TECHNICAL SPECIFICATIONS OF MEDICAL EQUIPMENTS PRIMARY HEALTH CENTRE

HEALTHCARE TECHNOLOGY DIVISION

NATIONAL HEALTH SYSTEMMS RESOURCE CENTRE

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1. AMBU BAG		
Version No:		02
Date:		August 2023
Done by: (Name/Institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		-
GMDN code		-
GENERAL		
1. USE		
1.1	Clinical purpose	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

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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...)	Should be capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	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

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2. **LARYNGOSCOPE**		
Version no. :		02
Date:		August 2023
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Laryngoscopes
GMDN code		CT1723
GENERAL		
1. USE		
1.1	**Clinical purpose**	For viewing vocal folds and glottis. Resuscitation, Surgical and mechanical ventilation/ 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

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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 ...)**	Should be capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	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, paramedical, technicians)**	NA
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	03 years ; LED up to 6 months
10. DOCUMENTATION		

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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

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3. RADIANT WARMER		
Version no. :		02
Date:		August 2023
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. USE		
1.1	**Clinical purpose**	Infant Radiant warmer is an electrically powered device with a radiant heating source intended to maintain the thermal balance of an infant by direct radiant of energy in the infrared region of the electromagnetic spectrum.
1.2	**Used by clinical department/ ward**	Neonatal ICU/ SNCU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. It should be microcontroller chip based radiant warmer with manual and servo options. 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 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 1000 Lux (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

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		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 be pliable, thin and soft. The attachment site of the probe with the wire should also be pliable and non-stiff.
	Settings	1. Should have Manual mode and Baby (Servo) mode

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2.2		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)**	maximum spec: 150kg.
3.4	**Noise (in dBA)**	Sound level of the alarm shall not exceed 80 dBA
3.5	**Heat dissipation**	Should maintain up to 36.5 deg temp 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
4.3	**Tolerance (to variations, shutdowns)**	± 10% input
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.

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6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Should be rugged and capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	**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, 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. 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/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any warning/ precautions to be declared

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4. PULSE OXIMETER-FINGER TIP		
Version no. :		02
Date:		August 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Pulse oximeter
GMDN code(s)		45607
GENERAL		
1. USE		
1.1	Clinical purpose	It is used for the transcutaneous measurement and display of haemoglobin oxygen saturation (SpO2). The signals are produced by light-emitting diodes (LEDs) and received by a photodetector. The device displays the SpO2 values and may also measure/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)	1. Should measure SpO2 and pulse rate for adults and children, for all skin pigmentations. 2. SpO2 detection range to include: 70–100%. 3. SpO2 resolution: 1% or less. 4. SpO2 accuracy should be within ± 3%. 5. Pulse rate detection range to include: 30–240 beats per minute (bpm) 6. Pulse rate resolution: 1 bpm or less. 7. Pulse rate accuracy: within ± 3 bpm. 8. Digital display for SpO2, pulse rate, sensor error or disconnect and low battery status. 9. 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

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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

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

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

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7.1	**Certifications**	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**	Electrical accessories as per standard Indian set-up
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operation checks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	• 03 years • 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. 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**	NA
11. NOTES		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or warnings**	Any recommendations for best use and supplementary warning for safety should be displayed.

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6. **LABOUR BED**		
Version no.:		02
Date:		August 2023
Done By:		HCT/NHSRC
NAME AND CODING		
GMDN Name		Birthing Bed/Table, Powered
GMDN Code		15732
GENERAL		
1. USE		
1.1	Clinical Purpose	Table for Obstetric labour (LDR) is specifically designed to support the 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 any stage, 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/m^3 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.

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		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.
2.3	Software and/or standard of communication (wherever required)	NA
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	Mobile
4. ENERGY SOURCE		
4.1	Power input	220-240V AC,50 Hz fitted with Indian plug
4.2	Power consumption	To be specified by the Manufacturer/Supplier
4.3	Protection	Overcurrent breaker must be present.
4.4	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 on and battery charge. 2. Should have facility to operate manually in case of power failure.
5. ACCESSORIES, SPARE PARTS AND CONSUMABLES		

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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 system should be provided free of cost. 2. Minimum 60 mm thick kg/m^3 high density foam mattress washable and waterproof 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 hook for hanging IV fluids.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere /Ambiance (air conditioning, humidity, dust ...)	Should be rugged and capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by manufacturer
7. STANDARDS & 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, safety and operation checks before handover.
8.3	Training of staff (medical, paramedical, technicians)	Hands on training to be provided to healthcare professional on using the equipment, day to day maintenance/cleaning.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	• 03 years

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		• Preventive Maintenance visits at least once in each quarter.
		10. DOCUMENTATION
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (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 routine maintenance. 3. Advanced maintenance tasks documentation.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost.
		11. NOTES
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Appropriate warning sign/labels should be adequately displayed on the LDR Bed.

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7. Foetal doppler / Fetoscope		
Version		02
Date:		August 2023
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Foetal Doppler System
GMDN code(s)		34040
GENERAL		
1. USE		
1.1	Clinical purpose	It is used non-invasively to detect fetal heart beats using ultrasound/doppler technology. The fetal heart beats are typically conveyed audibly via the measuring/display unit and attached probe which is applied to the surface of the pregnant women'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)	1. It should measure fetal heart rate (FHR) accurately. 2. It should have a back light display. 3. The probe should be highly sensible to pick up FHR. 4. The probe should be waterproof. 5. Probe (transducer) with 2-5 MHz frequency attached via a cable. 6. It should give an indication of low battery. 7. It should have built-in-speaker with volume adjustment. 8. Built-in rechargeable Li-on battery with minimum back up of 6-8 hours.
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 (metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA),	Noise: <60dBA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Yes, Handheld device
4. ENERGY SOURCE		
4.1	Power Requirements	220 V +/- 10% AC, 50 Hz
4.2	Battery operated	Built-in rechargeable battery with minimum backup of 6-8 hour
4.3	Power consumption	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		

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5.1	Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)	Doppler probe, battery charger, gel for application of probe.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity upto 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary, ..)	1. Should be CDSCO approved. 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 safety and operation check before handover.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	• 03 years • Preventive Maintenance visits at least once in each quarter.
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hardcopy and soft copy) of: 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. Satisfactory certificate for any existing installation from government hospital
10.2	Other accompanying	List of essential spares and accessories, with their part number and

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	documents	cost.
11. NOTES		
11.1	Service Support Contact details (Hierarchy wise; including a toll free/landline number)	Contact details of manufacture, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any warning sign should be adequately displayed.

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

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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)	< 20 kg
3.3	Noise (in dBA),	Noise: <60dBA
3.4	Heat dissipation	The temperature of baby bed and metal surfaces should not exceed 40 deg C and 43 deg C for other accessible surfaces.
3.5	Mobility, portability	Mobile
	4. ENERGY SOURCE	
4.1	Power Requirements	220 V +/- 10% AC, 50 Hz
4.2	Battery operated	NA
4.3	Power consumption	To be specified by manufacturer
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)	Complete set of replacement tubes to allow 3 months' continuous operation. Two replacement sets of fuses, if replaceable type used.
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity upto 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by manufacturer.
	7. STANDARDS AND SAFETY	
7.1	Certificates (pre-market, sanitary, ..)	1. Should be CDSCO approved. 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 handover.

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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 (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. Satisfactory certificate for any existing installation from government hospital
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost.
11. NOTES		
11.1	Service Support Contact details (Hierarchy wise; including a toll free/landline number)	Contact details of manufacture, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any warning sign should be adequately displayed.

