

## Endoscopy

### GIT Endoscopy System (Upper and Lower)

| No.      | Item Specifications                                                                                                                            |
|----------|------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1</b> | <b>Technical Specifications</b>                                                                                                                |
|          | Standard specifications                                                                                                                        |
| <b>2</b> | <b>Operating Environment</b>                                                                                                                   |
| 2.1      | The product offered shall be designed to be stored and to operate normally under Power Supply, Climate, Temperature, Humidity, etc. for Sudan. |
| <b>3</b> | <b>Standards and Safety Requirements</b>                                                                                                       |
| 3.1      | <b>Must submit ISO13485:2003/AC:2007 for Medical Devices AND</b>                                                                               |
| 3.2      | <b>CE (93/42 EEC Directives) or USFDA or TUV approved product certificate.</b>                                                                 |
| <b>4</b> | <b>Warranty</b>                                                                                                                                |
| 4.1      | <b>Comprehensive warranty for 2 years after acceptance.</b>                                                                                    |

### Bronchoscope

| No.      | Item Specifications                                                                                                                         |
|----------|---------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1</b> | <b>Description of Function</b>                                                                                                              |
| 1.1      | The flexible fiberoptic bronchoscope is used for diagnostic and therapeutic procedures in critically ill patients for difficult intubation. |
| <b>2</b> | <b>Operational Requirements</b>                                                                                                             |
| 2.1      | The flexible Fiberoptic Bronchoscope should be supplied complete with light source and trolley.                                             |
| 2.2      | Demonstration of the system is a must                                                                                                       |
| <b>3</b> | <b>Technical Specifications</b>                                                                                                             |
| 3.1      | Light weight, high resolution bronchoscope with light cable                                                                                 |
| 3.2      | Field of view 120 degrees or more                                                                                                           |
| 3.3      | Depth of field 3mm to 50 mm or better.                                                                                                      |
| 3.4      | Distal end dia 5 mm approx. (Should allow 6.5mm endotracheal tube to be mounted easily)                                                     |
| 3.5      | Bending range UP 180 degree or DOWN 130 degree.                                                                                             |
| 3.6      | Working length 600 mm or more.                                                                                                              |
| 3.7      | Total length 900 mm or more.                                                                                                                |
| 3.8      | Channel dia 2.2 mm or more.                                                                                                                 |
| 3.9      | Autoclavable suction valve to avoid risk of cross contamination.                                                                            |
| 3.10     | Telescopic eyepiece for direct compatibility to CCTV system                                                                                 |
| 3.11     | Bending mechanism knob without lock.                                                                                                        |
| 3.12     | Fully immersible in disinfectant solution                                                                                                   |
| <b>4</b> | <b>System Configuration Accessories, spares and consumables</b>                                                                             |
| 4.1      | Flexible Fiberoptic Bronchoscope- 01                                                                                                        |
| 4.2      | Light Source, Halogen -01                                                                                                                   |
| 4.3      | Mobile Plastic Operating cart- 01                                                                                                           |
| 4.4      | Spare Halogen Bulbs- 04                                                                                                                     |
| 4.5      | Reusable and autoclavable biopsy forceps- 2 nos                                                                                             |
| 4.6      | Cleaning/maintenance kit including container for disinfectant solution- 1set                                                                |
| 4.7      | Brush Biopsy (Protected)- 50 pieces.                                                                                                        |
| 4.8      | Foreign body forceps basket type- 2 nos.                                                                                                    |
| <b>5</b> | <b>Environmental factors</b>                                                                                                                |
| 5.1      | The unit shall be capable of operating continuously in ambient temperature of 10 -40deg C and relative humidity of 15-90%                   |
| 5.2      | The unit shall be capable of being stored continuously in ambient temperature of 0 -50deg C and relative humidity of 15-90%                 |
| <b>6</b> | <b>Power Supply</b>                                                                                                                         |
| 6.1      | Power input to be 220-240VAC, 50Hz                                                                                                          |
| 6.2      | Type of Protection Against Electric Shock Class I (3-core cord) to be supplied for the Light Source                                         |
| <b>7</b> | <b>Standards, Safety and Training</b>                                                                                                       |
| 7.1      | Product should be FDA/CE or ISI approved                                                                                                    |
| 7.2      | Manufacturer should be ISO certified for quality standards                                                                                  |
| 7.3      | Electrical safety conforms to standards for electrical safety IEC-60601-1 General Requirements                                              |
| 7.4      | Shall meet IEC-60601-1-2 :2001 (Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility.                        |

|          |                                                                                                                                                                                                     |
|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 7.5      | Degree of Protection Against Electric Shock Type BF -Should incorporate insulated patient attachment for light source.                                                                              |
| 7.6      | Certification to meeting Biocompatibility as per ISO 10993-1, "Biological evaluation of medical devices-Part 1: Guidance on selection of tests"                                                     |
| 7.7      | Certified to meet the current leakage requirement of IEC 60601-2-18 or equivalent standard for Medical Equipment particular requirement for safety of endoscopy equipments.                         |
| 7.8      | Comprehensive warranty for 2 years                                                                                                                                                                  |
| <b>8</b> | <b>Documentation</b>                                                                                                                                                                                |
| 8.1      | User Manual in English                                                                                                                                                                              |
| 8.2      | Maintenance Manual in English                                                                                                                                                                       |
| 8.3      | Certificate of Calibration and inspection from the factory                                                                                                                                          |
| 8.4      | List of important spares and accessories with their part number and costing.                                                                                                                        |
| 8.5      | Log book with instructions for daily, weekly, monthly and quarterly maintenance checklist. The job description of the hospital technician and company service engineer should be clearly spelt out. |
| 8.6      | List of Equipments available for providing calibration and routine maintenance support as per manufacturer documentation in service / technical manual                                              |

### Otoscope

| No.      | Item Specifications                                                                  |
|----------|--------------------------------------------------------------------------------------|
| <b>1</b> | <b>Technical Specifications</b>                                                      |
|          | Otoscope is used to perform examinations of the ear, focusing on the inner ear canal |
| <b>2</b> | <b>Diagnostic Set:</b>                                                               |
| 2.1      | Battery Handle with chargeable batteries                                             |
| 2.2      | Charging holder with the transformer                                                 |
| 2.3      | Otoscope head with halogen bulb                                                      |
| 2.4      | One each reusable ear speculum sizes: 2, 3, 4 and 5mm                                |
| 2.5      | Two magnifying enables you to see small details of tubes, eardrum and hearing aids   |

### Surgical Endoscopy (Labroscopy)

| No.      | Item Specifications                                                                                                                       |
|----------|-------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1</b> | <b>Description of Function</b>                                                                                                            |
|          | The system should have following features:                                                                                                |
|          | It should be a Three Chip high definition camera with digital video of 1920x1080 resolution camera head and console                       |
|          | The system should have Digital /Optical Zoom to enhance the quality of Image size regardless of the telescope used.                       |
|          | Button controls on camera Head to control vital functions of camera, like White Balance, Brightness etc.                                  |
|          | Video Outputs: DVI, S-Video and C- Video. Other Video Outputs like RGB, HDSDI etc                                                         |
|          | The Camera should preferably have Signal to Noise ratio range of 60-70dB.                                                                 |
|          | The Camera Head should have a focusing coupler for even focus control.                                                                    |
|          | Should offer both NTSC and PAL Video Formats.                                                                                             |
|          | The Unit should be compatible for recording of stills and videos and should have compatibility with recording options from other vendors. |
|          | The system should be Menu driven, thus allowing the surgeon to program the camera head functions as per the surgical needs & requirement  |
|          | <b>Technical Specifications:</b>                                                                                                          |
|          | Image System: 1/3" CCD                                                                                                                    |
|          | Pixels 1920 X 1080 pixels per chip                                                                                                        |
|          | AGC: Microprocessor controlled                                                                                                            |
|          | Signal-to-noise ratio 60-70 dB                                                                                                            |
|          | Video outputs: C- Video, S-Video & DVI (Minimum)                                                                                          |
|          | Peripheral Controls: Minimum Two for Image Capture & Printer Usage                                                                        |
|          | High Definition Medical Grade Monitor Qty-1                                                                                               |
|          | <b>The system should have:</b>                                                                                                            |
|          | Hi Definition Medical Colored Monitor 24"-26" Flat Panel Monitor                                                                          |
|          | PAL system compatible.                                                                                                                    |
|          | Composite, S-Video and DVI inputs(Minimum)                                                                                                |
|          | Compact & Lightweight design.                                                                                                             |

