

Notice Inviting e-Tender

West Bengal Medical Services Corporation Limited
Swasthya Bhawan Complex
GN-29, Salt Lake, Sector-V
Kolkata-700091

Phone No (033) 40340307/40340308

E mail: procurement@wbmsc.gov.in

SUPPLY OF PICU (PAEDIATRIC INTENSIVE CARE UNIT) EQUIPMENTS IN THE HOSPITALS AND MEDICAL COLLEGES OF THE GOVERNMENT OF WEST BENGAL.

(Submission of Bid through *online*)

Bid Reference No.: WBMSCL/NIT- 27/2015

Dated-14.07.2015

The following amendment has been made in the technical specification,

Amendment – I

(In Page: 37- 44)

SCHEDULE – II

Paediatric Ventilator

A. ESSENTIAL

1. A PICU (Paediatric Intensive Care Unit) Equipments must have all these components below:

- Ventilator
- Integrated display unit and user interface
- Air compressor (from OEM only)
- Reusable circuit
- Servo humidifier
- Nebulizer
- Support arm and trolley for ventilator (from OEM only)
- Battery backup
- Operator manual
- Service Manual

2. Type of ventilator:

- Advanced microprocessor based time cycled, pressure and volume controlled ventilator.

3. Modes:

- Non-invasive ventilation [CPAP (also nasal CPAP), pressure support & pressure control]
- SIMV, Assist Control (pressure and volume)
- Pressure support ventilation (with backup ventilation)
- Dual control or equivalent.
SIMV (volume control + PS), SIMV (Pressure control + PS), SIMV (PRVC + PS) or equivalent.

4. Range of set parameters:

| Sl. No. | Parameters | Essential |
|---------------------------|---|---|
| Non-invasive modes | | |
| i) | CPAP pressure (cm of H ₂ O) | 3 – 20 |
| ii) | PEEP (cm of H ₂ O) | 3 – 20 |
| iii) | Apnea alarm while on NCPAP | ➤ Must ➤ Apnea time should be 20 sec |
| iv) | PIP (cm of H ₂ O) | 10 – 50 |
| v) | Inspiratory time (sec) | 0.2 – 2.0 |
| Invasive Modes | | |
| i) | Peak Inspiratory pressure (cm of H ₂ O) | 10 – 70 |
| ii) | Positive End expiratory pressure (cm of H ₂ O) | 3 – 40 |
| iii) | Fraction of inspired oxygen (%) | 21 – 100% |
| iv) | Inspiratory time (sec) | 0.2 – 2.0 |
| v) | Rate (per min) | 1 – 80 |
| vi) | Tidal volume (ml) | 10 – 2000 |
| vii) | Pressure support | 10 – 70 |
| viii) | Trigger | Flow + pressure |

5. Display unit / User interface:

- Inbuilt / Integrated LED / LCD – TFT monitor with 10" or higher digital display
- **Display of following set parameters:**
 - PIP, PEEP
 - FiO₂
 - Rate
 - Ti, Te, I : E ratio
 - Tidal Volume
 - Minute Volume
- **Display of following measured parameters:**
 - Airway pressures (PIP, PEEP, MAP, Pplat)
 - FiO₂
 - Ti, Te, I : E ratio
 - Tidal Volume
 - Minute Volume
 - Compliance
 - Resistance
 - ETCO₂
 - Leak percentage
 - Alarm message

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

6. Alarms (Audio & Visual):

- Power / mains failure
- Battery Failure/Battery capacity low
- Compressor failure
- O₂ not connected / pressure low
- Air not connected
- MV low / high
- Leak alarm / low tidal volume
- Oxygen too high
- Oxygen too low
- High peak Inspiratory pressure
- High and low positive end expiratory pressure
- High and low nCPAP
- High / low respiratory rate
- Apnea alarm

7. Humidifier:

- Capable of working with both invasive and non-invasive mode
- 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)
- Capable of working at ambient temperature (20 – 30°C)

8. Medical Air Compressor:

- The ventilator and compressor should be of same manufacturer.
- The compressor should be inbuilt / integrated
- US – FDA and CE approved
- Oil free Medical Air Compressor
- Air Compressor should automatically be activated in the event of wall air supply loss
- Replacement of filters should be performed without removing and stopping the compressor
- Low noise 50 dB within 1 meter distance

9. Nebulizer:

- Purpose: aerosolized drug delivery while incubated.
- Technique : Vibrating mesh technology
- To be supplied with required reusable nebulisation chamber or unit along with tubing, cable and adapter / accessories for nebulisation.

10. FiO₂ / Oxygen cell from OEM:

- Preferably the FiO₂ monitoring should be using non-consumable type or permanent O₂ sensor rather than consumable or disposable type.
- The bidder should consider the cost of Oxygen sensor, if consumable in the offered quoted rate of the equipment considering as many numbers as may be required during the period of 2 years warranty & 8 years CMC.

