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No. F-8( ) RMSC/EPM/M-1/17-18/NIB-253/ 2017/ 5634

Dated: 24/11/17

**CLARIFICATION/CORRIGENDUM/ADDENDUM**

**Subject:- Amended Technical Specifications of Bid document of item Ultrasonic Cutting And Coagulating Device For Open & Laparoscopic Surgery and Laparoscope Set For Training With CO2 Insufflator , under NIB F-8( ) RMSC/EPM/M-1/17-18/NIB-253/ 2017/ 3831 Dated: 12.09.17**

In reference to subject cited above and NIB-253, the representations received from the various firms and issues raised by the Bidders, are examined by the competent Authorities and technical committee and approved by purchase committee. The following Clarification/Corrigendum/Addendum is issued for inclusion in Bid document Amended Technical Specification of items as below:-

**1. Amended Technical Specifications of Items Laparoscope Set For Training With CO2 Insufflator as below:-**

**Camera:**

1. It should be **3 chip full high definition digital camera** head and console with HD image production. **Resolution should be 1920 X 1080.**
2. **THE ASPECT RATION OF SENSOR SIZE AND VIDEO MONITOR SIZE SHOULD BE 16: 9 or 16:10**
3. Should be fully compatible to the color systems PAL / NTSC.
4. Resolution & progressive scan technology both on camera head & console. Multiple settings allow the user to select the preferred level of image enhancement.
5. Should have optical / digital zoom to enhance the quality of image size.
6. Should have the **auto exposure system** for consistent illuminable level.
7. Integrated gain / shutter / enhancement with automatic brightness control.
8. Automatic white balance with memory functions for two settings.
9. The system should be Mean driven, thus allowing the surgeon to programme the camera head functions as per the surgical needs and requirement.
10. **Composite, S-VHS , RGB and 2 or 1 DVI , HD SDI** output compatibility.
11. The system should have facility of attaching additions video printer / recorder functions and other peripheral units.
12. Camera head fully **soakable** for disinfection..
13. **Universal power supply compatible with Indian Electrical System .**

**LED LIGHT SOURCE:**

- LED Light should produce White Light.
- Patient safety & added protection in OR with safe light
- Single port universal Jaw assemble to adopt technology of fiber optic cable.
- LED Light source should produce **luminance not less than 2000 Lumen and having LED lamp life of minimum 25000 hrs or more.**

**FIBER OPTIC LIGHT CABLE**

- Diameter size 4.0 to 5.5 mm, Length should be not less than 250 cm.

**HIGH RESOLUTION MEDICAL GRADE VIDEO MONITOR:**

- Hi definition, Maximum resolution, colored monitor, size 26 inch or more. Flat panel LED monitor , **Resolution should be 1920 x1080 . THE ASPECT RATION SHOULD BE 16:9 or 16:10.**
- Color system PAL / NTSC compatible
- S-VHS, RGB and DVI , HD SDI input and output compatibility.

**CO2 Insufflator :**

- CO2 electronic insufflator, having minimum flow rate of 20 L/M or more.
- Unit should be easy to use clear, adjacent displays for set value and actual value allow easy monitoring of insufflation process touch keys for precise pre selection of set value optical and acoustic warning signals in the event of



over inflation.

- High Pressure (HP) HOSE WITH CONNECTOR – 10 NO's WITH B TYPE REGULATOR.
- STAND FOR KEEPING B TYPE CO2 CYLINDER

#### Live Recording System – 1

- System to be compact, easy to deploy. Portable mobile design and allows portability to any OT.
- User – centric, simple-to-use and with preview screen interface.
- Open architecture to give the hospital the flexibility to support any endoscopic vendor.
- Inputs support: DVI, S-Video, Composite, SD-SDI, HD-SDI & 3G-SDI.
- Video Resolution support up to 1920 x 1080 p.
- HD – Video Bit rates upto 60 MBPS.
- Still capture format supports JPG, BMP, PNG, DICOM.
- The system to allow playback recorded videos on the preview screen.
- Auto archive facility for external USB Drives, also for network drives.
- Direct data transfer facility to devices such as USB cable/ EXTERNAL DRIVE.
- Internal HDD: Minimum 500 GB or more, expandable.

#### Instruments:

##### Laparoscope:

- 10 mm 30 degree 30 – 35 cm
- 05 -5.5 mm 0 degree 30 - 35 cm

It should have

- Scope should be compatible with HD camera.
- Wide angle full screen, forward – Oblique and lateral scope.
- Optimal centre – to – edge resolution for enhanced picture quality.
- Fiber optic light transmission incorporated.
- Standard ocular window for coupling the camera head.
- Scratch resistance sapphire coated tip lens.
- Advanced Rod lens system for optimum brightness, contrast and definition.

#### Specification for Laparoscopic Hand Instruments and Accessories:

(Bidder may quote same hand instruments mentioned below with own nomenclature without compromising functional utility of hand instruments & accessories)

##### Trocars & Reducers

- 120 mm Veress Needle
- 5 mm Aspiration Needle, 17 Gauge, 33 cm
- 5.5 mm Cannula Sleeve with Automatic Valve, Stop Cock (2 each)
- Trocar, Pyramid Tip, 5.5 mm (2each)
- 11 mm Cannula Sleeve with Automatic Valve, Stop Cock (2 each)
- Trocar, Pyramid Tip, 11 mm (2 each)
- 5 m Hand Instruments with Insulated Shaft, Modular Design, Inner shaft flush port, 3600 Rotation & Shaft Rotation Lock.
- Right Angled Dissector – 1
- Curved Kelly Dissector – 1
- Maryland Dissector – 1
- Mixer Dissector – 1
- Alligator Grasper – 1
- Fundus Grasper – 1
- Cobra Tooth Grasper – 1
- Serrated, Fenestrated Grasper – 1
- Dorsey Grasper – 1
- Single Action Atraumatic Grasper – 1
- Paddle Babcock Grasper – 1



