

Amendment-I

Ref.: Tender No. HSCC/SJH/Med.Eqpt. /2016/25 dt. 23.12.2016

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

Item No. 8 Laparoscopic Surgical Instruments

REVISED Technical Specifications for to High Definition Endo-Vision system for Laparoscopic System (Qty.-1)

The system should be truly Digital HDTV endoscopic video camera. The system should have the maximum Resolution of 1920 X 1080 pixels, progressive scan and the consistent use of 16: 9 formats for Input & Output to guarantee genuine HDTV.

A. Full High Definition up Systems will consist of:

- 1) Full HD Video Image Processor -1no
- 2) 3 Chip CCD / CMOS Full HD Camera Head -1no
- 3) Powerful LED/ 300W Xenon Light Source for better illumination
- 4) 26" Full HD Medical Grade Monitor-1no
- 5) Telescope Autoclavable- 1no
- 6) Light Guide Cable-1no
- 7) High Flow Insufflator- 20 Liters -1no
- 8)Trolley /Video Cart -1no
- 9)Suction-Irrigation unit - 1no
- 10)Carbon Dioxide Cylinder- 2no
- 11)Hand Instruments & Other Accessories
- 12)Accessories, spares and consumables

1) **Full HD Video Image Processor:** Should have following specification:

- A full high definition processor should have resolution of 1920x1080 pixels.
- Should have special filter light for observation of capillary vessels and fine patterns in the superficial layer of mucosa for early detection of lesions, Or Optical image enhancement to view the capillary vessels and fine patterns in the superficial layer mucosa for early detection and recurrence of lesions.
- Should have a USB slot so as to take still pictures of Endoscope images.
- Should have provision for adjusting brightness automatically during to & fro of the scope movements.

2) **3 Chip /CMOS Full HD Camera Head:** Should have following specification:

- The full HD camera head should be of Eye piece type & have resolution of 1920x1080 pixels.
- Should have Digital / Manual focus function which can be varied seamlessly from coarse to fine image.
- Camera Head & coupler should be one piece.
- The camera head should /must have integrated(one piece) inbuilt zoom and focus lens/rings to make it fully soak able for sterilization/disinfection.

3) **Powerful LED Or300W Xenon Light Source:** Should have following specification:

- **A Powerful LED Or 300W Xenon Light Source**
- Automatically adjust light intensity to achieve ideal illumination.
- Should have special filter light for observation of capillary vessels and fine patterns in the superficial layer of mucosa for early detection of lesions.
- Colour temperature of at least 5800 K
- Manual and automatic adjustment of light intensity
- Brightness control to be regulated manually or automatically via the output signal of a video camera
- Lamp life 500 hrs or more
- Display of lamp life/Bulb usage meter warning light
- Standby mode with emergency lamp with visual indicator
- Electrical specifications
 - a. Power supply voltage: 100-240 VAC
 - b. Power frequency: 50-60Hz
- The light source should comply with IEC 60601-1, belong to Class II a with CE mark

4) **26" Full HD Medical Grade Monitor:** Should have following specification:

- 26 inch full HD LCD with LED backlit monitor with high resolution 1920x1080
- Aspect ratio 16:9
- Should have multi -modality display compatibility, including Picture-in-Picture for various image size combinations.
- Should have eco -friendly consumption by low power consumption, various powers saving mode, lightweight and thin body.
- Should have advance Image Multiplier Enhancer to enhance image quality.
- System should offer 2 x DVI-D output, 2 x 3G/HD SDi output
- Should have 2x DVI – D input and 2 x 3G/HD SDiinput .

5) **Telescope:** Should have following specifications:

- 10mm, 0 &30 degree – 1No each (approx. 30-35 cm long)
- 5mm, 0 &30 degree – 1No each (approx. 27-30 cm long)
- Completely distortion free.
- HD Optics for better contrast & color reproduction.
- Large field of view and depth of focus.

- Fully Autoclavable type.
- Color coded.

6) Light Guide Cable

- It should have High resistance protection against mechanical and thermal stress
- It should have small bending radius for comfortable use
- It should be 3 Meter or more in Length
- Should be ROHS compliant.

7 High Flow CO2 Gas Insufflator unit – 20L minute minimum

- Should be digital, microprocessor controlled & automatic type
- Large digital display on front panel for status checking
- Powerful Insufflation flow rate of 20 L/Min required.
- Automatic feedback control for any malfunction.