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|  | Resolution more than 1100 lines                                                                                                                 |
|  | <b>Xenon Light Source</b>                                                                                                                       |
|  | 300 W Xenon Light Source with 2 lamps, automatic changeover of lamp in case of failure of 1st lamp.                                             |
|  | Xenon bulb or better should emit light at temperature of 5700-6000K                                                                             |
|  | Minimum bulb life of 500 hours.                                                                                                                 |
|  | Light intensity adjustable from console.                                                                                                        |
|  | Multiple make Light cable acceptance on console.                                                                                                |
|  | Display of Bulb hours elapsed on console                                                                                                        |
|  | <b>Fiber Optic Light Cable</b>                                                                                                                  |
|  | Size should be diameter 3.5-5.5mm, length up to 250 cm                                                                                          |
|  | <b>Laparoscopes</b>                                                                                                                             |
|  | Wide Angle Full Screen, Forward-Oblique and lateral scope                                                                                       |
|  | Optimal centre-to-edge resolution for enhanced picture quality                                                                                  |
|  | Angle of view: 0° 30°                                                                                                                           |
|  | Diameter 10mm & 5mm                                                                                                                             |
|  | Length 30-32cm                                                                                                                                  |
|  | Fiber optic light transmission incorporated                                                                                                     |
|  | Standard ocular window for coupling the camera head                                                                                             |
|  | Scratch resistance sapphire quoted tip lens                                                                                                     |
|  | Advanced Rod lens system for optimum brightness, contrast and definition                                                                        |
|  | <b>Digital High Definition Recording System</b>                                                                                                 |
|  | The Full High-Definition Digital Documentation System should be a high-end computer system based on Windows embedded platform (for              |
|  | security purposes) designed specifically for recording, managing, editing and archiving surgical images and video in HD (1920x1080) resolution. |
|  | The captured full high definition images & videos can be accessed from the hard drive for printing or saving onto multiple forms of external    |
|  | media which includes CD/DVD, USB Flash Drive or Hard Disk Drive(HDD)                                                                            |
|  | It should have a touch screen display with atleast 200GB Memory of Hard Disk Drive (HDD)                                                        |
|  | Video Formats compatible MPEG-1,MPEG – 2 and MPEG-4 (Minimum)and Still Image formats like JPEG(.jpg) and BMP(.bmp)                              |
|  | Should offer multiple video signals like S Video, DVI, C-Video in both NTSC and PAL Formats.                                                    |
|  | Video Signals available : DVI, S- Video, C-Video(Minimum)                                                                                       |
|  | Should be compatible to 100-240V 50/60 Hz Power requirements,                                                                                   |
|  | Part B: Insufflator & Hand Instruments Set for Laparoscopic Surgery                                                                             |
|  | <b>High Flow Insufflator</b>                                                                                                                    |
|  | High flow of 30 liters or more with LCD display                                                                                                 |
|  | Microprocessor controlled & Software driven for upgradeability                                                                                  |
|  | Soft approach pressure control for safe recovery of abdominal pressure                                                                          |
|  | Should have visual and audible alarms with min 0.1 L flow rate                                                                                  |
|  | Internal leakage detection capability                                                                                                           |
|  | Integrated Gas heating                                                                                                                          |
|  | Having internal venting system for safety                                                                                                       |
|  | Unit should include heated tubing, hose & yoke                                                                                                  |
|  | <b>Laparoscope Trolley</b>                                                                                                                      |
|  | <b>Environmental factors</b>                                                                                                                    |
|  | The unit shall be capable of operating continuously in ambient temperature of 10 -40deg C and relative humidity of 15-90%                       |
|  | The unit shall be capable of being stored continuously in ambient temperature of 0 -50deg C and relative humidity of 15-90%                     |
|  | <b>Power Supply</b>                                                                                                                             |
|  | Power input to be 220-240VAC, 50Hz                                                                                                              |
|  | Type of Protection Against Electric Shock Class I (3-core cord)to be supplied for the Light Source                                              |
|  | <b>Standards, Safety and Training</b>                                                                                                           |
|  | Product should be FDA/CE or ISI approved                                                                                                        |
|  | Manufacturer should be ISO certified for quality standards                                                                                      |
|  | Electrical safety conforms to standards for electrical safety IEC-60601-1 General Requirements                                                  |
|  | Shall meet IEC-60601-1-2 :2001(Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility.                             |
|  | Degree of Protection Against Electric Shock Type BF -Should incorporate insulated patient attachment for light source.                          |

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|  | Certification to meeting Biocompatibility as per ISO 10993-1, “Biological evaluation of medical devices-Part 1: Guidance on selection of tests”                             |
|  | Certified to meet the current leakage requirement of IEC 60601-2-18 or equivalent standard for Medical Equipment particular requirement for safety of endoscopy equipments. |
|  | Comprehensive warranty for 2 years                                                                                                                                          |
|  | <b>Documentation</b>                                                                                                                                                        |
|  | User Manual in English                                                                                                                                                      |
|  | Maintenance Manual in English                                                                                                                                               |
|  | Certificate of Calibration and inspection from the factory                                                                                                                  |
|  | List of important spares and accessories with their part number and costing.                                                                                                |
|  | Log book with instructions for daily, weekly, monthly and quarterly maintenance checklist.                                                                                  |
|  | The job description of the hospital technician and company service engineer should be clearly spelt out.                                                                    |
|  | List of Equipments available for providing calibration and routine maintenance support as per manufacturer documentation in service / technical manual                      |
|  | <b>Laparoscopic Instrumentation</b>                                                                                                                                         |
|  | <b>Trocars Cannula &amp; Veresse Needle</b>                                                                                                                                 |
|  | 120mm Veress Pneumoperitonium Needle with spring loaded blunt stylet                                                                                                        |
|  | Metal Trocars & Cannulae with Sealing Caps & Insufflation Cock, Length 10-11 cm with ribbed/threaded outersurface for self retention on abdominal wall                      |
|  | Trocar, Pyramid Tip, 11 mm 11 mm Cannula Sleeve with Automatic Valve, Stop Cock                                                                                             |
|  | Metal Trocars & Cannulae with Sealing Caps & Insufflation Cock, Length 10-11 cm with ribbed/threaded outersurface for self retention on abdominal wall                      |
|  | Trocar, Pyramid Tip, 5.5 mm                                                                                                                                                 |
|  | 5.5 mm Cannula Sleeve with Automatic Valve, Stop Cock                                                                                                                       |
|  | Reducer 11mm-5.5mm                                                                                                                                                          |
|  | <b>5mm Hand Instruments and Handles</b>                                                                                                                                     |
|  | (For ease of usage and post surgical cleaning & Sterilization the Hand instruments should be provided with separate inserts and appropriate handles)                        |
|  | <input type="checkbox"/> Monopolar Autoclavable Multifunction Handle, 3 cm Inner Shaft Flush Port, 360° Rotation & Shaft Rotation Lock with Monopolar                       |
|  | Handle Ratcheted, facility for connection with monopolar electrosurgery, insulated, Easy to use Ergonomic Design & Easy to clean Shaft.                                     |
|  | <input type="checkbox"/> 5mm, Fundus Grasping Forceps 33 cm, Insert                                                                                                         |
|  | <input type="checkbox"/> Monopolar Autoclavable Multifunction Handle, 3 cm Inner Shaft Flush Port, 360° Rotation & Shaft Rotation Lock with Monopolar                       |
|  | Handle Ratcheted, facility for connection with monopolar electrosurgery, insulated, Easy to use locking                                                                     |
|  | <input type="checkbox"/> 5mm, Atraumatic Grasper 33 cm, Insert                                                                                                              |
|  | <input type="checkbox"/> Monopolar Autoclavable Multifunction Handle, 3 cm Inner Shaft Flush Port, 360° Rotation & Shaft Rotation Lock with Monopolar                       |
|  | Handle Non Ratcheted, facility for connection with monopolar electrosurgery, insulated, Easy to use locking                                                                 |
|  | <input type="checkbox"/> 5mm, Maryland Dissector 33 cm, Insert                                                                                                              |
|  | <input type="checkbox"/> Monopolar Autoclavable Multifunction Handle, 3 cm Inner Shaft Flush Port, 360° Rotation & Shaft Rotation Lock with Monopolar                       |
|  | Handle Non Ratcheted, facility for connection with monopolar electrosurgery, insulated, Easy to use locking Easy to use locking                                             |
|  | <input type="checkbox"/> 5mm, Metzenbaum Scissors, Single Action Jaws 33 cm, curved tip, Insert                                                                             |
|  | <input type="checkbox"/> Reusable Monopolar Cable                                                                                                                           |
|  | <input type="checkbox"/> Dissecting cannula, L - Shaped Electrode 5mm, Length 36 cm                                                                                         |
|  | <b>10mm Hand Instruments &amp; Handle(s)</b>                                                                                                                                |
|  | (For ease of usage and post surgical cleaning & Sterilization the Hand instruments should be provided with separate inserts and appropriate handles)                        |
|  | <input type="checkbox"/> Clip Applicator for use with Titanium Clips (Medium Large), Rotating shaft                                                                         |

