



Biomedical Engineering Department
Indira Gandhi Memorial Hospital
Male', Republic of Maldives

Wall-Mounted Cardiac Monitor

1. Equipment Details

- **Equipment Name:** Wall-Mounted Cardiac Monitor
- **Category:** Fixed Patient Monitoring Equipment
- **Mounting Type:** Wall-mounted (fixed installation)
- **Applicable Patient Types:**
 - Adult
 - Pediatric
 - Neonatal

2. Intended Clinical Use

The wall-mounted cardiac monitor is intended for continuous monitoring of vital physiological parameters of adult, pediatric, and neonatal patients. The system shall be suitable for permanent wall installation near patient bedsides, providing real-time monitoring, trend review, event storage, and alarm notification.

3. General Functional Requirements

The cardiac monitor shall meet the following requirements:

- Designed for **fixed wall-mounted installation**
 - Easy to use and suitable for continuous bedside monitoring
 - Suitable for adult, pediatric, and neonatal patients
 - Dual power operation:
 - AC mains power
 - Built-in rechargeable internal battery (for short-term power interruption)
 - User-friendly graphical interface
 - Touch screen operation with rotating control switch
 - LCD display size range: **5.5 to 6 inches**
 - Capability to review:
 - Trends
 - Events
 - Stored data within the system
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4. Monitoring Parameters

The monitor shall be capable of measuring and displaying the following parameters:

- ECG: 3-lead and/or 5-lead
 - Heart Rate
 - Respiration (RESP)
 - Non-Invasive Blood Pressure (NIBP)
 - Invasive Blood Pressure (IBP)
 - Oxygen Saturation (SpO₂)
 - Temperature (TEMP)
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5. SpO₂ and Signal Performance

- Digital SpO₂ measurement
 - High resistance to interference from:
 - Electrosurgical units (ESU)
 - Patient motion
 - Low perfusion conditions
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6. Safety and Alarms

- Electrically isolated against defibrillation effects
 - Audible and visual alarms for all monitored parameters
 - Alarm prioritization and configurable alarm limits
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7. Data Storage and Printing

- Internal memory for:
 - Trend data
 - Event review
 - Patient records
 - Built-in thermal printer for waveform and report printing
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8. Power Requirements

Power Requirements: 220–240 V AC, 50–60 Hz; equipped with a 13-amp Type G plug.

- Built-in rechargeable battery for backup
- Minimum battery backup: **2 hours** at full charge

9. Wall-Mounting and Installation Requirements

- Supplied with **manufacturer-approved and supplied wall mounting bracket**
 - Secure fixing to hospital wall structure
 - Provision for:
 - Cable management
 - Easy access to connectors
 - Service and maintenance access
 - Monitor shall be easily detachable from mount for servicing, if required
 - Wall mount shall support safe load capacity with appropriate safety locking mechanism
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10. Accessories and Configuration

All accessories required for commissioning and normal operation shall be supplied, including but not limited to:

- ECG lead wires and electrodes
 - SpO₂ sensors and cables (Adult / Pediatric / Neonatal)
 - NIBP cable and cuffs (Adult / Pediatric / Neonatal)
 - Temperature probes
 - IBP cables and transducers
 - Wall mounting bracket and fixing accessories
 - Power cord and internal battery
 - Printer paper
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11. Training and Technical Support

- Certified biomedical engineering training shall be provided, covering:

- Preventive maintenance
 - Repair and troubleshooting
 - Technical operation in accordance with manufacturer standards
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12. Testing, Calibration, and Preventive Maintenance

- All necessary connector and adaptor cables shall be included
 - Preventive maintenance shall be performed during the warranty period, including:
 - Required spare parts
 - Maintenance documentation
 - Manufacturer-approved checklists
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13. Standards and Safety Compliance

The wall-mounted cardiac monitor shall comply with the following:

- CE and/or FDA approval
 - ISO standards
 - IEC standards (IEC 60601 series)
 - RTCA DO-160 standards (where applicable)
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14. Warranty

- Minimum warranty period: **12 months**
 - Warranty shall commence from the date of installation, commissioning, and handover
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15.Documentation

The supplier shall provide the following documentation in **English**:

- User manual
- Technical manual
- Maintenance manual
- Certificate of calibration
- Certificate of inspection

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Defibrillator

1. SYSTEM OVERVIEW

Equipment: Defibrillator with Monitor, AED, and External Pacing

Clinical Purpose:

The defibrillator is intended for emergency cardiac resuscitation by delivering controlled electrical shocks to restore normal heart rhythm. The system shall also provide continuous monitoring of vital parameters during resuscitation and critical care situations.