11. EtCO₂:

- The machine should have in-built main-stream / micro-stream/ side-stream CO₂ monitoring, displaying VtCO₂, EtCO₂ and CO₂ waveforms in the same user interface of the ventilator (not on the extra monitor).
- Reusable CO₂ sensor should be supplied with a period of 2 years warranty & rate of 8 years CMC should be quoted in BOQ. The cost should be considered in the offered quoted rate.
- For disposable EtCO₂ sampling line 600 sampling line should be provided over a period of 2 (two) years for each machine

12. Environmental factors:

- The unit shall be capable of being stored continuously in ambient temperature of 0 – 60 deg C and relative humidity of < 95%.
- The unit should be capable of operating continuously in ambient temperature of 10 – 40 deg C and relative humidity of 15 – 90%.

13. Power supply with back-up power:

- Power input to be 220 – 240VAC, 50Hz
- Resettable over current breaker shall be fitted for protection
- Suitable UPS (for humidifier, Compressor and Ventilators) with maintenance free batteries for minimum one – hour back – up should be supplied with the system. The maintenance including battery should be considered in the offered quoted rate during the period of 2 years warranty & 8 years CMC.

14. Standards, safety and training:

- Ventilator & Compressor should be US FDA and CE approved product
- 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 8 years. Warranty & CMC should include entire equipment excluding the list of consumables for which rates are to be quoted in BOQ.

B. DESIRABLES

15. Desirable Parameter versus allotted marks:

| Parameters | Maximum allotted marks | Range versus allotted marks | | Marks obtained | |
|---|------------------------|---|--|----------------|--|
| | | Range of parameters | Allotted marks for individual parameters | | |
| Inspiratory time (sec) in TCPL | 5 | 0.15 to 3.0 | 5 | | |
| | | 0.15 to 2.0 < 3.0 | 3 | | |
| | | 0.20 to 2.0 | 1 | | |
| Upper Limit of NCPAP pressure / PEEP (cm of H ₂ O) | 5 | 25 | 5 | | |
| | | 20 to 24 | 3 | | |
| | | < 20 | 1 | | |
| Lower limit of Tidal Volume | 5 | < 5 ml | 5 | | |
| | | 5 to 9 ml | 3 | | |
| EtCO ₂ measurement | 5 | Main Stream | 5 | | |
| | | Micro Stream | 3 | | |
| | | Side Stream | 2 | | |
| Trigger mechanism | 5 | Pressure, flow and upgradable to neural trigger mechanism | 5 | | |
| | | Pressure and flow trigger only | 3 | | |
| Nebulizer | 5 | Integrated with in – built software | 5 | | |
| | | External | 3 | | |
| Availability of waveform and loops simultaneously | 10 | 4 waveforms and 2 loops | 10 | | |
| | | 3 waveforms and 2 loops | 5 | | |
| | | 2 or less waveforms and 2 or less loops | 2 | | |
| Record / trends saving | 5 | 24 hours | 1 | | |
| | | > 24 hours | 5 | | |
| Oxygen Cell Sensor Life | 10 | > 10 years | 10 | | |
| | | 5 to 10 years | 7 | | |
| | | < 5 years | 3 | | |
| Internal Battery backup time (only for ventilator) | 5 | 2 hrs or more | 5 | | |
| | | 90 mins | 3 | | |
| | | 60 mins or less | 1 | | |
| Upgradability to high frequency ventilation | 5 | Upgradable | 5 | | |
| | | Not upgradable | 3 | | |
| Accuracy | 5 | PIP | ± 3 % | 5 | |
| | | | ± 5 % | 3 | |
| | | | > ± 5 % | 1 | |
| | 5 | PEEP | ± 3 % | 5 | |
| | | | ± 5 % | 3 | |
| | | | > ± 5 % | 1 | |
| | 5 | FiO ₂ | ± 3 % | 5 | |
| | | | ± 5 % | 3 | |
| | | | > ± 5 % | 1 | |
| Alarm delay (support with manual) | 5 | FiO ₂ (±4%) < 30 sec | 5 | | |
| | | FiO ₂ (±4%) > 30 sec | 1 | | |
| | 5 | Circuit disconnection < 0.1 sec | 5 | | |
| | | Circuit disconnection > 0.1 sec | 1 | | |
| User friendliness | 10 | User interface & ease in operation. Compactness of whole system including compressor, Graphics etc. | 10 | | |
| Total | 100 | | | | |

