SPECIFICATIONS FOR ADVANCED PEDIATRIC AND NEONATAL VENTILATOR WITH HIGH-FREQUENCY OSCILLATION VENTILATION (HFOV)

- Should be a constant flow pressure controlled dedicated neonatal and pediatric ventilator designed for use in NICU / PICU.
- Should be for use on patients with body weight ranging from 500 gms to 25 Kg. HFOV application minimum 12 kg. (Stroke volume up to 20 ml)
- Should have integrated 10" or higher TFT Color Monitor/ screen
- Should have sleek design single rotary knob operation.
- Should have an integrated electronic Mixer for mixing Air and Oxygen
- Should have the following modes of ventilation available:
    - IMV/IPPV with Volume limit / VTV (Volume target ventilation)
    - Pressure controlled -Assist Control ventilation with pressure support (ITT based)
    - P-SIMV (with Pressure support ITT) with VTV (Volume target ventilation and PSV (ITT)
    - CPAP, Apnea Back up ventilation, Nasal CPAP, NIPPV
    - All modes should have a volume limit or volume target function.
    - All above modes should be able to use non-invasively by switching off the flow sensor.
- Advanced Ventilation Mode HFOV Software-based standard supply –
    - HFOV + CPAP,
    - HFOV + IMV with selection for switch on /off during expiratory phase
- It should have the following waveforms and loops
    - Curves/ waveforms: Pressure, Flow, Volume with user selection
    - Loops: PV, FV, PF with user selection with Freezing and measuring facility for Loops and curves. Freezing and measurement with two cursers to measure time constants.
- It should have adjustable inspiratory flow patterns from square wave, sinusoidal, decelerating wave
- Should have the following facility for Nebulizer, 100% O2 key for suction, Auto Set Alarm

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- Waveform and Loops freezing facility to review it with measurement cursor
- Should have the following settings:
    - Inspiration Time: 0.1 – 2 sec
    - Expiration Time: 0.1 – 60 sec
    - Flow: Preset patterns – square, sinusoidal, decelerating
    - PEEP: 0 – 30 mbar/ cmH2O
    - Inspiratory Pressure: 5 – 50 mbar/cmH2O
    - Target or Volume limit Tidal Volume: 2 – 150 ml
    - Pressure support from 2-40 cmH2O in the form % of PIP
    - Should have flow cycling / Inspiration time termination from 5% to 40%
    - Pressure and Flow Trigger facility
    - Pressure support – 0- 100% of the Inspiratory pressure in cmH2O
- Should have proximal flow sensor with proximal monitoring of:
    - Pressure: P-peak, P-min, PEEP, Oscillatory Pressure – with HFOV, Respiratory rate
    - FiO2, Temperature, Minute Volume,
    - Minute volume in HFOV, Tidal Volume in HFOV
    - Tidal Volume (Inspired and expired, Leak %), Oscillatory Volume -, Resistance, Compliance,
    - HFOV Frequency: 5 – 15 Hz, Amplitude adjustment 10-100 %, MAP 0-30 mbar-l
    - Stroke volume 2 to 24 ml (up to 12 kg patient body weight) & Should have Flow Limit alarm for faster disconnection alarm in HFOV ventilation-
- Should have provision for:
    - Central Air Line at 4 bar/ 60 psi OR External Compressor
    - External / Central O2 Line at 4 bar/ 60 psi
- Should have three level (High/medium/Low priority) alarms with text messages for High and Low with the facility to AUTO Set:
    - Power failure, Patient disconnection, Minute Volume, Tidal Volume, Pressure, PEEP
    - Oscillatory Pressure –

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- Respiratory Gas Temperature

- Unit should be supplied with reusable and autoclavable heated patient circuits -2 sets and both inspiratory and expiratory limbs should be heated.
- Humidifier integrated or external servo-controlled humidifier with water level alarm
- Should be supplied with the following standard accessories:
- The firm should agree to periodic regular replacement of oxygen cells, compressor filters, and ventilator filters during warranty and CMC
- Should facility for synchronized noninvasive positive pressure ventilation with external trigger mechanism – Price to be quoted separately.
- Accessories to be provided per ventilator
- Autoclavable reusable high quality neonatal specific low compliance dual (Insp & Exp) heated ventilator circuits - 02nos. Additional 2 nos. of the reusable patient circuit should be provided in case of separate patient circuits for HFOV application.
- Heater wires for ventilator circuits (wherever applicable) - 4 nos
- Guide wire for insertion of heater wires (wherever applicable) -4 no
- Reusable Proximal type flow sensors for neonatal use - 2 no (if differential pressure transducer type) or 60 nos (if heated wire anemometer type on yearly basis during the warranty and CMC period), Flow sensor should be covered under warranty and CMC
- Flow sensor cables (if heated wire anemometer type) - 3nos
- In case of standalone humidifier: 2 sets each reusable humidifier chambers, heater wire adaptors for reusable circuits.
- Reusable Nebulization kits/ Cartridges with all accessories - 1 no
- Neonatal test lung - 1 no
- Imported Air compressor with automatic switch over in case of failure of central air pipeline and with USFDA or European CE certificates- 1no.
- Manuals: Operator & Service manuals