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9. Shoulder Wheel		
Version no. :		01
Date:		August 2023
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDNS name		NA
GMDNS code(s)		NA
GENERAL		
1. USE		
1.1	Clinical purpose	The wheel allows carrying out a shoulder exercise safely and decrease the pain in shoulder and arms
1.2	Used by clinical department/ward	Physiotherapy
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. The shoulder wheel is a metal drum fitted with adjustable bars made of Stainless Steel. 2. The wheel should be wall mounted. 3. Adjustment bar to raise up and release down as per the height requirements fitted on a laminated board frame. 4. The wheel should provide smooth 360-degree revolution bidirectionally.
2.2	User's interface	Manual
2.3	Software and/or standard of communication (wherever required	Not required
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	Diameter- 50 cm or more
3.2	Weight (lbs, kg)	Not more than 10 kg
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Fixed
4. ENERGY SOURCE		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Not required.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance(air conditioning, humidity, dust …)	NA

6.2	User's care, Cleaning, Disinfection & Sterility issues	Should be easy to clean and maintain.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,); Performanceand safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 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 installation, safety and operation checks before handover
8.3	Training of staff (medical, paramedical, technicians)	NA
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	03 years
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	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 to be provided.
11.2	Recommendations or warnings	NA

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10. Shoulder Pulley		
Version no. :		01
Date:		August 2023
Done by : (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDNS name		NA
GMDNS code(s)		NA
GENERAL		
1. USE		
1.1	Clinical purpose	Shoulder pulleys help to stretch the shoulder in various directions to improve mobility and function of the shoulders.
1.2	Used by clinical department/ward	Physiotherapy
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Wall mountable unit and the set should include mounting hardware. 2. Construction: Tubular stainless-steel tube is fitted with two close hooks to fix pulleys. 3. Pulleys: Two, Nylon pulleys with hooks to fix. 4. Grip Handles: Two, spring steel wire handles with grips. 5. Rope/Cord: Durable interwoven Nylon cord of suitable length.
2.2	User's interface	Manual
2.3	Software and/or standard of communication (wherever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Fixed
4. ENERGY SOURCE		
4.1	Power requirements	NA
4.2	Battery operated	NA
4.3	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Not required.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		

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6.1	Atmosphere/Ambiance(air conditioning, humidity, dust …)	NA
6.2	User's care, Cleaning, Disinfection & Sterility issues	Should be easy to clean.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,); Performanceand safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 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	NA
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	NA
10.2	Other accompanying documents	NA
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer to be provided.
11.2	Recommendations orwarnings	NA

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

6.1	Atmosphere/Ambiance(air conditioning, humidity, dust …)	NA
6.2	User's care, Cleaning, Disinfection & Sterility issues	Should be easy to clean.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,); Performanceand safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 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)	NA
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	NA
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	NA
10.2	Other accompanying documents	NA
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer to be provided.
11.2	Recommendations or warnings	NA

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12. SUCTION MACHINE-FOOT & ELECTRIC OPERATED		
Version no. :		02
Date:		August 2023
Done by: (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		
GMDN code		
GENERAL		
1. USE		
1.1	Clinical purpose	To aspirate fluids, secretions, or other foreign materials from a patient's airway by means of suction
1.2	Used by clinical department/ ward	Emergency, ICU, OT, HDU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1.Should be designed for draining blood and other fragmented secretions in emergency settings. 2. Should be operable both electrically and foot operated during non-availability of electricity. 3. Should be fitted with oil immersed noiseless motorized vacuum 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 airtight lids and having overflow safety device. 6. Should have a motor of minimum ½ HP capacity single phase 1440 RPM with control knob. 7. Should have vacuum at least between 100 mmHg to at least 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

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4. ENERGY SOURCE		
4.1	Power Requirements	NA
4.2	Battery operated	NA
4.3	Protection	NA
4.3	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)	Collection bottles, clear unbreakable jar (one set extra)
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust...)	Should be rugged and capable of withstanding operation in extreme and ambient temperature (10 deg C to 50 deg C). Capable to work in relative humidity up to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	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	Supplier to perform installation, safety and operation checks before handover.
8.3	Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order)	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	• 03 years • Preventive Maintenance visits at least once in each quarter
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	User, technical and maintenance manuals to be supplied in English/Hindi language along with machine diagrams.
10.2	Other accompanying documents	NA
11. NOTES		
11.1	Service Support Contact details (Hierchy Wise; including a toll free/landline number)	Contact details of manufacturer should be provided.

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11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared.

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

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5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Not required.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	NA
6.2	User's care, Cleaning, Disinfection & Sterility issues	Easy to clean
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 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	Compatible electrical accessories as per standard Indian set-up.
8.2	Requirements for sign-off	Supplier to perform safety and operation check before handover.
8.3	Training of staff (medical, paramedical, technicians)	NA
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	03 Years
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	One copy (hard copy and soft copy) to be provided on user manual/ operating manual and service/Technical manual.
10.2	Other accompanying documents	List of essential accessories and cost should be quoted.
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed on equipment.

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

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	(open, closed system)	
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust …)	NA
6.2	User's care, Cleaning, Disinfection & Sterility issues	As specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 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	NA
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	One copy (hard copy and soft copy) to be provided on user manual/ operating manual.
10.2	Other accompanying documents	NA
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/ landline number)	Contact details of manufacturer, supplier should be provided
11.2	Recommendations or warnings	NA

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15. WEIGHING SCALE		
Version no.:		02
Date:		August 2023
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. USE		
1.1	Clinical purpose	Weighing scale is used to measure body mass.
1.2	Used by clinical department/ ward	OPD
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Should be made of sturdy mechanical structure to support/withstand heavy workload in public health centre. 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 their 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)		

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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.

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16. BABY WEIGHING SCALE		
Version no. :		02
Date:		August 2023
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Infant Scale, Electronic
GMDN code(s)		35324
GENERAL		
1. USE		
1.1	Clinical purpose	It is used to measure the weight of an infant, particularly a newborn, or to monitor weight changes.
1.2	Used by clinical department/ ward	Midwifery Led Care Unit/NICU/SNCU/PICU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Tabletop, light, portable and digital precision weighing scale. 2. Should have easy to read backlit digital display. 3. Weight displays up to 2 decimal point in kg/gm. 4. Weighing pan should be skin friendly, non-toxic durable material suitable for weighing newborn babies and the construction should not allow the baby to slip from the tray. 5. The Tray should be made of ABS/ Acrylic and must be devoid of any sharp edges. 6. Easy to clean baby tray. 7. Zero weight adjustment facility. 8. Quick, clear digital read outs. 9. Measurement does not change with position of baby on the pan. 10. Provision to measure the length of the baby in its laying position. 11. Accuracy: +/- 5 mg, Measuring limit: 10 gm to 20 kg. 12. Built in rechargeable battery/ AC mains.
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 (metric)	Pan Size : 500-550 mm X 300-350 mm X 80-100 mm
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	N.A.
3.4	heat dissipation	NA
3.5	Mobility, portability	Portable

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4. ENERGY SOURCE		
4.1	Power Requirements	220 V AC +/- 10%, 50 Hz
4.2	Battery operated	Built in rechargeable battery/AC mains
4.3	Protection	NA
4.4	Power consumption	To be specified by the 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 CONSIDERATONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Should be capable to withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	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	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.
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	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	NA
11. NOTES		

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

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

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5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust …)	Durable resistant to effects of excess humidity and high temperature.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Should be easily disinfected by using normal hospital grade cleaning solution.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 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)	NA
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	03 Years
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: User manuals should be supplied in English/Hindi language along with machine diagrams.
10.2	Other accompanying documents	NA
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer and supplier to be provided.
11.2	Recommendations or warnings	NA

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18. OPTHALMOSCOPE		
Version no. :		02
Date:		August 2023
Done by: (Name/Institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Direct Ophthalmoscope
GMDN code(s)		46786
GENERAL		
1. USE		
1.1	Clinical purpose	Handheld ophthalmoscopes designed for examining the eye (mostly the back of the eye, the funds) by providing a non-inverted image of the eye.
1.2	Used by clinical department/ward	Ophthalmology Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Should have LED/halogen as 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, slit aperture, hemi-spot and cobalt blue filter. 5. Should be rechargeable battery with Charger / battery/ mains operated. 6. Range of lenses not smaller than -30D to +20D with steps not greater than 1D. 7. 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	Portable
4. ENERGY SOURCE		
4.1	Power requirements	Rechargeable battery
4.2	Battery operated	Internal batteries, rechargeable preferred, Led display indicating the charging status.
4.3	Power consumption	NA

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5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)	a. 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 up to 90% in ideal circumstances
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre- market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 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 safety and operation check before handover
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation in basic maintenance shall be provided
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets of : User, technical and maintenance manuals should be supplied in English/Hindi/Regional language along with machine diagrams.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost.
11. Notes		

