<u>AMENDMENT - I</u>

- Ref.: Tender No. HSCC/SJH/Med.Eqpt./2015/19 dt. 15.6.2016.
- Sub.: Procurement of Medical Equipment for New Emergency Block & Super-Specialty Block at Safdarjung Hospital, New Delhi.

Existing as :

Sl. No.	Description	Schedule
i.	Closing date & time for receipt of Tender	07.07.2016, 1430 hrs IST
ii.	Time and date of opening of Techno – Commercial tenders	06.06.2016, 1500 hrs IST

<u>To be read as :</u>

Sl. No.	Description	Schedule
i.	Closing date & time for receipt of Tender	19.07.2016,, 1430 hrs IST
ii.	Time and date of opening of Techno – Commercial tenders	19.07.2016, 1500 hrs IST

TECHNICAL SPECIFICATION

ItemNo.1 IntraVascularUltrasoundMachine(IVUS)forCoronary Application

- A. Description of Functions: IVUS offers direct, accurate, real time topographically oriented 360 degree images not just of the vessel lumen, but of the vessel wall itself and any lesions it might contain.
- B. Technical Specification:
 - 1. Should be a Window based IVUS imagine system capable of accepting transducer ranging from 5-40 MHz
 - 2. Should be DICOM-3 Compatible.
 - 3. Should have DICOM storage to CD-R and PACS network compatible.
 - 4. **Amended a**s: Should be supplied with 18 inch LCD flat panel medical grade display, Data entry keyboards, track ball or mouse interface or touch panel.
 - 5. Should be capable of patient data entry and on screen annotation.
 - 6. Hard disk storage space should be sufficient to store at least 15 clinical case studies (Please specify CPU Features.)
 - 7. Should have Biophysical inputs: ECG
 - 8. **Amended as** Digital video loop storage: up to 8 minutes with still frames (JPEG) With full editing capabilities including offline editing.
 - 9. Should be capable of automatic and manual measurements: diameter and areas Quad /multiscreen format for comparison with prior measurements.
 - 10. Should have on line 2 D Longitudinal display and measurements.(Seen Longitudinal cut section

of the artery)

- 11. Should have automatic border detection, both lumen and vessel.
- 12. Should have facility to incorporate coronary angiographic data.
- 13. Should be compatible to be incorporated to existing Cathlab system.
- 14. Automatic border Detection: High light lumen and vessel boundaries real time during pullback.
- 15. Automatic Measurements- Ability to calculate key documentation endpoints including MLD, CSA and plaque burden , plaque composition that could be seen on cross section and longitudinal views.
- 16. Clear Visualization of Blood flow , Improved detection of Blood Flow , Dissections , stent appositions.

17. Color distinctions of plaque composition.

- c. Quantity: One IVUS machine with following accessories.
- a. Pull back device 3 nos.
- b. Printer
- c. CD/DVD writer built in
- d. IVUS Catheters -10 Nos.

d. Environment factors:

- 1. Shall meet IEC -60601-2:2001 (Or Equivalent BIS) General Requirements of safety for Electromagnetic Compatibility. Or should comply with 89/366/EEC; EMC directive.
- 2. The Unit shall be capable of being stored continuously in ambient temperature of 0 -50 deg C and relative humidity.

3. The unit shall be capable of operating continuously in ambient temperature of 10-40 deg C And relative humidity of 15-90% E. Power Supply

- 1. Power input to be 170 270 V AC, 50 Hz fitted with Indian plug.
- F. Standard, Safety and Training
 - 1. **A m e n d e d a s**: S h o u l d be US FDA approved product.
 - 2. Manufacturer/ supplier should have ISO certification for quality standards.

G. Documentation :-

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

H. Other Requirements:

- 1. Model should be latest generation.
- 2. Should have local service facility in Delhi.
- 3. **A m e n d e d a s**: Comprehensive warranty for 5 years and CMC for next five years
- 4. Availability of spares to be ensured for minimum 10 years period.
- 5. Demonstration, if required before approval and working demonstration after installation.

6. **A m e n d e d a s**: P r i c e of spares/ accessories /consumable /disposable etc. should also be quoted separately for the first three years and the price should also be fixed for CMC Period.

