UriSed mini

Urine Microscopy Analyzer

BRAND NEW FEATURE:
*Body Fluid Measurement mode**

New category in urine sediment analysis!

- Based on the patented UriSed Technology
- The only consumable is the UriSed Cuvette
- Cost-effective operation without any liquid reagents or calibrators
- Whole field of view microscopic images of urine sediment
- Automatic identification of urine particles by the Artificial Intelligence-based Evaluation Module (AIEM)
- Total measurement cycle is less than 1 minute
- Easy operation with minimal training needs
- Highly effective tool for small labs, emergency departments or as a back-up system for automated urine sediment analyzer
- Manual microscopy mode: Real-time view of any viewfield of the cuvette to see moving microorganisms as well
- User friendly and flexible Software for handling data, validating results and creating complete urinalysis reports
- Connection to Laboratory Middleware or direct connection to LIS in integrated mode

The UriSed mini is a professional semi-automated urine microscopy analyzer that improves accuracy, reproducibility and productivity in laboratories. It captures whole field of view microscopic images of the urine samples and enables the automatic classification and counting of urine sediment particles.

UriSed mini utilizes the traditional gold standard method. This unique procedure eliminates the most time-consuming and operator-dependent procedures in laboratories performed by manual microscopy. In addition, it can also serve as a backup instrument of automated sediment analyzers.

URISED TECHNOLOGY

UriSed cuvette

NEW BODY FLUID MEASUREMENT MODE

A brand new feature has been added to the UriSed mini: the Body Fluid Measurement mode - it is available only in RUO mode (Research Use Only mode, not for diagnostic purposes).

The two measurement phases of stained and unstained samples enable a wider range of sample analysis that includes various body fluid types.

*It is available only in Research Use Only mode, not for diagnostic purposes.

UMI-9301-5

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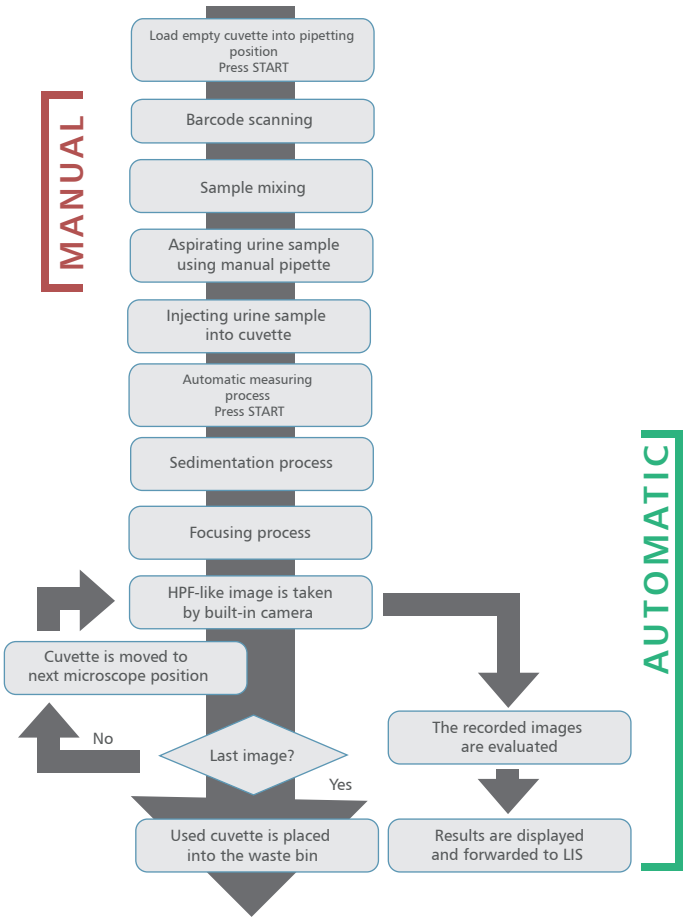
CE

