



Raa. Ungoofaaru, Republic of Maldives

TECHNICAL SPECIFICATION FOR MEDICAL EQUIPMENT

Equipment: Fully Automated Urine Analyzer (Quantity-01)

OBJECTIVE

Automated urinalysis can be used for urinary tract screening and for diagnosing and monitoring a broad variety of nephrological and urological conditions; newer applications show promising results for early detection of urothelial cancer.

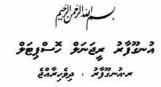
The Analyzer provides automated reading of the urinalysis tests include:

- Leukocyte
- Nitrite
- Protein
- Blood
- Glucose
- Ketone
- Bilirubin
- Urobilinogen
- pH
- Specific Gravity
- Creatinine
- Protein-to-Creatinine Ratio
- Albumin
- Albumin-to-Creatinine Ratio (ACR)
- hCG Pregnancy Test

SPECIFICATIONS

- 1. The analyzer should be compact benchtop, fully automated integrated urine analyzer, integrating urine chemistry and urine sediment analysis.
- 2. Chemistry parameters required to be provided should be glucose, protein, blood, bilirubin, urobilinogen, ph, ketones, nitrate, leukocyte, creatinine & albumin.
- 3. Additional instrument parameters should have specific gravity, turbidity & color.
- 4. The analyzer should be based on fluorescence flowcytometry/ Digital flowcytometry for accurate measurement of urine parameters such as RBC, WBC, epithelial cells, cast and bacteria.







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- 5. The instrument should provide scattergrams and histograms or actual images for easy interpretation.
- 6. The analyzer should provide additional RBC information, UTI information and conductivity.
- 7. The analyzer should have user friendly software with cross check function.
- 8. The analyzer should have a throughput 100 samples / hour (chemistry) & 50 samples / hour (sediment analysis).
- 9. The equipment should have a storage of 200 test strips at a time with continuous loading for true walkaway analysis.
- 10. The equipment should be capable of analysis in both manual and sampler mode.
- 11. Sampler should have the capacity of 60 sample tubes and internal barcode for sample identification
- 12. Controls should be available for both chemistry and sediment analysis
- 13. Data storage of 10000 samples including graphics & multiple qc files, with 300 data points each should be available.
- 14. The equipment should have interface for output to printer or transmitted to LIS / HIS and it would the responsibility of the supplier to do the interfacing.

OPERATION

User Interface: Touchscreen

Computer Interface: Uni-directional via Serial Port (RS232)

Data Entry: Onboard touchscreen

Temperature range: 18 to 30°C (64 to 86°F)

Humidity range: 18-80% Relative Humidity, non-condensing

Calibration: Automatic, self-calibrating

Memory: Data Storage up to 10,000 samples









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POWER REQUIREMENTS

Electrical Rating: 100V - 240V AC, 50-60 Hz (with in-line lead)

Battery operation: Recommended

Quality Standard

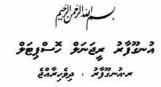
- Manufacturing should be compliant with ISO 13485, and ISO 9001:2008/2015
- Should be compliant with European CE Class IIA or US FDA
- Equipment must meet electrical safety specifications of IEC 61010-1.

Additional requirements:

- All equipment should specify qualifications for design, installation, operation and performance.
- Validation and calibration reports should have traceability to applicable international standards
- Warranty for 2 years and CMC/AMC for Three years with spare parts availability.
- The brand, rating, model, description, specifications, price quantity of each item should be furnished separately.
- Necessary catalogues, technical write up in English, should be attached with the offer both in hard and electronic copies.
- Performance, efficiency, other factors as applicable should be furnished.
- Demonstration and continued comprehensive training for user/biomedical staff and support services till expertise with the system.
- Should provide electronic and hard copies of User Manual (English), Service manual (English) and Complete construction details with respect to material specification, thickness, finish etc.
- Should provide a set of equipment's for calibration (e.g., Thermometer) and routine Preventive Maintenance as per manufacturer documentation in service/technical manual. Should provide Log book with instructions for daily, weekly, monthly and









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quarterly maintenance checklist. The job description of the hospital engineer/technician and company service engineer should be clearly spelled out.

