

ECG UNIT

Version no. :	1.0	
Date:	SEPT 2014	
Done by : (name/institution)	HCT/NHSRC	
NAME AND CODING		
GMDN name	Multichannel Electrocardiographic	
GMDN code(s)	CT 1115	
GENERAL		
1. USE		
1.1	Clinical purpose	Continuously detect, measure, and display a patient's electrocardiogram (ECG) through leads and sensors attached to the patient.
1.2	Used by clinical department/ward	All
1.3	Overview of functional requirements	<p>Continuous display of patient ECG and heart rate on screen.</p> <p>Allows display of single, 5 lead ECG or simultaneous display of at least 5 waves selected from up to 12 points.</p> <p>Operator can set audiovisual alarm levels for low or high heart rate.</p> <p>Operates from mains voltage or from internal rechargeable battery.</p> <p>Patient connectors that are sterilisable and reusable are preferred, though reusable cables that attach to disposable connection patches are also acceptable.</p> <p>Hard copy printout of traces will be required.</p>
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	<ol style="list-style-type: none"> Heart rate measurement range to be at least 30 to 250 bpm, with accuracy better than ± 5 bpm. Heart rate trend display of at least previous 24 hours. Arrhythmia detection facility required; minimum gradation of 1 bpm. Heart rate measurement range to be at least 30 to 250 bpm, with accuracy better than ± 5 bpm.
2.2	Settings	Audiovisual alarms required: high and low heart rate (operator variable settings), cardiac arrhythmia, sensor/wire disconnected, low battery.
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)	less than 5 kgs
3.3	Configuration	<p>Case is to be hard and splashproof.</p> <p>Display must allow easy viewing in all ambient light levels.</p> <p>Supplied in protective case for clean storage and safe transport.</p>

3.4	Noise (in dBA)	<50 dB
3.5	heat dissipation	Heat Dissipation: Should maintain nominal Temp and the heat should be disbursed through a exhaust cooling fan.
3.6	Mobility, portability	Supplied in protective case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO₂)		
4.1	Voltage (value, AC or DC, monophasic or triphase)	220 to 240V, 50 Hz
4.2	Battery operated	Battery powered, silenceable alarm for power failure. Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit. Internal, replaceable, rechargeable battery allows operation for at least one hour in the event of power failure.
4.3	Tolerance (to variations, shutdowns)	Voltage corrector/stabilizer to allow operation at $\pm 30\%$ of local rated voltage.
4.4	Protection	Electrical protection provided by fuses in both live and neutral supply lines.
4.5	Power consumption	
4.6	Other energy supplies	Mains cable to be at least 3m length.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories (mandatory, standard, optional)	12 lead ECG cable. 5 lead ECG cable (if option offered). 100 sets of ECG connection electrodes (if disposable type). 5 sets of ECG connection electrodes (if reusable type).
5.2	Spare parts (main ones)	Two sets of spare fuses (if non-resettable fuses used)
5.3	Consumables/reagents (open, closed system)	5 tubes electrode gel (if required)
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust ...)	Operating condition: – Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	The case is to be cleanable with alcohol or chlorine wipes.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international	Should be FDA/CE approved product; Manufacturer/supplier should have ISO 13485 certificate for quality standard. Electrical safety conforms to standards for electrical safety IEC-60601-1. Shall meet IEC-60601-1-2 (General requirements for safety - electromagnetic compatibility) and IEC 60601-2-25 (essential performance of electrocardiographs).
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	Availability of 5 amp/15 amp. Electrical socket.
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 year

9.2	Maintenance tasks	Maintainance manual detailing complete maintaining schedule.
9.3	Service contract clauses, including prices	Warranty of one year with free servicing (min. 3) during warranty.
9.4	Others	The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee/warranty period should be attached.
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	User, technical and maintenance manuals to be supplied in english language. Certificate of calibration and inspection to be provided. List to be provided of equipment and procedures required for local calibration and routine maintenance. List to be provided of important spares and accessories, with their part numbers and cost. Contact details of manufacturer, supplier and local service agent to be provided.
10.2	Other accompanying documents	User/Technical/Maintenance manuals to be supplied in English.
11. NOTES		
11.1	Other information	Any Contract (AMC/MC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any recommendations for best use and supplimentary warning for safety should be declared.

DEFIBRILLATOR

Version no. :	2
Date:	26/2/2015
Done by : (name / institution)	HCT/NHSRC
NAME AND CODING	
GMDN name	Defibrillators
GMDN code(s)	CT1150
GENERAL	
1. USE	
1.1	<p>Clinical purpose</p> <p>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 to the heart with a device.</p>
1.2	<p>Used by clinical department/ ward</p> <p>NICU and PICU</p>
TECHNICAL	
2. TECHNICAL CHARACTERISTICS	
2.1	<p>Technical characteristics (specific to this type of device)</p> <ol style="list-style-type: none"> 1) The Defibrillator should have biphasic technology having energy selection of 1-200 Joules. 2) 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 real time and visual on screen feedback. 3) Machine must be with sweep rate 25mm/sec, 50mm/sec. 4) It should be capable of monitoring ECG through ECG cables, electrodes & paddles. 5) Machine should have 24 hour trend storage facility. 6) The machine should have defibrillator facility for neonatal and pediatric patients. 7) The machine should have ECG waveform display with provision for synchronization. 8) The machine should be compact, portable with built in rechargeable battery & light weight. 9) The machine should have inbuilt auto & manual recorder for printing ECG trace & stored information. 10) The machine should have user selectable alarms setting. 11) The machine should work on mains (without battery) and on battery as well. 12) The machine should have AED feature as inbuilt with manual override for manual operations.
2.2	<p>User's interface</p> <p>Manual/Automatic</p>