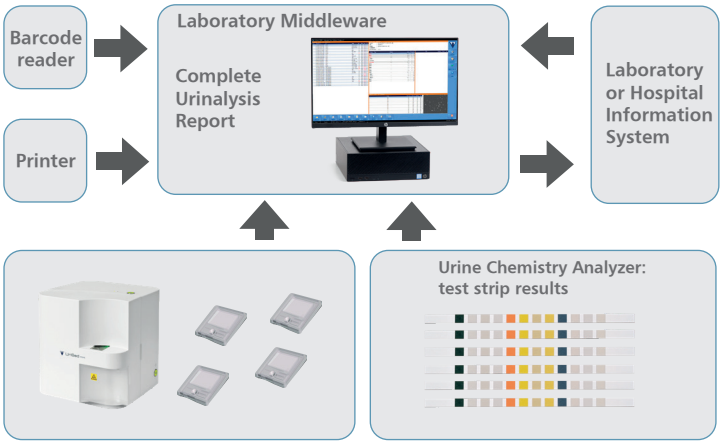
For professional Use
IVD

UriSed mini

MEASUREMENT PROCESS OF URISED MINI



SEMI-AUTOMATED URINALYSIS CONCEPT



CONNECTIVITY TO LABORATORY MIDDLEWARE

- Collecting chemical and sediment results
- Barcode identification – assigning chemical and sediment data according to ID
- Validating results
- Displaying data
- Creating complete urinalysis report
- Printing report
- Connection to LIS
- Storing results in database

The operation of this analyzer is based on the patented UriSed Technology, which is actually the automation of traditional manual microscopy. The operator only needs to load a special disposable cuvette and inject native urine sample into it using a manual pipette. Working without any special liquid reagents, UriSed mini performs all the rest automatically.

After centrifuging the sample, it takes 15 whole field of view images of each sample through a built-in microscope, and evaluates them using the Artificial Intelligence-based Evaluation Module (AIEM), which is a high-quality image processing software. The images and results can be viewed and validated in the user software of the UriSed mini.

ABOUT 77 ELEKTRONIKA

77 Elektronika Kft. is a major global developer, manufacturer and supplier of in vitro diagnostic medical devices, mainly urine analyzers, rapid test readers, blood glucose meters and their consumables. The products are supplied throughout the world under the 77 Elektronika brand and as OEM products for market-leading multinational companies. 77 Elektronika was established in 1986 and is headquartered in Budapest, Hungary (EU). The company is committed to providing superior products and services to the complete satisfaction of its customers.

TECHNICAL SPECIFICATIONS

Detected particle classes:	Red Blood Cells (RBC); White Blood Cells (WBC); WBC Clumps (WBCc); Hyaline Casts (HYA); Pathological Casts (PAT); Squamous Epithelial Cells (EPI); Non-Squamous Epithelial Cells (NEC); Bacteria Rod (BAC); Bacteria Cocci (BACc); Bacteria Rods (BACr); Yeast (YEA); Crystals (CRY); Calcium-oxalate monohydrate (CaOxm); Calcium-oxalate dihydrate (CaOxd); Uric acid (URI); Triple phosphate (TRI); Mucus (MUC); Sperm (SPRM); Further classes for manual subclassification are also available.
Technology:	UriSed Technology: cuvette-based automated microscopy and image processing
Throughput:	Up to 60 tests/hour
Min. sample volume:	0.5 ml
Database capacity:	5 000 results (max. 10 000)
Enhanced sedimentation:	YES
Built-in microscope:	YES
Images:	15 standard HPF-like images
Display:	Monitor
Barcode reader:	Optional, external
Printer:	Optional, external
Dimensions:	310 x 310 x 320 mm (W x D x H)
Weight:	~15 kg
Power	100-250V AC / 50-60 Hz / max. 100W
Interfaces:	USB, Ethernet
Consumables:	Standard UriSed cuvettes, Disposable pipette tips
Parameters identified (body fluids)*	Red blood cells (RBC, p/µL or p/HPF,quantitative) White blood cells (WBC, p/µL or p/HPF, quantitative) Mononuclear white blood cells (MN%, differential) Polymorphonuclear white bloodcells (PMN%, differential) Other nucleated cells (ONC, p/µL or p/HPF, semi-quantitative)
Body fluids available*	Cerebrospinal fluid (Liquor), Ascitic fluid, Pleural fluid, Pericardial fluid, Continuous ambulatory peritoneal dialysis (CAPD).

