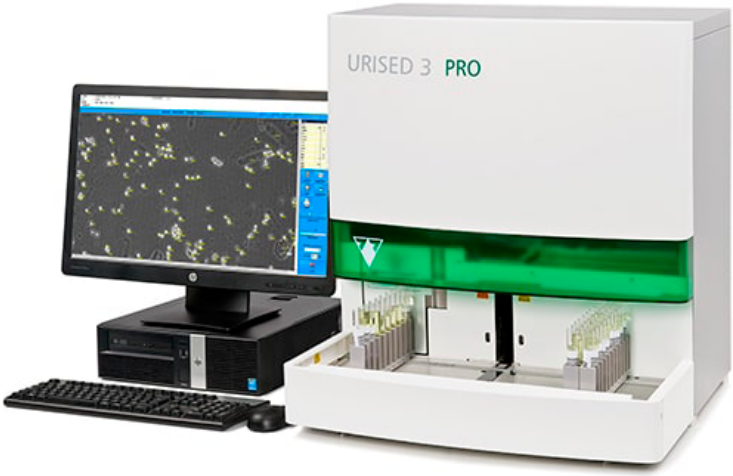
UriSed 3 PRO

77 ELEKTRONIKA

Fully Automated Urine Sediment Analyzer
User Manual
sw4.11



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1 Introduction

Thank you for choosing UriSed 3 PRO automatic urine analyzer. We hope that you will be satisfied with the device.

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 Modification history

Version	Date	sw	Modification
UriSed_3_PRO_sw4.0_User_Manual_v1	03/2018	4.0	First edition
UriSed_3_PRO_sw4.0_User_Manual_v2	04/2018	4.0	Correction of description on modifying records
UriSed_3_PRO_sw4.0_User_Manual_v3	09/2018	4.0	More detailed Diagnostic performance summary
UriSed_3_PRO_sw4.1_User_Manual_v1	03/2019	4.1	Features of new software (sw4.1) added New numbers of messages added
UriSed_3_PRO_sw4.1_User_Manual_v2	03/2020	4.1	Manual Measurement added
UriSed_3_PRO_cascade_sw4.2_User_Manual_v1	06/2021	4.2	Features of new software (sw4.2) added
UriSed_3_PRO_hw3_cascade_sw4.3_User_Manual_v1	03/2022	4.3	IVDR compliance Features of new software (sw4.4) added
IFU_URISED3PRO_08_EN	09/2023	4.6	Features of new software (sw4.6) added Complete design overhaul
IFU_URISED3PRO_09_EN	10/2024	4.11	Features of new software (sw4.11) added

1.2 General description of UriSed 3 PRO

UriSed 3 PRO is a professional automated urine sediment analyzer with a revolutionary new optical system combining bright-field and phase contrast microscopy. It offers a uniquely advanced visualization and recognition of formed elements in a urine sample. UriSed 3 PRO is designed specifically for professional use in clinical laboratories. It is a fully automated urine analyzer that meets all the usual requirements indicated by medical laboratories.

Operation of UriSed 3 PRO is easy and very efficient. The operator fills the device with Instrument Feed Water (IFW), places cuvette cartridges onto the rotating cuvette holder, the cuvette carousel and puts the racks with test tubes containing urine samples on the rack conveyor unit. The device takes care of everything else.

Test tubes are automatically forwarded to the sampling position and UriSed 3 PRO mixes the urine inside them to make it homogenous using a pipette. UriSed 3 PRO needs a urine sample of only 2.0 ml in the test tube for an accurate evaluation,

however, during measurement only 0.2 ml is taken up and transferred into special disposable cuvettes by the pipette. After transferring the sample the pipette is moved to the back of the device into a special rinsing chamber where both its inner and outer shell are rinsed with Instrument Feed Water (IFW) to avoid cross-contamination of urine samples.

Urine sample holding cuvettes are forwarded into the built-in centrifuge, where they are centrifuged at 2000 RPM for 10 seconds. This is to force all particles in the urine onto a single plane at the bottom of the cuvettes where the camera is focusing.

After centrifuging, the built-in camera takes both brighgtfield and phase-contrast pictures through a microscope at several points over the specimen (15 UriSed 3 PRO viewfields equal 10 regular microscope viewfields). The magnification corresponds to a 400x zoom. A high-performance image evaluation software processes all images to detect and further classify urine particles.

The results and all the images are stored in UriSed 3 PRO's memory, which has a capacity of 10000 records.

UriSed 3 PRO devices can be interfaced with LabUMat 2 fully automated urine chemistry analyzers. When LabUMat 2 has finished processing a rack, it forwards it to UriSed 3 PRO for sediment analysis. UriSed 3 PRO matches up the chemistry and sediment results and displays them in a single joint analysis report.

⚠ **Any disregard of the instructions in this User Manual may result in safety risk.**

Biohazard risk

This device may become infectious in the course of use.

Dispose of the device in accordance with the local regulation for biohazardous waste.

The analyzer still can be potentially infectious after removal from use and during transportation therefore should be treated as biological hazard.

1.3 Intended purpose

UriSed 3 PRO and its variants are an automated urine sediment analyzer for in vitro diagnostic use. It is a screening device for determination of the following parameters: Red Blood Cells; White Blood Cells in a quantitative way; WBC Clumps; Hyaline Casts; Pathological Casts; Squamous Epithelial Cells; Non-squamous epithelial cells; Bacteria: Rod Bacteria, Cocci Bacteria; Yeast; Crystals: Calcium-oxalate monohydrate, Calcium-oxalate dihydrate, Uric acid, Triple phosphate; Mucus; Sperm; Amorphous material in a semi-quantitative way. UriSed 3 PRO flags the possible presence of ghost RBC-s and RBC acantocytes.

It is intended for professional laboratory use.

The instrument measures human urine samples.

1.4 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.

1.5 Limitation of Liability

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

1.6 Symbols used in this manual

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

⚠ Caution: This symbol indicates operations, maintenance procedures and other processes that can cause equipment malfunction, equipment failure, or damage to the equipment if the instructions are not followed carefully. This symbol is also used to highlight situations that can compromise results.

This is an example of a caution text.

⚠ Warning: This symbol indicates maintenance procedures, operations, and other processes that can cause personal injury or personal harm if the instructions are not followed carefully.

This is an example of a warning text.

ⓘ Note: This symbol indicates important information or useful tips on operating the device.

ⓘ *This is an example of a note text.*

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

- **Bold text in light blue** indicates a cross-reference that points to a related subsection of the manual or to an external hyperlink.
- **Bold monospace type** indicates text that appears on a connected display.
- 1 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.

1.7 Safety information

Particular attention must be paid to the following safety informations. 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 procedures.

1.7.1 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.

1.7.2 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 container (liquid) and the waste bin (cuvettes), as it is described in **4.4 Taking UriSed 3 PRO out of operation** and **9 Maintenance**.

1.7.2.1 Possible accidents

- Sample or liquid waste spill

If any biohazardous material is spilled, wipe it up immediately and apply disinfectant. If it happens in the analyzer or on the rack conveyor, stop measurement process and start a daily cleaning procedure. (See **9 Maintenance**)

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.

- 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 it 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.

1.7.3 Protection from hot surface

After prolonged operation, the motor of the aspirational pump may become heated. To avoid burning injury, whenever open the front cover of the analyzer, please do not touch the motor with Hot surface label.

1.7.4 Waste management

The waste of the analyzer is potentially biohazardous and must be treated in accordance with the relevant laws and regulations. The maximum quantity of the biohazardous liquid waste is equal to the capacity of the waste container (5 liter).

- 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.

1.7.5 Safe and proper use of the analyzer

1.7.5.1 Accuracy and precision of measured results

An incorrect measuring result may lead to an error in diagnosis, therefore posing 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.

1.7.5.2 Installation and service

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

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

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.

1.7.5.3 Operational conditions

Operation outside the specified operating conditions may lead to incorrect results or malfunction of the instrument. (See **1 Introduction**)

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 devices and lead to false results.

Strong vibrations, knocking or tilting the instrument may lead a rack being moved to the rack entry position, which may lead to incorrect sample identification.

1.7.5.4 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.

1.7.5.5 Third-party software

It is forbidden to install any software on the operating PC.

1.7.6 Instrument approvals

The UriSed 3 PRO urine analyzer is manufactured and tested according to the following international standards:

- IEC 61326-2-6:2012
- IEC 61010-1: 2010, A1: 2016
- IEC 61010-2-020: 2016
- IEC 61010-2-081: 2019
- IEC 61010-2-101: 2018

2 Quick Start

This section shows the major steps in the measurement process. Check the following sections for more detailed information.

1. Turn the PC on and then turn the analyzer on.
   - Check, that all tubes and cables are connected properly and make sure, that the front cover is closed.
2. Log in (if necessary).
   - Enter your username and password in the Login popup window.
   - In case of by level login scheme, the system automatically logs in to the operator account after boot-up.
3. Prepare the analyzer.
   - Check wash container and, if necessary, fill it up.
   - Check the waste container and waste bin and, if necessary, empty them.
   - Check the cuvette cartridges and, if necessary replace them with full ones.
4. Prepare and load the samples.
   - Place barcodes on the test tubes.
   - Fill the samples in the test tubes.
   - Make sure that the barcode labels are facing the open side of the rack.
5. Run measurements.
   - Select measurement mode.
   - Place the racks on the rack mover.
   - Start measurements by clicking on START button.
6. Check and handle results.
   - View the test results on the database screen.
   - Validate, review, modify, or rerun tests, if necessary.
   - Send result records to LIS, print or save them to external storage.
7. Perform end of shift tasks.
   - Empty and clean waste bin.
   - Perform daily wash procedure (at shut down procedure, the analyzer automatically asks for it).
   - Empty and clean liquid waste container, clean rack mover and all areas that could be contacted with urine.

3 System overview

3.1 Analyzer parts an components

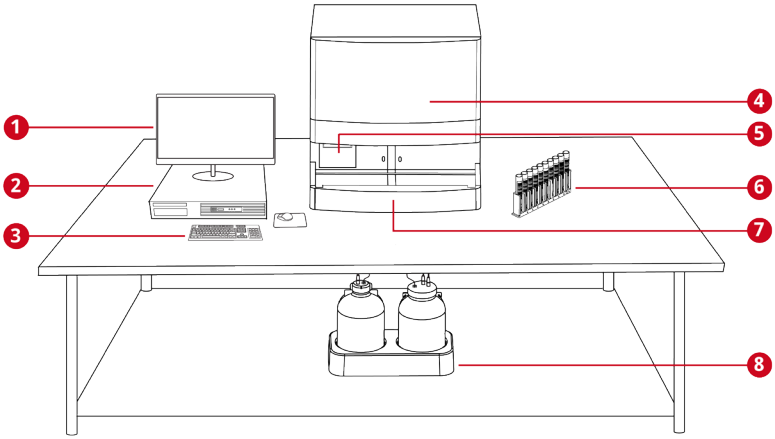


Figure 1. *UriSed 3 PRO after installation*

1 Monitor
2 PC
3 Keyboard and mouse
4 Front cover
5 Waste bin
6 Rack with test tubes
7 Rack conveyor
8 Wash and liquid waste containers

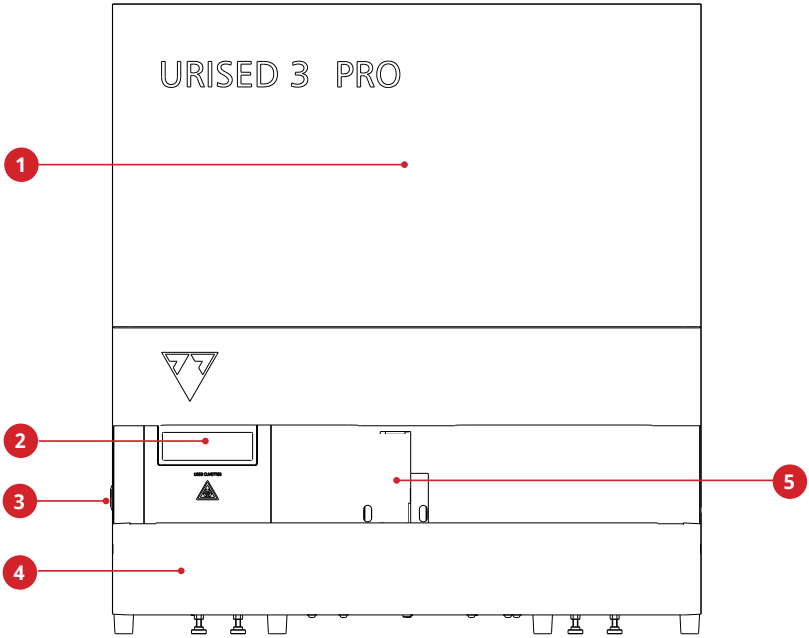


Figure 2. *Front of the analyzer*

1 Door
2 Waste bin
3 On/off button
4 Rack conveyor
5 Sampling area (with internal RFID and Barcode scanner)

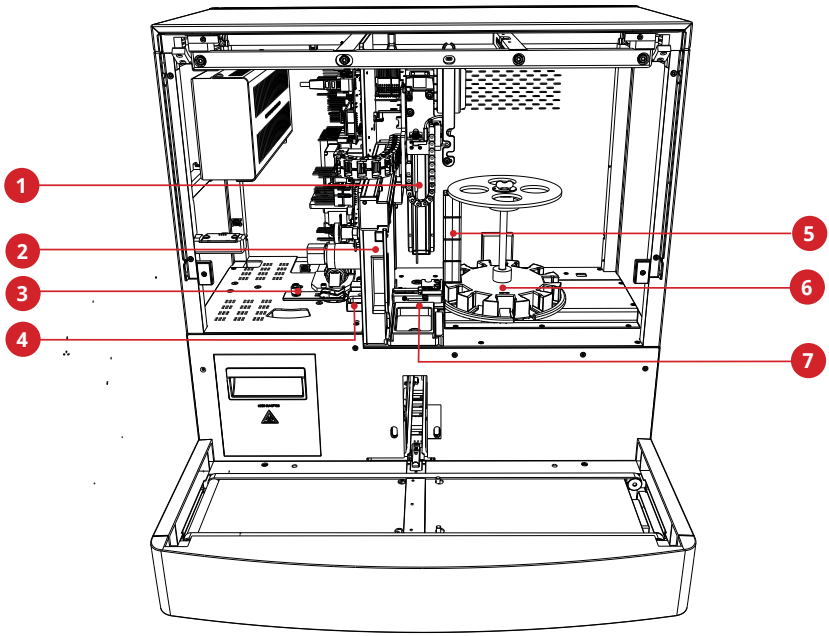


Figure 3. *Front and internal parts of the analyzer*

1 Pipetting probe

2 Centrifuge

3 Microscope arm

4 Rear cuvette guide

5 Cuvette cartridge

6 Cuvette carousel

7 Front cuvette guide

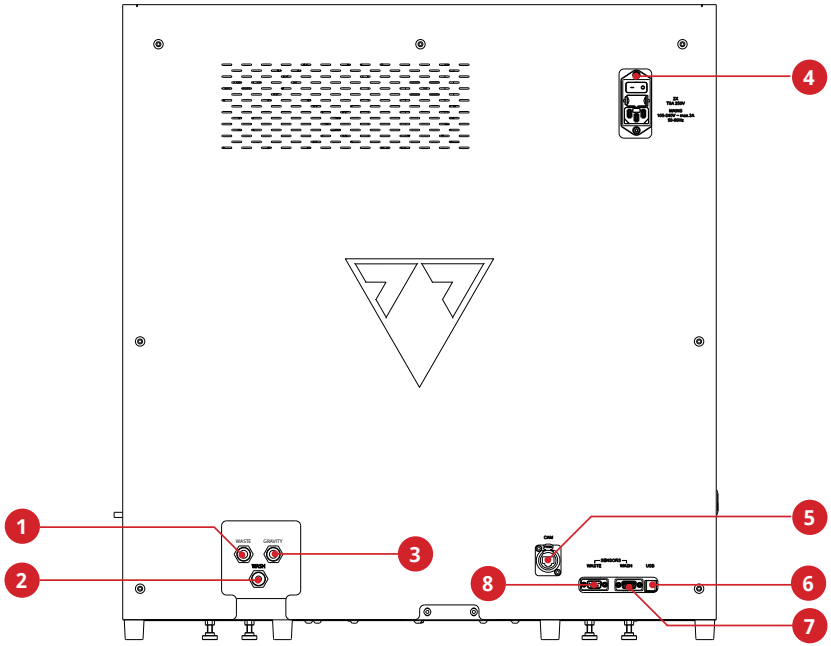


Figure 4. *Back of the analyzer*

1 Liquid waste outlet

2 Liquid waste safety outlet

3 Washing liquid inlet

4 Mains connector, power switch, fuse

5 Camera to PC connector

6 PC connection (USB-B type)

7 Washing liquid level sensor connector

8 Liquid waste level sensor connector

⚠ **The connectors are to be used only with the plugs of their appropriate accessories to avoid equipment malfunction or personal harm or injury.**

4 Installation

4.1 Preparing installation site

Prior to unpacking, clear the area where the device is to be operated: a 100 x 200 cm (39 per 78 inches) size table is needed that is strong enough to support the almost 63 kg (139 lbs) device (+ the PC and the LCD monitor).

⚠ **Make sure that you set up and operate the analyzer on a solid level surface in an environment without large variations in temperature or humidity. (see 1 Introduction)**

⚠ **Do not install or operate the device in environments with sources of vibration. Vibrations may interfere with inside parts movements, compromise evaluation process and reduce the useful life of the whole system**

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

⚠ **Do not operate this analyzer in close proximity to sources of strong electromagnetic fields (for example unshielded intentional RF sources), as these may interfere with the proper operation.**

⚠ **Make sure that there is enough room behind the device for the tubes of the liquid containers, the easy access to cables, the main connector and the ON/OFF switch and also for the proper ventillation of the analyzer. The recommended safety clearance is 25 centimeters (9.8 inches).**

⚠ **Observe the safety labels on the analyzer and its packaging. (see Figure 30. The Live view checkbox)**

4.2 Shipping list

UriSed 3 PRO device	1 pc
Power cord	1 pc
UTP cable	1 pc
USB cable	1 pc
Complete PC	1 pc
LCD monitor (with accessories)	1 pc
PC keyboard	1 pc
PC mouse	1 pc
Waste container	1 pc
Wash container	1 pc
Container holder	1 pc
Pipes	3 pcs
Rotor	1 pc
Rotor fixing	1 pc
Feeder top disc	1 pc
Front cuvette rail (positioner for sample injection)	1 pc
Rear cuvette rail (forwarder to microscope)	1 pc
Rack conveyor unit	1 pc
Cuvettes (in cartridges of 50pcs)	12 pcs
Test tube with barcode	1 pc
Racks	10 pc
User manual CD	1 pc
Packaging manual	1 pc
Interface between rack conveyor units*	1 pc
Connective spacer bridge*	1 pc

*: Parts only present if the UriSed 3 PRO device is shipped with a LabUMat 2 device.

4.3 First installation

4.3.1 Removing the packaging

⚠ **Check the shipping list to see if the shipment is complete and not damaged. If it is intact, follow the instructions below, otherwise please contact your distributor immediately.**

⚠ **Until installation, store the analyzer between +5°C and +40°C and between 10–85 % humidity.**

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

UriSed 3 PRO is shipped in 2 cardboard boxes. Refer to the detailed Unpacking manual – attached – on how to pack and unpack the device. Please follow the shipping marks on the boxes.

⚠ **We recommend that you keep the package cushioning and other reusable packaging material for future use.**

1. Cut off the straps on the wooden shipping box, and remove the lid and the package cushioning. Pull off the outermost packaging shell, and remove the flatpack box on top.
2. Remove the package cushioning and wrapping around the main unit box, then pull off its packaging shell.
3. Remove the Sediment Atlas, the ten (10) test tube racks and the rack adapters, and place them on the prepared table.
4. Remove the separately packed rack conveyor, and place it on the prepared table.
5. Remove the box with the User Manual and the small accessories detailed in the **4.2 Shipping list**.
6. Remove the two liquid tanks and their bowl, and place them in the bowl under the table.
7. Remove complete PC, LCD monitor, and keyboard, and place them on the table.
8. Cut off the tape around the main unit package shell, and pull off the shell. With a colleague to help you lift it, place the main unit on the table.
9. If UriSed 3 PRO and LabUMat 2 are shipped together, there will be another box below this one which contains the interface between the rack conveyor units and the connective spacer bridge. Take it apart.
10. Unwrap all the accessories, and refer to the Shipping list to check the completeness of the consignment.

⚠ **As the device is quite heavy (about 63 kg/139 lbs), two people are required to move it. Use both hands a grab the analyzer at its bottom corners from underneath each side.**

ⓘ *If you would like to install the device in another location, you need to remove all removable parts for transportation (the cuvette carousel, the front cuvette rail, and the rear cuvette rail). You also need to secure the pipette transfer arm with the supplied securing plate. For transportation, a trolley may be necessary because of the weight of the device.*

4.3.2 Installing the main unit

To remove the shipping-related safety elements, complete the following steps:

1. Open the doors and remove the sponge bolsters.
2. Find one extending screw in the device's pipette rail. It secures the pipette of UriSed 3 PRO during shipping. Unscrew the securing screw by hand and remove it from the equipment.

⚠ **It is important to remove the pipette securing screw before you can switch on the device. When the power is switched on, an initialization procedure is performed. This includes the motion checks, which may damage the equipment if you did not remove the securing screw.**

ⓘ *It is recommended that you keep the pipette securing screw and plate, as it might be needed if the device needs to be relocated.*

To install the removable elements of the system, complete the following steps:

1. Find the front cuvette rail among UriSed 3 PRO accessories and install it at the sample injection site to the right of the centrifuge.
2. Find the rear cuvette rail among UriSed 3 PRO accessories and install it next to the microscope, to the left of the centrifuge.
3. Install the rotating cuvette carousel onto the chassis of the device next to the front cuvette rail and secure it with the rotor fixing shaft. Load the rotating cuvette carousel with cuvette holder (☞ **Figure 58**).
4. Place the feeder top disc on the top of the rotor fixing and secure it with its attached wing nut.
5. To connect the non-removable accessories, complete the following steps:
6. Link the rack conveyor unit up with UriSed 3 PRO. Fit the two edges flush against each other and push the unit gently towards the main unit until it clicks.

ⓘ *Only the rack conveyor part supplied by the manufacturer is compatible with UriSed 3 PRO.*

7. Connect the power cable first to UriSed 3 PRO, then to the mains. For safety reasons UriSed 3 PRO can only be connected to earthed sockets.

⚠ **The analyzer can only be connected to the mains with its supplied power cable.**

8. Place the supplied PC and LCD monitor close to UriSed 3 PRO and connect them to the mains as well.

9. Connect the supplied monitor, mouse, and keyboard to the operating PC.
10. Connect UriSed 3 PRO to the PC properly with the supplied USB and UTP cables.

⚠ **There is a filter mounted on one end of the UTP cable. It is important to connect the filter end of the UTP cable to the UriSed 3 PRO main unit; the other end should be connected to the PC.**

⚠ **UriSed 3 PRO 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.**

⚠ **Do not remove the rear panel of the device! Only a specially trained service person may take the device apart.**

⚠ **Before connecting any external storage device to the PC, first always check it for viruses or any potencially harmful content.**

4.3.3 Installing the fluidic system

1. Lead the two larger size pipes through the two slots on the waste container lid. Make sure that the black rubber rings stay in the slots. Leave 10 centimeters (4 inches) from the ends of the pipes inside the container and connect the other ends into the slots on UriSed 3 PRO marked Waste and Gravity.

⚠ **There is no suction in the gravity pipe, so it must be installed so that it slopes downwards all the way to the Waste container.**

2. Connect the sensor for this container to the D-sub 9 connector of UriSed 3 PRO labeled Waste sensor.
3. Fill the wash tank with Instrument feed water (IFW). Lead the single smaller size pipe through the retainer of the “Wash” container and also the slot on its cover from the inside. Make sure that the black rubber ring stays in the slots. One end of the pipe has to be at the bottom of the container held by the retainer, and the other end has to be connected into the WASH slot of UriSed 3 PRO.
4. Connect the sensor for the tank marked Wash container to the D-sub 9 connector of UriSed 3 PRO marked WASH SENSOR.
5. Place both containers into their bowl of the container holder, and place the holder under the table supporting the device.