|  |                                                                                                                                                       |
|--|-------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <input type="checkbox"/> Monopolar Autoclavable Multifunction Handle, 3 cm Inner Shaft Flush Port, 360° Rotation & Shaft Rotation Lock with Monopolar |
|  | Handle Ratcheted, facility for connection with monopolar electrosurgery, insulated, Easy to use Ergonomic Design & Easy to clean Shaft. Locking       |
|  | <input type="checkbox"/> 10mm, Gall Bladder Extractor, 33 cm, Insert                                                                                  |
|  | <b>Miscellaneous</b>                                                                                                                                  |
|  | Laparoscopic suction irrigation machine or pelvis cleaner system –Laparo –pump & holder for irrigation stand reusable tube set,                       |
|  | power supply cable, Hygiene filter for aspiration, aspiration container, 3L autoclable pack & mounting for securing                                   |
|  | aspiration container to irrigator stand & suction irrigation tube set.                                                                                |
|  | Electro-surgical unit with accessories:                                                                                                               |
|  | It should have high frequency surgical unit more than adequate for all surgical procedures, can set a lower limit. Power –pack system                 |
|  | gives intelligent cutting and coagulation support for initial incisions for all situations. Bi –polar coagulation has to be included in the above     |
|  | unit. Sophisticated self –check program: Minimum power consumption and patient’s safety in top quality must be present. Cut control for               |
|  | consistent regulation of cutting quality & soft coagulation with no carbonization to reduced adhesive effect. Neutral electrode safety system.        |
|  | Auto start and auto coagulation during bipolar coagulation. Digital error code displays electronic memory.                                            |
|  | <input type="checkbox"/> Needle Holder with detachable Handle (Straight/ Curved)                                                                      |
|  | <input type="checkbox"/> 5mm Bipolar Forceps with Ring Handle includes Shaft, Insert, Handle & Sealing Cap                                            |
|  | <input type="checkbox"/> Reusable Bipolar Cable                                                                                                       |
|  | <input type="checkbox"/> 5.5.mm Aspiration Needle 17 G.                                                                                               |
|  | Suitable UPS for the complete system for 60 minutes backup.                                                                                           |
|  | Item must have CE & US FDA certificate                                                                                                                |

### Calposcopy

| No.      | Item Specifications                                                                                          |
|----------|--------------------------------------------------------------------------------------------------------------|
| <b>1</b> | <b>Description of Function</b>                                                                               |
|          | Video Colposcope with standard accessories with Latest Super HAD CCD                                         |
|          | 1/6 Microlens CCD                                                                                            |
|          | Imaging System from Original                                                                                 |
|          | Resolution> 850 CCD Lines                                                                                    |
|          | Digital Matrix Processor Technology                                                                          |
|          | Effective 16.2 Mega Pixels                                                                                   |
|          | Three modes of Electronic Green Filter                                                                       |
|          | Automatic Screening Diagnosis & Reporting                                                                    |
|          | Zooming 1-52x                                                                                                |
|          | E-Flip and Mirror Image                                                                                      |
|          | Automatic Focus and Manual Focus                                                                             |
|          | Corner to Corner Uniform Brightness                                                                          |
|          | Fast advanced fully Automatic Focusing                                                                       |
|          | Real Time Display of Magnification & Timer for acetic acid and iodine test.                                  |
|          | Ultra Bright White LED Cold Light                                                                            |
|          | Recommended Lamp Life 25000 Hours                                                                            |
|          | Minimum Illumination 0.2 Lux White BORZE Multi-function Image processing software with Imported Footswitch & |
|          | Imported Capture Card for Desktop PC.                                                                        |
|          | Integrated Management of View                                                                                |
|          | Examination, Image capture & Freeze,                                                                         |
|          | Recording, Observation, Processing, Saving and Printout.                                                     |
|          | More than 500 inbuilt Reference Pictures                                                                     |
|          | Can be integrated to LAN and HIS.                                                                            |
|          | Side by side Powerful Comparison of                                                                          |
|          | Colposcopic images.                                                                                          |
|          | Statistic Analysis function                                                                                  |
|          | Multi Format Report Facility                                                                                 |

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|--|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | Colposcopy RIED Evaluation                                                                                                                                                  |
|  | <b>Environmental factors</b>                                                                                                                                                |
|  | The unit shall be capable of operating continuously in ambient temperature of 10 -40deg C and relative humidity of 15-90%                                                   |
|  | The unit shall be capable of being stored continuously in ambient temperature of 0 -50deg C and relative humidity of 15-90%                                                 |
|  | <b>Power Supply</b>                                                                                                                                                         |
|  | Power input to be 220-240VAC, 50Hz                                                                                                                                          |
|  | Type of Protection Against Electric Shock Class I (3-core cord)to be supplied for the Light Source                                                                          |
|  | <b>Standards, Safety and Training</b>                                                                                                                                       |
|  | Product should be FDA/CE or ISI approved                                                                                                                                    |
|  | Manufacturer should be ISO certified for quality standards                                                                                                                  |
|  | Electrical safety conforms to standards for electrical safety IEC-60601-1 General Requirements                                                                              |
|  | Shall meet IEC-60601-1-2 :2001(Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility.                                                         |
|  | Degree of Protection Against Electric Shock Type BF -Should incorporate insulated patient attachment for light source.                                                      |
|  | Certification to meeting Biocompatibility as per ISO 10993-1, "Biological evaluation of medical devices-Part 1: Guidance on selection of tests"                             |
|  | Certified to meet the current leakage requirement of IEC 60601-2-18 or equivalent standard for Medical Equipment particular requirement for safety of endoscopy equipments. |
|  | Comprehensive warranty for 2 years                                                                                                                                          |
|  | <b>Documentation</b>                                                                                                                                                        |
|  | User Manual in English                                                                                                                                                      |
|  | Maintenance Manual in English                                                                                                                                               |
|  | Certificate of Calibration and inspection from the factory                                                                                                                  |
|  | List of important spares and accessories with their part number and costing.                                                                                                |
|  | Log book with instructions for daily, weekly, monthly and quarterly maintenance checklist.                                                                                  |
|  | The job descriptin of the hospital technician and company service engineer should be clearly spelt out.                                                                     |
|  | List of Equipments available for providing calibration and routine maintenance support as per manufacturer                                                                  |
|  | documentation in service / technical manual                                                                                                                                 |

