
8. Training and Installation		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	**Requirements for sign-off**	Supplier to perform safety and operation check before hand over.

8.3	**Training of staff (Medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. Warranty and Maintenance		
9.1	**Warranty**	03 years including all spares. Preventive maintenance visits at least once in each quarter.
10. Documentation		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 3. Satisfactory certificate for any existing installation from government hospital
10.2	**Other accompanying documents**	NA
11. Notes		
11.1	**Service support contact details (hierchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

BI-LEVEL POSITIVE AIRWAY PRESSURE (BiPAP) UNIT (ADULT/PEDIATRIC)		
Version no.:		01
Date:		September 2023
Done By:		HCT/NHSRC
NAME AND CODING		
GMDN Name		Bi-Level Positive Airway Pressure Unit (BiPAP Unit)
GMDN Code		60712
GENERAL		
1. USE		
1.1	Clinical Purpose	A BiPAP (bi-level positive airway pressure), device is a form of non-invasive ventilation (NIV) therapy used to facilitate breathing. This helps in providing positive pressure ventilation both in inspiration and expiration phase. The machine is connected with a tube to the face mask worn over nose & mouth by the patient. BiPAP is helpful in a variety of clinical conditions that make breathing difficult, such as chronic obstructive pulmonary disorder (COPD, obstructive sleep apnoea, obesity hypoventilation syndrome (Pickwickian Syndrome), Amyotrophic Lateral Sclerosis (ALS), Muscular dystrophy.
1.2	Used by clinical department/ward	ICU, PICU, Emergency, HDU, General Ward
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical Characteristics	1. Should have Real-time display – LCD display shows actual pressure, leak rate and patient breathing parameters such as breath rate, I/E ratio, minute volume and tidal volume, On board Filter Clean Reminder, etc 2. BIPAP (Bi-level Positive Airway Pressure) should be a complete unit with al standard accessories. 3. The device should allow adjustment of transitions in and out of IPAP and EPAP 4. IPAP: approx. 3 to 25 cm H2O, EPAP: approx. 3 to 25 cm H2O 5. Breath rate: approx.0 to 30 BPM with spontaneous for time mode or manual override 6. Timed inspiration: approx. 0.5 to 3.0s 7. Should have ramp function to lower the pressure at initial phase and slowly increase to allow pressure. 8. Should have automatic leakage compensation. 9. Should have customizable and the sensitivity of the trigger should be adjustable. 10. Should have operating mode of CPAP, Spontaneous, timed, PAC/PC (Pressure Assisted Control/Pressure Control). 11. Should provide with carry bag.

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

7.1	Certificates (pre-market, sanitary); Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	Requirements for sign-off	Supplier to perform installation and safety and operations check for the device before handover.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	• 03 years • Preventive Maintenance visits at least once in each quarter
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Supplier should provide 2 sets(hardcopy) of: - 1. User, technical, maintenance and service manuals to be supplied along with machine diagrams. 2. List of equipment and procedures required for local calibration and routine maintenance. 3. Certificate of calibration and inspection.
10.2	Other accompanying documents	NA
11. NOTES		
11.1	Service Support Contact details. (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to beprovided.
11.2	Recommendations or warnings	Any warning signs would be adequately displayed.

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

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

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

7.1	Certificates (pre-market, sanitary,..);Performa nceand safety standards (specific to the device type);Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature,values, quality, tolerance	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up
8.2	Requirements for sign-off	Supplier to perform safety and operation check before hand over.
8.3	Training of staff (medical,paramedical, technicians)	1. Hands on training to be provided to healthcare professionals on using the equipment, day to daymaintenance/cleaning. 2. Hand on training for in-house (Biomedical engineers)for preventive and Corrective maintenance.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	03 years all spares parts, battery and other accessories.
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hardcopy and soft-copy) of: - 1. User, technical and maintenance manuals to be supplied in English/Regional language along with machine diagrams. 2. List of equipment and procedures required for local calibration and routinemaintenance. 3. Service and operation manuals (original and copy) to be provided. 4. Advanced maintenance tasks documentation. 5. Certificate of calibration and inspection
10.2	Other accompanying documents	ISO Certification on quality of stainless steel used;
11. NOTES		