4.4 Taking UriSed 3 PRO out of operation

☣ **Since urine is a fluid of human origin, it 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 UriSed 3 PRO.**

No special arrangement has to be made in order to take UriSed 3 PRO out of operation. Perform the steps listed below to preserve good condition of the device while it is not being used:

6. Perform the washing cycle with the disinfectant solution. Switch off both the UriSed 3 PRO main unit and the operating PC and disconnect them from the mains.
7. Discard all used cuvettes from the waste bin.
8. Remove all fluids from both containers and clean them thoroughly. Let them dry and pack them up with their cap open.
9. Use the supplied securing plate to secure the pipette-moving robot.
10. Clean UriSed 3 PRO thoroughly, including all of its removable parts (☞ **9 Maintenance**). Let them dry and pack up UriSed 3 PRO as it was packaged when it arrived to you.

ⓘ *If you would like to put UriSed 3 PRO back into operation, follow the steps described in* **4 Installation** *to properly install the device.*

4.5 Tagging test tubes with barcodes

UriSed 3 PRO's built-in barcode reader can automatically identify urine samples by barcodes affixed to the side of test tubes. UriSed 3 PRO is able to identify the following types of barcodes:

- CODE 39
- CODE 128
- EAN-13
- EAN-8
- INTERLEAVED 2 of 5
- CODABAR

Barcodes should be affixed around the middle of the test tubes, between the levels indicated in red in **Figure 5**. Barcodes above or below these levels might not be identified by UriSed 3 PRO. When placing samples with barcodes in the racks, take care that the barcodes face the open side of the racks, otherwise the barcode reader will not be able to read the codes.

One of the supplied test tubes comes with a pre-affixed barcode. It models the optimal positioning of the barcode on the test tube, and can also be used to test the built-in barcode reader.

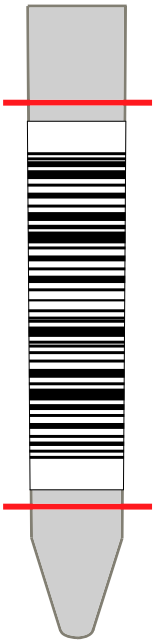


Figure 5.
Correct barcode placement

5 Overview of the interface

UriSed 3 PRO has an easy-to-use, intuitive menu structure. 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. 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 eight (8) discrete information fields of the status bar.

Key to the status bar fields (from left to right)	Possible displayed contents
Status of connection between UriSed 3 PRO and operating PC Online	Online Offline Initializing.. Upgrading.. Not ready (by HW error)
Status of connection between UriSed 3 PRO and LabUMat 2 LabUMat2 offline	LabUMat 2 Online (☞ **5.5.7 The LabUMat tab**) LabUMat 2 Offline LabUMat 2 initializing..
Connection status of bidirectional LIS (if enabled) LIS offline	LIS Online LIS Offline LIS initializing..
User rights according to login level or User name Service	Operator Administrator Service User name
Number of particles which are evaluated (It can be set in **Settings/Evaluation** menu up to a maximum of 54. ☞**5.5.4 The Evaluation tab**) Particle classes: 12	Classes: X
Number of remaining images waiting for evaluation Recognition threads: waiting 0	Recognition threads: waiting X
Number of cuvettes remaining in the cuvette holders. Cuvette: 94	Cuvettes: X

Key to the status bar fields (from left to right)	Possible displayed contents
Number of used cuvette in the waste bin Waste bin: 0	Waste bin: X
Current date and time 2013.01.24. 8:23:08	Date & time

5.1 User rights

Depending on the user login scheme selected by your service personnel, UriSed 3 PRO 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 UriSed 3 PRO: 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.

User level	User rights
Operator	run tests (patient sample, QC), initializate the instrument, handle results, modify result details, filtering, deleting the results
Administrator	all actions of the Operators, configure the system (modify settings), manage user accounts
Service	all actions of the Administrators, access to Service tab on Settings screen

ⓘ *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.*

5.1.1 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 UriSed 3 PRO 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.

In the 'By level' user login scheme, 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. 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.

Figure 6. *The Login window*

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.

1. After start-up, or after other user logout, the analyzer displays the **Login** window (see **Figure 6**).
2. Type your unique user name and password, then click **OK**. The User rights field of the status bar will 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.

5.1.2 Changing your password

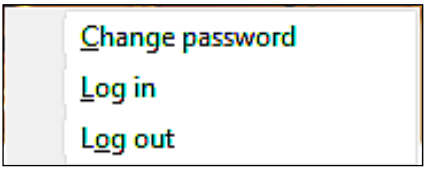


Figure 7. *The Login pop-up box for password-protected user accounts*

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 (see **Figure 7**). 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.

5.1.3 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 **Figure 7**). In the 'By level' user login scheme, your access level will automatically revert to Operator.

ⓘ *In the 'By user name' user login scheme, Adminstrator– 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.*

5.2 The Info button

This button is listed with the Menu buttons in all menu screens. Click this button to toggle displaying a splash window that lists all the currently installed device software, module firmware, and driver version data.

5.3 The Measure menu

By default, the **Measure** menu screen is displayed whenever the software starts, but you can access it by clicking the **Measure** button on the right. The **Measure** menu screen lists the currently active measurement records. The instrument serial number, date and time data, the rack and tube identifiers, the sample ID and the patient name, as well as the measurement status icons that correspond to each of the records is displayed with the entries.

ⓘ *Keep in mind that this current records list is a simple reference of the current measurement cycle, and exists for temporary information purposes only. It is not a searchable database, and will be deleted when you exit the software.*

5.3.1 Measure menu buttons

Click **Reset** button on **Measure** screen to clear the rack data list. Please note that **Init** does not clear the rack data list.

Click to start a system self-check, normally performed every time the system is started. Because every subsystem of the device is checked and restarted during Initialization, it is recommended that you run it whenever you encounter a problem with the device.

Click to remove the rack currently inside the rack passage. This function is disabled while a measurement is in progress.

Click to clear the current records list. This action does not delete the records from the device memory; they can still be accessed in the **Database** menu.

1. Click to start a statim—unscheduled, but urgent—measurement while a scheduled measurement cycle is already in progress. The statim measurement process is as follows:

2. The message **Wait until the device moves to STAT position!** is displayed until the measurement in progress is finished and the rack currently inside the rack passage is removed.

3. The rack conveyor moves the racks waiting for measurement backwards to make room for the statim sample. The **Load the urgent sample(s).** message is displayed when the device is ready to measure the statim sample.

4. Place a rack with the statim sample in front of the rack passage and click **OK** in the message window. The device will pull the rack inside, process the statim sample, then automatically resume the measurement cycle that was interrupted.

ⓘ *The **STAT** button is only active during normal measurement cycles.*

ⓘ *In case of Cascade system, the **STAT** measurement is done on the Secondary analyzer.*

Click to START, and click again to STOP a measurement cycle. ☞ **6.6 A typical daily routine** for further details. Click CONTINUE to continue the stopped measurements.

Click to start Pediatric measurements with low amount of sample. Only visible when enabled in **Settings/Measure** menu.

Click to start a measurement with live view and operator-taken viewfield images. ☞ **5.5.3.2 Live view** for further details.

Click the **DISINFECT** button to start a daily disinfection rinsing cycle that is identical to the 'daily washing cycle' that the device prompts you about every time you exit the software.

⚠ **The daily disinfection rinsing cycle completely drains the fluidic system. If you wish to perform measurements on the device after the rinsing cycle, make sure that you initialize the system first.**

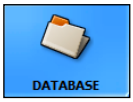
Click to exit the device software after confirmation. The device will prompt you to decide whether you wish to shut down the system with or without a rinsing procedure (see **9 Maintenance**).

⚠ **You must perform a rinsing at least once a day, preferably at the end of the workday.**

A progress bar indicates the progression of the shutdown operation. Once the shutdown has finished, press the power button on the side of the device (unless you have set up a full system shutdown), then switch off the power switch at the back of the device.

⚠ **The Exit button is disabled while a measurement is in progress.**

5.4 The Database menu



Data from the performed measurements is available on the **Database** menu. You can retrieve the summarized reports of the samples and also display all the viewfield images taken and evaluated by the device. Data management is accessible during the measurement as well.

The **Database** main menu screen is divided into two parts: records listed in the **Sample List** on the left identify the evaluated samples; information available on the currently **Selected Sample** is arranged on the right. The **Selected Sample** screen area is further divided into a summary of the analysis results and an **Image List**.

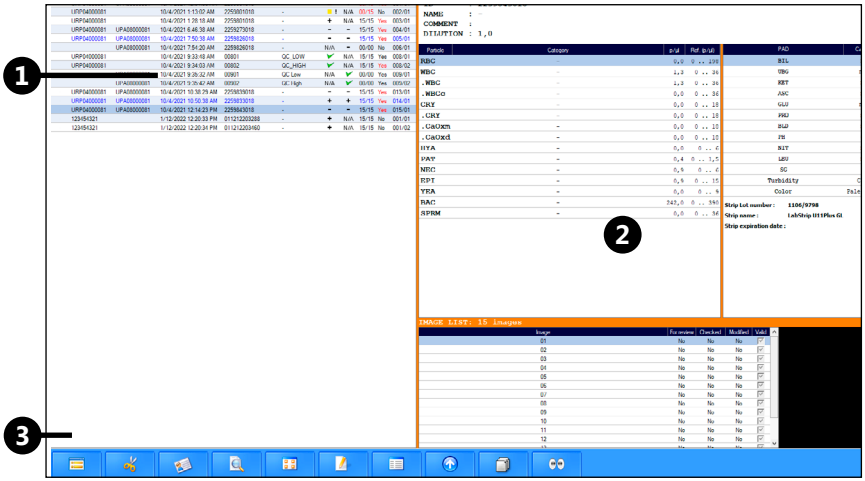


Figure 8. *Database menu:*

❶ Sample List

❷ Selected Sample

❸ Function buttons,

ⓘ *You can manually modify any of the automated evaluation results, as well as manually tag rare or unusual sediment particles on the viewfield images (☞* **5.4.4 The Sample View Editor (SVE)***).*

ⓘ *Only the analysis results of successfully processed samples are added to the* ***Sample List****.*

Click a record in the **Sample List** to select it and display all information —analysis results and **Image List**—available for the selected sample on the right.

ⓘ *Adminstrator-level users may specify the number and order of the columns displayed in the* ***Sample List*** *(☞* **5.5.2 The Display tab***).*

5.4.1 The Sample List screen area

ⓘ *The number of entries in the **Sample List** is indicated in the header. The selected sample record is highlighted in dark blue.*

- Double-click inside the **Mark** column of a record to toggle starring (marking with a golden asterisk) it as a way of highlighting it. You can filter for starred and unstarred records when searching (☞ **5.4.3 The Database menu function buttons**).
- The **Sed./Chem. Instrument** columns show the instrument serial numbers.

ⓘ *In case of Cascade system, the primary analyzer lists measurement records from both sediment analyzer. The instrument number identifies the analyzer that made the measurement.*

- Records are identified by the **Date&Time** of measurement, the **R/T** (Rack/Tube), their **ID**, and the **Name** of the patient (if a patient name was entered).
- The **Sed** column indicates whether the result of a sample is positive (+), negative (-) or if for some reason it is recommended to be verified by a laboratory professional (☞**5.4.1.1 Sediment results**).
- The **Chem** column displays the results of the sample's chemical urinalysis performed by the interfaced test strip–based urine analyzer (☞**5.4.1.2 Chemical results**).
- The **Eval** column indicates the number of images the system accepts as valid out of the total number of images.
- The **LIS** column indicates whether the record has been transferred to the predefined LIS.

ⓘ *If you manually modify any of the results for a transferred record, the* **Yes** *in the* **LIS** *column will turn red. The indicator will stay red as long as the record is not transferred to* **LIS** *once again.*

- **Sediment/Chemical measured by, Validated by, Sent to LIS by, Exported by, Printed by** - These columns display the name of the operator who performed the given operation for the sample.
- **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.)

5.4.1.1 Sediment results

After taking the set number of images of the centrifuged urine samples, UriSed 3 PRO evaluates them (☞ **Image evaluation**) to modify the number of automatic evaluations and the number of images). Usually, the images can be evaluated without difficulty and UriSed 3 PRO provides an accurate overall result. However, there might be some very crowded images from extremely pathological samples which cannot always be reliably evaluated automatically. UriSed 3 PRO has a range of symbols to display in the **Sed** column to draw attention to results that may require manual review by a laboratory professional.

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.

Skipped.

The sample was not analyzed by the sediment analyzer.

— Negative (normal) sample.

All values of the enabled particles are within the negative reference range, except for MUC, SPRM, AMO and ART particles.

ⓘ *If only MUC or SPRM particles are detected in the sample, it is categorized as negative.*

ⓘ *See* **5.4.4 The Evaluation tab** *to enable and disable particle classes and* **5.5.1 The Category tab** *for information on how you can modify particle classes.*

+ Positive (abnormal) sample.

The sample contains higher levels of one or more particle classes than the preset upper limit for the given particle class. Detection of MUC, SPRM, AMO, and ART particles has no effect on this attribute.

Hard review.

Some images are so crowded that it can be difficult to distuingish 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 (☞**"For review"**). 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 (☞**5.4.4 The Sample View Editor (SVE)**). The records will display N/A for every particle class as long as the results are not modified manually (☞**5.4.5.1 Modifying sediment results in the Database on page 51**). The automatic valida-

tion is disabled in case of hard review, therefore the operator has to validate the mesurement 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 (☞ **"For review"**). The comment **Please review images!** 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 (☞ **5.4.4 The Sample View Editor (SVE)**). Automatic result is available for the sample. The automatic validation is disabled in case of soft review, therefore the operator has to validate the mesurement 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.*

⊕ or ⊖ AMO review.

The Amorphous material 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 AMO review state and marking is only an indication for the operator, it is not exported, transferred or printed. The AMO 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.*

⊕ or ⊖ BAC review.

The Bacteria 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 BAC review state and marking is only an indication for the operator, it is not exported, transferred or printed. The BAC 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 viewfield images are manually unchecked;
- if the status of the sample is manually set to invalid (see **Figure 12** and its key);
- if the amount of the sample is low, but not low enough to trigger the Empty cuvette warning (between 1 and 2 milliliters).
- 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.

Empty cuvette.

UriSed 3 PRO measured an empty cuvette (without injected sample) and warns the user to avoid reporting false negative measurements because of missing samples. A pop-up window also appears displaying “Empty cuvette”.

ⓘ *Except for the actual warning messages displayed, samples with the Empty cuvette warning are exported and printed with the same indications as invalid samples.*

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 could 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 dese-

lect faulty images from evaluation by unclicking the **Valid** checkmark from the **Image List**. In case of frequent occurrence, please call service.

4. The measurement data suggest that unexpected event occured at the taking of one or more images of this sample. This phenomenon may effect the correct evaluation of the sample The comment **Abnormal image intensity, 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.

! Low sample level.

If the liquid level sensor indicates that the amount of the sample is below 2 milliliter, an exclamation mark will be stored and transferred with the measurement record, and the message **Low sample level** is displayed in the summary of the quantitative results.

⊞ or ⊟ Cross-check rule is triggered.

Any of the selected cross-check rule is true for the given sample result of UriSed and LabUMat. 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.

ⓘ ☞ **8 Quality control** *for the symbols used with QC measurements.*

5.4.1.2 Chemical results

ⓘ *The **Chem** column is only displayed in the **Sample List** if it is enabled in the **Columns of sample list** window (☞ **5.5.2 The Display tab**).*

ⓘ *The test strip pad result window in the **Selected Sample** screen area is only displayed if the **Show chemical data** checkbox is checked (☞ **5.5.2 The Display tab**).*

How to interpret the **Chem** column:

N/A Not available, e.g. because sample has been measured with the microscopy but not the chemical urinalysis 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.

− Negative (normal) sample. The sample was found within the normal reference ranges of the test strip analytes.

+ Positive (abnormal) sample. The sample was found to exceed the reference ranges of the test strip analytes.

5.4.2 The Selected Sample screen area

ⓘ *All the results are displayed rounded to two (2) decimal places.*

A summary of the quantitative analysis is displayed at the top of the right side of the screen.

ⓘ *See* ☞ **5.5.6 The Print tab** *for the available particle classes.*

5.4.2.1 The particle results window

Particle	Flag	Category	p/µl	Ref. (p/µl)
RBC		++++	3 236,6	0 .. 10
WBC		+	14,5	0 .. 12
CRY		-	2,2	0 .. 6
.CRY		-	0,0	0 .. 6
.CaOxm		-	2,2	0 .. 6
.CaOxd		-	0,0	0 .. 6
.TRI		-	0,0	0 .. 6
.URI		-	0,0	0 .. 6
HYA		-	0,9	0 .. 2
PAT		-	0,0	0 .. 1,5
NEC		-	0,4	0 .. 2
EPI		-	1,8	0 .. 5
YEA		+	8,4	0 .. 3
BAC		-	128,0	0 .. 130
.BAC		-	0,0	0 .. 130
.BACr		-	10,6	0 .. 130
.BACc		-	117,5	0 .. 130
MUC		-	240,2	0 .. 264
AMO		-	99,9	0 .. 660

Figure 9. *The particle results window in the Selected Sample screen area*

The results for the particle classes and subclasses that you have enabled on the Settings menu (☞**5.5.4 The Evaluation tab**) are displayed in the particle results window (see **4.2**). Subclass results are displayed with a starting dot.

Key to the particle results window	
Particle	The abbreviated names of the enabled particle classes and subclasses. Subclass results are displayed with a starting dot.
Flag	The operator can decide whether the system should indicate with a green flag that there is any ghost RBC (RBCg) or/and acanthocyte cell (RBC-Aca) detected in the sample or/and the WBC and BAC presence in the sample both reach a certain, previously set value (UTI) (☞**5.5.4.4 Flag settings**).

Key to the particle results window	
Category	The (☞ **5.5.1 The Category tab**) semi-quantitative relative category that the quantitative particle result is assigned.
p/HPF p/µl	Particle number per High Power Field or particle number per microliter. Change the preferred unit on Settings/Display tab.
Ref. (p/HPF)	The ranges defined for Semi-quantitative relative category number 1 (which is conventionally the negative category). You can disable this column (☞ **5.5.2 The Display tab**).

The following conventions govern the calculation and display of particle results:

- The result of a particle class is the sum of all the results of its subclasses.
- Each particle class that has one or more subclass results enabled is displayed with a 'duplicate' subclass that has the same name as the name of its parent particle class with a dot before it. The particles that do not fit any of the enabled subclasses are listed with this 'duplicate' parent class.
- 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 overriden.
- If a particle subclass is manually disabled, the particles assigned to it will be re-assigned to the 'duplicate' parent class.

5.4.2.2 The chemical results window

PAD	Category	Result	Unit
BIL	neg	neg	umol/l
UBG	norm	norm	umol/l
KET	neg	neg	mmol/l
ASC	neg	neg	g/l
GLU	norm	norm	mmol/l
PRO	neg	neg	g/l
BLD	neg	neg	Ery/ul
PH	6.5	6.5	
NIT	neg	neg	
LEU	neg	neg	Leu/ul
SG		1.005	
Turbidity	Clear		
Color	Pale yellow		

Strip Lot number : **1106/9798**
Strip name : **LabStrip U11Plus GL**
Strip expiration date :

Figure 10. *Chemical results*

If enabled (see ☞ **5.5.2.2 The Visible settings screen area**), chemical urinalysis results transferred from the interfaced test strip–based urine analyzer (see ☞ **6.7 Operating UriSed 3 PRO together with LabUMat 2** on how to interface the two devices).

5.4.2.3 The Image List

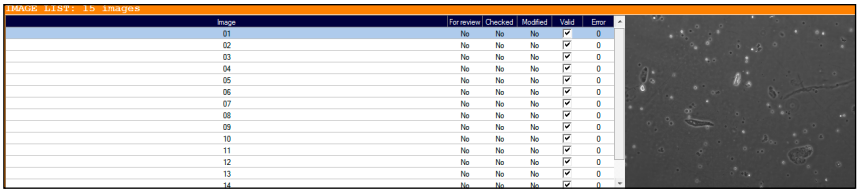


Figure 11. *The Image List*

In the **Image List** in the bottom right corner of the screen all the images taken of the selected sample are listed. Each record in the **Image List** is displayed with the following attributes:

- **Image** indicates the sequence number of the image.
- **For review** indicates whether the image is recommended for further review. A viewfield image may be marked for review for the following reasons:
- the image is so crowded with particles that particle detection is not reliable (see **Figure 20**).
- the evaluation image detects a bubble or other anomaly on the image.
- **Checked** indicates whether the image was opened in the SVE (Sample View Editor).

- **Modified** indicates whether the automatic evaluation of the image was modified manually in the SVE.
- In the **Valid** column you can toggle whether the given viewfield image is accepted as the basis for sample image evaluation. The overall result is based on the averaging of all the valid viewfields for a sample. The images with **Yes** in their **For review** column cannot be accepted as valid.

ⓘ *By default, every viewfield image is accepted as valid.*

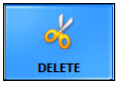
⚠ **By default, for samples below the minimum sample level (displaying the Low sample level warning message), none of the viewfield images are accepted.**

5.4.3 The Database menu function buttons

Like all the other menus, **Database** has a row of buttons for various database operations.

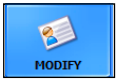
ⓘ *When you make any change in the **Settings** menu that affects the **Sample List** in the **Database**, the list will be refreshed. Depending on the number of sample records in the list, the refreshing process may take some time. This is indicated by the progress bar that is displayed during the process.*

Click to toggle selection of all the records on the **Sample List**. The button is inactive if there is only one record on the list.



Click to delete the results of the selected records from the database. This feature is disabled while a measurement is in progress.

⚠ **The records will be deleted permanently. This is an irrevocable command.**



Click to modify status or dilution factor of the selected sample or the ID or patient name associated with the record using a dialog box.

ⓘ *An empty field is not an acceptable sample ID. The maximum length of the ID is the same as that set in the the **Display length** dialog box (☞ 5.5.2.2 The Visible settings screen area).*

ⓘ *The button becomes inactive if more than one records or a QC record is selected.*

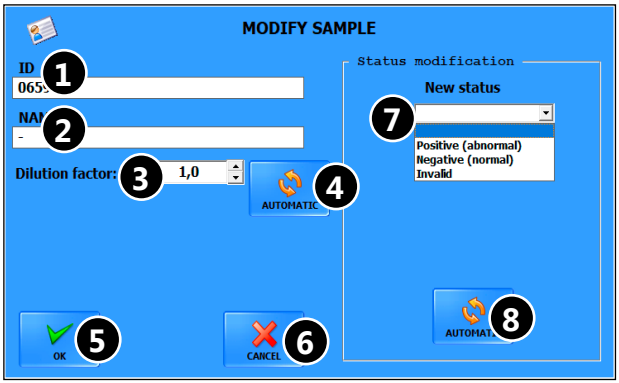


Figure 12. *The Modify Sample dialog box (for a sample with both chemical and sediment urinalysis results)*

1. Sample ID

2. Patient name associated with sample

3. Dilution factor

   ⓘ *Applicable only if the selected sample has been analyzed with the sediment method.*

   ⚠ **If the sample is very crowded, diluting the sample may be necessary for proper evaluation. If you dilute the sample, you must enter the dilution factor in this field to get precise results. You can calculate the dilution factor based on the DF=Final volume/original sample formula. You can adjust the factor in increments of 0.1 between 1.0 and 10, and in increments of 1 between 10 and 100.**

4. Click to reset the dilution factor to that determined by the automated evaluation

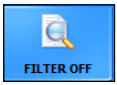
5. Click to store the modified data

6. Click to cancel your changes

7. Status modification options

   ⚠ **The sample status options are only available if manual sample status modification is enabled (☞ 5.5.2.2 The Visible settings screen area).**

8. Click to reset the sample status to that determined by the automated evaluation



Click to bring up the **Sample filter** dialog box (see **Figure 13**). 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 or chemistry method.

