

## Specification for Video Urodynamic Study System ( Adult & Pediatric)

- 1) Urodynamic system should be able to perform Uroflowmetry, Cystometry, Pressure Flow Studies, UPP, Uroflow with EMG, Wireless EMG Studies, Video Urodynamics with chair, Biofeedback with wireless EMG, Automatic Leak detector module and Anorectal Manometry.
- 2) **Integrated Cart / Trolley** - Should be supplied with original imported shockproof Powder coated integrated travel cart from OEM having integrated water proof Keyboard and touch pad / mouse pad to fit the complete UDS along with DC/PC. Console should be completely inside to protect from water spillage. Trolleys height and angel should be adjustable so that user can perform urodynamic test in sitting and standing position.
- 3) **Computer/All in One PC** - System should be supplied with All in one PC / DC computer running on Windows 10 /11 (latest), i7 processor, 16 GB RAM, 1TB SSD internal memory and 1TB external memory with Color Laser/Inkjet Printer, should have USB port, MS Office, Patient data base management software, CD/DVD writer external, Video Editing software, 1GB Graphic card and speaker for EMG. Should be supplied with Optical mouse and UPS of suitable rating with minimum 30 Min back up.
- 4) Should be supplied with 20-24 inch flat screen Color LED monitor for display. Monitor should have facility of RGB output so that it can be projected on screen in conferences.
- 5) The Urodynamic system should have at least three pressure channels, should be able to display at least 6 channels at a time and should have minimum five configurable ports
- 6) **Filling Pump** - Must have inbuilt software controlled infusion pump with infusion volume rate of 1ml/minute -150 ml/minute or more, with increment of 1ml, 5ml, & 10ml. (Slow fill, medium fill and fast fill modes can be changed during the test depending upon the requirement).
- 7) **Air Pump** - Should have Automatic Air Pump for applications like UPP & ARM.
- 8) **Infusion Sensor** - Should have integrated infusion Sensor / Infusion transducer to Check correct infused volume up to 3000 ml.
- 9) **Calibration & Infusion Volume** - Should have infusion volume up to 3000 ml and Software based calibration control. Should have inbuilt infusion sensor and should measure infusion volume through infusion Sensor / Infusion transducer and not through rotation of pump. Should have weight based infusion transducer.
- 10) **Pressure Kit** - Pressure Transducer should be reusable, color coded with automatic zero facility, pressure range of (-40 to +300cm and above of H2O) of H2O and minimum infusion volume range of 0-3000ml. Pressure transducer should be attached to a bracket mounted on a IV Pole and this should be rotatable 180 degrees to be able to keep either on left or right as per user's choice. Should have test Calibration button and software control calibration. The transducers should be Calibrated through software/ hardware, and have auto zero capability.
- 11) **Uroflowmetry** - Should have facility to attach up to two Uroflow transducers. Should be supplied with One Wired Weight Based Uroflow Transducer and another Wireless (With latest technology only). Should have flow range of 0-50ml per Minute and volume measuring capacity up to 2000ml or higher. Should be supplied with Plastic cover for flow transducer to protect from water spillage. Should be supplied with Graduated Beaker/Collection Jug with capacity of 2 litre or higher.
- 12) **Wireless EMG** - Should be supplied with 1 Channel wireless EMG amplifier two numbers with charger.
  - a. Should be compatible with surface electrodes, needle electrodes.

- b. Should have both Visual and sound EMG.
  - c. Should have facility to adjust Sound, Gain & Threshold.
  - d. Should have frequency upper and lower limit of 3.5KHZ & 2.4KHZ respectively with sensitivity of 500mvolt for full scale.
- 13) **Micturition Stand and Commode Chair**- Should be supplied with Micturition stand with removable funnel and height adjustable micturition chair with detachable arm for micturition studies with removable funnel.
- 14) **Automatic Leak Detector** - Should be supplied with Automatic Leak detector module, which can be attached to meatus of urethra to detect even small drops of urine leakage which do not come into beaker and mark leak automatically in to software. Leak detection should not involve any camera for recording video or clicking pictures for patient privacy.
- 15) **Urodynamic Software** - System should be supplied with latest Urodynamic software and following facility:
  - a. Should have Windows platform, unlimited number of templates
  - b. Should have Standards and terminology as according to the ICS (International Continence society) monograms, PURR, Pediatric, Siroky, Abrams-Griffiths
  - c. Should have Connectivity to Hospital information system and DICOM work-list & DICOM storage
  - d. Should have Event markers-user Colorable toolbars, and event markers (icons and/or text)
  - e. Should have latest Technology for Data recovery even when studies have not been saved & data protection
  - f. Should have Patient data base management software
  - g. Should have Real time data processing and on-line storage
  - h. Should have Back up manually or automatically to any location
  - i. Should have Intelligent patient search
  - j. System should be operational on windows 10 or latest
  - k. Should have 1-18 Points for test setting as per customer choice
  - l. Should have Report in MS Word or in PDF Format
  - m. Should have Post procedure editing in Word format of report
  - n. Should have Running tap water sound
  - o. Should have Playback facility of test after the procedure
- 16) **Nomograms**: Should have latest ICS and Pediatric Nomograms inbuilt in the software
- 17) **Anorectal Manometry** - Should be supplied with 4 Channel Anorectal Manometry Software and hardware for doing Anorectal Manometry.
- 18) **UPP** - Should be supplied with UPP Puller with stand with software and catheter for doing Urethra Pressure profilometry.
- 19) **Video Urodynamics** - Should be supplied with Digital Video Urodynamic Software and Hardware for doing Video Urodynamic Studies. Video urodynamic should simultaneously showing pressure flow and EMG curves parallel to fluoroscopy or X-ray sequence of the video. Should be able to record small videos and pictures and save in different directory. Report should contain Urodynamic traces as well as Video.
- 20) **Biofeedback with Wireless EMG** - Should be supplied with Biofeedback software with wireless EMG having games with wireless EMG for Pelvic floor training. Should be supplied with Anal Probe and Vaginal Probe 1 no. each with Android TV and can be synchronized with UDS machine for patient engagement.
- 21) Should be supplied with following Consumables and Accessories (Adult and Paediatric) (catheters should be from same OEM):-
  - a. EMG Patch/Surface Electrodes - 50 Nos.
  - b. Dual Lumen Catheter for Cystometry 7-8 Fr. - 50 Nos.

