HSCC/SJH/Med.Eqpt./2016 Date: 09.5.2016

Amendment-VI

Ref.: 1) Tender No. HSCC/SJH/Med.Eqpt./2015/13 dt. 13.3.2016..

Sub.: Procurement of Medical Equipment for New Emergency Block & Super-Specialty Block at Safderjung Hospital, New Delhi.

The amendment of tender specifications are enclosed. The bid submission date is extended from 09.5.2016 to 23.5.2016. Pre bid meeting on 16.05.2016 at 2:30 pm at Safderjung Hospital

All other tender terms and conditions remain unchanged.

Amendment to be issued will be uploaded on websites www.tenderwizard.com/HSCC & www.hsccltd.com.

Medical Superintendent
Safderjung Hospital & VMMC,
New Delhi.

Amended Technical Specification PET CT (Tender No. 13)

Point No. 1 (iv) The Quoted /Offered Product should be FDA & European CE approved. These approval should remain valid at least till its' successful commissioning. Following documents in respect of quoted product will form part of technical bid—

a) Valid FDA and European CE approval Certificate.
b) Valid AERB Type approval Certificate for CT.

Note: Bids not accompanying documents referred under clause 1 (IV) a) & b) will be summarily rejected.

Point: 12 IV (b) a. Easy chair for post injection PET waiting rooms –four no. (Biodex or equivalent)

b. Revolving chairs with cushion and arm –six no. (Godrej or Equivalent repute makes)

c. Cupboard in various rooms – approx 200 cu.ft total

Point 12 (Copy of AERB approved MAP in annexure –A)

Equipment Specifications for IABP (Intra Aortic Balloon Pump) – High End
Equipment should be quote top Model

1. Description of Function

Intra-aortic balloon pump (IABP) is a mechanical device that is used to decrease Myocardial oxygen demand while at the same time increasing cardiac output. By increasing cardiac output it also increases coronary blood flow and therefore myocardial oxygen delivery.

2. Operational Requirements

2.1 Microprocessor/microcontroller based system. System should be complete with Display Control system and pneumatic drive unit.

3. Technical Specifications

3.1 Pneumatics:
Amended as : Drive System: Stepper motor driven bellows i.e **should be compressor based system**
Drive gas-helium (available with disposable canister or refillable cylinder.
Pumping Volume: 0.5cc-50cc Counter pulsation rate: 40-200 pulsations per minute

3.2 In Automatic Mode: System should be capable of automatically selecting appropriate trigger i.e. ECG or Pressure and also accurately select the inflation and deflation points, in automatic mode. In automatic mode of operation user should be in control of the deflation point. In Automatic mode Advance software should automatically adapt the timings for various rhythms and rate variations, without any user intervention. In Automatic mode it should automatically identify Arrhythmias and adopt R wave deflation mode for better patient support, without any user intervention In Manual mode the system allows user control of most of the pump functions.

3.3 Should be able to trigger on 7 mm Hg of Pulse pressure when used in Pressure Trigger mode

3.4 Single key start-up to make it fast, user friendly and easy to use

3.5 Should be able to display at least 3 wave forms as ECG, Invasive Pressure and Balloon Pressure wave form & Pace maker spikes if paced.

3.6 Large display for brighter and very good visibility from a distance in lighting conditions

3.7 On screen indication for Helium level in the cylinder and battery level for timely intervention and correction.

3.8 ECG inflation marker to indicate inflation period on ECG which can be useful when arterial pressure form is not available.

3.9 On screen indication of standby time and should give alarm after 15-30 minutes, to draw users attention on the system being on standby

3.10 **Amended as : Point deleted** .

3.11 IABP to function without any disturbance, when cautery is used on patient; when on ECG trigger mode.

3.12 Optical Blood leak detect for early indication of blood coming into the balloon lumen due to IABP leak

3.13 Should have extensive Help Text available during startup to make the system easy to use even for new users.

3.14 Should give extensive Help messages to correct the alarm conditions that are specific to the alarm condition. This should help the user to overcome the alarm problems immediately and with ease.

