

Cystoscopy

No.	Item Specifications	Fill your Specification
1	Description of Function	
1.1	Laparoscope is used for minimally invasive surgery and comprises of telescope and associated instruments and units.	
1.2	Cystoscopy (cystourethroscopy) is a diagnostic procedure that is used to look at the bladder (lower urinary tract), collect urine samples, and examine the prostate gland.	
	Cystoscopy an endoscopic procedure is used by urologists to examine the entire bladder lining and take biopsies of any areas that look questionable.	
2	Operational Requirements	
2.1	Shall supply the set for Laparoscopic surgery which have units/groups of items/components as	
	Mentioned in the technical specifications.	
2.2	Cystoscope (urethroscope) set of instruments uses a lighted tip for guidance to aid in diagnosing urinary tract disease and prostate disease. This surgical test also enables biopsies to be taken or small stones to be removed by way of a hollow channel in the cystoscope.	
3	System Configuration	
3.1	Laparoscopic Instrument set with Adult Cystoscope and Resectoscope, complete system and with all standard accessories.	
4	Technical Specifications	
4.1	Telescopes:	
4.1.1	Straight forward Telescope 0o enlarged view diameter 10mm, length 30cm. autoclaveable: 01 no.	
4.1.2	<u>Telescopes shall have low risk of object bum.</u>	
4.1.3	Shall have colour coded for identification.	
4.1.4	Shall have fibreoptic light transmission incorporated.	
4.2	<u>Reusable Hand Instruments:</u>	
4.2.1	Hassan's Trocar, 10.5mm- 1 No.	
4.2.2	Trocar , size 10mm- 1 No.	
4.2.3	Trocar, size 5mm- 3 Nos.	
4.2.4	Maryland dissecting forceps 5mm dia, jaws with size 5-10mm for unipolar coagulation- 2 Nos.	
4.2.5	Gall bladder fundus holding Allis type grasping forceps 5mm dia, jaws with size 5-10mm and with fine teeth- 1 No.	
4.2.6	Gall bladder neck holding Allis type grasping forceps 5mm dia, jaws with size 5mm and with fine teeth- 1 No.	
4.2.7	Metzenbaum scissor for unipolar coagulation, size 5mm- 1 No.	
4.2.8	Hook scissor for unipolar coagulation, size 5mm with L shaped jaw-1 No.	

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4.2.9	Two ways Suction and Irrigation cannula: Size 5mm, length 36cm, used with suction and irrigation handle and hand piece with stopcock- 2 Nos.	
4.2.10	Gall Bladder extractor size 10mm dia, jaws with size 10mm and with big teeth- 1 No.	
4.2.11	Fenestrated grasping forceps size 5mm- 1 No.	
4.2.12	Needle aspirator size 5mm- 1 No.	
4.2.13	Needle holder size 5mm-1 No.	
4.2.14	Clip Applicator-Medium Large, 10mm- 1 No.	
4.2.15	Reduction Sleeves/Extractors: From 10/11mm to 5mm, metallic- 2 Nos.	
4.2.16	Reducers: From 10/11mm to 5mm- 2 Nos.	
4.2.17	High frequency cord- 2 Nos.	
4.3	Cystoscope Telescope: 2 nos.	
	<input type="checkbox"/> 30 degree Telescope of size 4mm, length 30cm (+/- 3cm).	
	<input type="checkbox"/> Must have very high quality of rod lens system.	
	<input type="checkbox"/> Must have fibre optic light transmission incorporated.	
	<input type="checkbox"/> The telescope must be autoclaveable.	
4.4	Cystoscope Sheath: 1 no.	
	<input type="checkbox"/> Cystoscope sheath with luer lock connection of two different sizes must be provided	
	<input type="checkbox"/> 16 Fr., 17 Fr., 18.5 Fr. and 20 Fr. sheath one each with slot for instrument.	
	<input type="checkbox"/> The sheath must be marked and graduated.	
4.5	Telescope Bridge: 1 no.	
	Telescope bridge with one instrument channel to fit with the cystoscope.	
4.6	Flexible Grasping Forcep: 1 no.	
	7 Fr. grasping forcep shall be provided.	
4.7	Flexible Biopsy Forcep: 1 no.	
	7 Fr. Biopsy forcep shall be provided.	
4.8	Rigid Biopsy and Grasping Forcep: 1 no.	
	Optical Rigid Biopsy forcep compatible with 20 Fr. Cystoscope sheath shall be provided.	
4.9	Toomey syringe 100 CC: 1 no.	
	Toomey syringe of 100 cc with adaptor to fit with the sheath shall be provided.	
4.1	Flexible Scissor: 1 no.	
4.11	ELLIK Evacuator: 1 no.	
	ELLIK Evacuator with spare rubber bulb and adaptor shall be provided.	
4.12	Urethrotome Sheath: 1 no.	
	21 Fr. optical Urethrotome sheath with one channel shall be provided.	
4.13	Cold Knife: 2 nos.	
	Straight cold knife shall be provided.	