- c. Dual Lumen Catheter for Cystometry 5-6 Fr. - 50 Nos.
  - d. Pigtail Catheter 5Fr. - 10 Nos.
  - e. Pigtail Catheter 6Fr. - 10 Nos
  - f. Rectal Balloon Catheter for Cystometry 10-12 Fr. - 50 Nos.
  - g. Channel Anorectal Manometry Catheter with balloon- 10 Nos.
  - h. Pump Tubing - 50 Nos.
  - i. Collection Jug/Beaker with protective cover - 5 Nos.
  - j. Measurement/ Connection Tubing - 50 Nos.
  - k. Disposable Dome for Pressure Transducer - 50 nos.
  - l. Plastic Cover for Uroflow Transducer - 25 Nos.
  - m. 500gm calibration weight for uroflow - 1 No.
  - n. Ultrasound Gel - 10 bottles
  - o. Thermal Printer Paper Roll - 10 nos.
  - p. Triple Lumen Catheter for UPP - 10 Nos.
  - q. Urethra Perfusion Line - 5 nos.
  - r. Air/perfusion cuff for UPP - 1 no.
- 22) **Certificate** - Urodynamic System should have BIS / US FDA /European CE with 4 digit notified body number or approved for the quoted model.
- 23) **CDSCO Registration** - For imported Video Urodynamic machine, Manufacturer should have CDSCO Registration in India and Bidder should submit MD-15 Form for quoted model of Urodynamic System.
- 24) **Bladder Scanner** - Should be supplied with Bladder Scanner with Probe/ PVR measuring device for calculation of Post Void Residual to complete urodynamic studies.
- 25) Should be supplied with Radiolucent Motorized Chair for doing Video Urodynamic Studies with following specifications:-
- a. Radiolucent motorised chair providing eight positioning functions capable of supine, sitting and standing position
  - b. It should allow patient to remain in one place for preparation, filling and voiding phases of the urodynamic test
  - c. It should eliminate the risk of catheters falling out or getting misplaced during transfer or ambulation
  - d. Chair should be protected against water incursion
  - e. There should be double wheel rolling casters offering unencumbered maneuverability
  - f. There should be side mounted cantilevered design offering anterior/posterior, lateral and oblique views without obstruction and to provide easier access to, and visualization of, the perineal area.
  - g. There should be radiolucent carbon fiber seat and back for head-to-toe imaging.
  - h. Weight capacity in standing position should be 250kg. Chair should be registered with CDSCO for import and Bidder should submit OEM authorization.
- 26) **C-ARM** - Should be supplied with compatible C-ARM for doing Video Urodynamic Studies. Should be supplied complete with:
- a. Lead Aprons - 05 nos.
  - b. Thyroid collars - 05 Nos.
  - c. Stand for Apron - 01 Nos.
  - d. Firm should do lead protection on windows and door of UDS Lab Room as per AERB guidelines
- 27) **Internal Civil Work** - Firm should do internal civil work of Urodynamic lab like:-
- a. Internal Plaster, Painting, Lighting, Wooden Work
  - b. Electrical requirements Like Fan, Cable, Wiring, A/c, Boards
  - c. Basin, Washroom, Bath fittings, Drainage
  - d. Android TV for Biofeedback System

- e. Toys, Beanbag, Mattresses, chairs etc. for Kids
  - f. Board for Video urodynamic Lab
  - g. Two Chairs for Faculty & two chairs for technicians in UDS room
  - h. Curtains Partitions inside room
- 28) The Urodynamic system should be upgradable and compatible with technical advances like ambulatory urodynamics and NIRS.
- 29) System should be supplied with 5 years warranty and CMC/AMC for next 5 years after warranty period. CMC/AMC rates should be quoted in price bid.
- 30) OEM/Bidder should have supplied same or similar model with identical specification of Video Urodynamic Machine with C-ARM at two or more premier Government institutes / hospitals in India in last three financial years and supply order copy along with performance should be attached and at least one must be in the name of Bidder with installation report and performance certificate.
- 31) Bidder must upload detailed technical quotation, technical Compliance with Supporting documents like technical brochure, feature sheet, manual etc. with highlighted each point of technical specification with referring page number. Without technical quotation and supporting documents with point wise matching technical specs will lead to rejection of tender out rightly.
- 32) Physical Demonstration of the quoted model as per technical specification of tender is required. Bidders will have to show VIDEO UDS with C-ARM Integration.
- 33) There will be 95% uptime warranty during CMC period on 24(hrs) x 7(days) x 365 basis, with penalty, to extend CMC period by double the downtime period. If non functional period exceeds two weeks at a stretch, a temporary standby machine of same specification should be provided.
- 34) Rates of consumables, spare parts and additional accessory items to be quoted separately by the firm. These quoted rates should be valid and freezed for at least 3 years. Anything which is not separately mentioned as a consumable will be considered to be a spare part and which would then be covered under warranty / CAMC. Spare parts and consumables should be made available for the life of the equipment .