3.15 Should be capable of removing condensation automatically without user intervention and should be maintenance free.

3.16 Should have Peripheral Vascular Doppler for detecting limb ischemia, which is attached to the main equipment

3.17 Should have automatic Altitude correction to make it safer for the use during Air Transport

3.18 Should have software which allows the user to monitor the IABP from any remote location via a modem

3.19 In-built Comprehensive Service Diagnostics to help the technician to locate the fault immediately

3.20 Should have capability to connect on the Hospital network

3.21 Integrated Printer OR Chart recorder to print the reports

4. System Configuration Accessories, spares and consumables

4.1 System as specified-

4.2 System should be supplied with the following:
ECG cable with Refillable Helium cylinder Compatible with the IABP system
Qty:3 Nos

4.3 Intra Aortic Balloon Catheter for Adults, Size: 40cc Qty:2 Nos
Amended as : Intra Aortic Balloon Catheter for Adults, Size: 34cc Qty:2 Nos

Reusable Invasive Blood pressure transducer system with pressure flush device system. Qty:2 Nos

5 Environmental factors

5.1 Shall meet IEC-606001-1-2:2001(Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility. Or should comply with 89/366/EEC;EMC directive.

5.2 The unit shall be capable of being stored continuously in ambient temperature of 0-40 deg C and relative humidity

5.3 The unit shall be capable of operating continuously in ambient temperature of 10-40 deg C and relative humidity of 1-90%

6. Power Supply

6.1 Power input to be 170-270 V AC,50Hz fitted with Indian plug

6.2 On line UPS of suitable rating with voltage regulation and spike protection for 60 minutes back up

7. Standards, Safety and Training
Should be Participant must have USFDA and European CE Approved.

7.1 Manufacturer/Supplier should have ISO certification for quality standards.

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

9 Should have 5 years guarantee + 5 years comprehensive warranty.

9.1 Amended as: Model should have be latest generation ie Fiber Optic technology.
9.2 Should have local service facility.

10 Company should make sure that after getting the complaint that instrument is non functional/malfunctional (telephonically or else) instrument must be functional within 24 hours and this period should be deducted from the warranty period or the company will provide the replacement of same or higher configuration equipment.

10 Demonstration is a must.

Specification of Blood Gas & Electrolytes Analyzer

A fully automatic, fast, precise blood gas analyzer with following features:-

1. Measured parameters : pH, PCO2, pO2, Cl, Na, K, Ca, Hct. Hb, Glucose, Lactate.
2. Calculated parameters: Std. pH, pCO2, pO2, CH+, HCO3, Std. HCO3, O2 Sat, BEX, BEecf, BB, O2 content, TCO2, all at patient's temperature
3. Sample size: Not more than 100ul
4. Throughput: 40 samples per hour
5. Readout time: Less than 1 min.
6. **Amended as : Printer: In-built with preferably thermal printer .**
7. Calibration: Automatic in cycle system
8. Display: Digital display on the screen
9. Electrodes: Maintenance free with shelf life not less than 1 year
10. Memory: More than 100 patients memory

Point added : Participant must have USFDA and European **CE Approved.**

Technical Specification for Sternal Saw

1. The Sternal Saw should be light weight and provide clear line of sight
2. The Sternal Saw should operate through a flexible drive cable by an electric motor.
3. It should be able to ETO Sterlized/autoclaved.
4. The blade holding mechanism should be chuck type assembly for quickly replacing the blades.
5. The reciprocating blade should have a 5-7 mm stroke length.
6. The saw should have a blade protector on it and blade protector should be easily replaceable.
7. Foot switch should permit variable saw speeds.
8. The system operates on 220V/250V, 50Hz, single phase.
9. It should be European CE & UD FDA approved.
10. AMC for 5 years
11. Demonstration of the apparatus is must.

