



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

**PORTABLE NON-INVASIVE VENTILATOR SYSTEM
Technical Specification**

1. General Requirements

The ventilator shall be a lightweight, portable, turbine-driven non-invasive ventilation (NIV) system intended for adult and pediatric patients who have spontaneous breathing but require mechanical ventilatory support. The device shall be suitable for use across urgent, acute, and alternative care environments, including in-hospital transport.

1.1 Patient Category

- Adult and pediatric patients with spontaneous breathing requiring non-invasive ventilation
- Minimum patient weight: 12.5 kg
- Minimum supported tidal volume: 100 mL

1.2 Gas Supply

Oxygen (O₂) Supply	
High Pressure Input	>35 psi / 2.4 bar Flow: ≤200 L/min
Low Pressure Input	≤ 11 psi / 0.75 bar Flow: ≤12 L/min
Air Supply	
Air Source	Integrated turbine blower

1.3 Display

Display Size	≥12-inch colour LCD
---------------------	---------------------

1.4 General Features

- Adaptive triggering and cycling to accommodate changing patient conditions
- Configurable apnea backup ventilation
- Dual HEPA filter protection for patient circuit and internal components
- Hot-swappable main battery for uninterrupted operation
- Internal backup battery for continuous operation during power transitions

- 72 hours of full-disclosure clinical data storage
- Suitable for in-hospital transport
- Automatic detection of CO₂ and SpO₂ monitoring accessories via smart cable interface

2. Ventilation & Oxygen Modes

The ventilator shall provide the following modes:

SPONT-PS	Continuous positive airway pressure with pressure support (spontaneous breathing)
S/T	Spontaneous mode with timed backup (bilevel)
PCV	Pressure control ventilation
PRVC	Pressure regulated volume control ventilation
PPV	Proportional pressure support ventilation
O₂ Therapy	High flow oxygen therapy

3. Monitored Parameters

4.1 Waveform Display

Airway Pressure (Paw)	-5 to 60 cmH ₂ O
Flow	-200 to +200 L/min
Volume	-50 to 3,500 mL
CO₂ Waveform (Capnogram)	0 to 150 mmHg

3.1 Numeric Monitoring Data

Pressure	
Peak Inspiratory Pressure (PIP)	0 to 99.9 cmH ₂ O
PEEP	0 to 99.9 cmH ₂ O
Flow	
Peak Inspiratory Flow	0.0 to 200.0 L/min
Peak Expiratory Flow	-200.0 to 0.0 L/min
O₂ Gas Usage	0 to 99 L/min
Flow Rate	0 to 99 L/min

Volume	
Inspiratory Tidal Volume (VTI)	0 to 3,500 mL
Expiratory Tidal Volume (VT)	0 to 3,500 mL
VT per Body Weight (VT/kg)	0.0 to 50.0 mL/kg
Minute Volume	
Total Inspiratory Minute Volume	0 to 99.9 L/min
Spontaneous Inspiratory Minute Volume	0 to 99.9 L/min
Total Expiratory Minute Volume	0 to 99.9 L/min
Spontaneous Expiratory Minute Volume	0 to 99.9 L/min
Rate & Timing	
Total Respiratory Rate (RR TOT)	0 to 150 /min
Spontaneous Respiratory Rate (RR SPONT)	0 to 150 /min
Inspiratory Duty Cycle (TI/TTOT)	0 to 90%
I:E Ratio	0.0 to 99.9
Inspiratory Time (TI)	0.00 to 99.99 s
Expiratory Time (TE)	0.00 to 99.99 s
Leak	
Total Leakage Flow	0 to 200 L/min
Patient Leakage Flow	0 to 200 L/min
Leakage Volume Ratio (Leak%)	0 to 100%
Spontaneous Breathing Ratio (Pt. Trig)	0 to 100%
Gas Monitoring	
FiO ₂	15 to 100%
SpO ₂	70 to 100% (nominal) 0 to 100% (display range)