8) Trolley (video cart) should be supplied for the system

- Made of Stainless Steel/ Epoxy coated metal with minimum 4 shelves.
- Portable on 4 antistatic dual castors, 2 with locking brakes
- Should have minimum 4 shelves
- Should have storage for CO2 gas bottle holder
- Should be from OEM
- Trolley should be able to hold monitor with tilt and swivel accordingly.
- Should have anti- static strong wheels

9) SUCTION-IRRIGATION UNIT :

- Controlled suction and irrigation unit with flow rate of at least 11/min.
- Irrigation pressure control between 0-400 mm Hg, preferably by roller pump.
- Suction pressure control between 0.75 bar.
- Control from control panel and /or foot pedal
- Main unit with digital display
- Overflow protection on suction bottles
- Accessories should include silicone tubing set with reusable pressure domes, bacterial filter and suction bottles with cap (minimum 5 ltrs.)

10) CARBON DIOXIDE CYLINDER - TWO

Two large size cylinders with required regulators and connecting pipe to the insufflators with pressure gauze.

11) HAND INSTRUMENTS & OTHER ACCESSORIES

S.No.	Instrument	Specification	Qty
1.	Reusable Veress Pneumoperitoneum	Spring loaded Length – 10cm Blunt style	02

	Needle	Luer lock - 15 cm	02
2	Reusable Trocar :- 5mm	Multifunctional valve, insufflations stopcock and smooth sleeves, pyramidal tip with safety outlet hole near tip, length (10.5cm), autoclavable	06
3	Reusable Trocar :- 10/11 mm	Multifunctional valve, insufflations stopcock and smooth sleeves, pyramidal tip with safety outlet hole near tip, length (10.5cm), autoclavable	05
4	Reusable Trocar :- 5mm	Multifunctional valve, insufflations stopcock and smooth sleeves, pyramidal tip with safety outlet hole near tip, length (10.5cm), autoclavable	02
5	Reusable Trocar :- 13.5mm	Multifunctional valve, insufflations stopcock and smooth sleeves, pyramidal tip with safety outlet hole near tip, length (10.5cm), autoclavable	01
6	Two ways Suction and Irrigation cannula	a- Size 5mm, length 32-38cm, used with suction and irrigation handle and handpiece with stopcock b- Size 10 mm, length 32-38 cm	01 01
7	Tissue Grasping forceps - toothed 2x3 teeth	Double action jaws of 20-23 mm, rotating with connector pin for unipolar coagulation, size 5mm, length 33-36cm, dismantling facility, plastic handles with ratchets, autoclavable	01
8	Tissue Grasping forceps - toothed 2x3 teeth	Single action jaws of 30-35 mm, rotating with connector pin for unipolar coagulation, size 5mm, length 33-36cm, dismantling facility, plastic handles with ratchets, autoclavable	01
9	Maryland forceps	Double action jaws with size 14-16 mm, rotating with connector pin for unipolar coagulation, size 5mm, length 33-36cm, dismantling facility, plastic handles without ratchets, autoclavable	02
10	Grasping forceps	Double action jaws, spoon shaped with multiple teeth of jaw length 18-23 mm and rotating with connector pin for unipolar coagulation, size 5mm, length 33-36cm, dismantling facility, plastic handles without ratchets, autoclavable	01
11	Dissecting and Grasping forceps - Alligator type	Double action jaws, rotating with connector pin for unipolar coagulation, size 5mm, length 33-36cm, dismantling facility, plastic handles with ratchets, autoclavable	01
12	Dissecting and Grasping forceps	Single action jaws, with dolphin nose tip of 16-20 mm, rotating with connector pin for unipolar coagulation, size 5mm, length 33-36cm, dismantling facility, plastic handles without ratchets, autoclavable	01
13	Grasping forceps Atraumatic - Reddick Olsen type	Double action jaws, with fine serrations on jaw length 12-18 mm and rotating with connector pin for unipolar coagulation, size 5mm, length 33-36cm, dismantling facility, plastic handles without ratchets, autoclavable	01
14	Grasping forceps - Fenestrated	Single action straight jaw of 24-26mm length with fine serrations and fenestration, rotating, size 5mm, length 33-36cm, dismantling facility, plastic handles with ratchet, autoclavable	01

