Notice Inviting e-Tender

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

Phone No (033) 40340307/320
E mail: procurement@wbmsc.gov.in

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-461/2023	Dated-07.08.2023

2nd call bid reference no. WBMSCL/NIT-316/2023, Dated-19.06.2023

Amendment-II

Revised Technical Specification

Item-II
Ventilator(HFO)

1. Aneonatal 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 frequency oscillatory 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 new born infants and compatible to deliver **inhaled Nitric Oxide(iNO)**.
   ii. It should have capability of Mechanical ventilation of a range of patients from 300gm to at least 20kgbodyweight.
   iii. It should have capacity to deliver targeted tidal volume along with primary modes.

iv. It should have active inspiration and expiration in HFOV
v. It should have inbuilt 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 O2 therapy with facility of leak compensation
b) Invasive modes ventilation like CMV, SIMV, pressure supported ventilation (with backup 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 ofH_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 O2therapy)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 H_2O)	5-50	0-40
• Fraction of inspired oxygen(%)	21-100	21-100
• ΔP (cm of H_2O)	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 Inter face

- LED/LCD–TFT monitor with 10"orhigherdigitaldisplay,preferablywithtouchscreen operation

- Simple and user friendly
- Trend of measured parameters withmemoryforatleast24hours
- 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)
    - 3waves -Pressure, volume and flow with time
    - 2 loops-P-V,F-V withfacilityofsavingof1loop for reference

5. Alarms (Audio/ Visual)

a) Power/Mains failure
b) Monitor Failure
c) O2not 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 (USFD Approved)
    a) Capable of working with both invasive and non-invasive modes
    b) MustconformtoIS08185
    c) Should be capable of always supplying fully saturated gas at 37°C
    d) Flow resistance <20cmH2O/L/sec(Ins R <12,ExpR<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 (<30min)

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 ISO8573.1compressedairpurityclass1.4.1
   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 (USFD Approved)
   a) Purpose: aerosolized drug delivery while Intubated
   b) Integrated or pre-installed software and required hardware for nebulization
   c) Reusable nebulisation 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:1-200ml
   d) Reusable and autoclaveable
11. FIO_2/Oxygen sensor
   a) Sensor shaving long lives more than 5 years are preferable.
   b) If supplied with cells with shorter lives, cost of cells to be required for 5 years are to be included in total cost.
   c) Environmental factors
12. Environmental factors
   a) The unit should be capable of being stored continuously in an ambient temperature of 10-50° C and relative humidity of 10-90%.
   b) The unit should be capable of operating continuously in an ambient temperature of 10 - 40°C and relative humidity of 10-90%.
   c) Shall meet lEC- 60601-1-2:2001(or Equivalent BIS) General Requirements of Safety 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

Complete Inter-phase kit /set: 50
Flow Sensor: 20
Breathing Circuit: 10 (Reusable) /100(Disposable)

14. Standards, Safety and Training

- Should be USFDA / CE ("Conformite Europeene") from European Union notified body having 4 digit identification number approved.
- Should meet IP21 rating for protection against water ingress
- Sound level should not be more than50 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