

# Equipment Specifications for Ventilator-High End (I.C.U)

UNSPSC Code: 42272205

ECRI Code: 17-429

## 1 Description of Function

SI	Name		
1.1	ICU ventilators provide artificial respiratory support to the critical patients in the Intensive Care Units.		

## 2 Operational Requirements

SI	Name		
2.1	Microprocessor Controlled ventilator with integrated facility for Ventilation monitoring suitable for New born to adult ventilation.		
2.2	Demonstration of the equipment is a must.		

## 3 Technical Specifications

SI	Name		
3.1	Standard hinged arm holder for holding the circuit		
3.2	Colored TFT screen, 12 Inch or more		
3.3	Facility to measure and display a) End tidal CO2 with capnography. b) 3 waves- Pressure and Time, Volume and Time and Flow and Time. c) 3 loops- P-V, F-V, P-F with facility of saving of 3 Loops for reference. d) Graphic display to have automatic scaling facility for waves e) Status indicator for Ventilator mode, Battery life, patient data, alarm settings, clock etc		
3.4	Trending facility for 72 hours with minimum 5 minutes resolution for recent 24 hours		
3.5	Automatic compliance & Leakage compensation for circuit and ET tube		
3.6	Following settings for all age groups. a) Tidal Volume b) Pressure (insp) c) Pressure Ramp d) Respiratory Rate e) SIMV Respiratory Rate f) CPAP/PEEP g) Pressure support h) FIO2 i) Pause Time j) Pressure & Flow Trigger		
3.7	Monitoring of the following parameters a) Airway Pressure (Peak & Mean) b) Tidal volume (Inspired & Expired) c) Minute volume (Inspired and Expired)		

	<ul style="list-style-type: none"> <li>d) Spontaneous Minute Volume</li> <li>e) Total Frequency</li> <li>f) FIO2 dynamic</li> <li>g) Intrinsic PEEP and PEEPi Volume</li> <li>h) Plateau Pressure</li> <li>i) Resistance &amp; Compliance</li> <li>j) Use selector Alarms for all measured &amp; monitored parameters</li> </ul>		
3.8	<ul style="list-style-type: none"> <li>Modes of ventilation</li> <li>a) Volume controlled</li> <li>b) Pressure Controlled</li> <li>c) Pressure Support</li> <li>d) SIMV (Pressure Control and volume control) with pressure support</li> <li>e) CPAP/PEEP</li> <li>f) Inverse Ratio Ventilation</li> <li>g) Advanced mode like pressure controlled volume guaranteed</li> <li>h) Non Invasive ventilation</li> <li>i) APRV</li> </ul>		
3.9	Apnea /backup ventilation		
3.10	Expiratory block should be autoclavable and no routine calibration required		
3.11	<ul style="list-style-type: none"> <li>Should have the ability to calculate / Procedure</li> <li>a. Intrinsic Peep &amp; Intrinsic PEEP Volume</li> <li>b. Occlusion Pressure</li> <li>c. Spontaneous Breathing trial</li> <li>d. Facility to calculate lower and upper inflection point</li> </ul>		
3.12	Nebuliser with capability to deliver particle size of < 3 micron & to be used in both Off and On line		
3.13	Automatic Patient Detection facility preferable		
3.14	<ul style="list-style-type: none"> <li>Medical Air Compressor. (Optional)</li> <li>a) Stand-alone Medical Air compressor</li> <li>b) Snap fit with the Ventilator module to provide an oil free Medical air.</li> <li>c) Peak output flow should be minimum 160 LPM.</li> <li>d) Air quality should comply with ISO compressed air purity class.</li> <li>e) Medical Air Compressor should automatically activate in the event of wall air supply loss.</li> <li>f) Replacement of internal filters should be performed without removing the compressor</li> <li>g) Should have washable air filter.</li> </ul>		
3.15	<ul style="list-style-type: none"> <li>Technical Specifications for reusable face mask &amp; nasal mask.</li> <li>Reusable face &amp; nasal mask with textured dual flap silicone cushion flap for easy fit.</li> <li>Removable forehead support and pad to match the angle of patient's forehead</li> <li>Stability Selector for easy fit and angle.</li> <li>Ball &amp; Socket headgear attachments.</li> <li>Should be autoclavable.</li> </ul>		
3.16	Battery back up for minimum 1 hour		
3.17	RS 323C interface for communications with networked devices.		
3.18	Automatic patient detection facility preferable.		

#### 4 System Configuration Accessories, spares and consumables

SI	Name		
4.1	ICU Ventilator - 01		
4.2	Adult and Paediatric autoclavable silicone breathing circuits – 02 each		
4.3	(a) Reusable Masks (Small, Medium, Large) with each machine. - 02 sets each  (b) All Accessories for non invasive ventilation – 2 sets		
4.4	Medical Air Compressor. (Optional)		
4.5	Humidifier -Servo controlled with digital monitoring of inspired gas temperature complete with heating wire - 02		
4.6	Filter paper for humidifier for 100 uses - 01		

#### 5 Environmental factors

SI	Name		
5.1	The unit shall be capable of being stored continuously in ambient temperature of 0 -50 deg C and relative humidity of 15-90%		
5.2	Shall meet IEC-60601-1-2: 2001(Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility.		
5.3	The unit shall be capable of operating continuously in ambient temperature of 10 - 40deg C and relative humidity of 15-90%		

#### 6 Power Supply

SI	Name		
6.1	Power input to be 220-240VAC, 50Hz		
6.2	Suitable Servo controlled Stabilizer/CVT		
6.3	Resettable overcurrent breaker shall be fitted for protection		
6.4	Suitable UPS with maintenance free batteries for minimum one-hour back up should be supplied with the system.		

#### 7 Standards, Safety and Training

SI	Name		
7.1	Certified to be compliant with ANS/IEC60601.2.12-01 Medical Electrical Equipment—Part 2-12; Particular Requirements for the Safety of Lung Ventilators—Critical Care Ventilators		
7.2	Should be FDA or CE approved product		
7.3	Certified to be compliant with ISO-7767 for Oxygen monitoring.		
7.4	Should meet IEC 529 Level 3 (IP3X)(spraying water) for enclosure protection, water ingress.		
7.5	Demonstration of quoted equipment model is a must.		
7.6	Should have local service facility .The service provider should have the necessary equipments recommended by the		

	manufacturer to carry out preventive maintenance test as per guidelines provided in the service/maintenance manual.		
7.7	Comprehensive warranty for 5 years and provision of AMC for next 5 years.		
7.8	Back to back warranty to be taken by the supplier from the principal to supply spares for a minimum period 10 years.		

## 8 Documentation

SI	Name		
8.1	Certificate of calibration and inspection from factory.		
8.2	List of Equipments available for providing calibration and routine maintenance support as per manufacturer documentation in service / technical manual.		
8.3	User Manual in English		
8.4	Service manual in English		
8.5	Log book with instructions for daily, weekly, monthly and quarterly maintenance checklist. The job description of the hospital technician and company service engineer should be clearly spelt out.		
8.6	List of important spare parts and accessories with their part number and costing.		
8.7	Compliance Report to be submitted in a tabulated and point wise manner clearly mentioning the page/para number of original catalogue/data sheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered.		
8.8	Must submit user list and performance report within last 5 years from major hospitals.		
8.9	Back to back comprehensive warranty to be taken by the supplier from the principal to supply spares for minimum 10 years.		