Point added : Participant must have USFDA and **CE Approved.**

EQUIPMENT SPECIFICATION FOR ICU MONITOR EIGHT CHANNEL WITH 3 INVASIVE BP

It should provide complete monitoring solution to meet the requirement of wide spectrum monitoring needs of critically ill patient

1. Operational Requirements

1.1 ICU should comprised of monitors at the bedside/O.T. and with one slave monitor.
1.2 Capability of storage of patient data and printing of patient reports.
1.3 Demonstration of the equipment is a must.

2. Technical Specifications

2.1 Amended as Minimum 19 inches multicolored TFT/LCD display screen.
2.2 Separate CPU/Module rack.
2.3 Eight digital and waveforms/traces display.
2.4 Combination of single, dual and multiparameter modules.
2.5 Parameter modules freely exchangeable between all the monitors.
2.6 Multichannel (upto 12 leads) ST segment analysis.
2.7 **Amedned as :** 6 Nos. monitor are required for General OT With Eeach Monitor should be provide with with slave with one Nos. CMS (Central Monitoring system) ECG, Respiration, Spo2, SvO2, NIBP, Co2, IBP (3 wave form), BIS, Gas, NMT (TOF), Temp, Cardiac output, EEG, ICP. (Three invasive BP with waveform)

2 Nos. monitor are required for Private OT With Eeach Monitor should be provide with with slave with one Nos. CMS (Central Monitoring system) ECG, Respiration, Spo2, SvO2, NIBP, Co2, IBP (3 wave form), BIS, Gas, NMT (TOF), Temp, Cardiac output, EEG, ICP. (Three invasive BP with waveform)

19 Nos. monitor are required for ICU Two Nos. CMS (Central Monitoring system) ECG, Respiration, Spo2, SvO2, NIBP, Co2, IBP (3 wave form), Gas, (TOF), Temp, Cardiac output, ICP. (Three invasive BP with waveform)

2.8 Automatic arrhythmia detection & alarm for standard and lethal arrhythmia.
2.9 EtCO2 – main stream/side stream. Display both inspired and expired values, showing capnography.
2.10 NMT Module/monitor: For measurement and display of TOF count, TOF %, ST, DBS, Tetanic and Trend for continuous usage. Automatic measurement facility in selected time interval. Automatic selection of supramaximal current. Include standard accessories.

2.11 EEG Module with all accessories.
2.12 BIS and entropy with all accessories.
2.13 **Amended as Central station for bedside monitors with independently controlled. 20" multi colour TFT Touch screen display** Monitor, complete with Ethernet LAN cabling, alarm management, 72 hours trending, bed to bed viewing of waveforms and remote alarm management like silencing of alarms etc. (Optional)
2.14 Should provide hemodynamic, oxygenation, Ventilation calculation package.
2.15 Should have drug calculation package.
2.16 Trend of at least 48 hours.
2.17 Amended as 200 nos. event recall/snapshot facility both manually and automatically triggered by alarm. with 30 minutes event recall / snapshot facility
2.18 Amended Point Deleted
2.19 The monitors should have monitor to monitor overview facility and data transfer over the network.
2.20 Web browsing facility to review each networked monitors data through hospital LAN via office PC in Hospital LAN Network and / or through Dial up facility from remote location (optional)
2.21 a) slave monitors-21 inches in ICU – one per central station
b) Battery back up of upto 3 hours. When fully charged.
2.22 Communications with information management systems:
a) To provide HL-7 compatible server for sending and receiving information to and from the monitoring network to and from Hospital Information system, Laboratory information etc for integration of various information (optional).
b) To provide suitable facility for sending and receiving DICOM Compatible Radiological Images like Ultrasound, X-ray etc to and from the monitoring network to and from Hospital Information System, Radiology Information System etc for integration of various information (optional).