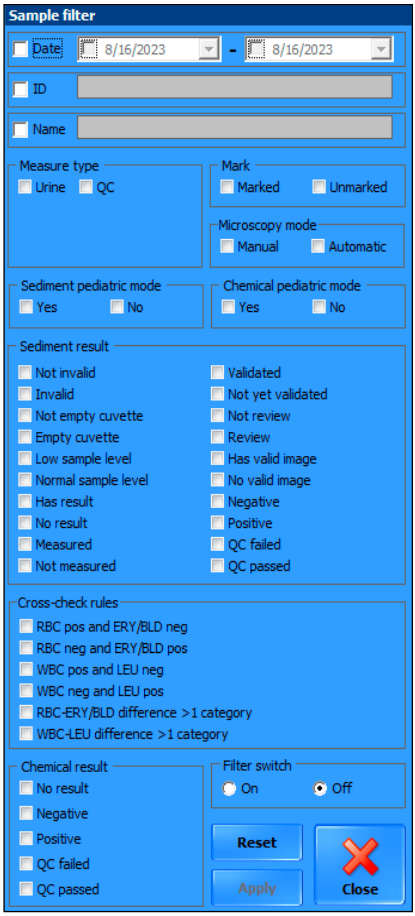


Figure 13. *The Sample Filter dialog box*

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 checkboxes 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 become red when an unuseable character typed in.

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

Filter of pediatric measurements

Filtering by the status of validation.

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

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.

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 chec-

king radio button **Off** in **Filter switch** bounding box and click **Apply**. When you check **On** again your previous selection becomes active again. Click **Reset** to clear selection.

Click the gallery button or double-click a record in the Sample List to display all the raw viewfield images for the selected sample.

ⓘ *The* **Gallery** *button is inactive if you select more than one record, or if the selected record does not have sediment urinalysis data.*

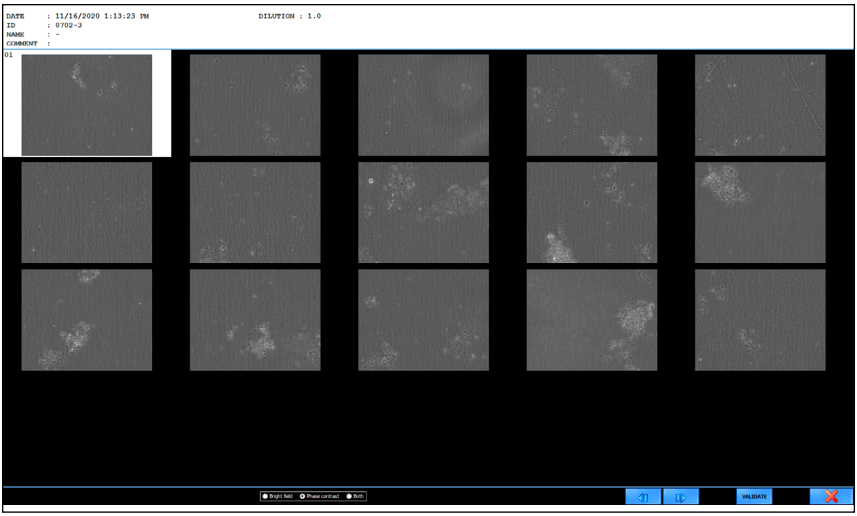
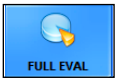


Figure 14. *The image gallery of a sample.*

The white border indicates the selected image. The radio buttons at the bottom changes between the display of brightfield or phase contrast microscope images and composite images. Check **All** for displaying all three types.

Click **VALIDATE** to mark the record as correct. This button has the same function as the **VALIDATE** button on **Measure** screen.

Double-click on an image to see it magnified in Sample View Editor (SVE) ☞ **5.4.4 The Sample View Editor (SVE).**

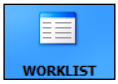


Click to re-evaluate every viewfield image for the selected records. The system will evaluate all images for the selected records, even the images that have not been evaluated automatically before.

ⓘ *You can check how many viewfield images have been evaluated out of the total number of viewfield images made.*

ⓘ *This feature is available only to users logged in as Administrator– or Service-level operators.*

Click to add comments to the sediment or chemical urinalysis results of the selected sample, and to view system comments (You may not edit system comments.) After saving the comment, it will appear in the **Comment** row of the **Database**, the **Gallery**, the **Sample View Editor**, the exported result, and on the result printout.



Click to launch the **Worklist editor** (see **Figure 15** and its key). 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 ☞**5.5.3 The Measure tab**.

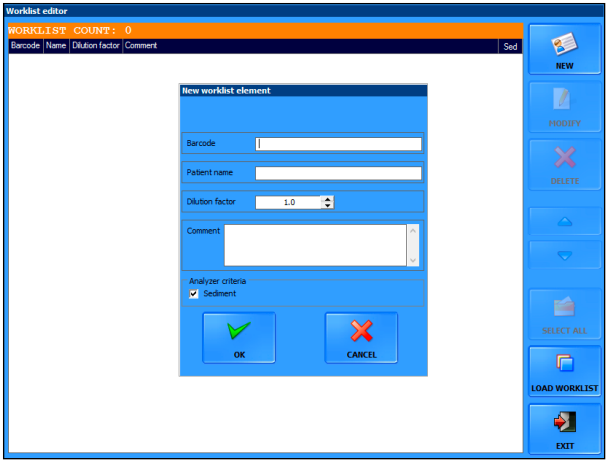
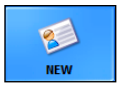
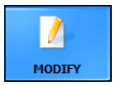


Figure 15. *The Worklist editor window with a New worklist element dialog box*

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. If sample measurement is based on worklists and an interfaced chemical urinalysis device is enabled, you can choose to measure the the sample with the sediment method, the chemical method, or both.
	Click to edit the details of the selected worklist element (see **Figure 12** and its key).
	Click to delete the selected worklist element or elements.

Key to the Worklist Editor	
	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. Make sure that the Worklist is saved as a text file with the .txt extension or without an extension. For the device to be able to correctly process the text file Worklist, the file must be created according to the following protocol: **<space>W|ANALYSER_ID|Barcode1^PatientName1^Comment1^Chemical1^Sediment1|Barcode2^PatientName2^Comment2^Chemical2^Sediment2|...|BarcodeN^PatientNameN^CommentN^ChemicalN^SedimentN<Enter>** Assign 0 to the Sediment and Chemical elements if you wish to skip the one or the other analysis method, and 1 if you wish to perform the analysis with the given method. Here is a well-formed example string for two (2) worklist elements: **W|SN12345|BAR143^Mr. Baker^Comment for Baker^1^1|4444^Mrs. Smith^Comment for Smith^1^0**
	Click to close the **Worklist editor.**

⚠ **When sample measurement is based on worklists, the device will only perform as many measurements as there are names on the Worklist. If you try to start measuring when there are no more patient names on the Worklist, the device will not respond and will display the Worklist elements are consumed! warning message.**

⚠ **Worklist data do not apply to STAT and Quality Control measurements.**

⚠ **You cannot edit a worklist when it is active and a measurement is in progress. However, you can add elements to a worklist with the New or Upload buttons even while a measurement based on that worklist is in progress.**

Click to open the transfer options dialog box (see **Figure 16** and its key.)

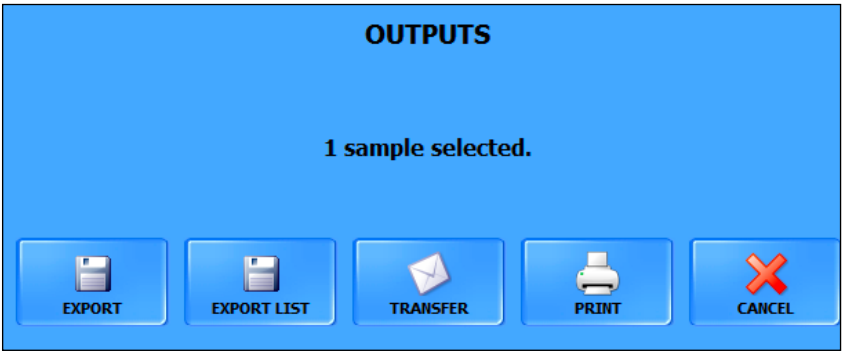
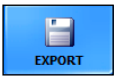
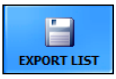


Figure 16. *The Transfer options dialog box*

Key to the Transfer options	
	Click to save the selected record and its viewfield images in a folder you specify on the connected computer Each record is saved inside its dedicated folder within the folder you specify. The results table for each record is saved as an HTML table (☞ **5.5.5 The Transfer tab** for further details). ⓘ *Depending on the number of particle types you enabled to be displayed, the exported report might not fit on a single page.*
	Click the **Export List** button to save the selected record as a HTML table that you can open as a spreadsheet as well (with spreadsheet software such as OpenOffice Calc or Windows Excel).
	Click to transfer the selected record to a host computer of LIS . ⓘ *Contact your distributor on how you can set up a transfer protocol.*
	Click to print a combined chemical and sediment urinalysis report with your default printer settings. ⓘ *Depending on the number of particle types you enabled to be displayed, the printed report might not fit on a single page.*
	Click to close the OUTPUT popup window.

Date&Time	ID	Name	RBC	WBC	CRY	.CRY	.CaOxm	.CaOxd	HYA	PAT	NEC	EPI	YEA	BAC	MUC
5/17/2012 1:48:28 PM	224485	-	0,00	330,00	52,80	0,00	0,00	52,80	0,00	13,20	0,00	13,20	0,00	712,80	19,80
5/18/2012 10:09:03 AM	297716	-	0,00	330,00	52,80	0,00	0,00	52,80	0,00	13,20	0,00	13,20	0,00	712,80	19,80

Date&Time	ID	Name	Lot number	Liquid type	Expiration date	RBC	WBC
5/17/2012 2:08:09 PM	224490	QC_HIGH	2345	Quantimetrix Dip and Spin	5/17/2012	0,00	330,00

Key to the Transfer options
Figure 17. *An example of two normal and one Quality Control measurement, exported as HTML tables*
⚠ **The instrument serial number is shown in every printed, exported and tarnsferred measurement record.**

Click to toggle the expanded view of the **Sample List** to see all the fields that are enabled but that you chose not to be displayed in the standard-size **Sample List** (for example **Sediment measured by**, **Chemical measured by**, **Validated by**, etc.: these fields display the name of the user who performed the processes in question). (See **Figure 28** for details.)

Click to validate the selected result as correct (☞ **5.5.3.8 Auto-validation**).

⚠ **If you change any of the details of an already validated result, its Validated by field will revert to Not yet validated.**

⚠ **Only validated results can be exported, transferred to the LIS, or printed.**

5.4.4 The Sample View Editor (SVE)

By default, the device processes all of the viewfield 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 viewfield image thumbnails in the **Image List** in the bottom right corner of the **Database** menu screen, or the measurement record associated with the viewfield image.

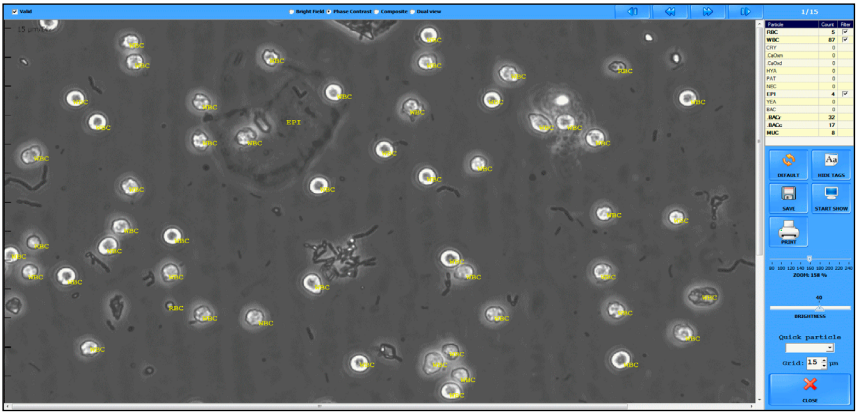


Figure 18. *The Sample View Editor (SVE)*

There are essentially two types of viewfield images:

- Viewfield images that are not crowded with particles are, regardless of whether they are negative or pathological, considered **Normal** (see **Figure 19**)—they have **No** in their **For review** column in the **Image List**. The majority of viewfield images are of this type.

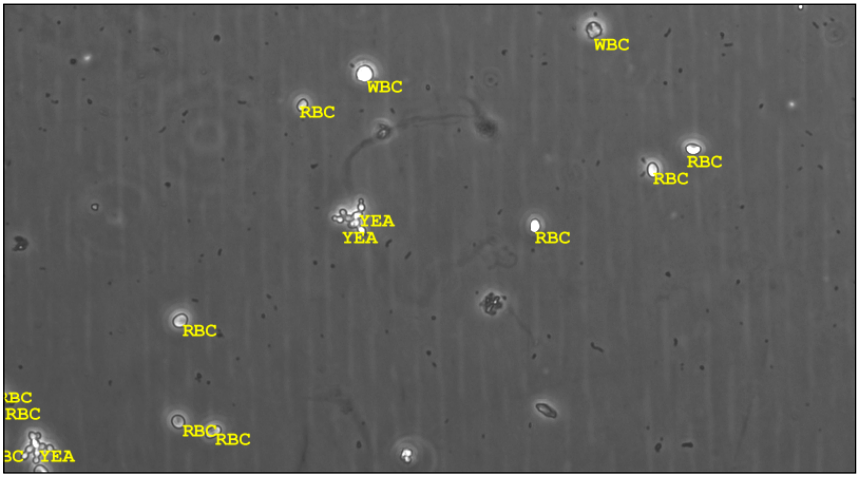


Figure 19. *Automatically evaluated and tagged view field image of a Normal image*

- Viewfield images that are so crowded with particles that it is difficult to distinguish between various elements are considered **Images for review** (see **Figure 20**)—they have **Yes** in their **For review** column in the Image List, and the message **Image excluded from the automatic evaluation!** is displayed in red in the SVE header.

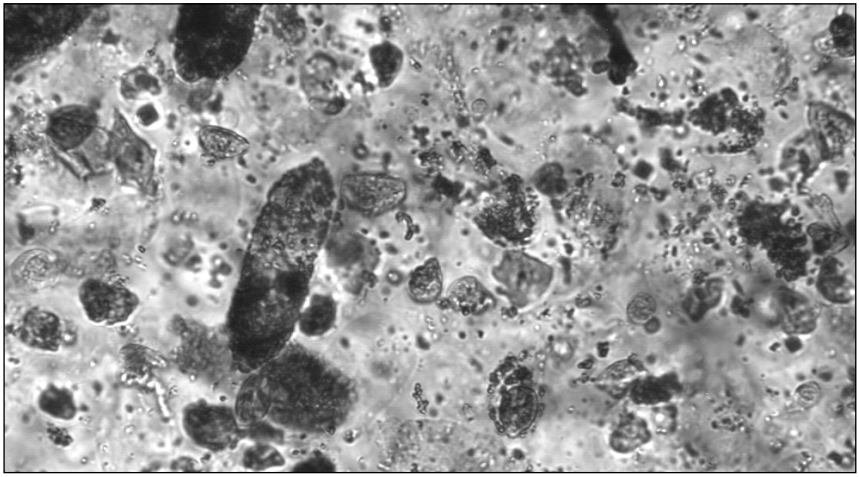


Figure 20. *A crowded viewfield image without automatic tags added*

ⓘ *The images that have **Yes** in their **For review** column, cannot be displayed with automatic result and particle tags cannot be added to them.*

ⓘ *Keyboard shortcuts: C—toggles all the particle tags ('captions') in the image; R—toggles a ruler running along the sides of the screen; G—toggles a grid over the image for the better estimation of particle size; Insert—toggles all of the above graphical elements; Delete—hides all of the above graphical elements.*

Breakdown of the elements of the **SVE**:

- The Sample ID of the current image can be seen in the header of the **SVE**.
- The number of the current viewfield image out of all the viewfield images available for the given sample is displayed in the top right corner.
- Use

radio buttons to toggle between the images of the bright field or phase contrast microscope and composite images or the dual view.

ⓘ *The composite image is not stored.*

- Select **Dual view** option to see the bright field and the phase contrast images next to each other. In **Dual view**, the operator can zoom in and out by scrolling with the mouse. The magnified view is highlighted in blue in the smaller upper

images. Move the highlighted part by clicking into the upper images or by holding down the left click and moving the mouse.

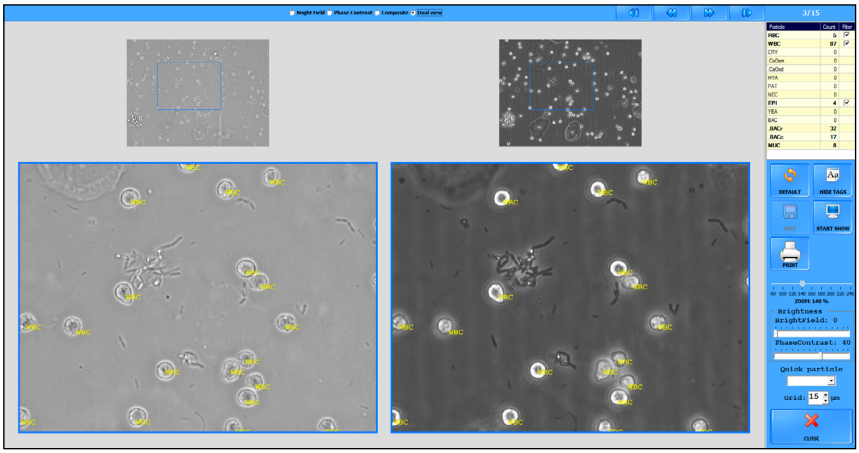
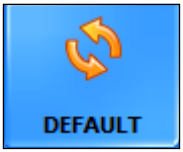


Figure 21. *The Dual view*

- Use the **Valid** checkbox to toggle whether the given viewfield image is accepted as the basis for sample image evaluation. It works the same as the **Valid** checkbox in the **Image List** (see **5.4.2.3 The Image List**).
- Use the buttons to scroll through the viewfield 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 viewfield image is displayed on the right. Each of the particle classes that were identified in the image have a check box inside the table. Use the check boxes to toggle the tagging of the particle in question. The tagging preference you set in one of the viewfield images applies to every other viewfield image in the series for the current sample, but not to the viewfield 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 viewfield images for the selected sample.



Click to cancel all manual modifications and revert to the automated evaluation results for the currently displayed viewfield image.

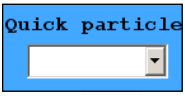
ⓘ *All manual modifications will be lost when the image is reveted to default.*

Click to toggle all the tag text over the raw viewfield image currently displayed. (Works just like the C keyboard shortcut.)

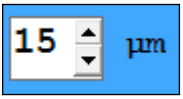
Click to toggle a slideshow of the viewfield images. A new image is displayed every three (3) seconds.

ⓘ *When slideshow reaches the last image for the current sample, it will continue with the next sample in the database without prompting the user.*

ⓘ *The* **Default**, *and* **Print** *buttons are disabled during the slide-show.*



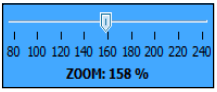
To quickly apply multiple instances of a particle type: choose a particle type from the drop-down list to 'load' the particle type into your cursor, then click anywhere in the image to apply the particle tag (see **5.4.4**).



Click the arrows to adjust the gradation of the grid that the G keyboard shortcut displays over the viewfield image.

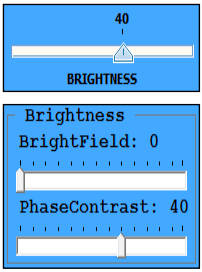
Click to save the current viewfield image as displayed (with out without particle tags) as a bitmap image. You can specify where you want to save the image in a dialog box.

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.



Slide the **ZOOM** scale bar for changing the enlargment ratio of the selected image.

ⓘ *It does not change the* ***Zoom mode*** *settings in* ***Display*** *tab.*



Slide the **BRIGHTNESS** scale bar for changing the degree of brightness of the phase contrast or the brightfield image. The composite image cannot be changed. In case of using the **Dual View**, the brightness of the phase contrast and the brightfield can be adjusted separately.

Its keyboard shortcuts are Page up and Page down.

ⓘ *It does not change the **Brightness** settings in **Display** tab.*

5.4.5 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 overriden.**

UriSed 3 PRO was developed to help the work of the doctors and not to replace them: all automated evaluation results can be modified manually. There are several ways to edit the results that the device generates: in the **Database** menu, in the **Sample View Editor**, and in using the **Modify** button in the **Database** menu.

ⓘ *Modified records are highlighted in blue.*

5.4.5.1 Modifying sediment results in the Database

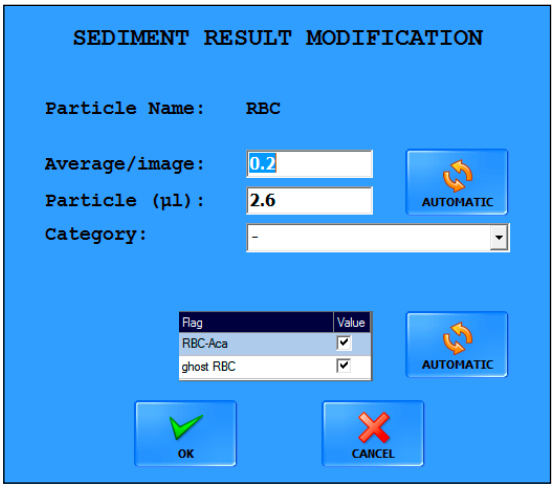


Figure 22. *A dialog box to modify a sediment urinalysis result*

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

1. In the summarized sediment 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 (see). The system will automatically apply the change you made in one of the text boxes to both text boxes.

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

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.**

⚠ **The operator can enable/disable RBC-Aca and RBCg flagging for the particular sample (☞ 5.5.4.4 Flag settings).**

5.4.5.2 Modifying chemical urinalysis results in the Database

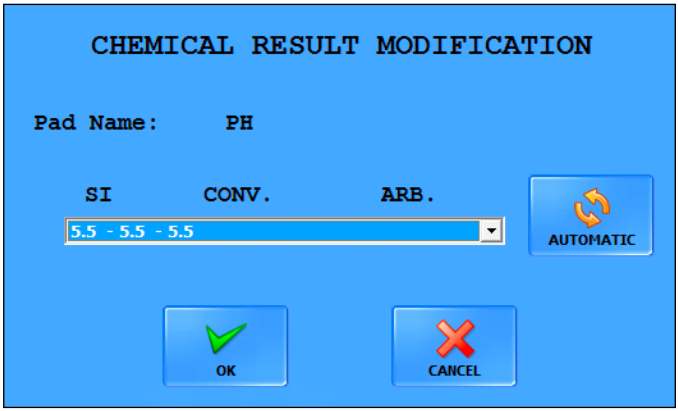


Figure 23. *A dialog box to modify a routine urinalysis result*

1. In the summarized chemical urinalysis report, double-click on the row of the analyte result or physical measurement data you wish to modify to display the modification dialog box (see **5.1.2**).
2. Choose the desired result in the dialog box.

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

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

5.4.5.3 Adding particle tags in the Sample View Editor

⚠ **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 viewfield image, do the following:

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 viewfield image to apply the particle type tag. You can apply the selected tag as many times as necessary.

⚠ **There are several particle classes and subclasses ('added particles') that are not available for automated evaluation, but can be added manually. You need to enable their use before they become available choices (☞5.5.4 The Evaluation tab).**

ⓘ *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**.*

ⓘ *The software takes all the new particles that you added into consideration when generating the sediment report.*

ⓘ *New particle tags are displayed in blue to indicate that they have been modified.*

5.4.5.4 Modifying particle tags in the Sample View Editor

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

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

3. Choose a particle type in the **Quick particle** drop-down list in the right sidebar of the **Sample View Editor**.
4. Move the cursor above the tag you wish to modify.
5. Right-click the tag. You can apply the selected tag as many times as necessary.

⚠ **There are several particle classes and subclasses ('added particles') that are not available for automated evaluation, but can be added manually. You need to enable their use before they become available choices (☞5.5.4 The Evaluation tab).**

ⓘ *The software takes all the new particles that you added into consideration when generating the sediment report.*

ⓘ *The selected particle tag will be displayed in blue to indicate that it was manually modified.*

5.4.5.5 Deleting particle tags in the Sample View Editor

To delete a particle tag in the SVE image, complete the following steps:

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

ⓘ *The software will take the modified particle into consideration when generating the sediment report.*

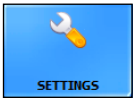
⚠ **You can discard every manual modification by clicking the Default button. This will restore the particle results of the automated evaluation.**

5.4.5.6 Modifying analysis results with the Modify button

See **Figure 12** and its key.

