



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- 67/2017

Dated-23.09.2017

2nd call of Bid reference no. WBMSCL/NIT-41/2017, dated: 21.07.2017

The following amendments have been made in the tender document,

Amendment – I (Revision of Technical Specification)

The revised technical specifications for the item is given below,

Neonatal High Frequency Ventilator (iNO compatible)

1. A neonatal ventilator must have all these components below:
 - Ventilator.
 - Display monitor and user interface

- Same reusable circuits for both conventional ventilation and high frequency oscillatory ventilation (HFOV) and compatible with NO system
- Servo humidifier
- Nebulizer (standalone)
- Proximal flow sensor
- Stand for circuits
- Internal battery backup (for ventilator, monitor)
- Operator manual
- Service manual

2. Type of ventilator

- Advanced microprocessor based continuous flow, time cycled, pressure limited ventilator capable of ventilating newborn infants and compatible to deliver **inhaled Nitric Oxide (iNO)**.
- It should have capability of Mechanical ventilation of a range of patients from 30 gm to at least 10 kg body weight.
- It should have capacity to deliver targeted tidal volume along with primary modes.
- It should have active inspiration and expiration in HFOV
- It should have in built trigger sensitivity parameter for synchronized modes.

3. Modes

- Nasal **CPAP** with facility for single and dual limb, Non- invasive mode of ventilation including NIPPV, nasal HFOV, High Flow O₂ therapy with facility of leak compensation
- Invasive modes ventilation like CMV, SIMV, pressure supported ventilation (with back up ventilation), integrated volume ventilation with Volume targeted ventilation high frequency oscillatory ventilation (HFOV) and various hybrid mode (like HFOV + CMV +, Simv + PSV).

4. Range of set parameters

Parameters	Desirable	Essential
Non-invasive modes		
• NCPAP pressure/ PEEP	0-20	3-10
• Apnes alarm while on Ncpap		Must
• PIP (NIV) – cm of H ₂ O	0-65	10-50

Parameters	Desirable	Essential
• Ti (NIV) – cm of H ₂ O	0.10-5.0	0.15-2.0
• FIO ₂ (%)	21-100	21-100
• Rate (NIV)	1-150	20-120
• Flow rate (for High flow O ₂ therapy) L/min	2-30	2-10

Parameters	Desirable	Essential
Invasive modes		
• Peak inspiratory pressure (cm of H ₂ O)	1-65	10-50
• Positive end expiratory pressure (cm of H ₂ O)	0-30	3-10
• Fraction of inspired oxygen (%)	21-100	21-100
• Inspiratory time (sec)	0.10-5.0	0.10-2.0
• Rate (per min)	1-150	20-120
• Expiratory Tidal volume (Volume targeted mode) ml	2-100	2-100
• Pressure support (cm of H ₂ O)	1-65	10-50
• Additional parameters	Rise time and termination sensitivity (% peak inspiratory flow)	Rise time and termination sensitivity (% peak inspiratory flow)
Parameters	Desirable	Essential
HFOV mode		
• Frequency/rate Hz	3-20	3-10
• MAP (cm of H ₂ O)	1-45	0-40
• Fraction of inspired oxygen (%)	21-100	21-100

• ΔP (cm of H ₂ O)	4-180	10-100
• Sigh P	0-45	1-25
• I:E ratio	1:1-1:3	1:1-1:3

5. Display unit/User Interface

Essential

- LED/LCD – TFT monitor with 10" or higher digital display, preferably with touch screen operation
- Simple and user friendly
- Trend of measured parameters with memory for at least 24 hours
- Display of following set parameters:
 - Airway pressures (PIP, PEEP)
 - FIO₂
 - Rate
 - Ti, Te, I:E ratio
 - Tidal volume
 - Minute volume
 - Status indicator for ventilator mode
- Display of following measured parameters
 - Airway pressures (PIP, PEEP, MAP, Delta P)
 - FIO₂
 - Rate
 - Ti, Te, I:E ratio
 - Leak percentage
 - Tidal volume (V_{te})
 - Minute volume
 - Compliance
 - Resistance
 - Alarm message
 - Calibration
 - Battery life

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

6. Alarms (Audio/ Visual)

- Power/Mains failure
- Monitor Failure
- O₂ not connected/pressure low
- Air not connected
- MV low/ high
- Leak alarm
- Battery low
- Flow sensor not connected
- Flow sensor not calibrated
- Oxygen too high
- Oxygen 100 low
- Low & High pressure
- High/ low respiratory rate
- Apnea alarm
- Compressor failure
- Tube obstructed

7. Humidifier

- Capable of working with both invasive and non-invasive modes
- Must conform to ISO 8185
- Should be capable of always supplying fully saturated gas at 37°C
- Flow resistance < 20 cm H₂O/L/sec (Ins R < 12, Exp R < 8)
- Temperature range: 31- 40°C
- Temperature control: $\pm 2^{\circ}\text{C}$
- Digital display of temperature: 5 - 80° C
- Capable of ambient humidity compensation
- Should be compatible with both reusable & disposable chambers and circuits
- Must have water level indicator
- Minimum warm up time (< 30 min)

8. iNO compatibility

- Should be compatible with iNO system.
- Should be supplied with NO dual hose scavenging filter assembly.
- Should be supplied with NO delivery kit with adaptors.

