Ministry of Health & Family Welfare
Government of India

TECHNICAL SPECIFICATIONS OF MEDICAL EQUIPMENT FOR SPECIAL NEONATAL CARE UNIT AND NEONATAL & PAEDIATRIC INTENSIVE CARE UNIT

NATIONAL HEALTH SYSTEMS RESOURCE CENTRE
MINISTRY OF HEALTH & FAMILY WELFARE

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TRANSPORT INCUBATOR		
Version No.:		2.0
Date:		November 2024
Done by: (Name / Institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Transport Infant Incubator
GMDN code(s)		35121
GENERAL		
1. USE		
1.1	Clinical purpose	Designed to provide an enclosed controlled environment to maintain appropriate temperature and humidity levels mainly for premature infants and other newborns who cannot effectively regulate their body temperature.
1.2	Used by clinical department/ ward	NICU and PICU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	• Built for the transport of infants between wards or health facilities, including by vehicle. • Control of air temperature and infant skin temperature. • Patient skin temperature range: 35-37.5 deg C with manual override option. • Air temperature range: 30 deg C to 39 deg C; Temperature resolution ±0.1 deg C; Temperature accuracy ± 0.2 deg C. • Safety cut off at 38 deg C for skin and 39 deg for air with audio and visual alarms. • Easy access control panel. Facility to elevate base, adjustable range. • Self-test functions are performed. • Must have skin temperature display. • The transport incubator should have a transparent hood for infant viewing. • Visual and audible alarms for air circulation / probe / system / power failure alarm. • Air velocity: minimum 0.30m/sec • Adjustable oxygen input (Flow rate range: 5 to 15 liters/min) and oxygen concentration range 25 to 70% with digital display unit. • Maximum CO_2 concentration inside incubator 0.2%. • Mode of operation should be properly displayed. • Infants' straps (non-allergic & soft material) should be provided to restrict the baby's movement. • Skin temperature probe should be small in size not more than 10mm diameter and 4mm in height to fix the probe firmly on the infant. Baby contact material should be biocompatible as per ISO 10993 standard requirement.

		• Infant bed should be drawable. Mattress foam density should be minimum 25kg./cm3 and infant bed mattress cover should be biocompatible material (washable). • Examination light should be provided for inspection. • Should have heater power indicator. • Warmup time 30-40 minutes and shall not differ by more than 20%. • It should be equipped with a thermal cut-out. It shall be arranged so that the heater is disconnected, and an auditory and visual warning is given at an incubator temperature which does not exceed 40 deg C. • It should have elbow operable ports and head access door. • It should not topple over at 10 deg inclined plane. • It should be wheeled into an ambulance.
2.2	User's interface	Display allows easy viewing in all ambient light levels
2.3	Software and/or standard of communication	In built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	The baby bed should be minimum 60X30cm and the canopy should be minimum 80 (L) X40 (B) X 60 (H) cm.
3.2	Weight	Not exceeding 40kg. (without cylinders).
3.3	Configuration	• Oxygen port with tubing, also mount for oxygen cylinder of 5 liters size. Accommodates shelves, suction unit and I/V poles. • Double-walled cabinet with at least two hand ports. Should have collapsible trolley with lockable castors. • Mounted on mobile base, lowest height setting of which is at least 80 cm high. • At least two castors must be fitted with brake facility. • Castors must be made of conductive material such as Static dissipative Polyurethane and rotate (swivel) freely around the vertical axis. • The canopy and infant bed should be crevice free for ease of cleaning.
3.4	Noise (in dBA)	<60dB
3.5	Mobility, portability	Yes, on castors
4. ENERGY SOURCE		
4.1	Power Requirements	220VAC ± 10%, 50 Hz
4.2	Battery operated	Battery backup of 04 hours. The battery should be protected from overcharging.
4.3	Power consumption	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories	With washable and removable straps and binders
5.2	Spare parts (main ones)	Two extra sets of all sensors, Two extra sets of filters, two extra set of fuses (if replaceable fuses used).
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of upto 90%.

6.2	User's care, Cleaning, Disinfection & Sterility issues	Cleaning and disinfection steps should be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	Certificates, 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 conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1 General requirements of electrical safety standards. 5. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	Supplier to perform safety and operation check before hand over.
8.2	Requirements for sign-off	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	02 Years
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hardcopy) of: - 1) User, technical and maintenance manuals to be supplied in English/Local 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 important spares and accessories, with their part numbers and cost.
11. NOTES		
11.1	Other information	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared.

TRANSPORT VENTILATOR (NEONATAL & PEDIATRICS)		
Version No.:		2.0
Date:		November 2024
Done by: (Name / Institution)		HCT/ NHSRC
NAME AND CODING		
GMDN Name		Transport pneumatic high-frequency ventilator
GMDN Code		66260
GENERAL		
1. USE		
1.1	Clinical purpose	To provide automated, alveolar ventilatory support for patients during interhospital or intrahospital transport, and in emergency situations.
1.2	Used by clinical department/ ward	Emergency /Critical Care
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	• Mountable transport ventilator (Neonate/Pediatric). • Invasive Modes (CMV and SIMV) and Non-invasive Mode (CPAP). • Pressure controlled - Peak Pressure up to 40 cm H_2O. • Respiration Rate up to 80 bpm • There should be two FiO_2 settings between 21% and 100%. • PEEP 0- 10 cm of H_2O. • Trigger sensitivity - Pressure. • The associated cylinder (to be supplied along with the machines) should be such that it could be locally filled. • Oxygen cylinder connector (to be supplied along with the machine) should be compatible with ventilator. • Audio and visual alarm for disconnection and high pressure. • The device should be capable of operation in various environments such as Emergency, Ambulance, Aircraft, & Hospital.
2.2	User's interface	Automatic
2.3	Software and/or standard of communication	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	NA
3.2	Weight	<8kgs
3.3	Noise (in dBA)	<60dB
3.4	Mobility, portability	Yes
4. ENERGY SOURCE		
4.1	Power Requirements	220 VAC +/- 10%, 50 Hz, Electricity and battery driven; should be compatible with ambulance power supply system with other life-saving equipment running parallel in the ambulance.

4.2	Battery operated	With minimum 04 hours battery backup
4.3	Power consumption	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories & spares	Battery, leakage adapter.
5.2	Consumables / reagents	Full face mask, 4 reusable breathing circuit of silicone material (2 for pediatric and 2 for neonates), ventilator connecting tubes, neonatal size tubing
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of upto 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Cleaning and disinfection steps to be specified by the manufacturer.
7. STANDARDS AND SAFETY		
7.1	Certificates, 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 sockets
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	02 years
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hardcopy) of: - 1) User, technical and maintenance manuals to be supplied in English/Local language along with machine diagrams. 2) List of equipment and procedures required for local calibration and routine maintenance. 3) Certificate of calibration and inspection. 4) List of essential spares and accessories, with their part number and cost.
11. NOTESs		
11.1	Other information	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared.

INTENSIVE CARE VENTILATOR (NEONATAL & PEDIATRIC)		
Version No.:		2.0
Date:		November 2024
Done by: (Name / Institution)		HCT/ NHSRC
NAME AND CODING		
GMDN Name		Intensive care ventilator
GMDN Code(s)		42411
GENERAL		
1. USE		
1.1	Clinical purpose	To provide automated, alveolar ventilatory support for patients in emergency situations.
1.2	Used by clinical department/ ward	Emergency /Critical Care (NICU/PICU)
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	• Should have facility for Invasive and Non-Invasive ventilation. • Medical grade air compressor or turbine-based technology. • Microprocessor control ventilation with integrated heated humidifier and power back-up. • Should have the following modes of ventilation: ▪ Assist-control ▪ Volume control ▪ Pressure control ▪ SIMV with pressure support (Pressure and volume control) ▪ PEEP ▪ Inverse ratio Ventilation ▪ Noninvasive ventilation-BIPAP, CPAP & HFNC ▪ Apnea ventilation, user selectable, volume & pressure control. • Should have built in color screen TFT/LCD display of minimum 12" fordisplay of waveforms and monitored value. • It should have an inbuilt facility to upgrade with $EtCO_2$. • It should have the facility to measure and display the following parameters: • Airway Pressure (Peak & Mean) • Tidal volume (Inspired & Expired) • Minute volume (Inspired & Expired) • Respiratory mechanics • Spontaneous Minute Volume • Total Frequency • FiO2 dynamic • Intrinsic PEEP

		• Plateau Pressure ▪ Resistance & Compliance ▪ Use selector Alarms for all measured & monitored parameters ▪ Occlusion Pressure ▪ Pressure Flow & Volume curves. • Automatic compliance and leakage compensation for circuit and ETtube. • Should have facility of logbook, for events and alarms with date & time. • Should have the following setting: ▪ Tidal volume (Minimum 2ml, Maximum up to 2000ml); pre-set range for both neo-natal & pediatric modes to be provided ▪ Inspiratory pressure (up to 40 cm of H_2O) ▪ Respiratory rate 1 to 150 bpm ▪ CPAP/PEEP ▪ Pressure support ▪ FiO2 setting range between 21% and 100% ▪ Pause time ▪ Pressure/flow Trigger ▪ Inspiratory flow up to 120 Lpm • Oxygen cylinder/central pipeline connector/ (to be supplied along withthe machines) should be compatible with ventilator. • Should have the facility for 'inspiratory-hold' and 'expiratory-hold' maneuvers to measure respiratory dynamics. • Internal, replaceable, rechargeable battery allows operation for a minimum of four hour in the event of power failure. • It should be supplied with one servo-controlled humidifier with digital monitoring of inspired gas temperature with heating wire, reusable chamber and autoclavable. • In compressor-based ventilator, supply compatible external air compressor having oil free medical grade air, with peak output flow should be 150 LPM or more and air quality complying with ISO compressed air purity class. In turbine-based ventilator, the turbine should be inbuilt and it should provide adequate air to the ventilator. • The Ventilator should have an internal facility to calibrate the Flow Sensor and Oxygen Fuel cell as and when required within a short time period. • Proximal flow sensors (Heated wire or ultrasonic or differential pressure sensor flow sensor positioned at Proximal End of Neonatal Patient are mandatory for neonatal ventilators. • Oxygen sensor can be permanent or consumable type. If sensor is consumable type, 4 nos. of oxygen sensor should be supplied along with equipment
2.2	User's interface	Should have audio visual alarm for battery low, source gas low

		and high/low pressure in the breathing circuit or source gas inlet.
2.3	Software and/or standard of communication	Inbuilt software.
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	<50kg including trolley
3.3	Configuration	1) Compatible hinged arm for holding the circuit. 2) Should have caster wheels with a braking system;
3.4	Noise (in dBA)	>60 dB
3.5	Mobility, portability	Yes
4. ENERGY SOURCE		
4.1	Power Requirements	220 V +/- 10% AC, 50 Hz
4.2	Battery operated	Yes, with minimum four hour backup
4.3	Power consumption	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories & spares	NA
5.2	Consumables / reagents	1) Full face mask- 5 Nos each of 0,1 and 3 2) Nasal cannula for neonates- 05 3) Reusable breathing circuit of silicone material (05) 4) Air & oxygen hose- 1 each 5) External oxygen & compressed air tubing – 2 each
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of up to 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	Certificates, 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 conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1 General requirements of electrical safety standards. 5. Should comply with USFDA/European CE standards in case of non-availability of BIS standards.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	1) Availability of 5 amp/15 Amp. Electrical sockets. 2) Oxygen supply. 3) Medical air supply.
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	02 years
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets(hardcopy) of:- 1) User, technical and maintenance manuals to be supplied in English/Local language along with machine diagrams. 2) List of equipment and procedures required for routine calibration androutine maintenance. 3) Certificate of calibration to be provided by the manufacturer. 4) List to be provided of important spares and accessories, with their partnumbers and cost.
11. NOTES		
11.1	Other information	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared

RADIANT WARMER		
Version No.:		2.0
Date:		November 2024
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Infant warmer
GMDN code(s)		36812
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)	• It should be microcontroller based radiant warmer with manual and servo options. • Should have two displays – One for patient temperature and one for set temperature • Manual mode should allow control over heater output and also timer controlled to allow the user to set the duration for the manual warming between 0-30 minutes. It should give an alarm after 30 minutes of operation in manual mode with the timer & cutoff facility. • The warmer head should be rotatable in different directions, so as to allow taking x-ray. Heater output should be cut-off, while the heater unit in the swivel position and unit should be automatic lock when it comes to the straight position. • Should have facility to display skin set, skin observed temperature and air temperature (in deg C) and heat power separately. • It should have ceramic or quartz infrared or calrod heater. • It should have audiovisual alarm & cutoff facility for overheating beyond set temperature range (0.5^{o} C – 37^{o} C). The machine should sense the skin probe failure and cut off the heater. It should have alarms for probe failure, power failure, system failure and heater failure. • Should have the integral bed with tilting facility at both ends up to +/- 15 deg • Observation light preferably high intensity LED of 90-to-100-foot candles or at least 1000 Lux (color temperature range 3700K to 5100K) should be provided for inspection • Battery backup for Power failure indication during power fail. • The desired temperature ranges from 25 to 40 degree C and

		settable temperature can be from 32 to 38 deg C. • Thermistor based temperature detection resolution should be 0.1 degree C and accuracy should be 0.2 °C. Should have interchangeable probe without requiring to be calibrated. • The height of the warmer should be adjustable for different types of bed. Its base should be elevated to ensure cleaning procedures can be carried out beneath the warmer without moving the unit. • It should have separate bassinet trolley, bed area should be at least 750-800 mmx500-550 mm & 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. • Control Panel should be liquid proof and allow easy and hygienic disinfection. • Bed should be about 80 - 100 cm from the floor and 80-90cms from the heat source. • It should have lockable castor wheels. • Marking on the bassinet and X-Ray cassette holder is mandatory to enable proper positioning of the baby while doing the X-Ray. • 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, transparent and made up of polycarbonate or acrylic. • X-Ray cassette tray should be at least 750X350mm and should adopt upto 20mm thick X-Ray cassette. • The baby bed should be crevice free for ease of cleaning and infection control. The mattress used should be of biocompatible material and should be sealed. • 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.
2.2	User's interface	Manual and Servo controlled temperature regulation.
2.3	Software and/or standard of communication	Inbuilt software, Interruption and restoration of the power supply should not change the preset values.
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions	NA
3.2	Weight (lbs, kg)	Maximum: 150kg.
3.3	Configuration	At least 60-degree angle adjustment must be possible in the heat source, and it should provide shielding to the infant in case of breakage of tubes/bulbs.
3.4	Noise (in dBA)	>60dB
3.5	Mobility, portability	Yes, on castors (2 of the castors should have brakes).
4. ENERGY SOURCE		
4.1	Power Requirements	220 V +/- 10% AC, 50 Hz
4.2	Battery operated	NA, should be line power operable.
4.3	Protection	A suitable auto voltage corrector with a spike protector

		should be available.
4.4	Power consumption	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories & spares	Should have standard IV pole (sturdy; non-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 detachable probes – 05
5.2	Consumables / reagents	Thermal reflector to fix the skin probe on baby.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of 0 to 50deg C and 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, 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 conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1 General requirements of electrical safety standards. 5. Should comply with USFDA/European CE standards in case of non-availability of BIS standards.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	Availability of electrical socket.
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(hardcopy) of: - • User, technical and maintenance manuals to be supplied in English/Local language along with machine diagrams. • List of equipment and procedures required for routine calibration androutine maintenance. • Certificate of calibration to be provided by the manufacturer. • List to be provided of important spares and accessories, with their partnumbers and cost.
11. NOTES		
11.1	Other information	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared.

PHOTOTHERAPY		
Version No.:		2.0
Date:		November 2024
Done by: (Name / Institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Phototherapy units/systems
GMDN code(s)		35239
GENERAL		
1. USE		
1.1	Clinical purpose	Device designed to emit a blue light in the visible wavelength of around 425-475 nm to treat neonatal jaundice (hyperbilirubinemia).
1.2	Used by clinical department/ ward	Newborn stabilization unit, SNCU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	• Phototherapy should be based on LED technology, which after filtering should provide a light wavelength approximately 450 to 470 nm withpeak wavelength of 450-460nm range. Should be free from UV and IR radiation. • Irradiance to be minimum 35-40 µW/cm2/nm at 35 cm between bed and light unit and UVshould not exceed 10-4 W/m2 in 180nm to 400nm. • Digital Timer for monitoring therapy hours (resettable) & lamp usage hours to be clearly visible by operator. • Effective surface area should be at least 250 X 500 mm within an irradiance ratio of 0.4 (min/max irradiance). • Lamp life should be minimum 100000 hours for LED and should havetimer to indicate its usage. • Safety auto cutoff for over temperature (Not exceeding 38 Deg C). • Light head should be compact to use along with the radiant warmer & incubator and should be provided with tilting facility (±45 degree) so that the unit is not coming directly under warmer. • The unit should be mounted with castor wheels with brakes. • Variation in intensity over 5-6 hours < 10%. • The irradiance ratio (min to max) shall be greater than 40 % on mattress. • Interruption and restoration of the power supply do not change preset values. LED heat can be reduced by natural cooling. • LED should be protected from free fall and should not topple on 10 deg inclined angle. • 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). • Light unit tilting facility and height adjustment facility. • 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. • Epoxy/powder coated body for scratch and rust prevention and PU coating for plastic materials.
2.2	User's interface	Digital Timer for monitoring therapy hours
2.3	Software and/or standard of communication	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	NA
3.2	Weight	<20 kg
3.3	Configuration	• Clear cabinet for observation of infant. • Infant bassinette to be an integral unit which should be detachable. Unit to provide shielding of infant in the event of bulb breakage. • All surfaces to be made of corrosion resistant materials.
3.4	Noise (in dBA)	<60dBA
3.6	Mobility, portability	Minimum 3 castors and at least 2 with brakes
4. ENERGY SOURCE		
4.1	Power Requirements	220 V +/- 10% AC, 50 Hz
4.2	Battery operated	NA, should be line power operable.
4.3	Power consumption	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories & spares	Two replacement sets of fuses, if replaceable type used.
5.2	Consumables / reagents	Total 500 nos. Infant eye masks of both available sizes (term and preterm babies).
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity up to 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by the manufacturer.
7. STANDARDS AND SAFETY		
7.1	Certificates, 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 conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1 General requirements of electrical safety standards. 5. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation	Availability of electrical sockets.

	requirements: nature, values, quality, tolerance	
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	01 Year
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets(hardcopy) of: - • User, technical, maintenance and service manuals to be supplied in English/local language along with machine diagrams. • List of equipment and procedures required for routine calibration and routine maintenance. • Certificate of calibration to be provided by the manufacturer. • List to be provided of important spares and accessories, with their partnumbers and cost.
11. NOTES		
11.1	Other information	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared

TRANSCUTANEOUS BILIRUBINOMETER		
Version No.:		1.0
Date:		November 2024
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Transcutaneous Bilirubinometer
GMDN code(s)		16166
GENERAL		
1. USE		
1.1	Clinical purpose	Transcutaneous Non-Invasive Bilirubinometer is used to test transcutaneous concentration of bilirubin correlative with serum bilirubin concentration.
1.2	Used by clinical department/ ward	NICU and PICUs
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. It should be portable, easy to carry rugged devices and should be suitable for non-invasive measurement of bilirubin in neonates. 2. Should use light reflecting testing method / light Transmitting technology. 3. Light source should be pulse xenon arc lamp. 4. The measurement range should be 0-20 mg/dl or 0-340 µmol/L. 5. **Error of Estimate (SEE):** +/- 1.5 mg/dl or +/-25.5 Rmol/L 6. The device should measure the optical density difference at two wavelengths to determine the yellowness of the subcutaneous tissue. 7. It should have at least 3 digit reading display and built in keypad or touch screen for operation.
2.2	User's interface	Digital Display allows easy viewing in all ambient light levels
2.3	Software and/or standard of communication	In built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	Light weight, less than 250 g
3.3	Configuration	Compact and easy to use.
3.4	Noise (in dBA)	<65 dB
3.5	Mobility, portability	Yes, portable
4. ENERGY SOURCE		
4.1	Power Requirements	220VAC, +/-10% , 50 Hz for charging
4.2	Battery operated	Yes, it should measure a minimum of 500 single measurements when fully charged. Should have over-charging cut-off with visual symbol.

4.3	Power consumption	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories (mandatory, standard, optional), Spares	Charger unit with adapter. Power cable adapter set.
5.2	Consumables / reagents (open, closed system)	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of up to 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Cleanable with alcohol or chlorine wipes.
7. STANDARDS AND SAFETY		
7.1	Certificates, 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 conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1 General requirements of electrical safety standards. 5. Should comply with USFDA/European CE standards incase of non-availability of BIS 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, service manuals, other manuals	Should provide 2 sets (hardcopy) of: - 1) User, technical and maintenance manuals to be supplied in English/local language along with machine diagrams. 2) List of equipment and procedures required for local calibration and routine maintenance. 3) Certificate of calibration and inspection. 4) List of important spares and accessories, with their part numbers and cost.
11. NOTES		
11.1	Other information	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared.