### **Gastro, Duodeno and Colonoscopy**

| No.        | Item Specifications                                                                                                                                                                                                                                                                                                                                                                                   |
|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1</b>   | <b>Description of Function</b>                                                                                                                                                                                                                                                                                                                                                                        |
| 1.1        | Combined gastroscopy (Gastro, Duodeno and Colonoscopy) is an examination of oesophagus (gullet), stomach and the first part of your small bowel called the duodenum.                                                                                                                                                                                                                                  |
|            | The second procedure is called a colonoscopy. This is an examination of large bowel (colon).                                                                                                                                                                                                                                                                                                          |
| 1.2        | The instrument used for this is called Gastro, Duodeno and Colonoscopy.                                                                                                                                                                                                                                                                                                                               |
| <b>2</b>   | <b>Operational Requirements</b>                                                                                                                                                                                                                                                                                                                                                                       |
| 2.1        | The video endoscopy system, including camera system, all video endoscopes and all other peripheral equipment offered must be of the same BRAND and same MANUFACTURER. All video endoscopes offered in this TSF must also be able to share one common camera system in order to promote sharing of such camera system and hence increase its utilisation. All bidders must comply with this condition. |
| <b>3</b>   | <b>System Configuration</b>                                                                                                                                                                                                                                                                                                                                                                           |
| 3.1        | Video Gastro, Duodeno, Colonoscope with Camera system, LED light source and with complete accessories.                                                                                                                                                                                                                                                                                                |
| <b>4</b>   | <b>Technical Specifications</b>                                                                                                                                                                                                                                                                                                                                                                       |
| <b>4.1</b> | <b>Video Gastroscope:</b>                                                                                                                                                                                                                                                                                                                                                                             |
|            | <input type="checkbox"/> Field of View : 130 - 140 deg.                                                                                                                                                                                                                                                                                                                                               |
|            | <input type="checkbox"/> Observation Range: 5 - 100mm                                                                                                                                                                                                                                                                                                                                                 |
|            | <input type="checkbox"/> Distal end diameter of not more than 10.5 mm                                                                                                                                                                                                                                                                                                                                 |
|            | <input type="checkbox"/> Direction of view must be zero degree.                                                                                                                                                                                                                                                                                                                                       |
|            | <input type="checkbox"/> Insertion tube diameter of less than 10 mm.                                                                                                                                                                                                                                                                                                                                  |
|            | <input type="checkbox"/> Angulations of tip up at least 200 degrees and down 90 degrees with right and left movement of at least 100/100 degrees.                                                                                                                                                                                                                                                     |
|            | <input type="checkbox"/> Inner diameter of instrument channel more than 2.5mm                                                                                                                                                                                                                                                                                                                         |

|             |                                                                                                                                                                                                                                                                                                                                                                    |
|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             | <input type="checkbox"/> Working length not less than of 1000mm                                                                                                                                                                                                                                                                                                    |
|             | <input type="checkbox"/> Total length not less than of 1300mm                                                                                                                                                                                                                                                                                                      |
|             | <input type="checkbox"/> Must be compatible with the video system specified                                                                                                                                                                                                                                                                                        |
| <b>4.2</b>  | <b>Video Colonoscope:</b>                                                                                                                                                                                                                                                                                                                                          |
|             | <input type="checkbox"/> Field of View : 130 - 140 deg.                                                                                                                                                                                                                                                                                                            |
|             | <input type="checkbox"/> Observation Range: 5 - 100mm                                                                                                                                                                                                                                                                                                              |
|             | <input type="checkbox"/> Distal end diameter of not more than 13 mm                                                                                                                                                                                                                                                                                                |
|             | <input type="checkbox"/> Direction of view must be zero degree.                                                                                                                                                                                                                                                                                                    |
|             | <input type="checkbox"/> Insertion tube diameter of less than 12 mm.                                                                                                                                                                                                                                                                                               |
|             | <input type="checkbox"/> Angulations of tip up at least 180 degrees and down 180 degrees with right and left movement of at least 160/160 degrees.                                                                                                                                                                                                                 |
|             | <input type="checkbox"/> Inner diameter of instrument channel minimum 3.5mm                                                                                                                                                                                                                                                                                        |
|             | <input type="checkbox"/> Working Length: 1650 - 1700mm                                                                                                                                                                                                                                                                                                             |
|             | <input type="checkbox"/> Total length: 1950 - 2000mm                                                                                                                                                                                                                                                                                                               |
|             | <input type="checkbox"/> Must be compatible with the video system specified                                                                                                                                                                                                                                                                                        |
| <b>4.3</b>  | <b>Video Duodenoscope:</b>                                                                                                                                                                                                                                                                                                                                         |
|             | <input type="checkbox"/> Field of vision more than 100 deg.                                                                                                                                                                                                                                                                                                        |
|             | <input type="checkbox"/> Direction of view 5deg backward / oblique.                                                                                                                                                                                                                                                                                                |
|             | <input type="checkbox"/> Depth of view app 5-50 mm                                                                                                                                                                                                                                                                                                                 |
|             | <input type="checkbox"/> Distal end outer diameter not exceeding 13 mm                                                                                                                                                                                                                                                                                             |
|             | <input type="checkbox"/> Insertion tube outer diameter : 11 mm                                                                                                                                                                                                                                                                                                     |
|             | <input type="checkbox"/> Bending angulation must be at least up 120 deg., down 90 deg., Right 110 deg. Left 90 deg.                                                                                                                                                                                                                                                |
|             | <input type="checkbox"/> Instrumental channel not less than 4 mm                                                                                                                                                                                                                                                                                                   |
|             | <input type="checkbox"/> Working length not below 1200 mm                                                                                                                                                                                                                                                                                                          |
|             | <input type="checkbox"/> Total length - 1500 mm                                                                                                                                                                                                                                                                                                                    |
|             | <input type="checkbox"/> Compatible with video system specified.                                                                                                                                                                                                                                                                                                   |
| <b>4.4</b>  | <b>Video processor with light source &amp; Monitor</b>                                                                                                                                                                                                                                                                                                             |
| <b>4.5</b>  | Digital Single-Chip Medical-Video-Camera – colour system PAL, NTSC with integrated Image Processing Module.                                                                                                                                                                                                                                                        |
| <b>4.6</b>  | The video processor offered shall be compatible with all type of video scopes, such as video gastroscope, video colonoscope, video duodenoscope, paediatric scope, double channel scopes, therapeutic scopes and double balloon enteroscope for small bowel intervention. It shall be compatible with all type of flexible endoscopes by using a suitable adapter. |
| <b>4.7</b>  | Fully compatible to the colour systems PAL & NTSC.                                                                                                                                                                                                                                                                                                                 |
| <b>4.8</b>  | Controls for colour adjustment, to enhancement and balance settings.                                                                                                                                                                                                                                                                                               |
| <b>4.9</b>  | Controls to freeze images enhance a portion of frozen image (zoom & post-processing).                                                                                                                                                                                                                                                                              |
| <b>4.1</b>  | Patient and physician data input key board.                                                                                                                                                                                                                                                                                                                        |
| <b>4.11</b> | Must have Automatic Gain Control (AGC) illumination adjustment function.                                                                                                                                                                                                                                                                                           |
| <b>4.12</b> | Multiple settings allow the user to select the preferred level of image enhancement.                                                                                                                                                                                                                                                                               |
| <b>4.13</b> | <b>Light Source &amp; Fiberoptic Cable:</b>                                                                                                                                                                                                                                                                                                                        |
|             | <input type="checkbox"/> LED light source.                                                                                                                                                                                                                                                                                                                         |
|             | <input type="checkbox"/> Lamp life more than 50000 hrs.                                                                                                                                                                                                                                                                                                            |
|             | <input type="checkbox"/> Light intensity comparable to 300W Xenon                                                                                                                                                                                                                                                                                                  |
|             | <input type="checkbox"/> Colour temperature 6000 degree Kelvin                                                                                                                                                                                                                                                                                                     |
|             | <input type="checkbox"/> The intensity of light shall be continuously adjustable. The adjustment shall be in both Manual and AUTO mode.                                                                                                                                                                                                                            |
|             | <input type="checkbox"/> The light source shall have air pump must have selectable pressure settings.                                                                                                                                                                                                                                                              |
| <b>4.14</b> | <b>Monitors:</b>                                                                                                                                                                                                                                                                                                                                                   |
|             | <input type="checkbox"/> Digital Flat screen high resolution 21” colour LCD / TFT monitor.                                                                                                                                                                                                                                                                         |
|             | <input type="checkbox"/> Colour system: PAL/NTSC.                                                                                                                                                                                                                                                                                                                  |
|             | <input type="checkbox"/> Input signal: Analog (RGB analog), Digital (DVI standard 1.0).                                                                                                                                                                                                                                                                            |
| <b>4.15</b> | <b>Suction Unit:</b>                                                                                                                                                                                                                                                                                                                                               |
|             | Suction unit designed for endoscopic and surgical suction with variable suction control, strong suction capability, with a 2 litre autoclavable jars.                                                                                                                                                                                                              |
|             | Bidder shall indicate the suction pressure here.                                                                                                                                                                                                                                                                                                                   |
| <b>4.16</b> | <b>Manual scope disinfectant:</b>                                                                                                                                                                                                                                                                                                                                  |
|             | <input type="checkbox"/> Washer/disinfectant for disinfection of endoscopes, both flexible and video endoscopes.                                                                                                                                                                                                                                                   |
|             | <input type="checkbox"/> The unit shall be mobile on castors.                                                                                                                                                                                                                                                                                                      |
|             | <input type="checkbox"/> Dimensions approx.: 100w x500d x 900mmh                                                                                                                                                                                                                                                                                                   |
|             | <input type="checkbox"/> Weight: ~30kg                                                                                                                                                                                                                                                                                                                             |
|             | <input type="checkbox"/> Tray Capacity: min. 6 L                                                                                                                                                                                                                                                                                                                   |

