



Notice Inviting e-Tender

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SUPPLY OF NEONATAL CARE EQUIPMENTS FOR FACILITY BASED NEWBORN CARE (FBNC) UNITS IN THE HOSPITALS AND MEDICAL COLLEGES OF THE GOVERNMENT OF WEST BENGAL.

(Submission of Bid through *online*)

Bid Reference No.: WBMSCL/NIT- 41/2017

Dated-21.07.2017

The following amendment have been made in the tender document,

Amendment –II

Neonatal Ventilator

A. ESSENTIAL

1. A neonatal ventilator must have all these components below:

- Ventilator
- Integrated display unit and user interface
- Ventilator should be compressor / compressed air driven.
- Reusable Circuit
- Servo Humidifier
- Nebulizer (integrated or standalone)
- Proximal flow / volume sensor
- Stand for circuits
- External battery backup (for ventilator, monitor, humidifier and compressor)
- Operator manual
- Service Manual

2. Type of ventilator:

Advanced microprocessor based Continuous flow, time cycled, pressure limited ventilator capable of ventilating Newborns weighing ≤ 500 grams.

3. Modes

Nasal CPAP, Non-invasive ventilation, IMV (IPPV), SIMV, Assist/Control (A/C), pressure supported ventilation (with backup ventilation).

4. Range of set parameters

| Parameters | Essential |
|---|-----------|
| Non-invasive modes | |
| • NCPAP pressure / PEEP | 3 - 10 |
| • Apnea alarm while on NCPAP | Must |
| • PIP (NIV) – cm of H ₂ O | 10 – 50 |
| • Inspiratory time (NIV) - sec | 0.2 – 2.0 |
| Invasive Modes | |
| • Peak inspiratory pressure (cm of H ₂ O) | 10 – 50 |
| • Positive and expiratory pressure (cm of H ₂ O) | 3 – 10 |
| • Fraction of inspired oxygen (%): | 21-100% |
| • Inspiratory time (sec) | 0.2 – 2.0 |
| • Rate (per min) | 20-120 |
| • Tidal volume (ml) | 2-100 |
| • Trigger | Flow |

5. Display unit / User interface:

LED/LCD - TFT monitor with 10" or higher digital display

Display of following set parameters:

- Airway pressures(PIP, PEEP)
- FiO₂
- Rate
- Ti, Te, I:E ratio
- Tidal Volume
- Minute Volume

Display of following measured parameters:

- Airway pressures (PIP, PEEP, MAP)
- FiO₂
- Ti, Te, I:E ratio
- Tidal Volume
- Minute Volume
- Compliance
- Resistance
- Leak percentage
- Alarm message

- Graphics – Scalars (pressure, volume, flow)/
Loop (pressure-volume, flow volume)
 - a) 3 waves-Pressure, volume and flow with time,
 - b) 2 loops – P-V, F-V with facility of saving of 1 (one) Loop for reference

6. Alarms (Audio & Visual)

- Power / mains failure
- Compressor failure
- O2 not connected / pressure low
- Air not connected
- MV low / high
- Leak alarm / low tidal volume
- Flow sensor not connected
- Flow sensor not calibrated
- Oxygen too high
- Oxygen too low
- Low & High pressure
- High / low respiratory rate
- Apnea alarm

7. Humidifier

- i. Capable of working with both invasive and non-invasive mode
- ii. Must conform to ISO 8185
- iii. Should be capable of always supplying fully saturated gas at 37°C
- iv. Flow resistance < 20 cm H₂O/L/sec (Ins R < 12, Exp R < 8)
- v. Temperature range 31-40° C
- vi. Temperature control ± 2°C
- vii. Digital display of temperature – 5-80°C
- viii. Capable of ambient humidity compensation
- ix. Should be compatible with both reusable & disposable chambers and circuits
- x. Must have water level indicator
- xi. Minimum Warm up time (< 30 min)

8. Medical Air Compressor [Optional; price to be quoted in Form 9(a)]

- a) Imported standalone or in-built or integrated, USFDA and CE approved.
- b) Oil free Medical Air Compressor, not turbine generator
- c) Air quality should comply with ISO 8573.1 compressed air purity class 1.4.1
- d) Air Compressor should automatically be activated in the event of wall air supply loss
- e) Replacement of filters should be performed without removing the compressor (in-built)
- f) Low noise

