UriSed mini

Semi Automated Urine Sediment Analyzer
User Manual
sw4.9

77 ELEKTRONIKA

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1 Introduction

The goal of this manual is to help qualified operators of the analyzer use the instrument effectively, with accurate results, and up to its full potential.

It provides information about every relevant aspect of the installation, use, and database management of the analyzer, as well as basic maintenance and troubleshooting information. Please read the User Manual carefully, as it contains the directions you need to use the device correctly and safely and keep it in good working condition.

Keep the User Manual in a safe place to ensure that it is not damaged and remains available for use. It must be easily accessible at all times.

1.1 About the analyzer

The instrument is a semi-automated microscopy urine sediment analyzer. The installation kit includes the analyzer and the device software that lets the operator interact with the automated processes and the image and measurement results database.

The analyzer takes special cuvettes that hold the urine samples, centrifuges the cuvettes to form a monolayer of urine sediment inside them, then takes high power field–like images of the particles with a camera under a bright-field microscope.

ⓘ   *You do not need any special reagents to make measurements with the analyzer. The cuvettes and the pipette tips are the only consumables of the instrument.*

The UriSed mini images are evaluated by a neural network-based software called AIEM (Artificial Intelligence-based Evaluation Module). This software detects and categorizes sediment-forming particles in the images.

The operator only needs to load the analyzer with cuvettes, inject urine samples in them with manual pipette — cuvette forwarding, centrifugation, microscopy focusing, image capture, image evaluation and storage, and the disposal of used cuvettes are automated.

1.2 Intended purpose

UriSed mini is a semi-automated analyzer. The analyzer is intended for professional in vitro diagnostic use in clinical laboratories.

UriSed mini is a screening device for human urine samples. The measurement results are useful in the evaluation of renal, urinary and metabolic disorders by analyzing the following parameters in urine samples: Red Blood Cells (RBC); White Blood Cells (WBC) in a quantitative way; WBC Clumps (WBCc); Hyaline Casts (HYA); Pathological Casts (PAT); Squamous Epithelial Cells (EPI); Non-squamous epithelial cells (NEC); Bacteria (BAC): RodBacteria (BACr), Cocci Bacteria (BACc); Yeast (YEA); Crystals (CRY): Calcium-oxalate monohydrate (CaOxm), Calcium-oxalate dihydrate (CaOxd), Uric acid (URI), Triple phosphate (TRI); Mucus (MUC); Sperm (SPRM); in a semi-quantitative way.

1.3   Limitations of Use

Do not use the results that the analyzer provides automatically to make diagnostic or therapeutic decisions without manual review (validation) of the relevant microscopy images by a trained medical technician.

If the equipment is used in a manner, that is not specified in this manual, the protection impairment could be reduced.

1.4   Limitation of Liability

To the maximum extent permitted by applicable laws, under no circumstances shall 77 Elektronika be liable for any loss of data or income or any special, incidental, consequential, or indirect damages howsoever caused.

1.5   Use of Third-Party Computer Products

⚠ **All connected devices must comply with the EN 60950 standard and all its extensions relevant to the type of connected device.**

77 Elektronika does not provide a warranty or take any responsibility for the functionality, content, or end-user support of third-party computer products used in conjunction with the analyzer.

1.6 How to Use This Manual

1.6.1 Symbols and Formatting Conventions

This manual uses the following symbols to help you navigate the text:

⚠	WARNING This symbol indicates maintenance procedures, operations, and other processes that can cause personal injury or harm if the instructions are not followed carefully.
	This is an example of warning text.
⚠	CAUTION This symbol indicates maintenance procedures, operations, and other processes that can cause equipment malfunction, equipment failure, or damage to the equipment if the instructions are not followed carefully.
	This is an example of caution text.
ⓘ	NOTE This symbol indicates important information or useful tips for operating and handling the device.
	This is an example of note text.

The manual uses the following formatting conventions to highlight important information and help you navigate the text:

- ***Bold italic blue*** text indicates a cross-reference that points to a related subsection of the manual or to an external hyper link.
- `Bold monospace type` indicates text that appears on a connected display.
- [Text in square brackets] indicates article numbers for parts and accessories that you can order for the device.
- numbering within procedures indicates steps that you need to perform in sequence.
- Bullet points (•) indicate items on a list or steps that you do not need to perform in sequence.

2   Quick Start

After the analyzer is installed and connected to a monitor, keyboard and mouse, you are ready to start analyzing urine samples. Complete the following steps to start a measurement:

1.   Turn on the analyzer.
2.   Open the analyzer door and load it with cuvettes. Close the door.
3.   Push START button and the analyzer loads a cuvette into pipetting position.
4.   Manually pipette 0.175 ml previously homogenized sample into the cuvette.

ⓘ   *It is important to homogenize the sample before measurement to make sure of the particle's equal distribution.*

5.   Press START button to continue the measurement. The analyzer transfers the cuvette to the centrifuge. After the short spin, the cuvette is taken to the microscope and the camera takes predefined numbers of images and evaluates them.
6.   At the end of the measurement cycle the analyzer discards the cuvette into the waste bin.
7.   The result gets stored in the Database.

3 System Description

3.1 Theory of Operation

The analyzer aims to emulate manual microscopy urine sediment analysis as closely as possible while partially automating sample processing and result evaluation for increased throughput and analysis accuracy. The following steps demonstrate a typical analysis workflow:

1. The operator loads a cuvette into the filling position by pressing the START button.
2. The operator homogenizes and pipettes a native urine sample into a cuvette.
3. After pressing the START button again the analyzer centrifuges the cuvette to produce a monolayer of urine sediment particles at the bottom of the cuvette.
4. The system takes 15 whole field of view HPF-like images through a bright-field microscope after automatic focussing.
5. An image processing software that runs on the built-in computer evaluates the images. The Evaluation Module of the software identifies particles in the image, to arrive at a semi-quantitative analysis result. If the recognition of a sample is not reliable (for example due to overcrowded images), it is flagged for the operator's review.

3.2 Overview of Operating Elements

The following table summarizes the functional and interactive components of the analyzer.
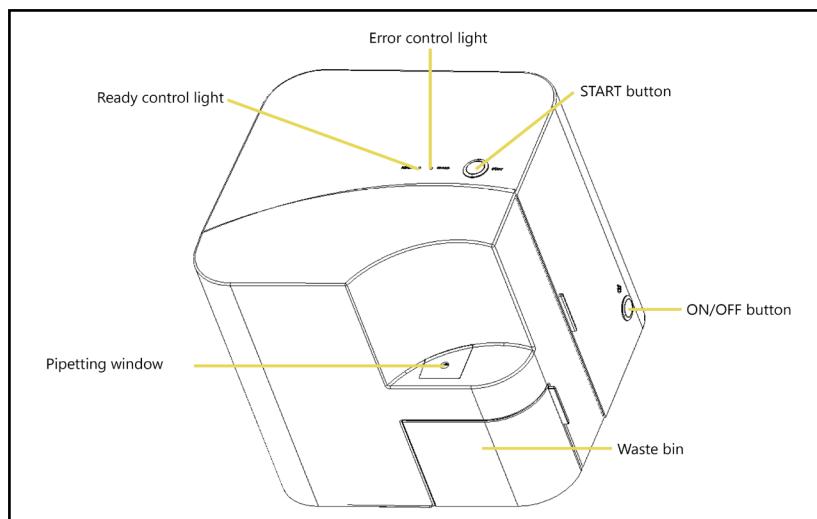
Fig. 1: *Front view of the analyzer*
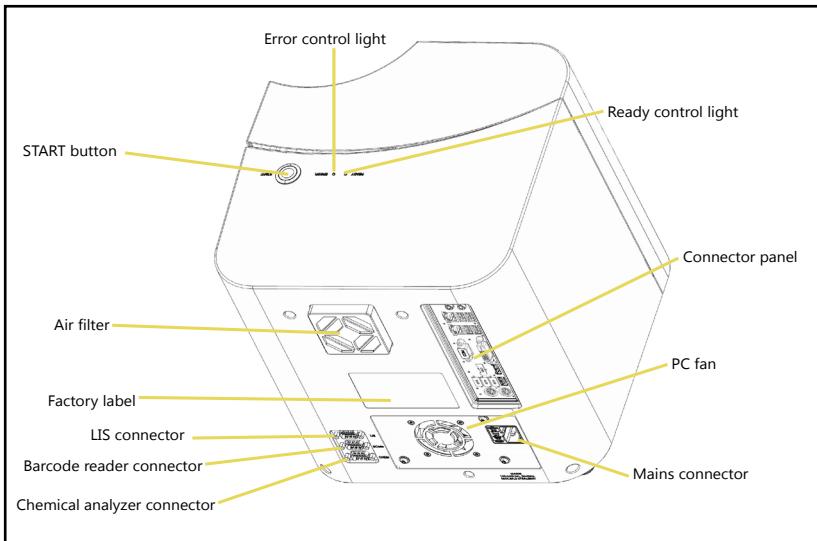
Fig. 2: *Rear view of the analyzer*
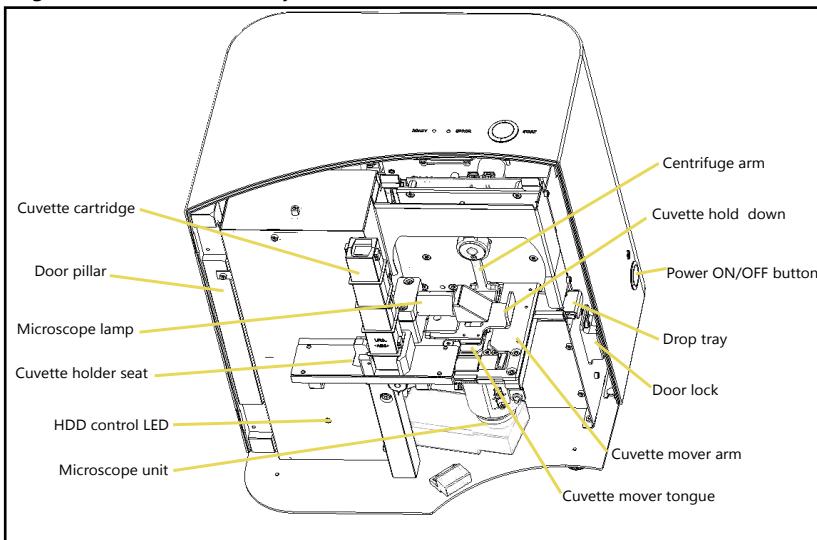
Fig. 3: *Front view of the analyzer without the door, the waste bin and the centrifuge cover*

3.3 Technical Specifications

ⓘ *Technical specifications may change without notice. Every effort has been made to ensure that all the information is correct at the time of publication. However, 77 Elektronika reserves the right to make any necessary changes without notice as part of ongoing product development.*

|	
Technology	Automated microscopy and image processing
Throughput	Up to 60 samples per hour
Sample volume	175±5 microliters
Dispenser pipette tip outer diameter	1.2-2.8 mm
Operating conditions	
Not suitable for wet location application.	
Ambient room temperature	15 - 32°C (59 °F to 90 °F)
Relative humidity	30% - 80%, non-condensing
Altitude and pressure	Max. 2000 meters (6561 feet) above sea level
Pollution	Degree 2 (EN 61010-1)
Storage conditions	
Ambient room temperature	5 - 40°C (41 °F to 104 °F)
Relative humidity	10% - 85%, non-condensing
Transportation conditions	
Temperature	(-25) - (+60)°C (59 °F to 104 °F)
Relative humidity	10% - 85%, non-condensing
Power requirements	
Line voltage	100 - 240 VAC +-10% / max 6A
Line frequency	50 - 60 Hz
Fuse	2 x T8AL250V
Overvoltage category	II
Dimensions (w × d × h)	305mm × 315mm × 325mm
Weight	10 kilograms
Database capacity	10000 measurement results (of 15 microscopy images each)
Waste drawer capacity	50 used cuvettes
Interfaces	2 x PS/2, 1 x DVI-D, 1 x RS232, 2 x DisplayPort, 2 x Ethernet (RJ45) port, 2 x USB 3.0, 2 x USB 3.1, 4 x USB 2.0, 2 x Audio jack

3.4 Analytical performance

Performance characteristics of this analyzer are evaluated by determining analytical sensitivity (limit of detection), accuracy, and precision to measure the reported analytes:

– Quantitative: Red Blood Cell (RBC); White Blood Cell (WBC)

– Semi-quantitative: WBC Clump (WBCc); Hyaline Cast (HYA); Pathological Cast (PAT); Squamous Epithelial Cell (EPI); Non-Squamous Epithelial Cell (NEC); Bacteria (BAC); Rod Bacteria (BACr); Coccus Bacteria (BACc); Yeast (YEA); Crystal (CRY); Mucus (MUC); Sperm (SPRM)

3.4.1 Reference range study

ⓘ *This Information is provided as a guideline only. 77 Elektronika recommends that each laboratory conduct a study to determine the reference range specific to its location and patient population.*

Common findings in a urine sample from a healthy individual may include low levels or few red blood cells (RBCs), white blood cells (WBCs), and epithelial cells. An abundance of RBCs or WBCs may suggest pathology; therefore, reference ranges are determined. The presence of epithelial cells in urine generally reflects contamination of the sample with skin flora. The reference range is dependent on the specific study, its location, and sample population.

The normal reference range was determined following the Clinical & Laboratory Standards Institute (CLSI) guidelines described in Defining, Establishing,and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline–Third Edition (EP28-A3c).

For reference range study 226 normally voided urine specimens from a population of 148 male and 78 females in apparent good health were investigated on the analyzer. The measured samples with normal urine chemistry showed the following distribution of particles:

Parameter	RBC			WBC		
Expected Values		N	95th percentile		N	95th percentile
	Female	78	5.28 p/µl	Female	78	7.0 p/µl
	Male	148	2.2 p/µl	Male	148	3.1 p/µl

3.4.2 Method comparison

ⓘ *Method comparison acc. to CLSI EP9-A3*

Method comparison against manual microscopy with KOVA chamber counting with human.

Number of samples measured: 311

The diagnostic performance results of the analyzer compared to manual microscopy by KOVA counting chamber are summarized below.

3.4.2.1 Quantitative diagnostic performance: linear regression

	RBC	WBC
Pearson R2	0.94	0.91

3.4.2.2 Semi-quantitative diagnostic performance: concordance table analysis

	RBC	WBC	EPI	NEC	HYA	PAT	CRY	YEA	BAC	MUC
Sensitivity (%)	82	90	82	62	68	77	88	78	95	72
Specificity (%)	87	91	90	82	82	69	90	84	87	74
Exact category agreement (%)	71	74	84	71	75	65	87	82	81	70
+/-1 category agreement (%)	95	99	99	93	92	91	98	97	98	96
Accuracy (%)	84	90	88	77	80	70	89	83	88	73
Prevalance (%)	60	59	22	27	17	10	8	6	14	18

3.4.3 Precision

For precision measurements the following control was used:

Quantimetrix Dip&Spin Normal and Abnormal Level

The below tables are the summary of the investigations.

3.4.3.1 Between run precision

ⓘ *Precision acc. to CLSI EP5-A2*

20 days measurement series with 2 sets of measurements per day, both performed in duplicate on one instrument.

For low concentration SD is calculated as a precision value. For high concentration the CV is calculated instead.

Between-run precision	RBC			WBC		
	Average (p/µl)	CV	SD	Average (p/µl)	CV	SD
QC normal	10.1	-	2.5	5.8	-	2
QC abnormal	43.8	16%	-	28.2	12%	-

3.4.3.2 Inter-system precision

ⓘ *Precision acc. to CLSI EP5-A2*

5 days measurement series with 2 sets of measurements per day, both performed in duplicate on 4 instruments.

For low concentration SD is calculated as a precision value. For high concentration the CV is calculated instead.

Inner-system precision	RBC			WBC		
	Average (p/µl)	CV	SD	Average (p/µl)	CV	SD
QC normal	19.8	-	5	12.2	-	3
QC abnormal	136.3	14%	-	66.1	10%	-

3.4.3.3 Within-run precision

ⓘ *Precision acc. to CLSI EP5-A2*

20 repetitions on one instrument in one run.

For low concentration SD is calculated as a precision value. For high concentration the CV is calculated instead.

Within-run precision	RBC			WBC		
	Average (p/µl)	CV	SD	Average (p/µl)	CV	SD
QC normal	9.4	-	1.5	4.6	-	1.6
QC abnormal	43.9	12%	-	26.1	12%	-

Limitations: Limitations given include specific substances and conditions that may affect the test results. As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result or method.

3.4.4   Lower limit of measurement

The Limit of Blank, Limit of Detection and Limit of Quantitation were determined in accordance with the CLSI EP17-A2 requirements.

The Limit of Blank is 95th percentile value from n ≥ 60 measurements of analyte-free samples over several independent series. The Limit of Blank corresponds to the concentration below which analyte-free samples are found with a probability of 95%.

The Limit of Detection is determined based on the Limit of Blank and the standard deviation of low concentration samples. The Limit of Detection corresponds to the lowest analyte concentration which can be detected (value above the Limit of Blank with probability of 95%).

The Limit of Quantitation is the lowest analyte concentration that can be reproducibly measured with a coefficient of variation (CV) of 60%

LoB [p/µl] result												
RBC	WBC	NEC	EPI	HYA	PAT	BAC	BACc	BACr	CRY	YEA	MUC	SPRM
0.5	0.32	0.05	0.07	0.18	0	12.32	12.3	0.11	0.71	0.05	13.01	0.05

LoD [p/µl] result		
RBC	WBC	EPI
2.8	2.18	1.71

LoQ [p/µl] result	
RBC	WBC
3.7	3.2

3.4.5 Preservative tubes

The interference measurements were performed based on CLSI EP7-A2 guideline, applied to urine sediment microscopy analysis.

The goal of the evaluation of preservatives test was to evaluate if the two supported tube types (Boritex urine tube, BD vacutainer urinalysis preservative tube) cause any interference on the analyzer measurements.

The evaluation does not target the preserving capabilities of the tubes themselves, as this is the tube manufacturer's responsibility.