|      |                                                                                                                                                                                                                                                               |
|------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4.17 | <b>Ultrasonic cleaner for endoscopic accessories:</b>                                                                                                                                                                                                         |
|      | The unit shall be specially designed for cleaning of endoscopic accessories.                                                                                                                                                                                  |
| 4.18 | <b>Endoscopy Trolley:</b>                                                                                                                                                                                                                                     |
|      | <input type="checkbox"/> Must have all different racks for complete mounting of video endoscopy system components.                                                                                                                                            |
|      | <input type="checkbox"/> Must have lockable castor wheels for easy & smooth movement of trolley from one place to another place.                                                                                                                              |
|      | <input type="checkbox"/> Must have hanger in-built for hanging of scopes.                                                                                                                                                                                     |
| 5    | <b>Accessories, Spare Parts and Consumables</b>                                                                                                                                                                                                               |
| 5.1  | <b>Accessories for Video Gastroscope:</b>                                                                                                                                                                                                                     |
|      | <input type="checkbox"/> Biopsy forceps: 2pc (one type each)                                                                                                                                                                                                  |
|      | <input type="checkbox"/> Injection needle for sclerotherapy: 2pc                                                                                                                                                                                              |
|      | <input type="checkbox"/> Dialators: 1                                                                                                                                                                                                                         |
|      | <input type="checkbox"/> Foreign body grasper: 1                                                                                                                                                                                                              |
| 5.2  | <b>Accessories for Video Colonoscope:</b>                                                                                                                                                                                                                     |
|      | <input type="checkbox"/> Biopsy forceps: 2 pc (one type each)                                                                                                                                                                                                 |
|      | <input type="checkbox"/> Polypectomy snares: 2 set                                                                                                                                                                                                            |
|      | <input type="checkbox"/> Bite Block, 1 piece per each scope                                                                                                                                                                                                   |
| 5.3  | <b>Accessories for Video Duodenoscope:</b>                                                                                                                                                                                                                    |
|      | <input type="checkbox"/> Biopsy forceps, 2 pcs (one type each)                                                                                                                                                                                                |
|      | <input type="checkbox"/> Foreign body removal forceps, 1 pc                                                                                                                                                                                                   |
|      | <input type="checkbox"/> Haemostasis injection needle, 1 pc                                                                                                                                                                                                   |
|      | <input type="checkbox"/> Haemostasis loops, 1 pc                                                                                                                                                                                                              |
|      | <input type="checkbox"/> Gastric Balloon Dilatation Device, 1 pc                                                                                                                                                                                              |
|      | <input type="checkbox"/> Papillotomy knife, 1 pc                                                                                                                                                                                                              |
|      | <input type="checkbox"/> Bite Block, 1 piece per each scope                                                                                                                                                                                                   |
| 5.4  | <b>Other Accessories:</b>                                                                                                                                                                                                                                     |
|      | <input type="checkbox"/> CD/DVD Recorder                                                                                                                                                                                                                      |
|      | <input type="checkbox"/> Colour Video Printer                                                                                                                                                                                                                 |
|      | <input type="checkbox"/> 2 boxes of 100 pieces colour video printing paper.                                                                                                                                                                                   |
| 5.5  | All standard accessories/consumables/parts required for the proper operation of the above item shall be included in the offer.                                                                                                                                |
| 5.6  | All standard Maintenance tools and cleaning /lubrication materials where applicable shall be included.                                                                                                                                                        |
| 5.7  | One set of the standard maintenance accessories, for example, cleaning brushes, rubber seal, cleaning cap, cleaning adapter silicone oil EO gas sterilisation venting cap, shall be included for each scope.                                                  |
| 6    | <b>Operating Environment</b>                                                                                                                                                                                                                                  |
| 6.1  | Power supply: 220 – 240 VAC, 50Hz fitted with appropriate plug. The power cable must be at least 3 metres in length.                                                                                                                                          |
| 6.2  | UPS of suitable rating with voltage regulation, spike protection and maintenance free batteries for 30 minutes backup.                                                                                                                                        |
| 7    | <b>Standards &amp; Safety Requirements</b>                                                                                                                                                                                                                    |
| 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 meet IEC 60601-2-18 Medical Electrical Equipment PART 2: Particular Requirements for the Safety of ENDOSCOPIC Equipment.                                                                                                                                |
| 8    | <b>User Training</b>                                                                                                                                                                                                                                          |
| 8.1  | The Supplier shall conduct user training for this equipment to enable operators to use the equipment properly. The training shall include the use of all operational functions of the equipment, as well as routine checks and maintenance expected by users. |
| 9    | <b>Warranty</b>                                                                                                                                                                                                                                               |
| 9.1  | Comprehensive warranty for 2 years from acceptance.                                                                                                                                                                                                           |
| 10   | <b>Maintenance Service During Warranty Period</b>                                                                                                                                                                                                             |
| 10.1 | During the warranty period supplier must ensure planned preventive maintenance (PPM) along with corrective/breakdown maintenance whenever required.                                                                                                           |
| 11   | <b>Documentation</b>                                                                                                                                                                                                                                          |
| 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.                                                                                                                                                                                                       |

