Technical Specification of Ventilator, ICU (Paediatric to Adult)

S.N.	Purchaser's Specifications	Bidder's offer
	Ventilator, ICU (Infant to Adult)	
	Manufacturer	
	Brand	
	Type / Model	
	Country of Origin	
1	**Description of Function**	
1.1	The ventilator should be suitable for use in Adult and Paediatric patients in all critical care areas with selection between adult and paediatric modes or patient hoses	
2	**Operational Requirements**	
2.1	Microprocessor Controlled ventilator with integrated facility for ventilation monitoring suitable for paediatric to adult ventilation.	
3	**System Configurations**	
3.1	Electrically Controlled turbine ventilator capable of ventilating paediatric to adult patients with dedicated modes of Invasive and non-invasive ventilation and with inbuilt nebulization, complete unit with all standard accessories.	
4	**Technical Specifications**	
4.1	Should have a Built in High pressure Inlet for Oxygen Source. Each high-pressure input ports should have a filter and water trap	
4.2	Should have possibility for using external low-pressure oxygen as source	
4.3	Colour touch screen of 10" or more.	
4.4	Automatic compliance & leakage compensation for circuit and ET tube.	
4.5	Display parameters: • End tidal CO2 with capnography. • 3 Waves: Pressure & Time, Volume & Time and Flow & Time. • 3 Loops: P-V, F-V, P-F with facility of saving of 3 loops for reference. • FiO2. • Airway pressures (peak, plateau mean and PEEP) • Tidal volume (inspired and expired). • Minute volume (inspired and expired) • I:E ratio • Respiration Rate (spontaneous and mechanical) • Status indicator for ventilator mode, battery life, patient data, alarm settings, clock etc • Display easily readable in low ambient light and sunlight.	
4.6	Must have following settings for all age groups (paediatric to adult): • Tidal Volume at least 20 to 2000ml. • Pressure setting : 0–40 cmH2O • Respiratory rate: 10- 60 breaths per minute. • Internal PEEP range: 0-20cmH2O minimum • FiO2: 21-100% • I:E inverse ratio • I:E Ratio: 1:10 to 4:1 • Inspiratory pause manoeuvre capability to measure plateau pressure; • Peak pressure limitation/pressure-cycling mechanism above measured peak pressure	
4.7	Alarms: should have audio visual alarms for • High/low tidal volume (not achieved or exceeded); • High/low FiO2	

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	• High/low inspiratory pressure and PEEP • Apnoea, • High/low respiratory rate; • Continuously high pressure/occlusion; • Breathing circuit disconnect • Low minute volume • Gas supply failure; • Power failure and low battery • self-diagnostics failure alarm	
4.8	Should have following modes of ventilation: • Volume control ventilation (VCV) • Pressure control ventilation (PCV) • Pressure support ventilation (PSV) • Non-Invasive ventilation (CPAP and BIPAP) • Pressure regulated volume control (PRVC) or equivalent • Synchronized intermittent mandatory ventilation (SIMV)	
4.9	Shall have apnoea /backup ventilation	
4.10	Shall have automatic patient detection facility.	
4.11	Event log for errors traceability	
4.12	Trending facility for 72 hours with minimum 5 minutes resolution for recent 24 hours	
4.13	At least IP21 degree of protection to harmful ingress of water	
4.14	Shall have built-in rechargeable battery with battery operating mode with standard ventilation not less than 3 hour	
4.15	Total recharging time not greater than 6 hours	
4.16	RS 232 interface or equivalent for communications with networked devices.	
5	**Accessories, spares and consumables**	
5.1	**Consumables** • Breathing circuits for adult and paediatric: double-limb with standard outlet/inlet connectors with 22mm outside diameter with double water traps: 10 nos each • Exhaled gas filter: 10 nos • Heat moisture exchanger filters (HMEF): 10 nos • Viral/Bacterial filters of minimum efficiency 99.97% of all 0.3 microns particles; inspiratory and expiratory: 10 nos each • Non-invasive ventilation masks of medium and large sizes for both adult and pediatrics: 10 nos • Filter paper for humidifier for 50 uses • T-piece connector: 10 nos	
5.2	**Reusable:** • Beathing circuits for paediatric and adult: reusable, autoclavable double-limb with standard outlet/inlet connecters with 22mm outside diameter with double water traps: 2 each • Active humidifier with relevant connectors and humidifier bracket: 1 nos • Expiratory housing with in-built bacteria filters; as well as the possibility to accommodate heat moisture exchanger (HMEs) • CO2 sensors: 1 no • Exhalation valve • Standards hoses and connectors for oxygen and medical air wall outlets and cylinders • Pressure regulators (from wall outlet to ventilator) to avoid damaging ventilator as required to operate: 1 no	

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	• Reusable Masks (Medium, and Large) with textured dual flap silicone cushion flap for easy fit: 2 each • Removable forehead support and pad to match the angle of patient's forehead. • Silicone test lung adult and child size: 01 set each • Flow sensors: 1 no • in-built nebulizer, autoclavable: 1 no • O2 cell with O-ring: 1no	
5.3	Non corrosive imported trolley with wheels & brakes and hinged arm: 01 no.	
5.4	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer. Bidders must specify the quantity of every item included in their offer (including items not specified above).	
6	**Operating Environment**	
6.1	The system 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.	
6.2	Power supply: 220 – 240V AC, 50-60Hz fitted with appropriate plug. The power cable must be at least 3 metre in length.	
7	**Standards and Safety Requirements**	
7.1	Must submit ISO13485:2003/AC:2007 for Medical Devices **AND**	
7.2	CE (93/42 EEC Directives) and USFDA approved product certificate.	
7.3	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.	
8	**User Training**	
8.1	Must provide user training (including how to use and maintain the equipment).	
9	**Warranty**	
9.1	Comprehensive warranty for 2 years after acceptance.	
10	**Maintenance Service During Warranty Period**	
10.1	During the warranty period supplier must ensure preventive maintenance and corrective/breakdown maintenance whenever required.	
11	**Installation and Commissioning**	
11.1	The bidder must arrange for the equipment to be installed and commissioned by certified or qualified personnel; any prerequisites for installation to be communicated to the purchaser in advance, in detail.	
12	**Documentation**	
12.1	User (Operating) manual in English.	
12.2	Service (Technical / Maintenance) manual in English.	
12.3	List of important spare parts and accessories with their part numbers and costing.	
12.4	Certificate of calibration and inspection from factory.	

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