

Notice Inviting e-Tender

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SUPPLY OF VENTILATOR STANDARD FOR CRITICAL CARE UNIT (CCU) AND HIGH DEPENDENCY UNIT (HDU) IN THE HOSPITALS AND MEDICAL COLLEGES OF THE GOVERNMENT OF WEST BENGAL.

(Submission of Bid through *online*)

Bid Reference No.: WBMSCL/NIT-74/2016

Dated-29.12.2016

3rd call of tender no. WBMSCL/NIT-55/2016, dated: 28.09.2016 (Supply of Ventilator Standard)

Amendment – III (Revision of Technical Specification)

The revised technical specifications for the item is given below,

Ventilator - Standard

1. To serve adult & pediatric age group patients.
2. It should have integrated US FDA and European CE ("Conformité Européene") approved Compressor. The ventilator should be compressor driven.
3. Provision for running with compressed air supply with separate air inlet port. In absence or low pressure of air supply, ventilator should be run by compressor.
4. Hinged arm holder for holding.
5. Inbuilt Monitoring Screen (10 inches or more).
6. Automatic Compliance & Leakage compensation for circuit and artificial airway.
7. **Following settings for all age groups**
 - a. Tidal volume –30 ml to 2000ml (and beyond both limits)
 - b. Pressure (Insp) –upto 60 cm H₂O or more.
 - c. Respiratory Rate – upto 80 breaths per minute or more.
 - d. PEEP –upto 40 cm of H₂O or more.
 - e. FiO₂ 21 to 100%.

- f. Pause time – 0-30% or equivalent time in seconds of breath cycle time.
- g. Flow trigger with or without pressure triggering.
- h. Peak Flow up to 140 LPM or more (either set directly or indirectly).

8. Monitoring of the following parameters

- a. Airway Pressure (Peak, Plateau & Mean)
- b. Tidal Volume (Mandatory:- Inspiratory & Expiratory, Desirable:- Spontaneous)
- c. Minute Volume (Inspiratory, Expiratory & Spontaneous)
- d. Total Frequency of breaths & I:E ration
- e. Alarms for all measured & monitored parameters

9. Modes of Ventilation

- a. Volume Controlled Ventilation
 - i. Assist / Controlled / SIMV
- b. Pressure Controlled
 - i. Assist / Controlled / SIMV
- c. CPAP/PSV
- d. Provision of future upgradation to the following modes: Pressure Regulated Volume Control (PRVC) / Proportional assist Ventilation / Volume assured pressure support / Volume support / Adaptive support ventilation / Airway Pressure Release Ventilation (APRV) / Bilevel / Noninvasive (or equivalents) - Bidder should quote the rates for available upgradation separately in **Form 9 (c)**.

10. Apnea / Back-up ventilation: - Volume and/ or pressure controlled in user friendly manner

11. Alarm for

- a. Airway Pressure
- b. High continuous Pressure
- c. FiO₂
- d. Expired minute volume
- e. Apnea
- f. End expiratory pressure
- g. Respiratory rate
- h. Gas Failure
- i. Battery

12. Preferably Automatic Patient Detection facility.

13. Battery Back-up for minimum 1 hour (including compressor).

14. System Configuration Accessories, Spares & Consumables

- a. ICU Ventilator – 1
- b. Adult & Pediatric reusable silicon breathing circuit – 02 each
- c. US FDA and European CE ("Conformité Européene") approved Heated Humidifier – 01
- d. US FDA and European CE ("Conformité Européene") approved Inbuilt / integrated nebulizer – 01.

15. Environmental Factor

- a. The Unit shall be capable of being stored continuously in ambient temperature of 0 – 50°C & relative humidity of 15 – 90%
- b. Shall Meet IEC – 60601 – 1 – 2:2001 (or Equivalent BIS) general requirements of safety for electromagnetic compatibility.

- c. Shall be capable of operating continuously in ambient temperature of 10 – 40°C and relative humidity of 15 – 90%.
- d. All sensors and other non-consumable items (other than reusable silicon ventilator circuits) should be free of cost during warranty and CMC.

16. Power Supply

- a. Power input should be 220 – 240 V AC, 50Hz.
- b. Resettable over current breaker shall be fitted for protection.
- c. Suitable online UPS with commensurate capacity for all ventilators including compressor supplied in each CCU with maintenance free batteries for minimum one hour back-up should be supplied.

17. Standards, safety and training

- a. Should be US FDA and European CE ("Conformité Européene") .
- b. Certified to be compliant with ISO-7767 (or equivalent) for Oxygen monitoring.
- c. Demonstration of quoted equipment model is a must.
- d. The successful bidder will have to setup its own service center in West Bengal and submit proper documents in support within 15 days of received of AOC (Award of Contract). The manufacturer will also have to setup their regional office in West Bengal.
- e. The service provider should have the necessary equipment recommended by the manufacturer to carry out preventive maintenance test as per guidelines provided in the service/maintenance manual.
- f. Warranty for 2 years and CMC for 5 years

18. Documentation

- a. Certificate of calibration and inspection from factory.
- b. List of equipment available for providing calibration and routine maintenance support as per manufacturer documentation in service / technical manual.
- c. User manual in English.
- d. Service manual in English.
- e. Log Book with instructions for daily, weekly, monthly and quarterly maintenance checklist. The job description of the hospital technician and company engineer should be clearly spelt out.
- f. List of important spare parts and accessories with their part number and costing.
- g. 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.
- h. The bidders should submit a declaration from the original equipment manufacturer (OEM) that the quoted model is in line of production and it is not obsolete and availability of spare parts and accessories will be ensured for next 10 years.

NOTE:

- 1) Reusable consumables (other than reusable silicon ventilator circuits) should last during the warranty period.
- 2) In case any additional reusable consumables are required during the warranty period those will be supplied free of charge by the supplier.

- 3) The life expectancy of the reusable consumable is expected to be of at least one year from the date of purchase of the same. The reusable consumables will be procured at the prices accepted as per the contract.
- 4) Any reference to brand / product in case it occurs anywhere in the technical specification is purely for indicative/illustrative purposes and should be read as including its equivalent.
- 5) The product quality requirement in this ICB will be European CE ("Conformité Européene") and US FDA.
- 6) Unless specified otherwise in the Technical Specifications, all offers should include UPS unit or battery backup of at least one hour, as the case may be, with each equipment.
- 7) Offered product catalogue to be attached in original (2 in nos.) with each bid.
- 8) Attach valid quality certification document(s); no self-certifications admissible.
- 9) Quality Management System in conformity with ISO 1901:2008 where specified.
- 10) Product quality standard (European CE ("Conformité Européene") and US FDA) to be supported by authentic documents; Warranty, its scope and service facilities to be clearly indicated in the documents.
- 11) One CD/DVD of demonstration video must be supplied with the equipment for end users.
- 12) One CD/DVD of demonstration video must be submitted along with the bid.