Indira Gandhi Memorial Hospital
Male', Republic of Maldives
Biomedical Engineering Department

Technical Specification for Equipment

Technical Specification: Uroflowmetry System

---

1. General Requirements
   - Latest generation, microprocessor-controlled Uroflowmetry System.
   - Intended for non-invasive measurement and analysis of urinary flow parameters.
   - Suitable for use in urology clinics, outpatient departments, and hospitals.
   - System shall be supplied complete with all necessary accessories and software for full operation.
   - CE and/or FDA approved product preferred.
   - Electrical safety compliance according to applicable IEC standards.
2. System Configuration
   - Uroflowmetry unit with integrated or external load cell/flow sensor.
   - Patient funnel and collection vessel.
   - Dedicated analysis software.
   - Computer workstation or embedded display system.
   - Integrated or external thermal/laser printer.
   - Communication cables and required accessories.
   - User manuals and service manuals in English.
3. Performance Requirements
   - Measurement of urinary flow rate and voided volume.
   - Real-time graphical display of flow curve.
   - Automatic calculation of:
     - Maximum Flow Rate (Qmax)
     - Average Flow Rate (Qavg)
     - Voided Volume
     - Voiding Time
     - Flow Time
     - Time to Maximum Flow
   - Automatic generation and storage of patient reports.
   - High accuracy flow measurement.
   - Low-noise measurement technology.
   - Automatic start and stop detection.
   - Repeat measurement capability.
4. Software Requirements
   - User-friendly graphical interface.
   - Patient database management.
   - Search, review, and retrieval of historical records.
   - Trend analysis and report comparison.
   - Report export in standard digital formats.
   - Password-protected user access.
   - Data backup and restoration capability.
5. Display and Reporting
   - Color display monitor or equivalent integrated display.
   - Real-time display of:
     - Flow rate curve
     - Voided volume
     - Measurement status
   - Printable reports with graphical and numerical data.
   - Ability to print patient information and examination results.
6. Connectivity
   - USB and/or Ethernet connectivity.

- Capability to transfer reports to hospital information systems.
- Data export capability via USB storage device or network.

7. Power Requirements
   - Input Power: 220–240 VAC, 50/60 Hz (BS 1363).
   - Suitable for local power supply conditions.
   - Built-in protection against voltage fluctuations preferred.
8. Environmental Conditions

Operating Conditions
   - Temperature: 18°C to 30°C.
   - Relative Humidity: 30% to 80% non-condensing.
   - Atmospheric Pressure: 700 hPa to 1060 hPa.

Storage and Transport Conditions
   - Temperature: -10°C to +50°C.
   - Relative Humidity: 10% to 95% non-condensing.
9. Consumables
   - Disposable urine collection containers/bags (if applicable).
   - Disposable patient funnels or liners (if applicable).
   - Thermal printer paper (if thermal printer supplied).
   - Vendor shall clearly specify:
     - Consumable types.
     - Manufacturer recommended replacement intervals.
     - Unit prices.
     - Local availability.
   - Minimum one-year consumable requirement shall be quoted separately.
10. Accessories
    - All accessories required for complete operation shall be included.
    - Calibration tools/accessories where applicable.
    - Printer and starter pack of printing media.
    - Required communication cables and connectors.
11. Documentation
    - User Manual (English).
    - Service Manual (English).
    - Preventive Maintenance Procedures.
    - Electrical and Mechanical Schematics (where applicable).
    - Calibration and Quality Control Procedures.
12. Installation and Commissioning
    - Vendor shall perform complete installation, testing, and commissioning of the system.
    - Vendor shall verify proper operation prior to handover.
    - Vendor shall provide an Installation and Commissioning Report upon completion.
    - System shall be delivered ready for clinical use.
13. User Training
    - On-site user training for clinical staff.
    - On-site technical training for biomedical engineering staff.
    - Training shall include:
      - System operation.
      - Good operating practices.
      - Preventive maintenance procedures.
      - Basic troubleshooting and error handling.
      - Cleaning and disinfection procedures.
      - Data management and backup procedures.
14. Service Support
    - Local technical support and maintenance capability shall be available.
    - Vendor shall provide 24 × 7 technical support throughout the operational life of the system until decommissioning.
    - Preventive maintenance schedule shall be provided.
    - Service response time shall be clearly stated in the proposal.
    - Availability of spare parts for a minimum of 10 years preferred.
15. Spare Parts Support
    - Vendor shall provide an essential spare parts buffer stock locally.
    - Vendor shall submit:
      - Recommended spare parts list.

    - Major spare parts list.
    - Estimated prices for spare parts.
    - Expected replacement intervals where applicable.
- Spare parts availability shall be guaranteed for a minimum of 10 years preferred.

16. Warranty
- Minimum Warranty: 2 Years.
- Extendable warranty options preferred.
- Warranty shall include:
    - Labor.
    - Travel costs.
    - Software updates.
    - Preventive maintenance.
    - Corrective maintenance.
    - Replacement of defective parts.

17. Compliance
- Equipment shall comply with applicable international standards for medical electrical equipment and patient safety.
- Vendor shall provide certificates of conformity and product quality documentation.

End of Specification