Specifications for Equipment

CARDIAC OT EQUIPMENT

1. Sternal Saw Gun with Motor

- The Sternal Saw should be light weight and provide clear line of sight.
- The Sternal Saw should operate through a flexible drive cable by an electric motor.
- It is able to be ETO Sterilized /autoclaved.
- The blade holding mechanism should be chuck type assembly for quickly replacing the blades.
- The reciprocating blade should have a 5-7 mm stroke length.
- The saw should have a blade protector on it and blade protector should be easily replaceable.
- Foot switch should permit variable saw speeds & one extra foot switch to be provided.
- The system operates on 220V / 250V, 50Hz, single phase
- Response time should be less than 24hrs.
- Time to rectification should be less than 48hrs.
- If rectification time more than 48 hrs then standby unit to be provided.
- User & service manual should be provided (Soft copy & Hard copy).
- Operating & maintenance training should be given to BME.
- Calibration & quality testing certificate from manufacturer.
- Uptime guarantee should be 95%.
- Price list of the important spare parts with their parts number.
2. A) Heart Lung Machine

1) The Heart Lung Machine should have direct drive pump mechanism to prevent noise, vibrations, wear and tear. Less down time and prolonged lifetime.

2) Heart Lung Machine Should have Incremental encoder with both Fine tuning and course adjustment for high flow (v/s potentiometers).

3) Heart Lung Machine should have Individual processors (can bus connection) for every pump starts in less than 10sec. No possible total system breakdown.

4) Heart Lung Machine should have Individual screens for every pump, which can easily be replaced.

5) Heart Lung Machine should have UPS back up battery up to 90 minutes in normal working condition. (It shows time remaining, Charging conditions & Battery conditions).

6) Heart Lung Machine should have Horse Shoe pump head

7) Heart Lung Machine should have smallest foot print.

8) Heart Lung Machine should have Rotatable Heads.

9) Heart Lung Machine should have complete text message for warnings and alarms with different tones and with different color coding.

10) Heart Lung Machine should have Thumbwheel Locking Mechanism (Occlusion settings will not be drift and accuracy is 0.015mm).

11) Heart Lung Machine should have Touch Screen. BSA Factor can be set.

12) Heart Lung Machine should have Facility of making all the pumps pulsatile with master slave control.

13) Heart Lung Machine should have Mast Pump Available (Reduces tubing length and priming volume and can be taken close to the patient).

14) Should be modular / compact in design and the basic console should have a spill proof base which shall accommodate minimum 4 pumps with provision to attach an additional pumps as mast pumps. The console shall have (preferably) telescopic masts and cross arm, side guard where ever possible.

15) In all 5 numbers of direct driven roller pumps should be provided which should operate independently and should have controls such as power on-off, forward, reverse, pulsatile flow, etc. Of the 5 pumps 3 should be rated for flow capacity 0 -10 l/m and the other 2 pumps shall have flow capacity 0-1.5 l/m. At least one pump shall have pulsatile flow facility. One pump may be given as a mast pump with necessary fittings. Should have easy access connectors for interchanging the pump.
16) Each pump should be provided with tube clamp assembly and non-reversing hand crank. Should be provided with graduated clamps for venous or arterial line clamping. Each pump should have convenient hand occlusion setting. Each pump must display flow rates for various tubing sizes. Individual pump heads should have Harvey roller pumps with facility for tubing to be used adjustable from ¼” to 5/8” through 3/8” & ½” by easily changeable mechanism.

17) Individual pump heads should have display in digital- the total infusion volume in liters and delivery time, the flow rate in LPM and in RPM. Each pump should have easy mechanism for occlusion setting for different thickness of tunes available in the market, 1/32” to 3/32”.

18) Should be provided with air bubble detection and oxygenator blood level detection facility. The system should provide both audible and visual alerts and alarms on detection and the arterial pump should stop in case low blood level is sensed, or air is detected.

19) The console should have a compact base mount for the entire pump heads together with pole and handles.

20) Should have variable changeable tubing holder in each pump head: ¼”, 3/8”, 1/2”, 5/8” & double ¼”.

21) Should have a venous control module with single pole mast with electronic venous line occlude.

22) Should have movable oxygenator holder.

23) Should have a monitor mount with adjustable monitoring arm. Instrument tray positionable with long monitoring arm. Lightweight surface table; writing surface.