The LoB measurements with the supported preservative tubes were performed together with the LoB measurements with normal tube, therefore the same samples constitute the data pool. In case any deviations are visible, this can most likely be accounted to the preservative tube. The same measurements were performed as in case of the LoB measurement described in *„3.4.4 Lower limit of measurement"*.

Particles	RBC	WBC	NEC	EPI	HYA	PAT	BAC	BACc	BACr	CRY	YEA	MUC	SPRM
Non-preservative tube	0.5	0.3	0.1	0.1	0.2	0.0	12.3	12.3	0.1	0.7	0.1	13.0	0.1
BD vacutainer preservative tube	0.0	0.7	0.0	0.0	0.0	0.1	123.3	119.4	6.0	3.3	0.0	4.5	0.0
Boritex preservative tube	0.0	0.0	0.0	0.5	0.0	1.8	67.4	66.1	9.8	0.4	0.0	15.4	0.0

3.5 Instrument and Labeling Symbols

Symbols on the package

Symbol	Meaning	Symbol	Meaning
⬆⬆	This way up	🌡	Temperature limitation indicating upper and lower limits
🍷	Fragile	☂	Keep package out of rain and away from damp conditions
⊠	Do not stack		

Symbols on the analyzer

Symbol	Meaning	Symbol	Meaning
☣	Biological hazard	⚠	Warning
⚡	Electrostatic discharge sensitive	⏚	Protective ground
⚙	Moving parts	C E	The CE mark identifies that the product complies with the applicable directives of the European Union
🏭	Manufacturer	�	Date of manufacture
∿	Alternating voltage	📖	Consult instructions for use
REF	Reference number	**SN**	Serial number
IVD	In vitro diagnostic medical device	Ⓒ	This product has been tested to the requirements of CAN/CSA-C22.2 No. 61010-1, second edition, including Amendment 1, or a later version of the same standard incorporating the same level of testing requirements
📦	Distributor	**GTIN**	Global Trade Item Number

3.6 Safety information

⚠ **Particular attention must be paid to the following safety information. If they are ignored, the operator may suffer serious or fatal injury or patients may be put at risk through faulty sample evaluation.**

This safety summary contains the most important and general requirements and precautionary instructions about the safe operation of the analyzer. Additionally, you will find specific safety information in the form of warning or caution messages at the beginning of chapters and with the description of procedures.

3.6.1 Operator qualification

Operators are required to have a sound knowledge of relevant guidelines and standards as well as the information and procedures contained in the User Manual.

Do not carry out operation and maintenance unless you have been trained. Carefully follow the procedures specified in the User Manual for the operation and maintenance of the analyzer.

Leave maintenance, installation or service that is not described in the User Manual to trained service representatives.

Follow Good Laboratory Practices especially when working with biohazardous material.

3.6.2 Electrical safety

Removing the covers of electronic equipment can cause electric shock, as there are high voltage parts inside.

Do not attempt to work in any electronic compartment.

Do not remove any cover of the analyzer other than those specified in this User Manual.

To prevent fire or shock hazard, do not expose the analyzer to rain or moisture of any kinds.

To prevent electric shock, never use an extension cord. Ensure all plugs and sockets are fully inserted so that no parts of the plug prongs or blades are visible.

Installation, service, and repair must only be performed by personnel authorized and trained by 77 Elektronika only.

3.6.3 Protection from biohazardous materials

All components of the analyzer may come into contact with human urine and are therefore possible sources of infection. Urine specimens should be handled at Biosafety Level 2.

Be sure to wear appropriate protective equipment, including, but not limited to, eye protection with side shields, fluid resistant lab coat, and approved lab gloves. Wear a face shield if there is a chance of splash or splatter.

Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary. Do not wash or reuse disposable gloves.

Do not eat, drink, smoke, handle contact lenses, apply cosmetics or store food while in the laboratory.

Do not pipette any liquid by mouth; use only mechanical pipetting analyzers.

During service work, keep your hands and fingers away from your mouth, nose and eyes.

Remove your protective clothing and wash your hands before leaving for non-laboratory areas.

If you take the analyzer out of operation and/or want to transport it, first you have to clean and disinfect the analyzer, empty and disinfect the waste bin (cuvettes).

The analyzer still can be potentially infectous after removal from use and during transportation. Therefore, it should be treated as biological hazard.

3.6.4 Possible accidents

3.6.4.1 Sample or liquid waste spill

If any biohazardous material is spilled, wipe it up immediately and apply disinfectant. If it happens in the analyzer, stop the measurement process and start a cleaning procedure.

If sample or liquid waste comes into contact with your skin, wash it off immediately with soap and water and apply disinfectant. Consult a physician.

3.6.4.2 Solid waste dropping

When contaminated solid material drops on floor or analyzer (i.e. waste bin falls out and the used cuvettes scatter) collect and discard all of them into a waste container for biohazardous waste and clean the area with water and disinfectant.

⚠ **Inform your distributor's representative and your local competent authority about any serious incidents which may occur when using this product.**

3.6.5 Waste management

The waste of the analyzer is potentially biohazardous and must be treated in accordance with the relevant laws and regulations.

When disposing of any waste, do so in accordance with the appropriate local regulations.

Any substances contained in QC materials and other working materials, which are legally regulated for environmental protection, must be disposed of in accordance with the relevant water discharge facility regulations. For the legal regulations on water discharge, please contact the suppliers of the materials.

3.6.6 Safe and proper use of the analyzer

3.6.6.1 Accuracy and precision of measured results

An incorrect measuring result may lead to an error in diagnosis and therefore poses danger to the patient.

For proper use of the instrument, measure QC samples and monitor the instrument during operation.

Do not use consumables that have exceeded their expiry date, otherwise inaccurate data may be obtained.

For diagnostic purposes always assess the results in conjunction with the patient's medical history, clinical examination, and other findings.

3.6.6.2   Installation and service

The installation and servicing of the analyzer must be performed by personnel authorized and trained by 77 Elektronika only.

Connect the analyzer to the mains with its own power cable the analyzer is supplied with and always use grounded socket.

Do not try to replace electric or mechanical parts which are not described in the User Manual.

Do not use any cable that is longer than 3 m.

There is a safety interlock, which cuts the power and stops the sample processing when the analyzer door opens. Do not attempt to disable the interlock. Disabled interlock would not stop the analyzer operating and moving inside parts could cause accidents if you reach in the inside of the analyzer.

Removing the covers of electronic equipment can cause electric shock, as there are high voltage parts inside. Do not remove any cover of the analyzer other than those specified in this User Manual.

Do not attempt to work in the electric compartment.

The safety level of the analyzer does not change after servicing if it is done by personnel authorized and trained by 77 Elektronika only.

3.6.6.3   Operational conditions

Operation outside the specified operating conditions may lead to incorrect results or malfunction of the instrument. (See *3.3*)

Use the instrument indoors only and avoid heat and humidity.

Always comply with your local laboratory regulations.

Perform maintenance according to the specified intervals and when instructed to do so by the system software to maintain the required operating conditions for the analyzer. Ensure that the analyzer's ventilation openings remain unobstructed at all times.

Ensure that no vibrations influence the surface the analyzer stands on and take care not to knock or tilt the analyzer while processing tests.

Strong vibrations, knocking or tilting the instrument may influence the positioning of the measuring device and may lead to incorrect sample identification or incorrect results.

There is no further user action required in case of residual risk.

3.6.6.4   Approved parts

Use of non-approved parts or devices may result in malfunction and may render the warranty null and void.

Only use parts and devices approved by 77 Elektronika.

3.6.6.5   Third-party Software

It is forbidden to install any software on the instrument.

3.6.6.6   Instrument approvals

The analyzer meets the protection requirements laid down in IVD Directive 98/79/EC. Furthermore, our instruments are manufactured and tested according to the following international standards:

IEC 61010-1:2010
IEC 61010-2-020:2016
IEC 61010-2-081:2015
IEC 61010-2:101:2015

4 Installation

Read User Manual carefully before installation and follow the instructions carefully to ensure proper operation, correct results and avoid making any damage to the analyzer.

4.1 Preparing the installation site

⚠️ **Before start unpacking find a suitable space for the analyzer. Check the dimensions of the analyzer, monitor and keyboard and combine it with the needed workspace for sample handling to meet the requirements.**

⚠️ **The analyzer should only be used indoors.**

⚠️ **Keep out of direct sunlight. Intense light can interfere with the optical sensors.**

⚠️ **Make sure that there is enough room at the back of the analyzer for easy connection and disconnection of power supply, the peripherals and also for the proper ventillation of the analyzer. The recommended safety clearance is 10 centimeters (3.94 inches).**

⚠️ **Make sure that you set up and operate the analyzer on a solid level surface in an environment with fairly constant temperature and humidity. Do not operate the analyzer in temperatures below 15°C (59°F) or above 32°C (90°F)and outside of the 30-80 % relative humidity range. Do not expose the analyzer to strong light.**

⚠️ **Do not operate the analyzer in close proximity to sources of intense electromagnetic radiation (such as unshielded intentional RF sources). The analyzer is certified to meet the EMC requirements of EN 61326-1:2007 and EN 61236-2-6:2007.**

⚠️ **The device can be used only in normal electromagnetic environment for IVD medical equipment.**

⚠️ **Do not set up and operate the analyzer in an environment with vibration sources as it may influence the results and also could cause failures to the instrument.**

⚠️ **Make sure the instrument is allowed to acclimatize to room temperature prior to use.**

4.2 Unpacking

Check that the items in the shipping list are inside the delivered package, and that they are intact and in working condition. If there is any visible sign of damage, contact the distributor immediately.

ⓘ *It is recommended to keep the packaging and the package cushioning wrappers in case you would like to relocate the complete system in the future.*

4.2.1 Shipping list

1. UriSed mini device
2. PC keyboard
3. PC mouse
4. LCD monitor (with accessories)
5. Power cord

4.3 Installing the analyzer

UriSed mini operates with 100 to 240 VAC mains voltage. In this range the equipment manages voltage levels automatically. Do not use the equipment with different mains voltages.

1. Place the analyzer on a solid, level surface that can reliably bear the weight of the analyzer and its accessories.
2. Connect the power cable to the analyzer and plug it into a wall outlet. Connect the monitor, a keyboard and a mouse to the analyzer. Switch on the connected monitor.

⚠ **The analyzer can be used only with its own power cable that it is supplied with.**

3. Press the On/Off button on the right-hand side of the analyzer.
4. The user software of the instrument will start automatically after switching on.

4.4 Installing barcode reader

UriSed mini can be used with a barcode reader to identify samples.

UriSed mini is able to be connected to a barcode reader through its RS-232 or USB-A interface.

ⓘ *During barcode scanning via USB-A connection, the UriSed mini user software should be the active window.*

Contact your IT department to install it and refer to the user manual of the barcode reader and the analyzer service manual for help.

4.5   Taking the analyzer out of operation

⚠ **Since urine is a fluid of human origin, the device may be infectious and may carry biological risks.**

⚠ **Handle used cuvettes and urine contaminants with care!**

⚠ **Always wear rubber gloves or other protecting clothing when operating and cleaning the analyzer.**

To take the analyzer out of operation, perform the steps listed below to preserve good condition of the device while it is not being used:

1.   Switch off the analyzer and disconnect from the mains.
2.   Discard all used cuvettes from the waste bin.
3.   Clean the analyzer thoroughly, including all of its removable parts.
4.   Let them dry and pack up the analyzer as it was packaged when it arrived to you.

If you would like to put the analyzer back into operation, follow the steps described in the previous section to properly install the device.

5   Menu system

The analyzer has a menu structure which is very straight-forward and easy to use. The menu buttons are lined up on the right side of the screen. The buttons within each menu are lined up across the bottom of the screen and in bounding boxes across the screen. Some buttons have more than one state: When you click such a multi-state button, its displayed icon and text changes to indicate whether the process is in progress or has ended.

System status information is displayed in the status bar running along the bottom of the screen. The following table lists the information fields of the status bar.

Driver connection status	Online
	Offline
	Initializing...
	Not ready (by HW error)
	Upgrading..
LIS connection status	LIS Online
	LIS Offline
	LIS Initializing...
User rights according to login level or User name	Operator
	Administrator
	Service
	User name
Number of particles which are evaluated (It can be set in Settings/Evaluation menu up to a maximum of 49).	Classes: X
Measurement status	Ready to measure
	Measurement in progress. X/Y images arrived.
Current date and time	Date & time

5.1   System info

Click the **Info** button to toggle a splash window that lists the version of the currently installed device software, the module firmware versions, and driver version data. You can find the **Info** button among the menu buttons in each of the screens.

5.2   User rights

Depending on the user login scheme selected by your service personnel, the analyzer user accounts can be ranked and identified either only by pre-programmed access levels or by individual user names assigned to one of the pre-programmed access levels. Regardless of the user login scheme, there are three pre-programmed access levels in the analyzer: Operator, Administrator and Service.

In the ''By level'' user login scheme, the user names and the access level assigned to a particular user account are identical (for example, an Administrator-level user is always called Administrator).

In the ''By user name'' user login scheme, the user name, password, and the pre-programmed access level associated with user accounts can be customized. In the ''By user name'' user login scheme, whenever a user logs off the system, another user must be logged on. In this login scheme, the user software is non-operational unless someone is logged in.

ⓘ *For more information and to change the active login scheme, ask your service personnel.*

5.2.1 Logging in

In the ''By level'' user login scheme, it is recommended to use Administrator– and Service-level user accounts only when necessary, in order to avoid accidentally modifying system settings.

ⓘ *For more information and to change the active login scheme, ask your service personnel.*

In the ''By level'' user login scheme, each time you run the software, you are logged in as an Operator-level user by default. This access level allows you to perform measurements and manage sample data in the **Database**. To access system settings, you need to log in as Administrator.

Type ''administrator'' as user name and ''settings'' as password (both words without the inverted commas), and click **OK**. The User rights field will display **Administrator** to indicate the successful login, and the **Settings** menu button will appear on the right side of the screen.

In the ''By user name'' user login scheme, ideally, each person using the device should have their own individual user account with a unique, custom user name and password, and be assigned one of the three pre-programmed access levels.


Fig. 4: *The Login window*

1. After start-up, or after other user logout, the analyzer displays the **Login** window(see *Fig. 4*).

2. In the ''By user name'' user login scheme, type your unique user name and password, then click **OK**. The User rights field of the status bar wild display your user name, and, if your pre-programmed access level is Administrator or higher, the **Settings** menu button will appear on the right side of the screen.

5.2.2 Changing your password

When you are logged in with a password-protected user account, the Login pop-up box (accessed by right-clicking the User rights status bar field) will include an option to change your password. Click this option if you wish to modify the existing password. The system will prompt you to enter the existing password, then the new password, two times, for confirmation.
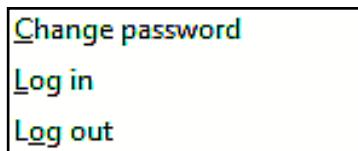
Fig. 5: *The Login pop-up box for password-protected user accounts*

5.2.3 Logging out from the system

1. Right-click into the User rights field of the bottom status line to display the Login pop-up box.
2. Click Log out in the pop-up box (see ***Fig. 5***). In the ''By level'' user login scheme, your access level will automatically revert to Operator.

ⓘ *In the "By user name" user login scheme, Administrator– and Service- level users can set up new user accounts.*

ⓘ *In the "By user name" user login scheme, whenever a user logs off the system, another user must be logged on. In this login scheme, the user software is non-operational unless someone is logged in.*

5.3 Database menu

The **Database** menu lets you manage analysis results. Using the functions on this screen, you can review, edit, or send to output the sediment analysis results and the microscopy images.
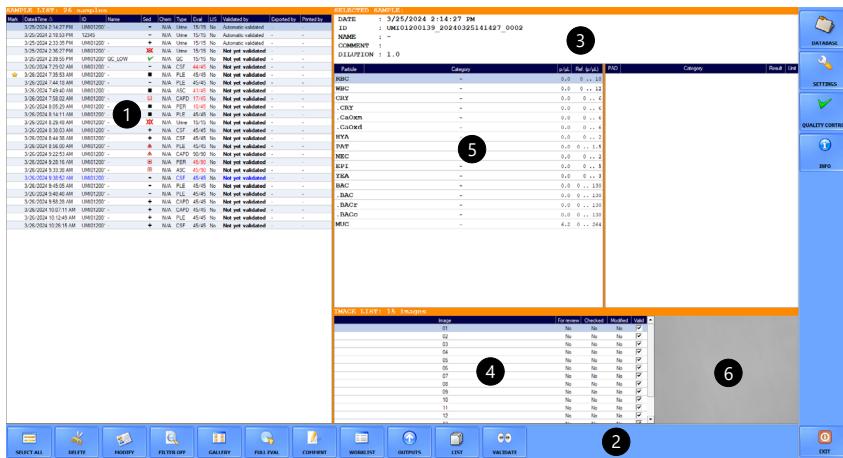
Fig. 6: *The database menu with windows and boxes numbered*

1. A scrollable list of the records for all the urine samples that the instrument has processed. In the default view, only a limited number of columns is displayed in the **Sample List**. To expand the **Sample List** to review the complete record for the processed samples, click the **LIST** button.

ⓘ *For information on how to set up the default columns of the* **Sample List***, see the* **Display** *tab.*

Key to all available columns of the Sample List	
Mark	Indicates (with a yellow star) whether you or another operator has marked the sample as special for any reason. ⓘ *Click on the mark field to mark and unmark samples.*
Sed/Chem. Instrument	The column shows the instrument serial number.
Date&Time	Displays the date and time when the instrument processed the sample. ⓘ *You can customize the format for the date and time on Display tab.*
ID	Displays the unique identifier of the urine sample: either the barcode on the test tube of the sample, or an identifier that the system generated based on the sequence of the sample, or the operator enters it during the measurement process.

