

WEST BENGAL MEDICAL SERVICES CORPORATION LTD.
(Wholly Owned by the Government of West Bengal)

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Memo No: WBMISC/PROC/PICU EQUIP/898/15/903

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Notice for Pre – Tender Meeting

West Bengal Medical Services Corporation Limited (WBMISCL) is going to float a tender for different medical equipments to be supplied at Paediatric Intensive Care Unit (PICU) at various healthcare establishments of the Govt. of West Bengal. Draft specifications of the equipments to be procured are given in the **Annexure A**. Interested Bidders are requested to go through the specifications and attend a pre – tender meeting in the **Conference Hall** (2nd Floor) of **WBMISC Ltd.** at 12:00 noon on 04.04.2015 for feedback, if any.

Sd/-
Managing Director

TECHNICAL SPECIFICATIONS

1. Paediatric Defibrillator

1. Operational requirements

- Defibrillator should be Bi-Phasic, light weight model
- Should monitor vital parameters and display them
- Should have 3 lead ECG facility.
- Should print the ECG on thermal recorders
- Should work on Manual and Automated external defibrillation (AED) mode, Manual selection upto 200 J or more.
- Should be capable of doing synchronized cardioversion & defibrillation.
- Can be operated from mains as well as battery
- Should have defibrillator testing facility
- Demonstration of the equipment is a must.

2. Technical specifications

- Should be a Low Energy Biphasic defibrillator monitor with Recorder, having capability to arrest all arrhythmia within a maximum energy of 200 Joules or more.
- Should monitor ECG through paddles, pads and monitoring electrodes and Defibrillate through pads and paddles. Should have Automatic Lead switching to see patient ECG through paddles or leads.
- Should measure and compensate for chest impedance for a range of 25 to 150
- Should have a built in 50mm strip printer / thermal recorder
- Should have charging time of 10 seconds for maximum energy. Charging indicator should be there.
- Should have bright electroluminescent / TFT display of screen size 8" or more for viewing message and ECG waveform of 4 seconds
- Should have external paddles with paddles contact indicator – for good paddle contact. Both Adult and paediatric paddles should be available.
- Should have event summary facility for recording and printing at least 250 events and 50 waveforms
- Should have a battery capable of usage for at least 90 minutes or 30 discharges.
- Should be capable of printing Reports on Event summary, configuration, self-test etc.
- Should have facility for self-test/check before usage and set up function
- Should be capable of delivering energy in increments of 1-2 joules up to 30J and

increments of maximum 50J thereafter

- Should have user friendly 1, 2, 3 color coded operation
- Necessary accessories and spares should be available
- Offered model should be US FDA & CE.
- Should be supplied with stainless steel trolley.

3. Environment factors

- The unit shall be capable of operating continuously in ambient temperature of 10-40 °C and relative humidity of 15-90%
- The unit shall be capable of being stored continuously in ambient temperature of 0-50 °C and relative humidity of 15-90%

2. Paediatric Ventilator

A. ESSENTIAL

1. A Paediatric ventilator 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)
- Internal Battery backup
- Operator manual
- Service Manual

2. Type of ventilator:

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

3. Modes:

- Nasal CPAP, Non-invasive ventilation
- 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)	5-20
ii)	PEEP (cm of H ₂ O)	5-20
iii)	Apnea alarm while on NCPAP	Must
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)	4-40
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:

- 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, Pplat)
 - FiO₂
 - Ti, Te, I : E ratio
 - Tidal Volume
 - Minute Volume
 - Compliance
 - WOB (Patient & Ventilator)
 - 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
- Breathing gas temperature
- 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 ± 2°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.

- 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

9. Nebulizer:

- Purpose: aerosolized drug delivery while incubated.
- Technique : Ultrasonic
- Integrated with pre-installed software and to be supplied with required reusable nebulisation chamber or unit along with tubing, cable and adapter / accessories for nebulisation.

10. FiO₂ / Oxygen cell:

- Preferably the FiO₂ monitoring using non-consumable type or permanent O₂ sensor.
- Otherwise, if consumable
- 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

11. EtCO₂:

- The machine should have in-built main-stream CO₂ monitoring. Displaying vtCO₂, etCO₂ and CO₂ waveforms in the same user interface of the ventilator (not on the extra monitor).
- Should be supplied with 2 nos. of CO₂ sensors per ventilator (re-usable).

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.

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	
Trigger mechanism	10	Pressure, flow and another optional trigger	10	
		Pressure and flow trigger only	5	
Oxygen sensor life 5 years	10	Available & integrated	10	
		Not available(consumable)	3	
Record / trends saving	5	24 hours	1	
		> 24 hours	5	
Internal Battery backup time	5	2hrs or more	5	
		90 mins	3	
		60 mins	1	
Screen size	5	12 " or more	5	
		< 12"	3	
Availability of waveform and loops simultaneously	10	4 waveform and 3 loops	10	
		3 waveform and 2 loops	5	
		2 or 1 waveforms and 2 or 1 loops	2	
NCPAP pressure / PEEP (cm of H2O) Upper Limit	5	25	5	
		> 20 to < 25	3	
		20	1	
Inspiratory time (sec) in TCPL	5	0.10 to 2.0	5	
		0.10 to > 2.0	3	
		> 0.10 to 3.0	1	