### Cupboard Endoscope s Storage

| No. | Item Specifications                                                                                                                                                 |
|-----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1   | The unit shall be capable of storing up to 10 endoscopes on an extendible support frame. To be ventilated with 50- mc/h fan units requiring a 240V 3A fused supply. |

### Washer & Disinfecting machines for Endoscopy

| No. | Item Specifications                                                                                                                            |
|-----|------------------------------------------------------------------------------------------------------------------------------------------------|
| 1   | <b>Technical Specifications</b>                                                                                                                |
|     | Standard specifications                                                                                                                        |
| 2   | <b>Operating Environment</b>                                                                                                                   |
| 2.1 | The product offered shall be designed to be stored and to operate normally under Power Supply, Climate, Temperature, Humidity, etc. for Sudan. |
| 3   | <b>Standards and Safety Requirements</b>                                                                                                       |
| 3.1 | <b>Must submit ISO13485:2003/AC:2007 for Medical Devices AND</b>                                                                               |
| 3.2 | <b>CE (93/42 EEC Directives) or USFDA or TUV approved product certificate.</b>                                                                 |
| 4   | <b>Warranty</b>                                                                                                                                |
| 4.1 | <b>Comprehensive warranty for 2 years after acceptance.</b>                                                                                    |

### Cystoscopy

| No.    | Item Specifications                                                                                                                                                                                                                                                            |
|--------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1      | <b>Description of Function</b>                                                                                                                                                                                                                                                 |
| 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      | <b>Operational Requirements</b>                                                                                                                                                                                                                                                |
| 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      | <b>System Configuration</b>                                                                                                                                                                                                                                                    |
| 3.1    | Laparoscopic Instrument set with Adult Cystoscope and Resectoscope, complete system and with all standard accessories.                                                                                                                                                         |
| 4      | <b>Technical Specifications</b>                                                                                                                                                                                                                                                |
| 4.1    | <b>Telescopes:</b>                                                                                                                                                                                                                                                             |
| 4.1.1  | Straight forward Telescope 0o enlarged view diameter 10mm, length 30cm. autoclaveable: 01 no.                                                                                                                                                                                  |
| 4.1.2  | Telescopes shall have low risk of object bum.                                                                                                                                                                                                                                  |
| 4.1.3  | Shall have colour coded for identification.                                                                                                                                                                                                                                    |
| 4.1.4  | Shall have fibreoptic light transmission incorporated.                                                                                                                                                                                                                         |
| 4.2    | <b>Reusable Hand Instruments:</b>                                                                                                                                                                                                                                              |
| 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.                                                                                                                                                                                                        |
| 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.                                                                                                               |
| <b>4.3</b>  | <b>Cystoscope Telescope: 2 nos.</b>                                                                                                       |
|             | <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.                                                                             |
| <b>4.4</b>  | <b>Cystoscope Sheath: 1 no.</b>                                                                                                           |
|             | <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.                                                                         |
| <b>4.5</b>  | <b>Telescope Bridge: 1 no.</b>                                                                                                            |
|             | Telescope bridge with one instrument channel to fit with the cystoscope.                                                                  |
| <b>4.6</b>  | <b>Flexible Grasping Forcep: 1 no.</b>                                                                                                    |
|             | 7 Fr. grasping forcep shall be provided.                                                                                                  |
| <b>4.7</b>  | <b>Flexible Biopsy Forcep: 1 no.</b>                                                                                                      |
|             | 7 Fr. Biopsy forcep shall be provided.                                                                                                    |
| <b>4.8</b>  | <b>Rigid Biopsy and Grasping Forcep: 1 no.</b>                                                                                            |
|             | Optical Rigid Biopsy forcep compatible with 20 Fr. Cystoscope sheath shall be provided.                                                   |
| <b>4.9</b>  | <b>Toomey syringe 100 CC: 1 no.</b>                                                                                                       |
|             | Toomey syringe of 100 cc with adaptor to fit with the sheath shall be provided.                                                           |
| <b>4.1</b>  | Flexible Scissor: 1 no.                                                                                                                   |
| <b>4.11</b> | <b>ELLIK Evacuator: 1 no.</b>                                                                                                             |
|             | ELLIK Evacuator with spare rubber bulb and adaptor shall be provided.                                                                     |
| <b>4.12</b> | <b>Urethrotome Sheath: 1 no.</b>                                                                                                          |
|             | 21 Fr. optical Urethrotome sheath with one channel shall be provided.                                                                     |
| <b>4.13</b> | <b>Cold Knife: 2 nos.</b>                                                                                                                 |
|             | Straight cold knife shall be provided.                                                                                                    |
| <b>4.14</b> | <b>Resectoscope Sheath: 1 no.</b>                                                                                                         |
|             | <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                                                                |
| <b>4.15</b> | <b>Working Element Set: 1 no.</b>                                                                                                         |
|             | Working element set passive type with standard accessories like, Kollins knife, HF cord, protection tube, cutting loop shall be provided. |
| <b>4.16</b> | Cutting loop 24 Fr.: 12 nos.                                                                                                              |
| <b>4.17</b> | <b>Formalin Chamber: 1 No.</b>                                                                                                            |
|             | Formalin chamber made of Virgin Acrylic 6mm thickness of appropriate size preferably with three trays for sterilizing the laparoscope.    |
| <b>4.18</b> | <b>Sterilization/Cidex Tray: 2 Nos.</b>                                                                                                   |
|             | Sterilization/Cidex tray with cover for storage of telescopes, hand instruments and other accessories of suitable sizes.                  |
| <b>4.19</b> | <b>Single Chip Camera System: 1 No.</b>                                                                                                   |
| 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.                                                                                                              |

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| <b>4.2</b>  | <b>High Resolution Video Monitor: 1 No.</b>                                                                                                                                                         |
| 4.20.1      | Shall have colour system PAL/ NTSC.                                                                                                                                                                 |
| 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      | Max horizontal screen resolution in lines > 1000 lines.                                                                                                                                             |
| 4.20.5      | Monitor menu displays all controls, capabilities and operations via curser 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.                                                                                                                       |
| <b>4.21</b> | <b>Xenon Light Source and Light Cable: 1 unit</b>                                                                                                                                                   |
| 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.                                       |
| <b>4.22</b> | <b>Electronic CO2 Insufflator: 1 unit</b>                                                                                                                                                           |
| 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.                                                                              |
| 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     | <b>CO2 Cylinder:</b>                                                                                                                                                                                |
|             | Shall provide one large size cylinders with required regulators and connecting pipe to the insufflator with pressure gauge.                                                                         |
| <b>4.23</b> | <b>Suction and Irrigation: 1 unit</b>                                                                                                                                                               |
| 4.23.1      | <b>The suction and irrigation unit shall be a combined unit for performing laparoscopy surgeries.</b>                                                                                               |
| 4.23.2      | <b>Irrigation pressure control between 0-400 mm Hg.</b>                                                                                                                                             |
| 4.23.3      | <b>Suction pressure control between 0.75 bar.</b>                                                                                                                                                   |
| 4.23.4      | <b>Main unit with digital display.</b>                                                                                                                                                              |
| 4.23.5      | <b>Overflow protection on suction bottles.</b>                                                                                                                                                      |
| 4.23.6      | <b>Control from control panel and/or foot pedal.</b>                                                                                                                                                |
| 4.23.7      | <b>Shall come with:</b>                                                                                                                                                                             |
|             | <b>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.</b> |