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77 ELEKTRONIKA

UriSed Cuvettes

REF

URS-9961HU
URS-9961-1
URS-9971
URS-9972
URS-9974
URS-9961CH-1
URS-9971CH

Instructions for use

Intended use:

UriSed Cuvettes are disposable, single use polycarbonate specimen receptacles used to analyze uncentrifuged, human urine samples with UriSed sediment analyzers. It is intended for professional, laboratory use. It is intended for in vitro diagnostic use.

Test principle:

UriSed Cuvettes are specimen receptacles allowing for microscopic analysis of urine samples.

Materials provided:

600 cuvettes in 12 cuvette holders of 50 cuvettes each

Materials not provided:

- Compatible urine sediment analyzer (UriSed,UriSed2, UriSed 3, UriSed 3 PRO, UriSed mini)
- General laboratory equipment

Using cuvettes:

1 Place the cuvette holder in your analyzer

2 Remove the closing tape of the cuvette holder

Environmental Conditions

Storage temperature	0 – 45°C
Transport temperature	-25°C – 60°C
Transport humidity	20 – 80 %
Operation conditions	According to your analyzer's conditions

⚠ Warnings and cautions

- Do not store cuvettes in direct sunlight
- Do not remove closing tape from the cuvette holder before installing in your analyzer
- Do not remove partially full cuvette holders from your analyzer
- Each cuvette is single use, never perform a test with previously used cuvette
- Since urine is a fluid of human origin, it may be infectious and may constitute a potential biological risk
- Handle used UriSed cuvettes and urine contaminants with care
- Dispose of waste according to accepted laboratory instructions and procedures.
- Contact your distributor to make sure to order cuvettes compatible with your specific analyzer
- Use cuvettes before expiration date

Check your analyzer's instructions for use for details on specimen collection, potential preparatory steps, result calculation, analytical and performance characteristics, interferences, limitations, quality control procedures, specific warnings and cautions.

Incident reporting

Report any serious incidents which may occur when using this product to your 77 Elektronika service representative and your local competent authority.

Symbols:

UDI	Unique Device Identifier
IVD	In vitro diagnostic medical device
REF	Catalogue Number
LOT	Lot Number
CE	The CE mark identifies that the product complie with the applicable directives of the EuropeanUnion
	Use by
0°C +45°C	Temperature Limitation
	Manufacturer
	Keep away from sunlight
	Consult instructions for use
20% 80%	Humidity Limitation
	Caution
	Biological Risks
Σ 600	Contents sufficient for 600 tests
	Do NOT Reuse
	Do not use if package is damaged
GB	English Language
CH	Batch number

Version history

Version	Date	Changes
3	2022.03.25	IVDR compliance update
2	2020.11.25	General update of content
1	2009.02.17	First release

Manufacturer:

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98. Fehérvári út, 1116 Budapest
HUNGARY
www.en.e77.hu
sales@e77.hu
Tel: + 36 1 206 - 1480
Fax: + 36 1 206 - 1481

Certificate

This Certificate recognizes

Buza Grigorii

as a UriSed 3 PRO, LabUMat 2 and
UriSed mini
Specialist

after having successfully completed the

Service Training Program between

06th - 10th March, 2023.