User friendliness	10		User interface & ease in operation. Compactness of whole system including compressor, Graphics etc.	10	
Air compressor	10		Integrated / In-built	10	
			Imported standalone	5	
Accuracy	5	PIP	$\pm 3\%$	5	
			$\pm 5\%$	3	
			$> \pm 5\%$	1	
	5	PEEP	$\pm 3\%$	5	
			$\pm 5\%$	3	
			$> \pm 5\%$	1	
	5	FiO2	$\pm 3\%$	5	
			$\pm 5\%$	3	
			$> \pm 5\%$	1	
Alarm delay (support with manual)	5		FiO2 ($\pm 4\%$) < 30 sec	5	
			FiO2 ($\pm 4\%$) > 30 sec	1	
	5		Circuit disconnection < 0.1 sec	5	
			Circuit disconnection > 0.1 sec	1	
Total	100				
Should have direct access to vital settings like PEEP, FIO2, RR, Pressure /volume					
Expiratory Cassettes autoclavable					

16. Consumables to be supplied with each Ventilator

Silicon patient circuit with "Y" piece	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	1 no.
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	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
NIV face mask (small, medium & large)	1 no. each size
Nasal prong & mask (S, M, L, XL) with all necessary accessories	1 no. each size
Expiratory Cassette (Reusable) / block per ventilator	2 nos.
Washable external air filters for compressor	2 sets
EtCO ₂ sensor	2 nos.
Expiratory Cassette 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	Silicon patient circuit with "Y" piece-Pediatric size	7
2	Silicon patient circuit with "Y" piece-Adult size	3
3	Expiratory Cassette membrane only*	25
4	NIV face mask (small)	10
5	NIV face mask (medium)	10
6	NIV face mask (large)	10
7	Nasal prong & mask (Small) with all necessary accessories	10
8	Nasal prong & mask (Medium) with all necessary accessories	30
9	Nasal prong & mask (Large) with all necessary accessories	30
10	Nasal prong & mask (Extra Large) with all necessary accessories	30
11	Washable external air filters for compressor	10
12	Expiratory Cassette filter to prevent bacterial, viral & fungal infection	50
13	Nebulizer chamber with all necessary accessories	5
14	Heater wire with adapter (Humidifier)	7
15	Temperature probe with cable	14
16	Low noise air compressor	1

3. Mobile X-Ray Machine

[This machine would be attached to Computed Radiography (CR) at Sl. No. 4. Both the systems should be compatible with each other]

a) **Operational Requirements**

- i) Compact, lightweight (< 100 Kg), easily transportable mobile radiographic unit suitable for bedside X-Rays.
- ii) The unit must have an effective braking system for parking and transport. The tube stand must be fully counterbalanced with rotation in all directions.
- iii) General purpose, high frequency, digital display of KV & mAs.
- iv) Exposures with remote control (wired or wireless) should be available (hand switch)
- v) The unit must have cassette storage facility for all size of cassettes.

b) **The Generator**

- i) Microprocessor controlled high frequency, output of 2 KW or more.
- ii) kV range: 40kV to 100 kV.
- iii) mA range: 60 mA or more.
- iv) maximum 100 mAs

c) **X-Ray Tube**

- i) Stationary Anode type with 1.8mm x 1.8mm or less focal spot size.
- ii) Manual collimator.
- iii) The collimator should have 90W or more lamp for clear visualization of radiation field in open areas like wards/ICUs.
- iv) Collimator should have auto shut off facility to ensure longer life of the Collimator lamp.
- v) Unit should operate on single phase voltage range from 190-240V, 15 Amp plug without any external Transformer.

d) **Standards, safety, and training**

- i) Should have the ISO certification and the copy of the same should be enclosed along with the technical bid.
- ii) Training should be provided for users.
- iii) Unit should have type approval certificate from AERB.
- iv) Should comply with AERB, BIS & ICRP Guidelines for radiation leakage and X-Ray equipments.
- v) Lead jacket with hanger- 02, Thyroid shield-02, Gonadal shield- 01

e) **Documentation**

User/Technical/Maintenance manual to be supplied in English. Certificate of calibration and inspection from factory.

4. Computerized Radiographic (CR) System

[This machine would be attached to Mobile X-Ray Machine at Sl. No. 3. Both the systems should be compatible with each other]

1. The system should comprise of:
 - a. Image recording system (Image plate/cassette)
 - b. Image reader
 - c. Image processing work station
 - d. Accessories and consumables
2. Should be of Single cassette (size – 10" x 12") speed –55 cassette/hr or more
3. Acquisition of image at monitor after insertion of the cassette: 40 sec or less
4. Cassettes: Should provide the following cassettes;-
 - i) 10 X 12 cassette – 2 no.
 - ii) 8 X10 cassette – 2 no.
5. Standard resolution of 10 pixel/mm
6. Console with 17" monitor – 1 no.
7. UPS from reputed manufacturer having at least 10 minute back up with appropriate KVA for the entire system.
8. System should have capability to pan, zoom, annotate, crop, noise suppression/control multiple image layout, customized formatting, CD/DVD writing etc.
9. System should be scalable for connectivity to PACS.
10. The equipment should be new and unused. The manufacturing date should not be more than 180 days when it would reach the consignee address.
11. **Standard & Safety**
Should be of US FDA and CE ("Conformité Européene")
12. **Warranty & CMC**
The machine, UPS and all other accessories should be under warranty for 2 years and followed by 5 years CMC with all spares.