HAND-HELD VIDEO LARYNGOSCOPE		
Version No.:		1.0
Date:		November 2024
Done by: (Name / Institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		**Video intubation laryngoscope handle/monitor**
GMDN code(s)		62671
GENERAL		
1. USE		
1.1	Clinical purpose	For viewing vocal folds and glottis. Surgical and mechanical ventilation/intubation
1.2	Used by clinical department/ ward	PICU/NICU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. It should have a color screen of size 3.5 inch or more, with twist and tilt feature. 2. It should have at least 2 MP camera with LED lights and 3. Should have free fog optical polymer material/poly carbonate material blades. 4. It should have a provision to take pictures and record videos. 5. It should have inbuilt memory/SD card to save pictures and videos. 6. Should have an illumination of 800 Lux or more and field angle of 60 degrees or more. 7. The blades should be re-usable and autoclavable preferably made of S/Steel (MS-304) of high quality. It should include miller type blade miller 0,1 mac 1,2 ,3.
2.2	User's interface	Should have provision for USB/HDMI connection ports.
2.3	Software and/or standard of communication	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	NA
3.2	Weight	Less than 250 g
3.3	Configuration	• Handheld unit, single piece when in use. • On/off switch to be robust and easy to use. • External material to be non-ferrous. • Blades to be surgical grade stainless steel.
3.4	Noise (in dBA)	Noiseless operation
3.5	Mobility, portability	Yes
4. ENERGY SOURCE		
4.1	Power Requirements	Rechargeable Battery
4.2	Battery operated	Minimum 03 hrs backup

4.3	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories & spares	Battery Charger
5.2	Consumables / reagents	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of 0 to 50deg C and relative humidity of up to 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Blades should be autoclavable
7. STANDARDS AND SAFETY		
7.1	Certificates, 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 conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1 General requirements of electrical safety standards. 5. Should comply with USFDA/European CE standards in case of non-availability of BIS 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(hardcopy) of: • User, technical, maintenance and service manuals to be supplied in English/local language along with machine diagrams. • List of equipment and procedures required for routine calibration androutine maintenance. • Certificate of calibration to be provided by the manufacturer. • List to be provided of important spares and accessories, with their partnumbers and cost.
11. NOTES		
11.1	Other information	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared

OXYGEN HOOD		
Version No.:		2.0
Date:		November 2024
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Oxygen administration enclosures
GMDN code(s)		-
GENERAL		
1. USE		
1.1	Clinical purpose	To provide an enriched environment of oxygen (O2) to increase the patient'sO2 uptake.
1.2	Used by clinical department/ ward	SNCU/NICU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	• Transparent Polycarbonate unbreakable single molded. • Silicon rubber Neck Port adjustment enabled to minimize the wastage of oxygen and to ensure use in Neonate/Infant/ Pediatric patients. • Oxygen inlet Port.
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	Light weight
3.3	Configuration	NA
3.4	Noise (in dBA)	NA
3.5	Mobility, portability	Portable
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 & spares	NA
5.2	Consumables / reagents	Tubing
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	NA
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by the manufacturer.
7. STANDARDS AND SAFETY		

7.1	Certificates, Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 2. 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	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	NA
9.2	Maintenance tasks	NA
9.3	Service contract clauses, including prices	NA
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	User manual to be supplied in English/local language.
11. NOTES		
11.1	Other information	Contact information of the manufacturer and the supplier should be provided.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared

Bubble CPAP		
Version No.:		2.0
Date:		November 2024
Done by: (Name / Institution)		HCT/ NHSRC
NAME AND CODING		
GMDN Name		Neonatal CPAP Unit
GMDN Code		61197
GENERAL		
1. USE		
1.1	Clinical purpose	This device is designed to apply Continuous Positive Airway Pressure to non-intubated neonatal and infant patients. It is commonly used in spontaneously breathing patients who require short-term mechanical assistance.
1.2	Used by clinical department/ ward	NICU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. BCPAP machines should have the following components: • CPAP generator • Servo humidifier including reusable chamber, temperature probe, heater wire with adaptor • Air-oxygen blender • Single equipment mounting stand with swivel brake casters (four) **2. CPAP generator** • Capable to deliver nasal/ nasopharyngeal CPAP and heated humidified high gas flow through nasal canulae/ mask (>2 LPM). • Circuits (reusable) should be compatible with different nasal interfaces • CPAP range: 1-10 cm of H2O, Accuracy: ±1 cm of H2O. • Gas flow range: 1 – 15 LPM • Pressure release valve: safety valve mechanism to release excessive pressure. • Generator tube: graduations in the tube should be clearly readable and it should be snugly fitting into the chamber and the chamber should be transparent for checking water level. **3. Servo controlled humidifier** • Capable of working with both CPAP and Heated Humidified High Flow Nasal Cannula (HHHFNC) • Should be capable of supplying fully saturated oxygen gas at 37^{o}C. • Flow resistance <20 cm H_2O/L/sec (Ins R<12, Exp R<8).

		• Temperature range: 31^0C – 40^0C • Temperature control: ± 2^0C • Digital display of temperature: 5^0C – 80°C • Capable of ambient humidity compensation • It should be compatible with both reusable & disposable chambers and circuits. • Must have water level indicator in the chamber (both types). • Minimum warm up time: <30 min **4. Air-oxygen blender** • Oxygen concentration range should be 21 – 100%. • Number of ports should be two (02). • Accuracy: ±3% full scale • Weight: should be less than 2 kilograms • Gas supply pressure: 30 – 75 PSIG • Primary outlet flow range: 1 – 15 L/ min • Auxiliary outlet flow range: 1 – 15 L/ min • It should be supplied with air & oxygen hose at least 5 metres in length with suitable adaptors. • It should be provided with a water trap in air inlet connection • Should be able to set oxygen concentration using soft touch (digital) key/ by using mechanical knob for CPAP system.
2.2	User's interface	1. User interface to be easy to operate, numbers and displays to be clearly visible. Display easily readable in low ambient light and sunlight, Pressure [cmH2O], FiO2%, Flow rate, Air leak %, Respiration rate, Temperature 2. Should have audio visual alarm for all the parameters mentioned above point (1). 3. PEEP should be sensed as close to the delivery point as possible
2.3	Software and/or standard of communication	In-built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	<8kgs
3.3	Configuration	NA
3.4	Noise (in dBA)	<60dB; Alarm > 65dB
3.5	Mobility, portability	Yes, Portable
4. ENERGY SOURCE		
4.1	Power Requirements	220VAC +/- 10, 50 Hz
4.2	Battery operated	Yes, with a minimum of 4 hours battery backup
4.3	Power consumption	To be specified by manufacturer.

5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories & spares	NA
5.2	Consumables / reagents	• Head bonnet of different sizes • Reusable neonatal bubble CPAP circuits- minimum 05 • Nasal interface including nasal prongs, and masks of different sizes • Air and O2 hose of 3m length each along with the appropriate socket.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of upto 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by the manufacturer.
7. STANDARDS AND SAFETY		
7.1	Certificates, 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 conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1 General requirements of electrical safety standards. 5. Should comply with USFDA/European CE standards in case of non-availability of BIS standards.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	Electrical sockets; Oxygen supply
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	02 Years
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets(hardcopy) of: - • User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. • List of equipment and procedures required for routine calibration androutine maintenance. • Certificate of calibration to be provided by the manufacturer. • List to be provided of important spares and accessories, with their part numbers and cost.
11. NOTES		
11.1	Other information	Contact details of manufacturer, supplier and local service

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

PULSE OXIMETER (TABLETOP)		
Version No.:		2.0
Date:		November 2024
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Pulse oximeter
GMDN code(s)		45607
GENERALs		
1. USE		
1.1	Clinical purpose	A pulse oximeter is a device used to measure the percentage of oxygen saturation in blood (SpO2) and heart rate (pulse).
1.2	Used by clinical department/ ward	All departments
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	• It should be a lightweight desktop model, suitable for all types of patient range: especially for Neo-natal (with wrap around probes) extremely birth weight neonates. • Should have digital display with parameters: SpO2, pulse rate, plethysmograph waveform, alarm message and battery state indication. Should display trends in both tabular and graphical form for all parameters. • It should be suitable for detection in low perfusion conditions. • SpO2 detection range to include: 0-100 % • 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), perfusion index 0.1% to 20%. • 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. • It should have trend data for HR, PI and SPO2 of at least 36 hrs. • Equipment performance should not be affected by electromagnetic interference radiated or conducted through power lines from another devices. • Equipment should have no sharp edges, should be securely mounted and should provide adequate protection against moving and electrically energized parts. • Controls (e.g switches knobs) should be visible and clearly identified. Labels and marking should be clear and visible.
2.3	User's interface	Manual

2.4	Software and/or standard of communication	In built.
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	Should be less than 5kg
3.3	Noise (in dBA)	<65 dBA
3.4	Mobility, portability	Yes, Portable
4. ENERGY SOURCE		
4.1	Power Requirements	220V +/- 10 VAC, 50 Hz
4.2	Battery operated	Yes, minimum of 02 hours back-up time.
4.3	Power consumption	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories & spares	NA
5.2	Consumables / reagents	Two reusable probes each for pediatric and infant use, Y Probes with clips for infant use and forehead SpO2 sensors for detection of lowsaturation levels (less than 70%)/ flex probe with provision of fixation.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity up to 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Cleaning with alcohol or chlorine wipes. Steps should be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	Certificates, 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 conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1 General requirements of electrical safety standards. 5. Should comply with USFDA/European CE standards in case of non-availability of BIS standards.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	Electrical sockets
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	01 year
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets(hardcopy) of: - • User, technical, maintenance and service manuals are to be supplied in English/local language along with machine diagrams. • List of equipment and procedures required for routine

		calibration and routine maintenance. • Certificate of calibration to be provided by the manufacturer. • List to be provided of important spares and accessories, with their partnumbers and cost.
11. NOTES		
11.1	Other information	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared

SELF-INFLATING RESERVOIR BAG		
Version No.:		2.0
Date:		November 2024
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Manual pulmonary resuscitator, reusable
GMDN code(s)		-
GENERAL		
1. USE		
1.1	Clinical purpose	To provide or assist ventilation in a patient who is apnoeic or exhibits inadequate respiration through manual pulmonary-driven pressure cyclefunctions.
1.2	Used by clinical department/ ward	It is used in ambulances, intensive care units (ICU), during internal patient transfer, accident and emergency (A&E), and mass casualty incidents (MCI).
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Manual resuscitator with transparent facemask. 2. Self-Inflating Resuscitator bag should be of medical grade silicone material. 3. Resuscitator volume of 220-260 ml. 4. It should be suitable for single hand operation and delivered volume one hand 150 +/- 10 ml. 5. Should have pressure release valve at 35-40cm H_2O. 6. Standard15/22 mm Swivel connector allows connections to all common masks Endotracheal Tubes both for adults and infants. 7. It should be easy to dissemble for cleaning and disinfection. 8. It should be autoclavable including bag and washers. 9. It should be supplied with an oxygen reservoir bag and should deliver tidal volume of 250/500/750 & 1000 ml.
2.2	User's interface	Manual
2.3	Software and/or standard of communication	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	Handheld
3.2	Weight (lbs, kg)	Light enough to be operable by hand/palm for long duration.
3.4	Noise (in dBA)	NA
3.5	Mobility, portability	Handheld
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 & spares	Silicon bellow