ItemNo. 2

VIDEO BRONCHOSCOPE

Tender Requirements:

- 1. Bronchoscope
- 2. Color Video Monitor
- 3. Video Processors
- 4. Cold LIGHT SOURCE
- 5. RECORDER
- 6. TROLLEY

Bronchoscope:-

- 1. The working length of the Bronchoscope should be 60 cm or more.
- 2. Amended as The outer diameter should be 6.0 to 6.5 mm approximately.
- 3. Amended as Working channel diameter 2.3 mm or above, with closed suction system.

4. Amended as Color CCD chip integrated with the bronchoscope which can generate brilliant high resolution images.

- 5. Leak testing facility.
- 6. Total length around 870 mm
- 7. Angulations up 180 degree, down 130 degree.
- 8. Field of view should be 120 degrees or more
- 9. Amended as Depth of field should be 3 to 50 mm or better.

COLOR VIDEO MONITOR

Amended as To Support endoscopic application with high resolution clarity of images perfect observation(Medical grade)

Easy to use controls.

Remote controls

On screen menu for image adjustment.

Variable inputs signals: REB, Y/C and composite.

Color setting: TWO REB input signals can be observed simultaneously for printer. REB split mode.

VIDEO PROCESSORS:

Should provide filker and blur free images.

Color CCD technology to provide perfect colour reproduction.

Amended as Provision for still images/video capturing and digital recording , images resolution at least 1.2 megapixels.(high end and latest video processor)

LIGHT SOURCE

Compatible light source for color CCD video Bronchoscope system. Automatic light adjustments to maintain optimum brightness **Amended as** Xenon lamp 300 W. xenon light source+ I scan /NBI/SPICE/FICE It should be supplied with suitable voltage stabilizer **RECORDER**

Amended as: Ability to record in digital format with ability to output image and video sequences in CD/DVD Rom/**External Hard drive**

Should provide standard accessories trolley

Standard Accessories made by principle manufactures.

Suction Valves=20 Biopsy valves =20 Biopsy forceps (reusable) =10 (including rat- tooth, alligator and cusp types) Cytology brush =5

Point Added: Video trolley +UPS +Computer recording software+printer

Point ADDED: Product should be USFDA/CE Certified

<u>ItemNo.3</u> <u>AdultFlexibleIntubationwithlightsource.cameramonitor&trolley</u> <u>(Bronchoscope)</u>

Should be light weight, high resolution flexible fiberscope.

 $Should have bending \,mechanism\,knob\,without\,lock.$

Should be water proof and fully immercible in disinfectant solution.

The fiberscope should be capable of connection to Endoscopic Camera to visualize images on the monitor

 $Provide \ with \ telescopic \ eyepiece \ for \ compatibility \ with \ video \ processing \ system \ .$

Airway Guide (Cum Bite Block) for Oral Intubation should be provided with the set (at least 10 airways.)

Should include – carrying case, tube holder suction adaptor (atuocalvable), cleaning brush, pressure compensation cap & leakage tester as standard accessories.

Amended as: Suitable grasping forceps should be provided (imported OEM)

Amended as: The Product must be US-FDA approved / ISO / CE certified.

TechnicalSpecificationAdultSet:

0	Amended as: Field of view-	95° or more	
0	Distal END Diameter	5.0-5.4 mm	
0	To Facilliate an Endo tracheal Tube with inner Diameter - 6mm or more		
0	Bending range	up 140° or more & down 130°or more	
0	Working Length	600 mm or more	
0	Total length	800 mm or more	
0	Instruments Channel Diameter	2.2 mm or more	
0	Amended as Depth of View	3-50 mm	

LightSource.Camerasystemandotheraccessories

A m e n d e d a s 1 – Chip Camera control Unit (CCU), with integrated electronic Fiberscopefilters, to provide video image and light source should be halogen /LED 150 watt. With compatible 21 inch medical grade monitor. Product should be USFDA/CE Certified

Guarantee /warranty for period of 5 years from the date of installation of equipment.

Supplier must guarantee and ensure minimum of 10 years of supply of spares and consumables specification the workstation as a whole

Demonstration of quoted model of equipment is essential.

Firm / supplier should offer comprehensive Maintenance Contract (CMC) FOR the next five year.

Must be provide complete price list of all consumables , accessories spare parts along with quotation .