15	Grasping forceps – Fenestrated	Single action curved jaws of 35-40mm length with fine serrations and fenestration, rotating, size 5mm, length 43-46cm, dismantling facility, plastic handles with ratchet, autoclavable	01
16	Babcock Grasping forceps- (5 mm)	Double action jaws, atraumatic fenestrated, rotating, size 5mm, length 33-36cm, dismantling facility, plastic handles with ratchet, autoclavable	01
17	Babcock Grasping forceps- (10 mm)	Double action robust jaws with large atraumatic gripping surface, rotating, size 10mm, length 33-36cm, dismantling facility, plastic handles with ratchet, autoclavable	01
18	Dissecting and Grasping Forceps	Single action, atraumatic, fenestrated, curved jaws of length 25-28mm, rotating, size 5mm, length 33-36cm, dismantling type, plastic handles with ratchet, autoclavable	01
19	Dissecting Forceps- Right Angled	Double action jaws, rotating with connector pin for unipolar coagulation, size 5mm, length 33-36cm, dismantling facility, plastic handles without ratchet, autoclavable	01
20	Fan shaped retractor	Rotating with 4-5 blades, size 5mm, length 33-36cm, dismantling facility	01
21	Hook Scissors	Double action jaws, rotating with connector pin for unipolar coagulation, size 5mm, length 33-36cm, dismantling facility, autoclavable	02
22	Rotating Metzenbaum Scissors	a- Double action jaws of length 14-16mm, rotating with connector pin for unipolar coagulation, size 5mm, length 33-36cm, dismantling facility, autoclavable b- Insert of Metzenbaum scissors	02 02
23	Bipolar coagulating forceps	Wide jaws for dissection, grasping large vessels, size 5mm, length 33-36cm fenestrated. Jaws with robust hinge and 360 degree rotational, ring handles, can be completely disassembled and a cleaning port, autoclavable	01
24	Spoon Forceps	10 mm size, without ratchet	01
25	Reusable Hem-o-lock clip applicator	10 mm size	01
26	Bipolar coagulating forceps (Only Insert)	Maryland type jaw of 18-20 mm length, and 34-36cm long to fit into the other part of No. 23, autoclavable	01
27	Needle Aspirator	Size 5mm, length 30-36 cm, Needle diameter of 1.5-2mm	01
28	Needle holder (Disengageable, coaxial type)	Size 5mm, tungsten carbide tip, straight handle with ratchet, single moving with curved tip to left, length 33-36cm.	01
29	Needle holder insert (straight type)	Size 5mm, tungsten carbide tip, single moving straight jaws, length 33-36cm.	01
30	Extracorporeal knot pushers	Closed Eye type, length 28-32cm, size 3mm	01
31	Endoloop applicator	To fit into trocar size of 6 mm	01
32	Clip Applicator – Medium Large	Rotatable, provision for locking the shaft conveniently, 10mm, compatible with clip LT 300	01
33	Clip Applicator - Large	Rotatable, provision for locking the shaft conveniently, 10mm, compatible with clip LT 400	01

34	Hassan cone	Adaptable to 10mm trocar	01
35	Reduction Sleeves / Extractors	From 10/ 11 mm to 5mm, metallic	01
36	Reducers	From 10/ 11 mm to 5mm	03
37	L - Hook	Size 5mm, length 33-36cm with pin for cautery	02
38	J - Hook	Size 5mm, length 33-36cm	02
39	Spatula	Size 5mm, length 33-36cm with pin for cautery	01
40	Fascia closure instrument	Size 2.8mm, length 17cm with single action jaw	01
41	High Frequency Cord	For 5mm & 10mm hand instruments with Monopolar Electrodes	02 each
42	Washers	For 5 & 10 mm cannula and reducers	10 pieces each
43	Fibreoptic Light cables	With straight connectors of 4.8mm diameter and 250cm long	01
44	Fibreoptic Light cables	With straight connectors of 4.8mm diameter and 300cm long	01
45	Light Adaptor	Angled 90 degree, diameter 4.8mm, free rotatable, to connect with standard telescopes	01
46	Container systems: Metal & Plastic	For sterilization and storage of telescopes, hand instruments and other accessories of different sizes.	03
47	Bipolar HF connecting cable		02
48	Unipolar HF cables		02
49	Hydatid suction cannula		01
50	Cleaning Brush	Length 35cm, 0.0-7mm	02
51	Cleaning Brush	Length 35cm, 0.0-2.5mm	02
52	Cleaning Brush	Length 50cm, 0.0-11mm	02
53	Cleaning Brush	Length 50cm, 0.0-7mm	02
54	Oil dropper	No 38	02
55	Silicon oil for instruments	Bottle of 50ml	04
56	Special lubricant for stopcocks		04
57	Duraglit for polishing metal sheaths and instruments		02
58	Formalin chamber	Made of Virgin acrylic 4.5mm thickness, size 26" x 8" x 8" (LxBxH) with three tray for sterilizing lap. set	02

