



**WEST BENGAL MEDICAL SERVICES CORPORATION LIMITED**  
**Through**  
**United Nations Development Programme, New Delhi.**

**Invitation to Bid (ITB)**

**SUPPLY OF MEDICAL EQUIPMENT FOR HOSPITALS AND MEDICAL COLLEGES OF THE  
GOVERNMENT OF WEST BENGAL**

**ITB: UNDP-WBMS-01-2014**

**Amendment-IV, dated 28 February 2014**

The following amendments are hereby made to the Bid document for the *Supply of MEDICAL EQUIPMENT FOR HOSPITALS AND MEDICAL COLLEGES OF THE GOVERNMENT OF WEST BENGAL*, with reference to above ITB:

<b>Reference:</b>	<b>Wherever appearing in the bid document, the date, time and venue for receiving / opening of bids shall be read as:</b>
<b>Last Date, Time and Place of Receiving of Bids</b>	<b>1300 Hrs. (IST) on March 07, 2014</b> at United Nations Development Programme (UNDP), 55, Lodhi Estate, New Delhi-110003.
<b>Date, Time and Place of Bid Opening</b>	<b>1430 Hrs. (IST) on March 07, 2014</b> at United Nations Development Programme (UNDP), 55, Lodhi Estate, New Delhi-110003.

**Section 3a - Schedule of Requirements and Technical Specifications are hereby replaced as  
in Annexure below of this Amendment.**

**Kindly go through the Schedule Number and description/item name and quote accordingly.**

**All other terms and conditions of the bid document, except as amended herein above,  
remain unaltered.**

United Nations Development Programme,  
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**Amendment IV - ITB : UNDP-WBMS-01-2014**



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## Annexure

### Section 3a: Schedule of Requirements and Technical Specifications

#### 1. List of Goods and Consignee-wise Distribution

Sch. No.	Description	Quantity	Bid Security	Consignee
1	Multi-Para Monitor	144	INR 10,00,000 / USD 15,000	(15 CCU units & 1 HDU unit spread across the State of West Bengal)
2	Biphasic External Defibrillator	11	INR 70,000/ USD 1,000	
3	Blood Gas Analyzer & Electrolyte Analyzer	9	INR 1,00,000/ USD 1,500	
4	Ripple Mattress	170	INR 25,000/ USD 400	
5	Ventilator-Standard	64	INR 10,00,000/ USD 15,000	
6	Non-invasive BI-PAP Ventilator	44	INR 1,50,000/ USD 2,500	
7	Portable X-Ray Machine	14	INR 3,00,000/ USD 4,800	
8	Automated Cell Counter	16	INR 1,00,000/ USD 1,500	
9	Microbial Culture Machine	16	INR 2,25,000/ USD 3,500	
10	Fogger Machine	30	INR 60,000/USD 900	
11	Trilaminar Flow	15	INR 90,000/USD 1,500	
12	Rapid Infusion Pump	48	INR 90,000/USD 1,500	

- Detailed consignee list will be provided at later stage.



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## **2. Delivery & Completion Schedule:**

i. **Delivery to Consignee as per the** Consignee Distribution List at **Appendix A** below.

ii. **Installation, Training & Commissioning:**

Satisfactory installation, training & commissioning as per the Consignee Distribution List (see Consignee Distribution List above) within 15 days from the respective dates of delivery of the goods.

The supplier will have to provide hands on training to the end user as and when required by WBMSCL / the end user for 2 year after the successful installation of equipment.

The successful bidder will have to set up service centre in West Bengal and submit proper document in support within 15 days of receipt of Award of Contract (AOC).

**Note:** *While installation at the designated site/location and commissioning will be the responsibility of the supplier, basic readiness of the site enabling such installation will be the responsibility of the consignee*



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## Appendix - A

### Timeline for delivery of CCU Equipment

S. No.	Equipment	Within 15 May 2014					Between 15 June 2014 to 30 June 2014											TOTAL
		Chinsurah DH	Barasat DH	Krishnanagar DH	Suri DH	Purulia DH	Asansol DH	Srerampur SDH	Tehatta SDH	Kalyani JNM	School of Tropical Medicine	Murshidabad MCH, Berhampur	ID&BG Hospital	Midnapur MCH	Howrah DH	Coochbehar DH	MRBH	
1	Multichannel Monitor	2	12	12	12	3	12	12	12	4	12	8	2	7	12	8	14	144
2	Biphasic External Defibrillator		1	1	1	1	1	1		1	1				1		2	11
3	Blood Gas Analyzer & Electrolyte Analyzer		1	1	1		1	1		1	1				1		1	9
4	Ripple Mattress	6	12	12	12	17	12	12	8	4	12	12		9	12	10	20	170
5	Ventilator – Standard		5	5	5	3	5	5	3		5	5	3	3	5	5	7	64
6	Non Invasive BiPAP Ventilator		3	3	3	2	3	3	2	2	3	3	3	3	3	3	5	44
7	Portable X-ray Machine		1		1		1	1	1	1	1	1	1	1	1	1	2	14
8	Automated Cell Counter	1	1	1	1	1	1	1	1		1	1	1	1	1	1	2	16
9	Microbial Culture Machine	1	1	1	1	1	1	1	1		1	1	1	1	1	1	2	16
10	Fogger Machine	2	2		2	1	2	2	2	1	2	2	2	2	2	2	4	30
11	Laminar Flow	1	1	1	1		1	1	1		1	1	1	1	1	1	2	15
12	Rapid Infusion Pump		3	3	3	4	3	3	2		3	3	3	2	3	3	10	48