24) There should be provision for monitoring arterial line pressure and cardioplegia line pressure. Facility for monitoring minimum 6 temperature viz. core i.e. nasopharyngeal, rectal, arterial blood and cardioplegia shall be there with all required sensors, probes, transducers, etc. Timer should be provided for measuring total bypass time, ischemia time and elapsed time from cardioplegia and total duration of cardioplegia delivery. 6 temperature display for patient monitoring and for cardioplegia monitoring with digital display in Celsius with 6 necessary compatible temperature probe and 6 additional probes (6x2=12 probes) with 3x2=6 of them for nasal, rectal & esophageal use.

25) Facility for 4 time display- 2 for arterial & 2 for cardioplegia delivery. With stop, reset and start function.

26) Pump should have self diagnostic circuit with provision to detect and display the following alarm conditions. (a) Over speed (b) Pump jams (c) Over occlusion. There should be provision of feeding the flow constant while using a tube of unknown internal diameter.

27) Should have computer interface capability.

28) Suitable line UPS with voltage regulation & spike protection for two hours & battery backup to provide power to minimum two higher flow pumps, all safety monitors and the console
LED/halogen lamp for minimum two hour. Switch over from main power to battery backup should be automatic and immediate. The battery unit should be built in to the pump base and it should be recharged automatically when the system is operating with main power supply.

29) Should have a suitable flexible high intensity halogen/LED lamp assembly with adequate length and maneuverability duly mounted. a. The unit should be provided with blender for air and oxygen. To work at 50-60PSI for membrane oxygenator with water trap attached with necessary hoses & connector of minimum of 5 meter length & with triple flow glass flow meter.

30) It should have suitable gas flow meter.

31) Should be provided with electronic or mechanical occlude for controlling venous occlusion.

32) The central control monitor shall preferably have a high resolution TFT touch screen display.

33) Should be provided with suitable poles and arms for mounting sensors and monitors.

34) Should be provided with holders for mounting pressure transducers.

35) Should be provided with hoses and hose adapters and connectors for connecting to local gas supplies O2 & Air. (As per site).

36) The shelf life of the Temp. Probes shall not be less than three years from supply date.

37) Safety monitor should have optional capability for computer interface to retrieve perfusion data ultrasonic air sensor: Ultrasonic air sensor to detect bubbles to work equally well with crystalloid and blood; should be possible to fit anywhere in the circuit easily. Level sensor system: Ultrasonic transducers to work with crystalloid and blood with adhesive pads, with alarm settings.

38) Remote control module for the temperature control monitor optional remote control unit should be capable of taking 9 temps. Probes and display temperature in digital readouts. Alarm limits setting for at least probes at crucial sites.

39) On line measurement of PH, PCO2 & HB for neonatal cardiac surgery.

40) Machine cover should be provided.

41) Occlusion: - Should have thump wheel locking mechanism

42) Pressure sensor should have 2 modes: - Stop & control mode

43) Level sensor should be with 2 modes: - Normal & control mode
B) Heating Cooling System

1) Simultaneous delivery of water for arterial and cardioplegia heat exchangers and to thermal blankets to be available from suitable ports. Pressure regulated blanket ports maintaining the temperature of the atrial port.

2) Temperature display range 0-50 degree Celsius remote accuracy of 0.3 degree Celsius & remote temperature display unit module with 3-temperature display.

3) Microprocessor based unit to control, cool, rewarm & maintain temperature.

4) Water outlet temperature of heat exchanger and blanket range 0-42 degree Celsius.

5) Maximum flow performance of oxygenator heat exchange supply port 15-22LPM for fast cooling; 480mmHg maximum pressure; blanket 1.5 to 2.5 LPM at zero head.

6) Built in Ice maker to provide 50lbs of ice in about 8 hours from 25 degree Celsius water.

7) Should be capable of providing ice water for cardioplegia independently with variable cooling rate.

8) Rewarming facility with venous different mode settable at 6 to 10 degree Celsius gradients to hold the water bath temperature at higher than the venous blood temperature.

9) Temperature probe module for the operating ranges of 0-50 degree Celsius.

10) The system should be supplied with heating-cooling unit and other mandatory parts like heat exchanger, etc. The temperature shall be from 0-40º C with an increment of 0.1º C and the display for the same shall be from 0-50º C. The accuracy of measurement shall be ± 0.3º C. The display shall preferably be LCD/LED and temperature, flow controls through touch pad.

11) Should have independent outlet for cardioplegia delivery system and exchanger.

