Amendment No. 5

Date: 05/08/2014

Sub: Amendment to the Tender Enquiry Document

Ref: Items tendered under NIT No. HLL/PCD/GNCTD/09/LNH/14-15 dated 04/06/2014

The following changes have been incorporated in the items tendered under the referred NIT.

Section – VII

Technical Specification

Item sl. no. 3
Operating Table

1. **Existing: Para 2:** Narrow base profile, automatic return to level, 500lb weight capacity, 4-point self levelling and brake system

   Amended as: Narrow base profile, automatic return to level, **150 Kg patient carrying weight capacity**, 4-point self levelling and brake system

2. **Existing: Para 4:** Positioning capabilities to include; lateral tilt of 25°, trendelenberg of 45^{0}, reverse trendelenberg of 20^{0}, back up of 90^{0}, back down of 30°, height adjustment range of 40" to 16", low speed for microscope interface and return top to level

   Amended as: Positioning capabilities to include; lateral tilt of 25°, trendelenburg of 45^{0}, reverse trendelenburg of 20^{0}, back up of 90^{0}, back down of 30°, height adjustment range of 40" to 16", **should have a top with dimensions 50cm (W) x 190-210cm (L)**, low speed for microscope interface and return top to level

3. **Added Para**: The table should be mobile, electrically controlled with battery powered hydraulic drive, table top should be divided into segments, topped with integral foam padding easy-rolling castors and should be fitted with brakes.

4. **Added Para**: Should have a powered longitudinal slide for 400-600mm.

5. **Added Para**: Should be electro-hydraulic with facility for various positions such as sitting, supine, prone and lateral positions under the microscope.

6. **Added Para**: Should have radiolucent top.

7. **Added Para**: Should have current leakage less than 70U/A AC (0.07m Amp)

8. **Added Para**: Should be USFDA and/or European CE approved Product.

9. **Added Para**: Accessories for Neurosurgery
   i. May field skull clamp with necessary adapters.
   ii. Attachment frame for positioning the patient in sitting position

iii. Arm Board
iv. Wristlet
v. Body straps
vi. Anesthesia screen
vii. Infusion body holders
viii. Radial setting clamp
ix. Horseshoe with connecting fixtures adults
x. Horseshoe with connecting fixtures pediatric
xi. Wrist support
xii. Accessories for Prone and Chest position
xiii. C-arm compatible and radio oblique
xiv. Should have a head holder for various positions. The head holder should be attached to the main unit.

Item sl. no. 4
Operating Microscope

1. **Existing: Microscope Section: Para3:** 5 Step Magnification (5x, 7.5x, 12.5x, 20x & 30x)

   Amended as: Magnification upto 18x

2. **Existing: Illumination Section: Para2:** *Light Source:* 24V/250W Halogen Lamp

   Amended as: Light Source*:* **300Watt Xenon with standby Xenon lamp, semiautomatic change over.**

3. **Existing: General Information:** Base Size: 600mm x 550mm

   Amended as: Base Size: 600mm x 550mm **approx**

4. **Existing: General Information:** Height : 1550mm

   Amended as: Height: 1550mm **approx**

5. **Existing: Optional Accessories:** CCD Camera

   Amended as: CCD Camera **- 3Chip with LCD touch screen**

Item sl. no. 5
Image Intensifier C-Arm

1. **Existing: Para A) Mobile C Arm Cart:** Pivot Rotation should be 300/-120 deg

   Amended as: Pivot **Rotation/Angulation should be +/-120 deg**

2. **Existing: Para A)** C arm Depth should be 660mm

   Amended as: C arm Depth should be 600mmor more

3. **Existing: Para B)** Inverter generator with inverter frequency of not less than 50 kHz

   Amended as: Inverter High frequency generator.

4. **Existing: Para B:** Fluoroscopy mA range: Max niA should be 9 rnA or more Pulse fluoroscopy: 9 mA, 2 - 15 fps

   Amended as: Fluoroscopy mA range: Max mA should be **8** mA or more Pulse fluoroscopy: 9 mA, 2 - 15 fps

5. **Existing: Para C:** Anode heat capacity - not less than 100 kHU. Higher capacity would be given preference

   Amended as: Anode heat capacity - atleast **50** kHU. Higher capacity would be given preference

6. **Existing: Para C:** Collimation - Iris type with parallel 86 rotation compensation filters

   Amended as: Collimation - Iris type.

7. **Existing: Para C:** Collimation position memory

   Amended as: Deleted

8. **Existing: Para:** It should have storage memory more than 15000 images.

   Amended as: It should have storage memory more than **10000** images.

9. **Existing: Para:** The systems should have AERB Type approval. It should have USA FDA approval. Vendor should have minimum 5 installations in Gov't Institution of the same model.

   Amended as: The model offered should be AERB Type approved (copy of certificate to be enclosed) and it should be European CE or USFDA approved (copy of certificate to be enclosed).

Item sl. no. 7
OT Light (Twin Ceiling Light)

1. **Existing: Para 2** Should have ESG safety glass for scratch-proof, simple, fast disinfection process and optimum light penetration throughout life-span of the light *Inbuilt graphic screen Graphic Display*

   Amended as: DELETED

2. **Existing: Para 3**: The heat filtration system should be based on aluminum reflectors for highest energy efficiency with the lowest heat generation

Amended as: The heat filtration system should be based on aluminum or **latest technology** reflectors for highest energy efficiency with the lowest heat generation

3. **Existing: Para 7:** The triangular design OT Light should be able to cover the operating area by combing both the light heads in to a single light source that maximizes the field of illumination and optimized illumination depth offering perfectviewing conditions

   Amended as: OT Light should be able to cover the operating area by combing both light heads in to a single light source that maximizes the field of illumination and optimized illumination depth offering perfect viewing conditions

4. **Existing: Para 8:** The life time of light source should be more than 50,000 hours

   Amended as: The life time of light source should be more than **40,000** hours

5. **Existing: Para 9:** Should have a BIANCE function in the Main Lamp Head through diffused backlight which is used for orientation and movement purposes during an endoscopic intervention

   Amended as: Should have a BIANCE /**Endo** function in the Main Lamp Head through diffused backlight which is used for orientation and movement purposes during an endoscopic intervention

6. **Existing: Para 11:** Should be homogenous light field and 360 deg. Illumination with 108 LEDs (Main Lamp) and 18 LEDs (Satellite Lamp).

   Amended as: Should be homogenous light field and 360 deg. Illumination with **80-100** LEDs (Main Lamp) and **>15** LEDs (Satellite Lamp).

7. **Existing: Technical Features: Para e:** Colour rendering index Ra : 96

   Amended as: Colour rendering index Ra **>94 both satellite lamp and main lamp**

8. **Existing: Satellite Lamp f: Weight of light head: not more than 3Kg.**

   Amended as: Deleted

9. **Existing: Technical Features: Para g:** Weight of light head: not more than 18 Kg

   Amended as: Should be light weight.

10. **Existing: Para 4: It should be made of aluminum and scratch proof monolayer safety glass for light weight.**

    Amended As: Deleted.

11. **Existing: Main Lamp: Para h:** Light head power consumption: Not more than 60 W

    Amended as: Light head power consumption should be **minimum.**

Item sl. no. 8
High Definition Ultrasound Machine with Colour Doppler 3D/4D

1. **Existing: Physical Features - Para a** High resolution TFT/LCD, Non-interlaced image monitor of 15-19 inches or more with tilt and swivel facility

   Amended as: High resolution TFT/LCD, Non-interlaced image monitor of **19 inches or more** with tilt and swivel facility

Item sl. no. 11
Mini C Arm for Hand Surgery

1. **Added Para: Detector: Flat Panel or CCD Detector.**
2. **Added Para: Field of view: 15x15cm**

Item sl. no. 12
C-ARM IMAGE INTENSIFIER

1. **Existing: X-RAY GENERATOR Para 1:High Frequency (approx. 50 KHz)**

   Amended as: X-RAY GENERATOR Para 1: High Frequency.

2. **Existing: X-RAY GENERATOR Para2: Output power approx. 6 KW**

   Amended as: X-RAY GENERATOR Para 2: Output power approx. 2.2 KW

3. **Existing X-RAY GENERATOR :Para 5b:** Radiographic mA: approx. 30mA to 100mA or more

   Amended as: Radiographic **mA: approx. 25mA to 100mA or more**

4. **Existing:** The Equipment must be CE Certified and should be approved by AERB

   Amended as: The Equipment must be **European CE and/or USFDA Certified** and **model offered should be AERB** type approved.

5. **Existing: Para: C-ARM MOVEMENTS: 3.** Horizontal Travel: approx. 220 mm or more

   Amended as: Horizontal Travel: approx. **210 mm or more**

6. **Existing: Para: Control: 3.** Indicators for left/right, up/down Image Rotation should be provided on **Control Panel**

   Amended as: Indicators for left/right, up/down Image Rotation should be provided on **Control Panel or Memory System**

Item sl. no. 13
ULTRASONIC BONE CUTTING DEVICE

1. **Existing: Para 2:** It should cause minimum or no damage to the soft tissues, vessels and nerves with maximum tip vibrations up to 200 micron and ultrasonic frequency in the rage of 25 to 35 KHz

   Amended as: It should cause minimum or no damage to the soft tissues, vessels and nerves with maximum tip **vibrations up to 300 micron** and **ultrasonic frequency in the rage of 22 to 35 KHz**

2. **Existing: Para 4:** The system should have full sets of 5-7 surgical tips for all kind of interventions, hand piece, pneumatic footswitch and irrigation sets Output power approx. 6 KW

   Amended as: The system should have full **sets of atleast 5 surgical tips of various size and shape** for all kind of interventions, hand piece, **pneumatic or electrical footswitch** and irrigation sets

3. **Existing Para 7:** The system should meet the highest International safety standards and should be manufactured by ISO certified company.

   Amended as: The system should be **USFDA and/or European CE** approved

Item sl. no. 16
Pediatric Ventilator for PICU

1. **Existing: Necessary additional parts: -** Humidifier
   Amended as: Humidifier should be servo controlled

2. **Existing: Necessary additional parts: -** Battery backup of at least 1 hr
   Amended as: Battery backup of at least 1 hr w**ith compressor**

3. **Added Para**: **Screen Size should be 12" or more**

Item sl. no. 17
Pediatric Ventilator for NICU

1. **Existing:** Inbuilt graphic screen Graphic Display

   Amended as: Integrated Inbuilt **touch** screen Graphic Display

2. **Existing:** Storage of graphic trends and trend tables up to minimum 10 days

   Amended as: Storage of **graphic trends up to 24 Hrs.**

3. **Existing:** Inspiratory Time : 0.1 - 2 sec

   Amended as: Inspiratory Time : 0.2 - 3 sec

4. **Existing:** Lung Mechanics - Resistance, Compliance , C20/C, Time constant Tc, RVR

   Amended as: Lung Mechanics - Resistance, Compliance, **Over distension indicator**

5. **Added Para: Ventilator should have Volume Guaranteed mode or PRVC mode.**

Item sl. no. 19
LED Ceiling OT Light with Camera System

1. **Existing:**
   Para 3 : Surgical light should consist of :One Central axis and four rotatable extension arms. **Having** Two arms (approx.800mm to 1000mm) to hold two equal size domes (Main & Satellite); one arm to hold LCD monitor and fourth height adjustable spring arm with provision for electrical connecting system 220V(50Hz.) power sockets, Video HDMI input/ output, provision for connecting other OT equipment and gadgets.

   Amended as:
   Para 3 : Surgical light should consist of One Central axis and four rotatable extension arms. **Two arms** (approx.800mm to 1000mm) to hold two equal size domes (Main & Satellite); one arm to hold **LED** monitor **26" high definition with 1080p resolution** and fourth height adjustable spring arm with provision for electrical connecting system 220V(50Hz.) power sockets **(3),** Video HDMI input/ output **from camera system, provision/tray for keeping equipment like laptop,cautery machine (maximum weight 10kg).**

2. **Existing:**
   Para 5 : Aerodynamic designed dome of the light head should not obstruct the effect of laminar air flow systems. The Light-heads (diameter not above 700mm) should be made of power-coated aluminium die case, with smooth and clean surfaces that are easy and safe to clean.

   Amended as:
   Para 5 : Aerodynamic designed dome of the light head should not obstruct the effect of laminar air flow systems. The Light-heads (diameter not above 700mm) should be made of **powder**-coated aluminium**/plastic** with smooth and clean surfaces that are easy and safe to clean.

3. **Existing:**
   Para 9: The optical light system **should be between 90 to 200 LED's**, with its own lens. In case of failure of one light source (LED), the illumination of the light field should not be affected.

   Amended as:
   The optical light system should have **40** to 200 LEDS with its own lens. In case of failure of one light source (LED), the illumination of the light field should not be affected.

4. **Existing:**
   Para: 10 Should have the provision of Ambient (Endo) **Green** Light so that during usage of Scopes, lights can be switched off and operations can be carried out in ambient light

   Amended as:
   Should have the provision of Ambient Endo Light so that during usage of Scopes, lights can be switched off and operations can be carried out in ambient light.

5. **Existing:**
   Para 14 : Colour temperature of: 4000k- 4500k.

   Amended as:
   Para 14 : Colour temperature of : **≥ 4500k.**

6. **Existing:**
   Para 15 : Colour rendering index: RA100 approx

   Amended as:
   Para 15 : Colour rendering index: **RA ≥ 95 .**

7. **Existing:**
   Para 16 : R9 (deep saturated red colour index): around 100 approx

   Amended as:
   Para 16 : R9 (deep saturated red colour index): ≥ **90**

8. **Existing:**
   Para 17 : Life span of main light source should be minimum 25,000hrs

   Amended as:
   Para 17 : Life span of main light source should be minimum **30000hrs**

9. **Existing:**
   Para 21 :
   Light Head Central axis mounted multiformat (full HD) Camera.
   Light should have **central**-integrated full high definition video camera system with sealed camera optics to save it from dust and fluids. Camera should not need independent power connection and should draw power from Light Head only.

   Amended as:
   Para 21 :
   Light Head integrated multiformat (full HD) Camera.

Light should have integrated full high definition video camera system with sealed camera optics to save it from dust and fluids. Camera should not need independent power connection and should draw power from Light Head only.

10. **Existing:**
Para 22 : Minimum 2 Megapixel full HD camera with 1/3 type CMOS sensor with 120x Zoom ration (10x Optical & 12x Digital) with possible to take video of object from min. 10mm distance.

Amended as:
Para 22 : Minimum 2 Megapixel full HD camera **(1080p or better resolution)** with **1/3"** CMOS **progressive scan type** sensor with 120x Zoom **ratio** (10x Optical & 12x Digital) with possible to take video of object from min. 10mm distance.

11. **Existing:**
Para 25 : LCD Flat Panel HD Monitor of min. size 26"

Amended as:
Para 25 : **LED** Flat Panel HD Monitor of min. size 26".

12. **Added Para :**

STORAGE SYSTEM
Suitable storage system (laptop) with latest configuration and minimum ITB storage capacity and licensed operative system and licensed Microsoft office and licensed software for video editing.

Item no.20

VESSEL SEALING SYSTEM WITH FOUR MONOPOLAR AND BIPOLAR CAUTERY

1. **Existing:**
Para 2 : The system must be micro-processor controlled which should identify the tissue type with a feedback **of thousands times/second** on real time basis, and adjust the power to get the desired surgical effect on the tissue.

Amended as:
Para 2 : The system must be micro-processor controlled which should identify the tissue type with a feedback on real time basis, and adjust the power to get the desired surgical effect on the tissue.

2. **Existing:**
Para 3 : System should have 2 monopolar output, 1 Bipolar output, 1 endoscopic monopolar output and 2 Vessel Sealing output.

Amended as:
Para 3 : System should have 2 monopolar outputs, **i.e., cutting and coagulation,** 1 Bipolar output, **endoscopic** monopolar output and **Vessel Sealing output.**

3. **Existing:**
   Para 4 : System should have separate monopolar, bipolar & Vessel Sealing foot pedal.

   Amended as:
   Para 4 : System should have separate **or 02 Double pedal foot switches for** monopolar, bipolar & Vessel Sealing foot pedal.

4. **Existing:**
   Para 9 : The system should have **two different** Vessel Fusion outputs which should be able to seal a vessel up to and including 7 mm in diameter and tissue bundles without dissection, isolation, sticking or **charring**. **When the seal cycle is complete, output to the hand-piece should be automatically** discontinued with an audible tone. Seals should withstand three times normal systolic blood pressure. The technology should monitor changes in tissue impedance **thousands of times a second**, and should adjust energy output accordingly to deliver the appropriate amount of energy for the desired tissue effect. Feedback-controlled response system should automatically discontinues energy delivery when the seal cycle is complete, eliminating the guesswork.(supporting documents in unambiguous language regarding this must be provided, both in original product brochure/catalogue of the manufacturer and by external agency like FDA).

   Amended as:
   Para 9 : The system should have Vessel Fusion outputs ,which should be able to seal a vessel up to and including 7 mm in diameter and tissue bundles without dissection, isolation, sticking or discontinued with an audible tone**.** Seals should withstand three times normal systolic blood pressure. The technology should monitor changes in tissue impedance and should adjust energy output accordingly to deliver the appropriate amount of energy for the desired tissue effect**.** Feedback-controlled response system should automatically discontinue energy delivery when the seal cycle is complete, eliminating the guesswork.(supporting documents in unambiguous language regarding this must be provided, both in original product brochure/catalogue of the manufacturer and by external agency like **US-FDA or European CE)**.

5. **Existing:**
   Para 12 : Should be compatible with Storz and Wolf Resectoscope.

   Amended as:
   Para 12 : Should be compatible with Storz and Wolf Resectoscope **or alternatively, necessary adapters should be supplied along.**

6. **Existing:**
   Para 13 : Machine should display error and not get activated if Return electrode monitoring (REM) is not connected.

   Amended as:
   Para 13 : Machine should display error and not get activated if **patient plate is not attached properly.**

7. **Existing:**
   Para 14 : System should have audio-visual alarm facility, to indicate any breakage of direct **contact between the patient and patient plate.**

Amended as:
Para 14 : System should have audio-visual alarm facility, to indicate any breakage of direct contact .

8. **Existing:**
Para 15. System should have 5 mm vessel sealing electrical instrument with Blunt tip for dissection and faster procedure.

Amended as:
System should have 5 mm vessel sealing electrical instrument with Blunt tip for dissection

9. **Existing:**
Para 18 : Should meet international quality such as European CE, ISO, FDA approved to medical directive and european standards.

Amended as:
Para 18 : Should meet international quality such as European CE, **US-FDA approved to medical directive .**

10. **Existing:**
Para 30 : The following accessories should be supplied with the system
1. Monopolar, Bipolar, Vessel Sealing Foot Switch 1 pcs each

Amended as:
1. Monopolar, Bipolar, Vessel Sealing Foot Switch 1 pcs each ***or 2 if double paddle is available.***

Item sl. no. 21

Pediatric Video Gastro & Colonoscopy system

1. **Existing: Pediatric Video Gastroscope –** Should have

Amended as: Pediatric Video Gastroscope (Qty. 01) – Should have

2. **Existing:**
Technical Specification (pg. 71 of TED)

Insertion tube Outer Diameter 5.5 mm or less
Working length 1100 mm or more
Total length 1400 mm or more

Amended as:
Technical Specification (pg. 71 of TED)

Insertion tube Outer Diameter **6 mm or less**
Working length **1100 mm approx**
Total length **1400 mm approx**
Added Para :
Optical zoom 10 X approx

3. **Existing:**
   Para 2 : Pediatric Video Colonoscope - Should have

   Amended as:
   Para 2 : Pediatric video Colonoscope (**Qty. 01)** - Should have
   Added Para :
   xi. Optical zoom 10X approx.

4. **Existing:**
   Technical Specification (pg. 72 of TED)
   Working channel diameter 3.8 mm or better
   Working length 170 cm or better

   Amended as:
   Technical Specification (pg. 72 of TED)
   Working channel diameter **3.2 mm** or better
   Working length **165 cm** or better

5. **Existing:**
   MEDICAL VIDEO PROCESSOR
   i. Should be equipped with **standard narrow band imaging capability and high resolution HDTV imaging** [**1080 interlaces**] compatible with the above video scopes.
   iii. Fully compatible to the color systems PAL & **NTSC.**[**SDTV**]
   iv. Should have HDTV and **RGB** output.
   x. High **horizontal** image resolution of **more than 450 lines [SDTV],** 1080[HDTV], therefore even the finest variations in tissue structures are perceivable on a high resolution HD monitor.
   xiii. Composite & S-VHS compatibility.

   Amended as:
   MEDICAL VIDEO PROCESSOR - **Quantity -1**
   i. Should be equipped with both **High definition white light and i-scan modes** compatible with the above video scopes.
   iii. Fully compatible to the color systems PAL &**HDTV.**
   iv. Should have **HDTV input and output.**
   x.High image resolution of 1080**p** HDTV therefore even the finest variations in tissue structures are perceivable on a high resolution HD monitor.
   xiii. Should have 1080p high definition video outputs.

6. **Existing:**
   XENON LIGHT SOURCE
   XENON light sources should be easy to operate and offer outstanding light delivery in compact
   design.(300 watt)
   Required Features:
   i. Optimal light delivery.
   ii. Excellent brightness with daylight spectrum.
   iii. Infinitely adjustable luminous intensity.
   iv. High-performance air filters with low noise level.
   v. Lamp service life display
   vi. Standby lamp with Easy lamp replacement.
   vii. Integrated insufflations pump with 3 output levels.

viii. Special light for mucosal observation

Amended as:

LED LIGHT SOURCE with insufflators Quantity 1(if not quoted with medical video processor)

LED light should be easy to operate and offer outstanding light delivery in compact design.

- **Light intensity ≥100000Lux**
- **Life of LED > 50000 hours**
- It should have color temp. approx. 6000 K
- It should have light continuously light adjustment either manually or Automatically by the camera's video output signal
- It should be supplied fiberoptic light cable dia 3.5mm/5mm length approx.230- 250 cm
- Unit should be according to international safety standard **US-FDA or European CE**
- Universal jaw assembly/**adaptor** to adapt to any make of fibreoptic cable

7. **Existing:**

Monitor

i. System should be supplied with suitable 17" or better LCD Medical Grade Colour Monitor[HD,1080 interlaces]

Amended as:

Monitor- Quantity 1

i. System should be supplied with suitable **26" LED** Medical Grade Colour Monitor, Resolution **1080pHD.**

8. **Existing:**

Other accessories

i. Imported mobile trolley (of same manufacturer) where the above instruments can be kept making mobile endoscopy unit

ii. Scope hangers for hanging the above scopes

iii. Suction with minimal noise and vibration

iv. Digital video recording, editing, image management, storage card and archival system compatible with above system and capability to take still images for presentation.

Amended as:

i. Imported mobile trolley (of same manufacturer) where the above instruments can be kept making mobile endoscopy unit- **Quantity- 1**

ii. Scope hangers for hanging the above scopes- **quantity- 3**

iii. Imported Suction (from same manufacturer) with minimal noise and vibration ; **should have pediatric flow of 8 ltrs/min approx. with two reusable 1 ltr jars. Quantity- 1**

iv. Digital **HD** video recording, editing, image management **system with high definition resolution of 1080p and** storage card **of at least 1TBimages, image management** and archival system compatible with above system and capability to take still images **in HD resolution of 1080p** for presentation. **Recording system should be of same make as camera system. Quantity- 1**

9. **Added Para:-**

The complete set should be US FDA or European CE approved and should be of highest standards.

Item sl. no. 22

HOLMIUM LASER

1. **Existing:**
   Para 4. Should have aiming beam.

   Amended as:
   Should have aiming beam, **preferably green**

2. **Existing:**
   Para 6 : Should have availability of fiber size from 200 micron to 1000 micron.

   Amended as:
   Deleted

3. **Existing:**
   Para 7 : Should be supplied with fibers size of 200 micron (Ten)

   Amended as:
   Should be supplied with **reusable** fibers size of **200 -240 micron** (Ten)

4. **Existing:**
   Para 8 : Should be supplied with fibers size of 365 micron (Ten)

   Amended as:
   Should be supplied with **reusable** fibers size of **350-400 micron** (Ten)

5. **Existing:**
   Para 9 : Should be supplied with fibers size of 555 micron (Ten)

   Amended as:
   Should be supplied with **reusable** fibers size of **550-600 micron** (Ten)

6. **Existing:**
   Para 10 : Should be supplied with fibers size of 150 micron for RIRS

   Amended as:
   Should be supplied with **reusable** fibers size of **150-200 micron** for RIRS **(Ten)**

7. **Existing:**
   Para 11 : Should be supplied with fibers size of 273 & 550 micron (one each number) for other applications.

   Amended as:
   Deleted.

8. **Existing:**
   Para 13 : Should be US FDA Approved

   Amended as:
   Should be US FDA **or European EC** Approved

9. **Existing:**
   Para 14 : Should have fiber single use and reusable.

   Amended as:
   Deleted

10. **Existing:**

    Technical Specification:
    Laser Type Pulsed Holmium: YAG (THC:YAG)
    Pulse Duration 350 microseconds

    Amended as:
    Technical Specification:
    Laser Type Pulsed Holmium: YAG **(Ho: YAG)**
    Pulse Duration **350 microseconds or above**

Item sl. no. 23

C-arm Compatible Paediatric O.T. Table

1. **Existing:**
   Para 2. It should have mobile battery and power operated electromechanical table with manual override (hand and foot).

   Amended as:
   It should have mobile battery and power operated **electrohydraulic** table with manual override (hand and foot).

2. **Existing:**
   Para 4. It should have a segmented radiolucent table top (each with its own mattress) with a longitudinal shift of at least 400mm for free movement of the C-arm. It should allow insertion
   of X-ray cassette from head to toe without manipulating the patient.

   Amended as:
   It should have a segmented radiolucent table top (each with its own mattress) with a longitudinal shift of at least **300mm** for free movement of the C-arm. It should allow insertion of X-ray cassette from head to toe without manipulating the patient.
3. **Existing:**
   Para 6. Table top width should be maximum of 450-500mm, including side railings.

   Amended as:
   Tabletop width should be 450-500mm **or less**, including side railings.

4. **Existing:**
   Para 7. It should have a range of height adjustment of approx .400mm.

   Amended as:
   It should have a range of height adjustment of approx **300mm.**

5. **Existing:**
Para 10. The leg section should be detachable and or have +20 to 90 degrees tilt.

Amended as:
The leg section should be detachable and or have +**15** to 90 degrees tilt.

6. **Existing:**
Para 15. It should have a full function cable remote control for obtaining different positions of the table with return-to-level **and preferably programmable patient orientation**.

Amended as:
It should have a full function cable remote control for obtaining different positions of the table with return-to-level.

7. **Existing:**
Para 16. The electro-mechanical adjustment for smooth and precise operation of head, upper back, lower back, leg section and kidney and all surgical and urological procedures should be possible.

Amended as:
The **electrohydraulic** adjustment for smooth and precise operation of head, upper back, lower back, leg section and kidney and all surgical and urological procedures should be possible.

8. **Existing:**
Para 17. The table should be provided with accessories (PEDIATRIC SIZE) such as anesthesia screen, IV pole, head rest, 1 pair arm rest, body straps, wrist straps, lithotomy poles, head section, **modem set for remote diagnosis (desirable),** leg holder, drainage basin with sieve, side
supports, gel pads, mayo trolley etc.

Amended as:
The table should be provided with accessories (PEDIATRIC SIZE) such as anesthesia screen, IV pole, head rest, 1 pair arm rest, body straps, wrist straps, lithotomy poles, head section, leg holder, drainage basin with sieve, side supports, gel pads, mayo trolley etc**.**

9. **Existing:**
Para 18. The table should be manufactured by a reputed company having **IS09001/BIS** or European CE or US-FDA standards

Amended as:
The table should be manufactured by a reputed company having European CE or US-FDA standards.

Item sl. no. 24

Pediatric Percutaneous Lithotomy set with Endovision System

1. **Existing:**
b. Dilatation systems (suitable for above nephroscope)
i. Dilatation cannula for sheath 15-18Fr with central channel for guide wire
ii. Dilatation cannula for sheath 16.5-19.5 Fr with central channel for guide wire

Amended as:

b. Dilatation systems (suitable for above nephroscope)

i. Dilatation cannula for sheath 15-18Fr **with or without** central channel for guide wire

ii. Dilatation cannula for sheath 16.5-19.5 Fr **with or without** central channel for guide wire

2. **Existing:**

e. An applicator consisting of sheath and rod should be supplied so as to use with haemostatic agents like floseal and surgiflow.

Amended as:

An applicator consisting of sheath and rod should be supplied so as to use with haemostatic agents like floseal and surgiflow. (optional)

3. **Existing:**

For children (3-7 years)

c. Operating sheaths(suitable for above nephroscope)

i. 20-22 Fr Sheath compatible with the above nephroscope- one only

ii. Hollow obturator and fascia' dilator

d. Forceps(suitable for above nephroscope)

i. stone grasping forceps - 3 Nos

ii. three pronged stone grasper— 2 Nos

iii. grasping forcep fenestrated jaw for stone fragments.

iv. Biopsy forceps

v. Scissors.

e. An applicator consisting of sheath and rod should be supplied so as to use with haemostatic agents like floseal and surgiflow.

Amended as:

For children (3-7 years)

c. Operating sheaths (suitable for above nephroscope)

i. 20-22 Fr Sheath **with obturator** compatible with the above nephroscope- one only

ii. Amplatz Sheath with or without obturator compatible with the above nephroscope- one only

iii. fascial dilator

d. Forceps (suitable for above nephroscope)

i. Grasping forceps fenestrated jaw for stone fragments.- **7-8 Fr and 10-11Fr one each.**

ii. Stone grasping forceps - 2 nos

iii. Three pronged stone grasper - 2 nos

iv. Biopsy forceps **7 -8 Fr**

v. Scissors.**8-10 Fr.**

e. An applicator consisting of sheath and rod should be supplied so as to use with haemostatic agents like floseal and surgiflow. (optional)

4. **Existing:**

For large children-(7-12 YEARS)

c. Operating sheaths (suitable for above nephroscope)

i. 24 Fr Sheath with obturator compatible with the above nephroscope- one only

ii. 26-27 Fr Sheath with obturator compatible with the above nephroscope- one

only
iii. Hollow obturator and fascial dilator

d. Forceps (suitable for above nephroscope)
i. stone grasping forceps - 3 Nos
ii. three pronged stone grasper— 2 Nos
iii. grasping forcep fenestrated jaw for stone fragments.
iv. Biopsy forceps
v. Scissors.

e. An applicator consisting of sheath and rod should be supplied so as to use with haemostatic agents like floseal and surgiflow.

Amended as:

For large children-(7-12 YEARS)

c. Operating sheaths(suitable for above nephroscope)
i. 24 Fr Sheath with obturator compatible with the above nephroscope- one only
ii. 24-27 **Amplatz Sheath with or without obturator compatible with the above nephroscope- one only**
iii. fascial dilator

d. Forceps (suitable for above nephroscope)
i. Grasping forceps fenestrated jaw for stone fragments.- **7-8Fr and 10-11Fr one each**.
ii. Stone grasping forceps - 2 nos
iv. Biopsy forceps **7-8** Fr
v. Scissors.**8**-10 Fr.

e. An applicator consisting of sheath and rod should be supplied so as to use with haemostatic agents like floseal and surgiflow.***(optional)***

5. **Existing:**

PENUMATIC INTRACORPOREAL LITHOTRIPTOR (compatible with above scopes)

f. It should have different sizes of probes as follows :
i. Probe 0.6mm diameter, 605mm working length - 2 Nos
ii. Probe 0.8mm diameter, 605mm working length — 2 Nos
iii. Probe 1.0mm diameter, 605mm working length — 2 Nos
iv. Probe 2.0mm diameter, 605mm working length —2 Nos

i. It should have noiseless air compressor complete with accessories to activate the Pneumatic Lithotriptor
iii. The equipment should be of international standards having recent International certification for quality of product' for example USFDA/ ISO/ CE/ TUV certification. Authenticated and legible certificate for the same to be annexed.

Amended as:

PENUMATIC INTRACORPOREAL LITHOTRIPTOR (compatible with above scopes)

f. It should have different sizes of probes as follows:
i. Probe **1.6mm** diameter,**350- 605mm** working length - 2 Nos
ii. Probe 0.8mm diameter, **350-605mm** working length -2 Nos
iii. Probe 1.0mm diameter, **350-605mm** working length -2 Nos
iv. Probe 2.0mm diameter, **350-605mm** working length -2 Nos

i. It should have noiseless air compressor complete with accessories to activate the Pneumatic Lithotriptor
iii. The equipment should be of international standards having recent International certification for quality of product' for example **US-FDA / European CE** certification. Authenticated and legible certificate for the same to be annexed.

6. **Existing:**

PEDIATRIC ENDOVISION CAMERA SPECIFICATION

1. High Defination Camera and camera controller unit

The system should have Special Features:

i. Optimizes to Any Size : The system should have **integrated Parfocal** Optical Zoom (F=14-30 mm, 2X) to enhance the quality of Image Size & cross specialty standardization of the camera system, regardless of the telescope used.

ii. **Digital and** Optical Zoom function **which** can be activated **via both** from camera head **as well as from control unit**

Amended as:

PEDIATRIC ENDOVISION CAMERA SPECIFICATION

1. High Definition Camera and camera controller unit

i. Optimizes to Any Size : The system should have **autoclavable camera head and autoclavable** Optical Zoom (F=14-30 mm, 2X) **approx** to enhance the quality of Image Size & cross specialty standardization of the camera system, regardless of the telescope used.

ii. **Optical Zoom function can be activated from camera head.**

7. **Existing:**

Technical Specifications :

Lens **Integrated Parfocal** Zoom Lens, f=14mm-30mm
Y/C signal to S-VHS socket **(2 x)**
RGB signal to D-sub socket
Digital SDI signal
DV-For digital recording
Control output 3.5mm stereo jack plug, (Acc 1, Acc 2)

The camera should be quoted with the CCU, camera head, connecting cables for printers and
recorders, BNC, S-VHS (Y/C), **Digital Video output and RGB sync**. Connecting cables, Keyboard for character generation.

Amended as:

Lens Zoom Lens, f=14mm-30mm approx
Y/C signal to S-VHS socket
Deleted
Deleted
Deleted
Deleted

The camera should be quoted with the CCU, camera head, connecting cables for printers and recorders, BNC, S-VHS (Y/C). Connecting cables, Keyboard for character generation.

8. **Existing:**

2. HDTV 16: 9 widescreen colour Monitor

The monitor should have:

LCD /LED crystal display.

Amended as:

2. HDTV 16: 9 widescreen colour Monitor

The **Medical grade** monitor should have:

LED crystal display.

9. **Existing:**

3. Xenon Light Source

- **i.** Xenon light source 300 watt with antifog air pump
- **ii.** It should be **supplied with one spare bulb** & fiberoptic light cable dia 3.5mm length approx.230- 250 cm
- **iii.** Unit should be according to international safety standard
- **iv.** Universal jaw assembly to adapt to any make of fibre optic cable

Amended as:

3. **LED cold** Light Sourcewith all suitable accessories

- **i.** **Deleted**
- **ii.** It should be supplied with fiberoptic light cable **dia 3.5mm/5mm** length approx.230- 250 cm
- **iii.** Unit should be according to international safety standard **US-FDA or European CE**
- **iv.** Universal jaw assembly/**adaptor** to adapt to any make of fibre optic cable
- **v.** **Light intensity ≥100000Lux**
- **vi.** **Life of LED > 50000 hours**

10. **Existing:**

4. High Definition Digital Documentation System (Recorder System)

- **i.** Should be capable of image capture: **Analog (640 x 480), Hi-Res (1024 X 768),and Hi-Def (1280 X 1024)**
- **ii.** Should have Disc Capacity of **1 TB**

Amended as:

4. High Definition Digital Documentation System (Recorder System)

- **i.** Should be capable of image capture: Hi-Def **1080p resolution**
- **ii.** Should have Disc Capacity of **1TB**

11. **Existing:**

5. ORIGINAL MOBILE UNIT TROLLEY consisting of

Imported mobile trolley of same parent company to house monitor, light source, camera unit and recorder unit because of compatibility and ergonomic issues.

- **i.** Mobile Universal Video Trolley Including 4 Shelves, 3 of which are fully height adjustable
- **ii.** Integrated Cable ducts, 4 Antisstatic Smooth-Running Double Casters, 2 of which can be
  locked Dimensions wxhxd. 675x1500x675 mm approx
- **iii.** Basic Electrics to connect Upto 8-12 Electrical Units, Mains Voltage, 230v, Consisting Of: 1 Housing, 1 Mains Module, 1 Unit Socket Outlet 1 Main Switch, 6 Unit Mains Cables.
- **iv.** Transformer Module Mains Voltage 230v, Isolating Transformer, Technical Data: Max.2000va, Max.9A, To Upgrade The Basic Electrics, Dimensions wzhzd 420x145x280.
- **v.** Cover Assembly into The Trolley Consisting Of: Lockable Safety Glass Doors and Lockable
  Rear Panel, Side Panels from the original manufacturer (preferable)
- **vi.** Drawer Unit For Mobile-Trolley, Wxhxd 525x125x550 approx
- **vii.** ISO Monitor

viii. Camera Head Holder For 3D Endocamera
ix. Articulated arm for 15" LCD Optimised
x. LCD Support arm with clamp

Amended as:
IMPORTED MOBILE UNIT TROLLEY consisting of
Imported mobile trolley **(preferably of the same parent company)** to house monitor, light source, camera unit and recorder unit because of compatibility and ergonomic issues.

i. Mobile Universal Video Trolley.
ii. Integrated Cable ducts, 4 **Anti-static** Smooth-Running Double Casters, 2 of which can be locked.
iii. Basic Electrics to connect Upto 8-12 Electrical Units, Mains Voltage, 230v.
iv. Transformer Module Mains Voltage 230v, Isolating Transformer/**CVT,** Technical Data : Max.2000va, Max.9A,
v. Deleted
vi. Deleted
vii. Deleted
viii. Camera Head Holder for Endocamera
ix. Deleted
x. Deleted

Item sl. no. 25

C-arm Image Intensifier

1. **Existing:**
Para 5. Auto Dose Rate control facility.

Amended as:
Auto**matic** Dose Rate control facility **with manual over ride possibility**

2. **Existing:**
Para 9. X-ray tube focal spot size for **small focus-** 0.6 mm and for **large focus-** 1.5 mm.

Amended as:
X-ray tube focal spot size for small focus- ***0.5*** mm and for large focus-1.5 mm

3. **Existing:**
Para 11. Image Memory -50 images or more with USB connectivity (preferred) for pen Drive for Image Transfer.

Amended as:
Static Image storage 100 images or more with USB connectivity (preferred) for pen Drive for Image Transfer.

4. **Existing:**
Para 12. Also must have all image processing features such as 360 degree image rotation, Orientation, averaging of frames up to 16 frames for image noise reduction.

Amended as:

Also must have all image processing features such as 360-degree image rotation, Orientation- **real time live mirror image**, **Temporal** Averaging of frames up to 16 frames for **real time** noise reduction.

5. **Existing:**
   Para 13. Image Zoom facility at least 3X.

   Amended as:
   Image Zoom facility at least **2X.**

6. **Existing:**
   Para 14. Radiation Safety Standard of AERB must be fully complied particularly a compulsory
   distance of 20 cm has to be maintained between focal spot and the skin for better radiation safety for everybody in OT Room.

   Amended as:
   Radiation Safety Standard of AERB must be fully complied particularly a compulsory distance of 20 cm has to be maintained between focal spot and the skin for better radiation safety for everybody in OT Room. **The unit should be AERB approved and US FDA or European CE approved.**

7. **Existing:**
   17. C-arm Mechanical Specifications
   (a) Focus Screen Distance - 850 mm
   (c) Vertical Movement of "C" motorized- 400 mm
   (d) Horizontal Movement- 200 mm
   (e) Wig wag +1- 12.5 degree
   (f) C-arm Rotation (Angulation) at least +1- 190 degree
   (g) Arc Orbital Movement- + 90 degree and -35 degree or more

   Amended as:
   17.C-arm Mechanical Specifications
   (a) Focus Screen Distance - 850 mm **approx**
   (c) Vertical Movement of "C" motorized- 400 mm **approx**
   (d) Horizontal Movement- 200 mm **approx**
   (e) Wig wag +/- **10** degree **approx.**.
   (f)C-arm Rotation (Angulation) at least +/- **180** degree **or more**
   (g)Arc Orbital Movement- + 90 degree and **-25** degree or more

8. **Existing:**
   Para18. CCD TV Camera with resolution of at least 752x 582 pixels

   Amended as:
   CCD TV Camera with **progressive scan sensor of 2/3"CMOS** resolution of at least **1K X 1K**pixels

9. **Existing:**
   Para19. Two 15 inch Medical Grade Monitors mounted on a trolley

   Amended as:
   Two 17 inch Medical Grade Monitors mounted on a trolley

10. **Existing:**
Para 22. Also companies have to give demonstration of quoted C-arm at some of user site at Delhi. Those companies will be technically shortlisted who pass demonstration. Quality will be assessed for:
4. Radiation safety features such as Distance of 20 Cms has to be maintained between focal spot and the skin for better radiation safety for everybody in OT Room, and other radiation minimization features.

Amended as:
Para 22 : Also companies have to give demonstration of quoted C-arm at some of user site at Delhi. Those companies will be technically shortlisted who pass demonstration. Quality will be assessed for:
4. Deleted

11. **Added Para :**
23. Integrated DICOM 3.0Interface for storage, printing.
24. Image processing software with real time image capturing, storage and display in 1K X 1K format.
25. Following accessories should be supplied
a. Lead apron Zero- 6
b. Thyroid shield-6
c. Gonadal shield-6
d. Wall mounted lead apron hanger- for 6
e. Textile cover with clips
f. Cassette holder14" x 14"- 2 Nos.

Item sl. no. 26

Plasma sterilizer

1. **Existing:**
Para 4. Sterilizer should be able to destroy Prions in compliance with CDC guidelines of 2008.

Amended as:
Deleted

2. **Existing:**
Para 5. Usable volume of chamber should be at least 100-120 liters.

Amended as:
Total volume of chamber should be at least **90** liters.

3. **Existing:**
Para 6. The chamber should be rectangular shaped.

Amended as:
Deleted

4. **Existing:**
Para 9. Should have selectable pre-programmed sterilization cycles for different types/ quantity of load with max. sterilization time not more than 50 min.(+/- 10 min)

Amended as:
Should have selectable pre-programmed sterilization cycles for different types/ quantity of load with max. sterilization time not more than **75 min.(+/- 10 min)**

5. **Existing:**
Para 10. Sterilant should be in a cassette with hydrogen peroxide concentration >55% with leak proof indicator (US FDA approved) for minimum 4 cycles per cassette /bottle or more.

Amended as:
Sterilant should be in a cassette**/bottle** with hydrogen peroxide concentration >55% with leak proof indicator (US FDA **or European CE** approved) for minimum 4 cycles per cassette /bottle or more.

6. **Existing:**
Para 16. Safety Features-Visual and Audible Alarms for abnormal deviations and end of Cycle with color coded alarms for easy identification from distance.

Amended as:
Safety Features-Visual and Audible Alarms for ***both*** abnormal deviations and end of cycle

7. **Existing:**
Para 20. Should be approved by FDA or CE &EPA.

Amended as:
Should be approved by **US** FDA **or European CE and should have process certificate EN ISO 14937 for plasma sterilization technology**

8. **Existing:**
Para 22: Should be supplied with following consumables sufficient for at least 1000 (average four cycles per day for 250 working days in a year with good shelf life of minimum 12 months) sterilization cycles.
   b. Chemical Indicator Labels (for putting outside pack)-= 10000 labels (adhesive)
   d. Biological Indicator (Validation in 24hrs) Vials = 1000 nos.
   e. Tyvek Pouch in Rolls size (4"x100ft) (100mmx40m)
   f. Tyvek Pouch in Rolls size 14" xl0Oft (300mmx40m)
   h. Printer paper rolls = 20 nos.
   i. Printer Ink cartridge = 10 nos.
   j. Boosters and endoscope adaptors- 2 each

Amended as:
Para 22 : Should be supplied with following consumables sufficient for at least 1000 (average four cycles per day for 250 working days in a year with good shelf life of minimum 12 months) sterilization cycles.
   b. Chemical Indicator Labels (for putting outside pack) = 10000 labels (adhesive)/**20 rolls (adhesive).**
   d.Biological Indicator (Validation in 24hrs) Vials = **500 nos.**
   e. Tyvek Pouch in Rolls **4" X 5000 feet (100mm X 1500m)**
   f. Tyvek Pouch in Rolls size 14" x 100 feet (300mm x40 m) **14" X 5000 feet (100mm X 1500m)**
   h.Thermal Printer paper rolls = 20 nos.
   i. Deleted
   j. Deleted

9. **Existing:**
   Para 24. Power input to be 220-240V AC 50Hz fitted with Indian Plug

   Amended as:
   Deleted

10. **Existing:**
    Para 25. Should be able to run on three phase 20A/415V.

    Amended as:
    Should be able to run on three phase**/ single phase power supply.**

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