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## **Terms of Delivery**

**DDP** final destination as per Consignee Distribution List provided in List of Goods (also see note below).

### **NOTE:**

- a) The responsibility of obtaining all required documents, including Custom clearance (if applicable), Road Permits etc. is of the Supplier.
- b) Installation of Medical Equipment will be at the Medical Colleges as per the Consignee Distribution List.
- c) Training on Medical Equipment at Medical Colleges as per the Consignee Distribution List; however with the prior approval of the consignee(s), training for more than one centre can be organized together at one location.
- d) The Consignee Receipt Certificate (CRC) will be issued to the Supplier within 72 hours of the delivery at the Consignee address.
- e) Liquidated Damages (LD) will be calculated separately on: (1) delay in the delivery of the Goods to the consignees; and (2) delay in installation, training & commissioning, attributable to the supplier, and not for reasons not attributable to the Supplier.
- f) With regard to charge of liquidated damages (LD) for delay in delivery of goods, the onus of proof will be on the supplier for establishing that delays were not due to reasons attributable to him, whereas in post-delivery installation in case of delay, assumption of non-readiness of site at consignee locations shall ordinarily prevail unless there is specific evidence /information/material to the contrary.

### **NOTE 1: The following points with regard to consumables should be noted while bidding for any of the schedules:-**

1. Reusable consumables should last during the warranty period.
2. In case any additional reusable consumables are required during the warranty period those will be supplied free of charge by the supplier.
3. The life expectancy of the reusable consumable is expected to be of at least one year from the date of purchase of the same. The reusable consumables will be procured at the prices accepted as per the contract.

### **Note2: Applicable for all the schedules:**

- 1) Any reference to brand of technology/ product, in case it occurs anywhere in the technical specification is purely for indicative/illustrative purposes and should be read as including its equivalent.
- 2) The product quality requirement in this ICB will be CE ("Conformité Européene") or US FDA or BIS.
- 3) Unless specified otherwise in the Technical Specifications, all offers should include UPS unit or battery backup of at least one hour, as the case may be, with each equipment.
- 4) Offered product catalogue to be attached in original (2 in nos.) with each bid.
- 5) Attach valid quality certification document(s); no self-certifications admissible.
- 6) Quality Management System in conformity with ISO 9001:2008 where specified;



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- 7) Product quality standard (CE/FDA/BIS) to be supported by authentic documents; Warranty, its scope and service facilities to be clearly indicated in the documents.
- 8) **Company 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.
- 9) **One CD/DVD of demonstration video must be attached with the submission of bid.**
- 10) **One CD/DVD of demonstration video must be supplied with the equipment for end users.**

# **Technical Specifications**

## **Schedule No. 1**

### **Multi-Para Monitor**

- **DISPLAY**
  - Type: High resolution Color TFT Display
  - Size: Minimum of 12 inches (diagonally)
  - Resolution: Excellent viewing from distance and angle
  - Parameters: ECG, Heart Rate, Respiration, SPO<sub>2</sub>, NIBP, Temperature, ETCO<sub>2</sub>, Invasive Pressure monitoring
  - Trace Speed: Appropriate
- **OPTICAL ENCODER/KEYS**
  - Optical Encoder: rapid access to all the functions and settings of parameters through single knob
  - Hot Keys (Non touch-key): quick action hot keys for alarm acknowledge, NIBP start/stop, recorder start/stop freeze, stand by, go-to and return to main screen
- **ECG Monitoring**
  - Lead: 3/5 lead with optional ST & arrhythmia
  - Protection: built-in cautery & defibrillator protection
  - HR Range: 20 to 300 BPM ( $\pm$  2 BPM or 2% whichever is greater)
- **Respiration (From ECG)**
  - Principle: impedance pneumography
  - RR Range: 4 to 100 BPM
- **Pulse Oximetry**
  - Tone Variation: tone variation with change in SPO<sub>2</sub> values: 1-100%
  - Principle – Spectrophotometry + Plethysmography
  - Accuracy: adult 100-70% ( $\pm$  2 digits) 0-69% (unspecified)
  - Perfusion Indicator: bar graph showing signal strength
  - Modes: normal response & fast response
  - Alarms: low 0-95%, high 5-100%
  - PR Range: 20 to 230 BPM
- **Temperature**
  - Channel: dual channel
  - Range: 0° to 50° C
  - Unit: °C or °F probe compatible with ysi 400 series probes (optional)

- **Non-Invasive Blood Pressure**
  - Principle: oscillometric
  - Display: systolic, diastolic & mean pressure
  - Modes: manual, stat (continuous 5 min. operation) and automatic (time interval 2-90 min. selectable)
  - Alarm Limits: selection possible for systolic & diastolic  
Range: 20-250 MMHG  
Accuracy:  $\pm 3$  MMHG
- **Capnography**

