

Amendment No. 8

Date: 09.02.2016

Sub: Amendment to the Tender Enquiry Document

Ref: NIT No.: HLL/PCD/PMSSY-II/NAGPUR/11/15-16 dated 06/11/2015 and subsequent amendments

Technical Amendment

Schedule No. 02

C-Arm for General Surgery

1. **Existing Para A.X-RAY GENERATOR: Power output : 2 KW or more**
Read as: X-RAY GENERATOR: Power output : 1.4 KW or more
2. **Existing Para: mA in radiography: 20mA or more**
Read as: mA in radiography: 12.2 mA or more
3. **Existing Para Para A: X-RAY GENERATOR: mA in fluoroscopy : 0.2 to 4 mA or more in normal fluoroscopy and 10 mA or more in High Level Fluro Should have facility for continuous fluoroscopy and Pulse fluoroscopy (Pulse rate upto 12 pulse persecond)**
Read as: X-RAY GENERATOR: mA in fluoroscopy : 0.2 to 4 mA or more in normal fluoroscopy and 8 mA or more in High Level Fluro Should have facility for continuous fluoroscopy and Pulse fluoroscopy (Pulse rate upto 8 pulse persecond)
4. **Existing Para A: X-RAY GENERATOR: Should have Digital Spot for high quality single image, 16 mA or more**
Read as: X-RAY GENERATOR: Should have Digital Spot for high quality single image, 10 mA or more
5. **Existing Para: X-ray tube head: Tube assembly filtration of 3.0 mm Al or higher**
Read as: X-ray tube head: Tube assembly filtration of 2.8 mm Al or higher
6. **Existing Para E: Integrated image processing,recording and memory system :Image intensifier tube: Input diameter 9" with Triple field (9/6)**
Read as: Integrated image processing,recording and memory system :Image intensifier tube: Input diameter 9" with double field (9/6)
7. **Existing Para E: Minimum central resolution (at monitor) : 1.4 lp/mm or better at 9" FOV**
Read as: DELETED
8. **Existing Para: Regulatory / Safety Requirement: Equipment should have CE for full product with notified body identification number and USFDA certificate**
Read as: Regulatory / Safety Requirement: Equipment should have CE for full product with notified body identification number and/or USFDA certificate

Schedule No. 04

OT Table - Surgery

Added Para: Offered model should confirm to IEC 60601 electrical safety standards latest

Schedule No. 05
OT Table – Bariatric

1. **Existing Para 1: Electro Mechanical**, remote control operated operation Theatre Table for Bariatric Surgery, requiring negligible maintenance, with following features
Read as: Electro Mechanical/Electro Hydraulic, remote control operated operation Theatre Table for Bariatric Surgery, requiring negligible maintenance, with following features
2. **Existing Para 1: Table Base: Patient load capacity of 350KGs**
Read as: Table Base: Patient load capacity of 270Kg or more
3. **Existing Para:** The product must have CE (European Directive) and ISO 13485 certification issued by notified body.
Read as: The product must have European CE with notified body number or USFDA certified.
The manufacturer should have ISO 13485 certificate
4. **Existing Para 7: Gel Mattress set: Gel pad mattress made of viscoelastic polymer gel for placing on top of OT table mattress, specially compatible for Bariatric patients, should cover the main table top mattress area. A circular gel head ring should also be provided along with**
It should be 100% free of silicon, latex or any plasticizer
Should be X-ray radiolucent and anti bacterial
Should be biocompatible with human tissues working temperature range: 10 deg C to 50 deg C.
5. **Read as: Gel Mattress set: Gel pad mattress for placing on top of OT table mattress, specially compatible for Bariatric patients, should cover the main table top mattress area. A circular gel head ring should also be provided along with**
It should be 100% free of silicon, latex or any plasticizer
Should be X-ray radiolucent and anti bacterial
Should be biocompatible with human tissues working temperature range: 10 deg C to 50 deg C.
6. **Existing Para 9: It should have at least 05 installations in India.**
Read as: DELETED

Added Para: Offered model should confirm to IEC 60601 electrical safety standards latest

Schedule No. 06
Ultrasonic Cutting and Coagulation Device

1. **Existing Para 4.1:** Accessories: Prices to be quoted for each of the accessories & it should be valid for the entire warranty period.
Read as: Accessories: Prices to be quoted **separately** for each of the accessories & it should be valid for the entire warranty period.
2. **Existing Para 4.1.3.a:** Coagulation shears – 5mm dia, 17cm long or more
Read as: Coagulation shears – **5mm dia, 10-20cm long or more**

3. **Existing Para 4.1.3.b:** Dissecting grasp 5mm for cogulation **17mm or more**
Read as: Dissecting grasp 5mm for cogulation **10-20cm or more**
4. **Existing Para 4.1.4.a:** Dissector Grasper 5mm diameter **30cm-45cm long**
Read as: Dissector Grasper 5mm diameter **35cm-45cm long**
5. **Existing Para 4.1.4.b:** Curved Shear,5mm diameter,30cm- 45cms long
Read as: Curved Shear,5mm diameter, **35cm- 45cms long**
6. **Added Para:** Ultrasonic Hand piece- 2 Nos. to be offered (unit Price to be quoted separately)

Schedule No. 07
Advanced Laparoscopic System

1. **Existing Para II.1:** HD Camera Head resolution 1920 x 1080 pixel, 1/3' Progressive Scan 60HZ with 2 freely programmable Camera Head buttons and optical zoom lens of 2x.

Read as: HD Camera Head resolution 1920 x 1080 pixel, 1/3" Progressive Scan **50-60Hz** with 2 freely programmable Camera Head buttons and optical zoom lens of 2x
7. **Existing Para III.2.a:** The system should have USB port to capture still images in Full HD resolution as well as Video Sequences in HD to a USB mass storage device

Read as: DELETED
8. **Existing Para III.2.c:** Should have the facility to add fiberoptic filter
Read as: DELETED
9. **Existing Para III. 7:** Should have safety certificate from a competent authority CE / FDA (US) / STQC CB certificate / STQC S certificate or valid detailed electrical and functional safety test report from ERTL for camera system
Read as: All the offered equipment should be European CE or USFDA approved.
10. **Existing Para V.1:** External recording device in high definition 1080p with **customized reporting, editing and** storage facility.
Read as: External recording device in high definition 1080p with storage facility.
11. **Existing Para V.3:** The system should support to take still images from recorded video footages.
Read as: DELETED
12. **Existing Para VI.7:** Fiberoptic light cable, size 4.8mm, length 250cms
Read as: Fiberoptic light cable, size 4.8mm, length 250cms – **2 nos.**
13. **Existing Para VII. 6:** Should have safety certificate from a competent authority CE / FDA (US) / STQC CB certificate / STQC S certificate or valid detailed electrical and functional safety test report from ERTL. Copy of the certificate / test report shall be produced along with the technical bid.
Read as: All the offered equipment should be European CE or USFDA approved.

- 14. Existing Para Para VIII:** Telescope — High definition
Read as: Compatible Telescope for full HD camera system
- 15. Existing Para IX.1:** Enlarged view, diameter 10mm, **length 29cm**. Autoclavable, fiber optic light transmission incorporated
Read as: Enlarged view, diameter 10mm, **length 29cm or more**. Autoclavable, fiber optic light transmission incorporated
- 16. Existing Para X. 1:** Telescope diameter 10mm, length 42cm, autoclavable, variable direction of view from 0 to 120 degree adjustment knob for selecting the desired direction for view: fiber optic light transmission incorporated.
Read as: DELETED
- 17. Existing Para XI.1:** Trocar, size 11mm. consisting of Trocar only, with pyramidal tip cannula without valve. with insufflations stop-cock, length 10.5cm. multifunctional valve.
Read as: Trocar, size 11mm. consisting of Trocar only, with pyramidal tip cannula without valve. with insufflations stop-cock, length 10.5cm. multifunctional valve- **2 Nos.**
- 18. Existing Para XI.3:** Trocar, Size 6mm consisting of : Trocar only, with pyramidal tip, cannula without valve, with insufflations stop cock, length 10.5 cm, Multifunctional Valve
Read as: Trocar, Size 6mm consisting of : Trocar only, with pyramidal tip, cannula without valve, with insufflations stop cock, length 10.5 cm, Multifunctional Valve – **3 Nos.**
- 19. Existing Para XI.5:** Grasping Forcep, rotating with connector pinfor unipolar coagulation, size 5mm, length 36cms, atraumatic fenestrated single action jaws consisting of plastic Handle, without ratchet, outer tube, insulated Forcep inset.
Read as: Trocar, Size 6mm consisting of : Trocar only, with pyramidal tip, cannula without valve, with insufflations stop cock, length 10.5 cm, Multifunctional Valve – **2 Nos.**
- 20. Existing Para XI.6:** Scissors, rotating, dismantling, insulated with connector Pin for Unipolar coagulation, wit LEUR Lock connector for cleaning, double action jaws, curved, length of blades 15mm, size 5mm, length 36cm consisting of Plastic Handle insulated, without ratchetMetal outer sheath, insulated scissors insert for usewithrocars size 6mm
Read as: Scissors, rotating, dismantling, insulated with connector Pin for Unipolar coagulation, wit LEUR Lock connector for cleaning, double action jaws, curved, length of blades 15mm, size 5mm, length 36cm consisting of Plastic Handle insulated, without ratchetMetal outer sheath, insulated scissors insert for use withrocars size 6mm– **2 Nos.**
- 21. Existing Para XI.9:** KOH MacroNeedle Holder, ergonomic Handle with ratchet, left curved jaws, with tungsten carbide inserts, 5mm, length33cms for use with suture material 0/0-7/0.
Read as: : KOH MacroNeedle Holder, **Assistance Needle Holder** ergonomic Handle with ratchet, left curved jaws, with tungsten carbide inserts, 5mm, length33cms for use with suture material 0/0-7/0.
- 22. Existing Para XI.10:** Clip Applicator for use with Piling- Weck Titanium Clips (Medium Large), Dismantling, rotating, with ratchet to lock the jaw part holding the clip, size10mm, length 36cm, consisting of : Metal Handle with ratchet Metal Outer Tube Insets.
Read as: Clip Applicator for use with Piling- Weck Titanium Clips (Medium Large), Dismantling, rotating, with ratchet to lock the jaw part holding the clip, size10mm, length

36cm, consisting of: Metal Handle with ratchet Metal Outer Tube Insets. **Titanium clips medium large 200Nos**

23. Added Para: Should be supplied with 1 no. xenon spare lamp

24. Added Para: The following are also to be offered

- a. Reducer 11/6mm-2Nos.
- b. Marrayland dissecting forceps 5 mm - 2 Nos.
- c. Babcock forceps 10 mm-1 No.
- d. Bowel Atraumatic Grasper 5 mm-1 No.
- e. Spatula 5 mm-1 No.
- f. Fan retractor 5 mm-1 No.
- g. Fan retractor 10 mm-1 No.
- h. Knot Tier 5 mm-1 No.
- i. Right angle dissecting forceps 5 mm-1 No.
- j. Allis grasper 5 mm-1 No.
- k. CO2 Cylinder 5KG - 2Nos
- l. HP hose for CO2 cylinder
- m. HF cord for unipolar instruments QTY: 5 Nos.
- n. Hook scissor 5 mm-1 No.

25. Added Para under Recording System: It should have 19" or more touch screen

All other contents of the tender enquiry including terms & conditions remain unaltered.

Note: Prospective Bidders are also advised to check the website regularly prior to the closing date and time of online submission of bids