Clinical Application / Departments:

All Wards and Departments

2. DEFIBRILLATION & CARDIOVERSION

- **Technology:**
Low-energy **Bi-Phasic defibrillation** technology.
- **Operating Modes:**
 - Manual Defibrillation
 - AED Mode
 - Synchronized Cardioversion
- **Energy Output Range:**
Adjustable from **2 Joules to 200 Joules**.

- **Impedance Compensation:**
Automatic compensation for patient impedance in the range of **25–150 Ω** .
 - **Charging Time:**
Maximum energy charge time < **5 seconds**.
 - **Discharge Mode:**
Facility for safe internal discharge of stored energy.
 - **Paddles & Pads:**
Defibrillation via **adult and pediatric paddles** and adhesive multifunction pads.
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3. MONITORING & DISPLAY

- **ECG Monitoring:**
Continuous ECG monitoring via paddles, pads, or monitoring electrodes.
 - **Display:**
High-resolution color display $\geq$ **6.5 inches**.
 - **Waveform Capability:**
Minimum **4 simultaneous waveforms** with at least **4 seconds sweep**.
 - **Optional Monitoring Parameters:**
 - SpO₂
 - NIBP
 - EtCO₂
 - **Alarms:**
Audible and visual alarms for abnormal parameters, system faults, and battery status.
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4. NON-INVASIVE PACING

- **Pacing Modes:**

- Demand Mode
- Fixed Mode

- **Application:**

External non-invasive pacing via adhesive pads.

5. RECORDING & DATA MANAGEMENT

- **Printer:**

Built-in **50 mm thermal strip printer**.

- **Event Recording:**

Internal memory capable of storing **$\geq 50-60$ events**.

- **Reports:**

Printing of:

- Event summary
- Configuration settings
- Self-test results
- Battery capacity and status

- **Self-Test:**

Automatic self-test and system diagnostics at startup with optional printout.

6. USER INTERFACE

- **Controls:**
Combination of **Graphical User Interface (GUI)** and dedicated physical keys.
 - **Operation:**
Simple and intuitive interface suitable for emergency use.
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7. POWER SUPPLY & BATTERY

- **AC Input:**
220-240 V AC, 50 Hz. with 13A **Type G** plugtop provided
 - **Battery:**
Internal rechargeable battery providing ≥ 5 **hours** of monitoring operation.
 - **Battery Indicators:**
On-screen battery status and low-battery alarms.
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8. PHYSICAL CHARACTERISTICS

- **Design:**
Compact, portable, and shock-resistant construction.
 - **Weight:**
Lightweight; exact weight to be specified by manufacturer.
 - **Portability:**
Suitable for bedside, transport, and emergency use.
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9. ACCESSORIES & CONSUMABLES

Mandatory / Standard Accessories

- Defibrillator with AED and External Pacemaker – 1 unit
- Adult & Pediatric External Paddles – 1 set each
- Patient ECG Cables – 1 set
- ECG Thermal Rolls – 50 numbers
- Adult Reusable SpO₂ Sensor – 1 number
- AED Multifunction Pads (Adult) – 10 pairs

Optional Accessories

- Pediatric multifunction pads
 - Adult NIBP cuff and hose
 - Carry case or transport trolley
 - External battery pack
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10.CLEANING, DISINFECTION & SAFETY

- Patient-contact components shall be:
 - Easy to disinfect, or
 - Protected with disposable/single-use covers
 - Device housing shall be compatible with standard hospital-grade disinfectants.
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11.STANDARDS & CERTIFICATION

- **Quality Certification:** ISO 13485
 - **Regulatory Approval:** CE and/or FDA
 - **Electrical Safety:** IEC 60601-1
 - **EMC Compliance:** IEC 60601-1-2
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12.ENVIRONMENTAL CONDITIONS

- **Operating Temperature:** 5°C to 45°C
 - **Relative Humidity:** Up to 95% (non-condensing)
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13.TRAINING

- On-site user training for doctors, nurses, and paramedical staff.
 - Technical training for Biomedical Engineers covering:
 - Preventive maintenance
 - Troubleshooting
 - Safety checks
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14.WARRANTY & MAINTENANCE

- **Warranty:**
Minimum **12 months** from installation and commissioning.