Main/Side /micro stream Capnography with display of CO<sub>2</sub> wave form and digital values of EtCO<sub>2</sub>, FiCO<sub>2</sub> & RR CO<sub>2</sub> gets priority for calculating respiration rate  
EtCO<sub>2</sub> Range: 0-99 MMHG  
Gain: 20,40,60,80 MMHG  
Invasive Pressure Monitoring

  - Basic Principle : Hydraulic coupling (Transducer Based)
  - Operating Pressure Range: -50 to +300 mmhg
  - Sensitivity: 5  $\mu$ V/V/mmHg,  $\pm 2\%$  (typically  $\leq \pm 1\%$ )
  - Overpressure Protection: -400 to + 400 mmHg
  - Operating Life: >500 hrs
- **Environmental Factors**
  - The Unit shall be capable of being stored continuously in ambient temperature of 10 – 40° C & relative humidity of 15-90%
  - Shall Meet IEC – 60601 – 1 -2:2001 (or Equivalent BIS) general requirements of safety for electromagnetic compatibility
  - Shall be capable of operating continuously in ambient temperature of 10-40°C and relative humidity of 15-90%
- **Power Back-up**
  - Power input: 220-240V/50 Hz Single phase or 380-400 V AC50 Hz three phase fitted with appropriated Indian plugs & sockets.
- **Standards, Safety & Training**
  - Should be USFDA or CE approved product
  - Electrical safety conforms to standards for electrical safety IEC – 60601/IS-13450
  - Manufacturer should have ISO certification for quality standards
  - 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
  - User manual in English
  - Service manual in English





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- List of important spare parts and accessories with their part number and costing
- Certificate of calibration and inspection from factory
- List of equipments available for providing calibration and routine maintenance support as per manufacturer documentation in service/technical manual
- Compliance report to be submitted in a tabulated and point wise manner clearly mentioning the page/para number of original catalogue/data sheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered.
- Must submit user list and performance report within last 3 years from major hospitals

## **Schedule No. 2**

### **Biphasic External Defibrillator**

- Biphasic, Manual and AED with voice prompt, compact and light weight
- Energy selection 5J to 200J in steps
- Momentary energy selection access on front panel
- Should have adult and pediatric paddles integrated on same handle.
- Momentary charge key on front panel and on the apex hand.
- Monitor 8" or more should display selected and delivered energy
- Should have disarm facility
- Energy should be delivered within 30ms after the detected R wave in synchronization mode
- Charging time maximum 5 sec for 200J
- Should have battery backup (3 to 4 hrs) for 50 discharges of 200J
- Should have ECG inputs through paddles or 3 lead cables
- Should have display for selected ECG input source (I, II, III paddles)
- Lead off message should appear with alert tone.
- Amplitude gain of ECG waveform should be adjustable
- Should have display for heart rate
- Should have alarm for high and low HR.
- Should have an inbuilt thermal recorder-paper size 60 mm, paper speed 25mm/sec
- Should have enable/disable option for printer
- Should supply 2 bottle of jelly, 12 roll of thermal paper.
- Should supply three pairs of AED pads
- Should operate on mains 230V, 50Hz
- **Environmental Factors**
  - The Unit shall be capable of being stored continuously in ambient temperature of 10 – 40° C & relative humidity of 15-90%
  - Shall Meet IEC – 60601 – 1 -2:2001 (or Equivalent BIS) general requirements of safety for electromagnetic compatibility



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- Shall be capable of operating continuously in ambient temperature of 10-40°C and relative humidity of 15-90%
- **Power Back-up**
  - Power input: 220-240V/50 Hz Single phase or 380-400 V AC50 Hz three phase fitted with appropriated Indian plugs & sockets.
- **Standards, Safety & Training**
  - Should be US FDA approved product
  - Electrical safety conforms to standards for electrical safety IEC – 60601/IS-13450
  - Manufacturer should have ISO certification for quality standards
  - 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
  - User manual in English
  - Service manual in English
  - List of important spare parts and accessories with their part number and costing
  - Certificate 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
  - Compliance report to be submitted in a tabulated and point wise manner clearly mentioning the page/para number of original catalogue/data sheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered.
  - Must submit user list and performance report within last 3 years from major hospitals

### **Schedule No. 3**

#### **Blood Gas Analyzer & Electrolyte Analyzer**

- **MEASURED PARAMETERS:** pH, PO<sub>2</sub>, PCO<sub>2</sub>, Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>2+</sup>, Cl, Hematocrit (or) Hb, Lactate (optional)
- **CALCULATED PARAMETERS:** Total CO<sub>2</sub> or TCO<sub>2</sub>, HCO<sub>3</sub> (Total), HCO<sub>3</sub> (Standard), Base Exc Base ECF, D(A-a) O<sub>2</sub> Total Buffer Base, SO<sub>2</sub>.
- Should display all results in print out.
- Should have input parameters of patient Temperature, Hemoglobin FIO<sub>2</sub>, patient ID etc.
- Should have a sample temperature control of 37 degree centigrade. It should have inbuilt printer. Analysis time should not be more than 90 to 120 seconds.
- System should be based on liquid/gas calibration technology. Should have both auto & Manual calibration.