12) Two Tanks with three circuits to ensure fast cooling and heating preferred.

13) Should have provision for connecting patient blanket.

14) Should have two adult and two pediatric heating cooling blankets of standard sizes.

General Specification:

1) Equipment in (3A) and (3B) above shall operate on 230 V, 50 Hz, single phase electric supply. The necessary protective relaying/circuitry shall be there with the machines. The mains supply voltage variation may be max. 10% and frequency variation max. 3 %.

2) The equipment shall have valid CE marking/ FDA approval and documentary evidence to that effect shall be submitted.

3) Electrical safety conforms to standards for electrical safety IEC-60601/IS-13450

4) One engineer should be posted for a week to impart training.
5) The equipment should be provided with one hard & soft copy in original of the detailed service manual and operation manual.

6) Repairs and maintenance training to Bio-Medical engineers should be given.

7) Above machine A & B should supplied with certificate of calibration & inspection from factory.

8) Warranty should be three years & two years AMC free.

9) List of important spare parts and accessories with their part number and costing available in stock with the supplier.


11) Uptime guarantee should be 95%.

12) Response time should less than 24 hrs.

13) Time to rectification should be less than 48 hrs.

14) If rectification time more than 48 hrs than standby arrangement to be provide.

3. IABP Machine

1. DESIGN
   - IABP should have Fiber optics capable (AP signal transmitted at speed of light).
   - IABP should have Proprietary WAVE algorithm.
   - IABP should have Auto Pilot Mode operation.
   - IABP should have proprietary Aortic flow timing method.
   - IABP should have microprocessor based system architecture.
   - IABP should have Modular system consisting of display/control module and pneumatic drive unit.
   - IABP should have proprietary deflation timing management.

2. ELECTRICAL
   - IABP should have AC requirement: 90-264 VAC 47-63 Hz.
   - IABP should have typical power consumption: 245watts
   - IABP should have maximum power consumption: 420watts
   - IABP should have battery operating time:
     a) 90 minutes minimum with full charge.
     b) 180 minutes with optional second battery.
   - IABP should have typical battery recharging time:
     a) 80% in 4hrs from full discharge.
b) Recharge to 80% indicated by yellow light.

3. MECHANICAL DIMENSIONS AND WEIGHT

- IABP should have control module with monitor:
  10” high (25.4cm) x 13.75” wide (35cm) x 2” deep (5cm).
- IABP should have pneumatic drive unit:
  31.5” high (80cm) x 13.5” wide (34.3cm) x 21” deep (53.3cm).
- IABP should have control module: 5lbs (2.3kg).
- IABP should have pneumatic unit: 95.5lbs (42.4kg).
- IABP should have total weight: 100.5 lbs (44.7kg).

4. PNEUMATICS

- IABP should have stepper motor-driven bellows.
- IABP should have drive gas: USP-grade helium & one extra USP grade helium cylinder should be supplied with machine.
- IABP should have Helium tank: disposal canister or refillable cylinder
- IABP should have pumping volume: 0.5cc to 50cc, adjustable in 0.5cc increments
- IABP should have counter pulsation rate: 40 to 200 pulsation/minute.
- IABP should have assist ratio options.

5. CONDENSATION REMOVAL

- IABP should have thermoelectric system removes moisture continuously from pneumatic system without interrupting counter pulsation.

6. SYSTEM MODES

- IABP should have Auto-Pilot:
  a) Automatically selects ECG/AP signal, sources, trigger mode, and timing method as well as timing settings.
  b) Automatically changes settings to optimize assist.
  c) Proprietary software sets timing to correspond to individual patient needs.
- IABP should have Operator: allows user control of most pump functions.

7. TRIGGER MODES

- IABP should have ECG (PATERN, PEAK, and AFIB).
- IABP should have PACER (VPACE, APACE).
- IABP should have ARTERIAL PRESSURE (AP).
- IABP should have INTERNAL: Default to 80bpm; adjustable 40 to 120 bpm.
- IABP should have filtering: diathermy, 30 Hz low pass.
8. GENERAL TRIGGER SELECTION CRITERIA (AUTO PILOT MODE)

- IABP should have ECG trigger modes:
  - PATTERN: HR < 130 bpm no arrhythmia
  - PEAK: HR > 130 bpm or arrhythmia detected and arrhythmia timing OFF.
  - AFIB: Any HR with arrhythmia detected.
  - VPACE: single or dual pacer
  - APACE: single pacer with R wave > 100 msec later. Transition only.
- IABP should have AP TRIGGER MODE: No ECG signal or noisy ECG signal.

