

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	Maintenance 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 supplementary warning for safety should be declared.