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| 4.24    | <b>Electrosurgical Generator (Monopolar, Bipolar &amp; in saline mode) :</b>                                                                                                                                  |
| 4.24.1  | <b>High frequency microprocessor/microcontroller based digitally controlled device.</b>                                                                                                                       |
| 4.24.2  | <b>Shall have approx. 6.5” or more touch screen for convenient use. There shall be no extra button for confusing.</b>                                                                                         |
| 4.24.3  | <b>Shall be suitable for Open, Laparoscopic, Endoscopic, Urology &amp; Gynaecology procedures.</b>                                                                                                            |
| 4.24.4  | <b>Full range of monopolar &amp; bipolar modes for general surgery.</b>                                                                                                                                       |
| 4.24.5  | <b>EFFECTS’ mode to fine tune energy delivery to make even finer adjustments for precise tissue management.</b>                                                                                               |
| 4.24.6  | <b>Tissue-adaptive power output for controlled, precise and fast cutting.</b>                                                                                                                                 |
| 4.24.7  | <b>Quick memory function to set and recall settings easily.</b>                                                                                                                                               |
| 4.24.8  | <b>Automatic smoke evacuation function when combine with insufflators providing a ‘HD’ view of the cavity.</b>                                                                                                |
| 4.24.9  | <b>Universal connector with instrument recognition URO &amp; GYN.</b>                                                                                                                                         |
| 4.24.10 | <b>Saline detection ensuring the right medium is used in resection-in-saline.</b>                                                                                                                             |
| 4.24.11 | <b>Saline modes for improved ignition and vaporization performance.</b>                                                                                                                                       |
| 4.24.12 | <b>Shall have double pedal foot switch.</b>                                                                                                                                                                   |
| 4.24.13 | <b>Automatic activation of coagulation current as soon as coagulation electrode touches tissue with both branches.</b>                                                                                        |
| 4.24.14 | <b>Activation of HF Functions possible via footswitch or manual control switch.</b>                                                                                                                           |
| 4.24.15 | <b>Connecting sockets for unipolar and bipolar application can be selected according to individual requirements.</b>                                                                                          |
| 4.24.16 | <b>Switchover function enables switching between two modes within a user programme via a footswitch from the sterile area.</b>                                                                                |
| 4.24.17 | <b>Readily plug &amp; play most common bipolar &amp; monopolar diathermy instruments with international 4mm single &amp; 3pin instruments, 5mm &amp; 8mm single pins e.g. Bovie connectors/ banana plugs.</b> |
| 4.24.18 | <b>Maximum Bipolar saline coagulation at 150-250 watt, bipolar saline cut-100 watt, bipolar saline –c- cut at 300 watt.</b>                                                                                   |
| 4.24.19 | <b>Unipolar maximum at 200-300 watt where standard coagulation at 200 watt, forced coagulation at 120 watt, spray coagulation at 120 watt.</b>                                                                |
| 4.24.20 | <b>LF / HF leakage current monitor.</b>                                                                                                                                                                       |
| 4.24.21 | <b>Neutral Electrode safety system.</b>                                                                                                                                                                       |
| 5       | <b>Accessories, spares and consumables</b>                                                                                                                                                                    |
| 5.1     | <b>Video Cart: 01 no.</b>                                                                                                                                                                                     |
|         | <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     | <b>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.</b>                   |
| 6       | <b>Operating Environment</b>                                                                                                                                                                                  |
| 6.1     | <b>The product offered shall be designed to be stored and to operate normally under Power Supply, Climate, Temperature, Humidity, etc. for Sudan.</b>                                                         |
| 6.2     | <b>Power supply: 220 – 240 VAC, 50Hz fitted with appropriate plug. The power cable must be at least 3 metre in length.</b>                                                                                    |
| 6.3     | <b>Suitable UPS with maintenance free batteries, voltage regulation and spike protection for minimum 30 min. back-up shall be supplied with the system.</b>                                                   |
| 7       | <b>Standards and Safety Requirements</b>                                                                                                                                                                      |
| 7.1     | <b>Must submit ISO13485:2003/AC:2007 for Medical Devices AND</b>                                                                                                                                              |
| 7.2     | <b>CE (93/42 EEC Directives) or USFDA or TUV approved product certificate.</b>                                                                                                                                |
| 7.3     | <b>Shall be certified to be meeting safety standard IEC 60601-2-18 part 2 Particular requirements for the safety of Endoscopic Equipment.</b>                                                                 |
| 8       | <b>User Training</b>                                                                                                                                                                                          |
| 8.1     | <b>Must provide user training (including how to use and maintain the equipment).</b>                                                                                                                          |
| 9       | <b>Warranty</b>                                                                                                                                                                                               |
| 9.1     | <b>Comprehensive warranty for 2 years after acceptance.</b>                                                                                                                                                   |
| 10      | <b>Maintenance Service During Warranty Period</b>                                                                                                                                                             |

|      |                                                                                                                                   |
|------|-----------------------------------------------------------------------------------------------------------------------------------|
| 10.1 | <b>During warranty period supplier must ensure preventive maintenance and corrective/breakdown maintenance whenever required.</b> |
| 11   | <b>Documentation</b>                                                                                                              |
| 11.1 | <b>User (Operating) manual in English.</b>                                                                                        |
| 11.2 | <b>Service (Technical / Maintenance) manual in English.</b>                                                                       |
| 11.3 | <b>List of important spare parts and accessories with their part numbers and costing.</b>                                         |
| 11.4 | <b>Certificate of calibration and inspection from factory.</b>                                                                    |

#### **Segmodscope**

| No.      | Item Specifications                                                                                                                            |
|----------|------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1</b> | <b>Technical Specifications</b>                                                                                                                |
|          | Standard specifications                                                                                                                        |
| <b>2</b> | <b>Operating Environment</b>                                                                                                                   |
| 2.1      | The product offered shall be designed to be stored and to operate normally under Power Supply, Climate, Temperature, Humidity, etc. for Sudan. |
| <b>3</b> | <b>Standards and Safety Requirements</b>                                                                                                       |
| 3.1      | <b>Must submit ISO13485:2003/AC:2007 for Medical Devices AND</b>                                                                               |
| 3.2      | <b>CE (93/42 EEC Directives) or USFDA or TUV approved product certificate.</b>                                                                 |
| <b>4</b> | <b>Warranty</b>                                                                                                                                |
| 4.1      | <b>Comprehensive warranty for 2 years after acceptance.</b>                                                                                    |