Pulse Rate (PR)	30 to 300 /min
Perfusion Index (PI)	0.00 to 99.99%
Inspiratory CO₂	0.0 to 150.0 mmHg
Expiratory CO₂	0.0 to 150.0 mmHg
CO₂ Respiratory Rate	0 to 150 /min

4. Alarm System

4.1 Adjustable Alarms

PIP, High	6 to 50 cmH ₂ O
PIP, Low	OFF, 4 to 39 cmH ₂ O
PEEP, High	EPAP/CPAP setting + 5 cmH ₂ O
PEEP, Low	EPAP/CPAP – 3 cmH ₂ O (≤5), – 4 cmH ₂ O (6–11), – 5 cmH ₂ O (≥12)
Minute Volume, High	0.2 to 30.0 L/min, OFF
Minute Volume, Low	OFF, 0.1 to 29.9 L/min
Tidal Volume, High	10 to 3,500 mL, OFF
Tidal Volume, Low	OFF, 5 to 3,495 mL
Respiratory Rate, High	2 to 150 /min, OFF
Respiratory Rate, Low	OFF, 0 to 149 /min
Apnea	5 to 60 seconds
FiO₂, High (high-pressure O₂)	FiO ₂ setting + 7%
FiO₂, High (low-pressure O₂)	22 to 100%, OFF
FiO₂, Low	18 to 99%
SpO₂, High	51 to 100%, OFF
SpO₂, Low	OFF, 50 to 99%
Pulse Rate, High	31 to 300 /min, OFF
Pulse Rate, Low	OFF, 30 to 299 /min
EtCO₂, High	2 to 99 mmHg, OFF
EtCO₂, Low	OFF, 1 to 98 mmHg
FiCO₂, High	1 to 99 mmHg, OFF

CO₂ Respiratory Rate, High	2 to 150 /min, OFF
CO₂ Respiratory Rate, Low	OFF, 0 to 149 /min
Apnea (CO₂)	5 to 40 sec, OFF

5. Data Management

Event Logs	Alarm and operation logs: ≥10,000 entries
Trend Data Storage	≥48 hours of trend graphs and trend lists

6. Electrical & Power

Mains Power	220 to 240 V AC, 50Hz
Main Battery	Li-ion, 14.4 V Run time: ≥4 hours (fully charged) Hot-swappable
Backup Battery	Rechargeable NiMH, 12 V Run time: ≥1 hour
Total Battery Run Time	Up to 5 hours (main + backup combined)
Plug Type	13 Amp hospital-grade Type G

7. Standards, Certification & Safety

The ventilator shall comply with the following standards and hold the indicated regulatory approvals:

General Safety	IEC 60601-1
Electromagnetic Compatibility	IEC 60601-1-2
NIV / Critical Care Ventilators	ISO 80601-2-12 or equivalent NIV-specific standard
Alarm Systems	IEC 60601-1-8
Ingress Protection	Minimum IP21
Regulatory Approvals	CE Mark (Notified Body) and/or US FDA Clearance
Quality Management	Manufacturer certified to ISO 13485

8. Optional Accessories & Features

- Rechargeable Lithium-Ion Battery
- Battery Pack
- Galvanic Oxygen Sensor, 1 piece per box
- Oxygen Hose – ISO to British / US Standard Connector
- Mobile Equipment Cart (Medium Size)
- Two-Section Support Arm
- Single-Limb Breathing Circuit with Expiratory Valve, 10 pieces per box
- Non-Invasive Ventilation (NIV) Mask Set – Medium Size , 3 pcs
- Non-Invasive Ventilation (NIV) Mask Set – Small Size , 3 pcs
- Rail Hook
- IV Pole (if available)

9. Warranty & Documentation

9.1 Warranty and Support

- Minimum 12 months comprehensive warranty from date of installation and commissioning
- Availability of spare parts and service support for a minimum of 5 years.

9.2 Required Documentation (in English)

- User Manual
- Technical / Service Manual
- Maintenance Manual
- Calibration and inspection certificate
- Recommended preventive maintenance schedule

10. Training

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