2.3	Software and/or standard of communication(whenever required)	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	Configuration	Should have audio visual alarm for battery low.
3.4	Noise (in dBA)	<60db
3.5	Heat dissipation	1) Should maintain nominal Temp of the control unit and the heat should be disbursed through an cooling mechanism.
3.6	Mobility, portability	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)		
4.1	Power Requirements	Input voltage 220 VAC +-10%, 50Hz;
4.2	Battery operated	1) Battery powered, silenceable alarm for power failure. 2) Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit. 3) Internal, replaceable, rechargeable battery allows operation for a minimum of two hour in the event of power failure.
4.3	Tolerance (to variations, shutdowns)	Voltage corrector / stabilizer to allow operation at ± 15% of local rated voltage. Use of SMPS to correct voltage.
4.4	Protection	1) Electrical protection, resettable over current breakers or replaceable fuses (fitted in both live and neutral lines). 2) Leakage
4.5	Power consumption	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)	1) Machine must be supplied with ECG cable, Battery, Paddle (Adult integrated with pediatric). 2) 3 No. Reusable CPR feedback sensor. 3) 300 gel sheet or pads for monitoring and defibrillation.
BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	1) Operating condition: Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90% in ideal circumstances. 2) Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	1) Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international	1) FDA (US) /CE (EU) from authorized third party and BIS/ISO 13485. 2) Relevant IEC-60601-Part 1 & 2, certificates by a notified agency.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	1) Availability of 5 amp/15amp socket. 2) Safety and operation check before handover.

8.2	Requirements for sign-off	<ol style="list-style-type: none"> 1) Supplier to perform installation, safety and operation checks before handover. 2) Local clinical staff to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	<ol style="list-style-type: none"> 1) Training of users on operation and basic maintenance. 2) Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years
9.2	Maintenance tasks	<ol style="list-style-type: none"> 1) Maintenance manual detailing. 2) Complete maintenance schedule.
9.3	Service contract clauses, including prices	<ol style="list-style-type: none"> 1) The spare, accessories & consumables price list required for maintenance and repairs in future after guarantee / warranty period should be attached. 2) Free servicing during warranty period.
10. DOCUMENTATION		
10	Operating manuals, service manuals, other manuals	<p>Should provide 2 sets(hardcopy) of:-</p> <ol style="list-style-type: none"> 1) User, technical, maintenance and service manuals to be supplied along with machine diagrams. 2) List of equipment and procedures required for local calibration and routine maintenance. 3) Certificate of calibration from the manufacturer.
10	Recommendations for maintenance	List of important spares and accessories, with their part numbers and cost.
11. NOTES		
11	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	<ol style="list-style-type: none"> 1) Contact details of manufacturer, supplier and local service agent to be provided. 2) Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer.
11	Recommendations or warnings	Any warning signs would be adequately displayed.

SYRINGE PUMP

Version no. :	3.0
Date:	26/2/2015
Done by : (name / institution)	HCT/ NHSRC
NAME AND CODING	
GMDN name	Syringe pump
GMDN code(s)	CT111
GENERAL	
1. USE	
1.1	<p>Clinical purpose</p> <p>designed to precisely drive the plunger of a syringe down its barrel to infuse a solution when it must be administered with a high degree of volume accuracy and rate consistency.</p>
1.2	<p>Used by clinical department/ ward</p> <p>NICU/PICU</p>
TECHNICAL	
2. TECHNICAL CHARACTERISTICS	
2.1	<p>Clinical performances</p> <p>Should accept all internationally produced/marketed syringes and should be able to detect it automatically, Should support the Bolus supply of drug on press of single button, as per need and should be able to preset different range of Bolus supply.</p> <p>Preferably the unit should be of Bottom / side loaded to avoid accidental spilling of drugs and damage to the machine.</p>
2.2	<p>Technical characteristics (specific to this type of device)</p> <ol style="list-style-type: none"> 1. Flow rate programmable range at least from 0.1 to 200 ml/hr, in steps of 0.1 ml/hr; and at least from 100 to 1200 ml/hr in steps of 1 ml/hr. 2. Saves last infusion rate even when the AC power is switched off. 3. Bolus rate should be programmable to approx 500 ml, with infused volume display. 4. Selectable occlusion pressure trigger levels selectable from 300, 500 and 900 mmHg. 5. Must work on commonly available 20, 30 and 50 ml syringes 6. Accuracy of $\pm 2\%$ or better. 7. Maximum pressure generated ≤ 20 psi. 8. Automatic detection of syringe size and proper fixing. 9. Anti-bolus system to reduce pressure on sudden release of occlusion. 10. Pause infusion facility required. 11. Self-check carried out on powering on. 12. Comprehensive alarm package required including: occlusion alarm, near end of infusion pre-alarm and alarm, volume limit pre-alarm and alarm, low battery pre-alarm and alarm, AC power failure, drive disengaged, syringe loading error, maintenance required. 13. Should include KVO (Keep vein open) enabling feature. 14. It should be an open system compliant.