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

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19. FULLY LOADED DENTAL CHAIR ELECTRICALLY OPERATED		
Version no. :		02
Date:		August 2023
Done by: (name. Institution)		HCT/NHSRC
NAME AND CODING		
UMDNS name		10792
UMDNS code(s)		Chairs, Examination/Treatment, Dentistry
GENERAL		
1. USE		
1.1	Clinical purpose	Examination/treatment chairs designed to facilitate dental examination, treatment, and/or minor surgical procedures. These chairs are typically adjustable up to a height that allows the healthcare staff to perform procedures while standing; the chairs usually include head- and armrests, a reclining back that may be tilted from a vertical to a horizontal or near-horizontal position, and rotating capabilities to facilitate examination and/or treatment.
1.2	Used by Clinical department/ward	Dental Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. It should have double articulating headrest with seesaw movement. 2. It should be provided with soft cervical support. 3. Dental unit should have latest overhead delivery system. 4. It should have two 3 way syringes (Tip autoclavable, with spare tips) one on unit side and other on the assistant side. 5. It should have two high speed Air rotor terminals with two rotor hand pieces and accessories and one terminal for fiber optic. One for air motor/micro motor having straight and contra angle hand pieces and other for air rotor terminal with two air rotor hand pieces with two spare cartridges. 6. It should have LED light cure unit with minimum intensity 1200 mW/cm2. 7. It should have infection control system with non-retraction valves (Bio system /equivalent). 8. All hand pieces / terminals should be kept on Autoclavable pads. 8 spare autoclavable pads should be supplied. 9. Arm of unit should be pneumatically locked. 10. All air tubing of the delivery system can be disinfected internally after every dental procedure. 11. It should have one in built piezo ultrasonic scalar (max frequency should be 36 KHZ) 12. Removable auxiliary tray (autoclavable) shall be supplied – 10 sets. 13. It should have integrated latest foot operated LED light (30000 - 50000 Lux). 14. It should have rotatable water system with removable spittoon. 15. It should have Medium Vacuum Suction and high suction (Motorized Suction). 16. Should have following multiple programmes i. Two programmable working positions. ii. Spitting and last working position with light ON and OFF automatically. iii. Return to Zero position with light OFF automatically.

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		iv. It should have emergency stop control with luminous indication. v. Programmable bowl water and cup filler water. 17. It should have LED based X-ray viewer (For I.P.G/O.P.G films). 18. It should be provided with right arm. 19. It should have multi functional foot control base. 20. It should be provided with two stool with adjustable backrest tilt including an adjustable ring for foot rest 21. Oil free medical grade compressor of 1. HP (fully imported)
2.2	User's interface	Manual
2.3	Software and/ or standard of communication (where ever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise-free system
3.4	Heat dissipation	Should maintain nominal temp and the heat should be disbursed through a cooling mechanism
3.5	Mobility, portability	Stationary Installation
4. ENERGY SOURCE		
4.1	Power requirements	220 +/- 10% VAC, 50 Hz
4.2	Battery operated	No
4.3	Protection	Stabilizer or inbuilt protection to voltage fluctuation/current surge.
4.4	Power consumption	To be specified by manufacturer.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	<u>LED LIGHT CARE UNIT:</u> 1. Ensures up to 1200 mW/ sq.cm <u>ULTRASONIC SCALAR:</u> 1. Piezotronic Scalar with frequency of 28000-36000 Hz 2. Autoclavable hand piece , Total control is Micro processor based 3. Hand Pieces most sleek. 4. The scalar supplies with: Piezotronic scalar with 4 tips. <u>FOOT OPERATED LIGHT:</u> 1. LED light with 3 intensity with 3 axis movement. 2. Intensity is between 30000 - 50000 Lux 3. On/off Switch by sensor switch - non touch. 4. Step intensity control by non touch sensor. <u>AIR ROTOR:</u> 1. Air Rotor hand piece clean head with a speed of 350000 RPM 2. Supplies with a. Titanium/ SS Air rotor torque hand piece. b. Ultra push type non retraction valve. <u>BRUSHLESS MICROMOTOR:</u> 1. It should have digital display of speed. 2. High Torque Micro motor (Foot Controlled) with Speed range of

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		2000 -40000 RPM 3. It should have reverse and forward speed along. 4. It should have auto cut off system for over load. 5. It should be supplied with a. Contangle Hand piece (Autoclavable) : Speed - 40000 RPM b. Straight Hand Piece (Autoclavable): Speed- 40000 RPM. <u>AIR COMPRESSOR:</u> 1. Medical grade, Oil free, Noise free at least 1 HP Compressor. 2. The compressor should be fitted with a. Built in thermo cut off to save motor during excess of heat b. auto head air release valve, c. Automatic cut off d. Safety release valve e. Drain Valve f. The inner surface of the compressor tank (at least 35 L) is coated with Epoxy to prevent rusting.
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)	To be specified by manufacturer and compatible electrical accessories as per Indian standard set-up.
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover.
8.3	Training of staff (medical, paramedical, technicians)	Training of users on operation and basic maintenance.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	• 03 years

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		• 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. 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 (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.

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20. DENTAL CHAIR-BASIC		
Version no. :		01
Date:		August 2023
Done by : (name. Institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. USE		
1.1	Clinical purpose	Dental chair required for dental examination and dental procedures.
1.2	Used by clinical department/ward	Dental
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1.Dental unit with modular delivery system. Should be of high density PU (washable/disinfectable) with seamless upholstery. 2. Chair mechanical frame made of SS (MS-304) with capacity to withstand and lift weight upto 150 to 180 Kgs of weight. 3. The chair should have a safety brake system at the base and back-rest while going down for patient exit position. Should have synchronized backrest and footrest movement. 4. Should have provision for swivel off dental arm left/right with more than 300 degrees movement. 5. Spittoon should have motorized motion and programme cup filler and flush function. 6.It should have two 3-way syringes (tip autoclavable) 7.The controls for the air rotor and micromotor should be available in both main control panel and footrest unit. 8. It should have high speed air rotor terminal. 9.Should have one brushless autoclavable in-built micromotor (40000rpm) terminal with straight and contra angle handpieces. 10.It should have one in-built Piezo ultrasonic scaler (frequency 28-36 KHz) with 8kg or more scaler tips. 11. It should have LED/ halogen Light with sensor (min 30,000 LUX) 12. It should high and low motorized suction with auto drain and flush system. 13.Removable auxiliary tray (stainless steel) 14. Auto connection for tumbler and spittoon 15. It should have LED based X-ray viewer 16. It should be provided with one doctor's stool with adjustable backrest tilt including an adjustable ring for footrest.

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2.2	User's interface	Manual
2.3	Software and/ or standard of communication (where ever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise free system
3.4	Heat dissipation	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism
3.5	Mobility, portability	Stationary Installation
4. ENERGY SOURCE		
4.1	Power requirements	220 V +/- 10% AC, 50 Hz
4.2	Battery operated	NA
4.3	Power consumption	To be specified by manufacturer.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. Saliva ejector 2. Autoclavable High volume evacuator 3. Autoclavable 3-way syringe 4. High quality stain proof vitreous China bowl with adjustable cup full and bowl rinse timers 5. Clean water bottle system.
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 up to 90% in ideal circumstances
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 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 on operation and basic maintenance.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	• 03 years

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		• Preventive Maintenance visits at least once in each quarter.
10. DOCUMENTATION		
10.1	Operating manuals, 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. 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	NA
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contract details of manufacturer, supplier and local service agent should be provided
11.2	Recommendations or warnings	Any warnings should be clearly displayed.

