BBQRS FOR PROCUREMENT OF PORTABLE LIGHT WEIGHT COMPUTERIZED MULTI CHANNEL ECG MACHINE

1. Nomenclature Portable Light weight computerized Multi channel ECG machine with Capacity of acquiring all the 12 leads simultaneously. Printing on A4 size thermal paper with auto measurement parameters complete.

2. The machine should be *able* to operate on AC Mains (120-240V) 50-60 Hz.

3. It should be portable, lightweight & easy to operate.

4. It should have facility of auto measurement of parameters.

5. Should have internal rechargeable battery with minimum one hour operation when fully charged. Battery standby capacity should be in the range 120-240 Hrs.

6. The machine should be able to *record* all standard and chest leads with simultaneous acquisition of 12 leads on a single sheet of a paper measuring 25-30 cm x 19-21 cm on its own without help another computer & printer.

7. The machine should have the facility of built in RJ45/ RS232 & USB interface with software.

8. The machine should have facility to print the ECG on A4 size paper through computer.

9. The machine should have alphabetic keyboard for patient information.

10. The machine should have built in LCD/ LED colour display.

11. The machine should have real-time ECG wave form, Cases save/ replay facility.

12. Should have auto power shut off capacity when not in use.

13. The dealer should guarantee supply of ECG paper & spares.

14. The Equipment should have a warranty of 5 years & AMC for 5 years.

15. At the time of bidding it should be the latest model available in the manufacture portfolio.

BROAD BASED QR'S FOR PVMS NO. 280G08 ECG MONITER DEFIBRILLATOR WITH TRANSCUTANEOUS PACER

General Features.

1. Should be compact and portable and should weigh less than 7 kg.
2. Should have functions & controls which *are* user.
3. Should have facility for both automatic (AED mode) and manual defibrillation and mode for transcutaneous pacing.
4. Should work on both AC-110-240V 50 Hz supply and have a inbuilt battery with backup of >2 Hrs.
5. Should be able to function in temperatures between 0-45 ^{0}C and relative humidity 30-90%.

Display Functions & Operational Requirements.

6. Should be able to deliver shocks from 2-200 J or more (Biphasic Energy) in manual mode user selectable.
7. In automatic – automated electrical defibrillators (AED) mode energy delivered should be above 130 J as fixed/ escalating levels.
8. Should have a changing time for 200 J in < 10 Secs.
9. Should have built in facility for a least a 3 lead continuous ECG monitoring.
10. Both adult and pediatric hard paddles (reusable paddles) should be provided.
11. Should have facility for synchronous cardio version.
12. Should have a screen of at least 5 inches with the facility of displaying waveforms (Colour).
13. Display should be clear from a distance for ECG trace heart rate and energy selected/ charge a available for defibrillation/ cardio version.
14. ECG trace displayed should have following minimum paddle mode/ leads I/II/III (as selected by the user).
15. Should have facility to automatically/ manually print critical events/ code summary ECG records with an integrated recorder and printing speed of 25 mm/ sec.
16. Should have adjustable heart rate alarm limits.
17. Should be able to deliver at least 30 shocks on a fully charged battery at 200 J transcutaneous pacing mode.
18. Should be provided with disposable/ reusable paddies for transcutaneous pacing along with the connections from patient to equipment.
19. Should have user adjustable pacing rate from 50 to at least 100 beats per minute.

20. Should have pacing output range from 10-100 mA or more standards & miscellaneous.

21. Should be USFDA/ European CE/ BIS approved.

22. Should be supplied with the following accessories :-

(a) External defibrillator paddle adult and pediatric.

(b) 3 or 5 lead ECG cable.

(c) AED & transcutaneous pacing pads.

23. Should have warranty for 5 years from date of installation, Comprehensive Annual Maintenance Contract for the 5 years and spares availability certificate for 10 years from date of supply.

ECG/ NIBP/SPO2/TEMP MONITOR

Name & Coding.

GMDN Name	: Patient Monitors/ Monitoring Systems.
GMDN Code	: CT 1444
Definition	: A device assembly designed to continuously measure and display multiple vital physiological parameters of newborn and premature infants, especially those under critical care. It is typically capable of monitoring parameters such as electrocardiogram (ECG), respiration rate, heart rate, blood pressure, and body temperature; it may also assess hemoglobin oxygen saturation (SPO2 J through transcutaneous sensors that measure both transcutaneous oxygen (TCP 02) and transcutaneous carbon dioxide (TCP 02) saturation. The system typically includes sensors with appropriate size and design for infant use.

General Use.