2.3	Settings	Single loadable with one syringe of minimum 20ml.
2.4	User's interface	Automatic
2.5	Software and/or standard of communication	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Configuration	Tamper-resistant case made of impact resistant material. Securely mountable on tabletop, IV stand or bed fitting.
3.4	Noise (in dBA)	Noise free
3.5	heat dissipation	
3.6	Mobility, portability	Yes
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)		
4.1	Voltage (value, AC or DC, monophase or triphase)	220 to 240V, 50 Hz
4.2	Battery operated	Internal rechargeable battery having at 4 to 6 hours backup for 10ml/hr flow rate with 50ml syringe.
4.3	Tolerance (to variations, shutdowns)	10%
4.4	Protection	Battery powered alarm for power failure or disconnection.
4.5	Power consumption	25W
4.6	Other energy supplies	Na
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories (mandatory, standard, optional)	Clamp for mounting pump on IV stand.
5.2	Spare parts (main ones)	
5.3	Consumables / reagents (open, closed system)	Battery, syringe holder, PMO lines
5.4	Others	
BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Operating condition: – Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Capable of cleaning with alcohol or chlorine wipes.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type)	CE or FDA certified. Manufacturer / supplier should have ISO 13485 certificate for quality standard. Electrical safety conforms to standards for electrical safety IEC-60601-1, class II. Shall meet IEC 60601-1-2 EMC standard requirements. Certified to IEC-60601-2-24: Particular requirements for the safety of infusion pumps and controllers.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	Supplier to perform installation, safety and operation checks before handover.
8.2	Requirements for sign-off	As per requirement

8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.
8.4	Others	
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 year
9.2	Maintenance tasks	Advanced maintenance and calibration tasks required shall be documented.
9.3	Service contract clauses, including prices	Local clinical staff to affirm completion of installation.
9.4	Others	
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	User, technical and maintenance manuals to be supplied in english language. List to be provided of equipment and procedures required for local calibration and routine maintenance.
10.2	Other accompanying documents	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11. NOTES		
11.1	Other information	Contact details of manufacturer, supplier and local service agent to be provided.
11.2	Recommendations or warnings	

INFUSION PUMP (VOLUMETRIC)

Version no. :	2.0	
Date:	JULY 2014.	
Done by : (name/institution)	HCT/NHSRC	
NAME AND CODING		
GMDN name	Infusion Pump (Volumetric)	
GMDN code(s)	CT1821	
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
1.3	Overview of functional requirements	Alarms indicate if any error situations occur. The drive arm infuses the medication at a steady, programmed rate.
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Clinical performances	Should accept all internationally produced/ marketed bottle and should be able to detect it automatically, Should support the Bolus supply of drug on press of single button, as per need and should be able to preset different range of Bolus supply. Preferably the unit should be of Bottom/side loaded to avoid accidental spilling of drugs and damage to the machine.
2.2	Technical characteristics (specific to this type of device)	<ol style="list-style-type: none"> 1. Flow rate programmable range at least from 0.1 to 200 ml/hr, in steps of 0.1 ml/hr; and at least from 100 to 1200 ml/hr in steps of 1 ml/hr. 2. Saves last infusion rate even when the AC power is switched off. 3. Bolus rate should be programmable to approx. 500 ml, with infused volume display. 4. Selectable occlusion pressure trigger levels selectable from 300, 500 and 900 mmHg. 5. Accuracy of $\pm 2\%$ or better for set parameters. 6. Maximum pressure generated 20 psi. 7. Pause infusion facility required. 8. Self-check carried out on powering on. 9. Comprehensive alarm package required including: occlusion alarm, near end of infusion pre-alarm and alarm, volume limit pre-alarm and alarm, low battery pre-alarm and alarm, AC power failure, drive disengaged. 10. It should be open system .
2.3	Settings	Single loadable

2.4	User's interface	Automatic
2.5	Software and/or standard of communication	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Configuration	Tamper-resistant case made of impact resistant material. Securely mountable on tabletop, IV stand or bed fitting.
3.4	Noise (in dBA)	Noise free
3.5	heat dissipation	
3.6	Mobility, portability	Yes
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO₂)		
4.1	Voltage (value, AC or DC, monophasic or triphasic)	220V ± 10%, 50 Hz
4.2	Battery operated	Internal rechargeable battery having a minimum of 2 hours backup
4.3	Tolerance (to variations, shutdowns)	± 10%
4.4	Protection	Battery powered alarm for power failure or disconnection
4.5	Power consumption	NA
4.6	Other energy supplies	NA
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories (mandatory, standard, optional)	Clamp for mounting pump on IV stand
5.2	Spare parts (main ones)	NA
5.3	Consumables/reagents (open, closed system)	NA
5.4	Others	
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust...)	Operating condition: – Capable of operating continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Capable of cleaning with alcohol or chlorine wipes
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type)	1) FDA (US)/CE (EU) from authorized third party and BIS/ISO 13485. 2) Relevant IEC-60601-Part 1 & 2, certificates by a notified agency.
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	Supplier to perform installation, safety and operation checks before handover.
8.2	Requirements for sign-off	As per requirement
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided.
8.4	Others	

9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years
9.2	Maintenance tasks	Advanced maintenance and calibration tasks required shall be documented
9.3	Service contract clauses, including prices	1) The spare, accessories & consumables price list required for maintenance and repairs in future after guarantee/warranty period should be attached; 2) Free servicing during warranty period;
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	Should provide 2 sets (hardcopy) of:- 1) User, technical, maintenance and service manuals to be supplied along with machine diagrams; 2) List of equipment and procedures required for local calibration and routine maintenance; 3) Certificate of calibration to be provided by the manufacture;
10.2	Other accompanying documents	List of important spares and accessories, with their part numbers and cost;
11. NOTES		
11.1	Service Support Contact details (Hierchy Wise; including a toll free/landline number)	1) Contact details of manufacturer, supplier and local service agent to be provided; 2) Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer;
11.2	Recommendations or warnings	Any warning signs would be adequately displayed.