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

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

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

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

PULSE OXIMETER-FINGER TIP		
Version no. :		02
Date:		September 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Pulse oximeter
GMDN code(s)		45607
GENERAL		
1. USE		
1.1	Clinical purpose	It is used for the transcutaneous measurement and display of haemoglobin oxygen saturation (SpO2). The signals are produced by light-emitting diodes (LEDs) and received by a photodetector. The device displays the SpO2 values and may also measure/display pulse rate.
1.2	Used by clinical department/ ward	All Departments
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	• Should measure SpO2 and pulse rate for adults and children, for all skin pigmentations. • SpO2 detection range to include: 70–100%. • SpO2 resolution: 1% or less. • SpO2 accuracy should be within ± 3%. • Pulse rate detection range to include: 30–240 beats per minute (bpm) • Pulse rate resolution: 1 bpm or less. • Pulse rate accuracy: within ± 3 bpm. • Digital display for SpO2, pulse rate, sensor error or disconnect and low battery status. • Suitable for detection in low perfusion conditions.
2.3	User's interface	Manual
2.3	Software and/or standard of communication	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	heat dissipation	NA
3.5	Mobility, portability	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)		
4.1	Power Requirements	NA

4.2	Battery operated	Yes
4.3	Protection	NA
4.4	Power consumption	NA
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	Accessories & Spares parts; Consumables / reagents (open, closed system)	NA
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity upto 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Easy to clean
	7. STANDARDS AND SAFETY	
7.1	Certificates (pre-market, sanitary, ..), Performance and safety standards (specific to the device type);Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards
	8. TRAINING AND INSTALLATION	
8.1	Pre-installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	NA
8.3	Training of staff (medical, paramedical, technicians)	NA
	9. WARRANTY AND MAINTENANCE	
9.1	Warranty	03 Years
	10. DOCUMENTATION	
10.1	Operating manuals, service manuals, other manuals	User manuals to be provided in English/Hindi language along with machine diagram.
10.2	Other accompanying documents	NA
	11. NOTES	
11.1	Other information	NA
11.2	Recommendations or warnings	NA

Multipara Monitor with Central System		
Version no. :		01
Date:		September 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. USE		
1.1	**Clinical purpose**	Designed to continuously measure and display multiple vital physiological parameters of patients, especially those under critical care. Central monitors display various parameters, from bedside monitors connected to same including ECG, respiratory rate, NIBP and IBP, body temperature, SpO2, SvO2, cardiac output, ETCO2, intracranial pressure, and airway gas concentrations. They include computing capabilities and additional displays to observe trend information.
1.2	**Clinical department/ward**	Intensive Care Unit (ICU)
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics**	1. Should have modular Multi parameter monitor with TFT/LED/LCD/touch screen display with more than 15 inches with at least 8 wave forms and upgradable up to 14 waveforms & 22 parameter numeric on single display. 2. The waveforms should be user selectable. 3. Monitor should have in built Lithium-ion type battery for 2 Hour continuous operation. 4. Should have keys for quick access to main functions. 5. Should be able to monitor ECG (3,5,12 leads), SPO2, NIBP, 2 IBP, Respiration Rate, 2 temp, ETCO2, for adult, pediatric and neonatal patients as standard and Anesthesia gas monitoring. 6. Monitor must have facility for at least 2 IBP measurements simultaneously. Also should have SPV/PPV monitoring facility. 7. 5 Lead ECG monitoring with full range of lethal arrhythmia recognition capability and ST analysis up to 12 leads and 72hour trend facility. 8. Respiration, Apnea alarm, Prioritized audio-visual alarms and snapshot facility. 9. Transport module with display and battery backup of at least 1 hour. 10. Pulse Oxymeter (SPO2) with Plethysmogragh & Pulse strength indicator WithVariable pitch with