9. Nebulizer

- (i) Purpose : aerosolized drug delivery while intubated.
- (ii) Technique : Ultrasonic / vibrating mesh technology

- (iii) Standalone / Integrated with pre-installed software and to be supplied with required reusable nebulization chamber or unit along with tubing, cable and adapter / accessories for nebulization.
- (iv) Particle size (MMD): $\geq 2\mu\text{m} \leq 5\mu\text{m}$

10. Proximal flow / volume sensor

- (i) Type : flow sensor / volume sensor
- (ii) Dead space : ≤ 1 ml
- (iii) TV : 0.5 – 200 ml
- (iv) If reusable, costs for required sensors and cable for a total of 5 years are to be included in the quoted price of the equipment. Quoted CMC price should include cost for required sensors and cable during CMC period.
- (v) If disposable, costs of required units for a total of 5 years (approx.. minimum 150 per year) are to be included in the quoted price of the equipment. Quoted CMC price should include cost of required units (approx. 150 per year) during CMC period. Supply of disposables will be in a staggered manner as per the demand of the end – user.

11. FiO₂ / Oxygen cell

Cost of the cells during the warranty period should be included in the quoted price of the equipment and that during the CMC period should include in the quoted CMC price.

12. Environmental factors

1. The unit shall be capable of being stored continuously in ambient temperature of 0-60 deg C and relative humidity of <95%.
2. The unit should be capable of operating continuously in ambient temperature of 10-40 deg C and relative humidity of 15-90%.
3. Shall meet IEC-60601-1-2:2001 (Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility.

13. Power supply with back-up power

1. Power input to be 220-240VAC, 50Hz
2. Resettable over current breaker shall be fitted for protection
3. Suitable UPS (for humidifier, Compressor and Ventilators) with maintenance free batteries for minimum one-hour back-up should be supplied with the system.

14. Standards, safety and training

1. Certified to be compliant with ANS/IEC60601.2.12-01 Medical Electrical Equipment – Part 2-12. **Should be US FDA and CE (“Conformite Europeene”) from European Union notified body having 4 digit identification number approved product.**
2. Certified to be compliant with ISO-7767 for Oxygen monitoring
3. Should meet IEC 529 Level 3 (IP3X) (spraying water) for enclosure protection, water ingress.
4. Demonstration of quoted equipment model is a must
5. Should have local service facility. 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.
6. **Warranty for 2 years and provision of CMC for next 8 years**

15. Spares with each Ventilator*

* Price of the spares listed below are to be quoted separately along with the bid. The bidder should ensure the availability of spares for another 5 years after the completion of warranty & CMC. **The Base price for the spares should be valid for a period of 5 years from date of issue of Award of Contract.**

| | |
|---|-------------|
| Modular corrosion free original trolley | 1 unit |
| Silicon patient circuit with WYE piece for neonates | 5 sets |
| Servo controlled humidifier, with digital temperature display reusable chamber and capable of working in both invasive and non-invasive modes | 1 unit |
| Reusable humidifier chamber | 5 such |
| Nasal CPAP Disposable Circuit | 10sets |
| Temperature probe & adaptor (Humidifier) | 5 such |
| Heater wire (Humidifier) | 5 such |
| Heater wire adaptor (Humidifier) | 5 such |
| Flow sensor cable if reusable | 3 such |
| Flow sensor if reusable | 3 such |
| Flow sensor if disposable (number per year at least) | 150 sets |
| Nebulizer – Integrated / standalone | 1set |
| Stand for patient circuit | 2 such |
| Test lung for each ventilator | 1 set |
| Hose for O ₂ connection (for wall connection) | 5 metres |
| Hose for compressed air (for wall connection) | 5 metres |
| Nasal mask and prongs (three different sizes) | 2 sets each |
| Expiratory valve / block per ventilator | 2 units |
| Low noise air compressor | 1 unit |
| Washable external air filters for compressor | 2 sets |
| Expiratory Cassette/membrane | 10 unit |

The end user may indent the spares in staggered manner as and when required.