9. INFLATION/DEFLATION TIMING METHODS

INFLATION TIMING METHOD:
- IABP should have AORTIC FLOW.
- IABP should have PREDICTIVE: AP waveform analysis to set inflation.
- IABP should have WEISSLER: ECG only, inflation timing based on systolic time intervals.

DEFLATION TIMING METHODS:
- IABP should have R-WAVE: Real time deflation on R-wave.
- IABP should have PREDICTIVE: deflation set to occur just prior to next systolic rise.
- IABP should have WEISSLER: ECG only, deflation timing based on diastolic intervals.

MANUAL
- User set inflation and deflation timing in operator mode

10. INFLATION/DEFLATION TIMING LIMITS (Operator Mode)

IABP should have
- ECG:
  - inflation, 20%-80% of R-R interval
  - deflation, 30%-120% of R-R internal
- AP:
  - Inflation, 0-35% of peak systole-peak systole interval
  - Deflation, 35%-75% of peak systole-peak systole interval
- AFIB Trigger Mode:
  - Inflation 80 to 430 ms after R-wave trigger event
  - Deflation on R-wave

11. DISPLAY

- IABP should have Type: color LCD flat screen
• IABP should have Channels:
  Three Channels- 1) ECG
  2) AP
  3) BALLOON PRESSURE
• IABP should have TIMING REFERENCE DISPLAY:
• IABP should have CURSOR: measurement of AP and balloon pressure waveforms

12. ALPHANEUMARIC DATA
• IABP should have PATIENT HEMODYNAMICS
• IABP should have DISPLAY PARAMETERS
• IABP should have OPERATIONS STATUS
• IABP should have DIAGNOSTIC ALARM/HELP MESSAGES

13. STRIP CHART RECORDER
• IABP should have RECORDER: dual-channel dot matrix
• IABP should have WAVEFORMS: ECG, AP OR BALLOON PRESSURE
• IABP should have ALPHANEUMARIC

14. DISPLAY FREEZE
• IABP should have freezes approximately 7 seconds of patient data on screen.

15. PATIENT SIGNAL INPUTS
• ECG: 5 lead skin cable & high level monitor input.
• AP: fiber optic signal input from light wave and high level monitoring.

16. Machine should be supplied with one extra helium cylinder with O ring.

17. Machine should be supplied with dual chamber pacemaker.
  ➢ Response time should be less than 24hrs.
  ➢ Time to rectification should be less than 48hrs.
  ➢ If rectification time more than 48 hrs then standby unit to be provided.
  ➢ User & service manual should be provided (Soft copy & Hard copy).
  ➢ Operating & maintenance training should be given to BME.
  ➢ Calibration & quality testing certificate from manufacturer.
  ➢ Uptime guarantee should be 95%.
  ➢ Price list of the important spare parts with their parts number.
4. Hemodialysis Machine  

2 Units

General

1. The haemodialysis unit shall be microprocessor control and capable of providing the following features:

- Acetate & bicarbonate dialysis
- Volumetric ultrafiltration
- Sodium & UF profilings
- Upgradeable to link up with central monitoring & data collection system.
- Built in Online Clearance Monitoring for real time clearance surveillance and Urea clearance measurement (OCM)

2. Graphical User Interface

- Keyboard function keys are provided.
- An enlarged and high resolution color screen for dialysis data display:
- High resolution LCD color display.
- Its brightness is adjustable adaptively to the illumination of the environment.
- The keyboard function keys and LCD color display can provide an immediate overview of the machine status for treatment supervision. A number of treatment parameters can be shown upon different pop-up menus:
- Cumulative graphical display of treatment data and physiological trends including sodium and ultrafiltration profiles

3. Safety Feature

- **Closed system design**
  The equipment have a close balancing system to ensure that the inflow of fresh dialysate is always equal to the outflow of spent dialysate.

- **Volumetric ultrafiltration**
  The rate of ultrafiltration is determined entirely by the UF pump, which attached to the closed balancing system.

- **Volumetric concentrate dilution**
  The dialysate is mixed with a fixed-volume proportioning system to avoid risks associated with intake of incorrect concentrates.

- **Startup test**
  The equipment performs a self-test before treatment to ensure system functions.

