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No. F-8( )RMSC/EPM/M-1/NIB-66/2015/ 7633

Dated: 12/2/15

**CLARIFICATION/CORRIGENDUM/ADDENDUM**

**Subject:- Revised technical Specifications and other terms and conditions of Bid document of item (01) Laparoscope Set For Training With CO2 Insufflators, (02) Ultrasonic Cutting And Coagulating Device For Open & Laparoscopic Surgery (03) Adult Cystoscope and Resectoscope For TURP under NIB No. F-8( )RMSC/EPM/M-1/14-15/NIB-66/ 7254 Dated: 24.12.2014**

In Reference to subject cited above and NIB-66, the various representations received from the firms and issues raised by the Bidders are examined by the competent Authorities and technical committee. The following Clarification/Corrigendum/Addendum is issued for inclusion in Bid document & Technical Specification of items as below:-

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

<p><b><u>Amended Technical Specifications of item Laparoscope Set For Training With CO2 Insufflator,</u></b></p> <p><b><u>Camera:</u></b></p> <ol style="list-style-type: none"> <li>1. It should be full high definition digital camera head and console with HD image production. Resolution should be 1920 X 1080.</li> <li>2. Should be fully compatible to the color systems PAL / NTSC.</li> <li>3. Resolution &amp; progressive scan technology both on camera head &amp; console. Multiple settings allow the user to select the preferred level of image enhancement.</li> <li>4. Should have optical / digital zoom to enhance the quality of image size.</li> <li>5. Should have the auto exposave system for consistent illuminable level.</li> <li>6. Integrated gain / shutter / enhancement with automatic brought ness control.</li> <li>7. Automatic white balance with memory functions for two settings.</li> <li>8. The system should be Mean driven, thus allowing the surgeon to programe the camera head functions as per the surgical needs and requirement.</li> <li>9. Composite, S-VHS &amp; RGB compatibility.</li> <li>10. The system should have facility of attaching additions video printer / recorder functions and other peripheral units.</li> <li>11. Camera head fully so- akable for disinfection..</li> <li>12. World power supply.</li> </ol>
<p><b><u>LED LIGHT SOURCE:</u></b></p> <p>Light engine – Red, Green &amp; Blue LED                  Patient safety &amp; added protection in OR with safe light                  Single port universal Jaw assemble to adopt technology of fiber optic cable.</p>
<p><b><u>FIBER OPTIC LIGHT CABLE</u></b></p> <p>Diameter size 4.8 to 5.5 m, Length should be not less than 250 c.</p>
<p><b><u>HIGH RESOLUTION MEDICAL GRADE VIDEO MONITOR:</u></b></p> <ul style="list-style-type: none"> <li>• Hi definition, Maximum resolution, colored monitor, size 26 inch or more. Flat panel LED monitor.</li> <li>• Color system PAL / NTSC compatible</li> <li>• S-VHS, RGB compatibility.</li> </ul>
<p><b><u>Insufflator :</u></b></p> <p>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 acoushc warning signals in the event of patient over procedure.</p>
<p><b><u>Live Recording System – 1</u></b></p> <ul style="list-style-type: none"> <li>• System to be compact, easy to deploy,. Portable mobile design and allows portability to any OT.</li> <li>• User – centric, simple-to-use and with preview screen interface.</li> <li>• Open architecture to give the hospital the flexibility to support any endoscopic vendor.</li> <li>• Inputs support: DVI, S-Video, Composite, SD-SDI, HD-SDI &amp; 3G-SDI.</li> <li>• Video Resolution support up to 1920 x 1080 p.</li> <li>• HD – Video Bitrates upto 60 MBPS.</li> <li>• Still capture format supports JPG, BMP, PNG, DICOM.</li> <li>• The system to allow playback recorded videos on the preview screen.</li> </ul>

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- Auto archive facility for external USB Drives, also for network drives.
- Direct control from devices such as iPad, iPhone.
- Direct data transfer facility to devices such as iPad, iPhone using Wi-Fi & USB cable.
- Internal HDD: Minimum 750 GB.

### **Instrument:**

#### **Laparoscope:**

- 10 mm 30 degree 30 cm
- 10 mm 45 degree 45 cm

It should have

- 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:**

#### **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, 360° Rotation & Shaft Rotation Lock.

- Right Angled Dissector 33 cm – 1
- Curved Kelly Dissector 33 cm – 1
- Maryland Dissector 33 cm – 1
- Mixer Dissector 33 cm – 1
- Alligator Grasper 33 cm – 1
- Fundus Grasper 33 cm – 1
- Cobra Tooth Grasper 33 cm – 1
- Serrated, Fenestrated Grasper 33 cm – 1
- Dorsey Grasper 33 cm – 1
- Single Action Atraumatic Grasper 33 cm – 1
- Paddle Babcock Grasper 33 cm – 1
- Allis Single Row Grasper 33 cm – 1
- Curved Metzenbaum Scissors 33 cm – 1
- 5 mm Needle holder with Handle -1
- 5 mm straight needle holder with Y Handle 33 cm – 1
- 5 mm Curved Left needle holders with Y Handle 33 cm- 1
- 5 mm Curved Right Needle Holder with Y Handle 33 cm – 1
- Clip Applicator – 10 mm and 5 mm
- Suction irrigation – 10 mm and 5 mm.
- Note:- Medical Grade USFDA / European CE approved products to be quoted.