#### **Ureteroscope**

| No.      | Item Specifications                                                                                                                              |
|----------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1</b> | <b>Technical Specifications</b>                                                                                                                  |
|          | Working length of [50-70] cm                                                                                                                     |
|          | Outer diameter of the shaft should be between 7fr & 7.5fr                                                                                        |
|          | It should have an instrument channel between 3fr to 4fr                                                                                          |
|          | Direction of view should be 0 degree                                                                                                             |
|          | Angle of view should be between 80 to 90 degree                                                                                                  |
|          | Maximum angle of deflection up to 270 degree downward and 270 degree upward is needed.                                                           |
|          | It should have a ceramic liner in the distal end of the working channel to protect it from thermal or electrocautery damage                      |
|          | Should be waterproof and fully immersible in solution                                                                                            |
|          | It should adhere to sterilization method with ETO, FO gas, Steris & Sterrad                                                                      |
|          | Following compatible accessories should be supplied with this instrument – Grasping forceps, Biopsy forcep, and case for the instrument,         |
|          | Pressure compensation cap, and leakage tester and cleaning brush.                                                                                |
|          | Nitinol Core wire guide with hydrophilic coating and should have the ability of being straight at one end and angled at other end, length 150 cm |
|          | Ureteral Access sheath with inner diameter 9.5 fr and length of 35 cm and 45 cm, 13 cm                                                           |
|          | Ureteral access sheath with inner diameter fo 12.0 fr and length of 35 cm, 45 cm and 28 cm                                                       |
|          | Tipless stone extractor with length of 115 cm and size of 2.2 fr and 1.5 fr                                                                      |
|          | Nitinol stone extractor with partially closer redesign the basket to provide the tight weave of a 12 or 16 wire basket                           |
|          | Ballon ureteral dilator of 7 fr & 5 fr with catheter length 65 cm, inflated ballon diameter 6 mm & 5 mm, ballon length of 4 cm & 10 cm with      |
|          | Should have ergonomic laser dial with integrated locking mechanism to advance the laser fibre and minimize laser damage                          |

#### **Endoscope, ENT**

| No.      | Item Specifications                                                                                                                           |
|----------|-----------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1</b> | <b>Description of Function</b>                                                                                                                |
| 1.1      | ENT Endoscopes are used for the diagnosis and observation of the otolaryngological area including the vocal cords, nasal cavity, and eardrum. |
| <b>2</b> | <b>Operational Requirements</b>                                                                                                               |
| 2.1      | Straight forward Telescope, Cold Light fountain, Fibre optic light, compatible camera and LCD Monitor.                                        |
| <b>3</b> | <b>System Configuration</b>                                                                                                                   |

|           |                                                                                                                                                                                                                                                                                                     |
|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 3.1       | ENT Endoscope complete unit and with complete accessories.                                                                                                                                                                                                                                          |
| <b>4</b>  | <b>Technical Specifications</b>                                                                                                                                                                                                                                                                     |
| 4.1       | Endoscope:                                                                                                                                                                                                                                                                                          |
|           | <input type="checkbox"/> Straight forward Telescope 0 ° 1.9 mm 10cm length. 1 no.                                                                                                                                                                                                                   |
|           | <input type="checkbox"/> Straight forward Telescope 30 ° 1.9 mm 10cm length. 1 no.                                                                                                                                                                                                                  |
|           | <input type="checkbox"/> Straight forward Telescope 0 ° 4 mm 6 cm length. 1 no.                                                                                                                                                                                                                     |
|           | <input type="checkbox"/> Straight forward Telescope 30 ° 4 mm 6 cm length. 1 no.                                                                                                                                                                                                                    |
|           | <input type="checkbox"/> Pneumatic adapter for Oto- Endoscope.                                                                                                                                                                                                                                      |
|           | <input type="checkbox"/> Shall come with all the attachments.                                                                                                                                                                                                                                       |
| 4.2       | Cold light fountain 150 watt halogen bulb.                                                                                                                                                                                                                                                          |
| 4.3       | Fibreoptic light 2.5 mm diameter and 1.5 meter in length.                                                                                                                                                                                                                                           |
| 4.4       | Compatible camera and LCD monitor of 14" or more for image display.                                                                                                                                                                                                                                 |
| 4.5       | Sialendoscopy:                                                                                                                                                                                                                                                                                      |
|           | <input type="checkbox"/> Miniature straight forward Telescope 0°, semi –rigid, diameter 1mm, length 16cm, with remote eyepiece and light connection, LUER lock adaptor, fibre optic light transmission incorporated, including protective tube.                                                     |
|           | <input type="checkbox"/> Examination Sheath, diameter 1.3 mm. working length 16cm, with blunt obturators, with lateral LUER lock adaptor for irrigation, for use with miniature endoscope.                                                                                                          |
|           | <input type="checkbox"/> Operation Sheath, oval, 1.3 and 1.3 mm. working length 16 cm, with working channel 1.15 mm and telescope channel 1.15 mm, with 2 or 3 obturators, with lateral LUER lock adaptor for irrigation.                                                                           |
|           | <input type="checkbox"/> Grasping forceps double action jaws, flexible, diameter 1mm, working length 19 cm.                                                                                                                                                                                         |
|           | <input type="checkbox"/> Biopsy Forceps double action jaws, flexible, diameter 1mm, working length 19 cm.                                                                                                                                                                                           |
|           | <input type="checkbox"/> Stone Extractor, diameter 0.6 mm. basket with 6 wires, sterile, single use.                                                                                                                                                                                                |
|           | <input type="checkbox"/> Balloon Catheter, diameter 0.7mm, sterile, single use, package of 10.                                                                                                                                                                                                      |
|           | <input type="checkbox"/> Compatible light source.                                                                                                                                                                                                                                                   |
| <b>5</b>  | <b>Accessories, spares and consumables</b>                                                                                                                                                                                                                                                          |
| 5.1       | Accessories:                                                                                                                                                                                                                                                                                        |
|           | <input type="checkbox"/> Endoscopy Coupler                                                                                                                                                                                                                                                          |
|           | <input type="checkbox"/> Endoscopy trolley                                                                                                                                                                                                                                                          |
| 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. Bidders must specify the quantity of every item included in their offer (including items not specified above). |
| <b>6</b>  | <b>Operating Environment</b>                                                                                                                                                                                                                                                                        |
| 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.                                                                                                                                                                                 |
| <b>7</b>  | <b>Standards and Safety Requirements</b>                                                                                                                                                                                                                                                            |
| 7.1       | Must submit ISO13485:2003/AC:2007 for Medical Devices AND                                                                                                                                                                                                                                           |
| 7.2       | CE (93/42 EEC Directives) or USFDA approved product certificate.                                                                                                                                                                                                                                    |
| 7.3       | Shall meet IEC-60601-1-2:2001 General Requirements of Safety for Electromagnetic Compatibility or must comply with 89/366/EEC; EMC directive                                                                                                                                                        |
| 7.4       | Electrical safety conforms to standards for electrical safety IEC 60601-1 General requirement for Electrical safety of Medical Equipment.                                                                                                                                                           |
| <b>8</b>  | <b>User Training</b>                                                                                                                                                                                                                                                                                |
| 8.1       | Must provide user training (including how to use and maintain the equipment).                                                                                                                                                                                                                       |
| <b>9</b>  | <b>Warranty</b>                                                                                                                                                                                                                                                                                     |
| 9.1       | Comprehensive warranty for 2 years from acceptance.                                                                                                                                                                                                                                                 |
| <b>10</b> | <b>Maintenance Service During Warranty Period</b>                                                                                                                                                                                                                                                   |
| 10.1      | During the warranty period supplier must ensure planned preventive maintenance (PPM) corrective/breakdown maintenance whenever required.                                                                                                                                                            |
| <b>11</b> | <b>Installation and Commissioning</b>                                                                                                                                                                                                                                                               |
| 11.1      | The bidder must arrange for the equipment to be installed and commissioned by certified or qualified personnel; any prerequisites for installation to be communicated to the purchaser in advance, in detail.                                                                                       |
| <b>12</b> | <b>Documentation</b>                                                                                                                                                                                                                                                                                |
| 12.1      | User (Operating) manual in English.                                                                                                                                                                                                                                                                 |
| 12.2      | Service (Technical /Maintenance) manual in English.                                                                                                                                                                                                                                                 |
| 12.3      | List of important spare parts and accessories with their part number and costing.                                                                                                                                                                                                                   |
| 12.4      | Certificate of calibration and inspection from factory.                                                                                                                                                                                                                                             |