Notice Inviting e-Tender

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Procurement of different Medical Equipment for the Department of NICU & PICU, at R.G.Kar Medical College and Hospital
(Submission of Bid through *online*)

Bid Reference No.: WBMSCL/NIT-316/2023	Dated-19.06.2023

Amendment-II

REVISED TECHNICAL SPECIFICATION
Item-III

Ventilator (HFO)

1. A neonatal ventilator must have all these components below:
   i. Ventilator.
   ii. Display monitor and user interface
   iii. Same reusable circuits for both conventional ventilation and high frequencyoscillatory ventilation (HFOV) and compatible with NO system
   iv. Servo humidifier
   v. Nebulizer (standalone)/built-in.
   vi. Proximal flow sensor
   vii. Stand for circuits
   viii. Internal battery backup (for ventilator, monitor)
   ix. Operator manual
   x. Service manual

2. **Type of ventilator**
   i. Advanced microprocessor based continuous flow, time cycled, pressure limited ventilator capable of ventilating newborn infants and compatible to deliver **inhaled Nitric**

Oxide (iNO).

ii. It should have capability of Mechanical ventilation of a range of patients from 300 gm to at least 20 kg body weight.

iii. It should have capacity to deliver targeted tidal volume along with primarymodes.

iv. It should have active inspiration and expiration in HFOV

v. It should have in built trigger sensitivity parameter for synchronized modes.

b. Modes

a) Nasal CPAP with facility for single and dual limb, Non-invasive mode of ventilation including NIPPV, nasal HFOV, High Flow 02 therapy with facility of leak compensation

b) 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).

3. 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_2O	0-65	10-50
• Ti (NIV) – cm of H_2O	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 02 therapy) L/min	2-30	2-10
Parameters	Desirable	Essential
Invasive modes		
• Peak inspiratory pressure (cm of H_2O)	1-65	10-50
• Positive end expiratory pressure (cm of H_2O)	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	2-200	2-200
• Pressure support (cm of H_2O)	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	5-20	3-10
• MAP (cm of H2O)	5-50	0-40
• Fraction of inspired oxygen (%)	21-100	21-100
• ΔP (cm of H2O)	4-180	10-100
• Sigh P	0-45	1-25
• I:E ratio	1:1-1:3	1:1-1:3

4. Display unit/User Interface

- LED/LCD – TFT monitor with 10" or higher digital display, preferably with touchscreen 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 (Vte)
    - 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 1loop for reference

5. Alarms (Audio/ Visual)

a) Power/Mains failure

b) Monitor Failure
c) O2 not connected/pressure low
d) Air not connected
e) MV low/ high
f) Leak alarm
g) Battery low
h) Flow sensor not connected
i) Flow sensor not calibrated
j) Oxygen too high
k) Oxygen too low
l) Low & High pressure
m) High/ low respiratory rate
n) Apnea alarm
o) Compressor failure
p) Tube obstructed

6. Humidifier (US FDA approved)
   a) Capable of working with both invasive and non-invasive modes
   b) Must conform to ISO 8185
   c) Should be capable of always supplying fully saturated gas at 37°C
   d) Flow resistance <20 cm H2O/L/sec (Ins R <12, Exp R<8)
   e) Temperature range: 31- 40°C
   f) Temperature control: ± 2°C
   g) Digital display of temperature: 5 - 80° C
   h) Capable of ambient humidity compensation
   i) Should be compatible with both reusable & disposable chambers and circuits
   j) Must have water level indicator
   k) Minimum warm up time (<30 min)

7. iNO compatibility (Same Manufacturer)

a) Should be compatible with iNO system.
   b) Should be supplied with NO dual hose scavenging filter assembly.
   c) Should be supplied with NO delivery kit with adaptors.

8. Medical Air Compressor (Same Manufacturer)
   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 supplyloss

e) Replacement of filters should be performed without removing the compressor(in- built)

f) Low noise

9. Nebulizer (US FDA approved)

a) Purpose: aerosolized drug delivery while Intubated

b) Integrated or pre-installed software and required hardware for nebulization

c) Reusable nebulization chamber or unit along with tubing, cable and adapter/accessories

10. Proximal flow sensor

a) Type: flow sensor/ volume sensor; Flow/ volume should be measured proximally.

b) Dead space: ≤1 ml

c) TV: 1-200 ml

d) Reusable and autoclaveable

11. FIO_2/ Oxygen sensor

a) Sensors having long lives more than 5 years are preferable.

b) If supplied with cells with shorter lives, cost of cells to be required for 5 yearsare to be included in total cost.

c) Environmental factors

12. Environmental factors

a) The unit should be capable of being stored continuously in an ambienttemperature of 10 - 50° Cand relative humidity of 10-90%.

b) The unit should be capable of operating continuously in an ambient temperatureof 10 - 40°C and relative humidity of 10-90%.

c) Shall meet lEC - 60601 - 1 - 2: 2001 (or Equivalent BIS) General Requirements ofSafety for Electromagnetic Compatibility.

13. Power Supply

a) Power input to be 100-240VAC, 50Hz

b) Resettable over current breaker shall be fitted for protection

c) System should have suitable internal battery back-up for minimum one hour.

Accessories

Nasal Prong

- Neonatal, infant, paediatric – 100 each

Non-invasive mask

- Neonatal, infant, paediatric – 100 each

Inter-phase: 200

14. Standards, Safety and Training

- Should be US FDA / CE ("Conformite Europeene") from European Union notifiedbody 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