Key to all available columns of the Sample List	
Name	Displays the name of the patient who supplied the sample.
Sed	Indicates (with pictograms) whether the sediment analysis result is positive, negative, or recommended for review by a laboratory professional.
Chem	The **Chem** column displays the results of the sample's chemical urinalysis performed by the interfaced test strip–based urine analyzer.
Type	Indicates the type of the analyzed liquid. It can be urine, one of the chosen body fluid type or QC solution.
Eval	Indicates the number of images that the system accepts as valid out of the fifteen that the system makes for each analyzed sample.
LIS	Indicates whether the sample was transferred over the connected LIS.
Sediment/ Chemical Measured by	These columns display the name of the operator who performed the given operation for the sample.
Validated by	
Sent to LIS by	
Exported by	
Printed by	
RUO	Indicates if the sample was analyzed in Research Use Only mode.
Microscopy mode	Automatic, when the analyzer evaluates the automatically taken images. Manual, when Live View is on and the operator positions the camera to take the viewfield images.
Cuvette LOT	Indicates the LOT number of the cuvette used for the given sample. (Only on analyzers equipped with RFID reader.)
Cuvette exp. date	Indicates the expiry date of the cuvette used for the given sample. (Only on analyzers equipped with RFID reader.)

2. **Database** menu function buttons bar. You can edit, filter, or modify one or more selected samples using the function buttons in this screen area.

Key to the function buttons of the Database menu	
Select All/ Deselect All	Click this button to select or deselect every record in the sample list. ⓘ *The button becomes inactive if there is only one sample record in the list.*
Delete	Click this button to delete the selected sample record or records from the sample list. ⓘ *If you delete sample records from the list, you will not be able to get them back.*
Modify	Click this button to edit some of the details of the selected sample. ➲ *The button becomes inactive if you select a QC result or more than one sample record.*
Filter Off/ Filter On	Click this button to toggle on or off the sample filter dialog box. (see **5.3.2**)
Gallery	Click this button (or double-click the row of a sample record) to display every microscopy image that the instrument has taken of the selected urine sample. Double-click any image in the gallery, or any record in the database to open it in Sample View Editor (SVE). Use **Quick particle** (***page 73***) feature to modify results in full-screen viewing. ➲ *The images will appear as a grid of numbered thumbnails, without any particle tags. Press letter c for particle tags to appear.*
Full Eval	Click this button to make the evaluation module evaluate every single microscopy image that is available for the selected urine sample or samples. ➲ *This function requires confirmation.* ➲ *This function is only available for users with administrator rights or above.*
Comment	Click this button to add a comment to the record of the sample, and to review the system comments for the sample. ➲ *This button becomes inactive if you select more than one sample record.*
Worklist	Click to launch the **Worklist editor**.
Outputs	Click this button to set up the export, transfer, or printing of the selected sample or samples.
List	Click this button to toggle between the expanded, full-screen view of the **Sample List**, and the limited default view of the list.
Validate	If manual validation is active, click this button to validate the selected sample or samples.

3. Selected sample header. This box displays the basic identifiers of the sample that you selected in the **Sample List**.

4. Microscopy image list box for the selected sample. You can review the basic details of all the view field images that the microscope took of the sample that you selected in the **Sample List**. Click any of the rows to preview the associated image in the image list thumbnail. The selected row will be highlighted in blue. Double-click any of the rows to view the associated image in the SVE (Sample View Editor).

5. Sediment analysis result box for the selected sample. This box lists the detailed sediment analysis result for the selected sample record for each particle type. You can modify the particle sediment results of a sample by double-clicking any of the particle class rows in the sediment analysis result box. In case of a connected chemical analyzer and checked **Show chemical data** checkbox on **Settings/Display** menu, the **Selected Sample** window is divided into a sediment and a chemical result window.

Key to the Image List header	
Image	The sequence number of the image. The numbering corresponds to the numbers used in the Gallery.
For review	This column indicates whether the image is recommended for review by a laboratory professional.
	There are two main reasons why a microscopy image is recommended for further review:
	• the image is so crowded with particles that sediment particle detection is unreliable
	• the detected number of mucus particles in the image exceeds the allowed level of mucus (you can disable this function)
Checked	This column indicates whether an operator has opened the image in the SVE (Sample View Editor).
Modified	This column indicates whether an operator has modified the automatic evaluation results in the SVE.
Valid	Select or deselect the checkbox in this column to accept or reject the image as the basis for automatic image evaluation.

6. Thumbnail of the view field image that is selected in the image list. Double-click the thumbnail image to view the view field image in the SVE (Sample View Editor). For more information about SVE see **7.2.1**.

5.3.1 Result indicator meanings

N/A

No sediment results available. The sample was analyzed only with the interfaced chemical urinalysis device but not using the microscopy method, or the sediment and chemical results could not be matched to a single sample because the sample was not barcoded, or because there was a barcode reading error.

+

Positive (abnormal) sample. The concentration of one or more particle classes exceeds the negative reference range in the sample. Detection of MUC, SPRM, and ART particles has no effect on this attribute.

-

Negative (normal) sample. All values of the enabled particles are within the negative reference range, except for MUC, SPRM and ART particles.

Hard review. Some images are so crowded that it can be difficult to distinguish all the particles present in them. The majority of the images of this sample have Yes in their `For review` column in `Image List` indicating that they are not accepted by the system. The comment **Review of images is necessary!** is displayed in the Sample list and **Image excluded from the automatic evaluation** in the Sample View Editor for these records, as they require manual re-evaluation (See *7.2.1 The Sample View Editor (SVE)*). The records will display N/A for every particle class as long as the results are not modified manually (See *7.2.2.1 Modifying microscopy results in the Database*). The automatic validation is disabled in case of hard review, therefore the operator has to validate the measurement records manually.

 or

Soft review. Only a few images of this sample have **Yes** in their `For review` column in `Image List` indicating that they are not accepted by the system. The comment **Review of images is necessary!** is displayed with the quantitative results and **Image excluded from the automatic evaluation** in the Sample View Editor for these records, as they require manual re-evaluation (See *7.2.1 The Sample View Editor (SVE)*). An automatic result is available for the sample. The automatic validation is disabled in case of soft review, therefore the operator has to validate the measurement records manually.

 or

MUC review. The mucus level in the sample is higher than the user-enabled limit in **Settings/Evaluation** tab. The measurement record has result, but has to be validated manually. The MUC review state and marking is only an indication for the operator, it is not exported, transferred or printed. The MUC review marking can be taken off, if the feature is disabled in **Settings/Evaluation** tab, its limit is raised or the Valid checkmark is taken off of some of the images.

ⓘ *This feature is enabled by default.*

■

Invalid sample.

Samples are indicated as invalid

- – if the Valid checkbox for all their view field images are manually unchecked;
- – if the status of the sample is manually set to invalid;
- – when records of invalid samples are exported or printed
- – the Sample status field indicates that the sample is invalid;
- – the message General sediment result: invalid is displayed in the header;
- – the message Invalid measurement is displayed in the Sediment result field;
- – N/A is displayed in all of the value fields and in all of the Category fields.

■

The analyzer indicating sample image review in the following cases:

1. The measurement data suggest that one or more images of this sample may have been taken slightly out of the normal focal plane range. The comment **Multiple images may be out of focus, please review** appears in the **Selected Sample** header. The measurement record has result, but has to be validated manually. It is recommended that the operator checks the images in the **Gallery** or the **SVE** and deselect faulty images from evaluation by unclicking the **Valid** checkmark from the **Image List**. In case of frequent occurrence, please call service.

2. The measurement data suggest that one or more images of this sample may have been taken slightly out of the normal focal plane range. The comment **Some images might be out of focus, please review** appears in the **Selected Sample** header. The measurement record has result, but has to be validated manually. It is recommended that the operator checks the images in the **Gallery** or the **SVE** and deselect faulty images from evaluation by unclicking the **Valid** checkmark from the **Image List**. In case of frequent occurrence, please call service.

3. The measurement data suggest that one or more images of this sample contains much more or much less particles than others. This phenomenon may occur naturally or as a measurement inaccuracy. The comment **Uneven particle distribution suspected, please review** appears in the **Selected Sample** header. The measurement record has result, but has to be validated manually. It is recommended that the operator checks the images in the **SVE** and deselect faulty images from evaluation by unclicking the **Valid** checkmark from the **Image List**. In case of frequent occurrence, please call service.

⊞ or ⊟
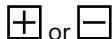
Cross-check rule is triggered.

Any of the selected cross-check rule is true for the given sample result of the sediment and chemistry analyzer. The operator with Administrator access can select the rules on the **Settings/Evaluation** tab.

ⓘ *This feature is not enabled by default.*

✔

QC measurement passed.

✘

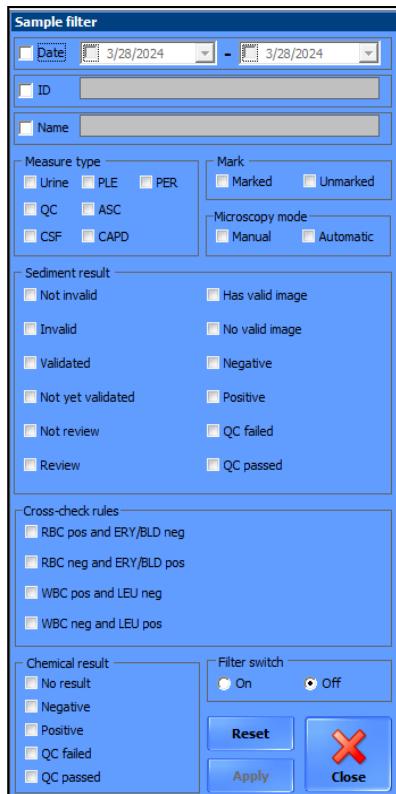QC measurement failed.

5.3.2 Data filtering

The data filtering function is not working during measurement with more than 5000 results in the database.

Click **FILTER ON** to bring up the **Sample filter** dialog box. Records can be filtered by date of measurement, patient name, ID, status, positive or negative result, standard or QC measurement, marked or non-marked and many parameters in sediment method.

Filtering by dates: Starting and/or finishing dates can be set by typing in or with the drop-down lists. You have to click in the checkbox to make the selections active.

Filtering by ID and Name: Click in the checkbox first to be able to type in the text box. The text box becomes red when an unusable character typed in.

Filtering by measure type or marking: Click in the checkbox for selecting between results of standard, body fluid or QC measurements, and marked or non-marked results.

ⓘ *Selecting none of the two choices is the same as both were selected.*

Filtering by the status of validation.

Fig. 7: *The sample filter dialog box*

Filtering by microscopy mode: Click in the checkbox for selecting between results of manual microscopy or automatic measurements.

Filtering by the characteristics of sediment results: Click in a checkbox that is for a parameter you want in your selection. If you do not select any checkbox the filtered sample list will show all results.

Filtering by the characteristics of chemical results: You can filter here for records of a sample with chemical results. Click in a checkbox that is for a parameter you want in your selection. If you do not select any checkbox the filtered sample list will show all results.

Filtering by the cross-check rule: You can filter for records of any cross-check rule compliance.

After making a selection of filter options tap `Apply` to display in the `Sample List` only the records that fit your conditions. Revert to the full `Sample List` by checking the radio button `Off` in the `Filter switch` bounding box and clicking `Apply`. When you check `On` again your previous selection becomes active again. Click **Reset** to clear selection.

5.4 The Settings menu

Click the **Settings** button to enter the Settings menu, where you can configure various aspects of the analyzer's functionality, categorized into tab groups that run along the top of the Settings menu.

ⓘ *The Settings button is disabled while a measurement is in progress.*

5.4.1 The Category tab

Fig. 8: *The Category tab in the Setting menu*

The analyzer device provides quantitative results for RBC and WBC and semi-quantitative category to all other sediment parameters. The relative ranges and the names of these semi-quantitative categories can be fully customized to fit the conventions of the testing site.

ⓘ *By default, the Category tab displays only the default set of particle classes and subclasses. The Category tab will only display the additional particle classes and subclasses that are specified on the Evaluation tab (See **Fig. 18)**, and only if the Enable extended categories checkbox is checked on the Category tab (See **Fig. 8)**.*

5.4.1.1 Modifying semi-quantitative relative categories

1. Double-click on the particle class row that you wish to modify to display the `Category modification` dialog box (see **Fig. 9**).
2. Enter the upper cutoff for the quantitative ranges of the semi-quantitative relative categories. The upper cutoff for a category will automatically be entered as the lower cutoff for the next category so that overlapping is prevented.

⚠ **Semiquantitative relative category number 1, topmost in the dialog box, is displayed as reference for each of the particle classes in the particle result window on the Database menu. You can disable the display of this reference range on the Display tab of the Settings menu.**
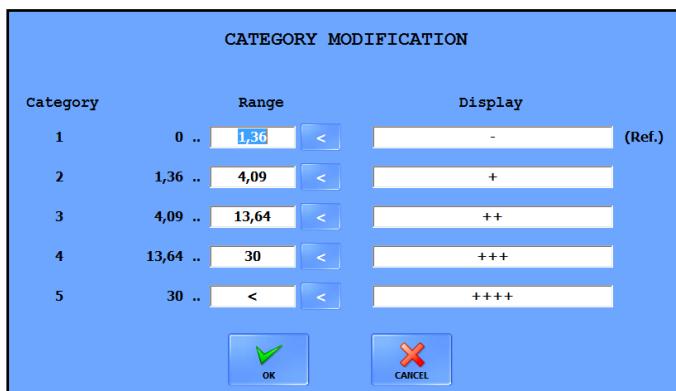

Fig. 9: *The Category modification dialog box*

ⓘ *The < symbol indicates the upper cutoff of the highest relative category range for the given particle class or subclass—modifying it will create a new relative category higher, up to a maximum of eight (8) relative categories.*

3. Enter the name that you would like the device to display for the semi-quantitative relative category.

ⓘ *The maximum length of twenty (20) characters is allowed for the category names. Empty and duplicate category names are not allowed.*

4. Click OK to store your changes or CANCEL to discard the changes. Click SET on the Category tab screen to save your modifications. The system will re-calculate the results and use the new categories to display results in the Database menu, the Sample View Editor, and on transferred, exported and printed analysis reports.

ⓘ *You can revert to the default relative category names and ranges by clicking DEFAULT DEFINITIONS.*

⚠ **The relative categories of particle classes and their subclasses are identi-cal by default. However, you can modify any of the particle subclasses independent of their parent particle class.**

5.4.1.2   Exporting and importing relative categories

• You can export the customized relative category ranges that you have set up to other analyzers, in a .csv file. To export the current ranges, click the `Export` but-ton in the top right-hand corner of the Category tab, set the path for the export in the pop-up dialog box, and then exit the dialog box.

• To import a previously exported set of relative category ranges, click the `Import` button on the Category tab, select a .csv file in the pop-up dialog box, click the `SET` button, and then close the dialog box.

ⓘ *If you are creating a category range .csv file from scratch, create a table (us-ing Microsoft Excel, for example) that matches the following formatting protocol:*

Header			
Particle	Maximum	Display	…
[abbreviated name of particle class]			
…			

5.4.2   The Display tab

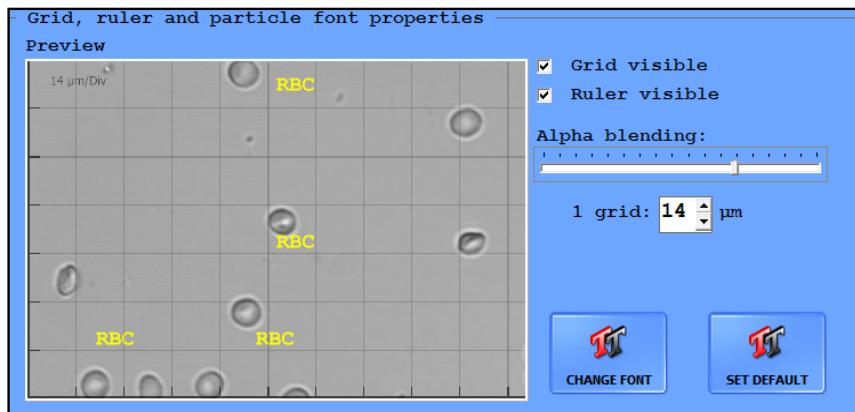### 5.4.2.1   Grid, ruler and particle font properties

Fig. 10: *The Grid, ruler, and particle font properties window*

This screen area displays a preview of a random microscopy image as displayed in the **Database** menu. The settings that you make here take effect in the **Sample View Editor.**

- Toggle the grid and the ruler overlay in the **SVE** screen with the **Grid visible** and Ruler visible checkboxes, respectively (SVE keyboard shortcuts)
- You can specify the opacity of the grid lines (how clearly visible the lines are) with the Alpha blending slider: Increase the width of the lines by moving the slider to the right.
- In the 1 grid: text box, you can set the length (μm) of the sides of the unit square of the grid for easier determination of the size of particles in the images.

ⓘ   *If the ruler is enabled, the unit grid size is displayed in the top left corner of the microscope images in the SVE.*

- Click **CHANGE FONT** to display a pop-up window with options for how you would like the tags in the microscopy images to appear: font, font style, font size, effects, color, and script can be set.

ⓘ   *The language used in the Fonts dialog box is the language specified for the operating system of the connected PC as the display language.*

- Click **SET DEFAULT** to revert to the default font settings: 14-point yellow Courier New Bold characters using the Central European script.
- Click the radio buttons next to the flags and country demonyms to modify the display language of the system.
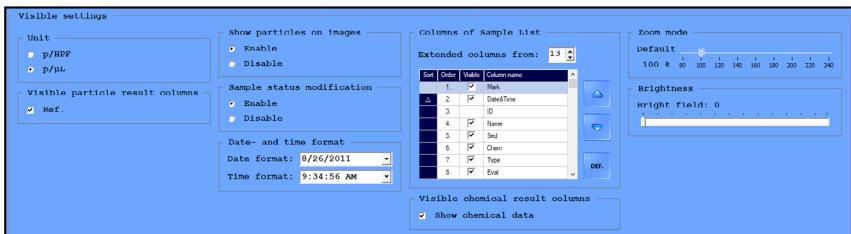
5.4.2.2 The Visible settings screen area

Fig. 11: *The Visible settings window*

- Click the radio buttons in the **Unit** dialog box to set the default measurement units to either particles per High Power Field or particles per sample microliter.

