



Biomedical Engineering Department
Indira Gandhi Memorial Hospital
Male', Republic of Maldives
Electrocardiogram (ECG)
Technical Specification

1. System Overview

- **Equipment:** 12-Channel Diagnostic Electrocardiograph (ECG)
- **Clinical Purpose:** Acquisition, display, analysis, and digital storage of ECG signals for cardiac assessment.
- **Patient Population:** Adult, Pediatric, and Neonatal.
- **Clinical Areas:** ICU/CCU, Emergency Department, OT/Recovery, and General Wards.

2. General Functional Requirements

- **Design:** Lightweight, portable, and ergonomically designed for bedside use.
- **Interface:** User-friendly interface with a **High-Resolution Color Touch Screen (≥ 7 inches)**.
- **Workflow:** One-touch "Auto" mode for simultaneous 12-lead acquisition, analysis, and printing.
- Highly resistant to electrical noise/interference (ESU protected) and motion artifacts.
- **Self-Diagnostics:** Automatic built-in self-test and fault diagnosis at startup.

3. Technical Specifications

Signal Acquisition & Analysis

- **Leads:** Simultaneous 12-lead ECG acquisition.
- **Sampling Frequency:** Digital sampling rate of $\geq 8,000$ Hz for high-fidelity signal acquisition.
- **Frequency Response:** 0.05 Hz to ≥ 150 Hz.
- **Common Mode Rejection Ratio (CMRR):** ≥ 110 dB to ensure minimal interference from external bedside equipment.
- **Input Impedance:** ≥ 10 M Ω .
- **Pacemaker Detection:** Automatic detection and marking of pacemaker pulses in compliance with IEC standards.
- **Filters:** Comprehensive digital filters for Line Frequency (50/60Hz), Baseline Wander, and Muscle (EMG) Artifacts.

ECG Recording & Printing

- **Printer Type:** Built-in high-resolution thermal strip printer.
- **Print Formats:** User-selectable 3, 6, or 12-channel formats.

- **Paper Speed:** 5, 12.5, 25, and 50 mm/s.
- **Sensitivity:** ≤ 5 - ≥ 20 mm/mV.
- **Reports:** Automatic measurement table, average complexes, and interpretation statements.
- **(Optional) Z-Fold Support:** Support for A4-size Z-fold or roll paper for easy filing.

Analysis & Storage

- **Internal Memory:** Capacity to store $\geq 1,000$ ECG events in PDF or XML format.
- **Review Capability:** Full-disclosure review of the last 5–10 minutes of ECG data.
- **Interpretation:** Built-in algorithm for automatic interpretation and arrhythmia detection.
- **Trend Analysis:** Support for R-R interval trend analysis.

4. Interface & Connectivity

- **Networking:** Built-in **Wi-Fi** and **Ethernet (RJ45)** for data transmission to hospital servers.
- **Integration:** Support for **DICOM** and **HL7** protocols for seamless EMR/PACS integration.
- **Data Export:** USB ports for data transfer to pen drives or direct connection to external USB printers.

5. Power Supply & Battery

- **AC Input:** 220–240 V AC, 50–60 Hz with a 13A hospital-grade 3-pin plug.
- **Battery Type:** Internal rechargeable Lithium-Ion battery.
- **Performance:** Must support ≥ 2 hours of continuous monitoring or acquisition of ≥ 200 ECG reports on a single charge.
- **Status Indicator:** Clear on-screen battery level and charging status.

6. Accessories & Consumables

Standard Accessories (Supplied with Unit)

- **ECG Patient Cable:** 10-lead patient cable (IEC Standard) – 1 unit.
- **Adult Electrodes:** Set of 6 suction bulbs and 4 limb clips – 1 set.
- **Pediatric/Neonatal Electrodes:** 1 set of pediatric limb clips and 50 packs of disposable adhesive neonatal electrodes.
- **Mobile Trolley:** Dedicated transport cart with locking casters, cable hangers, and storage baskets.
- **Paper:** 50 rolls/packs of thermal ECG paper.
- **Conductive Gel:** 5 bottles of ECG transmission gel.

7. Standards, Certification & Safety

- **Patient Safety:** Fully floating and isolated inputs; **Type CF** defibrillation protection.
- **Regulatory:** CE (MDR) and/or FDA approved.
- **Electrical Safety:** Compliance with IEC 60601-1 and IEC 60601-2-25 (Safety of Electrocardiographs).
- **Quality:** Manufacturer must be ISO 13485 certified.

8. Training & Support

- **Clinical Training:** On-site training for doctors, nurses, and technicians on waveform interpretation and device operation.

- **Technical Training:** Full service training for Biomedical Engineers including preventive maintenance, troubleshooting, and calibration.
- **Warranty: Minimum 24 months** comprehensive warranty from the date of commissioning, including coverage for the patient cable.
- **Support:** Guaranteed availability of spare parts and technical support for a minimum of 5 years.

9. Documentation

- User and Service Manuals (English) provided in both Hard and Soft copies.
- Factory Calibration Certificate and Inspection Report.
- Detailed list of spare parts with part numbers and localized pricing.

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