



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

Vital Signs Monitor

1. EQUIPMENT DETAILS

Equipment: Vital Signs Monitor

Clinical Purpose:

The vital signs monitor is intended for continuous and non-invasive monitoring of essential physiological parameters to support patient assessment, diagnosis, and clinical decision-making.

Clinical Application / Departments:

All Wards, ICU, HDU, Emergency Department, OPD, Recovery Rooms, and Transport Areas.

Patient Type:

Adult, Pediatric, and Neonatal (where applicable).

2. MONITORING PARAMETERS & PERFORMANCE

Heart Rate

- **Heart Rate Range:**
Minimum **30 to 250 bpm**.
- **Accuracy:**
Better than ± 5 bpm.
- **Resolution:**
Minimum **1 bpm**.

Temperature

- **Probe Type:**
Reusable, external skin-contact temperature probe.
- **Measurement Range:**
At least **20°C to 40°C**.
- **Resolution:**
Minimum **0.1°C**.
- **Accuracy:**
As per IEC standards for patient monitoring.

SpO₂ (Oxygen Saturation)

- **Measurement Range: 0–100%**
- **Accuracy:**
 - Better than ± 3 % in 70–80% range
 - Better than ± 2 % in 80–100% range
- **Resolution:**
Minimum **1%**.
- **Sensor Type:**
Reusable SpO₂ sensor (adult), pediatric/neonatal optional.

Non-Invasive Blood Pressure (NIBP)

- **Measurement Range:**
At least **30 to 300 mmHg**.
- **Resolution:**
Minimum **1 mmHg**.
- **Modes:**
Manual, Automatic, and STAT modes.
- **Cuffs:**
Adult cuff standard; pediatric and neonatal cuffs optional.

3. DISPLAY & USER INTERFACE

- **Screen Type:**
High-resolution **TFT color display**.
- **Screen Size:**
Suitable for clear bedside viewing.
- **User Interface:**
Intuitive menu-driven interface with touch keys or physical controls.

4. TRENDS, ALARMS & DATA

- **Trend Storage:**
Graphical and tabular trend display of all parameters for **at least the previous 24 hours**.

- **Alarms:**

- Visual and audible alarms for all monitored parameters
- Adjustable high and low alarm limits
- Alarm priority levels (high/medium/low)

- **Event Storage:**

Capability to store alarm and event data.

5. POWER SUPPLY & BATTERY

- **AC Power Input:**

220–240 V AC, 50–60 Hz, fitted with **13 Amp plug**.

- **Battery Backup:**

Internal rechargeable battery providing **minimum 2–4 hours** of continuous operation.

- **Battery Indicators:**

On-screen battery status and low-battery alarm.

6. PHYSICAL CHARACTERISTICS

- **Design:**

Compact, lightweight, and portable.

- **Mounting Options:**

Tabletop use with optional wall mount or mobile trolley.

- **Durability:**

Suitable for continuous clinical use and frequent cleaning.

7. ACCESSORIES (STANDARD & OPTIONAL)

Standard Accessories

- Adult reusable SpO₂ sensor
- Adult NIBP cuff and hose
- Reusable temperature probe
- Power cord with 13 Amp plug

Optional Accessories

- Pediatric and neonatal SpO₂ sensors
- Pediatric and neonatal NIBP cuffs
- Wall mount or trolley (**trolley preferred**)
- Central monitoring connectivity module (if supported)

7. CLEANING, DISINFECTION & SAFETY

- Patient-contact accessories must be reusable, autoclavable, or easy to disinfect.
- Device housing must be compatible with standard hospital-grade disinfectants.
- Electrical and patient safety protections against leakage currents and overload.

8. STANDARDS & CERTIFICATION

- **Regulatory Approval:** CE and/or FDA approved.
- **Quality Certification:** ISO 13485.
- **Electrical Safety:** IEC 60601-1.
- **EMC Compliance:** IEC 60601-1-2.
- **Monitoring Standard:** IEC 60601-2-49

9. DOCUMENTATION

- User / Operating Manual (English)
- Technical / Maintenance Manual (English)
- Certificate of Calibration and Inspection
- Preventive maintenance checklist

10. TRAINING

- On-site user training for nursing and clinical staff.
- Technical training for Biomedical Engineers covering operation, troubleshooting, and preventive maintenance.

11. WARRANTY & SUPPORT

- **Warranty:**
Minimum **12 months** from date of installation and commissioning.
- **Support:**
Availability of spare parts and service support for a minimum of **5 years**.