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- System should not be a cartridge based system i.e. electrodes should not be in the cartridge system.
- Should work on whole blood and should have syringe and capillary sampling.
- Should be numeric keypad, graphic/LCD display, and inbuilt printer.
- Analyzer with memory of 200 tests.
- System should be supplied complete with all standard accessories, electrodes and start up kits.
- Onboard life of reagents should not be less than one month.
  
- **Environmental Factors**
  - The Unit shall be capable of being stored continuously in ambient temperature of 10 – 40° C & relative humidity of 15-90%
  - Shall meet IEC -60601-1-2:2001 (or Equivalent BIS general requirements of safety for electromagnetic compatibility)
  - Shall be capable of operating continuously in ambient temperature of 10-40° C & relative humidity of 15-90%
  
- **Power Back-up**
  - Power input: 220 – 240V/50 Hz Single phase or 380-400 V AC50 Hz three phase fitted with appropriated Indian plugs & sockets.
  
- **Standards, Safety & Training**
  - Should be USFDA or CE approved product
  - Electrical safety conforms to standards for electrical safety IEC – 60601/IS – 13450
  - Manufacturer should have ISO certification for quality standards
  - 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
  - User manual in English
  - Service manual in English
  - List of important spare parts and accessories with their part number and costing
  - Certificate 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
  - Compliance report to be submitted in a tabulated and point wise manner clearly mentioning in the page/para number of original catalogue/data sheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered
  - Must submit user list and performance report within last 3 years from major hospitals

## **Schedule No. 4**

### **Ripple Mattress**

- Size: Rippled part 6ft X 3ft
- Alternate rippling effect with air insufflations & sucking effect
- Air insufflators
- 2 tubes for alternate air insufflations
  
- **Environmental Factors**
  - The Unit shall be capable of being stored continuously in ambient temperature of 10 – 40<sup>0</sup>C & relative humidity of 15 – 90%
  - Shall Meet IEC – 60601 – 1 – 2:2001 (or Equivalent BIS) general requirements of safety for electromagnetic compatibility
  - Shall be capable of operating continuously in ambient temperature of 10 – 40<sup>0</sup>C and relative humidity of 15 – 90%
  
- **Power Back-up**
  - Power input: 220-240V/50Hz Single phase or 380-400 V AC50 Hz three phase fitted with appropriated Indian plugs & sockets.
  
- **Standards, Safety & Training**
  - Electrical safety conforms to standards for electrical safety IEC – 60601/IS – 13450
  - Manufacturer should have ISO certification for quality standards
  - Should have local service facility. The service provider should have the necessary equipments recommended by the manufacturer to carry out preventive maintenance test as per guidelines provided in the service/maintenance manual
  - Warranty for 2 years
  - User manual in English
  - Service manual in English
  - 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/data sheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered

## **Schedule No. 5**

### **Ventilator - Standard**

- To serve adult & paediatric age group patient
- In-built Compressor.
- Provision for running with compressed air supply additional port for ventilators which can be run with in-built compressor also.
- Hinged arm holder for holding
- Monitoring Screen, 10inch or more
- Automatic Compliance & Leakage compensation for circuit
  
- **Following settings for all age groups**
  - Tidal volume – 50ml to 2000ml
  - Pressure (Insp) – 0 to 60cm H<sub>2</sub>O
  - Support Pressure
  - Respiratory Rate – upto 60 breaths per minute
  - PEEP – 0 to 20 cm of H<sub>2</sub>O
  - FiO<sub>2</sub> 21 to 100%
  - Pause time – 0-30% or equivalent time in seconds of breath cycle time
  - Pressure & Flow Trigger – Pressure Trigger 0-20 cm H<sub>2</sub>O below PEEP; Trigger Flow 3 – 6 LPM
  - Inspiratory rise time – 0-20% of breath cycle time
  - I:E ratio – Standard Range (1:1.5 – 1:3) with Provision for inverse ratio ventilation
  - Ti – 10-80% or equivalent time in seconds of breath cycle time
  - Peak Output Flow up to 140 LPM or more
  
- **Monitoring of the following parameters**
  - Airway Pressure (Peak, Plateau & Mean)
  - Tidal Volume (Inspiratory, Expiratory & Spontaneous)
  - Minute Volume (Inspiratory & Expiratory)
  - Spontaneous Minute Volume
  - Total Frequency of breaths & I:E ration
  - Alarms for all measured & monitored parameters
  
- **Modes of Ventilation**
  - Volume Cycled Ventilation
    - Assist / Controlled
  - Pressure Controlled
  - SIMV
    - Pressure Cycled

- Volume Cycled
- CPAP/PSV
- **Apnea / Back-up ventilation**
- Audio – Visual Alarm for
  - Airway Pressure
  - High continuous Pressure
  - FiO<sub>2</sub>
  - Expired minute volume
  - Apnea
  - End expiratory pressure
  - Respiratory rate
  - Gas Failure
  - Battery
- Preferably Automatic Patient Detection facility
- Battery Back-up for minimum 1 hour (including compressor)
- **System Configuration Accessories, Spares & Consumables**
  - ICU Ventilator – 1
  - Adult & Paediatric Autoclavable silicon breathing circuit – 02 ea
  - Humidifier – 01
- **Environmental Factor**
  - The Unit shall be capable of being stored continuously in ambient temperature of 0 – 50°C & relative humidity of 15 – 90%
  - Shall Meet IEC – 60601 – 1 – 2:2001 (or Equivalent BIS) general requirements of safety for electromagnetic compatibility
  - Shall be capable of operating continuously in ambient temperature of 10 – 40°C and relative humidity of 15 – 90%
- **Power Supply**
  - Power input should be 220 – 240 V AC, 50Hz
  - Suitable Servo controlled Stabilizer/CVT
  - Resettable over current breaker shall be fitted for protection
  - Suitable UPS with maintenance free batteries for minimum one hour back-up should be supplied with the system
- **Standards, safety and training**
  - Should be US FDA or CE approved
  - Certified to be compliant with ISO-7767 (or equivalent) for Oxygen monitoring
  - Demonstration of quoted equipment model is a must