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

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	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 upto 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary, ...)	1.Should be CDSCO approved. 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.
7.2	Performance and safety standards (specific to the device type)	NA
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	Confirmation in no crack, no leak in hood structure
8.3	Training of staff (medical, paramedical, technicians)	NA
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	03 years
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	User and technical manuals to be supplied in English/Hindi language.
10.2	Other accompanying documents	NA
11. NOTES		
11.1	Service Support Contact details (Hierchy Wise; including a toll free/landline number)	Contact details of manufacturer and supplier should be provided.
11.2	Recommendations or warnings	NA

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22. ILR WITH VOLTAGE STABILIZER-SMALL		
Version no. :		01
Date:		August 2023
Done by : (name. Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		NA
GMDN code(s)		NA
GENERAL		
1. USE		
1.1	Clinical purpose	The Ice Lined refrigerator is a laboratory-based equipment used in the Cold Chain needs of various health facilities. Ice lined refrigerator maintain temperature of +2 deg C to + 8 deg C.
1.2	Used by clinical department/ward	Immunization
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Net Vaccine Storage Capacity: 90 to 105 liters within basket in place. 2. Construction: • Internal: Stainless 304 grade steel • An additional special ice lining consisting of icepacks covered by strong plastic shell. 3. External: Corrosion Resistance 4. Chest type with CFC-free insulation 5. Should have horizontal water cool pack covering the top of the basket. 6. Solid door with lock and handle 7. Type: Compression Cycled, CFC-Free (both for refrigeration and insulation) All system tubing (suction tube, freezer tube and condensing tube) should be of minimum 99.97% of pure copper coil. 8. Temperature of a full vaccines to remain +2 deg C to +8 deg C during continuous availability of energy at ambient temperature +5 to +45 deg. C with intermittent/ continuous electricity supply 8 hrs in a 24 hrs cycle. The temperature difference between any two points in the cabinet should not be more than +2 deg.C once stabilized. 9. Inlet of Capillary should be outside the PUF body. 10. ON/OFF Switch and power indicator should be available 11. A Micro-processor-based control unit should be provided for setting of temperature and display following features: • 3 digit digital display (to one decimal point) of cabinet temperature. The sensor should be placed 25 to 50 mm above base of storage chamber.

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		• Power on LED/LCD indicator • Audio (minimum 65 dBA) and visual alarm against the violation of temperature range (less than +2 and more than +8 degree C) • Min. & Max. cabinet temperature digital display of last 24 hrs. and breaches during last 24 hrs. • The unit should be sealed protected from dust, moisture or condensed falling over it. 12. Accuracy for digital controller +0.5 degree centigrade.
2.2	User's interface	1. Programmable Micro-processor control unit with child lock facility. 2. Should have provision to set minimum and maximum temperature at 0.1 degree Centigrade to programme the unit for continuous operation. 3. Should have provision for defrosting program.
2.3	Software and/ or standard of communication (where ever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Mobile
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	220 +/- 10% VAC, 50 Hz
4.2	Battery operated	NA
4.3	Protection	Voltage stabilizer should be provided.
4.4	Power consumption	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. Vaccine Storage Basket allowing free circulation of air, having the size to be able to accommodate 4 to 6 of them in the unit and suitable to match the net volume requirement. It should be minimum 5 wire basket. 2. Stem Alcohol thermometer -one piece per unit range of -30 to +50 degree centigrade.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust …)	The unit shall be 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	As specified by manufacturer.

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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	Availability of UPS for at least 24 hours back up and incompatible electric socket.
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, 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; 3. Advanced maintenance tasks documentation; 4. Certificate of calibration and inspection, 5. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

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23. DEEP FREEZER-SMALL		
Version no. :		01
Date:		August 2023
Done by : (name. Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. USE		
1.1	Clinical purpose	The deep freezers have vaccine storage capacity and ice pack freezing capacity. The Deep Freezer is provided with special insulation, which helps in maintaining inside temperature in the range of (-) 25 deg C to (-) 15 deg C.
1.2	Used by clinical department/ward	Immunization
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Gross Volume: 105 to 125 liters. 2. Construction: • Internal: Stainless 304 grade steel 3. External: Corrosion Resistance 4. Chest type with CFC-free insulation 5. Should have foam pad cover on top of the basket. 6. Solid door with lock and handle 7. Type: Compression Cycled, CFC-Free (both for refrigeration and insulation) All system tubing (suction tube, freezer tube and condensing tube) should be of minimum 99.97% of pure copper coil. 8. Temperature of compartment to be maintained between (-) 25deg C to (-) 15deg C continuous availability of energy at ambient temperature 5 to 45 deg. C. 9. Inlet of Capillary should be outside the PUF body. 10. ON/OFF Switch and power indicator should be available 11. A Micro-processor-based control unit should be provided for setting of temperature and display following features: • 3 digit digital display (to one decimal point) of cabinet temperature. The sensor should be placed 25 to 50 mm above base of chamber. • Power indicator • Audio (minimum 65 dBA) and visual alarm against the violation of set temperature range. • Min. & Max. cabinet temperature digital display of last 24 hrs. and breaches during last 24 hrs. • Temperature manual control with one decimal deg. scale. • The unit should be sealed protected from dust,

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		moisture or condensed water falling over it. 12. Accuracy for digital controller +- 0.5 degree centigrade.
2.2	User's interface	1. Programmable Micro-processor control unit with child lock facility. 2. Should have provision to set minimum and maximum temperature at 0.1 degree Centigrade to programme the unit for continuous operation. 3. Should have provision for defrosting program.
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	Mobile
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	Internal electrical protection.
4.4	Power consumption	To be specified by vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. Vaccine Storage Basket allowing free circulation of air, having the size to be able to accommodate 4 to 6 of them in the unit and suitable to match the net volume requirement. It should be minimum 5 wire basket. 2. Stem Alcohol thermometer-one piece per unit range of -30 to +50 degree centigrade.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust …)	1. The unit shall be capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 95%. 2. The unit shall be capable of operating continuously in ambient temperature of 5 to 45 deg C and relative humidity of 90% 3. The plug should be flexible and unbreakable sealed rubber type.
6.2	User's care, Cleaning, Disinfection & Sterility issues	As recommended by manufacturer
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,); Performance and safety standards (specific to	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE

	the device type); Local and/or international	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	Availability of stabilizer capable to operate during voltage fluctuations.
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, 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; 3. Advanced maintenance tasks documentation; 4. Certificate of calibration and inspection, 5. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

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24. ILR WITH VOLTAGE STABILIZER – LARGE		
Version no. :		01
Date:		August 2023
Done by : (name. Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		NA
GMDN code(s)		NA
GENERAL		
1. USE		
1.1	Clinical purpose	The Ice Lined refrigerator is a laboratory-based equipment used in the Cold Chain needs of various health facilities. Ice lined refrigerator maintain temperature of +2 deg C to + 8 deg C.
1.2	Used by clinical department/ward	Immunization
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Net Vaccine Storage Capacity: 135 to 160 liters within basket in place. 2. Construction: • Internal: Stainless 304 grade steel • An additional special ice lining consisting of icepacks covered by strong plastic shell. 3. External: Corrosion Resistance 4. Chest type with CFC-free insulation 5. Should have horizontal water cool pack covering the top of the basket. 6. Solid door with lock and handle 7. Type: Compression Cycled, CFC-Free (both for refrigeration and insulation) All system tubing (suction tube, freezer tube and condensing tube) should be of minimum 99.97% of pure copper coil. 8. Temperature of a full vaccines to remain +2 deg C to +8 deg C during continuous availability of energy at ambient temperature +5 to +45 deg. C with intermittent/ continuous electricity supply 8 hrs in a 24 hrs cycle. The temperature difference between any two points in the cabinet should not be more than +2 deg.C once stabilized. 9. Inlet of Capillary should be outside the PUF body. 10. ON/OFF Switch and power indicator should be available 11. A Micro-processor-based control unit should be provided for setting of temperature and display following features: • 3 digit digital display (to one decimal point) of cabinet temperature. The sensor should be

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		placed 25 to 50 mm above base of storage chamber. • Power on LED/LCD indicator • Audio (minimum 65 dBA) and visual alarm against the violation of temperature range (less than +2 and more than +8 degree C) • Min. & Max. cabinet temperature digital display of last 24 hrs. and breaches during last 24 hrs. • The unit should be sealed protected from dust, moisture or condensed falling over it. 12. Accuracy for digital controller +0.5 degree centigrade.
2.2	User's interface	1. Programmable Micro-processor control unit with child lock facility. 2. Should have provision to set minimum and maximum temperature at 0.1 degree Centigrade to programme the unit for continuous operation. 3. Should have provision for defrosting program.
2.3	Software and/ or standard of communication (where ever required	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Heat dissipation	NA
3.5	Mobility, portability	Mobile
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	Power requirements	220 +/- 10% VAC, 50 Hz
4.2	Battery operated	NA
4.3	Protection	Voltage stabilizer should be provided.
4.4	Power consumption	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. Vaccine Storage Basket allowing free circulation of air, having the size to be able to accommodate 4 to 6 of them in the unit and suitable to match the net volume requirement. It should be minimum 5 wire basket. 2. Stem Alcohol thermometer -one piece per unit range of -30 to +50 degree centigrade.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust …)	The unit shall be capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity upto 90%.