- Allis Single Row Grasper – 1
  - Curved Metzenbaum Scissors – 1
  - 5 mm Needle holder with Handle -1
  - 5 mm straight needle holder with Y Handle – 1
  - 5 mm Curved Left needle holders with Y Handle - 1
  - 5 mm Curved Right Needle Holder with Y Handle – 1
  - Clip Applicator – 10 mm
  - Suction irrigation – 10 mm and 5 mm (each)
  - REDUCER 11MM TO 5.5MM
  - L-HOOK DISSECTOR-5 MM
  - SPATULA-5 MM
  - PLASTIC/METAL TRAY FROM OEM FOR STORAGE AND STERILIZATION- 2Nos
  - All laparoscopic hand instruments should be of length 33 cm or more.
- Note:- Medical Grade USFDA / European CE approved products to be quoted.

**Endo Trolley:**

- IT SHOULD BE IMPORTED MEDICAL GRADE AND FROM SAME MANUFACTURER. IT SHOULD HAVE 4 SHELF AND 1 LOCKABLE DRAWER . with proper Wheel locking system .
- It should have extendible arm for monitor mount it should have isolation transference should have extendible video arm to mount Medical grade LED monitor.
- Instrument trolley should have attachment of UPS system of around 30 minutes back up should be provided with the set.
- Should be supplied with UPS of Suitable capacity as per demand of quoted items.

- Guarantee: Guarantee for 3 years from the date of installation.
- CMC: CMC will be given @ 2% (of net rate-inclusive of Taxes etc.) plus service tax (as applicable) The CMC will be awarded for five years (on yearly basis) after Guarantee period of three years.
- Laparoscopic set with attached instrumentation should we US FDA & European CE certification will be must.
- Product should have IEC safety standards wherever listed
- The core items of laparoscopy set like camera system, light sources, CO2 insulator, video monitor, all hand instruments, instrument trolley and Fiber optic light cable should be from same manufacturer for system compatibility for optimal performance of system as whole.
- Installation will be done by supplier free of cost.
- The service engineer should be based in Rajasthan.
- Demonstration of Equipment is must for final approval.
- The company should mention the make & model name/number of the quoted equipment and submit the technical brochure of the quoted model in the Technical bid along with compliance sheet as per technical specifications.
- Firm should mention all the pre-installation requirements in technical bid.

**2. Amended Technical Specifications of Items Ultrasonic Cutting And Coagulating Device For Open & Laparoscopic Surgery as below:-**

1. It should have single/combined generator system including Ultrasonic energy and advanced RF energy for dissection and vessel sealing.
2. It should have vessel sealing capacity up to 7 mm or more.
3. It should have instruments for both open and laparoscopy surgeries.
4. The generator should be compatible with variety of probes for open and laparoscopic surgery.
5. The generator should have facility to connect single / double pedal foot

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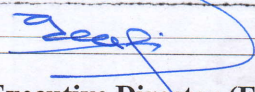


- switches.
6. It should have the facility of rotating hand switch adapter with integrated bilateral switches to enable precise operation of system by hand for hooks and blades.
  7. Coagulating shears must have inbuilt hand activation button.
  8. It should not have auto switch-off mechanism.
  9. It should have system diagnostics and troubleshooting guide to pinpoint and resolve alert/alarm conditions.
  10. The equipment should be European CE/US FDA approved.  
It should comprise of :  
**Hardware:**
    - 1 Generator
    - 2 Footswitch & Cable
    - 3 Generator Cart**Accessories:**
    - 4 Handpiece (Transducer)/Direct connectivity of instruments of generator.
    - 5 Adaptor for instruments (If required/Direct connectivity of instruments to generator).
  11. **Probes:**
    - 1 05mm to 30mm open surgery probes for variety of surgeries – 2 Nos(each).
    - 2 33mm to 45mm laparoscopy probes for variety of surgeries – 2 Nos(each).
  12. **Guarantee:** 12. Guarantee: Guarantee for 3 years from the date of installation.
  13. **CMC:** CMC will be given @2% (of net rate-inclusive of taxes) plus service tax (as applicable) and yearly escalation of maximum 5% on last year's CMC price. The CMC will be awarded for five years (on yearly basis) after Guarantee period of three years
  14. Manufacturer / supplier should have ISO certification for quality standards
  15. Installation will be done by supplier free of cost.
  16. The service engineer should be based in Rajasthan.
  17. Demonstration of Equipment is must for final approval.
  18. The company should mention the make & model name/number of the quoted equipment and submit the technical brochure of the quoted model in the Technical bid along with compliance sheet as per technical specifications.

It is also clarified that information of award of contract shall be communicated to all participating bidders on the website [www.rmsc.nic.in](http://www.rmsc.nic.in) and [sppp.raj.nic.in](http://sppp.raj.nic.in). Please note that individual bidder will not be intimated.”

**Note:-** Please note that all above amendments/corrigendum in technical specifications/bid conditions is the integral part of (Section-V, Schedule of Supply, and Point no. 3) and the bid document. This corrigendum/ addendum should be signed and annexed with bid document. All other terms & conditions remains the same.

This bears the approval of M.D., RMSCL, Jaipur.

  
Executive Director (EPM)  
RMSCL, Jaipur