		Non-Rebreathing Valve,2-meter oxygen tube, Guedel Airway, Oxygen Reservoir bag
5.2	Consumables / reagents	Neonatal Mask of 3 sizes viz 0, 01 and 2
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	NA
6.2	User's care, Cleaning, Disinfection & Sterility issues	Autoclavable
7. STANDARDS AND SAFETY		
7.1	Certificates, 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 conform to ISO 13485 quality standards. 4. Should comply with USFDA/European CE standards incase of non-availability of BIS 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 beforehandover.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	1 year.
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	User manuals are to be supplied alongwith machine diagrams.
11. NOTES		
11.1	Other information	Contact details of manufacturer and supplier to be provided.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared

BASINET		
Version No.:		2.0
Date:		November 2024
Done by: (Name / Institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Bed, Infant, general purpose
GMDN code(s)		-
GENERAL		
1. USE		
1.1	Clinical purpose	For care of neonate as a body positioning device.
1.2	Used by clinical department/ ward	NICU/SNCU, Labor room, Maternity ward
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	• Baby Tray with mattress, along with head up/down facility, Mattress density approx. 25Kg/m3 and with removable, washable, waterproof cover, mattress cover should be biocompatible and easy to clean. • Lower Shelf which is rotatable and swivel castors (100mm) - 2 castors with brakes. Baby tray should be of polycarbonate/acrylic material. • It should not topple on 30 deg inclined plane. • Baby bed should withstand up to 10kg weight. • It should have provision for baby name identification tag/label. • Minimum dimensions of the bassinet mattress should be 20X30" and walls both for the radiant warmer and baby bassinet.
2.2	User's interface	NA
2.3	Software and/or standard of communication	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	90cm-100cm height, 40cm-70cm width, 70-80cm length
3.2	Weight (lbs, kg)	Net weight: 30 kgs with loading capacity to be 10 kg
3.3	Noise (in dBA)	NA
3.4	Mobility, portability	Yes, on castors
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 & spares	Mattress, castors
5.2	Consumables / reagents	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance	NA

	(air conditioning, humidity, dust ...)	
6.2	User's care, Cleaning, Disinfection & Sterility issues	Easy to clean and disinfect.
7. STANDARDS AND SAFETY		
7.1	Certificates, Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 2. 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, service manuals, other manuals	User manuals to be supplied alongwith machine diagrams.
11. NOTES		
11.1	Other information	NA
11.2	Recommendations or warnings	NA

BREAST PUMP		
Version No.:		2.0
Date:		November 2024
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Breast pump, Electric
GMDN code(s)		38478
GENERAL		
1. USE		
1.1	Clinical purpose	Breast pump is used to extract milk from the breast, typically for collecting and feeding to an infant. The device produces a continuous low-grade suction through a funnel-like component that is applied to the breast; the milk collects in an attached vessel (e.g., a sterilized bottle).
1.2	Used by clinical department/ ward	NICU and PICU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1) It should be a portable electrically operated breast pump and should be for multiple users. 2) Double pump: Should be able to express milk from both breasts simultaneously. 3) Two Phase expression technology: to mimic baby sucking pattern • Stimulation Phase: cycle > 100/Minute, vacuum 45-110mmHg • Expression phase: cycles 30-60/minute: 50 – 250 mmHg 4) Automatic change of mode in preferable time from stimulation phase to expression phase and also manually changeable 5) Vacuum cycles should be user adjustable 6) It should be a closed system to avoid milk entering into the pump 7) Should have LCD display of mode, Suction range and cycle etc. 8) Collection bottles used for storage of milk should be autoclavable and biocompatible.
2.2	User's interface	Automatic
2.3	Software and/or standard of communication	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	Portable
3.2	Weight (lbs, kg)	Compact unit (weight less than 4 kg)
3.3	Configuration	LCD display suction timing
3.4	Noise (in dBA)	<60db
3.5	Mobility, portability	Yes

4. ENERGY SOURCE		
4.1	Power Requirements	220 V AC + 10%, 50Hz
4.2	Battery operated	Should have minimum of 3 hours battery back up after full charge- Lithium-Ion battery is preferable
4.3	Power consumption	It should be compatible with other lifesaving equipment running parallel.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories & spares	NA
5.2	Consumables / reagents	1) Reusable collection of bottles along with breast cups - 10 sets. 2) All kinds of tubes - 12 sets (If applicable). 3) Diaphragm, Breast shell, Lip valve
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of up to 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	Certificates, 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 conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1 General requirements of electrical safety standards. 5. Should comply with USFDA/European CE standards in case of non-availability of BIS standards.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	Availability of electrical sockets.
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks beforehandover.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	01 Year
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets(hardcopy) of: - • User, technical, maintenance and service manuals to be supplied alongwith machine diagrams. • List of equipment and procedures required for routine calibration and routine maintenance. • Certificate of calibration to be provided by the manufacturer. • List to be provided of important spares and accessories, with their partnumbers and cost.

11. NOTES		
11.1	Other information	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any warning sign should be adequately displayed.

BABY WEIGHING SCALE		
Version No.:		2.0
Date:		November 2024
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	Device designed to measure the weight of an infant, particularly a newborn, or to monitor weight changes, e.g., during critical care procedures.
1.2	Used by clinical department/ ward	NICU/SNCU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	• It should be a microprocessor-based electronic tabletop weighing machine. • It should have a large digital display with easy visibility. • Baby pan should be removable and washable. • Should show the accurate weight irrespective of the position of the baby over pan. • Weight displays up to 2 decimal point in Kg/gm. • 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. • The tray should be made of ABS/ Acrylic and must be devoid of any sharp edges. • Zero weight adjustment facility. • Quick, clear digital read outs. • Provision to measure the height of the baby in its laying position. • Accuracy: 5 gm, resolution: 1g, Measuring limit: 10 gm to 15 kg. • Built in rechargeable battery/ AC mains
2.2	User's interface	Digital display
2.3	Software and/or standard of communication	In built.
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	Pan: 520mm x 300mm x 85mm(minimum).
3.2	Weight (lbs, kg)	NA
3.3	Configuration	N.A.
3.4	Noise (in dBA)	N.A.
3.5	Mobility, portability	Yes, Portable
4. ENERGY SOURCE		

4.1	Power Requirements	220 V AC,+/-10 VAC, 50 Hz
4.2	Battery operated	Yes, minimum 02 hrs. battery backup
4.3	Power consumption	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories & spares	NA
5.2	Consumables / reagents	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of 0 to 50deg C and relative humidity of up to 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Easy to clean.
7. STANDARDS AND SAFETY		
7.1	Certificates, 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 conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1 General requirements of electrical safety standards. 5. Should comply with USFDA/European CE standards in case of non-availability of BIS 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 performance 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	01 year
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets(hardcopy) of:- • User, technical, maintenance and service manuals to be supplied alongwith machine diagrams. • List of equipment and procedures required for routine calibration and routine maintenance. • Certificate of calibration to be provided by the manufacturer.
11. NOTES		
11.1	Other information	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared

IRRADIANCE METER		
Version No.:		2.0
Date:		November 2024
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Blue light radiometer
GMDN code(s)		NA
GENERAL		
1. USE		
1.1	Clinical purpose	Used for checking radiance of phototherapy units.
1.2	Used by clinical department/ ward	Newborn stabilization unit, SNCU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	• Handheld, Band pass filter with max transmission 425-475 nm. • Light detector sensitivity range: 0-2000 µW/cm²/nm. • Measurement range: 0-100 µW/cm²/nm. • Minimal graduation: 1µW/cm²/nm. • Accuracy: ± 10%. • LED or LCD display. • Should be able to zero between measurements. • Fast measurement response- <5 sec. • Memory storage: required. • UV and IR should be blocked. • Hold function.
2.2	User's interface	Digital display
2.3	Software and/or standard of communication	In-built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	Light weight
3.3	Noise (in dBA)	N.A.
3.4	Mobility, portability	Portable
4. ENERGY SOURCE		
4.1	Power Requirements	220V +/-10 VAC, 50 Hz for charging
4.2	Battery operated	Yes
4.3	Power consumption	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories & spares	Charger
5.2	Consumables / reagents	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance	NA

	(air conditioning, humidity, dust ...)	
6.2	User's care, Cleaning, Disinfection & Sterility issues	NA
7. STANDARDS AND SAFETY		
7.1	Certificates, 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	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 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(hardcopy) of: - • User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. • List of equipment and procedures required for routine calibration androutine maintenance. • Certificate of calibration to be provided by the manufacturer. • List to be provided of important spares and accessories, with their partnumbers and cost.
11. NOTES		
11.1	Other information	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared

SUCTION PUMP, FOOT OPERATED		
Version No.:		2.0
Date:		November 2024
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Emergency suction systems
GMDN code(s)		47367
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	Newborn stabilization unit, SNCU.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	• It should be a portable and non-string foot pedal operation based suction pump. • There should be no sharp edges on the unit, the surface to be hard and corrosion resistant (mild steel power coated / Stainless steel). • Pump pedal to be spring loaded to return to “up” position after each stroke and the unit should be mounted on robust board with carrying handle. • It should give a vacuum of more than 550 mm Hg, with 200 ml/stroke. • It should have oil free diaphragm pump. • Pressure gauge should display the level of suction generated. • The unit should contain pair of jars of at least 300ml capacity each for collection fitted on the body. • Tubing to patients should be minimum 3 meter long, non-collapsible type.
2.2	User's interface	Manual
2.3	Software and/or standard of communication	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	Jars of at least 300ml capacity
3.2	Weight (lbs, kg)	2.5kg max
3.3	Configuration	N.A.
3.4	Noise (in dBA)	Less than 65 dBA
3.5	Mobility, portability	Yes
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 & spares	Microbial filter, Spare seals for each storage jar
5.2	Consumables / reagents	Silicon tubing (one set extra), Collection bottles, clear unbreakable jar (one set extra)
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	NA
6.2	User's care, Cleaning, Disinfection & Sterility issues	Storage containers should be easy to remove, empty, sterilize and reconnect.
7. STANDARDS AND SAFETY		
7.1	Certificates, 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	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(hardcopy) of: - • User, technical and maintenance manuals should be supplied in English/Hindi language along with machine diagrams. • List of equipment and procedures required for routine calibration androutine maintenance. • Certificate of calibration to be provided by the manufacturer. • List to be provided of important spares and accessories, with their partnumbers and cost.
11. NOTES		
11.1	Other information	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared

SUCTION PUMP, PORTABLE ELECTRIC		
Version No.:		2.0
Date:		November 2024
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		**Suction systems**
GMDN code(s)		
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	Newborn stabilization unit, SNCU.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	• It should be made up of high-quality material and corrosion resistant. • Apparatus should consist of the following: ▪ AC- powered suction pump ▪ Tubing ▪ Glass collection containers- 2 nos. ▪ Vacuum gauge ▪ Vacuum control knob ▪ Overflow trap ▪ Moisture filter- microbial filter • Low vacuum, low flow, oil free vacuum pump of Max. Vacuum: 0 to 760 mmHg +/- 10 regulable. • 1/2 HP;single phase 1440 RPM motor. • It should be provided with flutter free vacuum control knob. • Collection bottle of wide mount 2 x 2 litre (light weight, unbreakable and clear) with mechanical over-flow safety device. • Filter and overflow valve incorporated to prevent cross-contamination. • The pump should be incorporated with a bacterial filter. • It should also have a foot on/off switch for hands-free operation. • Tubing to patient should be minimum 3 metre long, non-collapsible type.
2.2	User's interface	Manual
2.3	Software and/or standard of communication	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	2 L Jar
3.2	Weight (lbs, kg)	Max: 30Kg
3.3	Configuration	N.A.