#### **Endo Trolley:**

It should have extendible arm for monitor mount it should have isolation transference should have extendible video arm to mount Medical grade LCD monitor.

It should have inbuilt electric switcher channeled through isolation transference. Voltage rating : Input 240V – 50 Hz, 2.4 KVA Output 220 / 240V – 50 Hz, 2.4 KVA Max.

**Guarantee:** Guarantee for 3 years from the date of installation.

**CMC:** CMC will be given @2% (of net rate-inclusive of Excise Duty & exclusive of VAT /CST etc.) 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

Manufacturer/supplier should have ISO certification for quality standards

Product should have IEC safety standards wherever listed

The core items of laparoscopy set 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.

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

<b>Ultrasonic Cutting and Coagulating Device for Open &amp; Laparoscopic Surgery</b>	
S. N.	Item with specification
1	It should have combined generator system including Ultrasonic energy and advanced RF energy for dissection and vessel sealing.
2	It should have vessel sealing capacity 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 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 CE/FDA approved.
	It should comprise of : <b>Hardware:</b> 1 Generator 2 Footswitch & Cable 3 Generator Cart <b>Accessories:</b> 1 Handpiece (Transducer) 2 Adaptor for instruments
11	<b>Probes:</b> 1) 9mm to 30mm open surgery probes for variety of surgeries – 2 Nos. 2) 33mm to 45mm laparoscopy probes for variety of surgeries – 2 Nos.
12	<b>Guarantee:</b> Guarantee for 3 years from the date of installation.
13	<b>CMC:</b> CMC will be given @2% (of net rate-inclusive of Excise Duty & exclusive of VAT /CST etc.) 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.
19	Firm should mention all the pre-installation requirements in technical bid.



03. Amended Technical Specifications of item Adult Cystoscope and Resectoscope for TURP as below:-

Adult Cystoscope and Resectoscope for TURP		
S.N.	Item with Specification	Qty.
1	<b>Cystoscope Telescope:</b> 30 degree Telescope of size: 4mm, Length 30cm (+ 3cm). Should have very high quality of rod lens system, Should have fiber optic light transmission Incorporated. The Telescope should be autoclavable.	2
2	<b>Cystoscope Sheath:</b> Cystoscope sheath with leur lock connection of two different size should be provided 20 FR and 17 FR sheath one each with slot for instrument The sheath should be marked and graduated.	1
3	<b>Telescope bridge:</b> Telescope bridge with one instrument channel to fit with the cystoscope	1
4	<b>Flexible Grasping forcep:</b> 5FR and 7 FR Grasping forcep to be provided to fit the purpose	1
5	<b>Flexible biopsy forcep:</b> 5FR and 7 FR Biopsy forcep to be provided to fit the purpose	1
6	<b>Rigid Biopsy and Grasping Forcep:</b> Optical Rigid Biopsy forcep compatible with 20 FR Cystoscope sheath to be provided.	1
7	<b>ELLIK Evacuator:</b> ELLIK Evacuator with spare rubber bulb and adaptor to be provided.	1
8	<b>Urethrotome sheath:</b> 21 FR optical Urethrotom sheath with one channel to be provided	1
9	<b>Cold knife:</b> Straight cold knife 2 Nos.	2
10	<b>Resectoscope sheath:</b> 26 FR continuous irrigation resectoscope sheath with ceramic beak to be provided to fit the purpose with set of silicon tube. Sheath should be provided with deflecting obturator.	1
11	<b>Working Element set:</b> Working element set passive type with standard accessories like, Kollins knife, HF cord, Protection tube, cutting loop to be provided	1
12	<b>Cutting loop 24 FR:</b> Cutting loop 24 FR, 12 Nos.	12
13	<b>HF cord:</b> High Frequency cord, 2 Nos.	2
14	<b>Halogen Light source:</b> LED Light source of 150 watts or more, having LED lamp life of minimum 40,000 hrs, the intensity should be able to control manually from front panel. Should be IEC 60601-1 and CE marked.	1
15	<b>Fiber Optic Cable:</b> 3.5mm size, length 230cm Fiber optic light cable is to be provided to fit the purpose.	2
16	<b>Brief case:</b> Plastic good quality brief case with slot for instruments is to be provided for storage	1
17	<b>Endovision Camera System:</b> <b>Camera</b> – It should have pure digital signal with high definition video of 1920 X 1080 native resolution with progressive / inter-less scan technology both on camera head and console. AGC - Microprocessor based Minimum Sensitivity – 3 Lux (f- 1.4 mm) Exposure Control – 1/50 Sec – 1/10000 Sec Should have Freezing Function & Antomoire filter function. Camera control unit should have accessories output to control external devices like video printer from the camera head buttons Programmable Functional Keys on camera head for various functions like automatic white balance, gain control, brightness control etc. Should have integrated focus control. Should have digital zoom. Should must have integrated Optical Par focal zoom lens 25-50MM Should have DV output and S-VHS and Composite video output Should have contrast enhancement and digital filter Should be certified IEC 601-1 and CE according to MDD.	1