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6.2	User's care, Cleaning, Disinfection & Sterility issues	As specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,); Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 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	Availability of UPS for at least 24 hours back up and incompatible electric socket.
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, 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; 3. Advanced maintenance tasks documentation; 4. Certificate of calibration and inspection, 5. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

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25. DEEP FREEZER-LARGE		
Version no. :		01
Date:		August 2023
Done by : (name. Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. USE		
1.1	Clinical purpose	The deep freezers have vaccine storage capacity and ice pack freezing capacity. The Deep Freezer is provided with special insulation, which helps in maintaining inside temperature in the range of (-) 25 deg C to (-) 15 deg C.
1.2	Used by clinical department/ward	Immunization
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Gross Volume: 275 to 300 liters. 2. Construction: • Internal: Stainless 304 grade steel 3. External: Corrosion Resistance 4. Chest type with CFC-free insulation 5. Should have foam pad cover on top of the basket. 6. Solid door with lock and handle 7. Type: Compression Cycled, CFC-Free (both for refrigeration and insulation) All system tubing (suction tube, freezer tube and condensing tube) should be of minimum 99.97% of pure copper coil. 8. Temperature of compartment to be maintained between (-) 25deg C to (-) 15deg C continuous availability of energy at ambient temperature 5 to 45 deg. C. 9. Inlet of Capillary should be outside the PUF body. 10. ON/OFF Switch and power indicator should be available 11. A Micro-processor-based control unit should be provided for setting of temperature and display following features: • 3 digit digital display (to one decimal point) of cabinet temperature. The sensor should be placed 25 to 50 mm above base of chamber. • Power indicator • Audio (minimum 65 dBA) and visual alarm against the violation of set temperature range. • Min. & Max. cabinet temperature digital display of last 24 hrs. and breaches during last 24 hrs. • Temperature manual control with one decimal deg. scale. • The unit should be sealed protected from dust,

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		moisture or condensed water falling over it. 12. Accuracy for digital controller +/- 0.5 degree centigrade.
2.2	User's interface	1. Programmable Micro-processor control unit with child lock facility. 2. Should have provision to set minimum and maximum temperature at 0.1 degree Centigrade to programme the unit for continuous operation. 3. Should have provision for defrosting program.
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	Mobile
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	Internal electrical protection.
4.4	Power consumption	To be specified by vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	1. Vaccine Storage Basket allowing free circulation of air, having the size to be able to accommodate 4 to 6 of them in the unit and suitable to match the net volume requirement. It should be minimum 5 wire basket. 2. Stem Alcohol thermometer-one piece per unit range of -30 to +50 degree centigrade.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust …)	1. The unit shall be capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 95%. 2. The unit shall be capable of operating continuously in ambient temperature of 5 to 45 deg C and relative humidity of 90% 3. The plug should be flexible and unbreakable sealed rubber type.
6.2	User's care, Cleaning, Disinfection & Sterility issues	As recommended by manufacturer
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,); Performance and safety standards (specific to	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE

	the device type); Local and/or international	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	Availability of stabilizer capable to operate during voltage fluctuations.
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, 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; 3. Advanced maintenance tasks documentation; 4. Certificate of calibration and inspection, 5. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided;
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

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26. VACCINE CARRIER WITH ICE PACKS		
Version no. :		01
Date:		August 2023
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. USE		
1.1	Clinical purpose	A portable case designed for the transportation, within a healthcare facility or between medical institutions, of vaccines contained within receptacles (e.g., glass vials, bottles, tubes). It is typically designed to be liquid-tight with a shock-absorbing liner to protect the box from adverse conditions and minimize the risk of breakage, and is constructed with insulating materials to maintain the contents within certain temperature ranges.
1.2	Used by clinical department/ ward	Immunization
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. It should be portable, light weight, ABS molded or unbreakable plastic case with a folding handle and easy to transport. 2. It should maintain the inside temperature between +2 degree centigrade to +8 degree centigrade for 12 hours or more, with four conditioned ice packs if not opened frequently. 3. It should carry minimum 16-20 vials with diluents form health institution to session site. 4. It should have vaccine storage capacity of 2.0 liters or more. 5. It should have insulation of CFC free polyurethane, (PUF) of 40-50 m.m. thickness minimum. 6. It should have hold over time of more than 24 hrs at 43 deg C ambient temperature. 7. It should be light weight and preferably less than 10kgs when fully loaded for ease to carry. 8. Vaccine carrier should contain Ice packs of WHO PQS performance specifications. Ice packs should contain water 0.35 to 0.40 ltr. and external dimensions of Ice packs should be 163x94x34 mm +2 mm. Ice packs should be of HDPE, and it should pass the robust and leakage test. Ice packs should have removable caps for water filling and also have a filling line mark clearly indicated. Ice packs when frozen, the thickness should not exceed 25% of unfrozen Ice packs thickness. 9. A soft foam pad of 30 mm thickness to be provided inside vaccine carrier as a temporary lid.

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		10. A rectangle/circular pan (plastic) of suitable size to be provided in between icepacks to carry the vaccine vials so that vaccines vials may not come in direct contact with Ice packs.
2.2	User's interface	N.A.
2.3	Software and/or standard of communication (where ever required)	N.A.
	3. PHYSICAL CHARACTERISTICS	
3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	N.A.
3.4	heat dissipation	NA
3.5	Mobility, portability	Portable
	4. ENERGY SOURCE	
4.1	Power Requirements	N.A.
4.2	Battery operated	N.A.
4.3	Protection	N.A.
4.4	Power consumption	N.A.
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)	Four ice packs need to be supplied along with vaccine carrier.
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Should be capable of withstand operation in extreme and ambient temperature (-10 deg C to 60 deg C). Capable to work in relative humidity up to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by manufacturer
	7. STANDARDS AND SAFETY	
7.1	Certificates (pre-market, sanitary, ...)	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. Vaccine carrier and Ice packs should also conform to WHO 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 checks before handover

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8.3	Training of staff (medical, paramedical, technicians)	NA
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	• 03 Years
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	User and technical manuals to be supplied in English/Hindi language.
10.2	Other accompanying documents	NA
11. NOTES		
11.1	Service Support Contact details (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.

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27. CELL COUNTER SEMI-AUTOMATIC (3 PART)		
Version no.:		02
Date:		August 2023
Done by: (Name/Institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Haematological cell analyser IVD
GMDN code(s)		35476
GENERAL		
1. USE		
1.1	**Clinical purpose**	An automated laboratory instrument intended to be used for the enumeration of a haematological cell population, using technology to measure and calculate white cell, red cell and platelet parameters and indices in a clinical specimen.
1.2	**Used by clinical department/ ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• The system should have End point, kinetic, fixed time and turbidimetric mode. • The system should be capable of 3 part WBC differential, estimating minimum 18 parameters with linearity (WBC, TC, RBC, Hb, hematocrit, MCV, MCH, MCHc, RDW- SD/RDW-CV, PLT, MPV, Pt Crit, PDW, PLCR optional). • The system should have memory of minimum 100 patient samples. • The system should have high intensity LED source for Hb estimation. • The system should have dual mode – flow cell and cuvette. Non-cyanide based is preferable. • External keyboard. • Automated standby and wake up. • Auto probe cleaning and sample dilution preferable. • System must have throughput of at least 60 samples per hour. • QC Mode: LJ, SD, CV, QC histogram • Provision for Bar Code/QR code reading should be available • Built-in voltage stabilizer and test results printing facility. • The equipment should have in-built digital display unit and PC interface facility
2.2	**User's interface**	• Touch screen (Coloured) • Provision for bi-directional LIS/HIS interface should be available.
2.3	**Software and/or standard of communication (wherever required)**	To be provided by manufacturer
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	N/A