PHOTOTHERAPY

Version no. :	3.0
Date:	26/2/2015
Done by : (name / institution)	HCT/ NHSRC
NAME AND CODING	
GMDN name	Phototherapy units/systems
GMDN code(s)	CT 2066
GENERAL	
1. USE	
1.1	Clinical purpose Emits in the main radiation spectrum in the range between 400 nm and 550 nm for reducing the concentration of Bilirubin
1.2	Used by clinical department/ ward New born stabilisation unit, SNCU
1.3	Overview of functional requirements a) Provides filtered light using radiant electric lights, not fibreoptics. b) Infant supported securely in bassinette below bulbs. c) Monitors hours of radiant light exposure.
TECHNICAL	
2. TECHNICAL CHARACTERISTICS	
2.1	Technical characteristics (specific to this type of device) <ol style="list-style-type: none"> 1. Phototherapy should be based on LED technology, which after filtering should provide, a light of wavelength approximately 450 to 470 nm with peak wavelength of 450-460nm range. 2. Irradiance to be minimum 35 μW/cm²/nm at 40 cm height and UV should not exceed 10-4 W/m² in 180nm to 400nm. 3. Digital Hour meter showing total exposure time for current patient to be clearly visible by operator. 4. Effective light field >700 cm². 5. Lamp life should be minimum 20000 hours for LED and should have timer to indicate its usage. 6. Over temperature safety cut out to be included. 7. Up, down and tilting of head should be possible. 8. The unit should be mounted with castor wheels with brakes. 9. Variation in intensity over 5-6 hours < 10%. 10. The irradiance ratio (min to max) shall be greater than 40 % on mattress. 11. Green indicator light shall be provided to indicate that equipment is ready for normal use. 12. Interruption and a restoration of the power supply do not change preset values. LED heat can be reduced by natural cooling. 13. LED should be protected from free fall. 14. It should not topple on 10 deg inclined angle. 15. The temperature of baby bed and metal surfaces should not exceed 40deg C and 43 deg C for other accesible surfaces.

		16. There should be intuitive method to indicate the light surface is at the appropriate treatment distance. 17. Mobile stand with movable castors and height adjustment facility along with easy swivelling of source box. Unit can be used along with Infant care trolley, Radiant Warmer and Incubator.
2.2	Settings	UP/DOWN adjustment of Over Head Unit; The phototherapy unit should be able to provide effective treatment for beds and incubators of varying heights (generally 1.0 to 1.6m). Adjustment of light intensity may be provided.
2.3	User's interface	Manual
2.4	Software and/or standard of communication (where ever required)	LED Display and inbuilt software
2.5	Others	
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	minimum spec: 1650mm Height X 750mm Width X 500mm Length
3.2	Weight (lbs, kg)	<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. Bulb mount to have angle adjustment of at least 30 degrees. All surfaces to be made of corrosion resistant materials. Light unit tilting facility and height adjustment facility.
3.4	Noise (in dBA)	<60dBA
3.5	heat dissipation	The temperature of baby bed and metal surfaces should not exceed 40deg C and 43 deg C for other accesible surfaces.
3.6	Mobility, portability	Minimum 3 castors and atleast 2 with brakes
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)		
4.1	Power Requirements	220 to 240V, 50 Hz
4.2	Battery operated	NA
4.3	Tolerance (to variations, shutdowns)	± 10% of input AC
4.4	Protection	Electrical protection by resettable overcurrent breakers or replaceable fuses, fitted in both live and neutral lines.
4.5	Power consumption	Should not be more than 160 W
4.6	Other energy supplies	Mains cable to be at least 2.5m length
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories (mandatory, standard, optional)	Complete set of replacement tubes to allow 3 months' continuous operation Two replacement sets of fuses, if replaceable type used.
5.2	Spare parts (main ones)	No spares required
5.3	Consumables / reagents (open, closed system)	Total 500 nos. Infant eye masks of both available sizes (term and pre term babies).
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	Atmosphere / Ambiance (air conditioning, humidity, dust ...)	Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90% in ideal circumstances.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Complete unit to be easily washable and sterilizable using both alcohol and chlorine agents.

7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary, ..); Performance and safety standards (specific to the device type); Local and/or international	<p>Should be FDA / CE approved product</p> <p>Shall meet IEC-60601-1-2:2007 Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Or Equivalent BIS)</p> <p>Should meet IEC 60601-1:2005 standard requirements</p> <p>Shall meet IEC 60601-2-50: 2009 Medical Electrical Equipment – Part 2-50: Particular Requirement for the basic safety and essential performance of infant phototherapy equipment;</p> <p>Manufacturer should be ISO 13485 certified</p>
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	Supplier to perform installation, safety and operation checks before handover.
8.2	Requirements for sign-off	Certificate of Calibration and inspection from the factory.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided
8.4	Others	
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years for the machine and 20,000 hours for LEDs
9.2	Maintenance tasks	Maintainance manual detailing complete maintaining schedule
9.3	Service contract clauses, including prices	Local clinical staff to affirm completion of installation
9.4	Others	
10. DOCUMENTATION		
10.1	Operating manuals, service manuals, other manuals	<p>Advanced maintenance tasks required shall be documented</p> <p>User, technical and maintenance manuals to be supplied in english language.</p> <p>List to be provided of equipment and procedures required for local calibration and routine maintenance</p>
10.2	Other accompanying documents	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11. NOTES		
11.1	Service Support Contact details (Hierchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided
11.2	Recommendations or warnings	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.