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18	<b>Video Monitor:</b> Monitor should be High Definition color monitor 22" or more (monitor should be of medical grade). Should have resolution of 1920 X 1080 Should take RGB, SDI and S-Video signals	1
19	<b>Electro surgical Unit:</b> Microcontroller based Digital Electrosurgical Cautery 400 Watts with Digital Display Push Switch Control Provides Consistent Performance for General Surgical Procedures & delivers its Optimum & Reliable Power by using latest & Advance Technology, Convenient for all Surgical Application. Unipolar as well as Bipolar facility having operating frequency between 500-700 KHz. Must have Dual Mono-polar Coagulation Facility on the unit: - Two surgeons can operate mono-polar coagulation at the same time on the same patient. Must have Patient Plate Contact Quality Monitoring system - With This Silicon Dual Pad Patient Plate Contact Quality Monitoring Takes Place, the moment the contact between Plate & Patient reduces it stops the HF delivery with an audio visual indications. Independent Mono-polar & Bipolar Output Can be used without Any Switch over from the Machine: - This facility Enables the operating surgeon to perform surgery without any Hassle. Facility for pure cut 300 watts, blend cut 250 watts, end cut 200 watts, Bipolar cut and coagulation 120 - 100 watts. In Accordance with IEC 60601-1 and IEC 60601-2-2; CE certified Unit should be supplied with footswitch, patient plate, patient cable, hand control pencil with standard accessories.	1
20	<b>Video Trolley:</b> Suitable video trolley to be supplied for mounting equipment's having minimum three self with drawer, with antistatic wheel casters, front lockable, high grade of electrical insulation and earth protection. 5 Ampere socket, 5 Nos, inbuilt with trolley.	1
21	<b>Tray for Sterilization:</b> Sterilization /Disinfection Tray: Disinfection / Sterilization stainless steel tray of steel grade 304 with sieve tray to lift. Size: 27"x7"x5" (LxBxD)	2
22	<b>Formaline Chamber:</b> Formaline Chamber made of Virgin Acrylic 6mm thickness; size: 26"x8"x8" (LxBxH) with three tray, for sterilizing the laparoscope, preferably with three tray.	1
23	<b>UPS System:</b> UPS – 1.5 KVA off line with One hour backup time (at 1000 Watts real load) with SMF Batteries. Should be able to work on wide input range between 160-270 VAC at frequency between 50Hz ± 2Hz, Should use PWM technology with power conversion with single transformer arrangements with an output of 220VAC ± 5%, protection of overload, short circuit and low battery. Should have indication on front panel for mains load/battery load/ battery overload-low and MCB protection in case of short circuit. ISI/CE approved good quality Indian make.	1
24	<b>Environmental factors:</b> The unit shall be capable of being stored continuously in ambient temperature of 0-50deg C and relative humidity of 15-90%. The unit shall be specified for operation up to 45 deg. C and 100% relative humidity.	CONFORMITY
25	<b>Standards:</b> All product should be US FDA & European CE approved except Formaline chamber, Tray for disinfection, UPS, CO2 Cylinder.	CONFORMITY
27	<b>Guarantee:</b> Guarantee for 3 years from the date of Installation.	CONFORMITY
28	<b>CMC:</b> CMC will be given @2% (of net rate-inclusive of Excise Duty & exclusive of VAT /CST etc) 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	CONFORMITY
29	Manufacturer/supplier should have ISO certification for quality standards	CONFORMITY
30	Product should have IEC safety standards wherever listed	CONFORMITY
31	The core Cystoscope and TURP set items like, Telescope, sheaths, Resectoscope, Working element, HF loops, camera system, light source, video monitor, fiber optic cable should be from same manufacturer for system compatibility to attain optimal performance as complete system.	CONFORMITY
42	Installation will be done by supplier free of cost.	CONFORMITY
43	The service engineer should be based in Rajasthan.	CONFORMITY
44	Demonstration of Equipment is must for final approval.	CONFORMITY

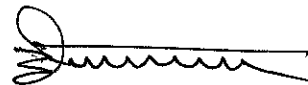
45	The company should mention the make & model name/number of the quoted equipment and submit the technical brochure of the quoted model in the Technical bid along with compliance sheet as per technical specifications.	CONFORMITY
46	Firm should mention all the pre-installation requirements in technical bid.	CONFORMITY

**04. Instruction to bidders as follows:-**

- i. Section IV technical bid submission sheet (Cover-A) point no. 12 (v) is Deleted.
- ii. Section III, evaluation and qualification criteria, point no. 2, clause no.8 is replaced as “ Bidders shall have to submit a valid ‘VAT’ clearance certificate from the concerned Commercial Taxes Officer or Affidavit and the ‘PAN’ issued by Income Tax Department.”
- iii. It is also clarified that information of award of contract shall be communicated to all participating bidders on the website [www.rmssc.nic.in](http://www.rmssc.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, 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