ⓘ *Sample records whose status you have modified appear in blue on the Sample List..*

5.5 The Settings menu

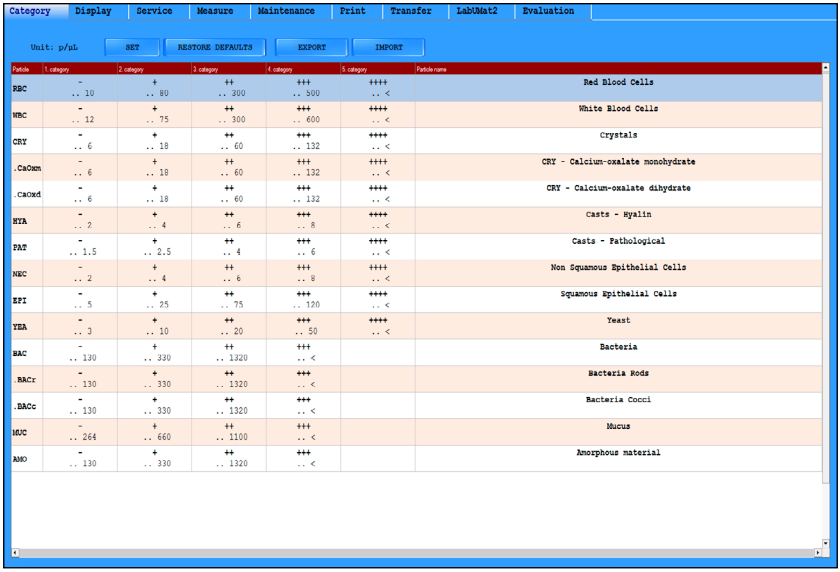


ⓘ *The **Settings** menu is available only to users logged in as Administrator– or Service-level operators (☞ **5.1 User rights**).*

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

The **Settings** submenus are accessible via tabs running across the top of the screen.

5.5.1 The Category tab



Particle	1. category	2. category	3. category	4. category	5. category	Particle name
RBC	- .. 10	+ .. 80	++ .. 300	+++ .. 500	++++ .. <	Red Blood Cells
WBC	- .. 12	+ .. 75	++ .. 300	+++ .. 600	++++ .. <	White Blood Cells
CRY	- .. 6	+ .. 18	++ .. 60	+++ .. 132	++++ .. <	Crystals
.CaOxm	- .. 6	+ .. 18	++ .. 60	+++ .. 132	++++ .. <	CRY - Calcium-oxalate monohydrate
.CaOxd	- .. 6	+ .. 18	++ .. 60	+++ .. 132	++++ .. <	CRY - Calcium-oxalate dihydrate
HYA	- .. 2	+ .. 4	++ .. 6	+++ .. 8	++++ .. <	Casts - Hyalin
PAT	- .. 1.5	+ .. 2.5	++ .. 4	+++ .. 6	++++ .. <	Casts - Pathological
NEC	- .. 2	+ .. 4	++ .. 6	+++ .. 8	++++ .. <	Non Squamous Epithelial Cells
EPI	- .. 5	+ .. 25	++ .. 75	+++ .. 120	++++ .. <	Squamous Epithelial Cells
YEA	- .. 3	+ .. 10	++ .. 20	+++ .. 50	++++ .. <	Yeast
BAC	- .. 130	+ .. 330	++ .. 1320	+++ .. <		Bacteria
.BACr	- .. 130	+ .. 330	++ .. 1320	+++ .. <		Bacteria Rods
.BACc	- .. 130	+ .. 330	++ .. 1320	+++ .. <		Bacteria Cocci
MUC	- .. 264	+ .. 660	++ .. 1100	+++ .. <		Mucus
AMO	- .. 130	+ .. 330	++ .. 1320	+++ .. <		Amorphous material

Figure 24. *The Category tab on the Settings menu*

Apart from presenting quantitative results for the detected sediment parameters, the analyzer device also assigns a semi-quantitative relative category to each sediment parameter. 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 (☞**5.5.4 The Evaluation tab**), and only if the **Enable extended categories** check box is checked on the **Category** tab.*

5.5.1.1 Modifying semiquantitative relative categories

ⓘ *The names of the particle classes and subclasses cannot be modified.*

9. Double-click on the particle class row that you wish to modify to display the **Category modification** dialog box (see **Figure 25**)

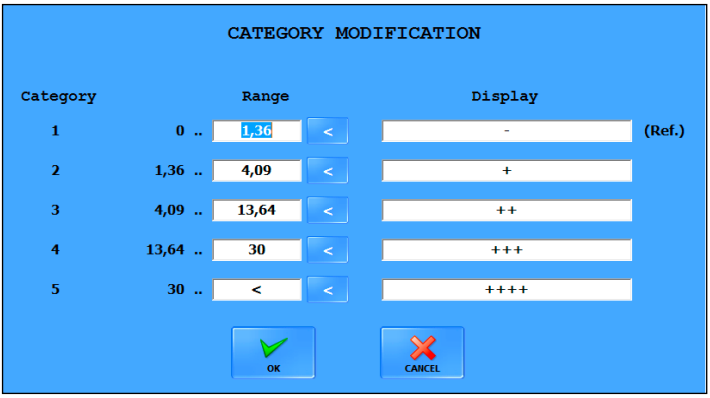


Figure 25. *The Category modification dialog box*

11. 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 (☞ 5.5.2 The Display tab).**

ⓘ *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.*

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

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

13. 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 recalculate 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* ***RESTORE DEFAULTS****.*

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

5.5.1.2 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** button 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 (using Microsoft Excel, for example) that matches the following formatting protocol:*

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

5.5.2 The Display tab

5.5.2.1 Grid, ruler and particle font properties

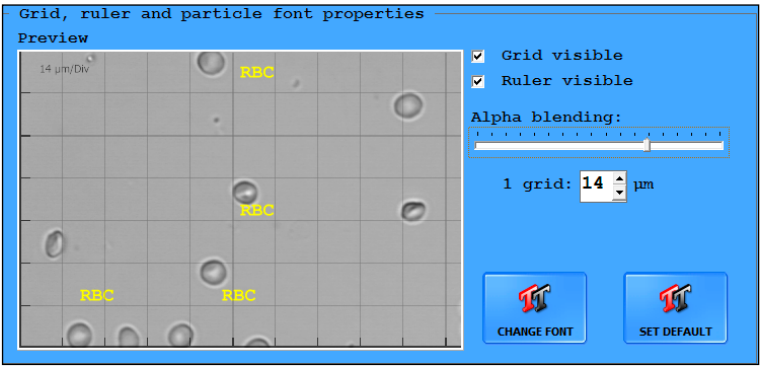


Figure 26. *The Grid, ruler, and particle font properties window*

This screen area displays a preview of a random miscroscopy 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** check boxes, 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, in 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.

5.5.2.2 The Visible settings screen area

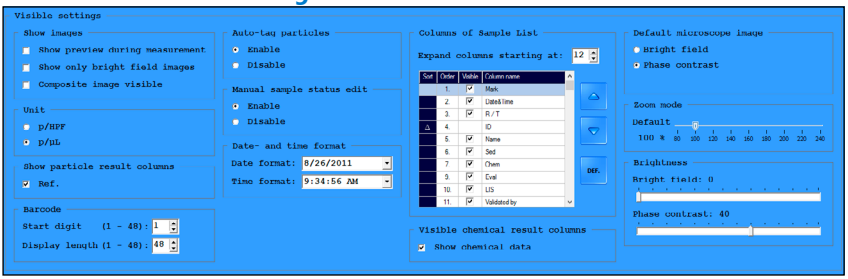


Figure 27. *The Visible settings window*

- Check the **Show preview during measurement** check box to display preview microscopy images of the currently measured sample in the **Status** column on the **Measure** screen while a measurement is going on. Check **Show only bright field images** to restrict to bright field images. Check **Composite image visible to enable composite image appearance.**
- 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 **Show particle result columns** dialog box to enable or disable the Ref. column in the results summary (☞ **"Key to the particle results window"**).
- Use the arrow keys next to the text boxes in the **Barcode** dialog box to specify which part of the barcodes you would like the device to use: **Start digit** indicates the first character of the sample ID where barcode reading begins; **Display length** indicates the number of characters considered following the starting digit.

ⓘ *If the **ID generate mode** is set to **Sequence number** (☞**5.5.3 The Measure tab**), the text boxes will not respond to the arrow keys.*

- Set which kind of microscope image **(Brightfield, Phase contrast or Composite)** you want as default in **Default microscope image** groupbox. The selected kind of image will appear during measurement, in the **Image List** on **Database** screen, in the **Gallery**, in **SVE** and will be printed in case you want images to be printed.

ⓘ *Phase contrast image is the factory default setting.*

- In the **Auto-tag particles** dialog box, click the radio buttons to enable or disable the automatic tagging of particles in the viewfield images.
- Check the check boxes in the **Manual sample status edit** dialog box to enable or disable manual modification of the status of samples (☞**"Status modification options"**)

- 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:

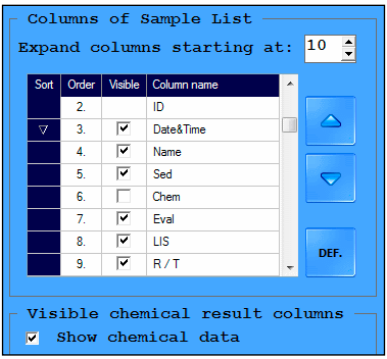


Figure 28. *The Sample List will display 8 columns in compact view; chemical urinalysis results will be omitted; the samples in the list will be sorted by date in descending order*

- enable or disable any of the available columns in the sample list by checking or unchecking their check boxes;
- 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 **Sort** 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 (see **Figure 28**);
- specify how many columns are displayed in the compact view of the Sample List by increasing or decreasing the number in the **Expand columns starting at** 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 UriSed 3 PRO device, use the check boxes in the **Visible chemical result columns** to enable the display of the chemical measurement results.
- Set the default percentege of magnification of the selected image on the Zoom mode/Default scale.
- Set the default degree of brightness to brightfield images for better visibility on the **Brightfield** scale. The scale appears in **SVE**.
- Set the default degree of brightness to phase contrast images for better visibility on the **PhaseContrast** scale. The scale appears in **SVE**:

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

5.5.3 The Measure tab

Use this tab to configure measurement-related settings.

5.5.3.1 Warning at generated ID

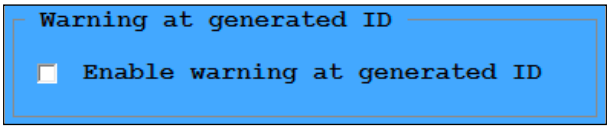


Figure 29. *The Warning at generated ID checkbox*

After you enable this feature, the device will display warning message when the currently measured sample was given a system-generated ID.

5.5.3.2 Live view

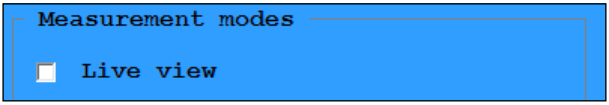


Figure 30. *The Live view checkbox*

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 remains the same – the analyzer feeds the cuvette to the pipetting position, injects the urine sample into the cuvette, and discards the cuvette as usual. The automated image evaluation module also analyzes the resulting images the usual way. To set up and perform a live view process, complete the following steps:

1. Go to the **Settings** menu and on the **Measure** tab, select the **live view** check box (☞ **Figure 24**). Still on the **Measure** tab, set the parallel measurement count to 1 (☞**3.5.3.4 Parallel count on page 36** and **1**).

2. Still staying in the **Settings** menu and on the **Measure** tab, select the **Auto evaluate images** option, and set the number of microscope view field images that you would like to take and evaluate (☞ **3.5.3.1 Image evaluation on page 37**).

3. On the **Measure** menu, click the **Live View** button.

4. Start the measurement cycle. When the cuvette with the sample inside it reaches the microscope, the cycle will stop, and the **Live view** screen will appear in place of the **Measure** menu (☞ **Figure 26**).

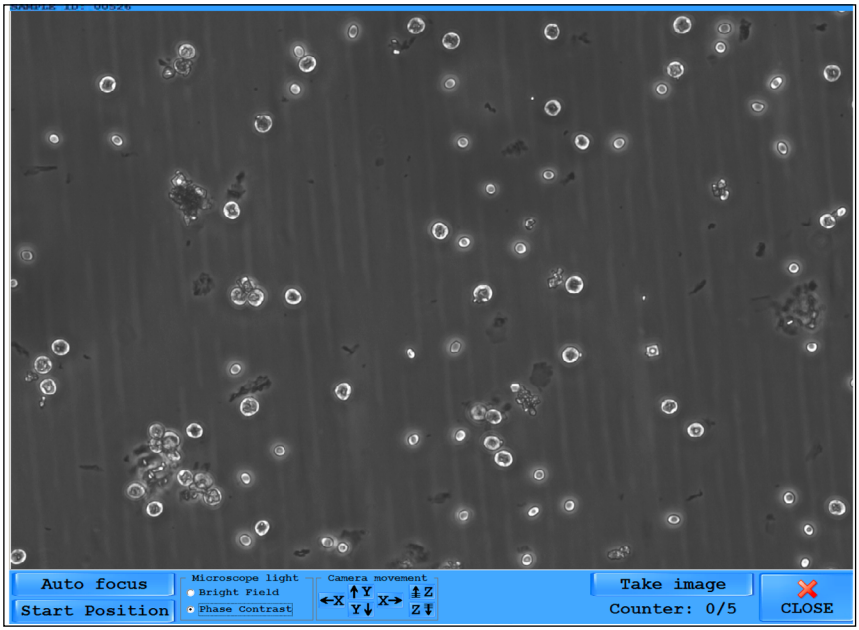


Figure 31. *The Live view screen*

ⓘ *The Sample ID appears in the top of the screen.*

5. Use the up and down 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 reset both the focus height and the image position to their start positions 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 you specified, the microscope arm discards the cuvette, and the screen switches back to the **Measure** menu.

5.5.3.3 Repeated barcode checking

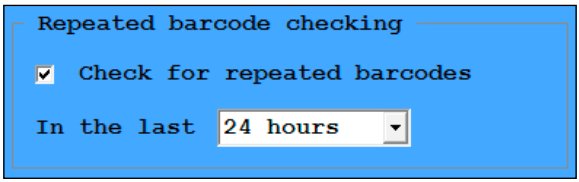


Figure 32. *The repeated barcode checking window*

After you enable this feature, the device will display the warning message **Repeated barcode**, if the currently scanned barcode has already been entered into the database within the selected time interval.

5.5.3.4 Parallel count

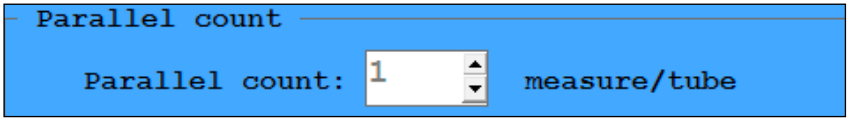


Figure 33. *The Parallel count window*

ⓘ *If you enable parallel measurements (that is, the number in this text box is >1), worklist usage is disabled.*

Use the up and down arrows to specify how many times the device should perform a measurement on the same sample.

ⓘ *The default is 1, meaning that each sample is analyzed only once. By default, there are no redundant measurements.*

Results from the same sample share the same ID with -1, -2, -3, and so on appended to differentiate them.

⚠ **If you set up parallel measurements for each sample, make sure that there is enough urine in the test tubes.**

⚠ **If you have set up the device to interface with a chemical urinalysis device and/or measurements are performed according to a worklist (☞ 5.5.7 The LabUMat tab), the Parallel count text box becomes disabled.**

5.5.3.5 Worklist

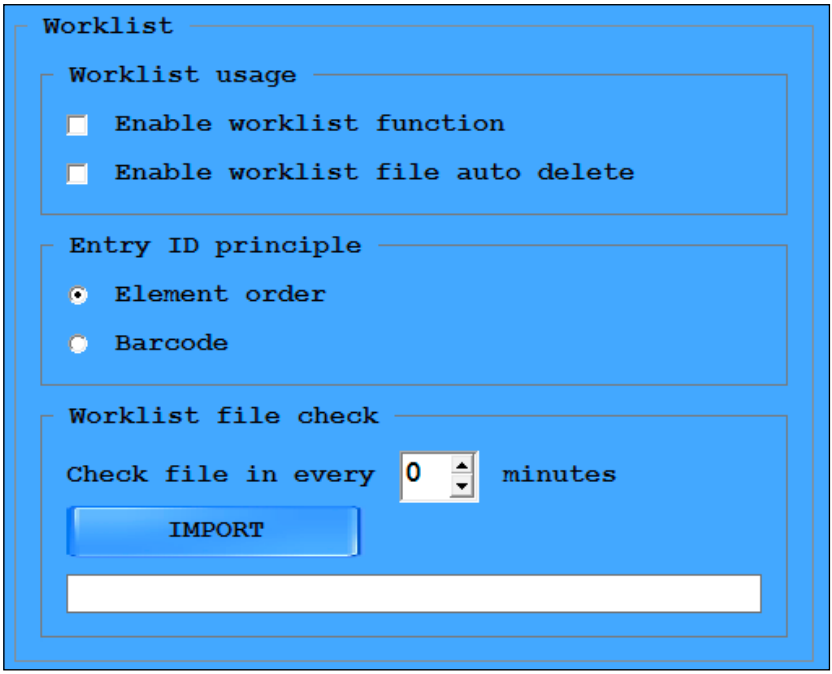


Figure 34. *The Worklist window*

ⓘ *If you enable worklist usage, parallel measurements will be disabled.*

- 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. (☞ **Figure 15** and its key for further details on worklist management)
- In case you are using a worklist uploaded as a text file from an external location (☞ **"Importing a Worklist"**), 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.

⚠ **If you have set up the device to interface with a chemical urinalysis device and measurements are performed according to a worklist (☞ 1.7.1 Operator qualification), the Enable worklist function check box becomes checked and disabled by default.**

- 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 barcodes 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 barcodes, make sure that you include not only patient names but barcodes as well in the worklist entries.**

⚠ **If you have set up the device to interface with a chemical urinalysis device and measurements are performed according to a worklist (☞ 1.7.1 Operator qualification), the Barcode radio button becomes selected and the Entry ID principle dialog box becomes disabled by default.**

- Worklist file check

If you wish to import a worklist (☞ **"Importing 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 inactive by default.**

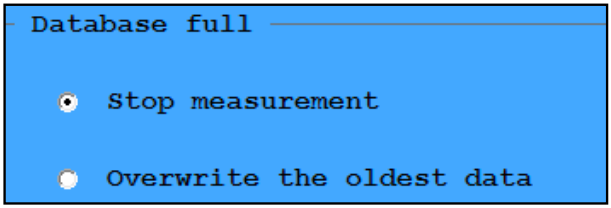


Figure 35. *The Database full window*

Database sample limit

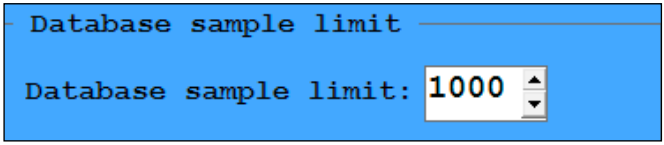


Figure 36. *The Database sample limit window*

- Use the **Database sample limit** text box to specify the size of the results database. Available limits: 1000, 2000, 3000, 4000, 5000 and 10000 records.

5.5.3.6 ID generate mode

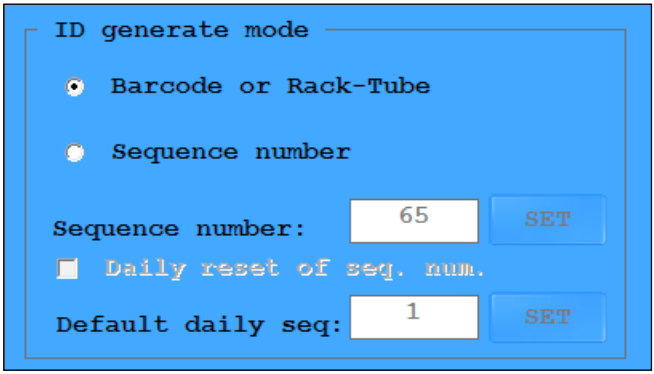


Figure 37. *The ID generate mode window*

Use the radio buttons to specify how the device should assign a unique ID to each sample.

- Select **Barcode or Rack-tube** if you would like to assign unique generated IDs based on the barcodes on the test tubes, or, in case barcodes cannot be read, automatically assign an identifier based on the time and date of measurement and rack and tube number of the given sample.

  If the instrument is unable to identify the rack, a rack ID will be generated for the rack. This is shown by a "G" postfix in the ID.

ⓘ *Rack and tube numbers are displayed in the extended **Sample List** in the **R/T** column.*

⚠ **The rack-tube ID (R/T column) assignment sequence is reset to 00101 every time you start the device and the date has changed since you last shut down the system.**

ⓘ *If you select the **Barcode or Rack-Tube** option, every other element in this dialog box will be disabled.*

- Select **Sequence number** if you would like to generate sample IDs based on the order in which the device measures the samples.
- The **Sequence number** text box is a counter indicating what number the device will assign to the next sample that is measured in the current measurement cycle. You can, however, specify what the number assigned to the next sample should be: Enter the desired value in the text box, and click **SET**.
- Check the **Daily reset of seq. num.** check box to reset the sequence number ID sequence to 1 or the number you specify in the **Default daily seq.** text box every time the date changes between a system shut-down and a system start-up

ⓘ *The **Default daily seq**. text box is enabled only if you check the **Daily reset of seq. num.** check box.*

- If you check the **Daily reset of seq. num.** check box, you can enter the sequence number that the device should reset to the next time the date changes between a system shut-down and a system start-up.

⚠ **The button is disabled if Barcode or Rack/tube-based sample ID generation is used.**

ⓘ ☞ **6.5 Test result identification** *for further details.*

5.5.3.7 Rack counter settings

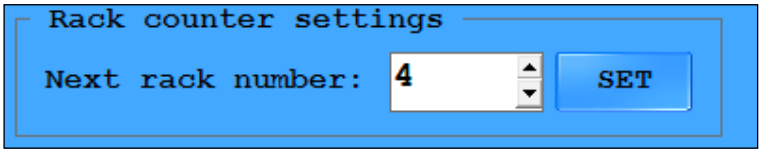


Figure 38. *The Rack counter settings*

The **Next rack number** text box is a counter indicating the number of the next rack in the current measurement cycle. You can, however, specify what the number assigned to the next rack should be: Enter the desired value in the text box, and click **SET**.

5.5.3.8 Auto-validation

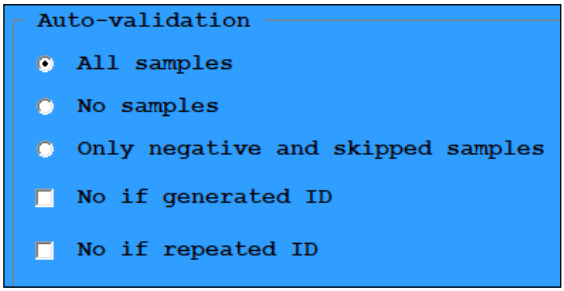


Figure 39. *The Validation window*

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

Use the checkboxes to cancel possibilities of autovalidation in case of generated and/or repeated ID.

⚠ **Only validated results can be exported, printed, or transferred.**

⚠ **A measurement result cannot be validated automatically if its status (☞ 5.4.1.1 Sediment results) is: Empty, Soft review, Hard review, MUC review, BAC review, Cross-check rule flagging or Low level.**

5.5.3.10 Predefined comments

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

1. Go to **Settings/Measure** menu.
2. Tap **NEW** button in **Predefined comments** section.
3. Enter the comment and tap **SAVE**.

5.5.4 The Evaluation tab

Figure 40. *The Particle settings window on the Evaluation tab*

On this tab, you can specify which sediment particles you would like the device to identify in the viewfield images by checking the check boxes that correspond to the particle classes and subclasses that you wish to include, and unchecking the ones to leave out. Press **SET** button to save changes.