Qualifying marks: 75

16. Consumables to be supplied with each Ventilator

| | |
|--|--|
| Reusable Silicon patient circuit with "Y" piece from OEM | 2 sets Pediatrics & 2 sets for adults |
| Servo controlled humidifier, with digital temperature display with reusable chamber and capable of working in both invasive and non- invasive modes. | 1 no |
| Reusable humidifier chamber | 2 nos. |
| Holder for Humidifier (OEM) | 1 no |
| Heater wire with adapter | 2 units |
| Temperature probe with cable | 2 nos. |
| Nebulizer chamber with all necessary accessories | 2 sets |
| Test lung for each ventilator (OEM) | 1 Neonatal & 1 Adult |
| Hose for O ₂ connection (for wall connection)- at least 3 meters in length | 1 no |
| Hose for compressed air (for wall connection)- at least 3 meters in length | 1 no |
| Reusable NIV face mask (small, medium & large) [OEM/ Respironics/ RESMED/ Fisher & Paykel] | 1 no. each size |
| Nasal prong & mask (S, M, L, XL) with all necessary accessories [OEM/ Respironics/ RESMED/ Fisher & Paykel] | 1 no. each size |
| Expiratory Cassette (Reusable) / block per ventilator (OEM) <i>If any consumables related to Expiratory Cassette are required to be changed periodically, its cost has to be included in the offered quoted rate during the period of 2 years warranty & 8 years CMC.</i> | 2 nos. |
| Washable external air filters for compressor (OEM) | 2 sets |
| EtCO ₂ sensor (Re-usable, if applicable) | 1 no |
| EtCO ₂ sensor (Consumable, if applicable) | 600 nos. |
| Expiratory filter to prevent bacterial, viral & fungal infection | 10 nos. |

17. List of Consumables for which rates are to be quoted in the BOQ

| Sl. No. | Consumables | Multiplier / Quantity required for operating the equipments for 10 years |
|---------|---|--|
| 1 | Re–usable silicon patient circuit with “Y” piece – Paediatric size (OEM) | 7 |
| 2 | Re–usable silicon patient circuit with “Y” piece-Adult size (OEM) | 3 |
| 3 | Re–usable NIV face mask (small) [OEM/ Respironics/ RESMED/ Fisher & Paykel] | 10 |
| 4 | Re–usable NIV face mask (medium) [OEM/ Respironics/ RESMED/ Fisher & Paykel] | 10 |
| 5 | Re–usable NIV face mask (large) [OEM/ Respironics/ RESMED/ Fisher & Paykel] | 10 |
| 6 | Nasal prong & mask (small) with all necessary accessories [OEM/ Respironics/ RESMED/ Fisher & Paykel] | 10 |
| 7 | Nasal prong & mask (medium) with all necessary accessories [OEM/ Respironics/ RESMED/ Fisher & Paykel] | 30 |
| 8 | Nasal prong & mask (large) with all necessary accessories [OEM/ Respironics/ RESMED/ Fisher & Paykel] | 30 |
| 9 | Nasal prong & mask (Extra Large) with all necessary accessories [OEM/ Respironics/ RESMED/ Fisher & Paykel] | 30 |
| 10 | Washable external air filters for compressor (OEM) | 10 |
| 11 | Expiratory filter to prevent bacterial, viral & fungal infection | 50 |
| 12 | Nebulizer chamber with all necessary accessories | 5 |
| 13 | Heater wire with adapter (Humidifier) | 7 |
| 14 | Temperature probe with cable | 14 |
| 15 | Low noise air compressor (OEM) | 1 |

Clinical Justification

Vibrating Mesh Technology:

- Negligible residual volume
- High flow not required
- Non bronchodilators can be easily aerosolized
- Duration of drug delivery small

Neural Triggering:

- There have been studies in paediatric age group which have shown that neural triggering improved synchrony between child and ventilator
- Ironically during SIMV more than half of the patient's breathing cycle, in overcoming asynchrony
- Synchrony is particular difficult to achieve in children due to small tidal volume, high respiratory rate and weak airway flow and pressure.
- Neural triggering was found to be useful in both invasive and non invasive ventilation
- As a result of improvement of synchrony, sedation was lesser, weaning was easier and duration of mechanical ventilation was shorter
- It has been shown that ventilator pressures during neural triggering follow the natural variability in breathing pattern

ETCO₂ (Extra Monitor)

- Extra power source
- Clumsy
- Spontaneous interpretation and decision making will be hampered if all parameters are not displayed on a single screen
- Length of display of waveforms of EtCO₂ on extramonitor will not be adequate. At least 5 waveforms at respiratory rate of 20 should be available

Sidestream/Microstream Disadvantage:

- Water trapping
- Different conditions at the sampling site and sample cell in terms of temperature and humidity
- Less accurate with high respiratory rates
- Variable pressure drop across the tubing and possible misinterpretation of the values
- Consumable sampling lines leading to recurring costs and difficulty in storage and future procurement