MONITOR

Version no. :	1.0
Date:	SEPT 2014.
Done by : (name/institution)	HCT/NHSRC
NAME AND CODING	
GMDN name	Patient monitors/monitoring systems
GMDN code(s)	CT1444
GENERAL	
1. USE	
1.1	<p>Clinical purpose</p> <p>Designed to continuously measure and display multiple vital physiological parameters of newborn and premature infants, especially those under critical care.</p>
1.2	<p>Used by clinical department/ward</p> <p>NICU and PICU</p>
1.3	<p>Overview of functional requirements</p> <p>Operates from mains voltage or from internal rechargeable battery. Operator can set audio visual alarm levels for low or high levels of each parameter independently. Allows display of single, 3 lead ECG or simultaneous display of at least 5 waves ECG selected from up to 12 points. Display to be digital of all active parameters and trace display for at least three selectable parameters. Continuous display on screen of neonatal or infant ECG, respiration and heart rates, invasive/non-invasive blood pressure, body temperature and SpO2.</p>
TECHNICAL	
2. TECHNICAL CHARACTERISTICS	
2.1	<p>Technical characteristics (specific to this type of device)</p> <ol style="list-style-type: none"> Should have facility for printing ECG at 25mm/sec and 50mm/sec speed. Should have facility for charging from both 12V DC & 220V AC. 3a. Should be supplied with. <ol style="list-style-type: none"> 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 adult, pediatric & neonatal size cuff/leads. The material of the probe should be such that it is non-breakable. Capable of saving data for min 24 hrs. Rates for consumables should be offered in price bid. Optional item to be quoted : invasive blood pressure-monitoring module complete with reusable transducer.
2.2	<p>Settings</p> <p>User operated 1mV ECG test marker function required.</p>
2.3	<p>User's interface</p> <p>Manual (touch screen or remote operated not mandatory).</p>

2.4	Software and/or standard of communication	Audio Visual alarms required: high and low levels for each parameter (operator variable settings), sensor/wire/probe disconnected, low battery.
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions (metric)	Screen size minimum: 10"
3.2	Weight (lbs, kg)	<6kg.
3.3	Configuration	Case is to be hard and splash proof. Display must allow easy viewing in all ambient light levels. Cable connectors to be designed so as fit correct socket only.
3.4	Noise (in dBA)	<50 dB; Lead disconnection Alarm > 65 dB.
3.5	heat dissipation	Should maintain nominal Temp and the heat should be disbursed through a exhaust cooling fan.
3.6	Mobility, portability	Supplied in protective case for clean storage and safe transport.
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO₂)		
4.1	Voltage (value, AC or DC, monophas or triphase)	220 to 240V, 50 Hz.
4.2	Battery operated	Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit. Battery powered, silenceable alarm for power failure. Internal, replaceable, rechargeable battery allows operation for at least one hour in the event of power failure. Battery backup of minimum 100 minutes.
4.3	Tolerance (to variations, shutdowns)	Voltage corrector/stabilizer to allow operation at $\pm 30\%$ of local rated voltage.
4.4	Protection	Electrical protection provided by fuses in both live and neutral supply lines.
4.5	Power consumption	<120Watt.
4.6	Other energy supplies	Mains cable.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories & Spares	2 pairs, 12 lead ECG cable. 2 packs of 100 disposable ECG connection electrodes. Two sets of reusable SpO ₂ probes ncluding adult, pediatric & neonatal probes. two sets of NIBP cuffs of each size. Two external skin temperature probes.
5.2	Consumables/reagents (open, closed system)	
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS		
6.1	Atmosphere/Ambiance (air conditioning, humidity, dust ...)	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Complete unit to be easily washable and sterilizable using alcohol and other chemical agents.
7. STANDARDS AND SAFETY		
7.1	Certifications	FDA/CE and BIS/ISO 13485:2003; ; IEC-60601-1-2:2007; IEC 60601-1-8-2006; IEC 60601-1-SER-Ed 1.0-2011; IEC/TRF 60601-1-8 Ed4.0-2010; ISO 13485; ISO 80601-2-56-2009 (Thermometer); ISO 80601-2-61-2011 (SpO ₂)
8. TRAINING AND INSTALLATION		
8.1	Pre-installation requirements: nature, values, quality, tolerance	Supplier to perform installation, safety and operation checks before handover.
8.2	Requirements for sign-off	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.

ANAESTHESIA WORKSTATION

Version no. :	Ver_1	
Date:	12/07/2018	
Done by : (name.institution)	HCT/NHSRC	
NAME, CATEGORY AND CODING		
UMDNS name	Anesthesia Units	
UMDNS code(s)	10134	
GENERAL		
1. USE		
1.1	Clinical purpose	Devices that continuously or intermittently administer a mixture of gases (e.g., oxygen, nitrous oxide, the vapor of a volatile liquid such as halogenated hydrocarbon), varying the proportion of gases in order to control an individual's level of consciousness. These devices are also designed to facilitate spontaneous, controlled, or assisted ventilation with these gas mixtures. An anesthesia unit is typically comprised of four basic subunits: a gas supply and control circuit, breathing and ventilation circuit, a scavenging system to help prevent the escape of exhaled gases, and a set of function and breathing circuit monitors (e.g., inspired oxygen concentration, breathing circuit integrity).
1.2	Used by clinical department/ward	Operation Theatre
TECHNICAL		
2. TECHNICAL CHARACTERISTICS		
2.1	Technical characteristics (specific to this type of device)	<p>Flow Management:</p> <ol style="list-style-type: none"> 1. Should be compact, ergonomic and easy to use. 2. Machine should provide electronic gas mixing. 3. Multi color TFT display of at least 15" size, with virtual meters for O₂, N₂O or Air. 4. Dual flow sensing capability at inhalation and exhalation ports. 5. Should have backup O₂ control which provides an independent fresh gas source and flow meter control in case of electronic failure. 6. Gas regulators (flow control valves) shall be of modular design/graphic display. 7. All pipeline connections should have diameter-indexed safety systems (DISSs) or another means of preventing connection of dangerous gases. 8. System should permit connection of at least two yokes, one dedicated to O₂ cylinder to meet clinical needs during failure of pipeline supply. All cylinder yokes (regardless of the gas for which they are intended) should include pin-index safety systems to prevent connection of dangerous gases. <ol style="list-style-type: none"> i. Hypoxic guard to ensure minimum 25% O₂ across all O₂-N₂O mixtures and Oxygen failure warning.