⚠ **You will need to check the Extended particle categories check box 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 check boxes become active.**

⚠ **Only the particle classes and subclasses that you have checked on this tab are available as tags in the Sample View Editor (☞ 5.4.5 Modifying automated evaluation results). However, if you enable the 'extended particle categories' and check any of them, the system will reevaluate all the pre-**

vious viewfield images and retroactively assign the newly enabled tags where necessary.

5.5.4.1 Using the particle settings

- Subclasses may be enabled only if their parent classes are enabled.
- All subclasses of a disabled parent particle class also become disabled.
- 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. An alert dialog box will pop up prompting you to confirm the action.
- Click the **SELECT ALL** button to enable all of the particle classes and subclasses.
- When BAC is enabled, BACr and BACc subclasses are automatically recognized and separated during evaluation, but either or both subclasses can be deselected.
- If you enable RBC-Aca subclass, its ratio to all RBC particles will be calculated, as well.

RBC	+	10,12 1,53	0 .. 5
.RBC	+	9,68 1,47	0 .. 5
.RBC-Aca	-	0,44 0,07	0 .. 5
RBC-Aca ratio: 4,5%			

ⓘ *The UNC particle class refers to unclassified particles that the system could not identify automatically.*

- 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.*

5.5.4.2 Particle setting defaults

Click **DEFAULT** to revert to the following default settings. Symbol ✓ means that the automated evaluation of this particle is enabled, symbol ✗ means that he automated evaluation of this particle particle is disabled.

RBC	✓	URI	✗
WBC	✓	TRI	✗
WBCc	✗	YEA	✓
NEC	✓	BAC	✓
EPI	✓	BACr	✓
PAT	✓	BACc	✓
HYA	✓	MUC	✓
CRY	✓	SPRM	✗
CaOxm	✓	AMO	✓
CaOxd	✓		

5.5.4.3 Full list of evaluated particles

Class	Subclass	auto*	added**
Red Blood Cells		RBC	
	Isomorphic RBC		RBCi
	Dismorph RBC		RBCd
	Acanthocyte		RBC-Aca
	RBC others		RBC-oth
	ghost-RBC		RBCg
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	

Class	Subclass	auto*	added**
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
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 – 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
Amorphous material		AMO	
UDP1,UDP2,UDP3....			

* particles in this category are evaluated automatically by the analyzer if enabled.

**particles in this category can be added manually to the sample result in SVE

5.5.4.4 Flag settings

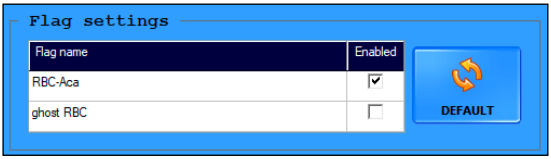


Figure 41. *Flag settings*

Enable/disable the automatic flagging of samples with ghost RBC (RBCg) and/or acanthocyte (RBC-Aca).

If the RBC-Aca or the ghost RBC flag is enabled, the automatic evaluation indicates by a green flag in **Database/Selected sample** window if RBC-Aca or ghost RBC is present in the sample. Flag can be added or deleted in the **Modify sediment result** (see **5.4.5.1 Modifying sediment results in the Database**) popup window.

All type of red blood cells receive RBC tags on the automatically evaluated images. RBC-Aca and RBCg tags can be given manually to the images, although these markings have no effect on the flag system.

ⓘ *RBC-Aca flagging is enabled by default.*

5.5.4.5 MUC review settings

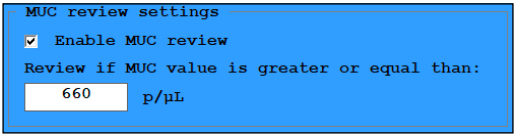


Figure 42. *MUC review settings*

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.*

5.5.4.6 AMO review settings

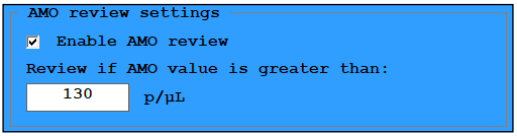


Figure 43. *AMO review settings*

Set a p/µl or p/ HPF value in the text box and check Enable AMO review in the dialog box to enable the automatic highlighting (with a red rhombus) of samples with a AMO 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 effec.*

5.5.4.7 BAC review settings

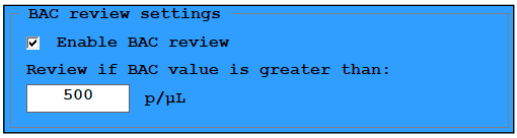


Figure 44. *BAC review settings*

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 (with a red rhombus) of samples with a BAC 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 effec.*

5.5.4.8 Cross-check rules

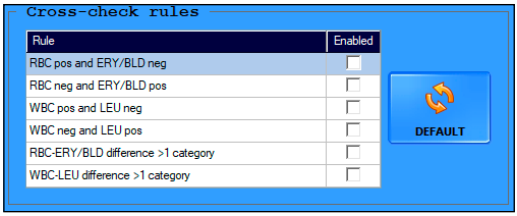


Figure 45. *Cross-check rules*

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 UriSed and LabUMat. Cross-check rules exist for RBC & ERY discrepancy, and WBC & LEU discrepancy to support operator decision for result modification/validation. The sample with cross-check mark cannot be auto-validated. After manual validation the mark and the comment are deleted.

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

5.5.5 The Transfer tab

The Transfer tab lets you adjust the data management settings.

5.5.5.1 The Transfer screen area

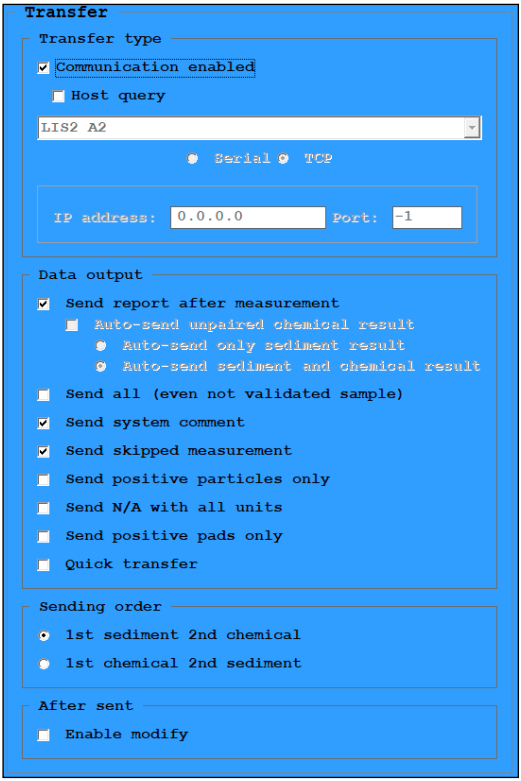


Figure 46. *The Transfer screen area on the Transfer tab*

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.
- Click the radio buttons to select the connector for transmission. HL7 only available via TCP connection.
- Set IP address and port or baud rate in drop-down list.
- If Communication enable checkbox is checked, the operator is able to select **Host query** checkbox to establish LIS controlled transfer management. The LIS protocol, that you can claim from your distributor, contains all the details about the setup.

ⓘ *This function only works with LIS2 A2 or HL7 transfer types.*

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

- Check the **Send report after measurement** check box 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 **Send system comment** to send system comments of the sample 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 chemical urinalysis 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** check box 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** (see **"N/A"**).
- Check the **Quick transfer** check box 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.

ⓘ *Although the system does not prompt you to confirm one-click transfer, the records that you would like to transfer this way need to be validated.*

- Chose the preferred sending order of the chemical and sediment results to LIS.
- Check the **Enable modify** check box in the **After sent** window panel to be able to modify results after they were sent to LIS.

5.5.5.2 The Export screen area

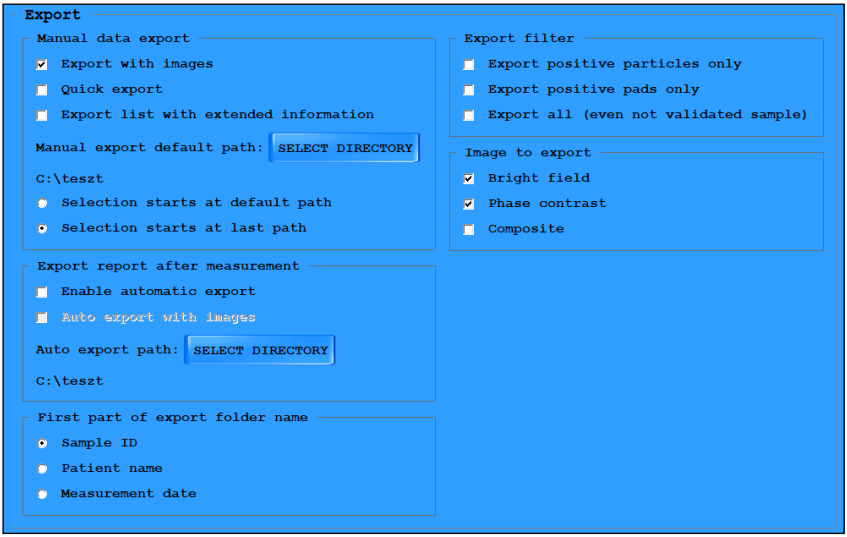


Figure 47. *The Export screen area on the Transfer tab*

- Check the **Export with images** check box to include viewfield images with the results tables when exporting results manually.
- Check the **Quick export** check box 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 either in same folder where you last exported sample records or if you previously set up a default export directory, Quick export will use this default path.

ⓘ *Although the system does not prompt you to confirm one-click export, the records that you would like to export this way need to be validated.*

- Check **Export list with extended information** when you want to add more details to the result lists. This information include test strip details, cuvette details, the dilution factor, any possible sediment, chemical and system comments connected to the selected result.
- Click the **Set 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 check boxes to enable the automatic export of each processed sample, with or without viewfield images, to a folder on the PC you can specify by clicking the **SET DIRECTORY** button. Results are exported as html tables and separate folders for each of the samples is generated inside the folder you specify.
- 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 the **Export positive particles only** or the **Export positive pads only** check boxes 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 transferred data. Check the **Export all (even not validated sample)** checkbox to be able to send all results to the preferred destination.
- Select the type of images that you would like to send with the results in the **Image to export** window.
- In the **Chemical pads** dialog box, use the text box to specify the default units for the exported chemical urinalysis results, and use the check boxes to control which test pad analyte results and which physical measurement results are exported with the chemical urinalysis results.

5.5.6 The Print tab

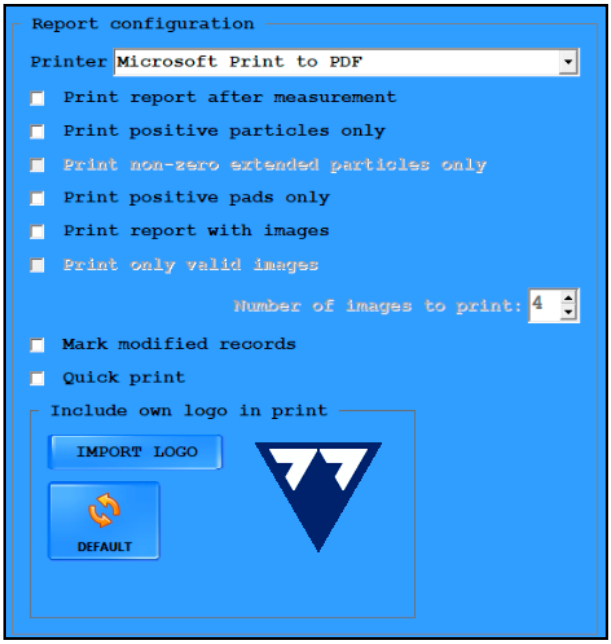


Figure 48. *The Report configuration dialog box on the Print tab on the Settings menu*

On this tab you can specify the settings for the printout.

- Select the printer you would like to use.
- Check the **Print report after measurement** check box to enable the automatic printing of each processed sample.
- Check the **Print positive particles only** or the **Print positive pads only** check boxes 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 the **Print report with images** check box to print viewfield 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...** spin box to determine the number of viewfield images that are printed for each record.

ⓘ *By default, viewfield images are not printed.*

- Check the **Mark modified records** check box 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** check box to enable the one-click printing of selected records. If you enable this feature and and the **Sample List** screen is active, press the F4 key to automatically print off any selected record.

ⓘ *Although the system does not prompt you to confirm one-click print, the records that you would like to print this way need to be validated.*

- Check **Print non-zero extended parti cles only** check box to make sure none of the enabled added particles with no actual findings are printed.

5.5.7 The LabUMat tab

ⓘ *This section details the setup options for interfaced UriSed 3 PRO and LabUMat 2 devices. For information on how you can connect the two devices,* ☞ **6.7 Operating UriSed 3 PRO together with LabUMat 2**

UriSed 3 PRO miscroscopy urinalysis devices can be interfaced with LabUMat 2chemical urinalysis device to provide a complete analysis of the samples.

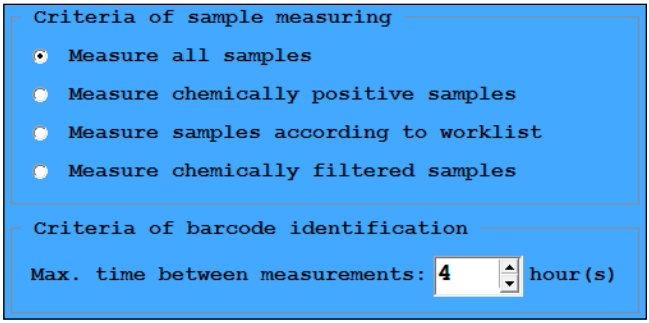


Figure 49. *The LabUMat connection*

- Click the radio buttons in the **Criteria of sample measuring** dialog box to set up certain filters for samples arriving to UriSed 3 PRO from the chemistry analyzer device.
- Select **Measure all samples** to disable filtering samples between the interfaced devices.
- Select **Measure chemically positive samples** to exclude from the UriSed 3 PRO measurement cycle the samples that tested negative on LabUMat 2.
- Select **Measure samples according to worklist** to be able to select worklist items for sediment measurement at worklist editing.

- Select **Measure chemically filtered samples** to exclude from the UriSed 3 PRO measurement cycle the samples that do not fall inside the filter ranges that you can set up in the **PAD reflex** window on LabUMat 2 for each of the test strip analytes separately.
- Use the **max. time between measurements** spin box to set up the maximum delay, in hours, between a barcode–identified sample to be measured by UriSed 3 PRO after it was processed by LabUMat 2. If a sample arrives from LabUMat 2 to UriSed 3 PRO outside the specified time frame, its measurement result will not be paired by UriSed 3 PRO.

5.5.8 The Maintenance tab

5.5.8.1 Laboratory name

Enter the name or code of your laboratory in the text box to display it as a header on printed reports, on results transferred unidirectionally in the device software versions up to 1.6.1, and on exported sample results.

5.5.8.2 Diagnostic report

Click the **DIAGNOSTIC** button in the dialog box to generate a status report of the software and driver versions, and the current settings of the device, 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.**

5.5.8.3 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.

5.5.8.4 Waste bin limit

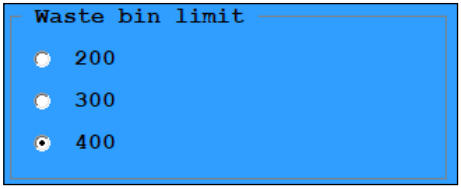


Figure 50. *Waste bin limit*

Click the radio buttons in the dialog box to specify how many measurements are allowed before the device displays a warning message to empty the waste bin. Waste bin capacity is 400 cuvettes.

5.5.8.5 Exit

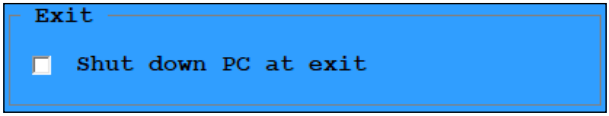


Figure 51. *Exit*

Check or uncheck the check boxes in the **Exit** dialog box to enable or disable automatic PC shutdown whenever you exit the software.

5.5.8.6 Enable QC result deleting

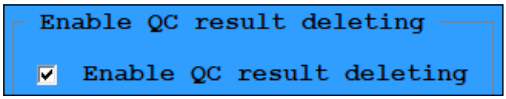


Figure 52. *Enable QC result deleting*

Check **Enable QC result deleting** to override the protection of QC data and disable the warning message **Samples were not deleted.** whenever you attempt to delete QC results.

5.5.8.7 Users

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

Figure 53. *The Users dialog box*

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 (see **Figure 53**).

⚠ **The default password for newly created user accounts is the same as the user name, which needs to be changed at the first login (☞5.1.2 Changing your password).**

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

⚠ **No user can delete his or her own account.**

5.5.8.8 Auto log out

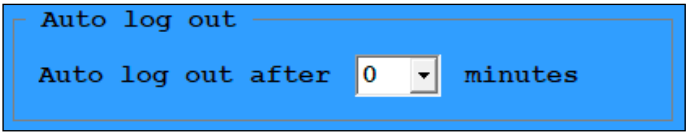


Figure 54. *Auto log out*

Select a number other than zero (0) in the **Auto log out after** drop-down list to enable automatically logging out the current user after the set number of minutes, if the system does not detect any user activity (clicking or measuring).

⚠ **Automatic logout is only available if the 'By user name' user login scheme is in use.**

5.5.8.9 Keep log size within

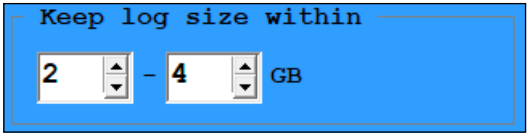


Figure 55. *Keep log size within*

The operator can maximize the size of log files.

5.5.8.10 Backup and Restore

Figure 56. *The Backup and Restore box*

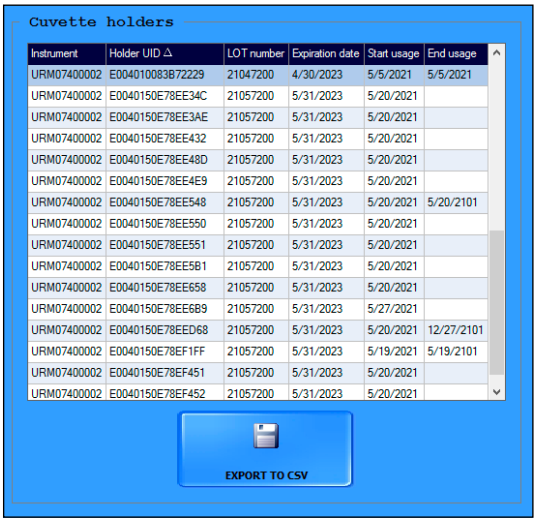
The database, the images and the .ini files can be saved in a password protected .ZIP file.

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.

5.5.8.11 Cuvette holders



Instrument	Holder UID Δ	LOT number	Expiration date	Start usage	End usage
URM07400002	E004010083B72229	21047200	4/30/2023	5/5/2021	5/5/2021
URM07400002	E0040150E78EE34C	21057200	5/31/2023	5/20/2021	
URM07400002	E0040150E78EE3AE	21057200	5/31/2023	5/20/2021	
URM07400002	E0040150E78EE432	21057200	5/31/2023	5/20/2021	
URM07400002	E0040150E78EE48D	21057200	5/31/2023	5/20/2021	
URM07400002	E0040150E78EE4E9	21057200	5/31/2023	5/20/2021	
URM07400002	E0040150E78EE548	21057200	5/31/2023	5/20/2021	5/20/2101
URM07400002	E0040150E78EE550	21057200	5/31/2023	5/20/2021	
URM07400002	E0040150E78EE551	21057200	5/31/2023	5/20/2021	
URM07400002	E0040150E78EE5B1	21057200	5/31/2023	5/20/2021	
URM07400002	E0040150E78EE658	21057200	5/31/2023	5/20/2021	
URM07400002	E0040150E78EE6B9	21057200	5/31/2023	5/27/2021	
URM07400002	E0040150E78EED68	21057200	5/31/2023	5/20/2021	12/27/2101
URM07400002	E0040150E78EF1FF	21057200	5/31/2023	5/19/2021	5/19/2101
URM07400002	E0040150E78EF451	21057200	5/31/2023	5/20/2021	
URM07400002	E0040150E78EF452	21057200	5/31/2023	5/20/2021	

Figure 57. *Cuvette holders information window*

The cuvette holders window contains the list and additional information of cuvette holders that has been inserted into the analyzer.

Cuvette holders window information table	
Instrument	The instrument serial number that the holder was inserted into.
Holder UID	The uniqe ID of each holder, that the RFID antenna detects.
LOT number	The LOT number of the given cuvette holder
Expiration date	The cuvette expiration date
Start usage	The date when the holder was inserted.
End usage	The date when the last cuvette of the given holder was used.

6 Operation

⚠ **Check the exterior of the analyzer before testing, do not use it or correct the failure, if the cover, the cables and the tubings are misplaced or damaged. Check the interior of the analyzer before testing, do not use it or correct the failure, if any of the internal parts are misplaced, damaged or contaminated.**

6.1 Loading cuvettes into UriSed 3 PRO

⚠ **UriSed 3 PRO can be operated only with its own cuvettes supplied by the device manufacturer.**

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

⚠ **Never touch unused cuvettes, as any contamintation may decrease the effectiveness of the microscopic evaluation.**

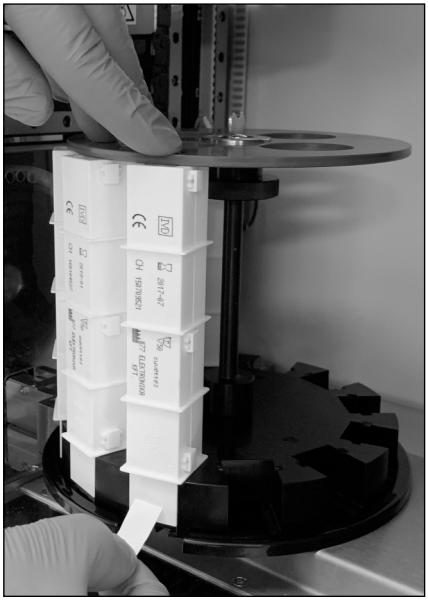


Figure 58. *Loading the rotating cuvette carousel*

Figure 59. *A fully loaded rotating cuvette carousel*

UriSed 3 PRO operates with single-use disposable cuvettes. Cuvettes are supplied in cartridges of fifty (50) cuvettes. They are identified automatically by the instrument. The relevant cuvette information is assigned to each measurement. Before starting the measurement cuvettes should be loaded into the device.

1. Take a cuvette cartridge supplied by the device manufacturer and insert it into the rotating cuvette carousel.

ⓘ *Because of its asymmetric shape, the cuvette cartridge can only be inserted in one way into the instrument.*

2. After placing the cartridge into the rotating cuvette carousel, move the cartridge manually to the gap on the cuvette deflector and remove the tape from the bottom of the cartridge by simply pulling it off (see **Figure 58**). Move the cartridge manually away from the gap.

⚠ **Hold the top of the cartridge firmly while pulling at the tape to prevent the cartridge from falling out.**

⚠ **Only remove the tape from the cuvette cartridge after you have inserted it into the slot of the rotating cuvette carousel. Otherwise cuvettes can fall out easily from the cartridge during insertion.**

⚠ **Empty cuvette cartridges should be removed from the device and disposed of separately.**

3. Repeat the previous steps until the rotating cuvette carousel is fully loaded (see **Figure 59**).

ⓘ *The rotating cuvette carousel's maximum capacity is twelve (12) cartridges.*

6.2 Rack RFID

The analyzer can be used with RFID tagged racks as an RFID rack ID system is installed. The rack ID will be the first three number of the content of **Database / Sample list / R/T** column.

6.3 Measurement

To start sample testing, the operator needs only to place the racks of test tubes filled with sample on the rack mover and click on **START** button in the user software **Measure** menu. The analyzer performs the measurements automatically.

⚠ **The device performs measurements continuously and stops only when there are no more samples on the rack conveyor, the device runs out of cuvettes, the IF water container is empty, waste container is full, solid waste bin is full, or when the operator clicks the Stop measurement button.**

⚠ **The measurement cycle is suspended if any problem arises during operation. If this should happen, consult 10 Troubleshooting for advice.**

You can make parallel (multiple) measurements of the same samples ☞ **5.5.3.4 Parallel count**.