ⓘ *If you change the default unit, the system will retroactively recalculate all the measurement results for every sample in the database.*

- Click the radio buttons in the **Visible particle result columns** dialog box to enable or disable the **Ref.** column in the results summary.

- In the **Show particles on images** dialog box, click the radio buttons to enable or disable the automatic tagging of particles in the view field images.

- Check the checkboxes in the **Sample status modification** dialog box to enable or disable manual modification of the status of samples.

- Use the **Date- and time** format text boxes to select how the date and time should appear in the displayed, exported, printed, and transferred measurement results.

- In the **Columns of Sample List** dialog box, you can:
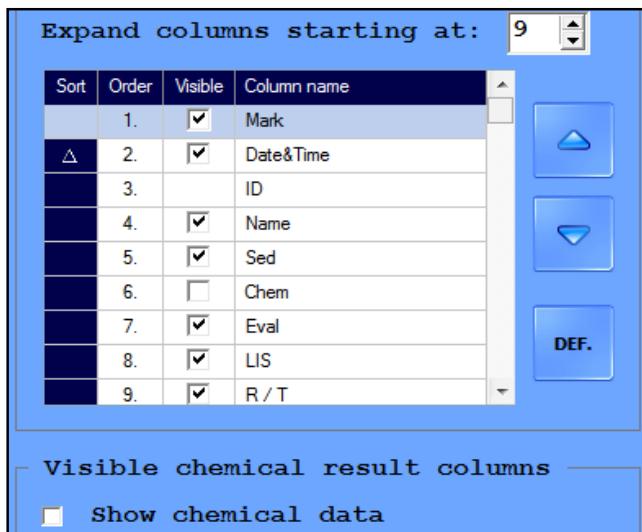
Fig. 12: *The Sample List will display 8 columns in compact view; chemical urinalysis results will be omitted; the samples in the list will be sorted by date in descending order*

- – enable or disable any of the available columns in the sample list by checking or unchecking their checkboxes;
- – modify the order in which they appear by selecting a row and moving it towards the beginning or end of the list using the [△] and [▽] buttons;
- – sort the samples based on any of the column parameter by clicking the box of the column: clicking once will sort the samples based on the selected parameter in ascending order; clicking twice will sort the samples based on the selected parameter in descending order;
- – specify how many columns are displayed in the compact view of the **Sample List** by increasing or decreasing the number in the **Extended columns from:** text box (for example, if the number in the box is 9, columns up to 9 (that is, 1–8) will be displayed in compact view;
- – and revert to the default **Sample List** setup by clicking **DEF**.

- If a chemical urinalysis device is interfaced to your device, use the checkboxes in the **Visible chemical result columns** to enable the display of the chemical measurement results.
- Set the default percentage of magnification of the selected image on the **Zoom mode/Default scale**.
- Set the default degree of brightness to images for better visibility on the **Brightness** scale. The scale appears in SVE.

ⓘ *Using the scale in SVE does not change the setting.*

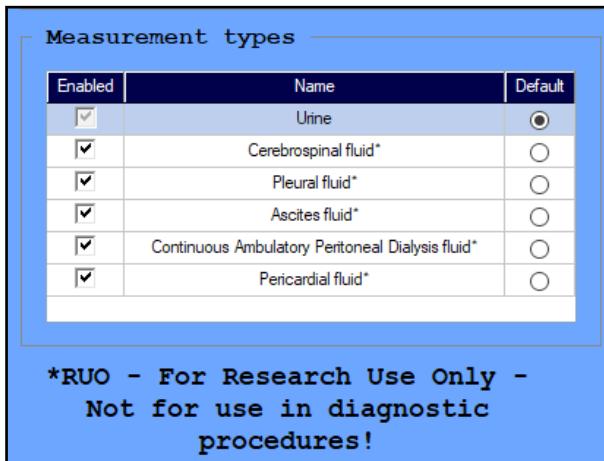### 5.4.3 The Measure tab

5.4.3.1 Measurement types

Fig. 13: *The Measurement types window*

Enable any measurement type by clicking in their checkbox. The analyzer is set to urine mode by default.

⚠ **The Body fluid measurement mode is for research use only.**

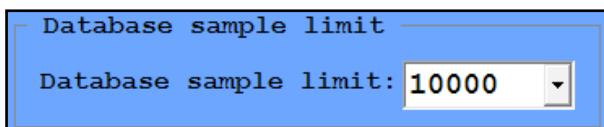#### 5.4.3.2 Database sample limit

Fig. 14: *The Database sample limit window*

- Use the **Database sample limit** text box to specify the size of the results database between 1000 and 10000 records.

ⓘ *If there is any body fluid measurements selected on* **Settings/Measurement** *screen, the limit is maximalized in 1000 measurements and the* **Database sample limit** *text box becomes unavailable.*

5.4.3.3 Validation

⚠ **Only validated results can be exported, printed, or transferred.**
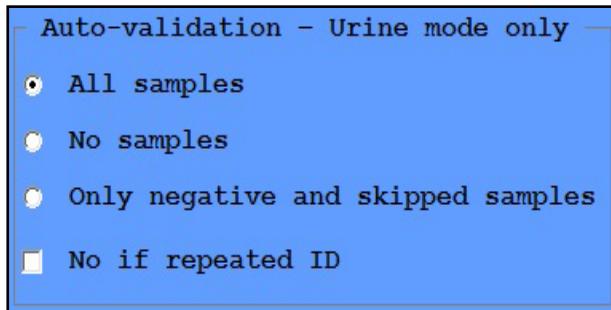
Fig. 15: *The Validation window*

Use the radio buttons to specify whether all, none or only the negative measurement results are required to be validated automatically.

Use the checkboxes to cancel possibilities of auto validation in case of a generated ID.

⚠ **A measurement result cannot be validated automatically if its status is: Empty, Soft review, Hard review, MUC review, BAC review, Cross-check rule flagging or Low level.**

5.4.3.4 Worklist settings
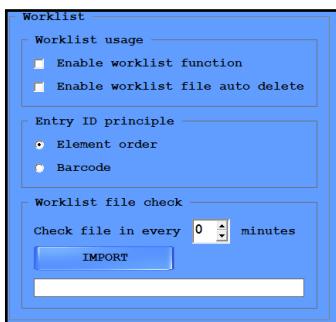
Fig. 16: *The worklist window*

Worklist usage

- Check the **Enable worklist function** check box to make the device automatically assign the patient names and comments in a predefined worklist to measurement results.)
- In case you are using a worklist uploaded as a text file from an external location, check the **Enable worklist file auto delete** check box to make the device delete a worklist file as soon as it has processed all the entries on the list.

Entry ID principle

– When performing a measurement cycle based on a worklist, you have the option to assign the patient names and comments defined in the worklist to sample measurement results either based on the sequence in which the device measures them, or based on the bar codes attached to the sample test tubes. Click the relevant radio buttons to select your preferred setting.

⚠ **If you wish to assign worklist data to measurement results based on bar codes, make sure that you include not only patient names but barcodes as well in the worklist entries.**

Worklist file check

– If you wish to import a worklist click IMPORT to display a dialog box to define the path for the worklist file. If you would like to continually update the worklist based on the imported worklist file, Check file in every X minutes text box to specify how often the system should refresh the worklist based on potential changes in the external worklist file.

⚠ **If you enable refreshing the worklist (the number of minutes in the check box is >0, the Enable worklist file auto delete check box becomes checked and disabled by default.**
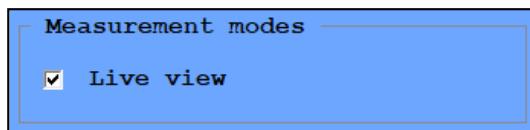
5.4.3.5 Enable Live view

Fig. 17: *Live view checkbox*

The Live view mode is a unique feature of the analyzer, which gives the opportunity to the user to examine the sample in the cuvette via live image of the camera. After the cuvette arrives to the microscope the user has the option to move the cuvette via on-screen buttons, to change the focusing height and to take images of any area of the cuvette. The user has live view of the cuvette during the process, which could be useful if the user wants to study any possible movements in the sample. The taken images are evaluated by evaluation module of the device.

Set up the possibility of manual microscopy on the **Settings/Measure** screen by checking **Live view** checkbox.

For more information about the Live view go to "*Operation*".

5.4.3.6 Predefined comments

Prepare predifined comments (maximum 30) that you can choose from for any the measurement records in the **Database**.

1. Select mesurement type from the drop-down list.
2. Go to **Settings/Measure** menu.
3. Tap **NEW** button in **Predefined comments** section.
4. Enter the comment and tap **SAVE**.

5.4.4   The Evaluation tab

On this tab, you can specify which sediment particles you would like the device to identify in the view field images by checking the checkboxes that correspond to the particle classes and subclasses that you wish to include, and unchecking the ones to leave out.

⚠ **You will need to check the enable extended particle categories checkbox to activate the particle classes and subclasses that are not automatically identified by the device. These 'added particles' are displayed in red after you activate them, and their checkboxes become active.**

⚠ **Only the particle classes and subclasses that you have checked on this tab are available as tags in the Sample View Editor. However, if you enable the 'Extended particle categories' and check any of them, the system will reevaluate all the previous view field images and retroactively assign the newly enabled parameters where necessary.**

Fig. 18: *The Particle settings window on the Evaluation tab*

5.4.4.1 Using the Evaluation tab

- Select measurement type from the drop down menu.
- Subclasses may be enabled only if their parent classes are enabled.
- All subclasses of a disabled parent particle class become disabled too.
- Whenever you enable a parent particle class, its subclasses' status will revert to the default setting. The default setting for subclasses is disabled except for CaOxm and CaOxd crystals.
- Click the **SET** button to save your changes. The system will reevaluate all previous samples using the new settings, and measurement results will be displayed, exported, printed, and transferred with the particle tags you enabled on this tab.
- Click the **SET ALL** button to enable all of the particle classes and subclasses. An alert dialog box will pop up prompting you to confirm the action.
- When **BAC** is enabled, BACr and BACc subclasses are automatically recognized and separated during evaluation, but either or both subclasses can be deselected.
- Set up a user defined particle (UDP1-5):
1. Enable extended particle categories in Settings/Evaluation tab.
2. Check in first unused UDP checkbox. The SET button becomes available.
3. Tap SET button and the Set cell properities window appears.
4. Give it a short and/or a longer name.
5. To use it, open SVE, select the required UDF from Quick Particle list and tag it on the images.

ⓘ *The UDPs do not get automatic results, the user can enter the result in the Average/ image text box of the SEDIMENT RESULT MODIFICATION window.*

5.4.4.2 Particle setting defaults

Click **DEFAULT** to revert to the following default settings.

✔: Enabled		✗: Disabled	
RBC	✔	CaOxd	✔
WBC	✔	URI	✗
WBCc	✗	TRI	✗
NEC	✔	YEA	✔
EPI	✔	BAC	✔
PAT	✔	BACr	✔
HYA	✔	BACc	✔
CRY	✔	MUC	✔
CaOxm	✔	SPRM	✗

5.4.4.3 Full list of evaluated particles

Class	Subclass	auto	added
Red Blood Cells		RBC	
	Isomorphic RBC		RBCi
	Dismorph RBC		RBCd
	RBC-Aca (Acanthocyte)		RBC-Aca
	RBC others		RBC-oth
White Blood Cells		WBC	
	White Blood Cells Clumps	WBCc	
Squamous Epithelial Cells		EPI	
Non Squamous Epithelial Cells		NEC	
	Superficial Trans. Epithelial Cells		s-TRA
	Deep Transitional Epithelial Cells		d-TRA
	Renal Epithelial Cells		REN
Lipids			LIP
	Lipids - Oval Fat Bodies		REN-L
	Lipids - Free Droplets		LDR
	Lipids - Cholesterol Crystal		CHOL
Casts - Hyalin		HYA	
Casts - Pathological		PAT	
	Casts - Hyalin-granular		C-HGR
	Casts - Granular		C-GRA
	Casts - with Renal Tubular Cells		C-NEC
	Casts - RBC		C-RBC
	Casts - WBC		C-WBC
	Casts - Crystal		C-CRY
	Casts - Microorganism		C-MIC
	Casts - Fatty		C-FAT
	Casts - Waxy		C-WAX
	Casts - Mixed		C-MIX

Class	Subclass	auto	added
Crystals		CRY	
	CRY – Calcium-oxalate monohydrate	CaOxm	
	CRY – Calcium-oxalate dihydrate	CaOxd	
	CRY – Triple-phosphate	TRI	
	CRY - Uric acid	URI	
	CRY - Calcium-phosphate		CaPh
	CRY - Amorphous urate		U-AMO
	CRY - Amorphous phosphate		P-AMO
	CRY – Cystine		CYS
	CRY – Leucine		LEU
	CRY – Tyrosine		TYR
	CRY – Atypical		ATY
Yeast		YEA	
Bacteria		BAC	
	Bacteria Rods	BACr	
	Bacteria Cocci	BACc	
Mucus		MUC	
Spermatozoa		SPRM	
Unclassified particles			UNC
Parassites – Schistosoma Haematobium			SCH
Artifacts			ART
UDP1,UDP2,UDP3….			

5.4.4.4   MUC review settings
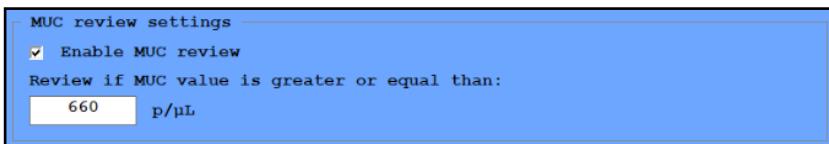
Fig. 19: *MUC review settings*

Set a p/µl or p/ HPF value in the text box and check **Enable MUC review** in the dialog box to enable the automatic highlighting (with a red circle) of samples with a Mucus particle level that exceeds the set p/µl or p/ HPF value.

ⓘ   *This setting is enabled by default. Users with administrator rights or above can alter the threshold limit. Altering the limit has no retroactive effect.*
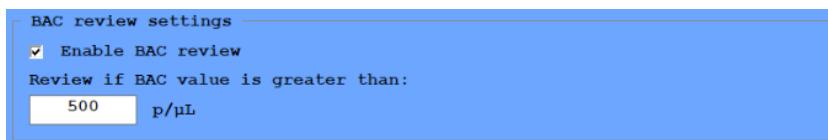
5.4.4.5 BAC review settings

Fig. 20: *BAC review settings*

Set a p/µl or p/ HPF value in the text box and check **Enable BAC review** in the dialog box to enable the automatic highlighting of samples with a Bacteria particle level that exceeds the set p/µl or p/ HPF value.

ⓘ *This setting is enabled by default. Users with administrator rights or above can alter the threshold limit. Altering the limit has no retroactive effect.*

5.4.4.6 Cross-check rules
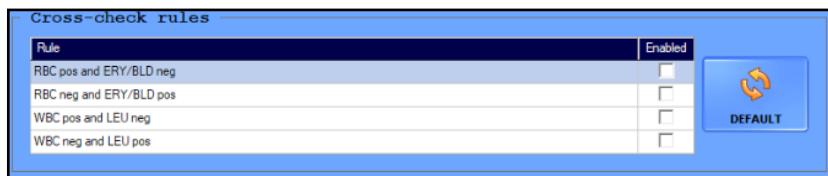
Fig. 21: *Cross-check rules*

In case a cross-check rule is selected, it provides a status mark (black square) and a specific comment, when the rule is true for the sample results of the sediment and chemistry analyzer. Cross-check rules exist for RBC & ERY discrepancy, and WBC & LEU discrepancy to support operator decision for result modification/ validation.

ⓘ *This setting is not enabled by default. Users with administrator rights or above can enable them.*

5.4.4.7 UTI-flag

Fig. 22: *Uti flag*

Enable/disable the automatic flagging of samples with WBC and BAC particle levels that equal or exceed the set values. The **UTI flag trigger level** box is visible only when the flag is enabled. The default levels are the upper limit of the negative range.

This setting is enabled by default. Users with administrator rights or abovecan alter the threshold limit. Altering the limit has no retroactive effect.

If the flag is enabled, the automatic evaluation indicates by a green flag in **Database/Selected sample** window if the WBC and the BAC levels equal or exceed the set limits in the sample. Flag can be added or deleted in the **Modify sediment result** (see *7.2.2.1 Modifying microscopy results in the Database*) popup window.

5.4.5 The Transfer tab

The **Transfer** tab lets you adjust the data management settings.

5.4.5.1 The Transfer screen area
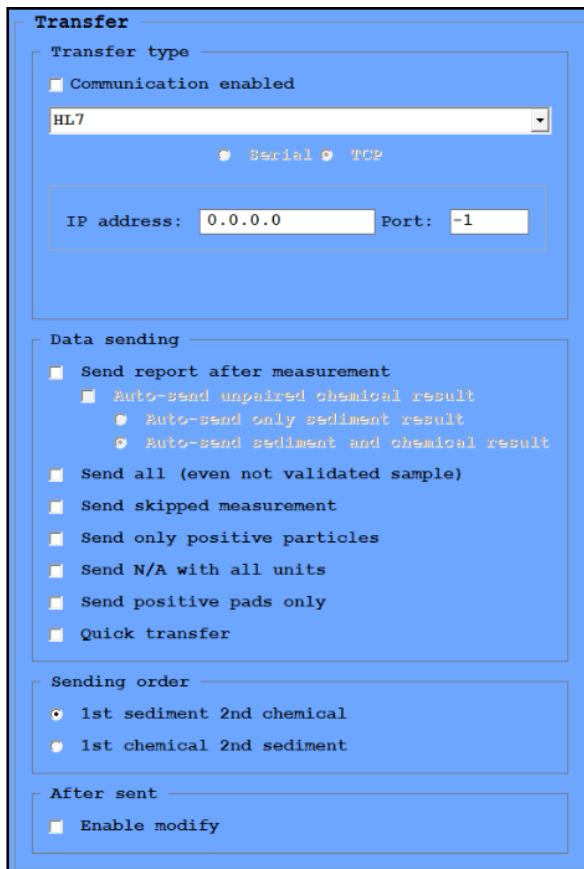
Fig. 23: *The Transfer screen area on the Transfer tab*

The settings in the two dialog boxes apply to data transferred.