- **Maintenance:**
Preventive maintenance schedule and checklist as per manufacturer standards.
 - **Spare Parts:**
Price list and availability of spares to be provided for post-warranty support.
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15.DOCUMENTATION

- User / Operating Manual (English) – Hard & Soft copy
 - Technical / Maintenance Manual (English)
 - Calibration Certificate and Inspection Report
 - Equipment diagrams and troubleshooting guides
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16.AFTER-SALES SUPPORT

- Manufacturer / Supplier / Local Service Agent contact details to be provided.
- Availability of spares and technical support for **minimum 5–6 years**.
- Any AMC / CMC / extended support contracts to be declared.



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Portable ECG Machine

1. Equipment Details

Equipment Name: ECG Machine

Category: Cardiology / Patient Monitoring Equipment

Patient Types:

- Adult
- Pediatric
- Neonatal

2. Intended Clinical Use

The ECG machine is intended for acquisition, display, analysis, and printing of electrocardiographic signals from adult, pediatric, and neonatal patients. It should provide real-time 12-lead ECG monitoring, arrhythmia detection, trend analysis, and PDF-based data storage to support clinical assessment and decision-making.

3. General Functional Requirements

The ECG machine shall meet the following requirements:

- Lightweight, portable, and easy to operate

- Dual power operation: AC mains and built-in rechargeable battery
 - User-friendly interface with touch screen operation
 - Capable of reviewing trends, events, and stored ECG data
 - **Highly resistant to electrical noise and interference**, including ESU and motion artifacts
 - Demonstration of monitor features, waveform interpretation, and analysis for users
 - Preventive maintenance training provided, including repair, troubleshooting, and documentation
 - Built-in self-test and fault diagnosis programs
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4. Technical Specifications

Signal Acquisition & Analysis:

- Simultaneous 12-lead ECG acquisition
- Automatic calibration signal injection and pacemaker detection
- **Frequency Response:** 0.05 – 150 Hz (within 3 dB)
- **Time Constant:** >3 seconds
- **Input Impedance:** >50 M Ω
- **Input Current:** 100 nA
- **A/D Conversion:** 24-bit
- **Sampling Frequency:** 1000 samples/sec per channel
- Filters: Line frequency, baseline, and muscle artifact filters

ECG Recording:

- 3 / 6 / 12-channel print formats
- Measurement table for all 12 leads
- Average complexes, marking, and interpretation statements
- **Modes:** Automatic and Manual
- **Printing:** High-resolution thermal printer
- Paper speed: 5 / 12.5 / 25 / 50 mm/s

Patient Safety:

- Fully floating and isolated patient inputs
- Defibrillation protected (Type CF)

Analysis & Storage:

- RR trend analysis
- Automatic interpretation and arrhythmia detection
- Built-in memory to store ≥ 800 ECG events in **PDF format**

5. Interface & Connectivity

- PC connectivity for PDF export with required software
- Direct connection to USB printers
- USB port for transfer to pen drives

- 8–6” color TFT LCD display with touch screen
 - Display formats: Real-time 3 / 6 / 12-lead ECG; full print preview
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6. Report Printing

- 3 / 6 / 12-lead ECG reports
 - Average / RR trend / arrhythmia / stress / tabular report
 - One-page A4 size Z-fold printing
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7. Standardization & Calibration

- Built-in standard ECG waveform for calibration
 - Self-maintenance program for fault diagnosis
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8. Accessories

- ECG cable: 10 electrodes IEC standard
 - Neonatal ECG bulb electrodes and clips (preferred)
 - All accessories required for immediate operation supplied
 - Manufacturer approved ECG cart
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9. Power Supply

- AC Line Voltage: 220–240 VAC
 - Frequency: 50–60 Hz
 - 13-Amp Type G plug
 - Built-in rechargeable battery for portable operation
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10. Standards, Certification, and Safety

- CE / FDA approved product
 - ISO certified
 - Compliance with IEC standards (IEC 60601 series)
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11. Training of Staff

- Biomedical engineering training for:
 - Preventive maintenance
 - Repair and troubleshooting
 - Technical operation according to manufacturer standards
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12. Warranty

- Minimum **12 months** from date of installation and commissioning

13.Documentation

- User, technical, and maintenance manuals in English (hardcopy and softcopy)
- Certificate of calibration and inspection
- Service and operation manuals including diagrams
- List of important spares and accessories with part numbers and cost

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