⚠ **Each measurement requires at least a 2 mL amount of sample.Make sure that there is enough urine in the test tubes before you start parallel measurements.**

6.4 Pediatric mode

To analyze small amount of samples, the user needs to activte pediatric mode on Settings/Measure tab. In case of onnected operation, the pediatric mode has to be activated on the the chemical analyzer, too. In pediatric measurement mode the analyzer can measure samples from regular or from pediatric tubes.

6.4.8.1 Tube types:

- Regular tube: As detailed in the user manual.
- Pediatric tube: Biosigma, code U9030, Conical tubes 6.5 ml.

6.4.8.2 Minimum sample volumes

	UriSed 3 PRO	LabUMat 2	Connected mode
Regular tube	1 ml	1 ml	1.25 ml
Pediatric tube	0.8 ml	0.8 ml	1 ml
Aspirated volume	400 µl	250 µl	650 µl

6.4.1 Activating pediatric mode

1. Go to **Settings/Measure** tab.
2. Check **Pediatric mode** in the **Measurement modes** box.

3. The **START PEDIATRIC** button appears in the **Measure** menu.

6.4.2 Measuring small amounts of samples

ⓘ *The instrument able to analyze only one rack at a time.*

1. Homogenize the sample(s)
2. Place the rack with the tube(s) onto the rack conveyor unit.
3. Tap **START PEDIATRIC** button.

4. In case of Cascade system, you have to choose which sediment analyzer should carry out the measurement.

ⓘ *Live view measurement mode can also be used in pediatric mode.*

ⓘ *Pediatric measurement mode is possible also in connected mode, but measurements has to be made separately on both instrument after the sample homogenization. Results still can be paired in this situation.*

6.4.3 Review Records

The results appear in the **Database** with **Pediatric Automatic** or **Pediatric Manual** marks in their **Microscopy mode** column. The comment **Pediatric mode** appears in the **Selected Sample** header **Comment** row.

The database can be filtered for measurements made in pediatric mode both with sediment and cehmical analyzers.

6.5 Test result identification

ⓘ *For further information* ☞ **5.5.3.6 ID generate mode**.

Test results can be identified based on:

- Automatically generated ID numbers: The device identifies samples based on their relative position. The first three (3) digits of the generated ID refer to the number of the rack, while the second two (2) digits refer to the position of the test tube that holds the measured sample within the rack. The numbering of racks restarts from **00101** if the date changes between a system shutdown and the following system restart. The rest of the ID is generated by the date and time of the measurement.
- Barcodes attached to the test-tubes: Urine samples can be identified by barcodes if you tag each test tube with a unique barcode. For further information about the types of barcodes the system can read and how to attach them to the test tubes ☞ **4.5 Tagging test tubes with barcodes**.
- Sequence numbers: Patient urine samples can also be identified by a running sequence number based on the placement of the sample test tubes in the racks. You can modify the starting value for the sequence number on the **Measure** tab of the **Settings** menu (☞ **5.5.3.6 ID generate mode**).

You can modify every type of automatic identification by renaming records in the **Database** menu using the **Modify** option (for example if a barcode was missed or misread).

ⓘ *The unique Rack number and Tube position values are always recorded in exported and printed reports regardless of the identification method you specify.*

6.6 A typical daily routine

⚠ **Although the system rinses the pipetting probe of the device after every pipetting cycle, in keeping with the recommendations of the effective guidelines (the ECLM European Urinalysis Guideline, and the CLSI GP16-A3 Vol.29 No.4), you are advised to perform any microbiological astudies on the urine samples before you analyze the samples with the UriSed 3 PRO device, or split the urine samples before analysis, and perform the microbiological study on a separate portion of each sample.**

⚠ **Only specially trained professionals are allowed to use the device.**

UriSed 3 PRO is easy to operate after it has been set up for normal operation, cuvettes have been loaded into the device, and the fluidic system has been properly installed (☞ **4 Installation**). Complete the following steps for a smooth laboratory workflow.

⚠ **The components of the urine analyzer normally handled during daily operation may come into contact with human urine and are therefore possible sources of infection. To prevent accidental contamination in the clinical laboratory,**

always wear disposable surgical gloves and protective clothing when handling fluids or any part of the device.

⚠ **It is strictly prohibited to open the analyzer door or remove the centrifuge house during operation.**

1. Remove all racks from the rack conveyor and switch on UriSed 3 PRO and the PC. Start the UriSed 3 PRO software on the PC.

ⓘ *A self-diagnostic procedure is automatically performed and the* **Measure** *menu is displayed.*

2. Prepare urine test samples in test tubes and put the test tubes in the supplied racks.

⚠ **If your test tubes are identified by barcode, take care to have the barcodes face open side of the racks, otherwise the built-in barcode scanner will not be able to detect them.**

3. Put the racks with test-tubes containing urine samples on the rack conveyor to the right of the rack delivery area at the test tube passage. Make sure that the open side of the racks face towards the right. UriSed 3 PRO automatically adjusts the parallelism of the racks before they reach the test tube passage.

⚠ **Fill test tubes with at least 2.0 mL of urine. Although only 0.2 mL is used for sample evaluation, a larger amount of sample is needed for proper sample aspiration.**

⚠ **Soiled test tubes can affect test results. Use only single-use tubes! Do not wash and reuse single-use tubes!**

4. Click **START** to start the measurement cycle.

Do not reach into the device under the front doors while it is in operation! Moving parts (for example the automatic microscopic arm, the automatic probe and its pipette) can cause injury.

Never touch the parts of the device that are marked with the ESD (Electrostatic discharge) symbol!

⚠ **Do not touch the rack conveyor during operation if there are racks with test tubes on it!**

ⓘ *You can follow the progress of the measurement cycle on the Measure menu: the instrument serial number, the date, time, sample position, ID, name and the status of each cuvette is continuously displayed.*

ⓘ *You can review the results of the measurements in the Database menu (☞***5.4.1 The Sample List screen area***).*

5. If the last rack remains inside the rack passage after finishing measurements, click the **Rack out** button on the **Measure** menu to remove the rack.

6. Open the used cuvette bin on the left side of the equipment and empty it. It is also recommended to disinfect the bin at the end of each day.
7. Switch off the device software by clicking the **Exit** button, available wherever you are in the software menu structure.

⚠ **Never switch off the device with the power switch on the side cover panel during while a measurement cycle is in progress. Always exit from the software by clicking the Exit button before switching off!**

⚠ **Before switching off the device at the end of the day, a disinfectant rinsing procedure has to be performed (☞ 9 Maintenance).**

8. Switch off the device hardware with the power switch on the side of the chassis. On the PC Desktop, click the **Start** menu and then **Shut down** to shut down the computer.

ⓘ *If you enabled the software to shut down the PC when it is switched off (☞ 5.5.8.5 Exit), you will not need to shut down the PC manually.*

6.6.1 Basic operation-related troubleshooting

⚠ **The device will not start, or will automatically stop, if**

...there are no more test tubes to measure.

...it runs out of cuvettes.

...it runs out of Instrument feed water (IFW).

...the cuvette waste bin is full.

...the waste tank is full.

...the rack conveyor is full.

6.7 Operating UriSed 3 PRO together with LabUMat 2

UriSed 3 PRO can be connected with LabUMat 2, a fully automated urine chemistry analyzer. The two devices together provide a complex solution in urinalysis, offering both chemical and sediment urinalysis results in a single package.

6.7.1 Establishing the connection

To have both urine sediment- and chemistry measurements done in a convenient way, the two devices should first be mechanically connected:

1. Find a site which is large enough to fit the two interfaced devices and their accessories (PC, water and waste tanks, cables and tubes, and so on) and that allows comfortable operation. Place both devices side by side on your worktop.
2. Place the connective spacer bridge (supplied with UriSed 3 PRO) between the two devices and connect it to both devices. Fit the two left-hand side feet of LabUMat 2 and the two right-hand side feet of UriSed 3 PRO into the holes on the connective spacer bridge.
3. Snap the rack conveyors to both devices and slide the rack conveyor interface element into place between the rack conveyor units from the top.
4. Connect LabUMat 2 to UriSed 3 PRO with the supplied serial cable.
5. Contact your distributor for details on how you can interface the two device software applications.

6. If the connection has been successfully established, it is indicated on the interfaced chemical analyzer and the message **LabUMat online** in the UriSed 3 PRO status bar (☞ **Key to the status bar fields (from left to right)**). Both devices check every twenty (20) seconds whether the link still exists between them and an error message is generated if the connection is lost.

⚠ **You will not have to repeat these steps once the link is established.**

7. Place all the samples you wish to analyze with both devices on LabUMat 2's rack conveyor, and tap **Start measurement** on its touch screen. Depending on your settings, the samples will be analyzed chemically by LabUMat 2, and forwarded to UriSed 3 PRO for urine sediment analysis.

⚠ **Keep the following conventions in mind when operating the two interfaced devices:**

Measurement results of LabUMat 2 and UriSed 3 PRO are matched either based on the barcodes of the samples or on their rack and tube–based identifying IDs. Results only appear in the joint urinalysis report if barcodes or generated IDs are used on both devices ☞**5.5.3 The Measure tab**

The current LabUMat 2 pad sequence settings override the default test strip pad settings when the joint measurement report is compiled. Further modifications to the pad sequence are only possible on LabUMat 2 when the device is disconnected from UriSed 3 PRO.

When UriSed 3 PRO and LabUMat 2 connect with each other, the time settings on UriSed 3 PRO take precedence and override any LabUMat 2 date and time settings during synchronization.

6.7.2 Flexible rack handling on the connected system

From sw4.11 the system able to handle if racks are added, taken away or mixed between the chemistry and sediment analyzers, if the sample identification is according to barcode (Measure tab / ID generate mode group box / Barcode or Rack-Tube radio button).

If a new rack is placed on the conveyor which was not measured on the chemistry analyzer then the sediment analyzers will receive and measure it. If a rack is taken away from the conveyor, click on **Reset** after the measurement is done.

ⓘ *The flexible rack handling only works flowlessly if the racks are RFID-identified. This is the only way to track the racks placed on or removed from the conveyor belt during operation.*

6.7.2.1 Basic joint operation–related troubleshooting

UriSed 3 PRO will reject joint measurement cycles that you initiate in LabUMat 2 and will display the error message The measurement start is rejected by the sediment analyzer! in the following cases:

If there is an error with UriSed 3 PRO or if its system has not initialized yet (☞ Basic operation-related troubleshooting for further possible causes).

If UriSed 3 PRO is performing a measurement cycle started separately, directly in UriSed 3 PRO. Wait for the currently running measurement to stop or stop it manually.

7 Cascade configuration

The UriSed Cascade system consist of two UriSed 3 PRO urine sediment analyzers and a LabUMat 2 urine chemistry analyzer. This configuration provides you high throughput with accuracy at analysing samples.

The connected system can be customized based on settings and user- defined software rules.

This chapter explains the details about the Cascade hardware and software, the settings configuration for the system, sample testing and result handling, maintenance work and error management.

7.1 Quick overview of operation

All components of the urine analyzer may come into contact with human urine and are therefore possible sources of infection. Urine specimens should be handled at Biosafety Level 2. To prevent accidental contamination in a clinical laboratory, always wear disposable surgical gloves when handling reagents, fluids, or any part of the analyzer. Use universal precautions, and consult your facility's infection control policy.

1. Start the instruments.
2. Check and/or fill up the system with IF water, the chemisty analyzer with test strips, the sediment analyzers with cuvettes and empty the waste bins and the liquid waste containers.
3. Check the settings of the Cascade system and customize if needed.
4. Prepare the samples.
5. Load samples.
6. Start the testing on the chemistry analyzer.
7. Handle test results on the Primary sediment analyzer.

8. At the end of service, clean the analyzers and and use the daily disinfection procedure.
9. Turn off the system.

7.2 Cascade hardware and software

UriSed 3 PRO urine sediment analyzers (2)

- attached rack mover at front
- attached washing and waste containers for IF water and liquid waste
- connected PC, monitor, keyboard and mouse
- rack transport, cuvette feeder, centrifuge, pipetting robot, microscope and washing modules

7.2.2.1 UriSed 3 PRO user software developments (v 4.2.65 or above)

- STAT measurement can be only on Secondary sediment analyzer.
- Live view mode is available only on the Primary sediment analyzer.
- Sample result modification is disabled on the chemistry analyzer and is possible on the Primary sediment analyzer only. The modified chemistry result is sent back to chemistry analyzer.
- No longer possible to choose chemical measurement unit on sediment analyzer instrument. Only the unit set on the chemistry analyzer is sent to the sediment analyzer and is visible on the result list and outputs of the sediment analyzer.
- Pop-up window to select instrument [primary sediment (1) and/or secondary sediment (2)] in case of Init, Disinfect, QC, Rack out and in only normal or pediatric sediment measurement:

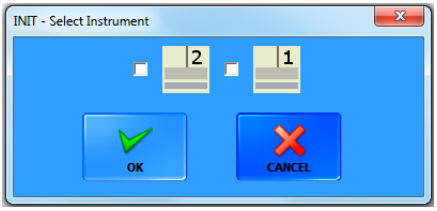


Figure 60. *Select sediment analyzer popup window: primary (1), seconrary (2)*

ⓘ *The Select Instrument popup window shows only on the primary analyzer.*

- The status bar shows the online status and the waste bin counter volume for both sediment analyzers in the order they are installed from the user point of view.

ⓘ *For all other new features that are not connected only to Cascade system, please, read the relevant section of this user manual.*

Urine chemistry analyzer

- attached rack mover at front
- attached washing and waste containers for IF water and liquid waste
- integrated PC and LED touchscreen
- rack transport, test strip feeder and pusher, pipetting robot, strip timer and photometer, PMC, sample dispenser and modules

7.2.2.2 Chemistry analyzer user software developments (v3.0.82 or above)

- Strip LOT information is stored.
- The trace category (where it is available) can be switched on and off.
- The positivity of any pad is adjustable.

ⓘ *For all other new features that are not connected only to Cascade system, please, read the relevant version of the chemistry analyzer's user manual.*

7.3 Turning on and off the system

1. Make sure the AC power cords of the analyzers are properly plugged into thier connectors on the back of the analyzers and into the grunded wall sockets.
2. Make sure that the power switches - which are just above the AC power connectors - are in the on position.
3. Power on the system, starting with the chemistry analyzer.
4. Turn on the PC's of the sediment analyzers.
5. In case of by user name login system, after a short period of time a Login window comes up. Enter the username and the password first on the primary analyzer.
6. To turn off the chemistry analyzer, click **EXIT** on the **Measure** menu. To turn off sediment analyzers, click **EXIT** on the **Measure** menu and press the On/Off button for a few seconds, until its light goes off on the side of the instruments.

7.4 Secondary sediment monitor

The secondary sediment analyzer also has a monitor, mouse and keyboard after starting to use sw4.11. In normal service, the secondary analyzer has control over a few function of itself only: starting a sediment-only measurement, STAT measurement, disinfection, and initialization. In case of failure of the primary analyzer, the control can be transferred to the secondary analyzer, and together with the chemistry analyzer they will be functioning as a regular connected system.

7.5 Barcode use

The system works with barcoded samples as well, which are identified by the integrated barcode readers in all three analyzers. The sample results are matched by their barcodes. For more information about the correct barcode tagging see **4.5 Tagging test tubes with barcodes**.

7.6 Settings

The system configuration is done by the distributor's service engineers. Administrator user level is necessary to change these settings on Settings screen.

- On the chemistry analyzer, on the **Settings/Measure** screen, the **Common measure start** checkbox shuld be ticked.

7.7 Testing samples

1. Switch on the chemistry analyzer first and follow it with both of the sediment analyzers (see **7.3 Turning on and off the system**).
2. Log in on the chemistry analyzer and after thet log in on the Primary sediment analyzer (see the relevant section of the LabUMat 2's user manual and **5.1.1 Logging in**).
3. Check the waste and IF water containers, empty or refill them, if necessary.
4. Check the waste bins and empty them, if necessary.
5. Check the volume of test strip and cuvettes, and load and register them, if necessary (see the relevant section of the LabUMat 2's user manual and **6.1 Loading cuvettes into UriSed 3 PRO**).
6. Load the tubes of samples on racks and make sure the barcodes are on the racks open side.
7. Load the racks onto the rack mover of the chemistry analyzer.
8. Start the measurement on the chemistry analyzer, the samples are transferred automatically to the sediment analyzers.
9. Time to time check the analyzers and monitor the results (see **7.8 Results handling**).
10. Unload used racks.
11. Complete daily maintinance and switch the analyzers off.

- For common disinfection process, see **7.10.1 Common disinfection procedure**.

7.7.1 Only sediment measurement

Samples can be measured only by the sediment analyzer, if needed.

1. Load the tubes of samples on a rack and make sure the barcodes are on the racks open side.
2. Load the rack onto the rack mover of the sediment analyzer you want to use.
3. Click on START on the Measure menu.
4. Select the required checkbox in the popup window (see **Figure 57**).

7.7.2 Pediatric measurement on cascade configuration

For the pediatric measurement, the operator has to follow instructions in **6.4 Pediatric mode**.

7.7.3 Flexible rack handling on cascade configuration

From sw4.11 the system able to handle if racks are added, taken away or mixed between the chemistry and sediment analyzers, if the sample identification is according to barcode (**5.5.3.6 ID generate mode**).

If a new rack is placed on the primary conveyor which was not measured on the chemistry analyzer then the sediment analyzers will receive and measure it. Take the added rack off the conveyor and click on **`Reset`** button after measurement.

ⓘ *Added rack can be measured on secondary analyzer only if the system has RFID rack identification.*

If a rack is taken away from the sediment conveyor, click on Reset button after the measurement is done.

ⓘ *The flexible rack handling only works flowlessly if the racks are RFID-identified. This is the only way to track the racks placed on or removed from the conveyor belt during operation.*

7.8 Results handling

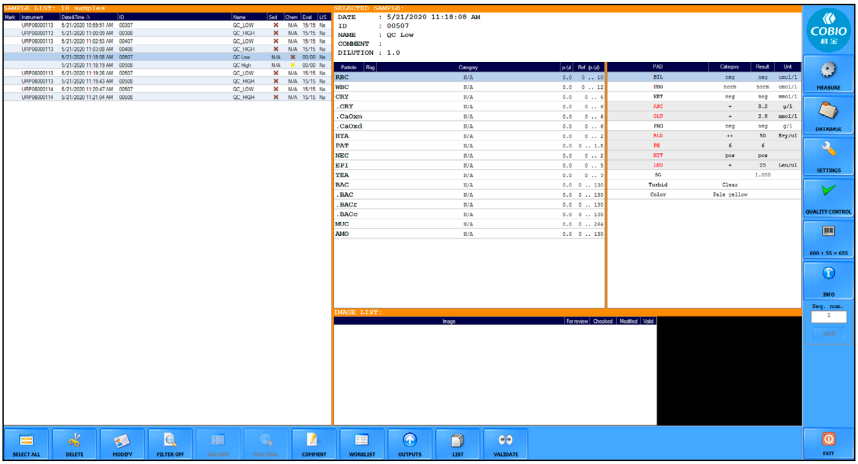


Figure 61. *The Database menu on UriSed 3 PRO Primary*

All results are displayed on the **Database** menu of the Primary sediment analyzer. In the **Sample List**, there is a column for the instrument serial number . That shows on which instrument was the actual measurement made.

Use the Primary sediment analyzer to view, filter, modify, validate and send the results (see **5.4 The Database menu**).

The chemistry results are on the **Chem** column of the **Sample List** (see **5.4.1.2 Chemical results**).

ⓘ *The chemistry results can be modified only on the Primary sediment analyzer. After the modification saved, the result gets updated in the chemistry analyzer.*

7.9 Common QC

Perform QC measurement at intervals as stated by your local healthcare regulations.

The system is able to handle a common QC measurement. All common QC measurement starts on the chemistry analyzer.

The procedure of QC measurement is exactly the same as at standalone or at connected operation, only the volume of control solution is needed to be increased to the minimum of 6 ml. Refer to the relevant sections of the user manuals to set up and perform the QC measurement on the Cascade system.

Its very important to select the same registered control solution on all three analyzers.

7.10 Maintenance

Apply maintenance procedures that are shown in the user manuals of the analyzers (see the relevant section of the LabUMat 2's user manual and **9 Maintenance**.

7.10.1 Common disinfection procedure

For common disinfection procedure, take three test tubes, pour 6 mL of 2% NaOCl (sodium hypochlorite) solution into each test tube. Remove all remaining racks with test tubes from the rack conveyor and place the tubes of NaOCl solution into a rack. Remove the front cuvette rail and click the **Disinfection** button (**General** menu) on the urine chemistry analyzer. Confirm the automatic rinsing process and wait for it to finish. This should take about 10 minutes.

7.10.2 Things to do at sediment analyzer malfunction

If one of the sediment analyzers fails, the remaining two analyzers can still be used as a connected system. The system can be used even when the failing analyzer is under service. It is possible to change the working status of the sediment analyzers in the **Instrument service mode** checkbox group, that is on the right side of the screen, under the menu buttons. During normal operation the service mode is **OFF** on both sediment analyzers. On the failing analyzer the operator has to select **Wait**. The measurements will take place as in case of normal connected operation. If the primary analyzer is at fail, its functions are transferred to the secondary analyzer but its rack conveyor is still working and carrying racks. When the service engineer is working on the failing analyzer, the **Instrument service mode** has to be changed to **ON**. In that case the rack conveyor of the analyzer is not working.

8 Quality control

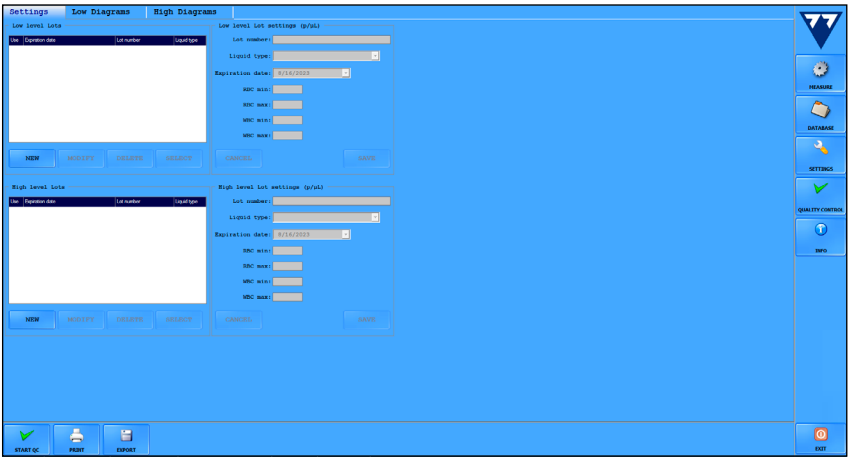


Figure 62. *The Quality Control menu*

You can test the performance of UriSed 3 PRO 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 (see **Figure 62**).

Generally there are two types of control solutions: normal (Low level) and abnormal (High level). The normal control solution, like normal urine, contains only a few sediment particles, while the abnormal control solution, like abnormal 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 formed 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 specify in **8.1 Setting up Quality Control solutions**.

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

8.1 Setting up Quality Control solutions

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.

1. 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.
2. Choose the type of control solution you are using from the drop-down list in the **Liquid type** text box.

⚠ **UriSed 3 PRO 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.**

3. Refer to the control solution package insert and enter the expiration date it indicates in the **Expiration date** field.
4. Set 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.

⚠ **Limit values of the control solutions are automatically re-scaled for the QC check to match the particle evaluation characteristics of the system.**

5. 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. However, you can delete the viewfield images while retaining the quality control summary results in the **Clear QC images** dialog box in the bottom left corner of the **Quality Control** menu. Use the drop-down calendar in the text box to specify a starting date for the image record deletion.

8.2 Performing Quality Control measurements

1. Pour at least 2 mL of both normal and abnormal control solutions in two separate test tubes and put them onto a rack.

2. Click a solution on the list. A star icon indicates selection. Enable it with the **Select** button, and then click **Start QC**.

⚠ **UriSed 3 PRO will prompt you to insert the test tube filled with the Level 1 (Low level) control solution into the number 1 slot on the rack, followed by the test tube containing the Level 2 (High level) control in the number 2 slot.**

3. Insert the rack with the control solutions just prepared and click **OK** on the confirmation message on the screen. UriSed 3 PRO will switch to the **Measure** menu to perform the measurements, the same as during normal sample measurement. The two control measurements will be named QC_LOW and QC_HIGH. After finishing quality control analysis, UriSed 3 PRO displays a message whether the test was successful, and label failed and passed quality control tests in the **Sample List** accordingly. 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.

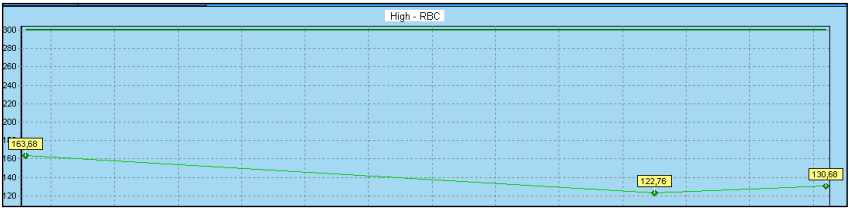


Figure 63. *An example of a Quality Control diagram. The x-axis represents the time period; the y-axis represents the measurement result values.*

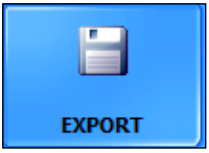
4. Click the **Low diagrams** and the **High diagrams** tabs on the **Quality control** menu to use the quality control visualisation feature. Select the time period you want to review using the radio buttons and the text boxes at the top of the screen, and click **Show** to display the results of all the quality control measurements during the given period on a chart (see **Figure 63**). Click the **Labels on/off** button to toggle the display of the exact result value captions. Check or uncheck the check boxes in the tabular summary in the top left corner to show or hide any given control solution lot.

ⓘ *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.*

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

ⓘ *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.*

5. 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.

Buttons on the Quality Control menu	
	Click to start QC measurement
	Click to print the diagrams selected and displayed in the Low and High Diagrams tabs in the **Quality Control** menu. Diagrams will be printed on 4 pages with all necessary data regarding the QC solution applied (Lot number, Limit ranges, and so on).
	QC reports can be exported along with diagrams. This function will create 6 files in the folder you designate. **QC Low level - Graficons.html** **QC Low level - Chart (RBC).bmp** **QC Low level - Chart (WBC).bmp** **QC High level - Graficons.html** **QC High level - Chart (RBC).bmp** **QC High level - Chart (WBC).bmp**

8.3 Creating your own QC

User may allow the use of the own QC.

1. Select the **Enable own QC with more levels** checkbox on the **Settings/Measure** tab, the **Own QC** tab appears in the **QC** menu.

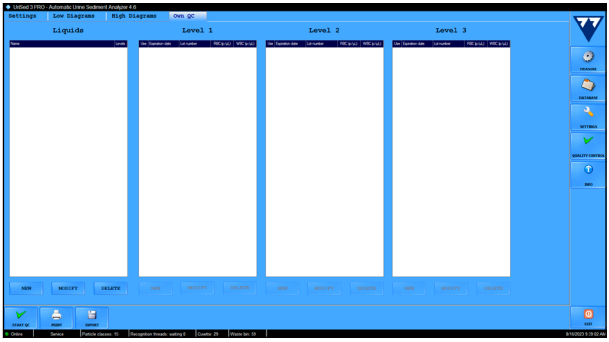


Figure 64. *Own QC menu*

2. In Liquids column tap **NEW** and enter the name of the liquid in the textbox of the appeared **Own QC liquid** popup window.

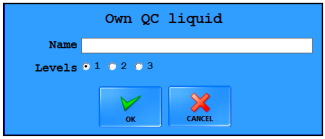


Figure 65. *Own QC liquid popup window*

3. Select the number of levels required and click **OK**.
4. Enter LOT number, expiration date and set ranges for WBC and RBC levels.

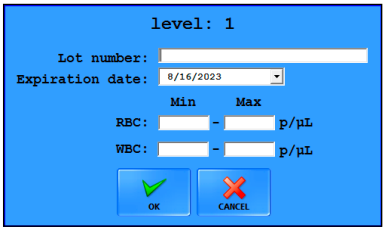


Figure 66. *Own QC level setup window*

5. Click **OK** to save it and set the other reqiured levels.

The user can modify the attributes of existing own liquid by clicking on **MODIFY** button and entering new values.

The **DELETE** button erases the selected own QC liquid and all the related QC measurement in the **Database**.

9 Maintenance

In order to keep your instrument functioning properly, you must make sure that your UriSed 3 PRO device is properly and regularly cleaned. Always clean the analyzer after end of shift and when any accidental spills occur to prevent corrosives or contaminants from drying on component surfaces. Use alcohol-based cleaning agents and aldehyde-free disinfectant (bactericide, fungicide, viricide) solutions.

Examples of accepted disinfectants

- Bacilol plus
- Mikrozid AF Liquid
- Sanisol S003
- Dispatch (Cal. Tech. Industries, Inc.)
- Staphasept (Correlated Products, Inc.).
- 2% sodium hypochlorite solution/bleach

⚠ **Using inappropriate cleaning solutions may damage the parts you cleaned.**

⚠ **Before using any cleaning or decontamination methods and cleaning solutions except those recommended in this manual, users should check with the manufacturer or the distributor that they will not damage the analyzer.**

⚠ **Since urine is a fluid of human origin, it may be infectious and may pose a biological risk.**

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

⚠ **Always wear surgical gloves or other protecting clothing when operating the urine analyzer.**

To keep UriSed 3 PRO in proper working condition, perform the following maintenance activities every day:

1. Before switching off the device at the end of the day, pour 6 mL of 2% NaOCl (sodium hypochlorite) solution into a test tube. Remove all remaining racks with test tubes from the rack conveyor and place a single tube of NaOCl solution into a rack. Remove the front cuvette rail and click the **Exit** button. Confirm the automatic rinsing process and wait for it to finish. This takes about 5 minutes.

⚠ **Remove the front cuvette rail before starting the automatic cleaning process and clicking the Exit button at the end of the day.**

⚠ **In case of an extreme clogging fill a 5% NaOCl (sodium hypochlorite) solution instead of a 2% one.**

2. Switch the device off. Open the waste bin on the left side of the equipment and empty it. It is also recommended to rinse it first with a 2% NaOCl solution, and then with water at the end of each day.

3. Empty the waste tank and clean it with a 2% sodium hypochlorite solution, and then rinse it with water.
4. Remove the rack conveyor for easy cleaning with a piece of cloth dipped in an alcohol-based, aldehyde-free disinfectant solution. This part does not contain any electrical parts, so there is no danger of a short-circuit if liquid enters inside it. However, immersing the rack conveyor in water is not recommended as flooding may damage the bearings inside.
5. Remove the following parts: the front and rear cuvette rail, the centrifuge cover and the centrifuge arm.

   a, You will need to remove the front cuvette rail to access the centrifuge cover. Remove the rear cuvette rail.

   b, Pull back the tumbler on the centrifuge cover to release it and easily remove the centrifuge cover.

   c, Hold the center of the centrifuge arm and pull to remove it.

ⓘ *You will need to remove the front cuvette rail to access the centrifuge cover. Pull back the tumbler on the centrifuge cover to release it and easily remove the centrifuge cover.*

6. Clean removable parts with a disinfectant solution. The most efficient way to clean removable parts is by using a disinfectant spray (such as Isorapid Spray, Dentiro Mikro Spray, and so on). Instead of spraying them, removable parts can also be rinsed in an alcohol– or NaOCl solution.

⚠ **Do not spray inside the device. Remove removable parts first. Use a moistened piece of cloth for cleaning internal parts.**

7. Visually examine the centrifuge arm and cover for cracks and fractures. Such damages would be detrimental to the satisfactory operation of the analyzer therefore the damaged parts has to be replaced with a new one.

ⓘ *Centrifuge arm catalogue number is URS-500206.*

⚠ **Dry removed parts before replacing them.**

8. Before replacing the front and the rear cuvette rail, clean the part of the supporting plate they are installed on, and the pins that keep them in place. Use a wipe dipped in a disinfectant solution.
9. Replace the centrifuge arm in a way that the magnet has to pull the arm into place.

ⓘ *Check the centrifuge arm by turning it around. Look for mechanical obstruction, backlash and unproper replacement and correct it.*

10. Replace the centrifuge cover and check if the cover is correctly replaced and cannot be moved without pulling the tumbler.

11. Without loosening its securing screw, turn the microscope arm above the microscope to the side and clean the microscope objective gently with cotton wool dipped in 70% alcohol.

⚠ **Do not loosen or unscrew the securing screw of the microscope arm above the microscope when turning it to the side.**

⚠ **Never touch the objective of the microscope with your fingers directly.**

⚠ **Do not use any other cleaning agent than alcohol to clean the objective.**

12. Periodically, and if necessary, use a wet piece of cloth to clean the covering panels as well.

⚠ **Never switch off UriSed 3 PRO by pushing the main switch before the automatic cleaning process is finished.**

10 Troubleshooting

10.1 Information messages

If an info message from the following list is displayed, follow the troubleshooting instructions and click **OK**. Some messages disappear when their cause is eliminated.

The following table gives an overview of all the information messages the system may display.

Code	Message	Info description
43	Safe to switch off the hardware.	The automatic rinsing is finished. You can replace the front cuvette rail and switch off the device.
44	Password successfully changed.	The new password is now valid.
45	N/A	N/A
46	There is not enough sample in tube. (Barcode: X)	The sample level in the test tube is less than 2 ml. Add more sample in the tube and repeat the measurement.
47	No particles detected - please validate X	Validate the sample manually.
48	Diagnostic report file created successfully.	The diagnostic file has been properly created in the designated location.
49	Empty cuvette: X	There were no particles detected in the given sample. Please measure again and/or verify with manual microscopy.
50	Quality control (Low level) passed.	Low level QC measurement was successful.
51	Quality control test (High level) passed.	High level QC measurement was successful.
52	Load control solutions. Low level first, then High level!	Place control solutions in the rack first for Low level then for High level!
59	Load the urgent sample.	Place the urgent sample in a rack onto the rack conveyor.
234	The bleach solution is lower than 6 ml.	
303	Raw data export created successfully.	
446	One sample was not commented, it is staying in output queue.	
447	More samples were not commented, they are staying in output queue.	
478	Quality control test passed! Level:	
484	Load control solutions in ascending order by level!	

Code	Message	Info description
485	Load control solution!	
489	After a successful restore, the software will restart	
510	printer was not found. The default printer is the selected.	

10.2 Warning messages

If a warning message from the following list is displayed, follow the troubleshooting instructions and click **OK**. Some messages disappear immediately if their cause is eliminated.

The following table gives an overview of all the warning messages the system may display.

Code	Warning message	Warning elimination
61	Cuvette waste bin full.	The waste bin is full, so the measurement stopped. Empty the waste bin to start measurement.
64	Rack remain on conveyor. Please, put it on sediment analyzer conveyor!	Follow on-screen instructions.
65	The next-in-line rack did not get a number, as the device is not ready.	The device was not connected to the operating PC when the next-in-line rack was assigned an arbitrary number on the Settings»Measure tab. Make sure that the PC and the analyzer are connected.
66	Please close centrifuge door.	Re-insert the centrifuge housing.
70	Database sample count limit is approaching.	Refer to the relevant section of the user guide and raise the database limit, or delete result records from the database.
72	The new database limit too low. Delete some samples and try again.	The number of result records in the database is higher than the database limit that you set. Delete some records or set a different limit.
75	ID contains an illegal character.	Do not use an apostrophe (') in the sample ID.
76	Name contains an illegal character.	Do not use an apostrophe (') in the name.
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.
80	Wait for the STAT position.	You can start the STAT measurement when the current measurement stops.

Code	Warning message	Warning elimination
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 seleted. Choose a liquid type.
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	Invalid password.	At password change the original password was given incorrectly. Enter the original password correctly.
87	Cannot delete active user.	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	Login only for service-level users.	You can only login as Service user. Use the proper name and password to login as Service user.
90	Username already on list.	The user name you tried is already in use by another person. Please choose another user name!
91	No more worklist elements.	Measurement can not be started, because the worklist elements are consumed. Enter new worklist items or disable this function.
92	Duplicate barcode	An existing barcode was given in the worklist. Give a new, not existing barcode.
93	Parallel chemical measurements not compatible with reflex mode.	Set the parallel count to 1 on interfaced chemical analyzer device.
94	Parallel chemical measurements not compatible with worklist.	Set the parallel count to 1 on interfaced chemical analyzer device.
95	No user is currently logged in.	Log in to a valid user account.
96	The device is not ready.	Wait for the device to finish system initialization.
97	Sample was not saved because Database limit would be exceeded.	The indicated measurement record would make the database size exceed the database limit. Raise the database limit.

Code	Warning message	Warning elimination
98	Sample was not saved, because it is over the Database limit! Measurement was stopped. Delete unused data!	The device received data from the connected chemistry analyzer, but does not have enough disk space to store it. Delete unused data from the database.
100	DAILY DISINFECTION RINSE 1. LOAD washing liquid 2. REMOVE the front cuvette guide 3. CLICK OK!	This message comes up before the daily disinfection procedure. Follow the instructions in the message to perform a daily disinfection.
101	Please remove the front cuvette guide then click OK.	This message comes up before the daily washing procedure if you click OK the first message without removing the front cuvette rail.
102	Init necessary.	The pipette is inside a test tube, and the system will not perform the command to prevent bending or breaking the pipette. Start a system initialization.
103	No more samples.	You have reached the end of the microscopy image slideshow in the Sample View Editor.
104	Repeated barcode!	A measurement record associated with the indicated barcode already exists in the database.
105	QC in progress.	Wait for the QC measurement to end.
106	Serial number does not match.	Call your service representative.
107	QC deletion not enabled.	One or more selected records are QC measurements. Enable QC result deletion in the user software on the Settings/Maintenance tab.
108	Name contains an illegal character.	The Name can not contain ' & / \ : * ? " < > | ^ ~ characters at Sample Data Modifying.
109	ID contains an illegal character.	The ID can not contain ' & / \ : * ? " < > | ^ ~ characters at Sample Data Modify-ing.
110	Comment contains illegal character.	The Comment can not contain ' & | ^ ~ characters at Comment changing.
111	Worklist name contains an illegal character.	The Name can not contain ' & / \ : * ? " < > | ^ ~ characters at Worklist elements.
112	Worklist ID contains an illegal character.	The ID can not contain ' & / \ : * ? " < > | ^ ~ characters at Worklist elements.
113	Worklist comment contains an illegal character.	The Comment can not contain ' & | ^ ~ characters at Worklist elements.
114	Category display contains an illegal character.	The Category display can not contain ' & | ^ ~ characters at Category definition settings.
115	Lot number contains an illegal character.	The Lot number can not contain ' & | ^ ~ characters at QC settings.

Code	Warning message	Warning elimination
116	Serial number is missing.	Call your service representative.
118	X sample(s) were not exported.	Validate the indicated sample(s) and try exporting again.
119	X sample(s) were not sent.	Validate the indicated sample(s) and try sending again.
120	X sample(s) were not printed.	Validate the indicated sample(s) and try printing again.
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.
122	Please check the front cuvette guide.	Make sure that the front cuvette rail that is inside the device was not designed for a different generation of sediment analyzer.
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.	Assign a longer ID.
125	Low disk space, less than...	Free disk space has dropped below the indicated level. Delete the measurement records that have been exported.
126	Parallel chemical measurements not supported in sequential mode.	Multiple analysis of the same sample is not supported if sequential sample ID assignment is enabled. Disable sequential sample ID assignment, or set the number of parallel measurements to 1.
127	Waiting for the rack(s) from the chemical analyzer.	You cannot start an independent measurement on the sediment analyzer while the connected chemical urinalysis device is performing a measurement cycle. Wait for the measurement cycle on the chemical urinalysis device to stop
128	Invalid start parameters.	N/A
129	The sediment analyzer is busy.	Wait for the independent measurement cycle on the device to stop before initializing a measurement on it from the connected chemistry urinalysis device.
130	X PCB version above .mhx file	Contact your service representative.
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. Change the transfer type later.	You cannot modify the transfer settings while a transfer is going on. Wait for the data transfer to end.
133	LIS port is busy.	Restart the analyzer and the PC.

Code	Warning message	Warning elimination
134	Must be a member of service.	The indstrument is in service mode. Contact your service representative.
135	No diagram available for these filter conditions.	Modify the filter settings so that a QC history diagram can be drawn.
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.
141	N/A	N/A
142	N/A	N/A
143	N/A	N/A
216	Log folder changing in progress. Please, try it later.	Wait until the change is finished.
218	No disinfectant liquid!	Place a rack with a test tube of 2% bleach solution onto the rack mover.
219	Barcode reading failure.	Start system initialization. Restart the analyzer and the PC. If the error persists, contact your service representative.
220	Invalid card configuration.	Call your service representative.
221	Front cuvette guide missing.	Insert the front cuvette rail. If the issue persists, call your service representative.
222	Rear cuvette guide missing.	Insert the rear cuvette rail. If the issue persists, call your service representative.
223	No cuvette.	The system cycled through all the cuvette cartridge slots, but could not detect a cuvette in the cuvette carousel. Load the carousel with one or more cuvette cartridges. If the issue persists, call service.
224	Waste tank full.	Empty the waste container. If it is already empty, check the waste cable soundness and its connections.
225	No washing liquid present.	Fill distilled water into the wash container. If the container is full, check the soundness and connections of the wash cable.
226	Waste tank warning level reached.	Empty the waste container. If it is already empty, check the waste cable soundness and its connections. If error persist, call service.

Code	Warning message	Warning elimination
227	Washing tank warning level reached.	Fill the washing container. If it is already empty, check the waste cable soundness and its connections. If error persist, call service.
228	Front cover open.	Close door(s) of the device.
229	No rack present.	Put a rack on the rack mover.
230	Rack mover full	Remove the processed racks from the rack conveyor.
231	Please close cuvette waste bin.	Close the waste bin.
232	Please close centrifuge door.	Check and close the centrifuge door.
233	Rack(s) remain on conveyor. Please, measure them manually.	Mesure the samples on the rack again.
234	The bleach solution is lower than 4 ml.	Pour at least 4 ml of 2% NaOCl solution in the test tube at daily disinfection wash.
292	The LOT has been expired!	Register new QC LOT.
293	The selected Low level lot has been expired, measurement can not start.	Register new QC LOT.
294	The selected High level lot has been expired, measurement can not 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	Tha sample is in output queue.	Wait until the export/transfer is finished.
307	STAT measurement is rejected. Try it later.	Follow on-screen instructions.
308	Rack transfer active.	Wait until the rack transfer is finished.
310	Rack out is impossible, try it later.	Follow on-screen instructions.
331	First generation is not supported.	The software is not compatible with this instrument.
345	Wait for the disinfecting rinse to finish.	Follow on-screen instructions.

Code	Warning message	Warning elimination
358	Comment Window opening in progress	Wait until the window is opened.
359	Evaluation Window opening in progress	Wait until the window is opened.
360	Validation window opening in progress	Wait until the window is opened.
361	Worklist deleting in progress	Wait until the deleting is finished.
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 gain.
375	The image of sample of this QC LOT is in evaluation queue.	Wait until the evaluation is finished.
376	Invalid card software.	Call your service representative.
380	ID was generated. ID:	The analyzer could not detect barcode on the tube and gave generated ID for the sample.
384	Port open error in chemical connection.	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.
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.
398	Last QC Measurement expired. Please measure QC!	Follow the on-screen instructions.
407	The service switches are in different position. Put them in same position.	Follow the on-screen instructions.

Code	Warning message	Warning elimination
408	No more registered cuvette.	Register new cuvettes.
409	Text already exists in predefined comments list!	Type in different comment.
410	Common measurement can not start.	
411	DAILY DISINFECTION RINSE 1. LOAD washing liquid 2. REMOVE the front cuvette guide from master and slave 3. CLICK OK!	Follow the on-screen instructions.
414	No more samples that fulfill the Filter criteria!	
416	Other measurement is running.	
417	Please set missing filter parameter!	Follow the on-screen instructions.
419	Sediment result modification temporarily not available. Sample is in queue/export/print/ transfer.	Wait until the procedure is finished, and try again.
420	A result rule has been activated on the sample with the comment.....	
434	DAILY DISINFECTION RINSE LOAD washing liquid CLICK OK!	Follow the on-screen instructions.
435	QC diagram start date should be smaller than end date! Please select new dates!	Follow the on-screen instructions.
436	Worklist element order assign not allowed in cascade measurement.	
438	Please set missing result rule parameter!	Follow the on-screen instructions.
439	The modified record has paired, please modify it again if necessary.	Follow the on-screen instructions.

Code	Warning message	Warning elimination
450	DAILY DISINFECTION RINSE 1. LOAD washing liquid 2. CLICK OK!	Follow the on-screen instructions.
451	Particle modification is not enabled!	
453	The binary channel is closed. Images were not sent.	
460	The sample is measured.	
462	Full Eval is not enabled for the sample.	
463	Full Eval is not enabled for some samples.	
464	Parallel measurement with Host query is not enabled.	
466	All activated QC Lots must be of the same solution type.	
467	Full name contains illegal character(s).	
468	Illegal format in category LOINC field.	
469	Illegal format in p/HPF LOINC field.	
470	Illegal format in p/µL LOINC field.	
471	This short name already exists.	
472	Please give a short name.	Follow the on-screen instructions.
477	The liquid is undeletable. Try it again after output has finished.	Follow the on-screen instructions.
479	Quality control test failed! Level:	
480	There is no level Lot. Please register one.	Follow the on-screen instructions.
481	Please select a level Lot.	Follow the on-screen instructions.

Code	Warning message	Warning elimination
482	This level lot does not exist in the database. Please select another Lot.	Follow the on-screen instructions.
483	The selected level lot has been expired, measurement can not start.	
487	Password mismatch	Enter the passwords again.
488	Password is empty	Enter password.
497	Tube cap identified: X has been skipped.	Remove the cap and repeat the measurement.

10.3 Error messages

During operation a control program checks the operational conditions needed for the proper execution of each process. If the checking indicates a problem, an error message will be displayed.

⚠ **If an error message is displayed, click the INIT button on the Measure menu. In some cases this will automatically solve the problem by reinitializing the device. If the problem persists, try switching the device off and on again—a hardware reset may help to eliminate the problem.**

The following table gives an overview of all the error messages the system may display.

Code	Hardware error message	Recommended corrective action (CLICK INIT AFTER EVERY ERROR MESSAGE)
235	Bar base position error	Check if there is no cuvette in the arm way and after that press Init. If the error persists, contact your service representative.
236	Bar pipette position error	Check if there is no cuvette in the arm way and after that press Init. If the error persists, contact your service representative.
237	Bar centrifuge position error	Check the centrifuge door. Check if there is no cuvette in the arm way and after that press Init. If the error persists, contact your service representative.
238	Bar microscope position error	Check if there is no cuvette in the arm way and after that press Init. If the error persists, contact your service representative.
239	Carousel position error	Moving it manually, check if the rotor can rotate and if there is no cuvette between the rotor and the cuvette frontline and after that press Init. If the error persists, contact your service representative.
240	Cuvette checking error.	Check if there is no object between the laser and the cuvette and after that press Init. If the error persists, contact your service representative.
241	Rack rotator inner end position error.	Check if there is no object in the way of Rack rotator arm and after that press Init. If the error persists, contact your service representative.
242	Rack rotator outer end position error.	Check if there is no object in the way of Rack rotator arm and after that press Init. If the error persists, contact your service representative.
243	Aspiration pump moving error.	Restart the analyzer and the PC. If the error persists, contact your service representative.
244	Pushing arm HW error.	Restart the analyzer and the PC. If the error persists, contact your service representative.
245	Rotor HW error.	Restart the analyzer and the PC. If the error persists, contact your service representative.