Clinical Purpose	: Designed to continuously measure and display multiple vital physiological parameters of newborn and premature infants, especially those under critical care.
Used by clinical Department/ Ward	: All
Overview of functional	: 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, non-invasive blood pressure, body temperature and SPO2.

Technical Characteristics.

Technical Characteristics (specific to this type of Device)	1. ECG patient connectors that are sterilisable and reusable are acceptable though reusable cables that attach to disposable connection patches are preferred. 2. Multichannel (up to 12 leads) ECG measurement and selectable display of up to 5 leads at a time. 3. Temperature probe to be reusable external skin contact type. Temperature range at least 30 to 40 degree C, minimum gradation 0.1 degree C.

4. Heart Rate measurement range to be at least 30 to .250 bpm, with accuracy better than ± 5 bpm and minimum gradation 1 bpm.

5. 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%.

6. Blood pressure monitoring range at least 30 to 300 mmHg, minimum gradation 1 mmHg.

7. Respiration rate measurement ranges at least 0 to 100 bpm, minimum gradation 1 bpm.

8. Trend display of each parameter over at least previous 24 hours to be selectable.

9. TFT screen.

Settings	: User operated 1mV ECG test marker function required.
User's Interface	: Manual (touch screen or remote operated not mandatory).
Software and/ or standard of communication	: Audio Visual alarms required: high and low levels for each parameter (operator variable settings), sensor I wire I probe disconnected, low battery.

Physical Characteristics.

Dimensions (metric)	: Screen Size minimum 8" x 6".
Weight (lbs, Kg)	: 5 Kgs-7Kgs.
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.
Noise (in DBA)	: < 50DB.
Heat Dissipation	: Heat Dissipation Should maintains nominal Temp and the heat should be disbursed through exhaust cooling fan.
Mobility Portability	: Supplied in protective case for clean storage and safe transport.

Energy Source (Electricity, UPS, Solar, Gas, Water, CO_2).

Voltage (Value, AC or DC monophase or triphase)	: 220 to 240 Volts, 50 Hz.
Battery Operated	: Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit Battery powered, silence able alarm for power failure Internal,

	replaceable, rechargeable battery allows operation for at least one hour in the event of power failure.
Tolerance (to variations, shutdowns)	: Voltage corrector I stabilizer to allow operation at ± 30% of local rated voltage.
Protection	: Electrical protection provided by fuses in both live and neutral supply lines.
Power Consumptions	:
Other Energy Supplies	: Mains cable to be at least 3m length.

Accessories & Spare Parts, Consumables.

Accessories & Spare Parts	: 2 pairs, 12 lead ECG cable. 5 sets of ECG connection electrodes (If reusable type) of ECG connection electrodes (If disposable type). 5 lead ECG cable, Two reusable SPO2 probes for infant use, Two reusable neonatal cuffs, Two external skin temperature probes, Two sets of spare fuses (if non-resettable fuses used).
Consumables/ regents (Open, closed system)	: 5 tubes electrode gel (If required).

Environmental and Departmental Considerations.

Atmosphere/ Ambiance	: Operating Conditions.
Air Conditioning, Humidity	: Capable of operating continuously in ambient temperature of 0 to 50 dust) degree C and relative humidity of 15 to 90% in ideal circumstances.
User's Care, Cleaning	: The case is to be cleanable with alcohol or chlorine wipes.

Standards and Safety.

Certificates (Pre-market, sanitary) performance and safety standards (specific) the device type) Local and/ or international	: Should be FDA I CE approved product. Electrical safety conforms to standards for electrical safety IEC-60601-1. Shall meet IEC-60601- 1-2 (General requirements for to safety - electromagnetic compatibility).Also conform to IEC 60601-2-27 (Particular requirements for the safety of electrocardiographic monitoring equipment). Manufacturer I supplier should have ISO certificate for quality standard. Shall meet IEC 60601-2-49 multifunction patient monitoring equipment standard requirement.

Training and Installation.

Pre installation requirements natures	: Suppliers to perform installation, safety and operation checks before handover.
Tolerance.	

Warranty and Maintenance.

Warranty	: 03 Years.
Maintenance Tasks	: Maintenance manual detailing complete maintaining schedule.
Service contract Clauses including prices	: Warranty of 3 years with free servicing (min 3 years) during warranty.
Others	: The spare price list of all spares and accessories (including minor) required for maintenance and repairs in future after guarantee I warranty period should be attached.

Documentation.

Operating Manuals & Service Manuals	: Advanced maintenance tasks required shall be documented 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.
Other Accompanying	: List to be provided of important spares and *accessories*, with their part numbers and cost. Certificate of calibration and inspection to be provided.

Notes.