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4.14	Resectoscope Sheath: 1 no.	
	<input type="checkbox"/> 26 Fr. continuous irrigation Resectoscope sheath with ceramic beak shall be provided with set of silicon tube.	
	<input type="checkbox"/> Sheath must be provided with deflecting obturator	
4.15	Working Element Set: 1 no.	
	Working element set passive type with standard accessories like, Kollins knife, HF cord, protection tube, cutting loop shall be provided.	
4.16	Cutting loop 24 Fr.: 12 nos.	
4.17	Formalin Chamber: 1 No.	
	Formalin chamber made of Virgin Acrylic 6mm thickness of appropriate size preferably with three trays for sterilizing the laparoscope.	
4.18	Sterilization/Cidex Tray: 2 Nos.	
	Sterilization/Cidex tray with cover for storage of telescopes, hand instruments and other accessories of suitable sizes.	
4.19	Single Chip Camera System: 1 No.	
4.19.1	Single chip endovision camera system with digital image processor module.	
4.19.2	Image sensor: ½” CCD chip.	
4.19.3	Pixels (approx.): 752 (H) x 582 (V).	
4.19.4	Resolution: 450 lines horizontal.	
4.19.5	AGC: Microprocessor based.	
4.19.6	Minimum sensitivity: 3 lux	
4.19.7	Exposure control: 1/50 sec-1/1000 sec.	
4.19.8	Shall have freezing function & automatic filter function.	
4.19.9	Programmable function keys on camera head for functions like automatic white balance, gain control, brightness control etc.	
4.19.10	Integrated optical parfocal zoom lens: 25-50mm	
4.19.11	DV output, S-VHS and composite video output.	
4.19.12	Shall have accessories output to control external devices like video printer from the buttons.camera head	
4.19.13	Focus control, digital zoom.	
4.2	High Resolution Video Monitor: 1 No.	
4.20.1	<u>Shall have colour system PAL/ NTSC.</u>	
4.20.2	Compatible with endovision camera of any make.	
4.20.3	Screen size diagonal 19-20” Ultra high resolution at least 1920x1200 pixels, flat screen, TFT/LCD.	
4.20.4	<u>Max horizontal screen resolution in lines > 1000 lines.</u>	

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4.20.5	Monitor menu displays all controls, capabilities and operations via cursor keys, user defined captions, easy to use and highly dependable.	
4.20.6	Must be composite, have multiple video input and out puts – BNC, RGB, Y/C, SDI, DVI etc. Power supply of 220-240 VAC. 50Hz.	
4.20.7	Must have facilities for recording the data on computer /digital video recorders/CD.	
4.20.8	On screen menu for monitor setting, compact and light weight, drip water protected dust proof, all connecting cables to be supplied.	
4.20.9	Brightness, at least 400cd/m2, contrast ratio 700.	
4.20.10	Antireflection coated front glass.	
4.20.11	Must have consistent illumination level.	
4.20.12	Drip water protected, dustproof housing.	
4.20.13	Must have facility for up gradation and must be compatible with lower models.	
4.21	Xenon Light Source and Light Cable: 1 unit	
4.21.1	Must be high intensity Xenon light source.	
4.21.2	Shall be light in weight.	
4.21.3	Shall have 300 watts bulb minimum 1000 hrs. of operation.	
4.21.4	Must have colour temperature more than 6000K.	
4.21.5	Monitoring of lamp function.	
4.21.6	Must have display of lamp service life.	
4.21.7	Facility of standby mode.	
4.21.8	Must have built in Antifog Pump.	
4.21.9	Light intensity adjustment continuously adjustable from 0 to 100% manually as well as fully automatically by the cameras video output signal.	
4.21.10	Universal jaw assembly to adapt cable of any make of fibre optic cable without adapter.	
4.21.11	Light Cable: Fibre optic light cable of size 4.8mm or as appropriate with the system in diameter and length 250-300 cm, the same must also be heat-resistant.	
4.22	Electronic CO2 Insufflator: 1 unit	
4.22.1	Microprocessor controlled, fully automatic gas fill.	
4.22.2	LCD based central display monitor with multilingual text & graphics.	
4.22.3	Must have an adjustable flow rate of 0 to 30-40 litres per minute and a pressure range adjustable between 0-30 mm Hg.	
4.22.4	Pin index connection.	
4.22.5	Silicon autoclaveable tubing with luer lock attachment.	
4.22.6	Soft approach pressure control for safe recovery of abdominal pressure.	
4.22.7	The insufflations must have an excellent operational safety to the patient and the surgeon and it must be easy to use.	

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4.22.8	Optical and acoustic warning signals for pressure exceeding set limits.	
	4.22.9 Provision for preheating gas to body temperature.	
4.22.10	The unit shall come with:	
	CO2 equipment with mains cord, a high - pressure hose with an appropriate length, universal wrench. The unit must be provided with 10 sterile disposable CO2 gas filters.	
	4.22.11 CO2 Cylinder:	
	Shall provide one large size cylinders with required regulators and connecting pipe to the insufflator with pressure gauge.	
4.23	Suction and Irrigation: 1 unit	
4.23.1	The suction and irrigation unit shall be a combined unit for performing laparoscopy surgeries.	
	4.23.2 Irrigation pressure control between 0-400 mm Hg.	
4.23.3	Suction pressure control between 0.75 bar.	
4.23.4	Main unit with digital display.	
4.23.5	Overflow protection on suction bottles.	
4.23.6	Control from control panel and/or foot pedal.	
4.23.7	Shall come with:	
	Silicone suction tubings set, reusable pressure domes, bacterial filter and sterilizeable, polycarbonate unbreakable suction and irrigation bottles of capacity minimum 1.5 litres with cap.	
4.24	Electrosurgical Generator (Monopolar, Bipolar & in saline mode) :	
4.24.1	High frequency microprocessor/microcontroller based digitally controlled device.	
4.24.2	Shall have approx. 6.5” or more touch screen for convenient use. There shall be no extra button for confusing.	
4.24.3	Shall be suitable for Open, Laparoscopic, Endoscopic, Urology & Gynaecology procedures.	
4.24.4	Full range of monopolar & bipolar modes for general surgery.	
4.24.5	EFFECTS’ mode to fine tune energy delivery to make even finer adjustments for precise tissue management.	
4.24.6	Tissue-adaptive power output for controlled, precise and fast cutting.	
4.24.7	Quick memory function to set and recall settings easily.	
4.24.8	Automatic smoke evacuation function when combine with insufflators providing a ‘HD’ view of the cavity.	
4.24.9	Universal connector with instrument recognition URO & GYN.	
4.24.10	Saline detection ensuring the right medium is used in resection-in-saline.	
4.24.11	Saline modes for improved ignition and vaporization performance.	
4.24.12	Shall have double pedal foot switch.	
4.24.13	Automatic activation of coagulation current as soon as coagulation electrode touches tissue with both branches.	
4.24.14	Activation of HF Functions possible via footswitch or manual control switch.	

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4.24.15	Connecting sockets for unipolar and bipolar application can be selected according to individual requirements.	
4.24.16	Switchover function enables switching between two modes within a user programme via a footswitch from the sterile area.	
4.24.17	Readily plug & play most common bipolar & monopolar diathermy instruments with international 4mm single & 3pin instruments, 5mm & 8mm single pins e.g. Bovie connectors/ banana plugs.	
4.24.18	Maximum Bipolar saline coagulation at 150-250 watt, bipolar saline cut-100 watt, bipolar saline –c- cut at 300 watt.	
4.24.19	Unipolar maximum at 200-300 watt where standard coagulation at 200 watt, forced coagulation at 120 watt, spray coagulation at 120 watt.	
4.24.20	LF / HF leakage current monitor.	
4.24.21	Neutral Electrode safety system.	
5	Accessories, spares and consumables	
5.1	Video Cart: 01 no.	
	<input type="checkbox"/> Customized, imported, epoxy powder coated/ stainless steel video cart.	
	<input type="checkbox"/> Portable on 4 antistatic, antirust, 360o swivel dual castors, 2 with brakes.	
	<input type="checkbox"/> Shall have required number of shelves for housing all the units of the set.	
	<input type="checkbox"/> Adjustable arm for fixation to either side for fixing the flat monitor.	
	<input type="checkbox"/> One drawer unit with lock and key.	
	<input type="checkbox"/> Shall have excellent cable management system.	
	<input type="checkbox"/> Power box with concealed wiring for providing electrical connections of proper rating to all the units.	
5.2	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer.	
6	Operating Environment	
6.1	The product offered shall be designed to be stored and to operate normally under Power Supply, Climate, Temperature, Humidity, etc. for Sudan.	
6.2	Power supply: 220 – 240 VAC, 50Hz fitted with appropriate plug. The power cable must be at least 3 metre in length.	
6.3	Suitable UPS with maintenance free batteries, voltage regulation and spike protection for minimum 30 min. back-up shall be supplied with the system.	
7	Standards and Safety Requirements	
7.1	Must submit ISO13485:2003/AC:2007 for Medical Devices AND	
7.2	CE (93/42 EEC Directives) or USFDA or TUV approved product certificate.	
7.3	Shall be certified to be meeting safety standard IEC 60601-2-18 part 2 Particular requirements for the safety of Endoscopic Equipment.	
8	User Training	

No.	Item Specifications	Fill your Specification
8.1	Must provide user training (including how to use and maintain the equipment).	
9	Warranty	
9.1	Comprehensive warranty for 2 years after acceptance.	
10	Maintenance Service During Warranty Period	
10.1	During warranty period supplier must ensure preventive maintenance and corrective/breakdown maintenance whenever required.	
11	Documentation	
11.1	User (Operating) manual in English.	
11.2	Service (Technical / Maintenance) manual in English.	
11.3	List of important spare parts and accessories with their part numbers and costing.	
11.4	Certificate of calibration and inspection from factory.	

Lithotripsy

No.	Item Specifications	Fill your Specification
1	Description of Function	
1.1	An extracorporeal lithotripter is a device that is used to fragment urinary (i.e., kidney, ureter, and bladder) and biliary tract stones. These devices are placed at the stone location via an endoscope or laparoscope.	
2	Operational Requirements	
2.1	System complete with all accessories and hand piece is required	
3	Technical Specifications	
3.1.1	Extracorporeal Lithotripter	
	a. Master control unit includes:	
	i. Holder for the stone catcher -1	
	ii. Electric foot pedal-1	
	iii. Instruction manual -1	
	iv. Spare tube for the pneumatic hand piece without connector -1 stone catcher set (with sterile suction tube, length 3m) - 1	
	vi. Carton package- 1	
	b. Ultrasound hand piece set includes:	
	<u>i. Ultrasound hand piece- 1</u>	
	ii. Silicone seals-1	
	iii. Wrench 5mm-1	
	<u>iv. Transportation case -1</u>	
	c. Pneumatic hand piece set includes:	
	i. Pneumatic hand piece-1	

No.	Item Specifications	Fill your Specification
	ii. Adjustment interface-1	
	iii. Probe cap -1	
	iv. Compressed air tubing for hand piece-1	
	v. Silicone probe guide set (packing unit 12 silicones) -1	
	vi. Transportation case -1	
	d. Pneumatic Probes includes:	
	i. Probe, 2mm, length 425mm -1	
	ii. Probe, 1mm, length 605mm-1	
	iii. Probe, 0.8mm, length 605mm -1	
	iv. Probe, 1mm, length 569mm for combination with 1 Ultrasound probes 3.3mm and 3.8mm-1	
3.2.2	Probes Set	
	a. Probe 3.8mm or 3.3mm for the ultrasound hand piece-5	
3.3.3	Compressed air tubing	
	a. Compressed air tube 1m for the compressor-1	
	b. Compressed air tube 3m for the compressor-1	
	c. Compressed air tube dragger -1	
	d. Compressed air tube france-1	
4	System Configuration Accessories, spares and consumables	
4.1	System as specified-	
4.2	1. IPP Treatment Kit -1	
	2. Gel pad -2	
	3. Scanner Advance Sono kit Linear 10/70mm-1	
	4. Collecting container -1	
	5. Transducer 7.50MHz linear array-1	
	6. Main Cord-1	
	7. Compressor-1	
	a. 8 bar/ 220V	
	8. Vacuum Set	
	a. Vacuum body with tub-valve (silicone tube 15cm with connector) - 1	
	b. Suction set for Vacuum (silicone tubing with 2 connecting pieces) 1	
	9. Vacuum Suction tube	
	a. Suction tube for Vacuum 1.6mm -1	
	b. Probe 0.8mm, length 668mm -1	
	c. Suction tube for Vacuum, 4mm -1	
	d. Suction tube for Vacuum, 3.5mm-1	
	e. Probe 1.6mm, length 453mm -1	

No.	Item Specifications	Fill your Specification
4.3	4.3 All standard accessories/consumables/parts required for the proper operation of the above item shall be included in the offer.	
5	5 Environmental factors	
5.1	The product offered shall be designed to be stored and to operate normally under Power Supply, Climate, Temperature, Humidity, etc. for Sudan.	
6	6 Power Supply	
6.1	Must work on 220-240V/ 50 Hz AC Single phase fitted with appropriate plugs and sockets. The power cable must be minimum 3 metres long.	
6.2	Suitable UPS with maintenance free batteries for minimum 30 min. back-up should be supplied with the system.	
7	7 Standards, Safety and Training	
7.1	Must be USFDA or CE or TUV	
7.2	Manufacturer must have ISO certification for quality standards.	
7.3	Electrical safety conforms to standards for electrical safety IEC 60601-1 General Requirements for safety.	
7.4	Comprehensive warranty for 2 years.	
7.5	Comprehensive training for staff and support services till familiarity with the system.	
8	8 Documentation	
8.1	User/Technical/Maintenance manuals to be supplied in English.	
8.2	Certificate of calibration and inspection.	
8.3	List of important spare parts and accessories with their part numbers and costing.	

C-Arm Machine

No.	Item Specifications	Fill your Specification
1	1 Description of Function	
1.1	A mobile C-Arm X-ray for fluoroscopy, image storage and retrieval	
2	Operational Requirements For fluoroscopy, image storage and retrieval The system offered shall be a general fluoroscopy/radiology system, it should be DICOM 3.0 compatible type.	
2.1	It shall operate on single phase AC power supply.	
2.2	Image manipulation - inverse rotation +/- , flip flop	
3	3 System Configuration	
3.1	X-ray C-Arm Mobile with complete accessories	
3.2	CD/DVD/RW drive, 1 unit.	
3.3	B/W thermal video printer, 1 unit.	
4	4 Technical Specifications	
4.1	X-Ray Generator	

No.	Item Specifications	Fill your Specification
	Microprocessor based, high frequency inverter generator	
	Generator Output: not less than 6 kW	
	<u>Fluoroscopic/ Radiographic KV range:</u>	
	Lower limit shall not exceed 40 KV	
	Higher limit shall not be less than 110 KV	
	<u>Fluoroscopic mA range:</u>	
	Lower limit shall be ~0.1 mA	
	Upper limit shall be more than 12 mA	
	Radiography ~ 80mA	
4.2	X-Ray Tube	
	Rotating anode type	
	Dual focal spot	
	Nominal voltage: 110 kV	
	Tube heat capacity not less than 200 KHU	
	Anode Thermal Capacity not less than 75 KHU	
	Anode Thermal Dissipation not less than 37 KHU/min	
	Heat Storage Capacity of the Housing not less than 953 KHU	
	Housing Dissipation not less than 16 KHU/min	
	Inherent filtration should be at least 3 mm Al eq	
4.3	Collimator	
	Operator controlled automatic collimation	
4.4	C-Arm	
	· Focus - I.I. Distance shall be at least 100 cm	
	· Depth shall be ~ 79cm	
	· Horizontal travel at least 200mm	
	· Vertical travel at least 450 mm	
	· Orbital movement shall be ~125°	
	· Swivel range shall be ~12°	
	· wig - wag Rotation about -10°	
	· Rotation about horizontal axis shall be more than +/-180°	
4.5	Image Intensifier	
	· At least 9 inch input screen with direct coupling with camera	
	· Shall be at least 52 lp/ cm	
	· Noise reduction, scattered light trap for high contrast dynamics	
	· CCD camera technology with ABC and AGC control	
4.6	TV Monitor	

No.	Item Specifications	Fill your Specification
	· 2 units LCD monitor side by side for live and reference image	
	· Shall be at least 17 inch with automatic brightness control	
4.7	Image rotation	
	· Shall be at least 625 scanning lines at 50 Hz	
	· Trolley for 2 display screens and with the alphanumeric keyboard included	
	· High resolution and anti glare	
4.8	Imaging Modes	
	· Fluoroscopy mode shall have the following facilities:	
	· Last image hold with at least two frames image memory	
	· Fluoroscopy with image acquisition rate: about 20 frame/second.	
	· Hard disk with image storage capacity of at least 30000 images	
	· RAM Memory of 256 images	
	· Mosaic display of 16 images	
	· Zoom (x 2)	
	· Measures: at least distances,angles	
	· Come with CD/DVD/RW drive	
4.9	Video printer for B/W thermal printing on paper, size 20 x 25 cm, resolutions about 300 dpi; The video printer can be placed on the monitor trolley	
4.1	Indicate here other features and software functions included in this offer	
5	System Configuration Accessories, spares and consumables	
5.1	Video printer for B/W thermal printing 01 no.	
5.2	Sterilizable textile cover and clips, for the X-ray tube and the Cassette holder for 24 x 30 cm	
5.3	All standard accessories/consumables/parts required for the proper operation of the above item shall be included in the offer.	
6	Operating Environment	
6.1	The product offered shall be designed to be stored and to operate normally under Power Supply, Climate, Temperature, Humidity, etc. for Sudan.	
6.2	Should work on 220-240V/ 50 Hz AC Single phase fitted with appropriate plugs and sockets.	
7	Standards and Safety Requirements	
	The unit offered shall be certified to meeting the relevant requirements of TUV, CE mark (MDD), FDA and/ or any equivalent quality and safety standards.	
	Certificates showing the compliance of this unit offered with any relevant quality and safety standards MUST be submitted with this TSF.	
8	User Training	
8.1	On site operational training till the familiarity of the system and satisfaction of end user shall be provided.	
9	Warranty	

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9.1	Comprehensive warranty for 2 years.	
9.2	The supplier should perform field change order free of charge if it is of safety concern and provide the FCO kits at cost FCO for improving functionality and performance.	
	10 Maintenance Service During Warranty Period	
10.1	Preventive & Corrective Maintenance:	
	During the warranty period supplier must ensure planned preventive maintenance (PPM) at least 3 nos. in a year along with corrective/breakdown maintenance whenever required.	
	11 Installation, Inspections and Commissioning	
11.1	Supplier must accomplish proper installation and commissioning of the equipment on site.	
11.2	Inspections to verify the compliance of the offered equipment as per the specifications	
	12 Documentation	
12.1	Performance Specifications	
12.2	Installation Document including data to calculate shielding	
12.3	physics acceptance test	
12.4	User (Operating) manual in English	
12.5	Service (Technical / Maintenance) manual in English	
12.6	List of important spare parts and accessories with their part numbers and costing.	
12.7	Certificate of calibration and inspection from factory.	
12.8	Log book with instruction for daily, weekly, monthly and quarterly maintenance checklist.	
14	Manufacturing Date must be less than 6 months before delivery	