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

- a) Imported standalone or in-built or integrated, **USFDA / 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

10. Nebulizer

- Purpose: aerosolized drug delivery while Intubated
- Integrated or pre-installed software and required hardware for nebulization
- Reusable nebulization chamber or unit along with tubing, cable and adapter /accessories

11. Proximal flow sensor

- Type: flow sensor/ volume sensor; Flow/ volume should be measured proximally.
- Dead space: ≤ 1 ml
- TV: 1-500 ml
- Reusable and autoclaveable

12. FIO₂/ Oxygen sensor

- Sensors having long lives more than 5 years are preferable.
- If supplied with cells with shorter lives, cost of cells to be required for 5 years are to be included in total cost.
- Environmental factors

13. Environmental factors

- The unit should be capable of being stored continuously in an ambient temperature of 10 - 50° Cand relative humidity of 10-90%.
- The unit should be capable of operating continuously in an ambient temperature of 10 - 40°C and relative humidity of 10-90%.

- Shall meet IEC - 60601 - 1 - 2: 2001 (or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility.

14. Power Supply

- Power input to be 100-240VAC, 50Hz
- Resettable over current breaker shall be fitted for protection
- System should have suitable internal battery back-up for minimum one hour.

15. Standards, Safety and Training

- Should be **US FDA / CE** (“Conformite Europeene”) from European Union notified body having 4 digit identification number approved.
- Should meet IP 21 rating for protection against water ingress
- Sound level should not be more than 50 dBA,
- Demonstration of quoted equipment model is a must
- 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
- Warranty for 2 years and provision of CMC for next 5 years

16. 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
Reusable patient circuit for all modes including HFO with Y 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	2 sets
Reusable humidifier chamber	5 sets
Nasal CPAP/NIPPV disposable kit, nasal HFOV interface	10 set each
High Flow O ₂ interface	10 sets
Temperature probe & adaptor for humidifier	5 sets
Heater wire for humidifier	5 sets
Flow sensor	5 sets
Flow sensor adaptor	5 sets
Flow sensor cable	15 sets

Nebulizer-standalone	1 set
Stand for patient circuit	2 sets
Test lung for each ventilator	1 set
Hose for O ₂ connection (for wall Collection)	5 metres
Hose for compressed air (for wall connection)	5 metres
Nasal mask and prongs for CPAP/NIPPV/n HFOV(at least three different sizes)	5 sets
Expiratory Valve/ block per ventilator(if present with ventilator)	2 sets
NO dual hose scavenging filter assembly	2 sets
NO delivery kit with adaptors	2 sets

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

17. Documentation

- Certified of calibration and inspection from factory
- List of Equipment available for providing calibration and routine maintenance support as per manufacturer documentation in service/technical manual
- User Manual in English
- Service manual in English
- 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.

- List of important spare parts and accessories with their part number and costing
- 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
- Must submit user list and performance report within last 5 years from major hospitals.

Amendment – II

Section I: Instructions to Tenderers

A. Important information at a glance

(The item suffixed by “E” in bracket indicates Eligibility Criteria for a bidder)

4. Annual Turnover requirements: (E)

The Tenderers should have annual sales turnover (i.e. total turnover of the company) of minimum on an average of last three financial years (2013-14, 2014-15, 2015-16) as per the Audited Accounts of the Organization as mentioned in the table below:

SCHEDULE	ITEM	Annual Turnover in Crore Rs.
Schedule-I	Bubble C PAP machine for Neonates	3.0
Schedule-II	Neonatal High Frequency Ventilator (iNO compatible)	5.0
Schedule-III	Neonatal Ultrasound with Multimodality Probe	5.0
Schedule-IV	Neonatal Transport incubator	2.0
Schedule-V	Neonatal Transport Ventilator (MR Compatible)	1.5
Schedule-VI	Neonatal Ventilator	3.0
Schedule-VII	Transcutaneous Bilirubinometer	1.5
Schedule-VIII	Air Oxygen Blender	1.0