NEONATAL VENTILATOR SPECIFICATIONS

1. Description of Function

   The unit should be dedicated to neonatal and pediatric ventilators and compressor driven. Should work on external compressor and central pipeline.

2. Should have the latest modes of operation

   a) Controlled Mode - Volume controlled, Pressure Controlled

   b) Support Mode -Volume Support, Pressure Support

   c) Synchronised modes - SIMV (Pressure Control and volume control) with pressure support, SIMV+ PRVC+PSV, Automatic Switchover from Spontaneous To back up and visa-versa

   d) Spontaneous Mode - CPAP/PEEP, NCPAP with flow setting for neonatal

   e) Non-Invasive ventilation, NIPPV mode

   f) Specialised modes - APRV / bivent /Bi-level / BiPAP or equivalent

   g) Advance Volume guarantee modes - PRVC or equivalent mode, SIMV + PRVC, N-CPAP (with the continuous flow), Time cycled pressure limited with continuous flow mode in controlled and SIMV for infant /neonatal patient

   h) Apnoea /backup ventilation with Automatic switch over from Spontaneous to back and visa-versa, in case patient trigger two con. Breath

3. Oxygen Therapy - should have high flow oxygen therapy (HFOT) as standard.

4. Ventilator System should be supplied with below Accessories, spares, and consumables

   a) NICU Ventilator with trolley - 01

   b) Proximal flow sensor -10 nos

   c) Distal flow sensor – 2 nos.

   d) Air compressor with CE certificate -1 no.

   e) Dispo Heated Inspiratory patient circuit - 2 nos,

   f) Detachable Reusable and autoclavable Flow sensor and exhalation valve - 2 each. The expiratory flow sensor and valve should have 2 years warranty.

   g) Hinged Support Arm - 1no

   h) Air and Oxygen Hose - each 1 no

   i) Servo-controlled Humidifier with standard accessories and temp. monitoring with CE and USFDA approval- 1 set

Prof. Avinash Agrawal
MD, IDCC, IFCCM, FICCM, FIACCM, FCCP (USA)
Head, Department of Critical care
King George's Medical University

5. ICU ventilators provide artificial respiratory support to critical patients in all types of Intensive Care Units with altitude compensation for volume and BTPS correction for monitoring. The ventilator should power on self-test / calibration for flow sensor, o2 sensor, PEEP valve, leakage, circuit compliance, humidifier type selection, etc. for checking the ventilator.

6. Operational Requirements The unit should be compressor based for precise gas delivery (not a turbine/piston/ blower based). Turbine/blower/piston-based machines will not be accepted.

7. Should have the following settings for all age groups or better. This is the minimum range required.

a) Tidal Volume 2 ml to not more than 350 ml in VCV mode.
b) Pressure (insp) 5- 90 cmH2O
c) Pressure Ramp/ Flow patterns
d) Respiratory Rate 1 to 150 bpm, Insp. Time 0.1 to 8 sec, I: E Ratio 5:1 to 1:10
e) Insp. Flow 2 to 40 LPM,
f) CPAP/PEEP 0-45 cmH2O
g) Pressure support 5-90 cmh2O
h) FIO2 21 to 100%
i) Pause Time 0 to 2-sec
j) Flow Trigger 0.3 to 12 lpm. Pressure Trigger 0.5 to 12 cmH2O
k) Expiratory trigger or exhalation sensitivity 5% to 75-% of flow
l) Should have Tidal volume setting of 2ml in volume guarantee modes like PRVG /PRVC etc.

8. **Technical Specifications**

a) Should have a Coloured Touch screen 12 Inches or more
b) should have a Facility to measure and display
c) b) 3 waves- Pressure and Time, Volume and Time, and Flow and Time.
d) c) 3 loops- P-V, F-V, P-F with the facility of saving 4 Loops for reference and can be called any time for comparison with the current loop
e) d) Graphic display to have automatic scaling facility for waves

Prof. Avinash Agrawal
MD, IDCC, IFCCM, FICCM, FIACCM, FCCP (USA)
Head, Department of Critical care,
King George's Medical University, UP, Lko.

f) e) Status indicator for Ventilator mode, Battery life, patient data, alarm settings, clock, etc. Simultaneous display of SET and exhaled parameters, 3 waveforms, 2 loops, and Alarm setting.

g) Should have Trending facility for 72 hours minimum, Alarm log for 5000 events including alarm, setting of ventilator parameters, etc.

h) Should have Automatic compliance & Leakage compensation for the circuit. The unit should have power on self-test to measure all the leakages & circuit compliances.

l) Should have Sigh breath delivery with the programmable setting.

9. Should have Monitoring of the following parameters
   a. Airway Pressure (Peak & Mean, platue)
   b. Tidal volume (Inspired & Expired)
   c. Minute volume (Expired)
   d. Spontaneous Minute Volume
   e. Total Frequency & spont. Frequency
   f. FIO2 dynamic
   g. Intrinsic PEEP and PEEPi Volume (or trapped Volume)
   h. Plateau Pressure, leak Mv, leak %, Time constant, spont. MV, Spont RR,
   i. Resistance (Rinsp & Rexp) & Compliance (Cdyn & Cstat)
   j. Use selector Alarms for all measured & monitored parameters with the help key

10. Should have below advanced monitoring based on patient category as applicable.
   a) Intrinsic Peep & Intrinsic PEEP Volume (Trapped Volume),
   b) RSBI / RVR, C20/C),
   c) Expiratory Time constant (Tcexp)Loop Saving facility
   d) Patient circuit compensation,
   e) Should alarm help key

11. Expiratory block should be autoclavable and no routine calibration required

12. Should have suction procedure setting with adjustable fiO2 for pre and post

13. Should have High Visibility Numeric Screen (only digits), Leak compensation in all operative's modes and can be switched ON/OFF."

14. Should have an Ideal Body Weight facility

15. Should have Battery backup for a minimum 2 hours for Main ventilator unit

16. Should have RS 232 interface for communications with networked devices.

Prof Avinash Agrawal
MD, IDCC, IPCCM, FICCM, FIACCM, FCCP (USA)
Head, Department of Critical care,
King George's Medical University, U.P., Lko.

17. Power and inlet gas pressure requirement
    - Power input to be 220-240VAC, 50Hz
    - Gas input (air and oxygen) - 50-100 psi
15. Should have VGA out for External / Additional Display,
16. HL7 Compatible.

Conditions for tenderers:

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

Prof. Avinash Agrawal
MD, IDCC, IFCCM, FICCM, FIACCM, FCCP (USA)
Head, Department of Critical care,
King George's Medical University, U.P, Lko.

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.
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,

Prof. Avinash Agrawal
MD, IDCC, IFCCM, FICCM, FIACCM, FCCP (USA)
Head, Department of Critical Care
King George's Medical University

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 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.

Prof. Avinash Agrawal
MD, IDCC, IFCCM, FICCM, FIACCM, FCCP (USA)
Head, Department of Critical care,
King George's Medical University, UP