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3.2	**Weight (lbs, kg)**	N/A
3.4	**Noise (in dBA)**	N/A
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.6	**Mobility, portability**	Stationary laboratory Installation.
	4. ENERGY SOURCE	
4.1	**Power Requirements**	220 +-10% VAC, 50 HZ
4.2	**Battery operated**	UPS system with minimum 1 hour back up
4.7	**Protection**	Internal electrical protection
4.8	**Power consumption**	To be specified by vendor
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	• 2D-Barcode/ QR code Scanner. • Built-in Thermal printer and provision for external printer. • All the consumables, controls and calibrators and any other reagents or items required for conducting 1000 tests should be mentioned and supplied with the equipment. • Online UPS for minimum 1 hour back up.
	6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS	
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 up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
	7. STANDARDS AND SAFETY	
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type);Local and/or international**	1. Should be CDSCO approved. 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**	As specified by manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	• Supplier to perform installation, safety and operation checks before handover. • Lab In-Charge to affirm completion of installation
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided on installation and during preventive maintenance visits.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	• 3 years, including all spares and calibration. • Preventive maintenance visits atleast one in each quarter.
	10. DOCUMENTATION	

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10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hardcopy and soft copy) of: 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 local calibration and routine maintenance. 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**	List of essential spare/ accessories, reagents/all other consumables along with their part number and cost should be quoted
11. NOTES		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier, and local service agent to be provided;
11.2	**Recommendations or warnings**	Any warning signs would be adequately displayed;

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28. SEMI-AUTOMATED BIOCHEMISTRY ANALYSER		
Version no.:		02
Date:		August 2023
Done by: (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Multichannel clinical chemistry analyser IVD, laboratory
GMDN code		56677
GENERAL		
1. USE		
1.1	**Clinical purpose**	A semi-automated laboratory instrument intended to be used for the qualitative and quantitative in vitro determination of multiple clinical chemistry analytes in a clinical specimen. Analytes detected may include electrolytes, specific proteins, lipids and kidney, liver and cardiac function test analytes.
1.2	**Used by clinical department/ ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Analyzer should have ability to use external cuvettes and integrated flow cell. • Analyzer should have more than 200 programmable channels. • **Open Ended system preferably.** • Analyzer should have 5 assay types: End point, Fixed time, Kinetic, absorbance and 1-point calibration with option for extended keyboard. • Analyzer should have calibration types: Linear factor, multi-point, point to point and Log-Log out • Facility for kinetic assay measurement with multiple standard mode. • Should have minimum 10,000 Patient Result memory Storage • Should have light source with working life of more than 10000 hrs. • Should have complete visual range. • 3 levels control with day-to-day Levey Jennings chart stored and displayed. • Provision for Bar Code/QR code reading should be available. • The equipment should have in-built digital display unit and PC interface facility
2.2	**User's interface**	• Facility for integration with PC • Provision for bi-directional LIS/HIS interface should be available.
2.3	**Software and/or standard of communication (wherever required)**	NA
3. PHYSICAL CHARACTERISTICS		

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3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.4	**Noise (in dBA)**	NA
3.5	**Heat dissipation**	Heat Dissipation: Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism
3.6	**Mobility, portability**	Stationary lab Installation
	4. ENERGY SOURCE	
4.1	**Power Requirements**	220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	UPS system for backup of minimum one hour
4.4	**Protection**	NA
4.5	**Power consumption**	To be specified by manufacturer/supplier
	5. ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	**Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	1. Light source/Lamp-1 no. 2. Micro pipettes (5 No.) - 2 variable (5-50), (100-1000) 3. Tips 500 - small and 500- big.
	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**	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
	9. WARRANTY AND MAINTENANCE	
9.1	**Warranty**	1. 3 years 2. Preventive maintenance visits atleast one in each quarter.

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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/Hindi language along with machine diagrams. 2) List of equipment and procedures required for local calibration and routine maintenance. 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**	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

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29. BINOCULAR MICROSCOPE		
Version no.:		02
Date:		August 2023
Done by: (name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDNS name		NA
GMDNS code(s)		NA
GENERAL		
1. USE		
1.1	**Clinical purpose**	A microscope is a laboratory instrument used to examine objects that are too small to be seen by the naked eye. Microscopic analysis of specimens helps diagnose diseases by looking at cellular morphology and presence of infectious agents and other microscopic structures. Binocular microscope is a microscope that lets the viewer use both eyes as it has 2 eye lenses.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Body-Single mold sturdy stand inclined Binocular body 30 °, 360º rotatable head without adjusting screws with inter-pupillary distance of 50-75mm. • It should have LED light source with rechargeable battery system. • Eyepieces-Paired high quality 10X/20mm wide angle anti fungus field eyepiece. one with pointer. Diopter adjustment must be present on both eye pieces. • Objectives-Parfocal, antifungal coated 4x, 10x, 40x and 100x having numerical aperture 0.1, 0.25, 0.60-0.65 and 1.25-1.65 respectively. Oil immersion objective (40x and 100x) should be spring loaded. All objectives should be plan achromatic, antifungal coated infinity and color corrected. Objective should be well centered even if their position on turret is changed. • Mechanical stag- ceramic coated surface with vernier scale on X-Y axis and slide holder. • Condenser, numerical aperture (NA) 1.25 focusable with rack and pinion arrangement incorporating spherical lens and iris diaphragm. It should have filter holder and swing in/out blue filter. • Should have inbuilt protective safety device which can withstand fluctuations of voltage from 140 V-280V. • LED illumination 3W with intensity control knob > 10,000 Hrs bulb lifespan with battery backup of 1 hrs and charging indication. • Focusing knob should have coaxial coarse and fine focusing knobs. Fine focusing movements should have sensitivity of 2 micron or less, coarse focus with torque adjustment, focusing stop for slide safety should be there.
2.2	**User's interface**	Manual
2.3	**Software and/ or standard of communication**	NA

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	(wherever required)	
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Stationary lab Installation
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		
4.1	**Power requirements**	**Power Supply:** 220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	No
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by manufacturer/vendor
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard, optional);** **Spare parts (main ones);** **Consumables/reagents (open, closed system)**	Should be provided with wooden storage box, dust cover, immersion oil.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Operating Condition: Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,); 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**	As specified by manufacturer and compatible electric accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory Training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration.

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		2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 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. 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**	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.

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30. GLYCATED HAEMOGLOBIN (HBA1C) ANALYSER		
Version no.:		01
Date:		August 2023
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		Glycated haemoglobin (HbA1C) analyser IVD
GMDN code(s)		35968
GENERAL		
1. USE		
1.1	**Clinical purpose**	A laboratory instrument intended to be used for the quantitative measurement of glycated haemoglobin (HbA1c), also known as glycohaemoglobin, glycosylated haemoglobin or glucosylated haemoglobin, in a clinical specimen.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Automated integrated system for HbA1c testing. • Should have automatic calibration system. • Should provide NGSP/IFCC certificate for equipment at the time of installation. • System should have a throughput of 20 test/hour. • Measuring range: HbA1c 3-20%. • High precision, CV ≤5% • Should have inbuilt battery backup • The system should have provision of bi-directional data flow. • The equipment should have digital display unit and PC interface facility. • The system should be equipped with an automated barcode/QR code reading facility
2.2	**User's interface**	Digital Display
2.3	**Software and/ or standard of communication (wherever required**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Portable
4. ENERGY SOURCE		
4.1	**Power requirements**	220VAC +/- 10%, 50 Hz
4.2	**Battery operated**	Should have inbuilt battery backup
4.3	**Protection**	Internal electrical safety
4.4	**Power consumption**	To be specified by vendor.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		

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5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Should provide Sample rack – 1 No, Pipette rack – 1 No, Printer rolls – 2 Nos, necessary pipettes and any other additional accessories required to perform the HbA1C test.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Operating Condition: Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of up to 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary); 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**	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. 2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 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. 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**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise;**	Contact details of manufacturer, supplier, and local service agent to be provided.