		change inSpO2(low perfusion motion tolerance technology). 11. Side-stream Capnography with display of CO2 wave form & digital values (ETCO2, FiCO2, RR). 12. Monitor should have provisions for automatic identification and measurement of anesthesia agents, CO2, 02, N2O and facility to measure at least S volatile agents with automatic detection. 13. Should be upgradable to monitor cardiac output (Thermo dilution/ PICCO), BIS/DA and NMT. 14. It should have provision for automatic identification and measurement and anesthetic agents, Co2, 02, N2O and facility to measure MAC. 15. The display setting should have at least 10 user defined setups variable as per applications for flexible use of the monitor in various clinical environments such as in OT, PACU, ICU, ER, NICU. 16. Monitor should have networking options with bidirectional & bed to bed communication. **Central Monitoring Station:** 1. Central station should have minimum 22" color display. 2. Should be supplied with network Laser printer & printing of review/trend data from central station & any bedside monitor connected in network should be possible. 3. It should have facility to view minimum last 120 hours stored information such as vital signs, alarm status, arrhythmia recall with ECG, trended parameters, patient data etc. for any selected bed from the central station. 4. It Should have facility to store and display full disclosure of waveforms for 120 hours. 5. Should have default alarm limits and customizable parameter settings. 6. Should have two-way communication with bedside monitor, alarm settings should be possible from central station. 7. All monitors including central station should have similar user interface for easy usage among all clinicians.
2.2	**User's interface**	Digital display
2.3	**Software and/or standard of communication**	In-built
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	<50dB.

3.4	**Heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through an exhaust cooling fan
3.5	**Mobility, portability**	-
	4. ENERGY SOURCE	
4.1	**Power Requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	Yes
4.3	**Protection**	Electrical protection provided by fuses in both live and neutral supply lines
4.4	**Power consumption**	To be specified by manufacturer
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables/reagents (open, closed system)**	Each monitor should be supplied with following accessories: a) 5 lead ECG/Respiration cable b) NIBP Cuff Adult, Pediatric & Neonate c) SpO2 Sensor Adult d) SpO2 sensor Pediatric e) SpO2 sensor disposable for infants/neonates f) Mainstream ETCO2 cable g) Invasive & noninvasive Adaptor for ETCO2 h) IBP Cable i) IBP transducers j) Rectal Temp Probe
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS	
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Operating condition: – Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance andsafety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
	8. TRAINING AND INSTALLATION	
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.

8.2	**Requirements for sign-off**	Supplier to perform safety and operation check before hand over.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter.
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided. 3. Satisfactory certificate for any existing installation from government hospital
10.2	**Other accompanying Documents**	List of essential spares and accessories, with their par number and cost.
11. NOTES		
11.1	**Other information**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or Warnings**	Any recommendations for best use and supplementary warning for safety should be declared.

Digital Infrared Thermometer		
Version no. :		01
Date:		September 2023
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		-
GMDN code		-
GENERAL		
1. USE		
1.1	**Clinical purpose**	Infrared (IR) thermometers allows to measure temperature quickly, at a distance, and without touching the object.
1.2	**Used by clinical department/ward**	All Departments
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. It should be non-contact type Infrared digital thermometer. 2. It should measure and display temperature in both units-degree Celsius and degree Fahrenheit. 3. Measuring range: 32 deg C (89.6 deg F) or lower to 43 deg C (109.4 deg F) or higher. 4. Accuracy of measurement: 0.2 deg C/Fahrenheit or better. 5. Measuring distance should be atleast 5cm. 7. It should have LCD display. 8. It should have auto shut down feature when not in use, audio/visual alarm facility.
2.2	**Settings**	NA
2.3	**User's interface**	Digital display
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	Light weight
3.4	**Noise (in dBA), heat dissipation**	NA
3.5	**Mobility, portability**	Portable
4. ENERGY SOURCE		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	Yes
4.3	**Protection**	NA
4.4	**Power consumption**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)**	NA

	Consumables / reagents (open, closed system)	
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Easy to clean.
7. STANDARDS AND SAFETY		
7.1	**Certificates**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	NA
8.3	**Training of staff (medical, paramedical, technicians)**	NA
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	01 years
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams.
10.2	**Other accompanying documents**	NA
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	Contact details of manufacturer and supplier should be provided..
11.2	**Recommendations or warnings**	Any recommendations for best use should be declared.