- Select unidirectional, bidirectional, LIS2 A2 or HL7 transfer option from the drop down list.

ⓘ *HL7 only works with TCP connection.*

- Click the radio buttons to select the connector for transmission. HL7 is only available via TCP connection.
- Set IP address and port or baud rate in drop-down list.

⚠ **Contact your distributor to determine which transfer type and transfer speed you require.**

- Check the Send report after measurement checkbox to enable the automatic transfer of the results table of each processed sample.
  - Check the **Auto-send unpaired chemical result** to send chemical records to LIS with no matching pair, straight after their arrival from the chemical analyzer. Choose between the options to **Auto-send only sediment result** or **Auto-send sediment and chemical** result after sediment measurement.
  - Check **Send skipped measurements** to send measurement records with intentionally cancelled sediment analisys.
- Check the **Send all (even not validated sample)** checkbox to be able to send all results to LIS.
- Check the **Send only...** check boxes in the **Data sending** screen area to leave out particle classes and subclasses or test strip pads (if urine chemistry results are available) with negative results to reduce the size of transferred data.

ⓘ *If you enable one or both of these features, the message **Only positive items** is displayed as the first line of the transferred results table.*

- Check the **Send N/A with all units** checkbox to send **N/A** to LIS in all unit (p/μL, p/HPF, number and category) when the sample is invalid or the result is **N/A**.
- Check the **Quick transfer** checkbox to enable the one-click transfer to LIS of selected records. If **Quick transfer** is enabled, and the **Sample List** screen is active, you can press the F3 key to automatically transfer any selected record.

ⓘ *The records that you would like to transfer this way need to be validated otherwise they won't be transferred without notice.*

- Choose the preferred sending order of the chemical and sediment results to LIS.
- Check the **Enable modify** checkbox in the **After sent** window panel to be able to modify results after they were sent to LIS.
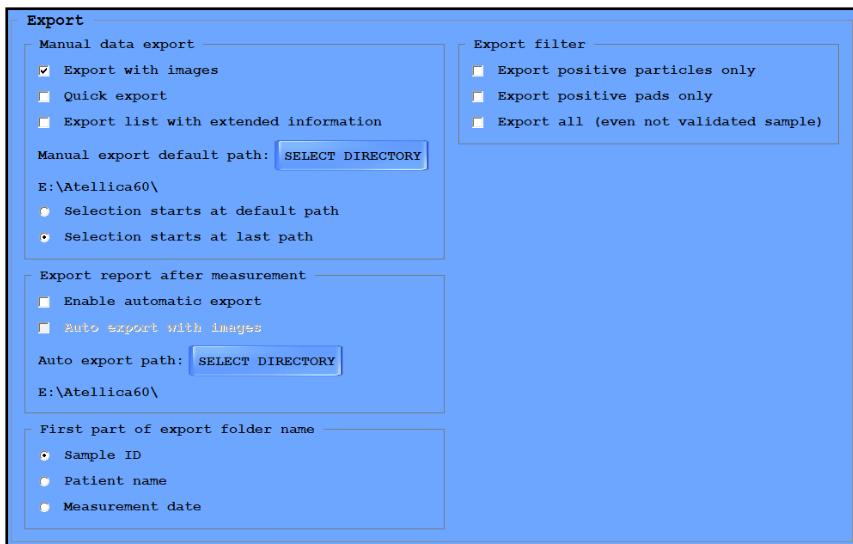
5.4.5.2 The Export screen area

Fig. 24: *The export screen area on the Transfer tab*

- Check the **Export with images** checkbox to include view field images with the results tables when exporting results manually.

- Check the **Quick export** checkbox to enable the one-click exporting of selected records. If **Quick export** is enabled, and the **Sample List** screen is active, you can press the F2 key to automatically export any selected record in the same folder where you last exported sample records.

ⓘ *The records that you would like to export this way need to be validated, otherwise they won't be exported without notice.*

- Check **Export with extended information** when you want to add more details to the result lists. These information include the dilution factor, any possible sediment and system comments connected to the selected result.

ⓘ *If you previously set up a default export directory, Quick export will use this default path.*

- Click the **SELECT DIRECTORY** button to set up a default export path for future sample record exporting.

- Select one of the radio buttons to determine whether the export path dialog box displays the default directory (if you have set one up), or the directory of the last sample export as the suggested export path.

ⓘ *The export path dialog box is displayed only if Quick export is disabled.*

- In the **Export report after measurement** dialog box, check the checkboxes to enable the automatic export of each processed sample, with or without view field images, to a folder on the PC you can specify by clicking the **SELECT DI-**

RECTORY button. Results are exported as html tables and separate folders for each of the samples is generated inside the folder you specify.

⚠ **If you enable automatic export, the Export button in the Outputs dialog box on the Database menu becomes active when no measurement is in progress.**

- Click the radio buttons in the **First part of export folder name** dialog box to specify whether you would like names of the folders generated for the sample results to start with the sample ID, the patient's name, or the date of the measurement.

ⓘ *All three details will be included in the name of the generated folders, regardless of which radio button you select.*

- Check or uncheck the **Export positive particles only** checkbox to enable or disable the editing of the measurement results when exporting them: you can decide to leave out particle classes and subclasses with negative results to reduce the size of transferred data.

- **Export positive pads only** checkboxes to enable or disable the editing of the measurement results when exporting them: you can decide to leave out test strip pads (if chemical urinalysis results are available) with negative results to reduce the size of transferred data.

- Check the **Export all (even not validated sample)** checkbox to be able to send all results to the preferred destination.
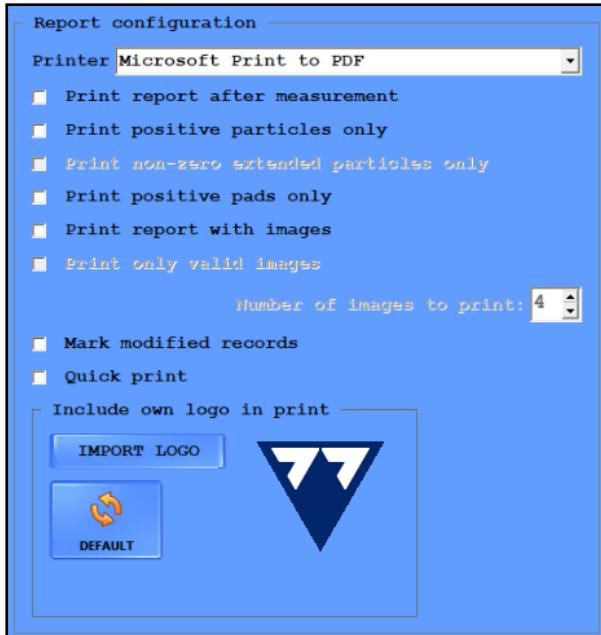
5.4.6 The Print tab

Fig. 25: *The Report configuration dialog box on the Print tab*

On this tab you can specify the settings for the printout on the connected printer.

- Select the printer you would like to use.
- Check the `Print report after measurement` checkbox to enable the automatic printing of each processed sample.

⚠ **The filters are available only if automatic printing is enabled.**

- Check or uncheck the `Print positive particles only` or the `Print positive pads only` checkboxes to enable or disable the editing of the measurement results when exporting them: you can decide to leave out particle classes and subclasses or test strip pads (if chemical urinalysis results are available) with negative results to reduce the size of printed data.

ⓘ *If you enable one or both of these features, the message Only positive items is displayed as the first line of the printed results table.*

- Check `Print non-zero extended particlePrint s only` checkbox to make sure none of the enabled added particles with no actual findings are printed.
- Check the `Print report with images` checkbox to print view field images when printing results. If you enabled image printing, you can choose `Print only valid images` and, use the up and down arrows next to the `Number of images to print...` spin box to determine the number of view field images that are printed for each record.

ⓘ *By default, view field images are not printed.*

- Check the `Mark modified records` checkbox to enable the highlighting of manual modifications of the automatic sample evaluations on the printout. If you enable this feature, the Mod. tag will appear on the printout next to the results that have been manually modified.

- Check the `Quick print` checkbox to enable the one-click printing of selected records. If you enable this feature and the `Sample List` screen is active, press the F4 key to automatically print off any selected record.

ⓘ *The records that you would like to print this way need to be validated, otherwise they won't be printed without further notice.*

5.4.7 The Maintenance tab

5.4.7.1 Laboratory name

Enter the name or code of your laboratory in the text box to display it as a header on printed reports, and on exported sample results.

5.4.7.2 Diagnostic report

Click the `DIAGNOSTOC` button in the dialog box to generate a status report of the software and driver versions, and the current settings of the analyzer, saved in the folder you specify in the file path popup window.

ⓘ *Report generation may take up to several minutes, during which the system will not respond.*

⚠ **It is highly recommended that you generate a diagnostic report every time you encounter a problem or upgrade the software, and send it to your distributor for evaluation.**

5.4.7.3 Raw data export

In case of noticed evaluation irregularities click this button to save measurement process-related information in a password-protected zip file to a selected folder. Send it to your distributor for investigation.

5.4.7.4 Users

Administrator– and Service-level users can manage (create, modify, or delete) user accounts in this dialog box by selecting the accounts and clicking the relevant buttons.

⚠ **The default password for newly created user accounts is the same as the user name, which needs to be changed at the first login.**
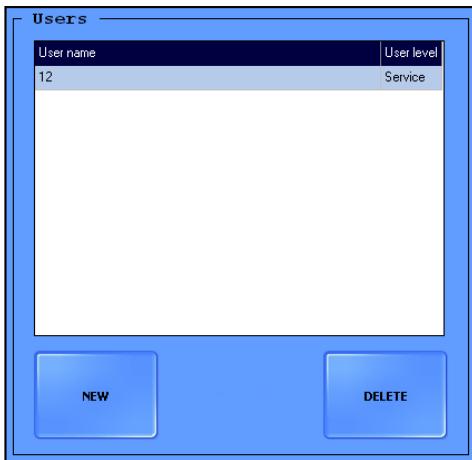

Fig. 26: *The Users dialog box*

ⓘ *Administrator-level users may only manage Operator– and Administrator-level user accounts.*

⚠ **You cannot delete your own user account.**

⚠ **The Users dialog box is available only if the "By user name" user login scheme is in use.**

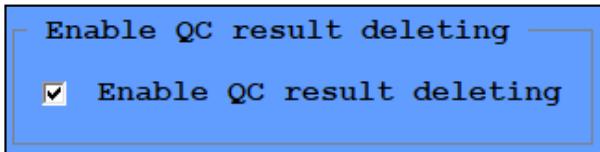### 5.4.7.5 Enable QC result deleting

Fig. 27: *Enable QC result deleting checkbox*

Check Enable QC result deleting to override the protection of QC data and disable the warning message Delete is not available, because QC result deleting is not enabled! whenever you attempt to delete QC results.
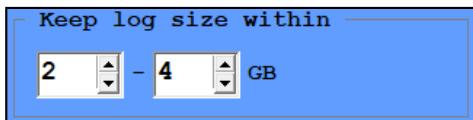
5.4.7.6 Keep log size within

Fig. 28: *The Users dialog box*

The operator can maximize the size of log files.

5.4.7.7 Backup and Restore

Fig. 29: *The Backup and Restore box*

The database, the images and the .ini files can be saved in a password protected .ZIP file.

1. Click **BACKUP** button.
2. Enter password twice in the appearing popup window.
3. Select target location for the backup file. Make sure that there is enough space for the backup file for the selected location. Enter name for the file.
4. Click **SAVE** to save the files. The database, the images and the .ini files are saved on the analyzer hard drive or the USB device in a password protected ZIP file.
5. Click **Cancel** the exit without saving the files

To restore the previously saved files:

1. Click **RESTORE** button.
2. The message **After a successful restore, the system will restart** appears. Click **OK** to continue the restore. You can click **Cancel** to exit without restore.
3. Enter password in the appearing popup window.
4. Select the location of the file to restore.
5. Click **SAVE** to restore the files.

6   Operation

Depending on the needs of your laboratory, there are two workflows you can choose from:

- Quick analysis using automatically generated sample IDs, where either you leave the sample ID as it was generated, or change it after the measurement (see *7.1.1 Editing test results*).
- Analyzing barcoded samples, where the data related to the patient of the given samples are attached to a barcode and are stored in the LIS.

You can further customize some aspects of the analysis process itself (see *5.4 The Settings menu*), and what happens to the analysis results after the analysis process is finished (see *7.1 Test results*).

6.1   Cuvette handling

The analyzer operates with single use disposable cuvettes. Cuvettes are supplied in containers, each holding 50 cuvettes. Before starting the measurement cuvettes should be loaded into the instrument.

Take a cuvette container supplied by the manufacturer and insert it into the cuvette holder seat. The asymmetric shape of the container assures the proper alignment. After placing the container into the cuvette holder seat, remove the sticker from the bottom of the container by simply pulling it. Hold firmly the top of the container while pulling the sticker, to prevent the container from falling out. Empty cuvette containers should be removed from the instrument and disposed separately.

Important!

The analyzer can be operated only with its own cuvettes supplied by the manufacturer or distributor of the instrument.

⚠ **Cuvettes are for single use only. Never use cuvettes for more than one time.**

⚠ **Never touch unused cuvettes, as any contamination might frustrate the microscopic evaluation.**

⚠ **Remove the sticker from the cuvette cartridge only after it has been inserted into the cuvette holder seat. Otherwise, cuvettes can fall out easily from the container during insertion.**

⚠ **Never refill the cuvette cartridges with any fallen out cuvettes.**

⚠ **Never use damaged or contaminated cuvette cartridges.**

⚠ **Cuvette cartridge can be removed from the instrument only with the cuvette holder seat. The cuvette holder seat with the cuvette cartridge must be handled carefully when taken out and is forbidden to be tilted or turned round as cuvettes could fall out or their directions could change.**

⚠ **Always empty the waste bin before placing a new cuvette cartridge in the analyzer.**

6.2   Worklist

 Click to launch the Worklist editor. You can populate the worklist with the names of the patients whose samples you want to analyze. The system software will automatically assign the names entered to test results during measurement based either on their sequence or on their identifying barcodes, according to your preferred setting. For further details see *5.4.3.4 Worklist settings*.
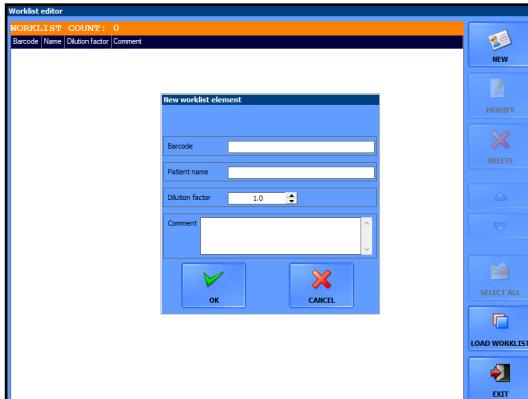

Fig. 30: The Worklist editor window with a New worklist element dialog box

Key to the Worklist Editor	
	Click to add a new **Patient Name** to the worklist. You can add a corresponding barcode if applicable, as well as a comment. (Comments are displayed in the results summary window of the **Selected Sample** screen area and appear on the printout.) No duplicate barcodes are allowed.
	Click to edit the details of the selected worklist element.
	Click to delete the selected worklist element or elements.
	Click to toggle selection of all the records on the **Worklist**. The button is inactive if there is only one record on the **Worklist**.
	Click to import a Worklist created on an external computer.
	Click to close the **Worklist editor.**

6.3 Measurement

6.3.1 Regular measurement

ⓘ *Before you begin, prepare your native urine samples for manual pipetting according to the standards in your laboratory. Homogenize the samples.*

1. Switch on the analyzer, and the connected computer monitor. The user software of the instrument will start automatically.
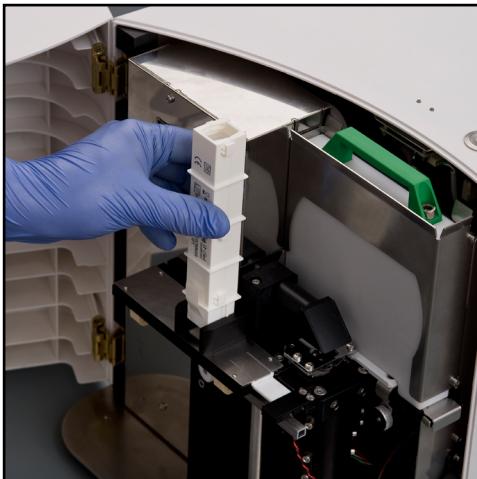
Fig. 31: *Press the On/Off button to switch on the analyzer*

Fig. 32: *Open the analyzer door to access the cuvette holder slot*

2. Open the door of the analyzer and place the cuvette holder into the holder slot. Carefully remove the piece of tape from the bottom of the cuvette holder after placing it into the instrument.

Fig. 33: *Slide a cuvette holder into the holder slot, then remove the tape from the bottom before you start a measurement*

3. Feed a cuvette from the holder into pipetting position, by pushing the **Start** button on the top of the analyzer.

Fig. 34: *The Start button on the top of the analyzer is the only interface element you need: press it once and the system feeds a cuvette into pipetting position.*

4. The system feeds a cuvette from the cuvette holder into the pipetting position, and prompts you to pipette the sample into the cuvette (see *Fig. 35*). If you are using barcoded samples you have to scan the barcode now to assign patient ID to the particular measurement.

ⓘ *The system stores only one patient ID at a time. At any multiple barcode scanning the system always uses the last scanned barcode.*

5. When a cuvette is in the pipetting position, manually pipette 175 µl of native urine sample into the cuvette's fillup inlet (see **Fig. 36**). Make sure to hold the pipette perpendicular to the cuvette. For pipetting the cuvette place the pipette tip onto the cuvette inlet and fill the cuvette by pressing the button of the pipette. Lift the pipette tip from the cuvette inlet and release the pipette button.

⚠ **Do not touch or put your finger through the pipetting window when the analyzer is in use to avoid accidents.**

Fig. 35: *When the cuvette is in the pipetting position, a message prompt appears. Scan the barcode or type in ID. Click OK and push the start button again to start cuvette processing.*

Fig. 36: *The backlighting under the see-through plastic cuvette helps you guide the tip of the pipette for fast and efficient work*

⚠ **Pay particular attention not to spill any sample inside the instrument. To avoid mechanical jam of the cuvette transporting system, clean the inside of the instrument after every unsuccessful pipetting.**

ⓘ *The pipette you can use with the instrument should be capable of aspiring 175±5 uL liquid. The dispenser hole of the pipette tip should be at an outer diameter of 1.2-2.8 mm). Do not use pipette tips with an outer diameter less than 1 mm.*

⚠ **If the diameter of the pipette tip is less than 1 mm, it may get stuck in the cuvette inlet.**

ⓘ *If there is a problem with the pipetting, and you would like to start over with a new cuvette, do not try to remove the cuvette by hand. Press the Start button and hold it until initialization is started. The system will push the cuvette directly into the waste drawer, then you can start the measurement again.*

⚠ **Pay particular attention to correct pipetting to avoid receiving false results.**

Fig. 37: *The proprietary disposable cuvette. Key:*
1: Fill up inlet
2: Fill up channel
3: Imaging chamber
4: Bubble capillary
5: Overflow

6. To start the centrifugation and the microscopy sediment analysis, press the Start button once again. At the end of evaluation the system disposes the used cuvette into the waste drawer.

⚠ **Do not try to tilt or move the analyzer during measurement as it could move the cuvette out of its place and cause the cuvette transporting system to jam and also could compromise the measurement result due to disrupting of the focusing process.**

7. Repeat steps 3–5 for each new sample that you want to analyze. If the cuvette holder runs out, you need to load another cuvette holder into the analyzer.

⚠ **Always change the tip of the pipette between the samples to avoid sample carryover.**

8. At the end of the day, remove and empty the waste drawer (see ***Fig. 38***), and dispose of the used cuvettes according to the laboratory guidelines for biohazardous waste.


Fig. 38: *Do not leave any used cuvettes in the waste drawer at the end of the day. Use the overhanging flap of the waste drawer to grip it and take it off the analyzer.*
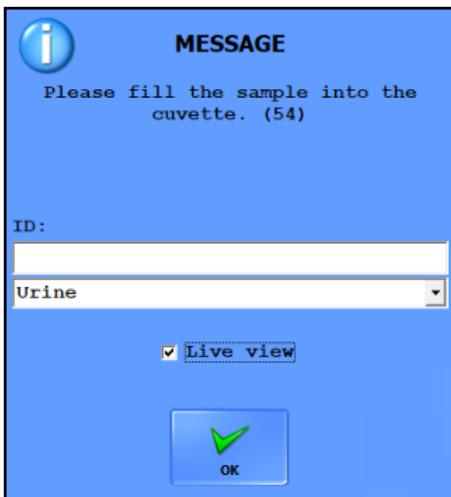
6.3.2 Live view

You can customize the positions where the microscope takes the view field images, and the microscope focus height during the imaging process for a single urine sample. All other elements of the measurement cycle remain the same – the analyzer feeds the cuvette to the pipetting position, waits for pipetting, centrifuges the sample and discards the cuvette after the images were taken, as usual. The automated image evaluation module also analyzes the resulting images the usual way. To set up and perform a manual microscopy process, complete the following steps:

1. Set up the Live view function by checking `Live view` checkbox on `Settings/Measure` screen.
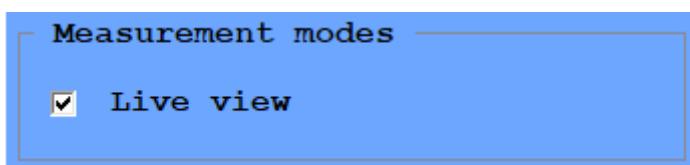

Fig. 39: *Live view checkbox on Settings/Measure screen*

2. Press **START** button to begin the measurement cycle. When the cuvette arrives into pipetting position a pop-up window appears with a `Live view` checkbox to check. If you leave it unchecked, the cycle goes on as regular measurement. Pipette the sample in the cuvette and press the **START** button.

Fig. 40: *The Live view checkbox appears with the Please fill sample into cuvette message, if you enabled the function in the Measure tab*

3. The cuvette with the sample inside it gets centrifuged and reaches the microscope.

4. The live image will appear in place of the previous screen.
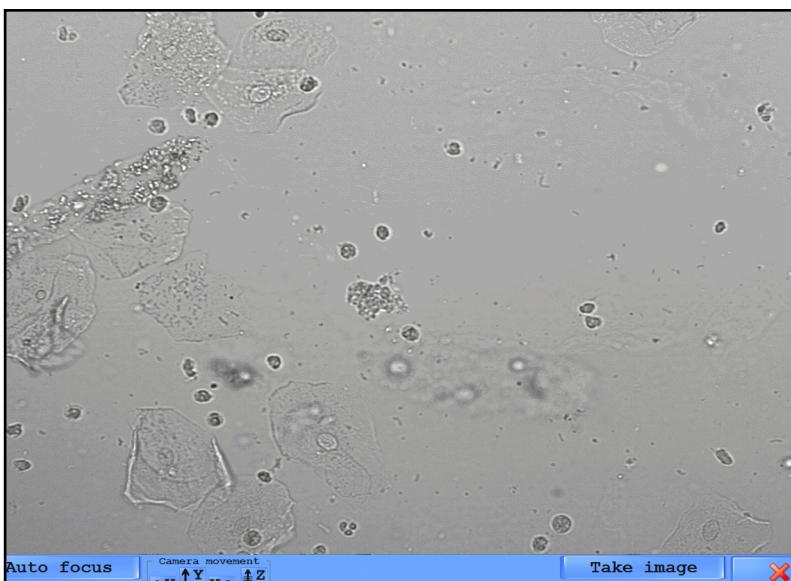
Fig. 41: *The live view screen*

5. Use the up and down (Y), left and right (X) arrows to move the microscope into your preferred image position, and the Z arrows to shift the focus height up or down. When you are satisfied with the image position, click the **Take image** button to take a view field image in the specified position. You can re-set both the focus height and the image position to their defaults by clicking the Autofocus and the **Start position** buttons, respectively.

6. The **Counter** marker keeps track of the number of view field images that you have taken. When the **Counter** reaches the number of images that is speci-fied, or you stop the process by tapping the **Close** button, the arm discards the cuvette.

6.4 Operating with chemical analyzer

To maintain complete urine analysis, the UriSed mini can be connected to a LabU-Mat 2, LabUReader Plus 2, DocUReader 2 PRO, URYXXON Relax or URYXXON 500 urine chemistry analyzers. The two devices together provide a complex solution in urinalysis, offering both chemistry and microscopy urinalysis results. The sample is analyzed first with the chemical analyzer and then with the connected UriSed mini sediment analyzer.
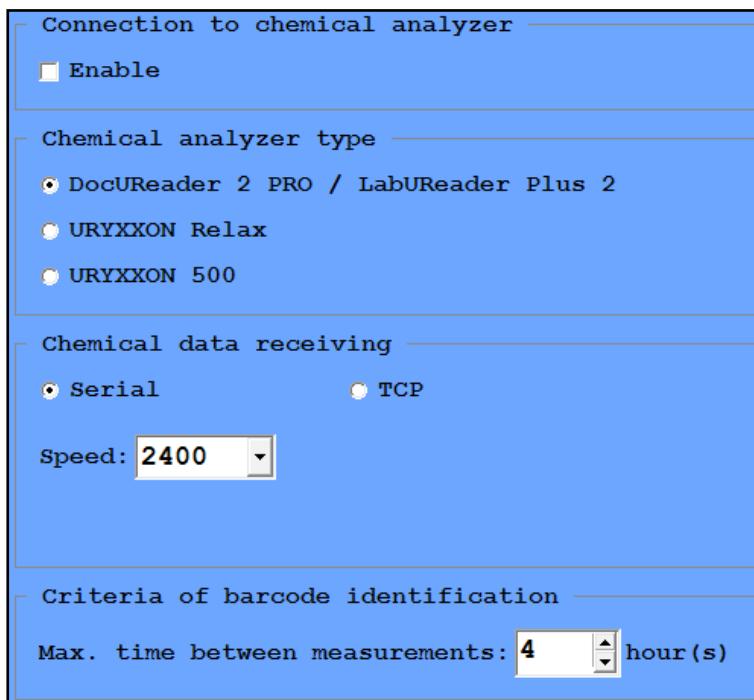

Fig. 42: *Chem analyzer connection box*

Establishing connection

⚠ **Please contact your service representative to connect your analyzers.**

6.4.2.1 Joint operation

The two analyzers can work together after they were connected correctly and the online status of the urine chemistry analyzer is displayed in the status bar. The measurement of urine sample is done in the urine chemistry analyzer first. The data is exported to the sediment analyzer where the analysis is finished.

6.4.2.2 Identification of a sample

The sample ID can be entered by typing in a unique string of numbers or using a barcode reader. At the end of each measurement the urine chemistry analyzer sends its report to UriSed mini with the ID in it. Each report can be found in the database with a comment: No sediment results. To assign microscopy measurement to a chemical result you either have to read the barcode of the sample or type in the same ID number.

6.4.2.3 Measurement

1. Prepare the samples.
2. Turn on both analyzers.
3. Establish and/or check the connection between the two instruments.
4. On the urine chemistry analyzer, enter patient ID by typing or using a barcode reader and start measurement.
5. Wait until the result is sent and perform the measurement on the sediment analyzer, too.

ⓘ *Type in the same ID or use the barcode reader to assign the measurement to the chemical result.*
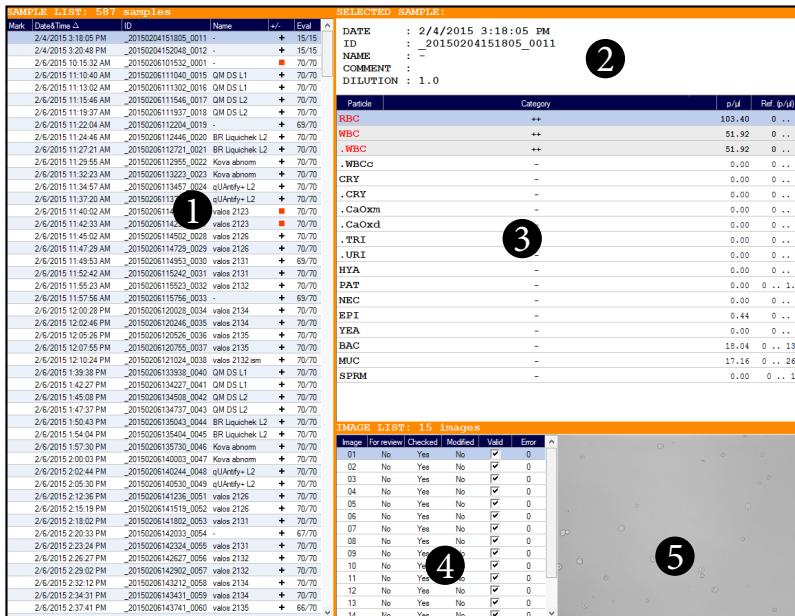
7 Managing results

7.1 Test results

To review the analysis results for the samples in the database, click the **Database** button.

The database menu will be displayed:

Fig. 43: *Database menu: 1) Sample List, 2) Selected Sample header, 3) Particle results, 4) Image List, 5) Thumbnail image*

ⓘ *The Database menu is available even while a measurement cycle is going on. Each processed sample appears in the Sample List (see 1 in* **Fig. 43**) *in real time, as soon as the analyzer successfully processes it.*

1. To review the detailed analysis results of a single urine sample, select the sample: click the row of the sample in the **Sample List**. The row will turn dark blue to indicate that you selected it, and the details of the selected sample will populate the **Selected Sample** window.

ⓘ *To select multiple sample records, hold down the Shift key or the Ctrl key while you click further samples for contiguous or non-contiguous selection, respectively.*

2. The results of the automatic image evaluation for the selected sample will appear in the particle results window (see 3 in **Fig. 43**), broken down by the particle types that are active. For more information on how to activate and disable particle types, see *5.4.4 The Evaluation tab*.

7.1.1 Editing test results

7.1.1.1 Selecting one or more test result records

- To select a sample result record in the database, go to the **Database** menu, and in the **Sample List** click the row of the record. Dark blue highlighting indicates that the record is selected.

ⓘ *To deselect a record that you accidentally selected, click to select another record.*

- To select more than one record, press and hold the Ctrl key on the connected keyboard while you click each record that you want to select. Dark blue highlighting indicates that the records are selected.

ⓘ *To deselect one of the selected records, click it again while still holding the Ctrl key.*

- To select a group of records, press and hold the Shift key on the connected keyboard while you click the first and last row of the group of records that you want to select. Dark blue highlighting indicates that the group of records is selected.

ⓘ *To deselect one of the selected records in the group, click it again while still holding the Ctrl key.*

- To select all the sample result records that are currently in the database, go to the database menu, and click the **Select all** button.
- To de-select every record, click the **Deselect all** button that the **Select all** button changed to when you clicked it.
- To mark a sample result record as special, click the row of its record inside the **Mark** column of the **Sample List**. A golden star will appear in the **Mark** column of the record. When you are filtering for specific records, you can choose to only look at starred records.
- To delete one or more sample result records, go to the **Database** menu, select the record or records in the **Sample List**, and click the **Delete** button. In the confirmation dialog that pops up, click the **OK** or the **Cancel** button to confirm or cancel the action.

ⓘ *You cannot restore result records after you deleted them from the database.*

7.1.1.2 Modifying test result records

To modify the ID, Patient name, Dilution factor, and Status of a sample, select the record in the **Sample List**, and click the **Modify** button. In the **Modify** dialog box that pops up, you can modify the ID, the Name, dilution factor, and the (+/-) status of the sample result record.
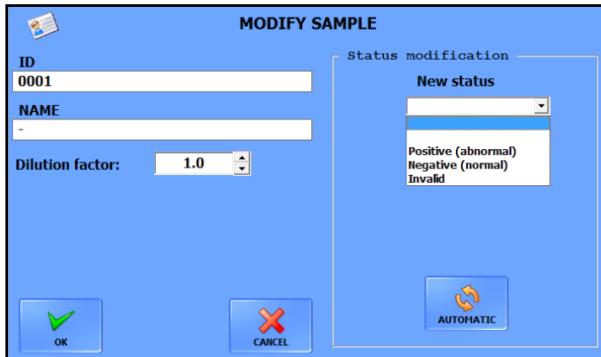
Fig. 44: *Modify sample pop-up window*

ⓘ *If the* `Status modification` *list is not available, you need to enable it: Go to the* `Settings` *menu, and on the* `Display` *tab, in the* `Manual sample status edit` *box, select* `Enable`*.*

ⓘ *If a sample is very crowded, you may need to dilute it with saline solution, and re-analyze it to get correct evaluation results. To calculate the dilution factor, use the formula:*

DF = final volume/original sample volume

ⓘ *The* `Modify` *button is inactive if you select more than one record in the* `Sample List`*.*

ⓘ *Click the* `Automatic` *button to reset the status of the sample record to the automated evaluation result.*

To modify the quantitative and semi-quantitative particle sediment results of a processed sample:

1. Go to the **Database** menu and select the record of the sample result in the **Sample List**.

2. In the particle results box, double-click the first particle class or particle subclass row that you would like to modify. The **Sediment Result Modification** dialog box will pop up (see ***Fig. 45***).

3. In the **Sediment Result Modification** dialog, enter a new value in the **Particle Number** text box, or select a new semi-quantitative category in the **Category** drop-down list for the given particle class or subclass. The **Category** drop-down list that indicates the semi-quantitative category results will change to conform to the modified particle/view field value.

ⓘ *If you select a new semi-quantitative category result in the Category drop-down list, the Particle Number value will change to conform to the new category.*

4. Click **OK** to save your changes or **Cancel** to discard them. To undo the changes without closing the dialog box, click the **Automatic** button.

ⓘ *The row of the class or subclass that you modified will be highlighted in blue in the Particle results box.*

⚠ **If you modify the results of a particle class that has active subclasses, the system will disable both the semi-quantitative and the particle number results for the active subclasses. You will only be able to modify subclass results if you undo the changes you made to the particle class (by clicking the Automatic button in its Result Modification dialog box).**

7.1.2 Validating analysis results

A laboratory professional needs to validate, that is, check that the automated image evaluation module has correctly detected and identified the sediment particles in the urine sample.

ⓘ *The system will not accept sample results as valid unless they are confirmed as correct. However, you can enable automatic validation to make the system accept every analysis result automatically.*

ⓘ *You cannot export, transfer to the LIS, or print sample results whose Validated by status in the Sample List is Not yet validated. If automatic validation is active, the Validate button on the Database menu is inactive, and the Validated by status of samples is automatically validated.*

• To validate a sample result (when automatic validation is inactive), select its record in the **Database** menu, and click the **Validate** button.

ⓘ *If an operator validates a sample result, the operator's name becomes part of the sample result record. Because of this, manual validation is only available in the "By user name" login scheme.*

• To activate or disable automatic sample result validation, go to the **Settings** menu, and on the **Measure** tab, select the Automatic or the **Manual** option in the **Validation** box.

ⓘ *If automatic sample validation is active, the Validate button on the Database menu becomes inactive.*

7.2 Microscopy images

7.2.1 The Sample View Editor (SVE)
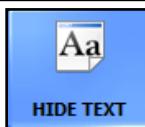
By default, the device processes all of the view field images and attempts to identify each of the detected particles in the images, then tags the identified particles. You can review and modify the automatically assigned tags using the SVE.
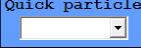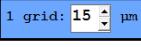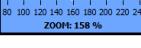
To access the SVE, and view a microscopy image and its particle tags in full screen, double-click any of the view field image thumbnails in the `Image List` in the bottom right corner of the `Database` menu screen, or the measurement record associated with the view field image. There are essentially two types of view field images:

- View field images that are not crowded with particles are, regardless of whether they are negative or pathological, considered Normal: they have `No` in their `For review` column in the `Image List`. The majority of view field images is of this type.
- View field images that are so crowded with particles that it is difficult to distinguish between various elements are considered `Images for review`: View field images that are so crowded with particles that it is difficult to distinguish between various elements are considered Images for review

7.2.1.1 Breakdown of the SVE interface elements

- The sample to which the enlarged view field image belongs is identified in the header of the SVE.
- The number of the current view field image out of all the view field images available for the given sample is displayed in the top right corner.
- Use the [⏮ ⏭] buttons to scroll through the view field images of a single sample; use the [◁] and [▷] to scroll through all the sample records in the database.
- A table summarizing the particle classes and their number found in the currently displayed view field image is displayed on the right. Each of the particle classes that were identified in the image have a checkbox inside the table. Use the checkboxes to toggle the tagging of the particle in question. The tagging preference you set in one of the view field images applies to every other view field image in the series for the current sample, but not to the view field images of other samples. For example, if you hide WBC (White Blood Cell) tags for one of the images, no WBC tags will be displayed in any of the view field images for the selected sample.

DEFAULT	Click to cancel all manual modifications and revert to the automated evaluation results for the currently displayed view field image.
HIDE TEXT	Click to toggle all the tag text over the raw view field image currently displayed. (Works just like the C keyboard shortcut.)

START SHOW	Click to toggle a slideshow of the view field images. A new image is displayed every three (3) seconds.
Quick particle	To quickly apply multiple instances of a particle type: choose a particle type from the drop-down list to "load" the particle type into your cursor, then click anywhere in the image to apply the particle tag.
`1 grid:` 15 `µm`	Click the arrows to adjust the gradation of the grid that the G keyboard shortcut displays over the view field image.
SAVE	Click to save the current view field image as displayed (without particle tags) as a bitmap image. You can specify where you want to save the image in a dialog box.
CLOSE	Click to close the Sample View Editor and return to the Database menu. You can also leave the SVE by pressing the Esc key on the keyboard.
80 100 120 140 160 180 200 220 240 **ZOOM: 158 %**	Slide the ZOOM scale bar for changing the enlargement ratio of the selected image. ➲ *It does not change the Zoom mode settings in the Display tab.*
40 **BRIGHTNESS**	Slide the Brightness scale bar for changing the degree of brightness of the image. Its keyboard shortcuts are Page up and Page down. ➲ *It does not change the Brightness settings in the Display tab*

7.2.2 Modifying automated evaluation results

⚠️ **Parent particle classes inherit the highest relative value present among their enabled subclasses. If any of the subclasses are manually assigned a relative value higher than that of their parent particle class, the parent class result will be overridden.**

The analyzer was developed to help the work of the doctors and not to replace them: all automated evaluation results can be modified manually. There are two ways to edit the results that the device generates: in the **Database** menu, and in the Sample View Editor.

7.2.2.1 Modifying microscopy results in the Database

ⓘ *Modifying results in the Database menu will not affect particle numbers displayed in the Sample View Editor.*

1. In the summarized microscopy urinalysis report, double-click on the row of the particle you wish to modify.

2. Enter the desired value in the dialog box that pops up. The system will automatically apply the change you made in one of the text boxes to both text boxes.
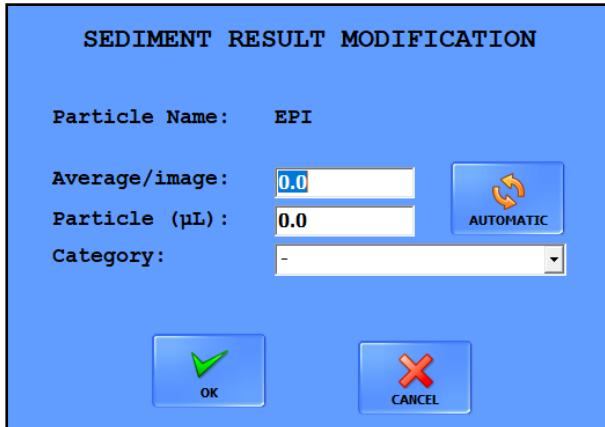
Fig. 45: *The Sediment result modification dialog box*

⚠ **If you change the semi-quantitative result category, the average particle per image and the quantitative result will be reset to the middle of the range of the new category.**

ⓘ *The maximum value you can enter into the particle number text box is 99999.9*

3. Click OK to save the changes, or Cancel to discard the changes. Click Automatic to undo the changes and revert to the automated evaluation.

ⓘ *Modified records will be displayed in blue in the report.*

⚠ **If the result of a particle class is modified, the Category columns of corresponding subclasses change to N/A and their values to 0. Further modification of subclasses is possible only in the Sample View Editor. However, if you revert to the automated evaluation results, you can restart the editing process.**

7.2.2.2 Adding particle tags in the Sample View Editor

⚠ **Any particle class– or particle number modifications in the Sample View Editor will affect the results summary in the Database menu.**

To tag any area of the view field image, do one of the followings:

1. Choose a particle type in the **Quick particle** drop-down list in the right sidebar of the Sample View Editor.
2. Left-click anywhere in the view field image to apply the particle tag. You can apply the selected tag as many times as necessary.

ⓘ *The cursor will stay 'loaded' with the particle type that you selected until you select another one, or you click another button in the Sample View Editor.*

⚠ **There are several particle classes and subclasses ("extended particle categories") that are not available for automated evaluation, but that you can add to the view field image manually. You need to enable their use before they become available choices (see _5.4.4_).**

ⓘ _The software takes all the new particles that you added into consideration when generating the microscopy report._

ⓘ _New particle tags are displayed in blue to indicate that they have been modified._

7.2.2.3   Modifying particle tags in the Sample View Editor

⚠ **Any particle class or particle number modifications in the Sample View Editor will affect the results summary in the Database menu.**

1. To modify a particle tag in the SVE image, complete the following steps:

Choose a particle type in the `Quick particle` drop-down list in the right sidebar of the `Sample View Editor`.

2. Move the cursor above the tag you wish to modify.
3. Right-click the tag. You can apply the selected tag as many times as necessary.

⚠ **There are several particle classes and subclasses ("extended particle categories") that are not available for automated evaluation, but can be added manually. You need to enable their use before they become available choices (see _5.4.4_).**

ⓘ _The software takes all the new particles that you added into consideration when generating the microscopy report._

ⓘ _New particle tags are displayed in blue to indicate that they have been modified._

7.2.2.4   Deleting particle tags in the Sample View Editor

1. Choose `DEL` in the `Quick particle` drop-down list in the right sidebar of the `Sample View Editor`.
2. Move the cursor above the tag you wish to delete.
3. Right-click the tag. You can delete as many tags as necessary.

ⓘ _The software takes all the new particles that you added into consideration when generating the microscopy report._

⚠ **You can discard every manual modification by clicking the Default button. This will restore the particle results of the automated evaluation.**

8 Quality Control

You can test the performance of the analyzer by using the integrated quality control procedure. Click the `Quality Control` button on the right of the software interface to access all information and parameters concerning quality control measurements.
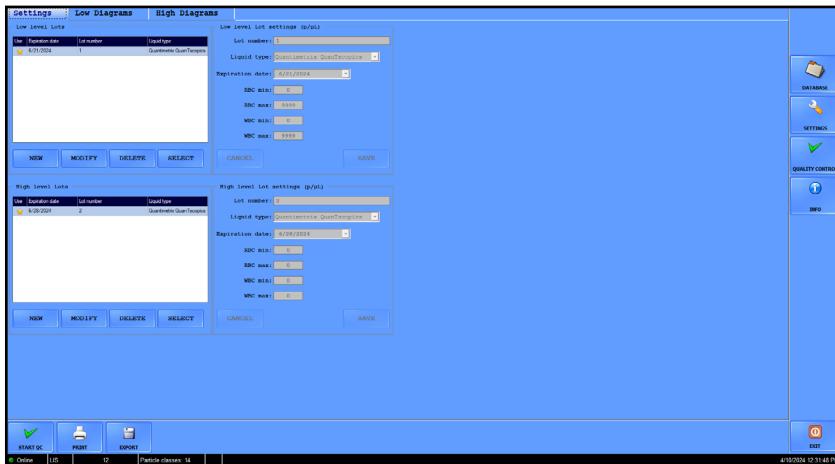
Fig. 46: *The Quality Control menu*

⚠ **Check the measurement ability of the analyzer regularly according to local regulations.**

Generally, there are two types of control solutions: normal (`Low level`) and abnormal (`High level`). The normal control solution, like non-pathological urine, contains only a few sediment particles, while the abnormal control solution, like pathological urine, contains more formed elements in a given concentration. During quality control the device analyses first the normal, then the abnormal control solution and checks whether diluted elements (RBC-and WBC-like particles) can be found at the concentration that was set for that particular control solution lot. Low level and High level control solutions pass Quality control analysis if both analyzed particles (WBCs and RBCs) are within the values you specified previously.

The user can easily collect and manage quality control solution lots on the `QC Settings` screen.

ⓘ *There are only RBC- and WBC-like particles in the control solution.*

8.1   QC settings

1. On the left side of the screen both the Low and High level controls will be listed if you have populated their database. The acceptance ranges of checked elements (RBC-and WBC-like particles) can be adjusted separately for the Low level and High level control solutions.

ⓘ *Before a new control solution lot can be used, you have to enter all its information.*

2. Click the **New** button below the **Low** or **High** level solutions list, and enter the control solution's unique lot number in the Lot number text field.
3. Choose the type of control solution you are using from the drop-down list in the Liquid type text box.

The device is compatible with the following quality control solutions:

–   Quantimetrix QuanTscopics
–   Quantimetrix Dip and Spin
–   KOVA Liqua-Trol
–   Biorad Liquichek

ⓘ *Contact your distributor for details of the quality control solutions.*

4. Refer to the control solution package insert and enter the expiration date it indicates in the **Expiration date** field.
5. Modify the values of acceptance ranges in the **Quality Control** menu by entering the expected limits in the relevant boxes according to the lot-specific ranges given in the control solution package inserts. Click the **SAVE** button to save your changes.
6. Click the **Modify, Select**, and **Delete** buttons to manage the list of control solutions. If you delete a quality control solution lot, all of its related QC data will also be erased.

8.2   QC measurement

1. Go to **QC** menu and click a solution on the list. Enable it with the **Select** button (a star icon indicates selection), and then click **Start QC**.
2. Push the **START** button.
3. Pipette normal (low level) control solutions in the forwarded cuvette.
4. Push **START** button again to start centrifugation and evaluation. The analyzer will switch to the **Database** menu to perform the measurements, the same as during normal sample measurement. After finishing the analysis, it displays a message whether the test was successful, and label failed and passed quality control tests in the **Sample List** accordingly. The record of the control measurement will be named QC_LOW.
5. The system will prompt you to perform the high level measurement.
6. Press **START** button and pipette the high level control solution in the forwarded cuvette.

7. Push **START** button again to start centrifugation and evaluation. After finishing the analysis, the analyzer displays a message whether the test was successful, and labels failed or passed quality control tests in the Sample List accordingly. The record of the control measurement will be named QC_HIGH.

8. Quality control analysis results are stored in the **Database**. In the **Database** the **Comment** fields for quality control analysis results include the failure or success of each test.
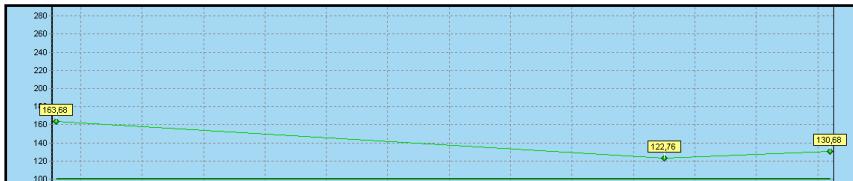
Fig. 47: *An example of a Quality Control diagram. The x-axis represents the time period; the y-axis represents the measurement result values.*

9. Click the **Low diagrams** and the **High diagrams** tabs on the **Quality control** menu to use the quality control visualization feature. Select the time period you want to review using the radio buttons and the text boxes at the top of the screen, and click **Show** to display the results of all the quality control measurements during the given period on a chart (see ***Fig. 47***). Click the **Labels on/off** button to toggle the display of the exact result value captions. Check or uncheck the checkboxes in the tabular summary in the top left corner to show or hide any given control solution lot.

(i) *Every control solution lot is represented by a different line color. Upper and lower range cutoffs are represented by darker lines of the same color as the results they refer to.*

(i) *If there is only a single QC result to display, the top and bottom cutoffs are represented by squares instead of lines.*

(i) *The QC lot data above the diagrams is listed for identification and statistical information purposes (CV%, SD) and also indicate specific color and measurement count for the lot.*

10. Ticking the **Show Average and SD lines** checkbox allows the user to visually display the mean for the given QC LOT, as well as the one, two and three standard deviation ranges on the chart. The standard deviation ranges are represented by red lines corresponding to the values also indicated in the table.

8.3   QC records management

QC records are stored in the database amongst other measurement records marked with the name of the used control solution in the **Name** column of the **Sample list**. Using database filter you can select only QC records to be displayed and the list can be narrowed down by applying the filter criteria.

9 Cleaning & Maintenance

9.1 Cleaning and disinfection

ⓘ *Do not use any solvent, oil, grease, silicone spray, or lubricating liquid to clean any part of the device.*

ⓘ *Use commercially available isopropyl alcohol or aldehyde-free and NaOH-free disinfectant (for example Isorapid, Microzid, etc.).*

9.1.1 Cleaning the analyzer every day

Complete the following steps every 24 hours, before you finish working with the analyzer at the end of the day or according to the regulations of your laboratory.

1. Switch off the analyzer and wipe the outside covers with a lint free cloth dipped in detergent solution.

ⓘ *Do not remove the partially used cuvette container alone. Remove the cuvette container along with the cuvette holder seat.*

2. Open the device door and remove the cuvette holder along with the cuvette holder seat. Remove the waste bin, empty it, and rinse it thoroughly with a detergent solution. Wipe it dry with a lint free cloth or let it dry completely before you replace it.
3. Using a detergent solution, wipe both surfaces of the see-through plastic pipetting guard that helps you direct the manual pipette into the fill up inlet of the cuvette.
4. Remove and rinse the following elements of the analyzer:
   – the metal cuvette holder seat
   – the plastic cuvette feeder arm
   – the cuvette hold down assembly
   – the drop tray
   – the centrifuge cover
   – the centrifuge arm

ⓘ *Turn the centrifuge arm until it is horizontal, snap it off its hub.*

⚠ **Make sure that you do not damage the microscope lamp when you remove the centrifuge arm.**

5. Wipe each of the elements with a lint free cloth.
6. Wipe the cuvette mover arm and the cuvette way underneath with a lint free cloth dipped in detergent solution.

⚠ **Do not replace any element before it has dried completely, and make sure that the outside covers are dry before you switch on the analyzer.**

⚠ **Do not forget to replace the centrifuge arm in the instrument after cleaning.**

7. When you switch on the analyzer again, initialize the system before you resume normal operation.

9.1.2   Cleaning the microscope lens

When you see scratches or blotches that repeat on every view field image, some dust or dirt has probably collected on the surface of the objective. To keep microscope image quality at the optimum level and prevent mistakes in the automated image evaluation, complete the following steps to clean the lens.

1. To access the microscope objective, remove the cuvette hold down.

ⓘ *Take care not to damage the microscope lamp as you remove the cuvette hold down.*

⚠ **Do not blow air on the microscope objective with your mouth.**

2. Push the cuvette mover arm assembly towards the back of the analyzer.
3. Use compressed air or an air bulb blower to blow the dust off the microscope objective.

⚠ **When cleaning the microscope objective, take special care not to scratch its surface or damage its reflective coating.**

4. If the surface is still not clean, use a special lens cleaning tissue, and lightly wipe the objective free of dust.
5. If the lens is still not clean, fold the objective cleaner cloth to produce a pointed triangular end or use a cotton swab and dip it into 96% ethanol. Wipe across the objective.
6. Re-insert the cuvette hold down before you resume normal operation.

9.1.3   Servicing contact information

77 Elektronika offers full service support for its products. Feel free to contact us if you encounter any problem with your UriSed mini analyzer. There are several ways to contact us:

Phone: +36 1 371 0546

Fax: +36 1 481 0139 or through

HELPDESK on our website.

10 Troubleshooting

10.1 Information messages

Message code	Message text	Information description
44	Password successfully changed.	The new password is now valid.
45	N/A	N/A
47	No particles detected - please validate X.	Validate the sample manually.
48	Diagnostic report created successfully.	The diagnostic file has been properly created in the designated location.
50	Quality control test (Low level) passed!	The QC measurement has shown proper instrument functioning.
51	Quality control test (High level) passed!	The QC measurement has shown proper instrument functioning.
54	Please fill the sample into the cuvette.	Pipette 175 microliter sample into the cuvette manually.
55	Please start to measure Low level QC.	Press START button to load the cuvette for Low level QC measurement.
56	Please start to measure High level QC.	Press START button to load the cuvette for High level QC measurement.
57	Please fill Low level QC into the cuvette.	Pipette 175 microliter Low level QC solution into the cuvette manually.
58	Please fill High level QC into the cuvette.	Pipette 175 microliter High level QC solution into the cuvette manually.
303	Raw data export created successfully.	The raw data export has been properly done.
446	One sample was not commented, it is staying in output queue.	After the output, the comment can be changed.
447	More samples were not commented, they are staying in output queue.	After the output, the comment can be changed.
452	First measurement phase is completed. Push the start button to continue measurement.	Follow on-screen instructions.
459	The summa must be 0 or 100	Wrong data entered. Try again.
489	After a successful restore, the software will restart.	The software will restart.

Troubleshooting

Message code	Message text	Information description
494	RUO - For Research Use Only - Not for use in diagnostic procedures.	Warning that the results of body fluid measurements cannot be used in diagnostic procedures.
510	X printer was not found. The default printer is the selected.	The selected printer was not found.

