



Biomedical Engineering Department
Indira Gandhi Memorial Hospital
Male', Republic of Maldives
Cardiac Monitor (Wall Mount)
Technical Specification

1. System Overview

Equipment: Multi-Parameter Bedside Patient Monitor

Intended Use: For continuous monitoring of physiological parameters of critically ill or high-dependency patients in hospital environments.

Patient Types: Adult, Pediatric, and Neonatal

Installation: Fixed wall-mounted configuration complete with manufacturer-approved mounting arm and accessory basket.

2. Functional Requirements

- High-resolution color TFT touch screen with a minimum display size of **12 inches**.
- Display resolution of **at least 1024 × 768 pixels**.
- Screen brightness of **at least 400 nits**, with adjustable brightness and optional automatic brightness control.
- Capable of displaying **a minimum of eight (8) simultaneous waveforms**.
- User-friendly graphical interface with both touch-screen operation and rotary knob navigation.
- Universal power supply: **100–240 VAC, 50/60 Hz**, supplied with a British Standard (Type G) power plug.
- Integrated rechargeable lithium-ion (or manufacturer specified alternate) battery providing **a minimum of four (2) hours** continuous operation.
- Automatic battery status indication with audible and visual low-battery alarms at **20% remaining capacity or below**.
- Fast system start-up and automatic recovery following power interruption.

3. Monitoring Parameters

ECG

- 3-lead and 5-lead ECG monitoring.
- Continuous Heart Rate and Respiration monitoring.
- 12-lead ECG acquisition (preferred).
- Heart rate measurement range suitable for Adult, Pediatric, and Neonatal patients.
- Full arrhythmia detection and analysis.
- ST-segment analysis.
- QT/QTc interval monitoring.
- Pacemaker pulse detection.
- Defibrillation-protected ECG input.

Respiration

- Impedance respiration monitoring.
- Adjustable apnea detection and apnea alarm.
- Configurable apnea delay.

SpO₂

- Digital SpO₂ technology resistant to patient motion and low perfusion.
- Measurement range: **0–100%**.
- Accuracy of **±2%** within the range of **70–100%**.
- Pulse Rate measurement.
- Plethysmographic waveform display.
- Perfusion Index (PI) display (preferred).

Non-Invasive Blood Pressure (NIBP)

- Oscillometric measurement technology.
- Adult, Pediatric, and Neonatal operating modes.
- Manual, Automatic, STAT, and Continuous measurement modes.
- Measurement accuracy of **±3 mmHg or better**.
- Simultaneous display of Systolic, Diastolic, Mean Arterial Pressure (MAP), and Pulse Rate.

Temperature

- Dual-channel temperature monitoring.
- Measurement range suitable for clinical use.
- Accuracy of **±0.1°C or better**.

Invasive Blood Pressure (IBP)

- Dual-channel invasive blood pressure monitoring.
- User-selectable pressure labels including ART, CVP, PAP, ICP, LAP, RAP and equivalent.
- Zero balancing and calibration functions.

4. Clinical Features

Alarm Management

- Three-level audible and visual alarm system compliant with **IEC 60601-1-8**.
- Dedicated 360° alarm indicator light visible from all directions.
- User-configurable alarm limits.
- Configurable alarm delay from **0–30 seconds**.
- Alarm pause and temporary alarm suspension with enforced time limits.
- Critical alarms shall not be permanently disabled.
- Separate physiological and technical alarms.
- Alarm history and event review.

Clinical Functions

- Night mode with reduced display brightness and alarm volume (optional).
- Automatic patient admission and discharge functions.

5. Data Management & Connectivity

- Storage of at least **120 hours** of graphical and tabular trend data.
- Storage of at least **1,000 NIBP measurements**.
- Alarm event storage and review.
- Waveform recall capability.

- Screenshot storage and export.
- USB data export.
- Built-in Ethernet (LAN) interface.
- Built-in Wi-Fi supporting **IEEE 802.11 a/b/g/n** or later.
- Compatible with Central Monitoring Systems.
- HL7 communication support.
- DICOM Modality Worklist support where applicable.
- Central monitor integration capability

Printer

- Integrated **50 mm (or manufacturer specified size)** thermal printer capable of printing at least three waveforms simultaneously.
- Real-time printing.
- Automatic alarm-triggered printing.
- Trend and report printing.

6. Accessories & Consumables

The monitor shall be supplied complete with all accessories necessary for immediate clinical operation, including but not limited to:

ECG

- One (1) reusable 5-lead ECG patient cable.
- One (1) reusable 3-lead transport cable.
- Starter pack of disposable ECG electrodes. (Minimum 150 pcs)

SpO₂

- One (1) reusable Adult sensor.
- One (1) reusable Pediatric sensor.
- One (1) reusable Neonatal sensor.

NIBP

- Adult Small cuff.
- Adult Medium cuff.
- Adult Large cuff.
- Adult Thigh cuff.
- Appropriate reusable hose(s).

Temperature

- Two (2) reusable temperature probes suitable for Adult and Pediatric patients.

IBP

- One (1) reusable invasive pressure cables.

Mounting

- Manufacturer-approved wall-mount arm with tilt, swivel, rotation, cable management, and accessory basket.

7. Standards, Certification & Safety

The equipment shall comply with the latest applicable versions of the following standards:

- ISO 13485 – Medical Devices – Quality Management Systems.
- CE Marking under EU MDR 2017/745 and/or FDA 510(k) clearance.
- IEC 60601-1 – General Requirements for Basic Safety and Essential Performance.
- IEC 60601-1-6 – Usability.
- IEC 60601-1-8 – Alarm Systems.
- IEC 60601-2-27 – Electrocardiographic Monitoring Equipment.
- IEC 60601-2-34 – Invasive Blood Pressure Monitoring.

- IEC 80601-2-30 – Non-Invasive Blood Pressure Monitoring.
- ISO 80601-2-61 – Pulse Oximetry Equipment.
- ISO 14971 – Application of Risk Management to Medical Devices.
- IEC 62366-1 – Usability Engineering.

Safety Requirements

- Defibrillation-proof CF applied parts.
- Protection against electrosurgical interference.
- Compliance with applicable EMC requirements.

Warranty

- Minimum **24 months comprehensive warranty** covering the monitor, accessories, sensors, cables, batteries, and printer.

Spare Parts

- Guaranteed availability of spare parts and consumables for a minimum of **five (5) years** after delivery.
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8. Training & Service Support

- Comprehensive on-site training for clinical users and Biomedical Engineering staff upon installation.
 - Complete User Manual, Service Manual, Technical Documentation, and Parts List supplied in English.
 - Biomedical-accessible service mode with diagnostic tools and documented error codes.
 - Software updates provided during the warranty period at no additional cost.
 - Availability of future software and hardware upgrades without replacement of the main monitor.
 - Local technical support with response time in accordance with supplier service agreement.
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9. Environmental & Operating Conditions

Operating Conditions

- Operating Temperature: **15°C to 40°C**
- Relative Humidity: **30–85%**, non-condensing

Storage Conditions

- Storage Temperature: **–20°C to 60°C**
- Storage Humidity: **10–95%**, non-condensing

Protection

- Minimum enclosure protection rating of **IP22** or better.
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End of Specification
