

Lot 2-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	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 to the 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)	<ol style="list-style-type: none"> 1) The Defibrillator should have biphasic technology having energy selection of 2-200 Joules. 2) The machine should have facility for ECG monitoring, defibrillation, transcutaneous pacing, defibrillation. 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	User's interface	Manual / Automatic

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 dissipated through a 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 $\pm 15\%$ 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) 50 Disposable pads for AED. 3) 300 gel sheet or pads for monitoring and defibrillation.
BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS		
6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS		
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	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)	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	1) Maintenance manual detailing. 2) Complete maintenance schedule.
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	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 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)	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.