3. System Configuration Accessories, spares and consumables

3.1 ECG/Resp : 5 Lead ECG Cable with clip-2 sets per monitor and 10 Lead ECG Cable with clip-1 set per monitor.
3.2 NIBP : Adult cuff –f 2 nos. per monitor and two sizes of pediatric cuffs – one per monitor (complete sets)
3.3 SpO2 : Adult SpO2 sensor with cable – two nos. per monitor and pediatric Spo2 sensors – one no. per monitor.
3.4 Amended as : IBP : Include four nos. per monitor holder and 100 nos. disposable domes per monitor.
3.5 BIS Electrode & Cable – one per monitor
3.6 EEG Electrode & Cable - one per monitor
3.7 Amended as C.O Cable with accessories - one per monitor
3.8 NMT Electrode - one per monitor
4. Include laser printer and dual channel strip chart recorder

5. **Amended as: Warranty 5 years**
6. **Amended as: CMC for 5 years**
7. **Amended as: US FDA and CE Certified**

TECHNICAL SPECIFICATIONS OF HEART LUNG MACHINE

1. DESCRIPTION :

Heart Lung Machine is an apparatus through which blood is temporarily diverted, during heart surgery, to oxygenate it and pump it throughout the body, thus maintaining circulation until the heart and lungs are able to return to normal functioning.

2. Technical Specifications:

a) The unit should have 5 pumps and can be used as arterial, two suction, vent and cardioplegia with separate power supply and control modules. Should have easy access connectors for interchanging the pump. Should have integrated centrifugal pump facility.

b) The design of pump must be horse shoe race way design and the pumps should have direct drive system and maintenance free. All the pumps should have pulsatile mode in built. Each module should work its own.

c) Each head should be controlled individually and rotatable in different direction with master-slave control.

d) Should have a spill proof base.

e) The quoted model should be of latest generation.

f) The unit should be supplied with a battery back up of minimum of 90 minutes for all the pumps. 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 automatic and immediate.

g) Should have unidirectional hand crank facility as a critical safety feature hand crank loading should be from top for faster access.

h) Accuracy: pump head raceway accuracy should be 0.03mm, occlusion accuracy should be-0.03mm, occlusion rollers accuracy should be-0.015mm & maximum flow upto 16.2 LPM should be there.

i) Occlusion: should have Thump wheel locking Mechanism.

j) Monitors: Pressure monitor (2), Timers (3), Temperature Monitor (4) and all the monitors should be touch screen.

k) Pressure Sensor should have 2 modes – Stop Mode & Control Mode.

l) Cardioplegia module should have both Manual as well as Automatic operation.

m) Should be provided with mechanical gas blender.

n) Should be provided with Level Sensor and air Bubble sensor.

o) Bubble Sensor should have different bubble detection thresholds and should also have micro-bubble detection function.

p) Level sensor should be with 2 modes – Normal & Control Mode.

q) Must have Master UPS – shows all the details like Battery time, Load time & Remaining time. Should have BSA Calculation.

r) The machine should start within 5 seconds.

s) Should be provided with venous line clamp and it should be of light weight design and can be placed near venous reservoir without any support.

t) Pumps should run on medically Safe voltage (24 V DC)

2.1) Roller pump should have a self diagnostic circuit with provision to detect and display the following alarm conditions:-
A) OVERSPEED
b) PUMP JAM
C) BELT SLIP
D) OVER OCCLUSION
E) PUMP DRIVE SYSTEM WITH DOUBLE V-GROOVED BELT SYSTEM
F) PROVISION OF FEEING THE FLOW CONSTANT FOR USING THE TUBING OF UNKNOWN I.D.
G) FLOW RATE DISPLAY SHOULD BE CALCULATED ON THE BASIS OF PUMP SHAFT SPEED.
2.2) Should have a flexible lamp to moniter the level of blood in oxygenator/reservoir.

3. HEATER COOLER MACHINE

a) The unit shall be capable of operating continuously in ambient temperature of 2 - 40.5 degree Celsius.

b) The unit should have 3 independent tanks and 3 separate circuits and these circuits should be able to control patients' temperature and also heating and cooling of cardioplegia and should work simultaneously.

c) The accuracy should be 0.1 C. Settings should be adjustable to 0.1

d) The heater cooler unit should also be compatible to get integrated into the heart lung machine and can be controlled from heart lung machine apart from remote control.

Both the heart lung machine & heater cooler machine should be of same principal company.
Both the heart lung machine & heater cooler machine should be US FDA And European CE approved.