Other Information	: Any Contract (AMC/MC/add-hoc) to be declared by the manufacturer.
Recommendations or Warning	: Any recommendations for best use and supplementary warning for safety should be declared.

SYRINGE INFUSION PUMP 220-240 VOLTS, 50/60 HZ, 20ML & 50ML WITH FACILITIES FOR SWITCH ON, INFUSION RATE PURGE, TOTALIZER, STOP ALARAM, ALARM SILNCE

Name & Coding.

GMDN Name	: Syringe Pump.
GMDN Code	: CT 111
Definition	: A device 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. Because of the lower flow settings and flow resolution, it is especially appropriate for neonatal, infant, and critical care applications in which small volumes of concentrated drugs are to be delivered over an extended period. It can also be used to administer epidural analgesia.

General Use.

Clinical Purpose	: 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.
Used by clinical Department/ Ward	: Intensive Care Unit (ICU), Radiology Department, Orthopedics & Emergency.
Overview of functional	: A syringe containing medication is securely mounted on the drive arm. Alarms indicate if any error situations occur. The drive arm infuses the medication at a steady, programmed rate.

Technical Characteristics.

Clinical Performances	: 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. Preferably the unit should be of Bottom/side loaded to avoid accidental spilling of drugs and damage to the machine.
Technical Characteristics (specific to this type of Device)	: 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, 50 and 100 ml syringes

6. Accuracy of 12% 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 infuser 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. Single loadable with one syringe of minimum 20ml.

Settings	: Single loaded with one syringe of minimum 20ml.
User's Interface	: Automatic.
Software and/ or standard of communication	: Inbuilt.

Physical Characteristics.

Dimensions (metric)	: N/A.
Weight (lbs, Kg)	: N/A.
Configuration	: Tamper-resistant case made of impact resistant material securely mountable on tabletop, IV stand or bed fitting.
Noise (in DBA)	: Noise free.
Heat Dissipation	: Heat Dissipation Should maintains nominal Temp and the heat should be disbursed through exhaust cooling fan.
Mobility Portability	: Yes.

Energy Source (Electricity, UPS, Solar, Gas, Water, CO_2).

Voltage (Value, AC or DC monophase or triphase)	: 220 to 240 Volts, 50 Hz.
Battery Operated	: Internal rechargeable battery having at 4 to 6 hours backup for 10ml/hr flow rate with 50ml syringe.
Tolerance (to variations, shutdowns)	: 10%
Protection	: Battery powered alarm for power failure or disconnection.
Power Consumptions	: 25W
Other Energy Supplies	: N/A.

Accessories & Spare Parts, Consumables.

Accessories & Spare Parts	: Clamp for mounting pumps on IV stand.
Spare Parts (Main Ones)	: N/A.
Consumables/ regents (Open, closed system)	: Battery, syringe holder & PMO lines.
Others	: As applicable.

Environmental and Departmental Considerations.

Atmosphere/ Ambiance	: Operating Conditions.
Air Conditioning, Humidity	: Capable of operating continuously in ambient temperature of 0 to 50 dust) degree C and relative humidity of 15 to 90% in ideal circumstances.
User's Care, Cleaning	: Capable of cleaning with alcohol chlorine wipes.

Standards and Safety.

Certificates (Pre-market, sanitary) performance and safety standards (specific) electromagnetic compatibility) or international	: CE or FDA certified. Manufacturer/ supplier should have ISO 13485 certified for Quality standard. the device type) Local and/ safety - Electrical safety conforms to standards for Electrical safety IEC-60601-1, Class II shall meet IEC 6060-1-2 EMC standard requirements. Certified to IEC-60601—2-24 particular requirement for the safety of infusion pumps and controllers.

Training and Installation.

Pre installation requirements, natures Tolerance	: Suppliers to perform installation, safety and operation checks before handover.

Requirments for sign-off	: As per requirement.
Training of Staff (Medical, paramedical, technicians)	:Training of users in operation and basic maintenance shall be provided.
Others	: As applicable.

Warranty and Maintenance.

Warranty	: 03 Years.
Maintenance Tasks	: Advance maintenance and calibration tasks required shall be documented.
Service contract Clauses Including prices	: Local clinical staff to affirm completion of installation.
Others	: As applicable.

Documentation.

Operating Manuals & Service Manuals, Other manuals	: User, Technical Maintenance manuals to be supplied in English language. List to be provided of equipment and procedures required for local calibration and routine maintenance.
Other Accompanying	: List to be provided of important spares and *accessories*, with their part numbers and cost. Certificate of calibration and inspection to be provided.

Notes.

Other Information	: Contact details of manufacturer, supplier and local service agent to be provided.
Recommendations or Warning	: