Annexure A

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1. Intensive Care Ventilator(Neonatal & Pediatrics)

Sr. No.	Description of Technical Specification
1	**Clinical purpose** - To provide automated, alveolar ventilatory support for patients in emergency situations.
1.2	**Used by clinical department/** Emergency/Critical Care (NICU/PICU) **ward**
2.1	**Technical characteristics (specific to this type of device)**
1)	Should have facility for Invasive and Non-Invasive ventilation;
2)	Microprocessor Control suitable for Neonatal and Pediatric ventilation;
3)	Should have modes of ventilation equipped with newer modes of ventilation:
3.1)	Assist/ Control
3.2)	Volume control
3.3)	Pressure control
3.4)	Pressure support
3.5)	SIMV with pressure support (Pressure and volime control)
3.6)	PEEP
3.7)	Inverse ratio Ventilation
3.8	Non invasive ventilation-BIPAP, CPAP
3.9)	Apnea ventilation, user selectable, volume & pressure control;
4)	Should have built in color screen TFT/LCD display of minimum 8" for display of waveforms and monitored value;
5)	Should have inbuilt facility to upgrade with EtcO2;
6)	Should have facility to measure and display of the following parameters:
6.1	Airway Pressure (Peak & Mean)
6.2	Tidal volume (Inspired & Expired)
6.3	Minute volume (Inspired & Expired)
6.4	Respiratory mechanics
6.5)	Spontaneous Minute Volume
6.6)	Total Frequency
6.7)	FiO2 dynamic
6.8)	Intrinsic PEEP
6.9)	Plateau Pressure
6.10)	Resistance & Compliance
6.11)	Use selector Alarms for all measured & monitored parameters
6.12)	Occlusion Pressure
6.13)	Pressure Flow & Volume curves;
7)	Automatic compliance and leakage compensation for circuit and ET tube;
8)	Should have Inbuilt Nebulizer facility.
9)	Should have facility of log book, for events and alarms with date & time;
10	Should have inbuilt or integrated compressor of same manufacture.
11	Should have servo controlled humidifier with neonatal chamber with heated wire.
12	Should have functional on single power plug or through extension cord
13	Should have following setting;
13.1)	Tidal volume (Minimum 2ml, Maximum up to 300ml); pre-set range for both neo-natal & pediatic modes to be provided
13.2)	Inspiratory pressure (upto 60cm of H2O);
13.3)	Respiratory rate 1 to 150 bpm;

13.4)	Apnea back up rate;
13.5)	CPAP/PEEP;
13.6)	Pressure support;
13.7)	FiO2 setting range between 21% and 100%;
13.8)	Pause time;
13.9)	Pressure/flow Trigger;
13.10)	Inspiratory flow up to 120 Lpm;
14	Oxygen cylinder/central pipeline connector/(to be supplied along with the machines) should be compatible with ventilator;
15	Automatic alarms :
15.1	Power failure
15.2	Circuit disconnection
15.3	Tube obstructed
15.4	High / Low minute volume
15.5	High /low pressure
15.6	High rate
15.7	High / low tidal volume
15. 8	Apnea alarm time
15.8	Gas failure
15.9	Patient disconnection
15.10	Low and high FiO2
15.11	Should have the facility to suspend the oxygen alarm indefinitely when oxygen cell is depleted or defective.
.16	**User's interface**- Manual and Automatic
17	**Software and/or standard of communication(where ever required)-**
17.1	Inbuilt software;
17.2	Convenient and quick USB interface;
18	**PHYSICAL CHARACTERISTICS**
18.1	**Dimensions (metric)- NA**
18.2	Should have imported trolley
18.3	**Configuration- 1.** Same manufacturer hunged arm for holding the circuit; 2. Should have caster with braking system;
19	**Noise (in dBA), heat dissipation-**
19.1	Noise of device operation max- 50dbA;
19.2	Should have audio visual alarm for battery low, source gas low and high/ low pressure in the breathing circuit or source gas inlet;
19.3	Should maintain nominal Temp of the control unit and the heat should be disbursed through an cooling mechanism;
19.4	Alarm volume - min. 65dB
20	**Mobility, portability- Yes**
21	**Power Requirements-** Input voltage 220 VAC, 50Hz;
22	**Battery operated- 1.** Battery powered, silence able alarm for power failure.
22.1	2)Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit.
22.2	3)Internal, replaceable, rechargeable battery allows operation for at least one hour in the event of power failure
23	**Tolerance (to variations, shutdowns)-** Voltage corrector / stabilizer to allow operation at ± 10% of 220V AC. Use of SMPS to correct voltage
24	**Protection** - 1) Electrical protection, resettable over current breakers or replaceable fuses (fitted in both live and neutral lines);
24.1	Leakage
24.2	**Power consumption**- TO be declared by the supplier

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25	**ACCESSORIES, SPARE PARTS, CONSUMABLES**
25.1	**Accessories & Spares- 1) Test lung – 2 No.**
25.2)	Nebulizer kit – 2 No .
25.3)	Reusable breathing circuit of silicone material (2Nos) with heated wire circuit .
25.4)	Guide wire for heated ventilator circuit .
25.5)	Air & oxygen hose- 1 each
26	**Consumables: 1) oxygen sensor 2) flow sensor 3) Battery 4) Disposable breathing circuit . (Price to be quote separately in technical bid.)**
27	**6. ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATONS**
28	**Atmosphere / Ambiance (air conditioning, humidity, dust ...)-**
1)	Operating condition: Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90% in ideal circumstances.
2)	Storage condition: Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%.
29	**User's care, Cleaning, Disinfection & Sterility issues-**
1)	Complete unit to be easily washable and sterilizable using alcohol and other chemical agents.
30	**STANDARDS AND SAFETY Certifications**
1	FDA (US) /CE (EU) from Authorized third party.
2)	Relevant IEC-60601-Part 1 & 2, certificates by a notified agency
31	**Local and/or international-** Manufacturer / supplier should have ISO certificate for quality standard.
32	**TRAINING AND INSTALLATION**
32.1	**Pre-installation requirements nature, values, quality, tolerance**
32.2	8.1 Availability of 5 amp/15 Amp. electrical sockets;
32.3	Oxygen supply;
33	**Requirements for sign-off**
33. 1	Supplier to perform installation, safety and operation checks before handover;
33.2	Local clinical staff to affirm completion of installation
34	**Training of staff (medical, paramedical, technicians)**
34.1	Training of users in operation and basic maintenance shall be provided;
34.2	Advanced maintenance tasks required shall be documented
35	**WARRANTY AND MAINTENANCE**
35.1	**Warranty- 3 years warranty & 3 years CMC**
36	**Maintenance tasks:**
36.1	Maintenance manual detailing;
36.2	Complete maintenance schedule;
36. 3	Mandatory preventive maintenance quarterly .
37	**Service contract clauses, including prices**
1)	The spare, accessories & consumables price list required for maintenance and repairs in future after guarantee / warranty period should be attached;
2)	Free servicing during warranty period;
38	**DOCUMENTATION**
38.1	**Operating manuals, service manuals, other manuals**
38.2	Should provide sets(hardcopy) of:-
38.3	User, technical, maintenance and service manuals to be supplied along with machine diagrams;
38.4	In manual should provide information regarding life of consumables items .
38.5	List of equipment and procedures required for routine calibration and routine maintenance;
38.6	Certificate of calibration to be provided by the manufacture;
39	**Other accompanying documents**
39.1	List to be provided of important spares and accessories, with their part numbers and cost.
40	**NOTES**
40.1	**Service Support Contact details (Hierchy Wise; including a toll free/landline number)**
40.2	1)Contact details of manufacturer, supplier and local service agent to be provided;
40.3	Any Contract (AMC/CMC/add-hoc) to be declared by the manufacturer;

40.4	**Recommendations or warnings-** Any warning signs would be adequately displayed