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- 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 CMC for 5 years

- **Documentation**

- Certificate 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 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/data sheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered

Must submit user list and report within last 5 years from major hospitals

## **Schedule No. 6**

### **Non-Invasive Bi-PAP Ventilator**

- **Modes of operation**

- Spontaneous
- CPAP
- Bi-PAP

- **Product Feature**

- Simplified standard setting menu
- Automatic Leak management
- Ti control (Ti Max/Min)
- Adjustable Breath trigger/cycle
- Easy Breath Motor

- **Technical Specification**

- **Performance**
  - Operating pressure range: 3 to 25 cm H<sub>2</sub>O
  - Maximum single fault pressure: 40 cm H<sub>2</sub>O
- **Dynamic pressure characteristics**
  - **S mode:** IPAP: 4 to 25 cm H<sub>2</sub>O; EPAP: 4 to 25 cm H<sub>2</sub>O

- **CPAP mode:** 4 to 20 cm H<sub>2</sub>O
- **Sound pressure level**
  - < 26 dB (tested in accordance with the requirements of ISO 17510-1:2002)
- **Display**
  - Leak
  - Pressure
    - ◆ IPAP
    - ◆ EPAP
  - Respiratory Rate
  - Minute Volume
- **Power Supply**
  - 220 – 240 V AC, 50 – 60 Hz
  - Battery Back-up minimum 1 Hour
- **Environmental condition**
  - Operating Temperature – 5-40<sup>0</sup>C
  - Humidity – 10-95%
- **Electromagnetic Compatibility**
  - Shall Meet IEC – 60601 – 1 – 2:2001 (or Equivalent BIS) general requirements of safety for electromagnetic compatibility
- **Air Filter**
  - Washable air filter
  - Filter to be changed whenever needed without disturbance to compressor
- **Standard, Safety and Training**
  - Should be US FDA or CE approved
  - Certified to be compliant with ISO-7767 (or equivalent) for Oxygen monitoring
  - 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 CMC for 5 years
- **Documentation**
  - Certificate 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 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/data sheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered



Must submit user list and report within last 5 years from major hospitals

## **Schedule No. 7**

### **Portable X-ray**

- **Description & Function**

- Mobile x-ray unit is required to perform x-ray studies in emergency & trauma departments & at bed side in wards & ICU

- **Operational Requirements**

- Compact, lightweight, easily transportable mobile radiographic unit suitable for bed side x-ray in Emergency, Ward, ICU, Operation Theater & also in the radiology Department for conventional radiography
- The unit must have an effective braking system for parking, transport & emergency breaking. The tube stand must be fully counterbalanced with rotation in all directions
- It must have an articulated arm/counter balanced arm for maximum positioning flexibility in any patient position
- All cables should be concealed in the arm system
- Exposures with remote control should be possible
- The unit must have cassette storage facility for all size of cassettes

- **Technical Specification**

- **The Generator**

- Must be microprocessor controlled high frequency, output 20kilo watt or above to give a constant output suitable for radiography
- It should have a digital display of mA & kV and an electronic timer
- kV range – 40 kV to 125kV
- mA range – 300mA or above
- Please specify mA & seconds separately & not mAs alone
- Shortest exposure time 2 ms

- **X-Ray tube**

- Output should match the output of the generator
- Must have a rotating anode with at least : 2500rpm & focal spot size should be less than 1mm
- Heat storage capacity of the anode >80,000J
- Collimator – manually adjustable multileaf collimator,
- The exposure release switch should be detachable with a cord of at least 5 meters rotatable  $\pm 90^\circ$
- Remote control operating distance >10meters
- Remote control operating Radius -  $180^\circ$