12(a) System Configuration Accessories, spares and consumables

- System as specified. But all the items should be of the same manufacturer of International repute only. All electronic devices should have CF protection.

- ACCESSORIES:- All possible accessories of the equipment should be quoted. The specific accessory and its quantity will be decided on the basis of actual requirement.
- The system should be capable of accepting standard accessories of major international brands, which should be specified and for which suitable adaptor, if required, is to be provided
- The codes and rates of all relevant individual accessories should be quoted separately with clear mention of period of validity of rates

12(b) Environmental factors

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

12(c) Power Supply

- Power input to be 220-240VAC, 50Hz fitted with Indian power-plug
- Electronic Voltage corrector/stabilizer of appropriate ratings for power supply to the whole set meeting BIS standards/specifications. (Input 160-260 V and output 220-240 V and 50Hz)
- Optional UPS of adequate rating for power supply to the system for 60 minutes.

12(d) Standard & Safety

- Should be FDA, CE, UL or BIS approved product
- Manufacturer and Supplier should have ISO certification for quality standards.
- Electrical safety conforms to standards for electrical safety IEC 60601-1 General Requirements (or equivalent BIS Standard)
- Shall meet internationally recognized standard for Electro Magnetic Compatibility (EMC) for electro medical equipment: IEC-60601-1-2: latest edition or Equivalent BIS) or should comply with 89/366/EEC; EMC- directive as amended
- Certified to be compliant with IEC 60601-2-2 Medical electrical equipment part 2-2: particular requirements for the safety of equipment mentioned above – wherever applicable

12(e) Training

- Comprehensive training for staff of user department and support services till familiarity with the system.

12(f) Warranty & Service

- Comprehensive warranty for 5 years and 5 years Comprehensive Maintenance service after warranty. The cost of CMC must be quoted in the price bid.

- Percentage of up time guarantee of the equipment during warranty and CMC period for which commitment is to be given must be specified with acceptance of applicable penalty clauses in case of failure to do so.
- Principal manufacturer must have registered service centre in India. After sales service must be provided in the city of installation. In situations requiring service/repair of the unit outside the city of Installation, the expenditure on account of this will have to be borne by the supplier.

12(g) Documentation

- Product Literature in original along with that of accessories and indigenous components if any photocopies /computer generated copies are not acceptable
- Statement of compliance with tender specifications with clear and unambiguous links to relevant portions of product literature /authentic document, which should be highlighted. Alternatives provided for noncompliant specifications with justification must be described in detail with supporting literature.
- Certificate of compliance with standards and approvals stated above
- Certificate of manufacturer /principal regarding authorization of service facility provided by the supplier
- List of equipment available in the Service centre for proving calibration and routine preventive maintenance support, as per manufacturer documentation in service/technical manual.
- List of important spare parts and accessories, which are required for maintenance and repair, with their part number and costing.
- Terms and conditions of warranty and CMC including schedules of visit by service personnel with check list of service to be carried out
- Commitment for supply of log book with check list for daily, weekly, monthly and quarterly preventive maintenance with contact details of service personnel along with the equipment. The job description of the hospital technician and company service engineer should be clearly spelt out in the log book.
- List of users of quoted model with performance certificate from major hospitals
- All the offered should be **USFDA &European CE approved.**
- All equipment's should be from the same manufacturer.
- The principal Company should have their own Service Centre in Delhi/ NCR
- Comprehensive Warranty of all equipment's should be of 5 years and 5 years comprehensive maintenance service after warranty.
- Cost of CMC must be quoted in price bid.

All other terms & conditions remains unchanged.

**Medical Superintendent
Safdarjang Hospital & VMMC,
New Delhi.**