		<p>Breathing System:</p> <ol style="list-style-type: none"> 1. Latex free fully autoclavable/ disposable with minimal flow of 250 ml of O₂. 2. Sensor should not require daily maintenance. 3. Bag to vent switch shall be bi stable and automatically begins mechanical ventilation in the ventilator position. 4. Adjustable pressure limiting valve shall be flow and pressure compensated. <p>Vaporizers:</p> <ol style="list-style-type: none"> 1. Provision to mount following selectable vaporizers such as Desflurane, halothane, isoflurane, sevoflurane with interlocking facility to allow use of only one vaporizer at a time. 2. All the vaporizers should be temperature, pressure and flow compensated vaporizers and maintenance free. <p>Ventilation:</p> <ol style="list-style-type: none"> 1. The work station should have integrated anesthesia ventilator system. 2. It should have following Ventilation modes Manual/spontaneous, VCV, PCV, SIMV or pressure support, advanced modes. 3. Tidal volume: A control adjusts the volume of individual breaths within range of 20-1,500 cc. 4. Minute volume: A control adjusts the total inspiratory volume-per-minute delivery from the bellows shall be >20 L/min. 5. The respiratory frequency can be set within range of 5-60 breaths per minute. 6. Inspiratory flow: The flow range of gas that the ventilator is capable of delivering to the patient shall be 0-180 L/min. 7. Pressure limit shall be adjustable and <70 preferred cm H₂O. Unit should have PEEP of 0-20 cm H₂O. 8. The workstation should be capable of delivery of low flow anesthesia. <p>Anesthesia Monitoring Specifications:</p> <ol style="list-style-type: none"> 1. Monitoring of vital parameters: ECG, NIBP, SPO₂, and Invasive Blood Pressure. 2. Twin temperature measurement with skin and core temperature probes – Two sets with each monitor. 3. Automatic identification and measurement of anesthetic agents EtCO₂, O₂, and N₂O and MAC value. FiO₂ measurement. 3. Facility to store snapshots during critical events for waveform review at a later stage. 4. Audio visual and graded alarming system. <p>Display of Ventilator: Mode of ventilation to be displayed, Respiratory rate, flow, pressure also to be displayed.</p>
2.2	User's interface	Manual

2.3	Software and/ or standard of communication(where ever required)	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise pressure level: ≤60 dbA.
3.4	Heat dissipation	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	Mobility, portability	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ...)		
4.1	Power requirements	Power input to be 220-240 VAC, 50Hz fitted with Indian Plug.
4.2	Battery operated	Yes, at least 30 minutes back up.
4.3	Protection	Stabilizer to be provided for protection.
4.4	Power consumption	To be specified by service provider.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/re-agents (open, closed system)	<ol style="list-style-type: none"> 1. Cylinders/ Pipeline. 2. Circle absorber – 01 No. 3. Vaporizer Halothene – 01 No. 4. Vaporizer Desflurane – 01 No. 5. Vaporizer isoflurane – 01 No. 6. Vaporizer sevoflurane – 01 No. 7. Adult and Pediatric autoclavable silicone breathing circuits – 2 each. 8. Reusable IBP cable -04. 9. Humidifiers – 1 No 10. Disposable transducer – 100 11. Temperature Probe Skin reusable – 02. 12. Temperature core reusable -04 (02-Adults, 02-paediatrics) 13. Depth of anesthesia sensors – 50 14. Accessories for neuromuscular transmission monitor -01 set. 15. Standard accessories to make all parameters working -01 set. 16. Disposable adult and pediatric circuit – 50 each. 17. HME Filters – 1000 nos 18. Vital parameter accessories (ECG Leads – 5 sets, NIBP Cuffs all sizes) -01 set. 19. Spo2 probes both adult and pediatric 2 in no should be supplied with each machine. 20. EtCo2 sampling line and connector should be supplied 25 no each with apparatus.
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust ...)	<ol style="list-style-type: none"> 1. Operating Condition: Capable of operating continuously in ambient temperature of 5 to 40 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 40 deg C and relative humidity of 15 to 90%

