Indira Gandhi Memorial Hospital

Male', Republic of Maldives

Biomedical Engineering Department

Technical Specification for Equipment

Equipment: BIPAP MACHINE

Clinical Usage:

Non-invasive ventilation (NIV) is a recommended and preferred method of ventilation for critically ill patients. NIV is delivered through Bi-level Positive Airway Pressure machines, (BiPAP). BiPAP machines use pressure to push air into the lungs and enhance gas exchange and ventilation. BiPAP machines has different modes that are used for patients depending on their condition.

Technical Specifications

Setting/parameters:

- Ventilation modes - CPAP, Spontaneous(S), timed(T), Spontaneous Timed (ST), PAC/PC (Pressure Assisted Control/Pressure Control), Intelligent Volume Assured Pressure Support (iVAPS).
- IPAP: approx. 2 to 40 cmH2O.
- EPAP: approx. 2 to 25cmH2O.
- CPAP: 4 to 20 cmH2O
- Intended tidal volume range: 50-2500ml.
- Breath rate: approx.0 to 30BPM with spontaneous for time mode.
- Timed inspiration: approx. 0.3 to 3.0s.
- Rise Time: 1 - 9
- Inspiratory trigger: 1 – 9
- Expiratory trigger: 1 – 9
- Target volume: 100 – 1500 ml
- Ramp up: off, 10 – 60 min
- Ramp down: off, 10 – 60 min
- Humidifier: off, Level 1 – 5
- Heated wire: off, Level 1 – 5
- Maximum single fault voltage : 60cm H2O(in all modes)
- Maximum flow : >200L/min at 20cm H2O
- Air outlet : 0.9" (22 mm) taper, compatible with ISO 5356-1 Anaesthetic & Respiratory Equipment - Conical Connectors
- Pressure measurement : Internally mounted pressure transducer
- Flow measurement : Internally mounted flow transducer
- [illegible] 18% to 100

- Pulse rate measurement Range: 40 bpm to 240 bpm, Resolution: 1 bpm

Other features:

- Real-time display – LCD display - LCD screen Dimension: (L x W x H): 3" x 2.5" x 0.1" (76.9 mm x 63.9 mm x 3.15 mm) Resolution: 320 x 240 pixels)
- Displayed Data:
    - Ppeak
    - EPAP
    - Leakage
    - Patient breathing parameters such as breath rate, I/E ratio, minute volume and tidal volume, Insp Time, Rise Time
    - Alarms
- Alarms: Must have fixed and adjustable alarms.
- Should have Integrated heated humidification system without requiring a separate hose or power cord.
- BIPAP (Bi-level Positive Airway Pressure) should be complete unit with all standard accessories.
    - BiPAP machine
    - Charger
    - Humidifier
    - Bipap Tube
    - Mask with Belt (clips if any)
- The device should offer patented flow rounding technology, which further enhances comfort by allowing for adjustment of transitions in and out of ipap and epap.
- Should be customizable and the sensitivity of the trigger should be adjustable
- Should have ramp function to lower the pressure at initial phase and slowly increase to allow pressure.
- Should have automatic leakage compensation
- Should have low noise level less than or equivalent to 30dBA.
- Should provide with carry bag.
- The product offered shall be designed to be stored and to operate normally under the conditions of the purchaser's country. The conditions include Power Supply, Climate, Temperature, Humidity, etc.
- Should have Auto Switching universal Power supply of: 100 – 240 VAC, 50Hzto 60Hz and must be operated from 12 V DC source.
- Dimensions: approximately or less than (L x W x H) 9.1" x 6.7" x 4.7" (230 mm x 170 mm x 120 mm)
- Weight : approximately or less than 4.6 lb (2.1 kg)

- External DC power supply : (isolated) either 12 0r 24 V
- Internal battery : Lithium-Ion battery, 14.4 V, 2.75 Ah, 40 Wh
- Operating hours: >3 h with a new battery under normal conditions
- Adaptable for adult and Paediatrics (>10kg)

Operating Environment

- The product offered shall be designed to be stored and to operate normally under the conditions of the purchaser's country. The conditions include Power Supply, Climate, Temperature, Humidity, etc.

Standards and Safety Requirements

- Must submit ISO13485:2003/AC:2007 for Medical Devices **AND**
- CE (93/42 EEC Directives) or USFDA approved product certificate.
- Electrical safety conforms to standards for electrical safety IEC 60601-1 General requirement for Electrical safety of Medical Equipment.

User Training

- Must provide user training (including how to use and maintain the equipment).

Warranty

- Comprehensive warranty for > 2 years after acceptance.
- During warranty period supplier must ensure corrective/breakdown maintenance whenever required.
- Supplier must accomplish proper commissioning of equipment onsite.

Documentation

- User (Operating) manual in English.
- Service (Technical / Maintenance) manual in English.
- List of important spare parts and accessories with their part numbers and costing.
- Certificate of calibration and inspection from factory