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	including a toll free/landline number)	
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

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31. Turbidometer		
Version no.:		01
Date:		August 2023
Done by : (name.institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. USE		
1.1	**Clinical purpose**	The turbidimeter is an instrument used for measuring the turbidity of a liquid by determining the degree to which particles suspended in the solution decrease the intensity of light lost as a beam is passed through it.
1.2	**Used by clinical department/ward**	Clinical Lab
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1. Material should be of high-grade SS (MS-304) 2. Should be benchtop type with LED/LCD display. 3. Suitable for measurement even for colored samples. 4. Range- 0-1000 NTU in four ranges minimum. 5. Resolution should be 0.01 NTU or better. 6. Accuracy: +/- 2 percent of full scale 1 and 1000 NTU 7. The detector should be photodiode. 8. Should have tungsten lamp light source. The lamp life should be minimum for 1 Lakh readings. 9. Measuring modes – Normal, Average & Continuous. The range selection should be automatic. 10. Should be operable in both electric and re-chargeable batteries mode.
2.2	**User's interface**	Manual
2.3	**Software and/ or standard of communication (wherever required**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	Noise-free system
3.4	**Heat dissipation**	Should maintain nominal temp and the heat should be disbursed through a cooling mechanism
3.5	**Mobility, portability**	Tabletop
4. ENERGY SOURCE		
4.1	**Power requirements**	220 +/- 10% VAC, 50 Hz
4.2	**Battery operated**	Yes
4.3	**Protection**	NA
4.4	**Power consumption**	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		

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5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Should be supplied with cuvettes and cuvettes stand.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 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 installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	3 years, including all spares and calibration. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 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. Advanced maintenance tasks documentation; 4. Certificate of calibration and inspection, 5. Satisfactory certificate for any existing installation from government hospital.
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided;

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11.2	**Recommendations or warnings**	Any warning sign would be adequately displayed.

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32. PORTABLE HANDHELD GLUCOMETER		
Version no.:		02
Date:		August 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Glucose self-testing
GMDN code(s)		CT296
GENERAL		
1. USE		
1.1	**Clinical purpose**	It intended to be used together for testing, either at the point-of-care or in self-testing by a layperson, for the quantitative measurement of glucose and/or ketones in a whole blood clinical specimen.
1.2	**Clinical department/ward**	All
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics**	1. Should be open system having compatibility with any make of available glucose strips in open market. 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

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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 forsign-off**	NA
8.3	**Training of staff (medical, paramedical, technicians)**	User training should be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	01 Years
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	User, technical and maintenance manuals should be supplied along with machine diagrams
10.2	**Other accompanying Documents**	NA
11. NOTES		
11.1	**Other information**	Contact details of manufacturer and supplier should be provided.
11.2	**Recommendations or Warnings**	NA

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

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5.1	**Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/reagents (open, closed system)**	Hb Strips
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience (air conditioning, humidity, dust …)**	Capable of operating continuously in ambient temperature -10 to 60 deg and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 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 checks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	01 year
10. DOCUMENTATION		
10.1	**Operating manuals, set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 1. User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams; 2. Certificate of calibration and inspection,
10.2	**Other accompanying documents**	NA
11. Notes		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landline number)**	Contact details of manufacturer and supplier to be provided;
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

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

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

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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	As indicated by Manufacturer and compatible electrical accessories as per standard Indian set-up.
8.2	Requirements for sign-off	1. Supplier to perform installation, safety and operation checks before handover. 2. Lab In-Charge to affirm completion of installation
8.3	Training of staff (medical, paramedical, technicians)	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	**1.** 3 years, including all spares and calibration. 2. Preventive maintenance visits atleast one in each quarter
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hard copy and soft copy) of: 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. 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**	List of all the important spares and accessories, with their part numbers and cost needs to be submitted.
11. NOTES		

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

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35. ISE BASED ELECTROLYTE ANALYSER IVD		
Version no.:		02
Date:		August 2023
Done by: (Name/Institution)		HCT/NHSRC
NAME, CATEGORY AND CODING		
GMDN name		Ion-selective Analyser IVD
GMDN code(s)		56682
GENERAL		
1. USE		
1.1	**Clinical purpose**	A laboratory instrument intended to be used for the quantitative measurement of electrolytes and other ions in a clinical specimen using ion-specific membranes to selectively measure electrical potential against a reference electrode to determine the target ion concentration.
1.2	**Used by clinical department/ward**	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	• Should be able to measure sodium [Na+], potassium[K+], chloride [Cl-]) in blood. • Should be based on measuring method of IonSelective Electrode (ISE) (Direct Potentiometer). • Should have individual electrodes for sodium, potassium, chloride, calcium and magnesium. • Should have automatic calibration. • Should have a throughput of minimum 40 samplesper hour. • Should have a memory of at least 100 samples. • QC should be based on test parameters. • The equipment should have in-built digital display unit, PC interface facility and provision for printing of reports • Should have provision for barcode/ QR code reader.
2.2	**User's interface**	• Touchscreen Display • Provision for bi-directional LIS interface should be available.
2.3	**Software and/ or standard of communication (wherever required**	Inbuilt-To be provided by manufacturer
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions(metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	**Mobility, portability**	Stationary lab installation
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ….)		

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4.1	**Power requirements**	220VAC +/- 10%, 50 Hz.
4.2	**Battery operated**	Online UPS for minimum one hour back up
4.3	**Protection**	Internal electrical protection
4.4	**Power consumption**	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories, (mandatory, standard,optional); Spare parts (main ones); Consumables/reagents(open, closed system)**	1. 2D-Barcode/QR code Scanner. 2. Built-in Thermal printer or provision for external printer. 3. All the consumables, controls and calibrators and any other reagents or items required for conducting 1000 tests should be mentioned and supplied with the equipment. 4. Online UPS for minimum one hour back up
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambience(air conditioning, humidity, dust …)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterilityissues**	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the devicetype); Local and/or international**	1. Should be CDSCO approved. 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**	As specified by manufacturer and compatible electric accessories as per standard Indian set-up.
8.2	**Requirements for sign-off**	Supplier to perform installation, safety and operationchecks before handover.
8.3	**Training of staff (medical, paramedical, technicians)**	Satisfactory training of users in operation and basic maintenance shall be provided on installation and during Preventive Maintenance visits and shall be documented
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	1. 3 years, including all spares and calibration. 2. Preventive maintenance visits at least once in each quarter
10. DOCUMENTATION		

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10.1	**Operating manuals,set manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: 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. Certificate of calibration and inspection,
10.2	**Other accompanying documents**	List of essential spares and accessories, with their part number and cost.
11. Notes		
11.1	**Service SupportContact details (Hierarchy Wise;including a toll free/landline number)**	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	**Recommendations or Warnings**	Any warning sign should be adequately displayed.

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36. OXYGEN CYLINDER "B" TYPE		
Version no.:		02
Date:		August 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Medical gas cylinders
GMDN code(s)		CT 659
GENERAL		
1. USE		
1.1	**Clinical purpose**	A container designed as a refillable cylinder used to hold compressed medical oxygen (O2) under safe conditions at high pressure; O2 is used as an essential life support gas, for anesthesia, and for therapeutic purposes.
1.2	**Clinical department/ward**	All Departments
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics**	1. Color coded, light weight. Aluminum alloy oxygen cylinder for providing oxygen therapy of total capacity of 4 cu M. 2. Mounted with pressure reducer and flow-meter provision of capacity upto 15 Liters per minutes and outlet for secretion aspiration. 3. Should have membrane pressure reducer with manometer complete with flow meter (0-15 liters /minute) and humidifier bottle. 4. Should be seamless cylinder of water capacity 10 liters. 5. Flowmeter for controlling unflow of oxygen.
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**heat dissipation**	NA
3.5	**Mobility, portability**	Trolley for mobility
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Protection**	NA
4.4	**Power consumption**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables/reagents**	Humidifier, key and flow meter

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	(open, closed system)	
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	**Atmosphere/Ambiance (air conditioning, humidity, dust ...)**	Capable of being operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90%.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	NA
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 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. Cylinder should have explosive safety certificate and should be provided along with each cylinder during installation
8. TRAINING AND INSTALLATION		
8.1	**Pre-installation requirements: nature, values, quality, tolerance**	NA
8.2	**Requirements for sign-off**	Certificate of Calibration, PESO certificate and inspection from the factory.
8.3	**Training of staff (medical, paramedical, technicians)**	Training of users in operation
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	10 years warranty
10. DOCUMENTATION		
10.1	**Manuals**	NA
10.2	**Other accompanying documents**	NA
11. NOTES		
11.1	**Other information**	NA
11.2	**Recommendations or Warnings**	Color Codes to be displayed on the cylinders.

