HSCC/SJH/MEDICALEQUIPMENT/2017 **Dated: 06.12.2017**

AMENDMENT -IV

Ref: Tender Enquiry No.: HSCC/SJH/Med. Eqpt. /35 dated 18.10.2017

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

Amendment have been received for item No.5 Hemodialysis Machine with Portable RO and item No. 8, Angiography System for Interventional & Hybrid Procedures including TAVI .(Enclosed) It is extended the bid submission date from 06.12.2017 to 13.12.2017

Regarding item No.2 Bi-Spectra Index monitor, and Item No. 7 ETO Sterilizer due to inadequate response on bid submission date i.e. 06.12.2017 it is extended the bid submission date from 06.12.2017 to 13.12.2017

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

All other tender terms and conditions remain unchanged.

Technical Amendments are as follows:

Item No. 5

Heamodialysis Machine with Portable RO

REVISED SPECIFICATION FOR PORTABLE RO UNIT

	Pre-treatment
1	Should have raw water inlet units with solenoid valve and mesh filter of 50micron or above
2	Should have raw water storage tank of food grade quality or equivalent of 750 ltr or above
3	Should have sand/multimedia filter with polyglass vessel and high TDS control, with automatic backwash and sample valve.
	Treatment – main RO
4	Should be able to provide water quality as per both ISO-13959/23500 and AAMI standards for dialysis
5	Should have compact design & portable type (easy to move on wheels) in a stainless steel/powder coated chassis
6	Should be able to produce 125lt/hr of permeate at 1.5 bar, able to support upto 5HD machines respectively
7	Should be microprocessor based and capable to display parameters such as permeate conductivity/ temperature/flow, feed flow, concentrate flow, yield'.
8	In build capabilities to show on display for Permeate (supply in Litre/min. temperature) & for Raw water (Consumption in Ltr./min & pressure)
9	Should have built in dual column softener (alternate mode) with fully automatic brine, fill & clean cycles, also have a brine tank incorporated in the system
10	Should have built in cartridge type charcoal filter
11	Should have semi-automatic decalcification system in place
12	Should have fully automatic disinfection system in place.
13	Should have built in cartridge filter of 05& 20 micron
14	Should have programmable fully automated Rinse cycle for membrane wash
15	There should be a provision of OFF line mode and ONLINE mode of Permeate supply. In case of permeate supply is to be used to run dialysis machine directly with collecting permeate to tank it should be possible
16	There should be water saving system in place which adjusts the output to the number of machine in use and control yield accordingly.
17	Yield setting should be between 50 to 70%
18	Should have an internal leakage sensor
19	Should have an in-built UV lamp before RO membrane
20	Should have EC certification attached with a tender document
21	Should be operatable on single phase power supply of 220-240V AC, 50 Hz
22	Should have 'AUTO START/STOP programming' facility
23	Should not have noise level more than 65 db.
	POST TREATMENT
24	Should have permeate RO o/p Storage tank of 750 ltr with food grade quality or equivalent

25	Should have transfer/Booster pump S/S 316 grade for permeate supply to HD Machines
26	Should have sub-micron bacterial filter of 0.2 micron manually backwashable.
27	Should be installed with PEX Piping including push-pull type 316 grade S/S connectors to supply to 5HD machines.

Item No. 8

SPECIFICATION FORANGIOGRAPHY SYSTEM FOR INTERVENTIONAL AND HYBRID RPOCEDURES INCLUDING TAVI

State of the art, single floor/ceiling mounted C-arm/G-arm system with flat detector technology digital imaging system for hybrid, interventional and TAVI procedure in Hybrid OR environment.