3.4	Noise (in dBA)	Less than 65 dB
3.5	Mobility, portability	Yes, Mobile
4. ENERGY SOURCE		
4.1	Power Requirements	220 V, +/-10 VAC, 50 Hz
4.2	Battery operated	NA
4.3	Power consumption	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories & spares	Collection container & its cap, suctions tube tips, a vacuum gauge, two setsof moisture & microbial filters and control knob.
5.2	Consumables / reagents	Silicone Tubing, 2x2 lt jar (one set extra)
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of 0 to 50 degC and relative humidity upto 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Easy to clean.
7. STANDARDS AND SAFETY		
7.1	Certificates, 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 conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1 General requirements of electrical safety standards. 5. Should comply with USFDA/European CE standards in case of non-availability of BIS standards.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	Availability of electrical socket.
8.2	Requirements for sign-off	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, service manuals, other manuals	Should provide 2 sets(hardcopy) of:- • User, technical, maintenance and service manuals to be supplied alongwith machine diagrams. • List of equipment and procedures required for routine calibration androutine maintenance. • Certificate of calibration to be provided by the manufacturer. • List to be provided of important spares and accessories, with their partnumbers and cost.
11. NOTES		
11.1	Other information	Contact details of manufacturer, supplier and local service

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

OXYGEN CONCENTRATOR		
Version No.:		2.0
Date:		November 2024
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		**Mobile/Portable Oxygen Concentrator**
GMDN code(s)		31321
GENERAL		
s1. USE		
1.1	Clinical purpose	To concentrate oxygen (O2) from ambient air and deliver the concentrated O2, typically through an attached nasal cannula, to a patient requiring oxygen therapy.
1.2	Used by clinical department/ ward	SNCU/NICU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Oxygen concentrator to provide oxygen from ambient air. 2. Oxygen output: 0-10 LPM, purity > 93%. 3. Should have an oxygen purity indicator and alarm for low oxygen concentration. 4. O2 delivery pressure: 0.03 to 0.07 Mpa (4.35 - 10.15 PSI). 5. It should have a digital display panel and low-pressure alarm, high pressure alarm and power failure alarm.
2.2	User's interface	Front panel access to reset switch.
2.3	Software and/or standard of communication	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	To be specified by manufacturer
3.2	Weight (lbs, kg)	Max 30 kg.
3.4	Noise (in dBA)	<65 db
3.5	Heat Dissipation	Maintain nominal temperature.
3.6	Mobility, portability	Yes
4. ENERGY SOURCE		
4.1	Power Requirements	220 +/- 10% VAC, 50 Hz
4.2	Battery operated	NA
4.3	Power consumption	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories & spares	Spare set of tubing, spare set of internal & external filter (bacterial), spare fuses, Humidifier Bottles-4nos, power cord-1no.
5.2	Consumables / reagents	Nasal Cannula with extension tubing-2 nos (Neonates & pediatric)
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of 0 to 50 degC and relative humidity of upto 90%.
6.2	User's care, Cleaning,	To be specified by manufacturer.

	Disinfection & Sterility issues	
7. STANDARDS AND SAFETY		
7.1	Certificates, 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 conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1 General requirements of electrical safety standards. 5. Should comply with USFDA/European CE standards in case of non-availability of BIS standards.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	Availability of electrical sockets.
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(hardcopy) of: - • User, technical, maintenance and service manuals are to be supplied alongwith machine diagrams. • List of equipment and procedures required for routine calibration androutine maintenance. • Certificate of calibration to be provided by the manufacturer. • List to be provided of important spares and accessories, with their partnumbers and cost.
11. NOTES		
11.1	Other information	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared.

INFUSION PUMP (VOLUMETRIC)		
Version No.:		2.0
Date:		November 2024
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		**Bedside Infusion Pump**
GMDN code(s)		13215
GENERAL		
1. USE		
1.1	Clinical purpose	An infusion pump infuses fluids, medication or nutrients into a patient's circulatory system. It is generally used intravenously, although subcutaneous, arterial and epidural infusions are occasionally used.
1.2	Used by clinical department/ ward	NICU and PICU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	• Flow rate programmable ranges at least from 0.1 to 200 ml/hr, in steps of 0.1 ml/hr; and at least from 100 to 1200 ml/hr in steps of 1 ml/hr. • Saves last infusion rate even when the AC power is switched off. • Bolus rate should be programmable to approx. 500 ml/hr with infused volume display. • Selectable occlusion pressure trigger levels selectable from 300, 500 and 900 mmHg. • Accuracy of ±2% or better for set parameters. • Maximum pressure generated 20 psi. • Pause infusion facility required. • Display should be LED or LCD with Backlight • Display should show all flow parameter and Battery status • Self-check carried out on powering on. • Comprehensive alarm package required including occlusion alarm, near end of infusion pre-alarm and alarm, volume limit pre-alarm and alarm, low battery pre-alarm and alarm, AC power failure, disengaged drive. • It should be open system, accepts IV sets of all brands and calibrated for major Indian brands and also for the Imported range.
2.2	User's interface	Manual for loading IV set
2.3	Software and/or standard of communication	In-built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	Weight not more than 2.5kg
3.3	Noise (in dBA)	Noise free
3.4	Mobility, portability	Yes, Portable

4. ENERGY SOURCE		
4.1	Power Requirements	220VAC, +/-10%, 50 Hz
4.2	Battery operated	Rechargeable battery (Preferably Lithium ion) Minimum 4 hours operating time - Minimum 24 hours standby
4.3	Power consumption	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories & spares	Clamp for mounting pump on IV stand
5.2	Consumables / reagents	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of 0 to 50deg C and relative humidity of up to 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Capable of cleaning with alcohol or chlorine wipes.
7. STANDARDS AND SAFETY		
7.1	Certificates, 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 conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1 General requirements of electrical safety standards. 5. Should comply with USFDA/European CE standards in case of non-availability of BIS standards.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks beforehandover.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	02 Year
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets(hardcopy) of: - • User, technical, maintenance and service manuals to be supplied alongwith machine diagrams. • List of equipment and procedures required for routine calibration androutine maintenance. • Certificate of calibration to be provided by the manufacturer. • List to be provided of important spares and accessories, with their partnumbers and cost.
11. NOTES		
11.1	Other information	Contact details of manufacturer, supplier and local service agent to be provided.

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

SYRINGE PUMP		
Version No.:		2.0
Date:		November 2024
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Syringe pump
GMDN code(s)		13217
GENERAL		
1. USE		
1.1	Clinical purpose	Designed to precisely drive the plunger of a syringe down its barrel to infusea solution when it must be administered with a high degree of volume accuracy and rate consistency.
1.2	Used by clinical department/ ward	NICU/PICU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	• Flow rate programmable ranges at least from 0.1 to 200 ml/h in steps of 0.1 ml/h; and at least from 100 to 1200 ml/h in steps of 1 ml/h. • Saves last infusion rate even when the AC power is switched off. • Bolus rate should be programmable to approx. 500 ml/hr with infusedvolume display. • Selectable occlusion pressure trigger levels selectable from 300, 500 and900 mmHg. • It must work on commonly available 5ml, 10 ml, 20 ml, 30ml and 50 ml syringes. • Accuracy of ±2% or better. • Maximum pressure generated ≤ 20 psi. • Automatic detection of syringe size and proper fixing. • Anti-bolus system to reduce pressure on sudden release of occlusion. • Pause infusion facility required. • Self-check carried out on powering on. • Comprehensive alarm package required including occlusion alarm, nearend of infusion pre-alarm and alarm, volume limit pre-alarm and alarm, low battery pre-alarm and alarm, AC power failure, drive disengaged, syringe loading error, maintenance required. • Should include KVO (Keep vein open) enabling feature. • It should be an open system compliant.
2.3	User's interface	Manual loading of syringe
2.4	Software and/or standard of communication	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	Not more than 2.5 kg

3.3	Noise (in dBA)	Noise free
3.4	Mobility, portability	Yes, Portable
4. ENERGY SOURCE		
4.1	Power Requirements	220V +/-10 VAC, 50 Hz
4.2	Battery operated	Yes, with a minimum of 04 hr backup.
4.3	Power consumption	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories & spares	Clamp for mounting pump on IV stand.
5.2	Consumables / reagents	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of 0 to 50deg C and relative humidity of upto 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Capable of cleaning with alcohol or chlorine wipes
7. STANDARDS AND SAFETY		
7.1	Certificates, 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 conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1 General requirements of electrical safety standards. 5. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks beforehandover.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	02 Year
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets(hardcopy) of: - • User, technical, maintenance and service manuals are to be supplied alongwith machine diagrams. • List of equipment and procedures required for routine calibration androutine maintenance. • Certificate of calibration to be provided by the manufacturer. • List to be provided of important spares and accessories, with their partnumbers and cost.
11. NOTES		
11.1	Other information	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared

MULTIPARA MONITOR		
Version No.:		2.0
Date:		November 2024
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		General-purpose multi-parameter bedside monitor
GMDN code(s)		33586
GENERAL		
1. USE		
1.1	Clinical purpose	Designed to continuously measure and display multiple vital physiologicalparameters of newborn and premature infants, especially those under critical care.
1.2	Used by clinical department/ ward	NICU and PICU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	• Temperature probe to be reusable, external skin contact type. Temperature ranges from 30 to 40 deg C, minimum gradation 0.1 deg C. • Heart rate measurement range to be at least 30 to 250 bpm, with accuracy better than ± 5 bpm and minimum gradation 1 bpm. • SpO2 measurement range at least 40-70 % and 70 to 99 %, with accuracy better than ± 1% for 40-70 range and better than ± 3% for 70-99 range and minimum gradation 1%. • NIBP: Oscillo metric method manual, automatic and stat modes should be available range at least 30 to 300 mmHg, minimum gradation 1 mmHg. • Blood pressure monitoring range: 30 to 300 mmHg, minimum gradation 1 mmHg. • Respiration rate measurement range at least 0 to 150 bpm, minimum gradation 1 bpm, • $ETCO_2$ upgradation optional • Should be supplied with. ▪ Pulse oximeter probe ▪ ECG cable -12 lead ▪ Temperature probe ▪ NIBP (non-invasive blood pressure) probe ▪ All probes should be supplied in 2 pairs, should be re-usable and should include pediatric & neonatal size cuff/leads. The material of the probe shouldbe such that it is non-breakable. • Trend display of each parameter over at least the previous 72 hours to be selectable. • Display (Multi color display. Minimum 12 inch. Minimum 640x480 resolution. iv. Touch screen. v. Wide viewing angle)