10.2 Warning messages

Message code	Message text	Recommended action
62	Empty the trash because it is full. Please press OK when emptied.	Remove the waste bin, empty it and place it back. Press OK.
63	Temperature exceeds warning limit.	Stop measuring samples and turn off the instrument. Check room temperature and never use the analyzer outside the operational condition ranges. If error persist, call your service representative.
66 232	Please close centrifuge door.	Re-install the centrifuge cover back.
67	Please replace the plate.	Re-install the centrifuge drop tray.
68	Please shut the door.	Close the analyzer door.
69	Cuvette holder is empty. Please change it. Please press OK when changed.	Replace the empty cuvette cartridge with a new one.
70	Database sample count limit is approaching.	Delete the unused data to have enough storage in the database.
72	The new limit is not correct. Please delete some samples, before you set this limit!	Delete results from database in order to decrease the number of elements in database below the set limit.
74	Shut the waste please.	Re-attach the cuvette waste bin to the instrument.
75	ID contains an illegal character.	The ID doesn't contain ' character at filter.
76	Name contains an illegal character.	The Name doesn't contain ' character at filter.
78	Quality control test (Low level) failed!	The result of the first quality control is outside the limits. Check the limits, the control type and the control. Repeat the measurement.
79	Quality control test (High level) failed!	The result of the second quality control is outside the limits. Check the limits, the control type and the control. Repeat the measurement. Open a new control solution.
81	Please enter a Lot number.	Please fill in the Lot number.
82	Pick a QC liquid type from the list.	None of liquid types was selected. Choose a liquid type.

Troubleshooting

Message code	Message text	Recommended action
83	This Low level lot does not exist in the database. Please select another Lot.	Select a Low level Lot from the list.
84	This High level lot does not exist in database. Please select another Lot.	Select a High level Lot from the list.
85	Login failed. Invalid user name or password.	Enter the correct password for log in.
86	Original password incorrect.	At password change the original password was given incorrectly. Enter the original password correctly.
87	You cannot delete the currently active user account.	It is not possible to delete your user name by yourself. It can only be deleted by another user from same or higher level.
88	The user name must be at least 2 characters long!	Change the user name to contain at least 2 characters.
89	The user is not Service user, login failed!	Exit service menu.
90	This user name is already in use.	The user name you tried is already in use by another person. Please choose another user name!
92	Duplicate barcode	A measurement record associated with the indicated barcode already exists in the database.
96	Instrument is not ready!	Initialize system. Restart PC. If error persists call service.
103	No more samples.	There is no more sample to check in the SVE.
104	Repeated barcode:	A measurement record associated with the indicated barcode already exists in the database.
106	Please enter the correct serial number.	Call service.
108	Name contains an illegal character.	The Name cannot contain ' & / \ : * ? " < > | ^ ~ characters at Sample Data Modifying.
109	ID contains an illegal character.	The ID cannot contain ' & / \ : * ? " < > | ^ ~ characters at Sample Data Modifying.
110	Comment contains an illegal character.	The Comment cannot contain ' & | ^ ~ characters at Comment changing.

Message code	Message text	Recommended action
111	Worklist name contains an illegal character.	The Name cannot contain ' & / \ : * ? " < > | ^ ~ characters at Sample Data Modifying.
112	Worklist ID contains an illegal character.	The ID cannot contain ' & / \ : * ? " < > | ^ ~ characters at Sample Data Modifying.
113	Worklist comment contains an illegal character.	The Comment cannot contain ' & | ^ ~ characters at Comment changing.
114	Category display contains one or more illegal characters.	The Category display cannot contain ' & | ^ ~ characters at Category definition settings.
115	Lot number contains an illegal character.	The Lot number cannot contain ' & | ^ ~ characters at QC settings.
116	Serial number is missing.	Call your service representative.
117	Instrument is not ready.	Initialize system. Restart PC. If error persists call service.
118	X sample(s) were not exported.	Validate the sample and try again to export!
119	Sample(s) were not sent.	Validate the sample and try again to send!
120	Sample(s) were not printed.	Validate the sample and try again to print!
121	Invalid SG parameter.	The connected automated chemical analyzer encountered a problem determining the specific gravity of the sample. The sample is probably too thick. Try measuring the sample again. If the issue persists, repeat the test strip measurement manually, and review the SG reagent pad.
123	Incorrect dilution factor.	Set the correct dilution factor (1-100) with correct decimal separator.
124	The ID must be at least 1 character long.	Insert at least one character in the ID textbox to make it valid:
125	Low disk space, less than X MB!	Free up disk space.
131	Not enough free disk space. Measurement has stopped.	Delete the unused data to have enough storage in the database.
132	The LIS is busy. Try again later."	Try to change transfer type later!

Message code	Message text	Recommended action
133	LIS port is busy.	Initialize system. Restart PC. If error persist call service.
134	Must be member of service.	The instrument is in service mode. Contact your service representative.
135	No diagram available for these filter conditions.	Perform different selection by the filter to get a diagram.
136	There is no Low level Lot. Please register one.	No Low level Lot has been saved. Add the data of a new Low level Lot.
137	There is no High level Lot. Please register one.	No High level Lot has been saved. Add the data of a new High level Lot.
138	Please select a Low level Lot.	Select a Low level Lot from the list.
139	Please select a High level Lot.	Select a High level Lot from the list.
140	Lot already on list.	The Lot number already exists. Please fill in another Lot number.
188	There is not enough free space on target drive.	Insert drive with enough free space.
216	Log folder changing in progress. Please, try it later.	Wait until the change is finished.
228	Front cover open.	Close door(s) of the device.
292	The LOT has been expired!	Register new QC LOT.
293	The selected Low level lot has been expired, measurement cannot start.	Register new QC LOT.
294	The selected High level lot has been expired, measurement cannot start.	Register new QC LOT.
297	The result has been sent to LIS.	The results, that had been sent, cannot be modified.
298	Raw data export is in progress	Wait until the export is finished.
301	Error creating raw data zip file.	Repeat creating raw data.
302	Export list is in progress	Wait until the export is finished.
304	The image of sample is in evaluation queue.	Wait until the evaluation is finished.
305	The sample is in output queue.	Wait until the export/transfer is finished.

Message code	Message text	Recommended action
362	Full Eval is not enabled at the moment for the sample, please try it later.	Follow on-screen instructions.
363	Full Eval is not enabled at the moment for some samples, please try it later.	Follow on-screen instructions.
373	A sample was not deleted.	This record is in use. Wait until the procedure is finished, and try gain.
374	samples were not deleted.	These records are in use. Wait until the procedure is finished, and try again.
375	The image of sample of this QC LOT is in evaluation queue.	Wait until the evaluation is finished.
381	No chemical setup	Call your service representative.
382	Chemical class creation error	Call your service representative.
383	TCP configuration is not permitted in chemical connection.	Call your service representative.
384	Port open error in chemical connection.	Call your service representative.
385	Cannot connect to chemical analyzer.	Call your service representative.
386	Chemical result was not saved, because invalid date arrived from chemical analyzer. Please set the date and time on chemical analyzer.	Follow the on-screen instructions.
388	Predefined comment contains illegal character(s)!	Predefined comment cannot contain ' & / \ : * ? " < > | ^ ~ characters.
389	Evaluation error: No image.	Call your service representative.
390	Evaluation error: BrightField convert error.	Call your service representative.
392	Evaluation error: No image information.	Call your service representative.
393	Evaluation error: dll loading error.	Call your service representative.
394	Evaluation error: invalid command format.	Call your service representative.
395	Evaluation error: unknown command.	Call your service representative.
396	The Lot is undeletable. Try it again after output has finished.	Follow the on-screen instructions.
397	The Lot is unmodifiable. Try it again after output has finished.	Follow the on-screen instructions.

Message code	Message text	Recommended action
416	Other measurement is running.	New measurement can be started after the current one is finished.
439	The modified record has paired, please modify it again if necessary.	Follow the on-screen instructions.
453	The binary channel is closed. Images were not sent.	Reconnect and try again.
460	The sample is measured.	No actions can be made until the measurement of the sample is still running.
462	Full Eval is not enabled for the sample.	The action is not allowed.
463	Full Eval is not enabled for some samples.	The action is not allowed.
466	All activated QC Lots must be of the same solution type.	Follow the on-screen instructions.
467	Full name contains illegal character(s).	The full name cannot contain ' & / \ : * ? " < > | ^ ~ characters.
468	Illegal format in category LOINC field.	Use valid code.
469	Illegal format in p/HPF LOINC field.	Use valid code.
470	Illegal format in p/µL LOINC field.	Use valid code.
471	This short name already exists.	Enter another name.
472	Please give a short name.	Follow the on-screen instructions.
486	The cuvettes have expired	Use new cuvettes.
487	Password mismatch	Enter the passwords again.
488	Password is empty	Enter password.

10.3 Error messages

Error code	Message text	Error elimination
146	Sample editing error	Database connection error, exit the program and restart.
147	Sample comment editing error	Database connection error, exit the program and restart.
148	Database error. The modification cannot be saved.	An error occurred during the save of chemical result modification into the database. Database connection error, exit the program and restart.

Error code	Message text	Error elimination
149	Database error. The modification cannot be saved.	An error occurred during the save of sediment result modification into the database. Database connection error, exit the program and restart.
150	The maximum enabled number is	At sediment result modification the given particle number cannot be more than 99999.9. Give a smaller number.
151	Cannot save modification. The min range is higher than max!	In QC menu at range setting: Give correct values.
152	Not a proper number format. Use decimal character.	Change the decimal character in the typed number. (Sample mod.)
162	Sample count exceeds sample limit. Please delete unused data.	It appears at measurement start. There is not enough storage in the database for measurement results. Delete the unused data.
172	Re-entered password does not match new password.	At password change the new password must be entered twice: Enter the new password twice correctly.
173	Password doesn't change!	Try to modify the passwords once more. If it was unsuccessful, there is a database error. Exit the program and restart.
174	New password must not match default password.	Change the password to a different one from default password.
175	The password must be at least 5 characters long!	Change the password to contain at least 5 characters.
176	Cannot connect to mini.	Restart PC. If error persists call service.
177	Device is not connected.	Restart PC. If error persists call service.
178	Temperature exceeds critical limit.	Stop measuring samples and turn off the instrument. Check room temperature and never use the analyzer outside the operational condition ranges. If error persist, call your service representative.
179	Category definition incorrect!	At category modification: Maximum value is less than minimum value. Enter correct values.
180	Empty category display strings.	At category modification: Enter the category name.
181	Category display strings are the same.	At category modification: Existing category name. Enter another name.

Error code	Message text	Error elimination
182	Minimum and maximum limits are the same in category definition.	Please increase X. category definition, because it is the same as the previous one.
183	Not a proper number format in category. Use decimal character.	Change the decimal character in the typed number. (Cat def.)
184	Empty maximum range.	Please fill in the maximum range.
185	The directory does not exist.	Select an existing directory.
186	Directory creation error	Do not use the following characters in folder names: ' & / \ : * ? " < > | ^ ~
187	Cannot save/overwrite the html file. Access denied!	Check the LIS cable, close the HTML file, if opened.
191	There is no connection with the Printer!	Restart PC. If error persist call service.
192	Error detected in CSV file in line:	Load the worklist file again. If error persists call your IT department or service.
194	Selected input file is missing.	Load the worklist file again, If error persist call your IT department or service.
195	There is not enough free space on target drive.	Insert drive with enough free space.
196	N/A	N/A
197	N/A	N/A
198	LIS communication error!	Check the Host settings and the Host program. Check the soundness and connections of the communication cable.
199 204	LIS connection offline.	Check the Host settings and the Host program. Check the soundness and connections of the communication cable.
200	LIS winsock open error.	Call your IT department. If error persists call service.
201	LIS socket open error.	Call your IT department. If error persists call service.
202	LIS TCP connection error	Call your IT department. If error persists call service.
203	Error in Chemical result	Check the measurement on the chemistry analyzer.
205	Not a proper number format in limit. Use decimal character.	Change the decimal character in the typed number. (QC)
206	Diagnostic report created NOT successfully.	Reconnect the USB flash drive, reinstall. If error persists call service.

Error code	Message text	Error elimination
207	Error during PCB upgrade.	Call service.
251	Delete the oldest sample failed. (May be all of them are QC.)	Enable QC deleting option in the maintenance tab of settings menu.
296	N/A	N/A
300	At least one cell has to be selected.	Select at least one particle type.
311	Chem. analyzer dll load error.	Call service.
312	Chem. analyzer no class error.	Call service.
313	Chem. analyzer no callback hook.	Call service.
314	Chem. analyzer port error.	Call service.
509	There is not enough free space on target drive.	Insert drive with enough free space.

10.3.1 Hardware related error messages

If you encounter an error that indicates a moving part might be stuck in the analyzer during patient testing, first you need to clean those moving parts that are exposed to a possible urine spill. Follow the procedure described in *9.1.1 Cleaning the analyzer every day*.

Error code	Message text	Recommended action
235	Forwarding bar base position error.	Initialize system. Restart PC. If error persists call service.
236	Forwarding bar pipetting position error.	Initialize system. Restart PC. If error persists call service.
237	Forwarding bar centrifuge position error.	Initialize system. Restart PC. If error persists call service.
238	Forwarding bar microscope position error.	Initialize system. Restart PC. If error persists call service.
264	Microscope table position error.	Initialize system. Restart PC. If error persists call service.
267	Focus motor base position error.	Initialize system. Restart PC. If error persists call service.
272	Centrifuge arm blocked.	Initialize system. Restart PC. If error persists call service.
273-279	PCB communication error.	Initialize system. Restart PC. If error persists call service.
281	Not enough serial ports present.	Restart PC. If error persists call service.
282	Too many serial ports	Restart PC. If error persists call service.
283	Connection error	Restart PC. If error persists call service.

Troubleshooting

Error code	Message text	Recommended action
284	Connection error	Restart PC. If error persists call service.
285	Connection error	Restart PC. If error persists call service.
288	Error during camera init.	Initialize system. Restart PC. If error persists call service.
289	Error during focus init.	Initialize system. Restart PC. If error persists call service.
290	Error during focus init.	Initialize system. Restart PC. If error persists call service.
315	Not enough serial ports present.	Restart PC. If error persists call service.
316	Too many serial ports	Restart PC. If error persists call service.
317	Protocol usage is not defined	Restart PC. If error persists call service.
318	Instrument port open error	Restart PC. If error persists call service.
319	Connection error	Restart PC. If error persists call service.
320	Arm home position error	Initialize system. Restart PC. If error persists call service.
321	Forwarding bar microscope position error.	Initialize system. Restart PC. If error persists call service.
322	Arm load position error	Initialize system. Restart PC. If error persists call service.
323	Focus home position error	Initialize system. Restart PC. If error persists call service.
324	Centrifuge rotation error	Initialize system. Restart PC. If error persists call service.
325	Camera error	Initialize system. Restart PC. If error persists call service.
326	Feeder cuvette position error	Initialize system. Restart PC. If error persists call service.
327	Feeder arm position error	Initialize system. Restart PC. If error persists call service.
328	Feeder arm moving error.	Initialize system. Restart PC. If error persists call service.
329	Arm moving error.	Initialize system. Restart PC. If error persists call service.
330	Microscope CTS timeout	Initialize system. Restart PC. If error persists call service.
401	Communication version is incompatible	Initialize system. Restart PC. If error persists call service..

Error code	Message text	Recommended action
402	Incompatible instrument category	Initialize system. Restart PC. If error persists call service.
403	Incompatible instrument type	Initialize system. Restart PC. If error persists call service.
404	Incompatible sales version	Initialize system. Restart PC. If error persists call service.
405	Configuration is disabled	Initialize system. Restart PC. If error persists call service.
432	Mot Y position error	Initialize system. Restart PC. If error persists call service.
433	Centrifuge arm is missing	Place the centrifuge arm back after cleaning.
441	RFID communication error	Initialize system. Restart PC. If error persists call service.
442	RFID not present	Initialize system. Restart PC. If error persists call service.
443	Customer ID error	Initialize system. Restart PC. If error persists call service.
490	The backup was not created	Retry backup.
492	The restore was unsuccessful	Retry restore.

11 Appendices

11.1 Disposal of the analyzer

The instrument must be treated as biological contaminated-hazardous waste. Proper disposal of old appliances (including its plastic parts, electrical components) prevents potential negative consequences for the environment and human health. All electrical and electronic products and other components of the analyzer should be disposed separately from the municipal waste system. Final disposal must be organized in a way that does not endanger waste handlers. As a rule, such equipment must be sterile before it is passed for final disposal. For more information about disposal of such product, please contact your city office, waste disposal service or your Local Safety Officer.

11.2 Recycling

Make sure that unwanted, old instruments do not pollute the environment more than is unavoidable is very important.

Parts and components of the analyzer could be sent to recycling after proper disinfection:

• the power cable: contact the manufacturer for disposal information or find a recycling center online

• the electrical wires: find a recycling center online

• the casing panels: follow the local guidelines and regulations for Acrylonitrile butadiene styrene (ABS) disposal

• the printed circuit boards (PCBs): find a specialized recycling firm

• the CR2032 real-time clock battery on the Mainboard: follow local regulations and guidelines for lithium battery disposal

• metallic elements: follow local guidelines and regulations for metal disposal

• silicone supports: dispose of these as municipal waste

11.3   Modification history

Version	Date	sw	Modification
UriSed_mini_UM_version_1.0	02/2016	3.1	First version
UriSed_mini_sw3. 2_User_Manual	05/2017	3.2	Features of new software added
UriSed_mini_sw4.1.65_User_Manual	11/2019	4.1.65	Features of new software added
UM_URISEDMINI_EN_04	05/2023	4.4.36	Features of new software added
UM_URISEDMINI_EN_05	08/2023	4.5.4	Features of new software added
			Complete design overhaul
IFU_URISEDMINI06_EN	05/2024	4.9	Out of focus reviews
			BoF measurement types
			Used Defined Particles
			BAC review
			UTI flag
			Backup and Restore
			Show Average and SD lines
			New messages in Troubleshooting.

ⓘ   *Due to software changes, some screens on the instrument may appear slightly different from those in this manual.*