Conditions for tenderer:

1. All accessories should be from the same Original Equipment Manufacturer for the main unit.

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2. Instruments must be ISO certified and a copy should be enclosed. (The ISO Certificate must be issued by any organization accredited by the Bureau of Indian Standard or accredited by the international accrediting forum "IAF" (Certificate to be attached).
3. Should be USA FDA and European CE be approved by 4 digits notified body.
4. Other necessary certifications if any required will be provided by the bidder for the smooth functioning of the machine.
5. Installation process should be performed by O.E.M trained service engineers/ service representatives on OEM letterhead or Service Report within 15 days of supply, with the mandatory provision of providing preventive services visit of OEM trained Service Engineer/ Service Representative quarterly per year till the completion of warranty period (i.e., 20 visits for the first 05 years) & further quarterly visits (04 visits/year) year till the completion of CMC period.
6. The equipment should have a Brand name/ Model Number embossed/etched on the equipment.
7. All the technical specifications in the compliance statement must be supported by Original Literature from the firm/ O.E.M with highlighting Numbering & flagging of all technical certificates.
8. Offered Equipment should have a strong Government Installation base.
9. Offered Equipment should have a Regional Sales Service Centre of the Original Equipment Manufacturer in the region for a 95 % uptime guarantee.
10. For the offered main unit, the essential, optional required consumables'/accessories' shelf life should be declared on the Original Equipment Manufacturer's letterhead.
11. In case of technical snag/failure/breakdown the response time for the inspection should be within 24 hours and repair within 05 days otherwise provide a service machine/ alternate arrangement to be made till the period of recovery of the breakdown of the unit, failing which attracts penal action as per the decision of institute/ hospital.
12. For offered equipment the Training of technical staff and users should be performed by Original Equipment Manufacturer trained Service Engineers at the proper designated place- at bidders' cost.
13. Company should quote their latest model and need to provide an affidavit for the same.

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14. As a tendering process the Demonstration of the offered Equipment is Mandatory at hospital/institute premises or other designated places at the bidder's cost.
15. The bidder must comply with the General Financial Rules and their modifications if any issued by the Government of India- 2017.
16. Any bidder from a country that shares a land border with India will be eligible to bid in the tender only if the bidder is registered with the Competent Authority (i.e., Registration certificate issued by the Ministry of Commerce and Industry (Department for Promotion of Industry and Internal Trade- DPIIT after October 2020). If any such bidder is not registered with DPIIT they will be liable for technical disqualification.
17. Principal (OEM) must authorize only one agent to be quoted in the bid otherwise multiple quotes through different agents in the same bid will be canceled.
18. The Bidder and its OEM both have to submit a notarized affidavit on the Indian Non-Judicial Stamp Paper of Rs.100/- that the bidder has not quoted the price higher than the current financial year and last financial year supplied to any government Institute/ Organization/ reputed Private Organization. OEM also has to submit that the price quoted by the bidder in the bid is on its behalf and the lowest in the current and last financial year in the country. Therefore, if at any stage it has been found that the supplier and its OEM have quoted lower rates than those quoted in this bid; the Institute (the purchaser) would be given the benefit of lower rates by the Supplier and any excess payment if any, will become immediately payable to the Institute (the purchaser). If such an affidavit is not submitted, the bid will be outrightly rejected. (Part of technical bid).
19. Guarantee / Warranty Period: Separate offers of Comprehensive Maintenance Contract (CMC on main equipment) and Annual Maintenance Contract (AMC on main equipment) for further 5 years after expiry of 5 years of warranty (i.e., 6th, 7th, 8th, 9th and 10th years) in rupees only (and on basis of percentage of price) should be included in a financial bid in the absence of which the offer is liable to be rejected. Payment for CMC/AMC shall be made only after the expiry of the warranty of 5 years, in case the Institute (the purchaser) decides for availing of CMC/AMC services. Contract for CMC/AMC shall be decided on expiry of warranty but rates (not more than 5% inclusive of all taxes for 6th to 10th year) will be frozen at the price of an issued purchase order before the release of payment by the Institute (the purchaser). However, the Institute (the

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purchaser) may decide not to enter into any CMC/AMC contract without assigning any reason for the same, which shall be binding upon the bid.

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