		• Audio Visual alarms required: high and low levels for each parameter (operator variable settings), sensor / wire / probe disconnected, low battery.
2.3	User's interface	Digital display
2.4	Software and/or standard of communication	In-built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	Screen size minimum: 12".
3.2	Weight (lbs, kg)	<5kg.
3.3	Noise (in dBA)	<50 dB; Lead disconnection Alarm > 65 dB
3.4	Mobility, portability	No
4. ENERGY SOURCE		
4.1	Power Requirements	220V +/-1- VAC, 50 Hz.
4.2	Battery operated	Yes, with minimum two hours backup in the event of power failure.
4.3	Power consumption	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories & spares	2 pairs, 12 lead ECG cable
5.2	Consumables / reagents	2 packs of 100 disposable ECG connection electrodes.Two sets of reusable SpO2 probes each for pediatric & neonatal use.Two sets of NIBP cuffs of each size. Two external skin temperature probes.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of 0 to 50deg C and relative humidity of up to 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Capable of cleaning with alcohol or chlorine wipes
7. STANDARDS AND SAFETY		
7.1	Certificates, 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 conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1 General requirements of electrical safety standards. 5. Should comply with USFDA/European CE standards in case of non-availability of BIS standards.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	Electrical 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	02 Years
10. DOCUMENTATION		
10.1	Operating manuals, service	Should provide 2 sets(hardcopy) of: -

	manuals, other manuals	• User, technical, maintenance and service manuals are to be supplied alongwith machine diagrams. • List of equipment and procedures required for routine calibration androutine maintenance. • Certificate of calibration to be provided by the manufacturer. • List to be provided of important spares and accessories, with their partnumbers and cost.
11. NOTES		
11.1	Other information	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared

DEFIBRILLATOR		
Version No.:		2.0
Date:		November 2024
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Defibrillators
GMDN code(s)		48052
GENERAL		
1. USE		
1.1	Clinical purpose	Defibrillation is a common treatment for life-threatening cardiac dysrhythmias, ventricular fibrillation and pulseless ventricular tachycardia. Defibrillation consists of delivering a therapeutic dose of electrical energy tothe heart with a device.
1.2	Used by clinical department/ ward	NICU and PICU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	• The Defibrillator should have biphasic technology and have energy selection of 5-200 Joules in steps. • The machine should have facility for ECG monitoring, defibrillation, transcutaneous pacing, defibrillation and synchronized cardioversion with CPR feedback to measure chest compression rate and depth in realtime and visual on-screen feedback. • The machine must be with a sweep rate of 25mm/sec, 50 mm/sec. • It should be capable of monitoring ECG though ECG cables, electrodes &paddles. • The machine should have 24-hour trend storage facility. • The machine should have a defibrillator facility for neonatal and pediatricpatients. • The machine should have ECG waveform display with provision for synchronization. • The machine should be compact, portable with built-in rechargeable battery & light weight. • The machine should have inbuilt auto & manual recorder for printing ECG trace & stored information. • The machine should have a user selectable alarms setting. • The machine should work on mains (without battery) and on battery as well. • The machine should have an AED feature as inbuilt with manual override for manual operations.
2.3	User's interface	Manual/Automatic
2.4	Software and/or standard of communication	1) Inbuilt software. 2) Convenient and quick USB interface.
3. PHYSICAL CHARACTERISTICS		

3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	Max 10kg
3.3	Noise (in dBA)	<60db
3.4	Mobility, portability	Portable
4. ENERGY SOURCE		
4.1	Power Requirements	220 VAC +/-10%, 50Hz;
4.2	Battery operated	Yes, with a minimum of two-hour backup in the event of power failure.
4.3	Power consumption	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories & spares	Must be supplied with ECG cable, Battery, Paddle (Adult integrated with pediatric).
5.2	Consumables / reagents	• 03 No. Reusable CPR feedback sensor. • 300 gel sheet or pads for monitoring and defibrillation
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of 0 to 50deg C and relative humidity of up to 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Capable of cleaning with alcohol or chlorine wipes
7. STANDARDS AND SAFETY		
7.1	Certificates, 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 conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1 General requirements of electrical safety standards. 5. Should comply with USFDA/European CE standards in case of non-availability of BIS standards.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	Availability of electrical sockets.
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	02 Year
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets(hardcopy) of: - • User, technical, maintenance and service manuals are to be supplied alongwith machine diagrams. • List of equipment and procedures required for routine calibration androutine maintenance. • Certificate of calibration to be provided by the manufacturer,

		• List to be provided of important spares and accessories, with their partnumbers and cost.
11. NOTES		
11.1	Other information	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared

TRANSILLUMINATOR COLD LIGHT SOURCE		
Version No.:		2.0
Date:		November 2024
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Light Sources
GMDN code(s)		-
GENERAL		
1. USE		
1.1	Clinical purpose	Clod light source is used for accessing tiny arteries and veins of the babies.
1.2	Used by clinical department/ ward	NICU and PICU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	• Suitable for visualizing limb vessels (arteries & veins) in term & preterm neonates. • It should consist of a light source and a flexible fiberoptic cable. • Light intensity should be variable and controlled by a microprocessor • Flexible fiber-optic cable with non-metallic sheath • Fiberoptic cables should be longer than 80 cm • The tip of Fiber Optic cable should be 0.5 cm or less. • Should not heat patient skin or tissues or cause burns when used for 5 minutes for transillumination.
2.3	User's interface	Manual
2.4	Software and/or standard of communication	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	Less than 600g
3.3	Configuration	NA
3.4	Noise (in dBA)	<60db
3.5	Mobility, portability	Yes
4. ENERGY SOURCE		
4.1	Power Requirements	220VAC ± 10%, 50Hz
4.2	Battery operated	Yes, rechargeable battery with minimum backup of 01 hr
4.3	Power consumption	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories & spares	Illumination spare lamp 2nos.
5.2	Consumables / reagents	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance	Capable of operating continuously in ambient temperature of -

	(air conditioning, humidity, dust ...)	0 to 50 deg C and relative humidity of up to 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Capable of cleaning with alcohol or chlorine wipes
7. STANDARDS AND SAFETY		
7.1	Certificates, Performance and safety standards (specific to the device type); Local and/or international	1. Should be CDSCO approved. 2. Should comply with BIS standards. 3. Should comply with USFDA/European CE standards incase of non-availability of BIS standards. 4. Should conform to ISO 13485 quality standards. 5. Should conform to IEC 60601-1 General requirements of electrical safety standards.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks beforehandover.
8.3	Training of staff (medical, paramedical, technicians)	Training of users on operation and basic maintenance.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	01 Year
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets(hardcopy) of:- • User, technical, maintenance and service manuals to be supplied alongwith machine diagrams. • List of equipment and procedures required for routine calibration androutine maintenance. • Certificate of calibration to be provided by the manufacturer. • List to be provided of important spares and accessories, with their partnumbers and cost.
11. NOTES		
11.1	Other information	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared

MOBILE X-RAY (100 mA)		
Version No.:		2.0
Date:		November 2024
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Mobile, Basic diagnostic x-ray system
GMDN code(s)		-
GENERAL		
1. USE		
1.1	Clinical purpose	General-purpose mobile diagnostic x-ray system used in a variety of routinex-ray imaging applications.
1.2	Used by clinical department/ ward	Radiology services in NICU & PICU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	Compact, easily transportable mobile radiographic unit suitable for bed side X-Ray in Emergency, ward, ICU, Operation Theatre & also in the radiology department for conventional radiography. **X-ray Generator:** • High frequency X-Ray generator having a frequency of 20 KHz or more suitable for radiography should be provided. • Power output of generator should be 20 KW Radiography KV range should be 40-120 KV or more. mA range (rad.): 100 mA or more. **Control:** • A very compact, soft touch Control panel having following functions & indications should be provided. • Machine ON/OFF switch, Digital display of KV & mAs, KV & mAs increase and decrease switches. Tube focal spot selection switch, Ready and x-ray on switch with indicators. • Bucky selection switch. • Self-diagnostic program with indicators for earth fault error, KV error, filament error & Tube's thermal overload. **X-Ray Tube:** • The X-ray tube should be rotating anode with focal spots of 0.8mm (Small Focus) and 1.8mm (Large focus) or less. • Anode heat storage capacity of the tube should be more than 140 KHU. One number manual collimator with aluminum filter & for adjustment of exposure area. • It should have a parking position of tube arm in an extremely lower position.
2.3	User's interface	The exposure release switch should be detachable, with a cord of

		at least 5meters long.
2.4	Software and/or standard of communication	In-built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	Maximum 500 Kg.
3.3	Configuration	• The unit must have an effective braking system for parking, transportand emergency braking. • The tube stand must be fully counterbalanced for rotation in all directions. • It must have an articulated arm for imaging with any patient position. • All cables should be concealed in the arm system.
3.4	Noise (in dBA)	<60db
3.5	Mobility, portability	Mobile
4. ENERGY SOURCE		
4.1	Power Requirements	220VAC ± 10%, 50 Hz.
4.2	Battery operated	• The battery should provide power for the motor to move the machine • If the battery is fully drained out the machine should be ready to work on direct mains.
4.3	Power consumption	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories & spares	To be supplied with 2 nos. adult size protective lead apron and 01 no. child/neonate size protective lead shield. Control cable, exposure switch.
5.2	Consumables / reagents	Radiation hazard warning signs to be supplied with unit.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of - 0 to 50 deg C and relative humidity of up to 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Capable of cleaning with alcohol or chlorine wipes
7. STANDARDS AND SAFETY		
7.1	Certificates, 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 conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1 General requirements of electrical safety standards. 5. Should comply with USFDA/European CE standards incase of non-availability of BIS standards.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	1) Dosimeters should be available with the operator. 2) Lead gown to be supplied for the operator.