- **DAP Measuring equipment (to be quoted as optional)**

- Technology – ionization chamber, display & control panel



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- Active area - >140X140mm
- Weigh < 250gms
- Resolution: 0.1Gym<sup>2</sup>
- Max Measurable DAP 10<sup>6</sup> Gym<sup>2</sup>
- **System Configuration Accessories, Spares and Consumables**
  - Main Unit with Generator and tube as specified – 01
  - Remote control kit – 01
  - DAP Equipment (optional) – 01
  - Lead aprons Lightweight – 02
  - Grid (ratio 6:1) of following sizes should be provided – 01 each – 12"x15", 10"x12"
- **Environmental Factors**
  - Operating temperature 10 – 40<sup>0</sup>C
  - Storage Temperature – 20 – 55<sup>0</sup>C
  - Operating Humidity – 30% - 80%
  - Storage Humidity – 10% - 100%
- **Power Supply**
  - Power input to be 220 – 240 VAC, 50Hz fitted with appropriate Indian Plug
  - Resettable Over current Breaker shall be fitted for protection
- **Standards & Safety**
  - Should be US FDA or CE Approved product
  - Safety aspects of radiation dosage leakage should be spelt out
  - Should comply with AERB/BIS Guidelines for radiation leakage & x-ray equipment
  - Protection against electrical shock: Class I, Type B, According to IEC 601-1
  - Log Book with Instruction for daily, weekly, monthly & quarterly maintenance checklist. The job description of the hospital technician and company engineer should be clearly spelt out
  - Warranty for 5 years of complete system including x-ray tubes & electronic items & all other parts for which order will be placed with uptime warranty of 98%. Comprehensive guarantee period will be extended by double the downtime if it exceeds more than 2% in a year
- **Documentation**
  - User manual in English
  - Service manual in English
  - List of important Spare parts & accessories with their part number & costing
  - Certificate of calibration & Inspection from Factory

Warranty 2 years and CMC for 5 years

Rates of CMC for complete System Including X-Ray tubes and electronic Items & all Parts for which order will be placed with an undertaking of 98% uptime & extension of AMC period By double the downtime if it exceeds >2%

## **Schedule No. 8**

### **Automated Cell Counter**

- It should be 3 part differential hematology cell counter with throughput of 60 samples/hour with 18 parameters like WBC, Lymph#, Mon#, Gra#, Lym%, Mon%, Gra%, RBC, Hb, Hct, MCV, MCH, MCHC, RDW, PLT, MPV, PCT, PDW and should give histograms and graphs of RBC, PLT and WBC 3-Diff
- The instrument should have a provision for paediatric sample analysis, analyzed at a lower volume of whole blood without using capillary it should use max specimen volume: 10µl – 50 µl for CBC + 3 Dif count and should have open tube.
- It should have two different chambers for WBC, RBC, HB, PLT
- The system should use the proven and approved “Volumetric Metering” system of cell counting for WBC’s, RBC’s and PLT’s for high precision of the results & stability of the calibration. WBC differential parameters such as Neut, Lym & Mixed Cells in absolute count will be preferred rather than total granulocytes.
- It should have liquid valves for precise volume & reliability
- It should have stepper motor vacuum pump which should be noiseless running on compressor
- It should not have any recurring cost of periodical replacement of clot filters
- Large Touch screen display with ports for LIS, LAN, RS-232 and user friendly software
- It should be based on 2/3 compact reagents. It should have integrated barcode reader, frontal USB port, integrated Printer, security & traceability of quality control with 3 level to plot L J graphs and XB management, DATA management and should be able to upload or download control information, display of results.
- Reagent for 9000 tests (with staggered supply) or as per requirement should be provided along with the machine
- Quality control tools/Reagents for six @ 50 samples a day – 01 set or as per requirement
- Cost of reagents should be quoted for comparative evaluation
- **Environmental Factors**
  - The Unit shall be capable of being stored continuously in ambient temperature of 10 – 40°C & relative humidity of 15 – 90%
  - Shall Meet IEC – 60601 – 1 – 2:2001 (or Equivalent BIS) general requirements of safety for electromagnetic compatibility
  - Shall be capable of operating continuously in ambient temperature of 10 – 40°C and relative humidity of 15 – 90%
- **Power Back-up**
  - Power input: 220-240V/50Hz Single phase or 380-400 V AC50 Hz three phase fitted with appropriated Indian plugs & sockets.
- **Standards, Safety & Training**
  - Should be US FDA or CE approved product



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- Electrical safety conforms to standards for electrical safety IEC – 60601/IS – 13450
- Manufacturer should have ISO certification for quality standards
- 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
- User manual in English
- Service manual in English
- List of important spare parts and accessories with their part number and costing
- Certificate 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
- Compliance report to be submitted in a tabulated and point wise manner clearly mentioning the page/para number of original catalogue/data 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.

## **Schedule No. 9**

### **Microbial Culture Machine**

#### **(Broad based QR for automated microbial growth detection system)**

- The system should be for minimum of 50 positions
- The system should be fully automated and should be capable of detecting growth of the pathogenic microorganisms from blood & sterile fluids
- The system should be able to detect fungal, aerobic and anaerobic organism from the blood
- The system should have the capacity to process samples of adult and pediatric patients and should have dedicated media for pediatric samples
- The system should have the capability of continuous monitoring of the clinical samples
- It should have automated continuous instrument quality check facility
- The system should be able to display growth kinetics on the screen. The system should be modular and upgradeable for future requirements
- The system should have the capacity of analyzing and detection of delayed entry of specimens at growth, stationary and decline stage (both log & lag phase)
- The media provided for blood, sterile body fluid or fungal culture should be provided with additional antimicrobial substances



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- Detection principal of the system should not have any bottle puncturing during sample analysis and thus no dangerous aerosols formation
- System should allow random loading of bottles in any position and should allow loading of bottles without any software intervention (if required)
- Media bottles should be made of safe materials and should comply to occupational safety guidelines
- System should have individual detection device for each position and should allow extension of no. of incubation days for any specific position
  