- **Self-test during treatment**
The equipment performs a self-test during treatment automatically in a fixed time slot not less than 15 minutes to ensure the integrity of closed system.

4. Performance Requirements

1. Blood Circuit

   Blood Pump
   - Flow rate range: 15 – 600 ml/min for haemodialysis in 5 ml/min increment
   - Accuracy: ± 10%
   - Effective blood flow rate calculated and displayed on the front panel in a real-time basis during dialysis automatically.
   - **It is easy and safe to thread with bloodline diameter from 2 mm up to 10 mm.**
   - Automatic set up and priming facility available.
   - An emergency hand crank is provided for returning blood to patient when electrical power is lost. Direction of rotation is visually indicated.

1.1. Heparin Pump

   - Infusion rate: 0.1 - 10 ml/hr in 1 ml/hr increment
   - Accuracy: ± 5%
   - Positive and negative extracorporeal circuit pressure will not affect the infusion rate.
   - Stop Time: Heparinization stop time (before end of treatment) 0 – 9 hr 59min user-adjustable in 1 min increment.

1.2. Pressure Monitoring and Alarms

   - Venous pressure monitoring
     - Range: -60 to +520 mmHg.
     - Accuracy: ± 10 mmHg
     - Venous pressure alarm
     - Adjustable high & low alarm limits
     - Alarm Limit can spread and be reset automatically on adjustment of blood flow
   - Arterial pressure monitoring
     - Range: -300 to +280 mmHg.
     - Accuracy: ± 10 mmHg
     - Arterial pressure alarm
     - Adjustable high & low alarm limits
     - Alarm Limit can spread and be reset automatically on adjustment of blood flow
1. Air Detection
   - Alarm shall be activated for air bubbles and micro-bubbles over the entire blood flow range.
   - The tenderer shall state the sensitivity of the detection mechanism in terms of air bubble size at particular blood flow rate.
   - On detection of excessive air on the venous line, the blood pump shall be stopped and the venous return line shall be clamped at a point below the air detector.
   - Ultrasonic sensor shall be used for preventing being affected by ambient light.

2. Dialysis Circuit

2.1. Treatment Facilities
   - Acetate dialysis
   - Bicarbonate dialysis
   - Variable sodium and bicarbonate
   - Volumetric Ultrafiltration
   - Sodium and UF profiles

2.2. Dialysate Flow Rate
   - 0, 300, 500, 800 ml/min, user-selectable
   - Accuracy: ± 10%

2.3. Temperature control and alarms
   - Control range: 35.0 to 39.0 °C in 0.5 °C increment
   - Alarm limits: 33.5 to 40.0 °C

2.4. Conductivity Control and Alarms
   - The dialysate conductivity shall be adjusted by setting the sodium concentration
   - For acetate dialysis, sodium concentration shall be adjustable from 125 to 150 mmol/L in 1 mmol/L increment
   - For bicarbonate dialysis, sodium concentration shall be adjustable from 125 to 150 mmol/L and bicarbonate concentration shall be adjustable of ±8 mmol/L from the original mixing concentration.
   - Conductivity measurement
     - Range: 12.8 to 15.7 mS/cm.
     - Accuracy: ± 0.1 mS/cm

2.5 Blood Leak Detection
   - Alarm shall be activated for blood loss rate not greater than 0.5 ml/min into dialysate at max. dialysate flow of hematocrit about 20-25%.
   - Photo detector shall be used.
   - Different types of alarms shall be shown to differentiate a true blood leak incident or dirtiness.
2.5. **Volumetric Ultrafiltration Control**
   - Control range: 0 to 4L/hr given by the set values of UF volume and treatment time
   - Accuracy: ± 1%
   - UF volume: 0 to 9.99L adjustable in 1 ml increment
   - Treatment time: adjustable up to 9 hr 59 min. in 1 min increment
   - TMP monitoring: -60 to +520 mmHg.
   - Isolated ultrafiltration process shall be provided.

2.6. **On-line preparation of bicarbonate dialysis fluid through dry bicarbonate powder cartridge facility.**

2.7. **It should have Ultrapure Dialysate Fluid Filter**

3. **Disinfection and Cleaning:**
   - Both chemical and heat disinfections can be performed at 83 deg. celcius
   - One-touch fully automatic operation including: pre-rinse, chemical-intake for combined disinfection & decalcification, post-chemical mandatory rinse, and automatic power-off; without extra end-user handling during the whole disinfection process.

