

## BIO-MEDICAL ENGINEERING SECTION

Addu Equatorial Hospital

### Category 1

<b><u>SPECIFICATIONS: Urology Scope</u></b>	<b>unit</b>
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### **Description:**

**All scopes should be compatible with OLYMPUS EVIS EXERA III light source and Endoscope**

### **System.**

#### **BIPOLAR RESECTOSCOPE**

- It should have one 30-degree and one 12-degree telescope, 4mm, autoclavable.
- Cutting loop, bipolar, 24 Fr, to be used with both 30- and 12-degree telescopes.
- Cutting loop, bipolar, 24 Fr, small, to be used with both 30- and 12-degree telescopes.
- Should have Bipolar resectoscope sheath, 26 Fr, oblique beak, rotatable inner tube with ceramic insulation.
- Should have working element bipolar, cutting using spring, Movable thumb support, in rest position the electrode inside the sheath.

#### **CYSTOSCOPE**

- Straight Forward oblique 30-degree telescope, 4mm diameter, autoclavable, length up to 30 cm.
- The below mentioned cystoscope Sheath should be available.
- 17 Fr size for Cystoscope Sheath
- 18 Fr size for Cystoscope Sheath
- 21 Fr size for Cystoscope Sheath
- 24 Fr size for Cystoscope Sheath
- Telescopes shall have a low risk of object bump.
- Shall have colour coded for identification.
- Shall have fiberoptic light transmission incorporated
- Single/Double Channel Bridge should be available.
- Cystoscope sheath with Luer-lock connection of two different sizes must provide.

## **NEPHOSCOPE SET**

- It should be wide angle straight forward rigid nephroscope , with continuous flow operating sheath capability 17 Fr
- It Should be Wide angle straight forward rigid nephroscope with angled eyepiece, with continuous flow operating sheath capability 20 Fr
- It Should have wide angle straight forward rigid nephroscope with parallel eyepiece, with continuous flow operating sheath capability 22 Fr.
- It Should have wide angle straight forward rigid nephroscope with parallel eyepiece, with continuous flow operating sheath capability 24 Fr (Individual of Scope to be there)
- It should have 6° or 12° compatible telescope

### **Miniature Nephroscope:**

- Miniature Nephroscope 12°, angled eyepiece, 11/12 Fr., length 22 cm, autoclavable,
- fibre optic light transmission incorporated.
- Grasping Forceps for Foreign Bodies, 5 Fr., double action jaws, flexible, length 40 cm
- It should also be capable of being used for irrigation or aspiration.
- Should have a telescopic dilator, 9-22 Fr. can be used over a j-guide wire consisting of one hollow guide rod.
- It should have stone grasping forceps rigid with alligator jaws.
- Should have stone grasping forceps rigid for soft stones
- It should have a three-pronged stone grasper rigid self-closing.

### **OPTICAL URETROTOMES**

- Urethrome sheath with Luer lock stopcock, 21 Fr., with obturator
- It should be 21 Fr. The working length is approximately 20 cm.
- It should have a straightforward miniature telescope.
- It should have a telescoping bridge, 5 Fr, with one lockable channel.
- It should have a supplementary sheath, slides open for the introduction of a balloon catheter to slip on the uretrome sheath.
- It should have a protection tube – for sterilization and storage of electrodes, loops, curettes and knives.
- It should have a supplementary sheath for continuous irrigation and suction to slip on the uretome sheath.

### **URETEROSCOPE – FLEXIBLE**

- Should be a flexible angulation gives access to the whole kidney
- Should have Significantly improved image quality
- It should have an Innovative tip design to ease insertion.
- It should be a great control with a one-handed operation.
- It should be a remarkable durability
- The Ureter scope should have a direction of view 5.3 Fr.
- Should have Cristal clear images for efficient diagnostics.
- The Distal End Outer Diameter of the Ureter scope should be between 6 to 7 Fr.
- The Working Length of the Ureteroscope should be around 400 — 450 mm.
- It should be autoclavable and durable.
- Ureteroscope should be Autoclavable.
- The Ureteroscope should have built-in maintenance-free stopcocks.

## **URETERO-RENOSCOPE**

- Should be High Image Quality and Durability in Super slim 8.4 Fr.
- Facilitated handling due to unique 120° shaft rotation
- Optimal 275° wide angulation range
- Optical System - Field of view 80°
- The direction of view - Forward viewing
- Depth of field is approximately 1.5–5.0 mm
- Insertion Tube - Distal end outer diameter 8.5 Fr. (2.83 mm)
- The shaft diameter should be 8.4 Fr. (2.8 mm) or more
- Working length up to 670 mm
- Instrument Channel - Inner channel diameter should have approximately 3.6 Fr. (1.2 mm)
- The average total length should be 980mm
- Bending Section Angulation Range Up 275° Down 275°
- A biopsy valve should be available.
- Semirigid ureteroscope range, two-channel instrument insertion
- Two channels for instrument insertion should be available.
- Continuous flow for an optimal viewing system should be there.
- Should have ergonomic finger rests

## **Dual Channel Ureteroscope**

- The ureter scope should have a view direction of 5 or 7 degrees.
- Semirigid ureteroscope range, two-channel instrument insertion
- Two channels for instrument insertion should be available.
- Continuous flow for an optimal viewing system should be there.
- Should have ergonomic finger rests
- It should have crystal clear images for efficient diagnostics.
- The distal end outer diameter of the ureter scope should be between 6 to 7 Fr.
- The working length of the ureteroscope should be around 400 — 450 mm.

## **URETERORENOSCOPE**

- Scope should have 4Fr to 5Fr self-dilating distal tip with 5.5Fr to 6.5Fr size outer diameter in proximal part
- Working channel should be not less than 3 Fr (Working length should be 350 to 450 mm).
- Eyepiece should be straight with 5-degree lens.
- All the accessories should be compatible with the quoted uretero-renoscope.

## **Required accessories and consumables:**

- UroPass, ureteral access sheath, 10/12 Fr. x 38 cm
- Ellick bladder evacuator
- Tommy syringe bladder evacuator
- Cobra nitinol guide wire, hydrophilic coated, straight 150cm, 0.38 and 0.35
- Zebra guide wire
- Ultra-Catch 4-wire no-tip nitinol basket
- UltraTrack Hybrid Guidewire 0.035"
- Disposable port seal
- Sof-Curl ureteral stent 6 Fr. x 26 cm
- Single-use, single-ended cleaning brush
- Channel cleaning brush

- Channel-opening cleaning brush
- Sterilization cap
- Forceps/irrigation plug
- Durable detachable bridge for irrigation.
- Instrument tray, for ureteroscope and light-guide cable
- Light-guide cable, size S, plug-type, 3 mm
- Self - sealing caps.
- Light guide adapters.
- URS knife
- URS forceps
- Dormia basket
- URS scissors
- rigid & flexible forceps, Triprong forceps, Biopsy forceps.
- Pathfinder, Brush for cytology, disinfectant tray.
- 21 Fr. optical Urethrotome sheath with one channel shall provide.
- 26 Fr. Continuous irrigation resectoscope sheath with ceramic beak shall provide silicon tubes.
- DJ Stent Removal Forceps (Flexible) should be available
- Collin's knife, HF cord, protection tube, and cutting loop.
- Formalin chamber made of Virgin Acrylic 6mm thickness of appropriate size preferably with three trays for sterilizing
- Sterilization/Cidex tray with cover for storage of telescopes, hand instruments and other accessories of suitable sizes
- Should have Optical Biopsy forceps, each with double action jaws, flexible, length up to 40cms.
- Ureteral balloon dilator
- Hydrophilic guide wire
- Supra stiff guide wire
- A straight cold knife.
- ELLIK Evacuator with spare rubber bulb and adaptor
- Grasping forceps- Biprong, Triprong, alligator and peanut
- Biopsy forceps.
- Endopyelotomy knife
- Sickle knife
- Suction tube
- Hollow obturator and fascial dilator (Preferably Amplatz)
- Initial puncture needle — 2 part and 3 parts
- Storage & transportation tray
- Aiken cannula
- Metal Aiken dilator set with central rod
- Amplatz sheath (Full set)
- Fascial dilator set
- Balloon fascial PCNL track dilator
- Seal for Instrument Ports
- LUER-Lock Tube Connector, male, tube diameter up to 9 mm
- Insertion Aid for guide wires
- Wire Tray including Cleaning Adaptor, for Instrument Ports

- Laser Hand Instrument, distal tip bent upwards, fixation for laser fibres and sealing system,
- working length up to 35 cm, for use with Nephroscope
- Insertion Aid, Instrument Port with Sealing System and Quick Release Lock, Seal,
- LUER-Lock Tube Connector, male, LUER-Lock Tube Connector,
- Tray for storage and cleaning
- Micronephroscope with outer sheath compatible with a laser source, with standard accessories One Set Dilator.
- Channel for guide wires, for use with Operating sheath of 15 / 18 Fr.
- Cold Knife straight
- Cold Knife round
- Cold Knife sickle shaped
- Cold knife hook shaped
- Protection tube
- Supplementary sheath
- Durable detachable bridge for irrigation.
- Instrument tray, for ureteroscope and light-guide cable
- Light-guide cable, size S, plug-type, 3 mm
- Flex Catch 1.9 Fr. Basket

**Standards and Requirements:**

- USFDA, CE and or ISO certifications or relevant standards certification.

**Additional Remarks or Requirements:**

- Complete product details to be enclosed with the original brochure or catalogue (Soft or hard copy).
- Details of the standard accessories, additional accessories, optional items, consumables and minimum supplies to be stated clearly.

**Training and Validations Requirements:**

- Onsite Application and Operator training for users and technical training for in house Engineers should be provided by the Authorized trainers.
- Equipment validation should be performed at the time of installation.

## **Category 2**

**SPECIFICATIONS:** Bipolar saline TURP Cautey Machine

**Quantity: 1**

**Description:**

- The system should have the possibility of vessel sealing up to 7mm
- Saline coagulation: 2 or more different strengths
- Base Frequency: 350 kHz and more than 500watts
- Protection against electric shock: Class I Type CF
- Weight should not be more than 15 Kg.
- Automatic Smoke Evacuation facility.
- The electrosurgical Unit should be available
- Footswitch should be available
- Bipolar Passive Working Element should be available
- Monopolar Passive Working Element should be available
- Bipolar HF-Cable should be available
- Monopolar HF-Cable should be available
- Two-way Irrigation Port for 24 Fr/22Fr sheath for intermittent flow TUR should be available.
- A compatible visual Obturator should be available.

**This system should be compatible with following procedures:**

- SalineTUR
- Conventional Monopolar TUR.
- Bipolar/Saline Enucleation of Prostate
- Open Monopolar
- Open Bipolar
- Laparoscopic-Monopolar
- Laparoscopic-Bipolar
- Open Vessel sealing
- Laparoscopic Vessel sealing

**This system should have following features:**

- Output mode: Monopolar, Bipolar and Saline,
- Monopolar cutting: PURE, BLEND
- Monopolar coagulation: SPRAY
- Bipolar Cutting: PURE.
- Bipolar Coagulation: SOFT, HARD
- Saline cutting: PURE, BLEND

**Required accessories and consumables:**

- TUR cutting electrode
- TUR hook electrode
- Cold knife electrode

**Standards and Requirements:**

- USFDA, CE and or ISO certifications or relevant standards certification.

**Additional Remarks or Requirements:**

- Complete product details to be enclosed with the original brochure or catalogue (Soft or hard copy).
- Details of the standard accessories, additional accessories, optional items, consumables and minimum supplies to be stated clearly.

**Training and Validations Requirements:**

- Onsite Application and Operator training for users and technical training for in-house Engineers should provide by the Authorized trainers.
- A Validation should verify at the time of installation.

### **Category 3**

#### **SPECIFICATIONS: LITHOCLAST MACHINE**

**Quantity:1 unit**

- Offers fast fragmentation and removal of calculi from the urinary tract, and is used in cystoscopy, ureteroscopy and percutaneous nephrolithotomy (PCNL) procedures.

#### **Description:**

- Should have a generator for both ultrasound and pneumatic (ballistic) Lithotripsy integrated into the same machine (Hydraulic, laser, ultrasonic)
- It should be possible to deliver these energies by separate probes and Handpieces.
- It should be possible to integrate both probes into the same handpiece.
- The Probe and Handpieces should have simultaneous suction facilities.
- The suction should be connectable to existing hospital wall suction or standalone suction units.
- There should be a facility to allow cooling of the probe during ultrasonic energy.
- The probes and Handpieces should be suitable for scopes from all manufacturers.
- The unit should be supplied with an ergonomic foot pedal control.
- In the event of malfunction of the pneumatic generator of the machine, it should be connectable to an external source of compressed air/gas.
- It should be possible to regulate the repetition rate of the pneumatic Lithotripter.
- The probes and Handpieces should be sterilizable by liquid, gas and autoclaving.
- Pneumatic Long lasting, rigid probe in different sizes such as 0.8 mm, 1.0 mm, 1.6 mm, 2.0 mm
- Suction tube 3.5 mm dia, Length 300-400 mm
- Suction tube 1.6 mm dia, Length 500-600 mm
- Suction tube 4mm dia, Length 300-350mm
- Probe Guides should be available.
- It should have a Silicone seal for single use.
- Should have a Transportation case for the Lithoclast handpiece.
- Should be provided with proper training in handling instruments and machines.

#### **Required accessories and consumables:**

- There should be a container for collecting stone fragments.
- The unit should be supplied with a variety of probes in sizes
- Silicon Suction hose

#### **Standards and Requirements:**

- USFDA, CE and or ISO certifications or relevant standards certification.

#### **Additional Remarks or Requirements:**

- Complete product details to be enclosed with the original brochure or catalogue (Soft or hard copy).
- Details of the standard accessories, additional accessories, optional items, consumables and minimum supplies to be stated clearly.

#### **Training and Validations Requirements:**

- Onsite Application and Operator training for users and technical training for in-house Engineers should provide by the Authorized trainers.
- A Validation should verify at the time of installation.