6.2	User's care, Cleaning, Disinfection & Sterility issues	Disinfection: Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	<ol style="list-style-type: none"> Should be US FDA/CE/BIS/CDSCO approved (USFDA/CE requirements will be applicable only when the Indian standards like BIS/CDSCO is not available.) Manufacturer and Supplier should have ISO 13485 certification for quality standards. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements (or equivalent BIS Standard). Shall meet Safety Standards IEC 60601-1:2005 (Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility and should comply with 89/366 EEC, EMCdi. The manufacturer must have a management system certified to ISO 9001.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	Availability of 5 Amp/15 Amp. Electrical Socket. Supplier to perform installation, safety and operation checks before handover.
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. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and calibration.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	Should provide 2 sets(hard copy and soft copy) of: <ol style="list-style-type: none"> User, technical and maintenance manuals should be supplied in English/Hindi/ Regional language along with machine diagrams; List of equipment and procedures required for local calibration and routine maintenance; Service and operation manuals(original and Copy) to be provided; Advanced maintenance tasks documentation; Certificate of calibration and inspection, Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. NOTES		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided; Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

MULTI PARAMETER MONITOR WITH ANESTHESIA GAS MONITOR

Version no. :	Ver_1
Date:	12/07/2018
Done by : (name.institution)	HCT/NHSRC
NAME, CATEGORY AND CODING	
UMDNS name	Monitoring System, Physiologic
UMDNS code(s)	12636
GENERAL	
1. USE	
1.1	<p>Clinical purpose</p> <p>These systems usually include a central station monitor that receives, consolidates, and displays the information and a set of monitors that are deployed near the patient (bedside monitors) to provide the required data from each patient (ECG, respiratory rate, noninvasive blood pressure (NIBP) and invasive blood pressure (IBP) (systolic, diastolic, and mean), body temperature, (SpO₂), mixed venous oxygenation (SvO₂), cardiac output, (ETCO₂), intracranial pressure, and airway gas concentrations).</p>
1.2	<p>Used by clinical department/ward</p> <p>Operation Theatre</p>
TECHNICAL	
2. TECHNICAL CHARACTERISTICS	
2.1	<p>Technical characteristics (specific to this type of device)</p> <ol style="list-style-type: none"> 1. Should have modular Multi parameter monitor with TFT/LED/LCD/touch screen display with more than 15 inches with at least 8 wave forms and upgradable up to 14 waveforms & 22 parameter numeric on single display. 2. The waveforms should be user selectable. 3. Monitor should have in built Lithium-ion type battery for 2 Hour continuous operation. 4. Should have keys for quick access to main functions. 5. Should be able to monitor ECG(3,5,12 leads), SPO₂, NIBP, 2 IBP, Respiration Rate, 2 temp, ETCO₂, for adult, pediatric and neonatal patients as standard and Anesthesia gas monitoring. 6. Monitor must have facility for at least 2 IBP measurements simultaneously. Also should have SPV/PPV monitoring facility. 7. 5 Lead ECG monitoring with full range of lethal arrhythmia recognition capability and ST analysis up to 12 leads and 72hour trend facility. 8. Respiration, Apnea alarm, Prioritized audio visual alarms and snap shot facility. 9. Transport module with display and battery backup of at least 1 hour. 10. Pulse Oxymeter (SPO₂) with Plethysmograph & Pulse strength indicator With Variable pitch with change in SpO₂ (low perfusion motion tolerance technology). 11. Side-stream Capnography with display of CO₂ wave form & digital values (ETCO₂, FiCO₂, RR). 12. Monitor should have provisions for automatic identification and measurement of anesthesia agents, CO₂, O₂, N₂O and facility to measure at least 5 volatile agents with automatic detection. 13. Should be upgradable to monitor cardiac output (Thermo

		dilution/ PICCO), BIS/DA and NMT. 14. It should have provision for automatic identification and measurement and anesthetic agents, Co2, O2, N2O and facility to measure MAC. 15. The display setting should have at least 10 user defined setups variable as per applications for flexible use of the monitor in various clinical environments as in OT, PACU, ICU, ER, NICU. 16. Monitor should have networking options with bidirectional & bed to bed communication.
2.2	User's interface	Manual
2.3	Software and/or standard of communication (where ever required)	Inbuilt
3. PHYSICAL CHARACTERISTICS		
3.1	Dimensions(metric)	NA
3.2	Weight (lbs, kg)	NA
3.3	Noise (in dBA)	Noise pressure level: ≤60 dbA.
3.4	Heat dissipation	Should maintain nominal temperature and the heat should be disbursed through a cooling mechanism.
3.5	Mobility, portability	Portable
4. ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2 ...)		
4.1	Power requirements	Power input to be 220-240 VAC, 50Hz fitted with Indian Plug.
4.2	Battery operated	Yes, at least 30 minutes back up.
4.3	Protection	Stabilizer to be provided for protection.
4.4	Power consumption	To be specified by service provider.
5. ACCESSORIES, SPARE PARTS, CONSUMABLES		
5.1	Accessories, (mandatory, standard, optional); Spare parts (main ones); Consumables/ reagents (open, closed system)	Should provide following accessories 1. 20 Nos of Disposable IBP transducers with all standard accessories & 6 nos of reusable adapter cable (type as requested by the end user) 2. Accessories for Anesthesia Gas/Co2 monitoring -25 Nos (disposable) 3. Reusable adult 5 lead ECG cable set – 2 nos. 4. NIBP cuffs for standard Adult(2 Nos), Obese Adult, Child and infant – all 1 each.(5 Nos) 5. Temperature Probe (esophageal/ rectal)- 2Nos Accessories 1. Spo2 probe adult (Reusable) – 2 Nos 2. Spo2 probe pediatric (Reusable) – 2 Nos 3. Fore Head Spo2 Sensor – 2 Nos
BIDDING/PROCUREMENT TERMS/DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
6.1	Atmosphere/Ambience (air conditioning, humidity, dust ...)	1. Operating Condition: Capable of operating continuously in ambient temperature of 5 to 40 deg C and relative humidity of 15 to 80% in ideal circumstances. 2. Storage condition: Capable of being stored continuously in ambient temperature of 0 to 40 deg C and relative humidity of 15 to 90%
6.2	User's care, Cleaning, Disinfection & Sterility issues	Parts of the Device that are designed to come into contact with the patient or the operator should either be capable of easy disinfection