- **System Configuration Accessories, Spares and Consumables**
  - Reagents bottles for 3000 tests (with staggered supply) or as per requirement should be provided along with the machine
  - Bar coded (scanner)card for 3000 tests (with staggered supply) should be provided along with the machine
  - Cost of cards and reagents should be quoted for comparative evaluation
- **Environmental 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%
  - Shall meet IEC – 60601 – 1 – 2:2001 (or equivalent BIS) general requirement of safety for electromagnetic compatibility
- **Power Back-up**
  - Power input: 220-240V/50Hz Single phase or 380-400 V AC50 Hz three phase fitted with appropriated Indian plugs & sockets.
  - 2 KVA UPS with minimum 30 minutes backup.
- **Standards, Safety & Training**
  - Should be US FDA or CE approved product
  - Electrical safety conforms to standards for electrical safety IEC – 60601/IS – 13450
  - Manufacturer should have ISO certification for quality standards
  - 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
  - User manual in English



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- Service manual in English
- List of important spare parts and accessories with their part number and costing
- Certificate 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
- Compliance report to be submitted in a tabulated and point wise manner clearly mentioning the page/para number of original catalogue/data sheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered

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### **Schedule No. 10**

#### **Fogger Machine**

- This unit is used to aerial of surface disinfection/fumigation of a specified area
- Droplet size – 5-15 $\mu$
- Chemical tank capacity – 5lt
- Light weight & easy to operate
- **Environmental Factors**
  - The Unit shall be capable of being stored continuously in ambient temperature of 10 – 40<sup>0</sup>C & relative humidity of 15 – 90%
  - Shall Meet IEC – 60601 – 1 – 2:2001 (or Equivalent BIS) general requirements of safety for electromagnetic compatibility
  - Shall be capable of operating continuously in ambient temperature of 10 – 40<sup>0</sup>C and relative humidity of 15 – 90%
- **Power Back-up**
  - Power input: 220-240V/50Hz Single phase or 380-400 V AC50 Hz three phase fitted with appropriated Indian plugs & sockets.
- **Standards, Safety & Training**
  - Should be US FDA or CE approved product
  - Electrical safety conforms to standards for electrical safety IEC – 60601/IS – 13450
  - Manufacturer should have ISO certification for quality standards
  - 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

- User manual in English
- Service manual in English
- List of important spare parts and accessories with their part number and costing
- Certificate 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
- Compliance report to be submitted in a tabulated and point wise manner clearly mentioning the page/para number of original catalogue/data sheet. Any point, if not substantiated with authenticated catalogue/manual, will not be considered

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## **Schedule No. 11**

### **Trilaminar Flow**

#### **1 Description of Function**

1.1 Laminar Airflow is required to make available an environment whose air supply is free of bacteria, fungi, pollen, and practically all air-borne dirt.

#### **2 Operational Requirements**

2.1 The basic equipment shall consist of a HEPA filter, pre filter, suitable blower assembly, necessary lighting, indicators and controls for the cabinet. The equipment should be mounted on a stand with levelling feet.

#### **3 Technical Specification**

- 3.1 Type of Flow: Vertical – Re-circulatory
- 3.2 HEPA FILTER : Face dimensions: 4ft (L) X 2ft (W) X 6 ft  
The HEPA filter should have rated efficiency of 99.97% (or better) at 0.3 microns to provide product protection of Class 100 or exceeding Class 100 requirements of Federal Standards 209E or equivalent ISO within the work. Area
- 3.3 PRE Filter with Synthetic, non-woven polyester fibers having casing of name painted CRCA frame with Retention of 10 - 15 Micron and 90 % Efficiency. Washable with an arrestance of 90% or better
- 3.4 Material of construction: Main body and rear panel: Electro-galvanized steel or Mild Steel, oven baked epoxy powder coated finish. Side window (panels): UV stabilized transparent Perspex or polycarbonate. Worktable (surface): SS304 or SS316

- 3.5 Working area should be 24 cuft.
- 3.6 Blower Assembly: DIDW type blower system with high RPM motor, enclosed in an powder coated MS casing suitably suspended in a pair springs & connected to the filter chamber through flexible canvas duct.
- 3.7 Front Windows Acrylic, fixed by clamps.
- 3.8 Illumination with Fluorescent tubes with diffusers. Light Intensity at Work Surface :800-1000 lux/75-90 foot candles
- 3.9 Laminar Airflow Velocity: Approx. 90 feet per minute (fpm)+/-10% average velocity measured 50 mm from the filter face. Uniformity +/-20% of average or better.
- 3.10 Additional Requirement: Vibration free Gas burner facility on working bench .Air pressure indicator with manometer (Differential Pressure Gauge MAGNEHELIC with Scale display in cms of water). Drain valve with smooth drainage arrangement. Exhaust ducting as per site requirement
- 3.11 Noise level
- 3.12 UV Germicidal lamp intensity >40 microwatt/sq. cm. over the entire work surface
- 3.13 Switched and indicators: Individual switches and indicator lamps for blower motor, florescent lamp and UV lamp.

#### **4 System Configuration Accessories, spares and consumables**

- 4.1 System as specified-
- 4.2 Spare HEPA Filters and PRE Filters- 2 SETS EA.
- 4.3 Other fitting required for attaching auxiliary services are
  - 1. Electrical outlet socket (5 ampere rating) qty: 2 nos.
  - 2. Valves for gas service-one each for gas and vacuum.