Schedule No.2- SPECIFICATION FOR ADVANCE ICU VENTILATOR

- Advanced technology time-cycled, volume-constant, pressure-controlled ventilator for use in intensive care suitable for ventilating all categories of patients from pediatric to adults.
- Ventilator should be supplied with inbuilt air source or external medical grade compressor based. If external compressor based, compressor should be US FDA approved and of the same make as that of ventilator manufacturer.
- The Ventilator should be US FDA and European CE approved. The bidder should be ISO 9001 certified.
- Should be suitable for use during transportation within the hospital on imported trolley of same make as that of the ventilator.
- Inbuilt Screen size should be minimum 12" color touch screen with possibility of screen configuration as per user preference.
- Should have the following modes of ventilation:
- Volume control – VC CMV
- Assist control – VC AC
- Pressure control PCV + or PC SIMV+
- CPAP with Pressure Support
- SIMV (Volume Control) with Pressure support
- BIVENTor BIPAP having mandatory facility of setting ventilation rate
- Dual control modes such as PRVC /AutoFlow / PAV for automatic adjustment of pressure and flow within a set PIP with unrestricted spontaneous breathing capability.
- Apnoea backup ventilation mode with adjustable settings for Volume & Frequency.
- NIV Mode in all volume and pressure controlled and spontaneous modes.
- Ventilator should have quick start setup depending on patient body weight or height
- Ventilator should be Upgradable to O2 Therapy.
- Should have following settings & features:-

A. Tidal Volume in Volume mode : 20 to 2000 ml
B. Inspiratory Pressure : 1 – 99 cmH2O
C. CPAP/PEEP /Intermittent PEEP : 0 – 50 cmH2O
D. Inspiratory Rate : 2 – 80 bpm
E. Inspiratory Time : 0.2 – 10 sec
F. Pressure support : 0 – 50 cmH2O above PEEP
G. FiO2 : 21 - 100%
H. I : E Ratio : 1:5 to 5:1
I. Inspiration termination Criteria : 5 – 75% of Peak Inspiratory Flow
J. Flow triggering up to 15 LPM or Pressure Triggering facility
K. Maximum Continuous Flow for press assist/spontaneous breath more than 220 LPM
L. Inbuilt or same make external compressed air source. Inbuilt compressed air, source should have 6 years guarantee.
M. Valve response time less than 5msec to ensure faster response to patient's effort.
N. Should have facility for Manual Breath, Inspiratory Hold, and Expiratory Hold.
O. Should be able to measure Intrinsic PEEP with display of volume trapped.
P. Should have display of weaning parameter like RSBI etc.
Q. Pressure Sign or Intermittent PEEP with duration of 2 cycles every 3 minutes

- It should display breath to breath measured values for Tidal Volume, Minute Volume, Spontaneous

Frequency, FiO2, Peak/Mean Pressures, PEEP, Tplateau, Resistance, Compliance etc.

- It should have three level (Advice/Caution/Warning) alarm management with different audio visual color coded alarms, including corrective help messages on the screen.
- Ventilator should have two stage filtering process for delivering medical grade air. First stage dust filters, second stage microscopic bacteria / virus filter.
- Should have built-in battery back-up for at least 1 hour for full unit including compressor and ventilator in the event of power failure.
- It should have facility of Oxygen enrichment for endotracheal suction with automatic detection of reconnection and post oxygenation.
- Additional Day/Night screen switch-over and Key lock facility to enhance user preference.
- It should be possible to display at least three types of filled waveforms & loops for each breath. Simultaneous display of minimum 2 waveform along with 2 loops should be possible.
- It should be possible to check readiness for operation of ventilator by a device check comprising of checking the breathing circuit for leakages, for correct functioning of LEDs and alarm tone, power failure, ventilation function etc. Ventilator should be able to ventilate the patient in case of failure of flow & Oxygen sensor.
- It should have at least 24 hours of graphical and numerical trend display of measured parameters along with Logbook facility to record minimum of 500 records for changed settings, events and alarms in chronological order.
- Ventilator should be upgradable to Mainstream EtCO2 monitoring.
- Screen should display following waveforms:
    - Flow – time,
    - Pressure – time,
    - Volume – time
    - Capnograph and following loops:
    - Pressure – volume,
    - Flow – volume,
    - Flow – pressure
    - Volume – CO2
    - It should have Scroll/Zoom functions with facility to freeze waveforms & loops and find UIP & LIP and compare at least 2 loops simultaneously.
    - Ventilator should have preferable electronic oxygen sensor only for lifetime use/or if chemical being provided then 6 Oxygen sensor as a standard scope of supply to last its life time.
    - The flow sensor should be of hot wire technology and usable for entire range of patients from Adult to Pediatric for accuracy and reliability.
    - Should have two nos. auto cleavable & Reusable Expiration Cassette /valves for complete disinfection capability.
    - It should be supplied with high quality reusable Face Masks with gel cushion for face, adjustable cushion pad for nasal bridge and magnetic connectors for quick fastening for non-invasive ventilation of same make.
    - A reusable and auto cleavable inspiration synchronized nebulizer should be provided with each ventilator as a standard feature, the particle size of medicament should be less than 5 Microns.
    - Should have facility for ventilation data transfer & network connection via RS232 port.
    - Scope of supply should include :-

        - Basic Unit (220 - 240 V) with modular corrosion free imported trolley of same make.