A) C-ARM/G-ARM MULTI-DIRECTIONAL FLOOR/CEILING MOUNTED:-

1. All movements should be motorized with C-Arm angulations of minimum RAO/LAO+100 deg. /-100 deg. CRAN/CAUD + -45 deg. At head end position. With 20 deg. /sec. or more speed for LAO/RAO and 15 deg./sec or more speed for CRAN/CAUD.
2. The system should have user defined 50 programmed position of the C-Arm and table.
3. Motorized parking of C-Arm away from table for operations on table when C- Arm not in use. C Arm mounting/base should not come in the area of the operation table and operating area.
4. The C-arm should have auto collision protection with patient and the table.
5. C-arm must not interfere with laminar airflow and accommodate planer of min sizeof 2400x2400 cm on ceiling and OT lights on table in working position or while moving the C arm to different positions.

B) TABLE:-

1 Floor mounted table with flat table with radiolucent table top and floating functions with rotation from the base.
2 Table should be integrated with the system and should have motorized vertical movement.
3 The table should have Integrated Emergency Stop; all motorized movements (including table), are stopped when the System emergency stop button is pressed. The table should have Integrated Collision detection, all motorized movements (including table),are slowed down or stopped when detects the patient Workflow.
4 The table should have motorized axis tilt (head-down and head-up as well lateral tilt) with at least 15 deg.
5 The system should have provision for collision protection.
6 Table should support wide range of accessories like arm rest, surgical screen,instrument tray, hand grips, and one IV pole.
7 Gantry controls, table system controls, Collimation controlsto be mounted on trolley away from table for better flexibility.
8 Table should support patient weight up to 200Kgs or more& should take full patient weight during CPR in extended table position.
9 The table should have head to toe coverage without need for repositioning of the patient . Please specify the table dimensions.
10 System should have well designed& light weight footswitch for releasing fluoroscopy, acquisition and table brakes.

C) X-RAY GENERATOR:

1 100 KW or more compatible with high resolution imaging
2 High frequency X-ray generator with automatic regulation of radiation dose rate for all fluoro DSA and acquisition imaging.
3 The minimum power rating should be 100 KW OR more at 100 KV compatible with high resolution imaging.
4 Fluoroscopy exposure and mA should be automatically controlled.
5 System should have pulsed fluoroscopy system.

D) X-RAY TUBE:

1 X-Ray tube should be with fine focal spots (2/3 focal spots for different application) with high cooling rate to ensure continuous operation, capable of pulsed fluoroscopy. The large Focus power output should be 65 kw to 80kW or more. The pulse Fluoroscopy should be offered with pulse rate of 3.75 Frame/sec to 30 frames/sec.
2 The X-ray tube should have Anode heat storage capacity of at least 2.4 MHU or more to run continuously for 6-8 hours without shutting off.

E) RADIATION PROTECTION:

1 The system should have integrated computer controlled X-ray Beam filtering with at least3/4 programmable copper filters of various sizes from 0.2 mm to 0.9 mm.
2 The system should have positioning of collimator blades without radiation.
3 The system should have monitoring and display of X-ray dose during the patient examination. It should be possible to create a DICOM based dose report of the patient.
4 System should meet all National & International safety standers, US FDA , European CE& comply with BARC & AERB guidelines.
5 System should have latest low dose radiation safety features of operator and patient (care & clear /clearity IQ or equvalant)

F) DIGITAL IMAGING SYSTEM:

1 A flat detector with a diagonal size of least 46 cm.
2 Digital system with acquisition and processing in 1024 x 1024 matrix at 25/30 fps with 8/10/12 bit digitization.
3 Image storage capacity of at least 1,00,000 images in 1024 x 1024 matrix at 10/12 bits on the main system disk and upgradeable further.
4 System should have capability of ECG display on the live image monitor during the cinaacquisitation andperferably archive along with angio images on CD, during the acquisition.
5 System should have on-line & off-line validated vascular analysis. The software should have Auto calibration facility for Stenosis measurement with geometrical and densitometry calculations. The analysis should be possible from table side in the examination room and from the control room.
6 The full system should have table side control operation with touch screen / knobs for complete acquisition and post processing capabilities.
7 The system should have on-line DSA capabilities with acquisition frame rate of 1 frame/sec to 6 frames /sec or more.
8 Rotational angiography facility with and without subtraction should be available. It should be possible to generate 3D and CT like images from rotational angiography data.
9 The system should have facility for storage of fluoro loop scene of at least 10 seconds.
10 System should be provided with all advanced 2D and 3D road mapping.
11 The latest complete software and hardware for visualizing stent with extra high- resolution from table side control& preferably stent enchancement with relation to lumen (fade in and fade out).
12 Separate work station should be provided with at least 3 GB main memory for 3D reconstruction to free the main system for continuation of procedure immediately after displayed both in the control room as well as the examination room. It should be possible to recall & view images acquired in the rotational mode (subtracted &un subtracted) alongside the 3D images. Review of all images should be fast interactive & user friendly in both the rooms. Table side controls for 3D reconstruction and C-Arm positioning with respect to 3D image & selection of 3D image with respect to C-Arm positioning should be provided. The 3D reconstruction should be in true 512 matrix. All options related to 3D (MIP, SSD, VRT, slicing, measurement tool, volume try etc.) should be available. Software to fuse CT, angio & MR images of the same patient at the independent workstation is desirable.
The 3D workstation should be capable of the following functions
i) 3D reconstruction using SSD, VRT, MIP in true 512 matrix with color display in the control & examination room.
ii) All post-processing functions for images including fusion of CT, MR and angio images with 3D display & 3D volume measurement.
iii) Immediate background transfer of all images as soon as they are acquired, to CD/DVD recording station.
iv) It should be possible to view dual density objects in one view to differentiate blood vessels from coils.
v) It should be possible to have 3D of aortic root from the rotational angiodata/ pre acquired CT data and auto marking of anatomical landmarks like coronary ostium. It should be possible to have overlay of live fluoro on this 3D image or valve marking lines with landmarks for guidance in TAVI procedures. C Arm should position itself automatically depending upon the 3D image.

G) MONITORS/DISPLAY:

1 The monitor display system in examination room should be ceiling suspended and it should be possible to position it on the left or right side of patient table. The monitor should be single high resolution monitor of at least 55" and 8 megapixel resolution with luminance of 700 CD / M. sq and 1000:1 contrast or more to display live,reference,3D image ,hemodynamic data .Two additional monitors of at least 19'' to be provided. One for live image and another for waveform display.

2 Console room should have monitors to display patient demographics, fluoroscopy images and 3D images. All monitors at least 19 " or more

3 **Hemodynamic specification:**

a. dedicated hemodynamic system for cardiac catheterization for adult and peadiatric patient
b. Hemodynamic system should have four invasive pressures & ECG.
c. Should have all Hemodynamic analysis tools to calculate cardiac output, shunt area and Gradient measurements
d. Should be able to store and print one week angio-studies.
e. 12 lead ECG and 4 lead Invasive pressure transducer and domes should be supplied with the system.
f. Should be connected with cath lab network printer.
g. 20 personal dosimeters should be provided which will give real time reading of the radiation dose.
h. There should be a provision for display of time taken for entervential procedures in the operating room the dosimeter should have wired connectivity to the dose monitoring system for according the doseages and archiving

H) CONTROL CONSOLE:

1) All system movements of C-Arm, table, image display, image review, image post processing and quantification shall be controlled both by the operator at the table in the exam room and in console room.
2) The system should have facility for edge enhancement, Positive/negative image display, windowing, contrast/brightness, electronic shuttering, image/pixel shifting, vertical and horizontal image reversal, zoom functions. System should have facility to allow overlying of fluoroscopy and reference image with fade-in and fade-out of these images possible.
3) The system should have fast and direct access to all series, single images, in both examination and control room.
4) System should have angle/distance measurement, Image labeling and patient positioning facilities.

I) DIGITAL ARCHIVING:-

1 System should be DICOM 3.0 ready.
2 Image transfer from digital system in background mode without affecting the system operation.
3 USB interface to copy images to memory disk/external hard disk.