#### **5 Environmental factors**

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

#### **6 Power Supply**

- 6.1 Power input to be 220-240VAC, 50Hz fitted with Indian plug
- 6.2 Resettable overcurrent breaker shall be fitted for protection
- 6.3 Voltage corrector/stabilizer of appropriate ratings meeting ISI Specifications.( Input 160-260 V and output 220-240 V and 50 Hz)
- 6.4 Electrical protection : Should be fitted with earth leakage circuit breaker (ELCB)

#### **7 Standards, Safety and Training**



- 7.1 Should be compliant to ISO 13485: Quality systems - Medical devices - Particular requirements for the application of ISO 9001 applicable to manufacturers and service providers that perform their own design activities.
- 7.2 Should be compliant with IEC 61010-1:(or any international equivalent eg EN/UL 61010) covering safety requirements for electrical equipment for measurement control and laboratory use.
- 7.3 Should be US FDA, CE,UL or BIS approved product.
- 7.4 The Laminar Airflow Cabinet should be tested and comply with the requirements:
  - 1. Down flow Velocity Profile
  - 2. Inflow Velocity Test
  - 3. Airflow Smoke Pattern Test
  - 4. HEPA Filter Leakage Test
  - 5. Electrical Leakage Ground Circuit Resistance and polarity Test
  - 6. Lighting Intensity Test
  - 7. Vibration Test.
  - 8. Noise Level Test
  - 9. UV Lamp Intensity Test
  - 10 The differential pressure gauge should be calibrated.

*Note: All the above Tests will have to be conducted and certified by an accredited agency. Please provide the name and address of the firm agency that will test and certify the LAF. Also necessary proof of accreditation with the appropriate national or international laboratory should be provided.*

- Warranty for 2 years and CMC for 5 years.

## **8 Documentation**

- 8.1 Certificate of calibration and inspection.
- 8.2 User/Technical/Maintenance manuals to be supplied in English.
- 8.3 List of Equipment available for providing calibration and routine maintenance support as per manufacturer documentation in service / technical manual.
- 8.4 List of important spare parts and accessories with their part number and costing
- 8.5 Log book with instruction for daily, weekly, monthly and quarterly maintenance checklist.  
The job description of the hospital technician and company service engineer should be clearly spelt out

## **Schedule No. 12**

### **Rapid Infusion Pump**

- **Delivery rate**

- 0.1 – 1,200 mL/h (0.1 – 99.9 mL/h: 0.1 mL/h step, 100 – 1,200 mL/h: 1 mL/h step)
- The delivery rate can be set in 1 mL/h step throughout the range by the internal mode select switch.

- **Delivery limit**

- 1 – 9999ml

- **Volume delivered**

- 0.0 – 9,999 mL (0.0 – 99.9 mL: 0.1 mL step, 100 – 9,999 mL: 1 mL step).
- The volume delivered reading is in 1 mL step from 1 to 9,999 mL by the internal mode select switch.

- **Purging**

- Higher than 500 mL/h

- **Alarms**

- Air/Occlusion/Flow err./Door/Low BATT.
- Pump stops except during the 'Low BATT.' alarm.

- **Occlusion detection** facility should be there

- **Pressure**

- The detection pressure can be adjusted in 3 levels (L, m, H) within the above range.

- **Completion function**

- When the total volume delivered reaches the preset delivery limit, the indicator and buzzer notify the operator.

- **Special functions**

- 'Keep vein open' function (After the delivery limit has been reached, delivery continues at 1 mL/h for a set flow rate of  $\geq 1$  mL/h: or at the delivery rate setting  $< 1$  mL/h.)
- Tubing clamp function (When the door is opened, tubing is automatically clamped.)
- Volume delivered clear function
- Time remaining (or) time lapsed display
- Battery capacity indicator (3 levels)
- Adjustable display brightness (Can be switched to 2 levels)
- Adjustable buzzer volume (single level)
- Operation history function (Storage/display of operation history). The unit should store the last settings.
- Standby function
- Repeat alarm function
- Start reminder function

- The following functions can be selected via internal switches:
  - Volume memory function
  - Delivery rate 1 mL/h step
- **Environmental Factors**
  - The Unit shall be capable of being stored continuously in ambient temperature of 10 – 40°C & relative humidity of 15 – 90%
  - Shall Meet IEC – 60601 – 1 – 2:2001 (or Equivalent BIS) general requirements of safety for electromagnetic compatibility
  - Shall be capable of operating continuously in ambient temperature of 10 – 40°C and relative humidity of 15 – 90%
- **Power Back-up**
  - Power input: 220-240V/50Hz Single phase or 380-400 V AC50 Hz three phase fitted with appropriated Indian plugs & sockets.
- **Standards, Safety & Training**
  - Should be US FDA or CE approved product
  - Electrical safety conforms to standards for electrical safety IEC – 60601/IS – 13450
  - Manufacturer should have ISO certification for quality standards
  - 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.
  - User manual in English
  - Service manual in English
  - List of important spare parts and accessories with their part number and costing
  - Certificate 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
  - Compliance report to be submitted in a tabulated and point wise manner clearly mentioning the page/para number of original catalogue/data 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.

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