		or be protected by a single use/disposable cover.
7. STANDARDS AND SAFETY		
7.1	Certificates (pre-market, sanitary,..); Performance and safety standards (specific to the device type); Local and/or international	<ol style="list-style-type: none"> 1. Should be US FDA/CE/BIS/CDSCO approved (USFDA/CE requirements will be applicable only when the Indian standards like BIS/ CDSCO is not available.) 2. Manufacturer and Supplier should have ISO 13485 certification for quality standards. 3. Electrical safety conforms to the standards for electrical safety IEC 60601-1-General requirements (or equivalent BIS Standard). 4. Shall meet Safety Standards IEC 60601-1:2005 (Or Equivalent BIS) 5. General Requirements of Safety for Electromagnetic Compatibility and should comply with 89/366 EEC, EMCdi. 6. The manufacturer must have a management system certified to ISO 9001.
8. TRAINING AND INSTALLATION		
8.1	Pre- installation requirements: nature, values, quality, tolerance	Availability of 5 Amp/15 Amp. Electrical Socket.
8.2	Requirements for sign-off	Supplier to perform installation, safety and operation checks before handover. Local clinical staff to affirm completion of installation.
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided. Advanced maintenance tasks required shall be documented.
9. WARRANTY AND MAINTENANCE		
9.1	Warranty	3 years, including all spares and calibration.
10. DOCUMENTATION		
10.1	Operating manuals, set manuals, other manuals	<p>Should provide 2 sets(hard copy and soft copy) of:</p> <ol style="list-style-type: none"> 1. User, technical and maintenance manuals should be supplied in English/Hindi/ Regional language along with machine diagrams; 2. List of equipment and procedures required for local calibration and routine maintenance; 3. Service and operation manuals(original and Copy) to be provided; 4. Advanced maintenance tasks documentation; 5. Certificate of calibration and inspection, 6. Satisfactory certificate for any existing installation from government hospital.
10.2	Other accompanying documents	List of essential spares and accessories, with their part number and cost;
11. Notes		
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	<p>Contact details of manufacturer, supplier and local service agent to be provided;</p> <p>Any Contract(AMC/CMC/add-hoc) to be declared by the manufacturer.</p>
11.2	Recommendations or warnings	Any warning sign would be adequately displayed.

Endoscopy Machine

SPECIFICATION FOR SIDE VIEWING ENDOSCOPE (DUODENOSCOPE / ERCP SCOPE) :

SI No.	Particulars	Remarks
	<ul style="list-style-type: none"> It should Superior image quality with crisp, clear images and true-to life Colour. 	
	<ul style="list-style-type: none"> Scope should have four user programmable remote switches to improve operability. 	
	<ul style="list-style-type: none"> Should be equipped with special optical image enhancement technology (NBI/BLI/OE i SCAN) for detailed diagnosis of mucosal and pit pattern 	
	<ul style="list-style-type: none"> It should preferably have a locking mechanism for holding guide wires during ERCP. 	
	<ul style="list-style-type: none"> It should provide high resolution vision. 	
	Direction of View	95° backward oblique
	Distal end outer diameter	14.0 mm or less.
	Insertion tube Outer diameter	11.5 mm or less
	Channel diameter	4.2 mm or more.
	Insertion tube length	1200 mm or more.
	Field of view	100° or more.
	Depth of Field	5-60 mm or better.
	Angulations	UP-120°, Down-90°, Right-110°, Left-90° or better.
	Minimum visible distance	10 mm or less.
	Video Processor & Light source	
	1. Integrated or separate unit with light source	
	2. Unit should be compact and light weight.	
	3. Light source – with 300 Watt Xenon/LED Lamp with emergency backup facility.	
	4. Should be equipped with special optical image enhancement technology (NBI/BLI/OE i SCAN) for detailed diagnosis of mucosal and pit pattern	
	5. Air pump - Inbuilt air pump with minimum two variable air flow control.	
	6. Electronic magnification up to 1.5X by a touch of scope remote switches	
	7. Video Output: DVI and HD-SDI output must be available	
	Monitor : 21" or more High Definition of Medical Grade	
	Trolley : Good quality trolley	

SI No.	Particulars	Remarks
	Accessories (preferably from the same company)	
	1. Single Use Guide Wire : 3 Nos	
	2. Single Use Shpincterotome : 3 Nos	
	3. Single Use Stone Extractor Balloon : 3 Nos	
	4. Biopsy Valve : 10pkts	
	5. Air-water and Suction valves : 2 units each	
	Terms and conditions:	
	1. The vendor must give a demonstration of the quoted equipment in the Department of Gastroenterology on their cost.	
	2. The system must have a standard comprehensive warranty of 5 years with spares and should quote CMC for next 5 years.	
	3. A certificate should be given by the supplier that the instrument has not been supplied at a rate lower than the rate quoted in the tender of AIIMS. If it is found to be so then the difference will be recovered from the supplier along with penal interest.	
	4. It should be certified that if the instrument becomes non functional, it will be repaired within the shortest possible time period otherwise a penal charge will be levied on the company.	
	5. The system should be meet the approved quality control standards of Government of India	