8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks beforehandover.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	02 Years
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets(hardcopy) of: - • User, technical, maintenance and service manuals are to be supplied alongwith machine diagrams. • List of equipment and procedures required for routine calibration androutine maintenance. • Certificate of calibration to be provided by the manufacturer. • List to be provided of important spares and accessories, with their partnumbers and cost.
11. NOTES		
11.1	Other information	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared

ECG UNIT-12 CHANNEL		
Version No.:		2.0
Date:		November 2024
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Multichannel Electrocardiographic
GMDN code(s)		62641
GENERAL		
1. USE		
1.1	Clinical purpose	An ECG is a noninvasive routine examination of the electrical activity of the heart that is used to reflect underlying heart conditions.
1.2	Used by clinical department/ ward	All Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	• It should be a 12 Channel ECG machine. Continuous display of patient ECG and heart rate on screen • It should have a digital display of channel 6 ECG and should have three modes (Automatic, Manual and Rhythm). • Heart rate measurement range to be at least 30 bpm to 250 bpm, with accuracy better than ± 5bpm. • The heart rate trend of minimum previous 24 hours. • Arrhythmia detection facility required; minimum gradation of 1 bpm.
2.2	User's interface	Manual
2.3	Software and/or standard of communication	In built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	less than 5 kgs
3.3	Noise (in dBA)	<60 dB
3.4	Mobility, portability	Yes
4. ENERGY SOURCE		
4.1	Power Requirements	220V +/-10 VAC, 50 Hz
4.2	Battery operated	Yes, with minimum 04 hour backup in the event of power failure.
4.3	Power consumption	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories & spares	• 12 lead ECG cable. • 2 sets of spare fuses (if non-resettable fuses are used) • 5 tube electrode gel (if required)
5.2	Consumables / reagents	5 tubes electrode gel (if required)
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		

6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of up to 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Capable of cleaning with alcohol or chlorine wipes
7. STANDARDS AND SAFETY		
7.1	Certificates, 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 conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1 General requirements of electrical safety standards. 5. Should comply with USFDA/European CE standards in case of non-availability of BIS standards.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	Availability of electrical 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 on operation and basic maintenance.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	02 Years
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets(hardcopy) of: - • User, technical, maintenance and service manuals to be supplied alongwith machine diagrams. • List of equipment and procedures required for routine calibration androutine maintenance. • Certificate of calibration to be provided by the manufacturer. • List to be provided of important spares and accessories, with their partnumbers and cost.
11. NOTES		
11.1	Other information	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared

EXAMINATION TREATMENT LIGHT		
Version No.:		2.0
Date:		November 2024
Done by: (name / institution)		HCT/ NHSRC
NAME 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 treatment.
1.2	Used by clinical department/ ward	All Department
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	• Should use a LED light source. • It should have a variable light intensity up to 50000 Lux. • Knob or buttons for adjusting the light intensity between 20,000 to 50,000 Lux. • The lifespan of LED lamp should not be less than 30,000 hours. • It should have a wide field size of illumination. • The arm should be adjustable horizontally, vertically and easy to focus on all directions. • It should have an on/off switch. • 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	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	Height should be adjustable.
3.2	Weight (lbs, kg)	Less than 30 kgs
3.3	Noise (in dBA)	NA
3.4	Mobility, portability	Mobile on castors.
4. ENERGY SOURCE		
4.1	Power Requirements	220VAC ± 10%, 50 Hz
4.2	Battery operated	Yes, Minimum backup time of 04 hrs.
4.3	Power consumption	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories & spares	NA
5.2	Consumables / reagents	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity,	NA

	dust ...)	
6.2	User's care, Cleaning, Disinfection & Sterility issues	Cleaning with alcohol or chlorine wipes.
7. STANDARDS AND SAFETY		
7.1	Certificates, 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 conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1 General requirements of electrical safety standards. 5. Should comply with USFDA/European CE standards in case of non-availability of BIS standards.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	NA
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	01 Year
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets(hardcopy) of: - • User, technical, maintenance and service manuals to be supplied alongwith machine diagrams. • List to be provided of important spares and accessories, with their partnumbers and cost.
11. NOTES		
11.1	Other information	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared

BLOOD GAS ANALYZER		
Version No.:		2.0
Date:		November 2024
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Blood gas analyser IVD, laboratory
GMDN code(s)		56661
GENERAL		
1. USE		
1.1	Clinical purpose	An electrically powered laboratory instrument intended to be used for the quantitative in vitro measurement of blood pH, partial pressure of oxygen (pO2) and partial pressure of carbon dioxide (pCO2), and the calculation of other blood gas parameters [e.g., bicarbonate (HCO3-), base excess, arterial-alveolar gradient] in a clinical specimen.
1.2	Used by clinical department/ ward	Clinical Diagnostic Laboratory
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	• Essential Measured parameters; pH, pCO2, pO2, tHb, Barometric Pressure, Na+, K+, Ca++, Cl-. All these parameters should be measured simultaneously. • Should have minimum 15 calculated parameters including SaO2, Bi carbonate (HCO3), Standard HCO3, Base Excess of Blood (BE), Base Excess of extra cellular fluid. • Sample volume-less than 100ul. • Should have minimum process time (less than 5 min). • Warm up time should be less than 30 minutes. • Maintenance free electrodes • Fully automatic liquid calibration of all parameters at user-defined intervals. • It should be with numeric keypad, graphic / LCD display, and inbuilt printer. Should have interface for PC compatibility. • QC should be based on test parameters. • Automatic result processing, test ordering and provision for a bi-directional LIS interface should be available. • Automatic data archiving and customizable layout. • Should have provision for data backup.
2.2	User's interface	LCD/Graphical Display
2.3	Software and/or standard of communication	In-built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	< 60 dB
3.4	Mobility, portability	Tabletop
4. ENERGY SOURCE		
4.1	Power Requirements	220VAC ± 10%, 50 Hz

4.2	Battery operated	Yes, with minimum 30 min backup
4.3	Power consumption	To be specified by manufacturer
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories & spares	NA
5.2	Consumables / reagents	• Reagents for a minimum of 200 tests should be provided along with the machine. • Electrodes for all the parameters specified -01 set. • Quality control tools/reagents for minimum 200 tests or as per requirement.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of -0 to 50 deg C and relative humidity of up to 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Cleaning with alcohol or chlorine wipes
7. STANDARDS AND SAFETY		
7.1	Certificates, 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 conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1 General requirements of electrical safety standards. 5. Should comply with USFDA/European CE standards incase of non-availability of BIS 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	02 years
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets(hardcopy) of: - • User, technical, maintenance and service manuals are to be supplied alongwith machine diagrams. • List of equipment and procedures required for routine calibration androutine maintenance. • Certificate of calibration to be provided by the manufacturer. • List to be provided of important spares and accessories, with their partnumbers and cost.
11. NOTES		
11.1	Other information	Contact details of manufacturer, supplier and local service agent

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

THERMOMETER (DIGITAL)		
Version No.:		2.0
Date:		November 2024
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 the 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. • It takes 60-90 seconds to measure temperature. • Can be used in the armpit/axilla, orally and rectally. • Should have auto shut down features for remaining idle for more than 1 minute.
2.2	User's interface	Digital display
2.3	Software and/or standard of communication	NA
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	Handheld device
3.2	Weight (lbs, kg)	Handheld device
3.3	Noise (in dBA)	NA
3.4	Mobility, portability	Portable
4. ENERGY SOURCE		
4.1	Power Requirements	NA
4.2	Battery operated	Yes
4.3	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories & spares	• Batteries

5.2	Consumables / reagents	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of up to 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Capable of cleaning with alcohol or chlorine wipes
7. STANDARDS AND SAFETY		
7.1	Certificates, 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	01 years
9.2	Maintenance tasks	NA
9.3	Service contract clauses, including prices	NA
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	User manual to be supplied along with device diagrams.
11. NOTES		
11.1	Other information	Contact details of manufacturer and supplier to be provided.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared

GLUCOMETER		
Version No.:		2.0
Date:		November 2024
Done by : (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		Glucose Monitoring System
GMDN code(s)		62537
GENERAL		
1. USE		
1.1	Clinical purpose	Glucometer is a small device used to measure and display the amount of sugar (glucose) in blood.
1.2	Used by clinical department/ ward	All
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	1. Should have LCD display screen and auto shut off feature when not in use. 2. Display of the sugar reading should be in mg/dl. 3. Should have a reading range/linearity from 20 to 700 mg/dl. 4. Should have a maximum reading time of less than 10 seconds. 5. Should be supplied with autoinjector pen and disposable lancets.. 6 Should have the feature of automatic code detection of glucose strips. 7. Should have a minimum memory of 100 tests
2.2	User's interface	LCD display
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	Configuration	NA
3.4	Noise (in dBA)	NA
3.5	Mobility, portability	Portable
4. ENERGY SOURCE		
4.1	Power Requirements	Battery Powered
4.2	Battery operated	Yes, 3-volt lithium coin cell battery or 2 x (AAA) Alkaline Batteries
4.3	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories & spares	NA
5.2	Consumables / reagents	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 0 to 50 deg C and relative humidity of up to 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Capable of cleaning with alcohol or chlorine wipes
7. STANDARDS AND SAFETY		
7.1	Certificates, 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 conform to ISO 13485 quality standards. 4. Should comply with USFDA/European CE standards in case of non-availability of BIS 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 years
9.2	Maintenance tasks	NA
9.3	Service contract clauses, including prices	NA
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets(hardcopy) of:- User, technical, maintenance and service manuals to be supplied alongwith machine diagrams.
11. NOTES		
11.1	Other information	Contact details of manufacturer and supplier to be provided.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared

BP APPARATUS (DIGITAL)		
Version No.:		2.0
Date:		November 2024
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
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	• Should be able to measure blood pressure and pulse rate in adult patients. • It should be based on Oscillo metric measurement technology, using dynamic linear deflation method. • Should have a backlit digital display with easy to view readings in dim light. • Pressure measurement range should be 60 to 250 mm Hg systolic, and 40 to 200 mm Hg diastolic. • Pressure display accuracy of +/- 2 to 3 mm Hg • Pulse rate measurement range of 40 to 220 per minute, pulse measurement accuracy of within +/- 5% • Single button operation for start and stop functions with auto inflation of blood pressure cuff. • The device should have a rechargeable battery.
2.2	User's interface	Digital display
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	Mobility, portability	Yes
4. ENERGY SOURCE		
4.1	Power Requirements	NA
4.2	Battery operated	Yes
4.3	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories & spares	Arm cuffs (size small, medium, large & extra-large) and inflation

		bulb, tubing Battery Charger
5.2	Consumables / reagents	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of up to 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Capable of cleaning with alcohol or chlorine wipes
7. STANDARDS AND SAFETY		
7.1	Certificates, 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 conform to ISO 13485 quality standards. 4. Should comply with USFDA/European CE standards in case of non-availability of BIS 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 years
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	User manual to be supplied alongwith machine diagrams.
11. NOTES		
11.1	Other information	Contact details of manufacturer and supplier to be provided.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared

DIRECT OPHTHALMOSCOPE		
Version No.:		2.0
Date:		November 2024
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		**Direct Ophthalmoscope**
GMDN code(s)		46786
GENERAL		
1. USE		
1.1	Clinical purpose	Direct ophthalmoscope is a hand-held and battery powered device containing illumination and viewing optics to examine the cornea, aqueous,lens, vitreous, and the retina of the eye.
1.2	Used by clinical department/ ward	NICU & PICU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	• Available with LED/Halogen light source. • Magnification up to x15 from direct vision to maximum magnification. • Red-free, blue and polarization filters and Anti-reflection lens. • It should have small and large spot sizes, fixation targets, slit aperture, hemi-spot and cobalt blue filter. • It should be rechargeable battery with Charger. • At least 3 apertures and fixation star. • Range of lenses not smaller than -30D to +20D with steps not greater than 1D. • Dust free sealed optics and aspherical optical system.
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	Mobility, portability	Yes, handheld device
4. ENERGY SOURCE		
4.1	Power Requirements	NA
4.2	Battery operated	Yes
4.3	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories & spares	Replacement bulb/illumination source -2 Nos. Storage case.
5.2	Consumables / reagents	NA
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance	Capable of operating continuously in ambient temperature of 0

	(air conditioning, humidity, dust ...)	to 50 deg C and relative humidity of up to 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Capable of cleaning with alcohol or chlorine wipes
7. STANDARDS AND SAFETY		
7.1	Certificates, 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 conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1 General requirements of electrical safety standards. 5. Should comply with USFDA/European CE standards in case of non-availability of BIS 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 years
9.2	Maintenance tasks	NA
9.3	Service contract clauses, including prices	NA
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets(hardcopy) of: - User, technical, maintenance and service manuals are to be supplied alongwith machine diagrams.
11. NOTES		
11.1	Other information	Contact details of manufacturer and supplier to be provided.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared

High Flow Nasal Cannula Device		
Version No.:		2.0
Date:		November 2024
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		**Professional High Flow Respiratory Unit**
GMDN code(s)		57828
GENERAL		
1. USE		
1.1	Clinical purpose	High flow nasal cannula (HFNC) is an oxygen supply system capable of delivering up to 100% humidified and heated oxygen at a high flow rate required in ICU settings.
1.2	Used by clinical department/ ward	NICU & PICU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	HFNC unit consists of a mobile trolley with tubing and oxygen hose holding set (Basket/Drawer), servo controlled auto heated humidifier with accessories and power cable. The unit should have the features for treating paediatric and adult patients in a single unit. • Should have the ability to generate flow from room air and mix with oxygen. Adaptable to all types of oxygen sources. • The mixed gas of air and oxygen should be humidified and warmed between 31^0C – 40^0C. • FiO2: 21 to 100 %. • Flow: 2 to 60 L/min with controls to adjust the flow rate. • Controls to be easy to operate, numbers and displays to be clearly visible. • Digital display of Temperature [°C], Flow [L/min], Oxygen concentration [%]. • Humidity compensation system. • Noise level to be less than 35 dB A at mid pressure range. • Trigger sensitivity range: 1-10 cmH2O, increments of 1 cmH2O or automatic. • All parts withstand high disinfection procedures • Visual and audible alarm for: High/Low FiO2; Incorrect • Temperature/Humidity; System leakage or blockage, lack of water, system failure, air filter to be replaced, power failure and low battery. • Display should be easily readable in low ambient light and sunlight. • Displayed parameters: Gas temperature (°C), FiO2 Tidal volume; Inspiratory pressure; Inspiratory and Expiratory time; I:E ratio; Mean Airway Pressure (MAP); Air leak [%].

		• The machine should be installed on Mounting Tray and Pole with Castor C& IV Hook. • HNFC tubing and hose should be kink proof pliable material with option of adhesive pads to stick on skin for pediatric patients. The should have smooth bore tubing to minimize risk of kinking and should be noiseless in operation. • Should have a tracheostomy interface for use in tracheostomy patients.
2.2	User's interface	User interface to be easy to operate, numbers and displays to be clearly visible.
2.3	Software and/or standard of communication	In-built
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	NA
3.4	Mobility, portability	Should be light weight and easily movable with minimal physical effort.
4. ENERGY SOURCE		
4.1	Power Requirements	220 V +/-10% VAC, 50 Hz
4.2	Battery operated	Yes, with minimum backup of 02 hr.
4.3	Power consumption	To be specified by the Manufacturer.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories & spares	1. Flowmeter, graduated in L/min 2. Humidifier 3. Water chamber 4 Connectors for air and oxygen outlets
5.2	Consumables / reagents	Housing and patient circuit withstands high level disinfection and sterilization.
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of up to 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	Certificates, 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 conform to ISO 13485 quality standards. 4. Should conform to IEC 60601-1 General requirements of electrical safety standards. 5. Should comply with USFDA/European CE standards in case of non-availability of BIS standards.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation	NA

	requirements: nature, values, quality, tolerance	
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	02 years
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	1. Should provide two sets of hard copy and a soft copy of user, technical and maintenance manual printed in English/Hindi along with the diagrams. 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. Certificate of calibration and inspection from the factory by the manufacturer
11. NOTES		
11.1	Other information	Contact details of manufacturer and supplier to be provided.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared

T-Piece Resuscitator		
Version No.:		1.0
Date:		November 2024
Done by: (name / institution)		HCT/ NHSRC
NAME AND CODING		
GMDN name		-
GMDN code(s)		-
GENERAL		
1. USE		
1.1	Clinical purpose	Infant Resuscitator inflates the baby's lungs and provide optimum oxygenation by delivering consistent PIP with each breath avoiding the risks associated with under or over inflation at uncontrolled pressures.
1.2	Used by clinical department/ ward	NICU & PICU
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	• Should be manually operated, gas powered resuscitator with consistent Peak Inspiratory Pressure (PIP) and Positive End Expiratory Pressure (PEEP) to infants. • Should accept and deliver oxygen concentrations from 21% to 100% • Able to set PIP (5-60 cm H_2O) and PEEP (1-8 cm H_2O) • Manometer able to display real time pressure delivery (0 to 80 cm of H2O) • Adjustable pressure relief valve: 5-60 cm of H2O • Pressure safety valve • Able to use face mask as well as endotracheal tube with the T-piece • Able to deliver free flow of oxygen
2.2	User's interface	To be easy to operate.
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	Mobility, portability	Should be light weight and easily movable with minimal physical effort.
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 & spares	NA
5.2	Consumables / reagents	Supplied with each unit

		• Reusable circuits: 30 • Face masks: 10 each of three different sizes (extreme preterm, preterm, and term)
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of up to 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	To be specified by manufacturer.
7. STANDARDS AND SAFETY		
7.1	Certificates, 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 conform to ISO 13485 quality standards. 4. Should comply with USFDA/European CE standards in case of non-availability of BIS 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, service manuals, other manuals	1. Should provide two sets of hard copy and a soft copy of user, technical and maintenance manual printed in English/Hindi along with the diagrams. 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. Certificate of calibration and inspection from the factory by the manufacturer
11. NOTES		
11.1	Other information	Contact details of manufacturer and supplier to be provided.
11.2	Recommendations or warnings	Any recommendations for best use and supplementary warning for safety should be declared

MISCELLENOUS EQUIPMENT/CONSUMABLES TECHNICAL SPECIFICATIONS

Air Oxygen Blender	• It should be a pneumatically controlled, compact air-oxygen mixing system.
	• Oxygen concentration range should be 21 – 100%.
	• The number of ports should be two (02).
	• Accuracy: ±3% full scale
	• Weight: should be less than 2 kilograms
	• Gas supply pressure: 30 – 75 PSIG
	• Primary outlet flow range: 1 – 15 L/ min
	• Auxiliary outlet flow range: 1 – 15 L/ min
	• It should be supplied with air & oxygen hose at least 5 meters in length with suitable adaptors
	• It should be supplied with Air and oxygen hose kit and connector for flowmeter and pole mounting bracket.
	• There should be a provision of blender Transition Kit that will help to fix HFNC Nasal Cannula without changing the existing circuit.
	• Supplies with each unit:
	  ○ Air hose with connector connecting to central air supply: 01
	  ○ Oxygen hose with connector connecting to oxygen supply from hospital main unit or oxygen cylinder – 01
	  ○ Two outlets with above-mentioned flow supply :01 each
	  ○ Hoses at the outlet for providing air-oxygen mixture which gets fit into humidifier: 01
	  ○ Mounted on stand (SS) with robust castors

Humidifier	• Capable of working with both CPAP and Heated Humidified High Flow Nasal Cannula (HHHFNC) • It should be capable of supplying fully saturated gas at 37^{o}C. • Flow resistance <20 cm H_2O/L/sec (Ins R<12, Exp R<8). • Temperature range: 31^{0}C – 40^{0}C, Temperature control: ± 2^{0}C • Digital display of temperature: 5^{0}C – 80°C • Capable of ambient humidity compensation • It should be compatible with both reusable & disposable chambers and circuits. • Must have water level indicator in the chamber (both types). • Minimum warm up time: <30 min
Hub Cutter	• The cutting blade of the cutter should be made of stainless steel.

	• The sharp container should be made of Polypropylene (PP) of not less than 4 mm thick and should be white/translucent. • The material should be autoclavable plastics, puncture resistant, high drop impact strength, material should be non-toxic and pyrogen free, the material will not wear out with normal usage. • Container should accept 500 cut needles along with the hub when it is 3/4th full (filling line). Needles should not penetrate container walls when filled up to the filling line. • Tamper-proofing: When contaminated needles are being dropped into the containers, it should remain sufficiently sealed so as to prevent a hand from entering. Needle should not protrude from the container when the box contains 500 needles with hub. • The container should be translucent white in color and will allow visual inspection from the outer surface to determine when the container is full. • Needle residue safety: All needles or residue collection containers should be puncture proof -have a separate handle or means to withdraw, carry and empty the container without risk of needle stick injury or contamination. -Any stub remaining on the syringe after the device has been used shall not have sharp edges or protrusions such as may cause inquiry to the user.
Oxygen Delivery Tubes	Tubing for external connection of an oxygen delivery source to a device used to administer oxygen such as a nasal oxygen cannula or catheter. • Tubing (bulk coil) should be suitable for delivering oxygen or oxygen/air mixtures. • Translucent, flexible and soft plastic tubing of uniform diameter. • Semi-rigid, star lumen, design, made of medical grade PVC, latex free. • Anti-kink tubing, non-permanent deformation if kinked or bent too tight. • Rubber or soft plastic tubing, semi-rigid, PVC or other material, BIS compliant and certified for medical use. • Length: 7.6 mtr (25 feet). Tubing terminated with standard or universal connectors. Individually packed. Non-sterile, single use.
CPAP Consumables/Circuits	**Single Use Patient Circuit** • Free From additives like DEHP & Latex Free • With 4 Feet suction Silicon Tube Hard suction tube • Sterile packing. • Tubing to connect Auto Fill chamber to blender should be disposable type and kink resistant. • Inspiratory limb must be heated. • CPAP range 4.5 cm H_2O to 10cm H_2O • Safety tube lock to avoid unintended changes of the PEEP level • Must be safety release valve at 17cm H2O

	• Must be DEHP (Plasticizer) free. • The heated chamber should be with auto fill facility. • Expiratory limb should be with water trap • Should be BIS compliant.