J) IVUS

1. Latest Generation Intra Vascular Ultrasound System 2.7 version.
2. Monitor-SVGA LCD Monitor-Minimum 19".
3. Colour map (iMap) overlay to visualize tissue type (Fibrotic, Lipidic, Necrotic, and Calcified) as well as an improved workflow design.
4. Area & length measurements graphics in the cross-sectional and long view images.
5. ECG and Audio signals capturing enabled.
6. Ease to eyes by colouring IVUS images.
7. Sterile field control option.
8. Compatibility with Coronary, **Peripheral** and optional intra cardiac echo catheters **(ICE)**.
9. Automated lumen and vessel measurement to aid in diagnosis and planning.
10. Dynamic review feature (blood flow, plaque morphology, dissections and stent apposition)
11. Long view and cross sectional imaging.
12. Coronary IVUS catheter with single Rotating/Mechanical transducer driven by a flexible drive cable with minimum 20 MHz frequency.
13. High storage capacity with removable hard disk and minimum of 25 cases storage.
14. Archiving options: CD ROM, 16X DVD, Removable Hard Disk and Network.
15. Maximum number of area measurements per cross section image for better imaging, Minimum-3d
16. Maximum number of distance measurements per cross section images for better imaging, Minimum-9
17. Minimum 30 GB hard disk with an option of removable storage with minimum storage of 20 cases or more.
18. DICOM storage & image formatting.
19. Digital Frame Grabber.
20. Data Entry: Touch Screen, Mouse
21. Multiple image screen format.
22. Automatic & manual pull back options.
23. Automated vessel and lumen measurements/detection with manual correction option.
24. Printer to print IVUS images.
25. Approval-International standards agency US FDA or Equivalent.
26. Clinical support for training of staff.
27. Technical back up for maintenance of machine

K) FFR (Fractional Flow Reserve) Measurement System for Physiological Lesion Assessment

1. Should be able to assess Arterial Pressure through Cath Lab transducer system wirelessly/ with wire.
2. Should be able to asses distal Pressure through device, both wired and wirelessly.
3. Should have the option to be wall mounted, table mounted or desktop as per the need.
4. Should be able to transmit and display recordings on the existing cath lab monitors
5. Display both real time pressure and mean pressure values.
6. Screen window displays real time FFR in both numerical and graphical form.
7. Should haveoptionalupgraded software to calculate CFR (Coronary Flow Reserve) this is real time. Both FFR and CFR simultaneously. IMR to be calculated using desktop software or should have optional upgraded software for instantaneous flow reserve (IFR) & IFR scout calculating software.
8. Should be capable of reading temperature (thermodilution)
9. Temperature readings in the range of 15-42 C
10. Should be able to do Pressure Reference equalization
11. Should measure pressure in a range of -30 to 300 mm Hg
12. Touch screen capabilities to be operator friendly, guide steps to follow for procedure.
13. Displays Calibration steps.
14. Should have a frequency response of 0-25Hz
15. Should give Graphical presentation of pressure waves.
16. Allows different beat settings in accordance with the cath lab system.
17. Should be compatible with different hemodynamic systems
18. Should have memory to save and record the data.
19. Should also enable cath lab to read AO pressure for monitoring.
20. Should communicate with PC.
21. Should be compatible with printer, DICOM and USB interface for transferring FFR recordings

L) ***OpticalCoherenceTomography(OCT) SystemwithrealtimeonIine3Dimagingfeatures***

1. The systemshould havean imaging engine that is based on the fiber optic technology.
2. The systemshould have wireless FFRmeasurement capabilities.
3. Itshould utilize catheterthat emitnear infra red light to produce high resolution realtime images.
4. Should have two monitors plusremote videooutputfor multiple
    a. sightlines.
5. The systemshould havean integrated drive-motorand Optical Controller (DOC).
6. Should have an isolationtransformer.
7. Should have a computer, a keyboard,and a mouse.
8. CPU with high end DAScard for faster 3-D dataacquisition speed
9. 22*CD/DVD RWdual player DVD RAM drive for fasterimage management.
10. DICOM compatibility

Thesystemshouldallowtheuserto:

1. Acquire, save and subsequentlyretrieve images for review.**Real-time 3D image**
    a. **Re-construction oflumen and vessel**
2. Immediate and accuratelumen boundary detection andLumen Profile Display
3. Stentplanning workflow with automatedminimumlumenarea and percent stenosis measurements
4. Automatic lumen detection onevery frame
5. Profile of mean diameter or lumen area across pullback
6. Automaticmarking ofMLAframe
7. User-defined proximal and distal reference frames
8. Automated display of reference frame area and diameters, distance between references,%AS and %DS
9. Automatedmeasurementsmode forcalculationsfor stentsizing
10. Seamless integration ofFFR and OCT with guided workflowsfor exceptional ease-of-use
11. Should allow user for easy orientation on Angiography
12. Allow to acquireandreview images in L-Mode(lateral view).
13. Overlay color maps to optimize contrast resolution.
14. Enlarge a defined area ofinterest (zoom).
15. Make measurement and calculationsof% Diameter stenosis
16. Add text annotations.
17. Play back and edit images with a full range of playback andeditingcapabilities.
18. Export still images andmovies in rawOCTformat or in standard AVI, TIFF, JPEG,BMP,or DICOM formats.

19. ImportOCTformat images and reviewand editthemwith fullOCT
    a. reviewand edit capability.
20. Performbasic file managementfunctions.

TheimagingParametersofthesystemshouldbe:

1. Maximumframe rate:Up to 180 fps
2. Longer pullback ofup to 75mmand up to 540 frames
3. Faster pullback speed up to 36 mm/sec
4. Allows user to do high resolutionimaging foronline real time3-D re-construction
5. # of lines per frame: 500
6. Scan diameter:10 mm
7. Axial Resolution: 15 microns

M) Training

Training to be provided to **six**doctors/staff of the department for operation & maintenance of the equipment for **two weeks** at**an International centre of repute abroad** with similar equipment installed.

N) UPS:-

Suitable online UPS of at least 120 KVA capacities with 30 min. battery backup for complete Cath Lab including cine and fluoroscopy. Emergency lighting should also be on UPS

O) ESSENTIAL ACCESSORIES TO BE SUPPLIED:

1. Lead glass 150 x 120 cm.(as per international radiation protection standard)
2. Good quality, wrap around light weight Lead Aprons with hangers-20 nos. (as per FDA standard)
3. Thyroid Guard-20 nos. (as per international radiation protection system)
4. Ceiling suspended radiation protection-1 no. (as per international radiation protection system)
5. Table mounted radiation protection -1 no. (as per international radiation protection system)
6. Integrated two way communication system between control room and examination room.
7. One laser Network Printer of high resolution (at least 1200 dots per inch) with minimum 128 MB memory and 1200 dpi
8. High –pressure injection system, having features of programmed flow rate, volume. Vendor should supply 200 syringes

Site Modification:

1. Area under the scope of the site modification is :-
    - Examination Room
    - Console Room
    - UPS cum Cabinet room
2. Examination room should be in line with AERB requirements
3. Lead Glass window and lead door to be provided on console and examination room common wall.Second lead lined door to be provided in the examination room for patient entrance
4. PVC Flooring, trenches and cable trays to be provided.
5. Air-conditioning of 2 x 2 TR(Split AC) to be provided in the UPS cum cabinet room
6. Total load of the equipment along with the accessories to be mentioned by the vendor
7. Hospital authorities to provide electrical cable upto electrical panel in the UPS room
8. LT panel should be Supplied &installed by the vendor
9. All general lighting, electrical fittings and fixtures to be provided by hospital authorities
10. Adequate fire detection system to be provided by the vendor, inside the area under the scope mentioned above
11. Partition to be provided between UPS and Batteries in the UPS room
12. All civil works related to successful installation of the machine as per the layout attached should be carried out by the vendor
13. Wall finishes in console and UPS room - upto fall ceiling skirting along with POP and plastic emulsion paint upto the false ceiling.

Furniture:

1. Workstation table – 1 no.
2. Computer chairs on castors – 2 nos.
3. Cupboard with laminated door shutters (1200 mm x 600 mm x 2100 mm) – 2 nos.

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