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37. BP APPARATUS (ANEROID)		
Version no. :		02
Date:		August 2023
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Sphygmomanometers
GMDN code(s)		
GENERAL		
1. USE		
1.1	**Clinical purpose**	Measures blood pressure non-invasively by displaying the pressure in a cuff wrapped around a patient's arm. The systolic and diastolic pressure is usually assessed by listening to Korotk off sounds generated by arterial blood flow using a stethoscope simultaneously.
1.2	**Used by clinical department/ward**	All clinical departments
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics (specific to this type of device)**	1) Should be based on non-mercurial aneroid based measurement technology . 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**	Adult arm cuffs of size medium & large and pediatric size, inflation bulb, tubing. Dial mano meter.

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	ones) **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 & Sterilityissues**	NA
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ...); Performanceand safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 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 languagealong with machine diagrams.
10.2	**Other accompanying documents**	NA
11. NOTES		
11.1	**Service Support Contactdetails (Hierchy Wise; including a toll free/ landline number)**	NA
11.2	**Recommendations orwarnings**	NA

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

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5.1	**Accessories (mandatory,standard, optional)**	Adult arm cuffs of size small, medium, large & extra-large and inflation bulb, tubing • Battery Charger
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	Easy to clean
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ...); Performance and safety standards (specific to the device type); Local and/or international**	1. Should be CDSCO approved. 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 users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	**Warranty**	01 Year
10. DOCUMENTATION		
10.1	**Operating manuals, service manuals, other manuals**	Should provide 2 sets (hard copy and soft copy) of: User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams.
10.2	**Other accompanying documents**	NA
11. NOTES		
11.1	**Service Support Contact details (Hierchy Wise; including a toll free/ landline number)**	Contact details of manufacturer and supplier to be provided.
11.2	**Recommendations or warnings**	Any warning sign should be adequately displayed.

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39. Stethoscope		
Version no.:		02
Date:		August 2023
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Stethoscopes, Mechanical
GMDN code(s)		13755
GENERAL		
1. USE		
1.1	**Clinical purpose**	Listening to sounds from the heart, lungs, and/or gastrointestinal tract.
1.2	**Used by clinical department/ward**	All
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics(specific to this type of device)**	1. Should have single lumen binaural. 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 Consumables / reagents (open, closed system)**	1 x spare set of earpiece, 1 x spare diaphragm.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		

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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/ landlir number)**	NA
11.2	**Recommendations or warnings**	NA

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

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5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional) Spare parts (main ones) Consumables / reagents(open, closed system)**	NA
BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity of upto 90% in ideal circumstances.
6.2	**User's care, Cleaning, Disinfection & Sterility issues**	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	**Certificates (pre-market, sanitary, ..); Performance andsafety standards (specific to the device type); Local and/orinternational**	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**	One year
10. DOCUMENTATION		
10	**Operating manuals, servicemanuals, other manuals**	User manual should be provided.
11. NOTES		
11.1	**Service Support Contact details (Hierarchy Wise; including a toll free/landlinenumber)**	NA
11.2	**Recommendations or warnings**	NA

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41. Examination Table-Gynae		
Version no.:		01
Date:		August 2023
Done By:		HCT/NHSRC
NAME AND CODING		
GMDN Name		Table for examination
GMDN Code		-
GENERAL		
1. USE		
1.1	Clinical Purposes	A portable, collapsible chair/table for performing an OB/GYN examination or procedure, comprising a collapsible chair structure having a seat, a back rest, a pair of armrests and a pair of substantially planar leg rests, said chair being moveable between a collapsed condition for storage and/or transport and an examination position in which it enables a patient to be seated in a position suitable for an OB/GYN examination or procedure, said chair when in said examination position.
1.2	Used by clinical department/ward	Examination Room
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical Characteristics	1) Should have Head side adjustment 75° up on ratchet 2) MS tubular construction 3) Perineal cut-out 4) Should be Mounted on PVC shoe 5) Pre-treated and powder coated 6) In built sliding side stool 7) Adjustable Lithotomy Rods with rexine covered padded crutches 8) U-Cut at leg end
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	Should be able to support patient weight upto 160kg
3.3	Noise	NA
3.4	Heat Dissipation	Not applicable

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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	NA
4.2	Power consumption	NA
4.3	Battery backup	NA
5. ACCESSORIES. SPARE PARTS AND CONSUMABLE		
5.1	Accessories, (mandatory, Standard, operational); Spare parts (main ones) Consumable/reagents (open, closed system)	Mattress 50 mm with U Cut thick should be tear proof covered with non-pinching Rexine, seamless joint, washable and water-proof.
BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	Atmosphere /Ambiance (air conditioning, humidity, dust ...)	NA
6.2	User's care, Cleaning, Disinfection & Sterility issues	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.

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8.3	Training of staff (medical, paramedical, technicians)	NA
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	NA
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 (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.

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

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5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)** **Consumables / reagents (open, closed system)**	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)**	Capable of operating continuously in ambient temperature of -10 to 60 deg C and relative humidity 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
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)**	Contact details of manufacturer and supplier should be provided.
11.2	**Recommendations or warnings**	NA

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

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

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43. Wheel Chair		
Version no.:		02
Date:		August 2023
Done by : (name/institution)		HCT/NHSRC
NAME AND CODING		
GMDN name		Wheel Chairs
GMDN code(s)		14449
GENERAL		
1. USE		
1.1	**Clinical purpose**	Chairs mounted on large wheels, designed for indoor (e.g., hospital, institution, home) or outdoor transportation of patients or individuals with impaired walking ability.
1.2	**Clinical department/ward**	All Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	**Technical characteristics**	1. Overall size 670 mm W x 1120mm D x 920 mm H. 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 the hand grips 7. Back wheel fixing bolt shall be covered with cup type nut. 8. Should have breaking system on both side 9. All pipes & Foot rest should be made of aluminum
2.2	**User's interface**	Manual
2.3	**Software and/or standard of communication**	NA
3. PHYSICAL CHARACTERISTICS		
3.1	**Dimensions (metric)**	NA
3.2	**Weight (lbs, kg)**	NA
3.3	**Noise (in dBA)**	NA
3.4	**Heat dissipation**	NA
3.5	**Mobility, portability**	Mobile
4. ENERGY SOURCE		
4.1	**Power Requirements**	NA
4.2	**Battery operated**	NA
4.3	**Protection**	NA
4.4	**Power consumption**	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	**Accessories (mandatory, standard, optional)** **Spare parts (main ones)**	NA

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

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MISCELLANEOUS EQUIPMENT

Sl. No.	Title	Specifications	Image of the equipment
44.	Finger Exerciser web	• Description: used for hand strengthening and hand therapy. Excellent for physical therapy, conditioning, and rehabilitation. • Use to perform finger flexion, extension, opposition, and supination exercises • Material: latex-free material with high quality rubber with special agents added for durability and strength which can accommodate all hand sizes and strength levels • Dimension: 14" in diameter • Available in 6 resistance levels.	
45.	Reciprocal walker	• Description: Lightweight foldable frame walker fitted with soft hand grip, used to provide stability. • Portability: foldable for easy storage and transportation • Material/Quality: made up of stainless steel rugged tubular frame to bear weight. • Distance between handgrips should be approx. 34 cms • Height: should be at least 175 cm, from ground and preferably adjustable/lockable. • Should have latex free handgrip with forearm support.	
46.	Spirometer	• Description: Spirometer is used for lung exercises. • Should be compact, lightweight and made up of high-quality break-resistant plastic. • Should have 3 chambers for different inhalation rates consisting of 3-balls spirometer.