4. **Dialysis Parameter Display**
   - The equipment digitally display the below parameters:-
     - Arterial pressure
     - Venous pressure
     - Blood flow rate
     - Dialysate conductivity
     - TMP
     - UF volume
     - UF rate
     - Remaining treatment time
     - Heparin infusion rate
     - Alarm information in text format

5. **Online Clearance Monitoring**
   - Built-in device for measurement and monitor of effective urea clearance (K), dialysis dose (Kt/V), and plasma sodium (Na) automatically during treatment
   - The measurement of effective urea clearance (K), dialysis dose (Kt/V) and plasma sodium (Na) shall be performed in non-invasive, real-time mode without additional disposable required during treatment
Measuring accuracy
- Clearance measurement accuracy: +/-5% (standard deviation)
- Kt/V determination accuracy: +/-9% (standard deviation)

6. **Online Blood Pressure Monitoring (BPM):** (Optional)
   - Built-in blood pressure monitoring for measuring the patient non-invasive blood pressure and pulse rate automatically.

7. **Battery Backup**

The equipment able to operate and monitor the extracorporeal circuit without interruption for at least 30 min. in case of AC power failure by backup battery.

Equipment should be supplied with suitable servo stabilizer.

- Machine should have facility for Acetate, Bicarbonate, sequential dialysis (Isolated UF)
- The blood pump should run even in the absence of water or dialysate flow
- Machine should have two bacterial filter (pyrogen filter) one at water inlet & one before water going to dialyzer
- Should have Na, & UF profiling dialysate temperature selected over a suitable range variable conductivity settling should have variable dialysate flow over wide range
- Should have facility to show trends curve of all parameter for 15-20 min.
- Heparin pump- syringe based should be available
- Ultra filtration rate: - 0 to 4 liters (Max)/Hr.
- Treatment parameter should be displayed by machine at the time of operation
- Should have accurate UF control by flow measurement technique/volumetric system facilities like blood volume sensor, Bicarb. Select technique & online clearance
- Should have integrated heat (80 degree Celsius) & Chemical disinfection facility
- Automatic self test & auto ON/OFF facility
- Blood pump rate over a wide range adaptable to standard A-V blood lines
- Touch Screen
- Ability to monitor pulse rate & Blood Pressure with graphic & tabulated trends. Cumulative graphical display of treatment data and physiological trends including
sodium and ultra filtration profiles. Color display can provide an immediate overview of the machine status for treatment supervision.

- Safety Feature- Closed system design. The equipment has a close balancing system to ensure that the inflow of fresh dialysate is always equal to the outflow of spent dialysate.
- Startup test- The equipment performs a self-test before treatment to ensure system functions.
- Self-test during treatment- The equipment performs a self-test during treatment automatically in a fixed time slots not less than 15 minutes to ensure the integrity of closed system.
- The unit shall be capable of being stored continuously in ambient temperature of 0-50 deg. C & relative humidity of 15-90%
- The unit shall be capable of operating continuously in ambient temperature 10-40 deg. C & relative humidity of 15-90%
- All Consumable required for installation & Standardization of system to be given free of cost.
- Also to be supplied free of cost servo controlled stabilizer 3kVA one & bacterial filter-2 set extra.
- Company should have a service centre at Nagpur with posting of one trained Engineer permanently.
- Company should undertake operating & maintenance training of Dialysis technician
- Company should submit certificates by various health regulatory authorities (FDA/CE approved), certifying machine’s fitness for use and quality assurance.
- Should have inbuilt function for Single needle dialysis.
- It should have Ultrapure Dialysate Fluid Filter.
- **Online Clearance Monitoring**
- Built-in device for measurement and monitor of effective urea clearance (K), dialysis dose (Kt/V), and plasma sodium (Na) automatically during treatment
- The measurement of effective urea clearance (K), dialysis dose (Kt/V) and plasma sodium (Na) shall be performed in non-invasive, real-time mode without additional disposable required during treatment.
- Should have air bubble detector & blood leak sensor.
- Should have in built quality for 3 phase chemical disinfection. Should have in built facility for thermal disinfection.
- Should have computer Interface for further up gradation.
- Time to rectification should be less than 48hrs.
- If rectification time more than 48 hrs then standby unit to be provided.
- User & service manual should be provided (Soft copy & Hard copy).
- Operating & maintenance training should be given to BME.
- Calibration & quality testing certificate from manufacturer.
- Uptime guarantee should be 95%.
- Price list of the important spare parts with their parts number.
Check List (to be submitted with Technical Bid)