16. Documentation

- a) Certified 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 service 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/date sheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered
- h) Must submit user list and performance report within last 5 years from major hospitals

B. DESIRABLES

17. Desirable Parameter versus allotted marks

| Parameters | Maximum allotted marks | | Range versus allotted marks | |
|--|------------------------|------------------|---|----------------|
| | | | Range of parameters | Allotted marks |
| Volume ventilation* | 5 | | Available & integrated | 5 |
| | | | Upgradable | 3 |
| | | | Not upgradable | 1 |
| High frequency ventilation* | 5 | | Upgradable | 5 |
| | | | Not upgradable | 1 |
| Oxygen sensor (longer life at least > 5 years) | 5 | | Available & integrated | 5 |
| | | | Not available | 1 |
| Record / trends saving | 3 | | ≤ 24 hours | 1 |
| | | | > 48 hours & integrated | 3 |
| NCPAP pressure / PEEP (cm of H ₂ O) | 3 | | 3 to 15 | 3 |
| | | | 3 to 25 | 2 |
| | | | 3 to > 25 | 1 |
| Inspiratory time (sec) in TCPL | 7 | | 0.10 to 2.0 | 7 |
| | | | 0.10 to > 2.0 | 3 |
| | | | 0.20 to ≥ 3.0 | 1 |
| Tidal volume (ml) | 15 | | 2 to 100 | 15 |
| | | | 2 to 150 | 10 |
| | | | 2 to 200 | 5 |
| | | | 2 to > 200 | 1 |
| User friendliness | 12 | | User interface & ease in operation. Compactness of whole system including compressor, Graphics etc. | 12 |
| Proximal flow / volume sensor | 7 | | Reusable & autoclavable | 7 |
| | | | Disposable | 1 |
| Air compressor | 5 | | Integrated / In-built | 5 |
| | | | Imported standalone | 1 |
| Nebulizer | 3 | | Vibrating mesh technique | 3 |
| | | | Ultrasonic | 1 |
| Accuracy | 6 | PIP | ± 3 % | 6 |
| | | | ± 5 % | 3 |
| | | | > ± 5 % | 1 |
| | 6 | PEEP | ± 3 % | 6 |
| | | | ± 5 % | 3 |
| | | | > ± 5 % | 1 |
| | 6 | FiO ₂ | ± 3 % | 6 |
| | | | ± 5 % | 3 |
| | | | > ± 5 % | 1 |

| Parameters | Maximum allotted marks | | Range versus allotted marks | |
|-----------------------------------|------------------------|----|---------------------------------|----------------|
| | | | Range of parameters | Allotted marks |
| | 6 | TV | ± 0.5 ml (< 5 ml) | 6 |
| | | | ± 1.0 ml (< 5 ml) | 1 |
| Alarm delay (support with manual) | 3 | | FiO2 (±4%) < 30 sec | 3 |
| | | | FiO2 (±4%) > 30 sec | 1 |
| | 3 | | Circuit disconnection < 0.1 sec | 3 |
| | | | Circuit disconnection > 0.1 sec | 1 |
| Total | 100 | | | |

* Bidders will have to quote the cost for upgradation separately. The same shall be considered during bid evaluation.

Important Note:

Equipment will be considered technically qualified if,

1. Conform with all essential specifications mentioned in A (ESSENTIAL); and
2. Secure at least 80 marks out of 100 in B (DESIRABLES) of the technical specifications.

Amendment –III

Form 9(a): PRICES FOR CONSUMABLES (to be uploaded for each schedule)

| Sl. No | Items | Basic Price of 1(one) number in INR excluding GST |
|--------|-------|---|
| 1 | | |
| 2 | | |
| 3 | | |
| 4 | | |

NOTE: The Tenderers should furnish the price of all the Consumables of the offered model in a separate sheet. If any Tenderer do not submit the price of any of the consumables, it will be presumed that those Consumables shall be supplied FREE OF COST by the Tenderer during Warranty & CMC period.

Form 9(b): PRICES FOR SPARES
(to be uploaded for each Schedule)

| Sl. No. | Items | Basic Price of 1(one) number in INR excluding GST |
|---------|-----------------------------------|---|
| 1 | Low noise air compressor | |
| 2 | Flow sensor if disposable | |
| 3 | Washable external air filters for | |
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Amendment –IV

The BOQ has been replaced.