ITEMNo.4

PediatricFlexibleIntubationwithlightsource.cameramonitor&trolley (Bronchoscope)

Should be light weight, high resolution flexible

fiberscope. Should have bending mechanism knob

without lock.

Should be water proof and fully immercible in disinfectant solution.

The fiberscope should be capable of connection to Endoscopic Camera to visualize images on the monitor

Provide with telescopic eyepiece for compatibility with video processing system.

Airway Guide (Cum Bite Block) for Oral Intubation should be provided with the set (at least 10 airways.)

Should include – carrying case, tube holder suction adaptor (atuocalvable), cleaning brush, pressure compensation cap & leakage tester as standard accessories.

Suitable grasping forceps should be provided.

The Product must be US-FDA approved & ISO & CE certified.

TechnicalSpecificationAdultSet:

90° or more

o Amended as :Distal END Diameter3.4-3.8 mmo To Facilliate an Endo tracheal Tube with inner Diameter -4.5 - 6.5 mm

o Amended as Bending range	up 130° or :	more & down 130°or more
o Working Length	600 mm oi	rmore
o Total length	830 mm or n	nore
o Amended as Instruments Chann	1.2 mm or more	
o Amended as Depth of View		3-50 mm

LightSource.Camerasystemandotheraccessories

1 – Chip Camera control Unit (CCU), with integrated electronic Fiberscope filters, **A m e n d e d a** s 1 – Chip Camera control Unit (CCU), with integrated electronic Fiberscopefilters, to provide video image and light source should be halogen /LED 150 watt. With compatible 21 inch medical grade monitor. **Product should be USFDA/CE Certified** Guarantee /warranty for period of 5 years from the date of installation of equipment.

Supplier must guarantee and ensure minimum of 10 years of supply of spares and consumables specification the workstation as a whole

Demonstration of quoted model of equipment is essential. Video Demonstration is not acceptable. Firm / supplier should offer comprehensive Maintenance Contract (CMC) FOR the next five year.

Must be provide complete price list of all consumables , accessories spare parts along with quotation .

<u>Item No. 5</u>

<u>NeonatalFlexibleIntubationwithlightsource,cameramonitor&trolley</u> (Bronchoscope)

Should be light weight, high resolution flexible fiberscope. Should have bending mechanism knob without lock.

Should be water proof and fully immercible in disinfectant solution.

The fiberscope should be capable of connection to Endoscopic Camera to visualize images on the monitor

Provide with telescopic eyepiece for compatibility with video processing system .

Airway Guide (Cum Bite Block) for Oral Intubation should be provided with the set (at least 10 airways.)

Should include – carrying case, tube holder suction adaptor (atuocalvable), cleaning brush, pressure compensation cap & leakage tester as standard accessories.

Suitable grasping forceps should be provided.

The Product must be US-FDA approved & ISO & CE certified.

TechnicalSpecificationAdultSet:

oField of view-	85° or mor	е		
o Amended as Distal END Di	iameter	2.5-3.00 mm		
oTo Facilliate an Endo tracheal Tube with inner Diameter 3.5 – 5.5mm				
o Amended as Bending range up 130° or more 8		e & down 130° or more		
o Working Le	600 mm or more			
o Total length	800 mm or more			
o Amended as Instruments	1.2 mm or more			
o Amended as Depth of View	3-50 mm			

LightSource.Camerasystemandotheraccessories

1 – Chip Camera control Unit (CCU), with integrated electronic Fiberscope filters,

Guarantee /warranty for period of 5 years from the date of installation of equipment.

Supplier must quote rates of CMC for the next 5 years.

Supplier must guarantee and ensure minimum of 10 years of supply of spares and consumables specification the workstation as a whole

Demonstration of quoted model of equipment is essential. Video Demonstrationp is not acceptable.

Must be provide complete price list of all consumables, accessories spare parts along with quotation.

<u>ITEM NO. 8</u>

Open Heart Surgery set (Valve Surgery) / Coronary Surgery Sets) / & Vascular Instruments Sets.

> Pre bid queries for **<u>item No. 8</u>** will be uploaded shortly

All other terms & conditions remain unaltered.

Medical Superintendent Safdarjung Hospital & VMMC, New Delhi.