The Vendor should submit following documents (duly attested) with Technical Bid
(Please give Annexure No. for submitted Documents as mentioned below)

Name of Company: ____________________________________________________________

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Name of the Document</th>
<th>Documents Submitted (Yes / No)</th>
<th>Annexure No.</th>
<th>Reason (for non submitted documents)</th>
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<td>FDA / BIS Approval</td>
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<td>VAT Registration &amp; CST Registration</td>
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<td>Manufacturing Certificate of Manufacturer Company</td>
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<td>6.</td>
<td>Authorized Distributor Certificate (Current Year's)</td>
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<td>7.</td>
<td>Last 3 years Tax Assessment &amp; Turn Over Certificates</td>
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<td>User List (wherever Equipments / Instruments supplied &amp; installed)</td>
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<td>PAN Card</td>
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Signature with Company Seal
Kasturba Health Society's  
Mahatma Gandhi Institute of Medical Sciences  
Sevagram, Wardha (Dist), Maharashtra - 442 102

Terms and Conditions for the tenders

Any non compliance of the following will amount to disqualification of the tender

1. Sealed tender should be addressed to the **DEAN, Mahatma Gandhi Institute of Medical Sciences, Sevagram, (P.O.) Wardha (Dist), Maharashtra - 442 102**

2. Tender should be submitted **on or before 24/06/2016 up to 1.00 P.M.** Tender received after the last date will not be accepted.

3. Separate tenders are to be submitted for each instrument. Mention on the envelope "*Tender for ..........(instrument name) of the Dept ..........(Dept name)*".

4. Tender should be in **two separate envelopes** one for **Technical Bid** and other for **Price Bid**

5. **The technical bid** must contain the following (duly attested) along with Check List:
   
   a) Detailed technical specifications of equipment quoted (Catalogue / illustrated literature) and options / other model.
   
   b) A soft copy (CD) in Microsoft Word / Excel Format showing compliance with our given Technical Specifications (i.e. Compliance chart).
   
   c) **Authorized dealer certificate (Current year's)** from the Principal of manufacturing company for supply and service
   
   d) **List of users / institutional installations / Govt. supply orders / Reputed private hospitals and copy of Manufacturing License from the manufacturer**.
   
   e) Income Tax and annual returns of Last three years
   
   f) FDA Approval Certificate for the equipment / item & FDA Registration of the manufacturer.
   
   g) VAT & CST Registration Certificate
   
   h) PAN Card copy
   
   i) Country of Origin of the equipment

6. **For equipment to be imported the prices should to be quoted in both**
   
   a) **Foreign Currency - CIF Mumbai and also**
   
   b) **INR – Delivery at Sevagram including all taxes and levies**

**Note:**

a) FOR CIF prices, the duty, transportation from Mumbai port to Sevagram, insurance will be borne by the buyer.
b) FOR INR prices-- no excise duty, sales tax, VAT, transportation, insurance will be paid by the buyer.

c) MGIMS is holding a central Govt. Certificate for import duty concession and nil rate of excise duty applicability.

d) For ease of computation you may furnish the import duty structure of your equipment and classification HSN code no of custom tariff. Import License and IEC code should also be submitted.

e) Kindly quote the prices strictly as per the scope of the supply written in the tender without offering your special features and accessories prices.

f) Performance Bank Guarantee and penalty clause for delay in supplying will be as per the negotiations.

7. Payment terms:

a) For CIF: L/C will be opened by the buyer on the condition of payment on successful installation of the equipment.

b) For INR quote: Payment will be against successful installation of the equipment

c) No advances are given with Purchase Order (PO).

8. **Delivery period** from date of Purchase Order (PO) to be written clearly in days. Penalty clause can be levied on case to case basis. Installation of the equipment should be free and to the satisfaction of the buyer.

9. Service and Guarantee conditions:

a) **Equipment will be under guarantee of two years from the date of installation.** On case to case basis Performance Bank Guarantee may be sought.

b) Mention the charges and terms of AMC & CMC (labour + Part) applicable from 3rd year onwards.

c) Mention about the nearest facility/office where service personnel are available.

d) Mention about the facility for training of personnel safety and quality standards.

10. **Dean M.G.I.M.S. reserves the right to reject all or any tender without assigning any reason.**