Continuous Renal Replacement Therapy Machine		
Version no. :		01
Date:		September 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. USE		
1.1	**Clinical purpose**	CRRT is used to provide atleast 24 hours continuous (nonstop) dialysis therapy used to support patients with kidney failure Patient Category Pediatrics and adults.
1.2	**Clinical department/ward**	Nephrology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics**	1. The Machine should be of latest technology with microprocessor-controlled user interactive menu with operating and malfunction removal instructions on display screen 2. The system should have four pumps, one each for Blood, Dialysate, Replacement fluid and Effluent/filtrate. 3. The system shall be capable of providing the following therapies: - • Slow Continuous Ultrafiltration (SCUF) • Continuous Venovenous Hemofiltration (CVVH) • High-volume Continuous Venovenous Hemofiltration (HVCVVH) • Continuous Venovenous Hemodiafiltration (CVVHDF) • Continuous Venovenous Hemodialysis (CVVHD) • Hemoperfusion (HP) • Therapeutic Plasma Exchange (TPE) 4. It should have a clear touch screen LCD/TFT Monitor. 5. Blood pump speed of approximately 10-450 ml/min. 6. It should have close blood circuit to prevent air to blood interface. 7. System should have short preparation and priming program and should be ready to start treatment within 10-20 minutes. 8. Should have arterial pressure range: (-) 250 mmHg +/- 50 mmHg 9. Should have venous pressure range:(+)350 mmHg

		+/- 50 mmHg. 10. Should have Pre Filter-Pressure: 50mmHg to -500 mmHg 11. Should have Effluent Pressure: 350 mmHg+/- 50 mmHg 12. Should have Programmable Substitution solution flow rate: 100-8000 mL/Hr 13. Should have Dialysate Flow rate: 0-4500 mL/Hr. 14. Should have Effluent Flow Rate: 0-10000 mL/Hr. 15. Should have integrated heparin pump with flow rate of 0.5 ml-5 mL/Hr. Bolus facility range 0.5mL5mL. 16. Should have capability of changing therapies. 17. Should have three weighing scales to control the system with balancing accuracy of less than 1 % of total turnover in normal conditions and weighing capacity of at least 0-20 kg. 18. Should have integrated Fluid/Blood warmer for blood/dialysate warming. 19. Should have Ultrasonic air bubble detector and Blood leak Detector. 20. Should have Alarm in case of blood leak, air in line, pressure limit violation, empty dialysate/ replacement bag, full effluent bag and advisory alarms in case of excessive TMP and filter clotting. 21. Should have a 30 min Battery back up for blood pump. 22. Should have an RS 232 Port for Data transfer and interface.
2.2	**User's interface**	Digital display
2.3	**Software and/or standard of communication**	In-built
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	<50dB.
3.4	**Heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through an exhaust cooling fan
3.5	**Mobility, portability**	Mobile
4. ENERGY SOURCE		
4.1	**Power Requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	Yes
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		

5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables/reagents (open, closed system)**	Should be supplied with 10 Nos. of essential accessories such as blood line set, haemofilters and ultra filtrate bags at no extra cost.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Operating condition: – Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ..); Performance andsafety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.
8.2	**Requirements for sign-off**	Supplier to perform safety and operation check before hand over.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	• 03 years • Preventive Maintenance visits at least once in each quarter.
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. 2. Service and operation manuals (original and Copy) to be provided.
		3. Satisfactory certificate for any existing installation from government hospital

10.2	**Other accompanying Documents**	List of essential spares and accessories, with their par number and cost.
11. NOTES		
11.1	**Other information**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or Warnings**	Any recommendations for best use and supplementary warning for safety should be declared.