- Flow sensor - 5 Nos. of same Make as of Ventilator
- Breathing Circuit Disposable of same Make as of ventilator- 10 nos
- Reusable auto cleavable expiratory valve- 2 Nos.
- Oxygen connecting Hose and Air connecting Hose – 1pc each
- US FDA Approved Compressor or inbuilt compressed air source of same make
- Nebulizer of same make
- Hinged arm for rail (Support for patient circuit) – should be imported of same Make
- Test Lung and Instruction Manual
- Reusable 2 autoclavable breathing circuit. Pediatric & Adult-1 each

Schedule No.3- Mid-end ICU Ventilator with non invasive, invasive and advanced ventilation modes

- Invasive/Non Invasive Ventilator suitable for Adult, Pediatric patients in all critical care areas with invasive modes for quick change from non invasive to invasive modes and back depending on patient condition.
- Upgradeable design with software/hardware upgradeability for new/future functions.
- Should be operable on mains and battery (at least 1 hour).
- Should have inbuilt blower and should be equipped to work with high pressure Oxygen source (central oxygen, etc) or low pressure Oxygen source (Oxygen concentrator, flow meter output etc) .
- Integrated color screen with display of pressure and flow waveforms
- The ventilator should have the following invasive/non-invasive ventilation modes as standard::
  - Non Invasive Ventilation
  - Volume Control SIMV with Automatic adjustment of pressure and flow (Auto Flow) within a set PIP
  - Pressure Control - BIPAP – Biphasic (and not Bi-Level)
  - Pressure Control - Assist
  - Volume Control- Assist
  - CPAP with/without Pressure Support
  - Selection for Mask or tube ventilation
  - Adjustable Apnoea backup ventilation
- Should have settings for :

Tidal Volume setting	200 – 2000 ML (Adult patient). 20 - 300 ML (Paediatric PC mode).
CPAP/PEEP	3 – 20 cmH2O
Peak Inspiratory Pressure	5 – 50 cmH2O
Pressure support	2 – 50 cmH2O
Inspiratory Rate	5 – 50 bpm
Inspiration time	0.3 – 8 sec
Inspiratory flow	0 - 180 lpm
Rise Time	Auto, 0.1 – 2 sec.
FiO2	21 - 100%

- Should have real time calculated monitoring of:
  - Pressure - PIP, Mean, PEEP
  - Volume – Inspired Vt, MV, MV leakage.
  - Rate - Set (Inspiratory).
- Should have alarm management including corrective help messages on the screen for -
  - High/low Pressure
  - High/low Minute Volume

    - Apnoea / disconnection
- Unit should have excellent leakage compensation as below :
    - Automatic leakage compensation upto maximum 50 lpm
    - Continuous automatic adaptation of trigger sensitivity to actual patient cycle
    - Algorithm based on flow, pressure , flow gradient resulting in Multi-Sense triggering capacity
- Scope of supply should include
    - Basic Unit (220 - 240 V) - 1no
    - Modular corrosion free Trolley – 1no.
    - Hose set for invasive and non-invasive ventilation with inbuilt exhalation valve – reusable- 1 no.
    - Oxygen connecting Hose -1 no.
    - Hinged arm for rail (Support for patient circuit)- 1 no.
    - The unit should be supplied with Adult autoclavable Face Masks with gel cushion for face, adjustable cushion pad for nasal bridge and magnetic connectors for quick fastening- 2 nos.
    - Extra bacteria/HEPA filter- 1 no.
    - Test Lung- 1no.
    - Instruction Manual -1 no.
    - Nebulizer-2 nos.

Quality Standards and Support requirements

- The offered unit should have European CE & USFDA certificate
- The unit should comply with relevant IEC Certification
- 1 week training should be provided to paramedical staff.