Máté Tóth
Instructor

77 Elektronika Kft.
Budapest, Hungary

Zsolt Eszes
Service Manager

Certificate

Standard **ISO 14001:2015**

Certificate Registr. No. **01 104 2024081**

Certificate Holder: **77 Elektronika Műszeripari Kft.**
Fehérvári út 98.
1116 Budapest
Hungary

77 ELEKTRONIKA

Including the locations according to annex.

Scope: design, development, manufacturing, sales and service of in vitro diagnostic (IVD) medical devices and veterinary devices.

Proof has been furnished by means of an audit that the requirements of ISO 14001:2015 are met.

Validity: The certificate is valid from 06.10.2024 until 05.10.2027.

24.09.2024

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

Annex to certificate

Standard **ISO 14001:2015**

Certificate Registr. No. **01 104 2024081**

No.	Location	Scope
/01	c/o 77 Elektronika Műszeripari Kft. Fehérvári út 98. 1116 Budapest Hungary	Design, development, manufacturing, sales and service of invitro diagnostic (IVD) medical devices, and veterinary devices.
/02	c/o 77 Elektronika Műszeripari Kft. Sztregova u. 1. 1116 Budapest Hungary	Design, development, manufacturing, sales and service of invitro diagnostic (IVD) medical devices, and veterinary devices.

24.09.2024

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

TÜVRheinland®
Precisely Right.

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1006099-1

Organization: 77 Elektronika Műszeripari Kft.
Fehérvári út 98.
1116 Budapest
Hungary

Scope: Design and development, production, distribution, installation and servicing of blood glucose measuring systems, urine analyzers and rapid test readers, including related consumables.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 93389457-30
Effective date: 2022-11-18
Expiry date: 2025-11-17
Issue date: 2022-11-09

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Rafał Byczkowski
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1006099-1

Organization: 77 Elektronika Műszeripari Kft.
Fehérvári út 98.
1116 Budapest
Hungary

The scope of certification includes the following additional sites:

No.	Facility	Scope
/01	77 Elektronika Műszeripari Kft. Fehérvári út 98. 1116 Budapest Hungary	Design and development, production, distribution, installation and servicing.
/02	77 Elektronika Műszeripari Kft. Telephely Sztregova utca 1 1116 Budapest Hungary	Manufacture and warehouse of blood glucose measuring systems, urine analyzers, related consumables and parts. Manufacturing of SMT technology.

Report No.: 93389457-30
Effective date: 2022-11-18
Expiry date: 2025-11-17
Issue date: 2022-11-09

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Rafał Byczkowski
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Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Quantimetrix

2005 Manhattan Beach Boulevard
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f (310) 536-0977
quantimetrix.com

Declaration of Conformity
European Directive 98/79/EC

Manufacturer: Quantimetrix Corporation
2005 Manhattan Beach Boulevard
Redondo Beach, CA 90278-1205
U.S.A.

+1.310.536.0006

Product: REF 1470-01 Dip&Spin® Urinalysis Dipstick & Microscopics Control, Level 1 & 2, 4x120 mL

Classification: EDMA Code: 11.50.02.06 / Risk Class "Other"

European directive: 98/79/EC

EU Representative: Medical Device Safety Service GmbH (MDSS)

Address: Schiffgraben 41 · 30175 Hannover, Germany

We, the manufacturer, declare that the product described above is in compliance with Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, and applicable harmonized standards.

We, the manufacturer, declare that we take sole responsibility of the above mentioned Medical product(s). This device is not one of the devices listed in Annex II, nor is it a device for performance evaluation, nor is it a self testing device, therefore the route followed will be the procedure in Annex III. The Technical File is maintained at Quantimetrix Corporation. As stated in article 16 of this Directive, the CE mark is displayed accordingly.

CE

Date of Issue: May 24, 2022

Signature of Authorized Person: _____

Name of Authorized Person: Kalyna Snylyk
Title of Authorized Person: Quality Assurance/Regulatory Affairs Director
Rev.05/22