Code	Hardware error message	Recommended corrective action (CLICK INIT AFTER EVERY ERROR MESSAGE)
246	Robot X HW error.	Restart the analyzer and the PC. If the error persists, contact your service representative.
247	Robot Y HW error.	Restart the analyzer and the PC. If the error persists, contact your service representative.
248	Horizontal rinse well position error	Restart the analyzer and the PC. If the error persists, contact your service representative.
249	Horizontal cuvette position error	Restart the analyzer and the PC. If the error persists, contact your service representative.
250	Horizontal test tube position error	Restart the analyzer and the PC. If the error persists, contact your service representative.
251	Vertical top position error	Restart the analyzer and the PC. If the error persists, contact your service representative.
252	Vertical cuvette position error	Restart the analyzer and the PC. If the error persists, contact your service representative.
253	Vertical test tube position error	Restart the analyzer and the PC. If the error persists, contact your service representative.
254	Vertical rinse well position error	Restart the analyzer and the PC. If the error persists, contact your service representative.
255	Sample dispenser error	Restart the analyzer and the PC. If the error persists, contact your service representative.
256	Inner catch position error	Restart the analyzer and the PC. If the error persists, contact your service representative.
257	Outer catch position error	Restart the analyzer and the PC. If the error persists, contact your service representative.
258	Aspiration pump error.	Restart the analyzer and the PC. If the error persists, contact your service representative.
259	Rack position error	Check if you use proper rack. Restart the analyzer and the PC. If the error persists, contact your service representative.
260	Rack aligner opening error.	Check the clear movement of rack aligner and the rack mover position. Restart the analyzer and the PC. If the error persists, contact your service representative.
261	Rack aligner closing error.	Check the clear movement of rack aligner and the rack mover position. Restart the analyzer and the PC. If the error persists, contact your service representative.
262	Barcode scanner not present.	Restart the analyzer and the PC. If the error persists, contact your service representative.
263	Rack pushing arm error.	Restart the analyzer and the PC. If the error persists, contact your service representative.
264	Microscope rotary home position error	Restart the analyzer and the PC. If the error persists, contact your service representative.

Code	Hardware error message	Recommended corrective action (CLICK INIT AFTER EVERY ERROR MESSAGE)
265	Microscope linear home position error	Restart the analyzer and the PC. If the error persists, contact your service representative.
266	Microscope linear end position error	Restart the analyzer and the PC. If the error persists, contact your service representative.
267	Focus home position error	Restart the analyzer and the PC. If the error persists, contact your service representative.
268	Rack aligner error.	Restart the analyzer and the PC. If the error persists, contact your service representative.
269	Microscope stage error.	Restart the analyzer and the PC. If the error persists, contact your service representative.
270	Linear motor error.	Restart the analyzer and the PC. If the error persists, contact your service representative.
271	Focus error.	Restart the analyzer and the PC. If the error persists, contact your service representative.
272	Centrifuge arm blocked.	Restart the analyzer and the PC. If the error persists, contact your service representative.
273	PCB 1 communication error.	Check if the instrument is switched on and the soundness and connections of the USB cable. Restart the analyzer and the PC. If the error persists, contact your service representative.
274	PCB 2 communication error.	Check if the instrument is switched on and the soundness and connections of the USB cable. Restart the analyzer and the PC. If the error persists, contact your service representative.
275	PCB 3 communication error.	Check if the instrument is switched on and the soundness and connections of the USB cable. Restart the analyzer and the PC. If the error persists, contact your service representative.
276	PCB 4 communication error.	Check if the instrument is switched on and the soundness and connections of the USB cable. Restart the analyzer and the PC. If the error persists, contact your service representative.
277	PCB 5 communication error.	Check if the instrument is switched on and the soundness and connections of the USB cable. Restart the analyzer and the PC. If the error persists, contact your service representative.
278	PCB 6 communication error.	Check if the instrument is switched on and the soundness and connections of the USB cable. Restart the analyzer and the PC. If the error persists, contact your service representative.

Code	Hardware error message	Recommended corrective action (CLICK INIT AFTER EVERY ERROR MESSAGE)
279	PCB 7 communication error.	Check if the instrument is switched on and the soundness and connections of the USB cable. Restart the analyzer and the PC. If the error persists, contact your service representative.
280	Chem. analyzer communication error.	If the Chem. Analyzer is connected, check the soundness and connections of the connective cable and the common operation settings in both programs. If it is not connected, remove tick from Settings/LabUMat is enabled.
281	Not enough serial ports present.	Restart the analyzer and the PC. If the error persists, contact your service representative.
282	Too many serial ports.	Restart the analyzer and the PC. If the error persists, contact your service representative.
283	UriSed connection error.	Make sure that the sediment analyzer is switched on, and that the USB cable connecting the PC and the device is intact and connected.
284	LabUMat connection error!	Restart the analyzer and the PC. If the error persists, contact your service representative.
285	LIS connection error!	Check that the LIS cable is properly connected. Restart the analyzer and the PC. If the error persists, contact your service representative.
286	Focus process timeout.	Restart the analyzer and the PC. If the error persists, contact your service representative.
287	Shutter calibration error.	Restart the analyzer and the PC. If the error persists, contact your service representative.
288	Error at camera init.	The software driver for the camera is outdated. Contact your service representative.
289	Error at focus init.	The software driver for the camera focus function was not found. Contact your service representative.
290	Error at focus init.	The software driver for the camera focus was not found. Contact your service representative.
291	Sediment analyzer is disconnected, please restart the instrument and the software.	Restart the analyzer and the PC.
354	Hardware initialization error.	Restart the analyzer and the PC. If the error persists, contact your service representative.
402	Incompatible instrument category	Restart the analyzer and the PC. If the error persists, contact your service representative.
403	Incompatible instrument type	Restart the analyzer and the PC. If the error persists, contact your service representative.

Code	Hardware error message	Recommended corrective action (CLICK INIT AFTER EVERY ERROR MESSAGE)
404	Incompatible sales version	Restart the analyzer and the PC. If the error persists, contact your service representative.
405	Configuration is disabled	Restart the analyzer and the PC. If the error persists, contact your service representative.
413	There is a rack in the instrument. Please, remove it.	Follow on-screen instructions.
431	Light interface error	Restart the analyzer and the PC. If the error persists, contact your service representative.
437	Close the door, please.	Follow on-screen instructions.
440	Instrument does not have serial number.	Restart the analyzer and the PC. If the error persists, contact your service representative.
441	RFID communication error	Restart the analyzer and the PC. If the error persists, contact your service representative.
442	RFID not present	Restart the analyzer and the PC. If the error persists, contact your service representative.
443	Customer ID error	Restart the analyzer and the PC. If the error persists, contact your service representative.
448	Robot X stall detection	Restart the analyzer and the PC. If the error persists, contact your service representative.
449	Robot Y stall detection	Restart the analyzer and the PC. If the error persists, contact your service representative.

The following table gives an overview of all the Miscellaneous error messages the system may display.

Code	Miscellaneous error message	Recommended corrective action
146	Sample editing error	There was a connection error in the database. Exit the user software and restart the system.
147	Sample comment editing error	There was a connection error in the database. Exit the user software and restart the system.
148	Database error. The edit cannot be saved.	An error occured during the save of chemical result modification into the database. Database connection error, exit the program and restart.
149	Database error. The edit cannot be saved.	An error occured during the save of sediment result modification into the database. Database connection error, exit the program and restart.
150	The maximum enabled number is	The number of particles stored with a sediment result may not exceed 99999.9. Enter a lower number.
151	Cannot save modification. The min range is higher than max!	The Quality Control valid ranges are mismatched. Review and modify the ranges.
152	Not a proper number format. Use decimal character.	Use the decimal mark indicated in the message text (either "." or ",") at sample modofications.
154	Driver is not connected, please restart the instrument and the software.	Restart the instrument and the software.
155	Invalid strip on LabUMat! (Barcode: xxx)	Refert to the User Manual of the chemical analyzer for troubleshooting.
156	Late strip on LabUMat! (Barcode: xxx)	Refert to the User Manual of the chemical analyzer for troubleshooting.
157	Bad strip position on LabUMat! (Barcode: xxx)	Refert to the User Manual of the chemical analyzer for troubleshooting.
158	Color problem on LabUMat! (Barcode: xxx)	Refert to the User Manual of the chemical analyzer for troubleshooting.
159	Lost strip on LabUMat! (Barcode: xxx)	Refert to the User Manual of the chemical analyzer for troubleshooting.
161	Control measurement failed on LabUMat! (Barcode: xxx)	Refert to the User Manual of the chemical analyzer for troubleshooting.
162	Sample count exceeds sample limit. Delete unused data!	It appears at measurement start. There is not enough storage in the database for measurement results. Delete the unused data.

Code	Miscellaneous error message	Recommended corrective action
163	Compatibility issue.	The connected sediment and chemical urinalysis devices are mismatched either in hardware or their device software version number.
164	Flipped strip on LabUMat! (Barcode: xxx)	Refert to the User Manual of the chemical analyzer for troubleshooting.
165	No strip under the head on LabUMat! (Barcode: xxx)	Refert to the User Manual of the chemical analyzer for troubleshooting.
166	Dry strip under the head on LabUMat! (Barcode: xxx)	Refert to the User Manual of the chemical analyzer for troubleshooting.
167	Horizontal flipped strip on LabUMat! (Barcode: xxx)	Refert to the User Manual of the chemical analyzer for troubleshooting.
168	Chemical analyzer is upgrading.	Wait until chemical analyzer is upgrading. Try to connect when upgrade was finished.
169	Chemical analyzer runs in simulator mode.	Call your service representative.
170	The sediment setting is off on chemical analyzer.	Refert to the User Manual of the chemical analyzer and set the chemical analyzer to work togetherwith the sediment analyzer.
171	Strip out of position	Refert to the User Manual of the chemical analyzer for troubleshooting.
172	Passwords do not match.	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.
179	X 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	Identical category strings.	At category modification: Existing category name. Enter an other name.
182	Min. and max. limits identical in category definition.	Please increase X. category definition, because it is the same as the previous one.

Code	Miscellaneous error message	Recommended corrective action
183	Incorrect 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!	The HTML export file is currently open. Close the file and try exporting again.
188	There is not enough free space on target drive.	Delete unnecessary files from the target disk, or use another device.
190	Error in condition!	Consult the user manual of the Menasoft software that you are using together with the analyzer.
191	Connection to printer lost.	Verify that the printer is connected to the PC and review the printer status in the Windows Device Manager.
192	Error detected in CSV file in line:	Category import file's format is corrupted, correct it or select another import file
193	LabUMat disconnected. Verify status and reinit.	Check the settings on the connected automated chemical analyzer, and reconnect the two devices.
194	Selected input file is missing.	Verify that the external drive is properly connected to the instrument and the file still exists and undamaged.
195	There is not enough free space on target drive.	Delete unnecessary files from the target disk at csv export.
196	N/A	N/A
197	N/A	N/A
198	LIS communication error!	Check the soundness and connections of the communication cable. Verify that the PC is connected to the host computer. Refer to the LIS protocol documentation and review the host computer settings.
199	The LIS is offline.	Check the soundness and connections of the communication cable. Verify that the PC is connected to the host computer. Refer to the LIS protocol documentation and review the host computer settings.(bidir)
200	LIS winsock open error.	Check the soundness and connections of the communication cable. Verify that the PC is connected to the host computer. Refer to the LIS protocol documentation and review the host computer settings.

Code	Miscellaneous error message	Recommended corrective action
201	LIS socket open error.	Check the soundness and connections of the communication cable. Verify that the PC is connected to the host computer. Refer to the LIS protocol documentation and review the host computer settings.
202	LIS TCP connection error.	Check the soundness and connections of the communication cable. Verify that the PC is connected to the host computer. Refer to the LIS protocol documentation and review the host computer settings.
203	Error in Chemical result	Check the measurement on the chemistry analyzer.
204	The LIS is offline.	Check the soundness and connections of the communication cable. Verify that the PC is connected to the host computer. Refer to the LIS protocol documentation and review the host computer settings.(unidir)
203	N/A	N/A
205	Incorrect number format in limit. Use decimal character.	Use the decimal mark indicated in the message text (either "." or ",".) (QC)
206	Diagnostic report was NOT created.	Make sure that the directory for the report is present and the portable device is properly connected.
207	Error during PCB upgrade.	Turn off the device and exit the program. Turn on the device and start the program. If the error persists, contact your service representative.
208	N/A	N/A
209	N/A	N/A
210	N/A	N/A
211	N/A	N/A
212	N/A	N/A
213	N/A	N/A
295	N/A	N/A
296	N/A	N/A
299	Upgrade bus error on centrifuge.	Call your service representative.
300	At least one cell has to be selected.	Select at least one cell on Settings/Evaluation tab.
306	The pulled out rack has stopped.	It is possible that the rack was taken from the rack mover before the system could detect it leaving the sampling area. Start system initialization. If error persist, call your service representative.
309	The robot must be taught. Call service.	Call your service representative.

Code	Miscellaneous error message	Recommended corrective action
368	Upgrade bus error on feeder.	Call your service representative.
369	Upgrade bus error on washer.	Call your service representative.
370	Upgrade bus error on robot.	Call your service representative.
371	Upgrade bus error on rack.	Call your service representative.
372	Upgrade bus error on microscope.	Call your service representative.
389	Evaluation error: No image.	Restart the analyzer and the PC. If the error persists, contact your service representative.
390	Evaluation error: BrightField convert error.	Restart the analyzer and the PC. If the error persists, contact your service representative.
391	Evaluation error: PhC convert error.	Restart the analyzer and the PC. If the error persists, contact your service representative.
392	Evaluation error: No image information.	Restart the analyzer and the PC. If the error persists, contact your service representative.
393	Evaluation error: dll loading error.	Restart the analyzer and the PC. If the error persists, contact your service representative.
394	Evaluation error: invalid command format.	Restart the analyzer and the PC. If the error persists, contact your service representative.
395	Evaluation error: unknown command.	Restart the analyzer and the PC. If the error persists, contact your service representative.
401	Communication version is incompatible	Restart the analyzer and the PC. If the error persists, contact your service representative.
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.
415	Cuvette registration necessary before STAT.	Restart the analyzer and the PC. If the error persists, contact your service representative.
490	The backup was not created	Retry backup.
492	The restore was unsuccessful	Retry restore.
509	There is not enough free space on target drive.	Insert drive with enough free space.

Code	Miscellaneous error message	Recommended corrective action
511	The new password is the same as the previous one	Enter new password.

If the recommended actions do not eliminate the problem, or if any other error message is displayed, contact your distributor for help. The device should be repaired only by specially trained service personnel.

⚠ **Do not attempt to repair the equipment without the assistance of a professional.**

11 Diagnostic performance summary

11.1 Reference range study

For reference range study 148 normally voided urine specimens from a population of 100 male and 48 females in apparent good health were investigated on UriSed 3 PRO instrument. 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	48	9.7 p/µl	Female	48	9.9 p/µl
	Male	100	5.3 p/µl	Male	100	6.6 p/µl

11.2 Method comparison

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

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

number of samples measured: 614

The diagnostic performance results of UriSed 3 PRO compared to manual microscopy by KOVA counting chamber are summarized below.

Quantitative diagnostic performance: Linear regression

	RBC	WBC
Pearson's r:	0.93	0.94
Slope	1.00	0.90

Semi-quantitative diagnostic performance: concordance table analysis

	RBC	WBC	EPI	NEC	HYA	PAT	CRY	YEA	BAC	MUC
Sensitivity (%)	93.1	91.5	93.1	78.0	75.0	70.0	75.0	81.3	83.9	65.3
Specificity (%)	86.6	95.3	93.9	87.8	96.0	95.4	99.5	98.8	90.1	85.3
Exact category agreement (%)	85.8	89.6	90.7	82.7	92.0	89.9	96.4	96.9	83.6	77.2
+/-1 category agreement (%)	99.7	100.0	100.0	92.7	97.2	97.2	99.7	98.7	98.4	93.0
Accuracy (%)	88.6	93.8	93.8	87.0	94.6	93.3	98.5	98.4	88.9	82.1
Prevalence (%)	30.6	38.1	11.7	8.1	6.5	8.1	3.9	2.6	19.2	16.0

11.3 Precision

For precision measurements the following controls were used:

- Quantimetrix Dip&Spin Normal and Abnormal Level
- BioRad Liquichek Normal and Abnormal Level
- Kova Liqua Trol Normal and Abnormal Level

The below tables are the summary of the investigations.

11.3.1 Between-run precision

ⓘ *Precision acc. to CLSI EP9-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	0.1-17.3	-	0.18-6.23	0-21.9	-	0-4.31
QC abnormal	120.7-899.8	8-22%	-	43.1-251.1	7-16%	-

11.3.2 Inter-system precision

ⓘ *Precision acc. to CLSI EP9-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.

Inter-system precision	RBC			WBC		
	Average (p/µl)	CV	SD	Average (p/µl)	CV	SD
QC normal	0.05-17.59	-	0.2-10.9	0.01-22.06	-	0.09-4.54
QC abnormal	117.61-856.55	6-15%	-	38.29-242.32	8-16%	-

11.3.3 Within-run precision

ⓘ *Precision acc. to CLSI EP9-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	0.04-23.63	-	0.20-6.65	0.00-22.70	-	0.00-4.96
QC abnormal	73.66-950.62	5-14%	-	39.80-254.43	7-14%	-

11.4 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%.

p/µl	RBC	WBC	EPI	NEC	HYA	PAT	CRY	YEA	BAC	MUC	SPRM
LoB	0.6	0.0	0.0	0.0	0.0	0.0	1.2	0.0	15.3	4.3	0.0
LoD	2.55	1.71	1.43	1.24	1.14	1.27	2.71	1.99	19.94	9.98	1.99
LoQ	3.30	3.15	-	-	-	-	-	-	-	-	

11.5 Linearity

The linearity measurements were performed in accordance with the CLSI Guideline *EP6-A* requirements.

The goal of the linearity measurement is to evaluate the linearity of the quantitative parameters (RBC and WBC) over the measurement range.

For the measurement series, 12 dilution were created from a high positive sample, each dilution was measured 4 times in different order.

Based on the measurement results the linearity range of the quantitative parameters are the following:

Linearity range:	
RBC	5-1800 p/µl
WBC	5-1200 p/µl

11.6 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 UriSed 3 PRO instrument 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 **1 Introduction**.

Result

Particles	RBC	WBC	CRY	HYA	PAT	NEC	EPI	YEA	BAC	MUC	SPRM	AMO
Tube no preservatives	0.6	0.0	1.2	0.0	0.0	0.0	0.0	0.0	15.3	4.3	0.0	0.0
BD Vacutainer	0.9	0.0	3.1	0.0	0.0	0.0	0.0	0.0	66.1	4.4	0.0	3.5
Boritex	0.0	0.0	0.4	0.0	0.0	0.0	0.0	0.0	19.1	3.9	0.0	0.0

BD Vacutainer tubes may cause a slightly increased crystal and amorphous material results. It may cause increased bacteria results but these values are still below the default cutoff range.

In case of Boritex tubes there wasn't any interference. All LoB values are similar to the non-preservative tube values.

11.7 Interferences

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

The goal of the evaluation is to identify and investigate a list of typical particles that can cause false results in the analyzer's evaluation module.

The interfering particles / conditions were identified and tested with the following results:

1. Next to an increasing concentration of mucus an increase in false hyaline recognition may be visible, in certain cases also leading to false positive results. No other interference is found.
2. With the increase of amorphous material in the sample, false BAC recognition increases. Visually bacteria and amorphous crystals (at low concentrations) can be very similar. No other interference is found.
3. With the high increase of YEA in the samples, RBC concentration slightly rises as well, due to false RBC recognition on individual YEA cells.

11.8 Carry-over

The carry-over measurements were performed based on *CLSI EP10-A3* guideline, applied to urine sediment microscopy analysis based on the paper: *Broughton PMG, Gowenlock AH, McCormack JJ, Neil DW. A revised scheme for evaluation of automatic instruments for use in clinical chemistry. Ann Clin Biochem 1974;11:207–18.*

The purpose of the measurement is to show that the washing capabilities of the instrument are sufficient to avoid carry-over from sample to sample.

In each case 3 high positive samples (denoted as a1, a2, a3) and 3 positive samples (denoted as b1, b2, b3) were measured after each other. The process was repeated 9 times to have a total of 10 measurement sets.

Results are calculated according to the following: Carry-over = (b1-b3)/(a3-b3)*100

All measurements of the positive samples were above the upper measurement range for RBC, WBC or BAC. In order to perform calculation, the raw results were used.

In case of RBC, WBC and BAC, the carry-over calculation is 0.00% for all 10 measurement sets.

No carry-over was identified.

12 Device support

12.1 Servicing

- The device can be repaired only by qualified and trained experts.
- Only original parts which are recommended by the manufacturer can be used as replacement parts.
- Before every operation that involves the removal of the device cover, the device should be switched off and unplugged from the mains cable.
- The manufacturer reserves the right to alter the software or hardware elements without prior notice.
- Contact the manufacturer for the latest documentation about various versions of the device.

12.2 Ordering information

URS-9971	RFID tagged packed cuvette (600 pcs)
UAZ-4339	RFID tagged rack for UriSed 3 PRO (10 pcs)

13 Technical specifications

General	
Throughput	Up to 150 samples/hour (depending on the number of set images)
Memory	10000 measurements (with all the images)
Dilution factor	1–100 setting available
Main unit dimensions	
Size (lenght x widht x height)	600 X 556 X 642 mm
Weight	63 kg
Main unit interfaces*	
USB	USB Type B
Waste	D-sub 9 pin (male)
Wash	D-sub 9 pin (female)
CAM	RJ45
Bridge (in case of AutionMAX connection)	D-sub 15 pin (female)
⚠ **The connectors are to be used only with the plugs of their appropriate accessories to avoid equipment malfunction or personal harm or injury.**	
Power	
Main Unit	100-240 VAC ± 10%, 50-60 Hz / Max. 3A
Operating PC	100V~127V | 47-63 Hz | Max. 400 W 220V~240V | 47-63 Hz | Max. 400 W
Fuse	2 x T 5A L 250V
Overvoltage ctegory	II
Operational conditions	
Temperature	+15˚C to +32˚C
Humidity	30% to 80% (without condensation)
Atmospheric pressure	106 kPa to 80 kPA (equates to an altitude of app. 0 – 2.000 m)
Ambient light influence	Up to 1 kLux of artificial direct light
Maximum pollution degree	Degree 2 (EN 61010-1)
Storage conditions	
Temperature	+5˚C to +40˚C
Humidity	10–85 %
Transportation conditions	
Temperature	-25˚C to +60˚C
Humidity	10% to 85% (without condensation)
Barcode reader	

Identified barcode types	CODE 39, CODE 128, EAN-13, EAN-8, INTERLEAVED 2/5, CODABAR
Min height of identified barcodes	20 mm
Rack	Only racks provided by the manufacturer can be used
Test tubes	
Min sample volume in tube	2 ml (1 ml/normal tube, 0.8 ml/pediatric tube in pediatric mode)
Urine homogenization	Stirring by sample liquid mixing
Height (if tube is conical)	70–110 mm
Height (if tube bottom is linear)	70–105 mm
Diameter at the top of tube	16–17.5 mm
Max. diameter at the top of rack (56 mm above bottom of tube)	16.5 mm
Cuvettes	
Package	50 pcs/container
Max. cuvette load	600 pcs (12 containers)
Sample volume	200 µL
Centrifuge	
Centrifuge speed	2000 RPM
Centrifuging time	10 s
Microscope	
Lamp bright field microscope phase contrast microscope	 green green
Depth of field	± 2,5 µm
Camera	
Chip size	Type 1/3
UriSed 3 PRO images	
Number of images per sample	15
Positions of images	Non-overlapping viewfields next to one other in the middle section of the cuvette

Magnification	Corresponds to ~400x magnification microscopic image
Image size	1280x960 pixels
Volume of a single UriSed 3 PRO viewfield	0.16 µL native urine

Washing system	
Washing liquid in container	IFW (Instrument Feed Water) Maximum microbial content: 1000 CFU/mL Maximum conductivity: 1µS/cm (25°C) Maximum silicate content: 0.1 mg/L CLSI standard: July 2006 (C3-A4 Vol. 26 No. 22)**
Volume of containers	5 liters
Washing liquid consumption	min. 300 measurements can be performed with 5L Instrument feed water (IFW)
Washing solution used for daily cleaning of UriSed 3 PRO	Min. 6 mL, 2% NaOCl solution in one test tube
Waste bin	
Waste bin size	app. 400 measurements
Rack and cuvette identification	
Rack	RFID tagged sticker
Cuvette	RFID tagged cuvette holder

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

** Clinical Laboratory Standards Institute (CLSI). Preparation and Testing of Reagent Water in the Clinical Laboratory: Proposed Guideline – Fourth Edition. CLSI Document C3-A4 Vol 26 No 2 (ISBN 1-56238-610-7). Clinical and Laboratory Standards Institute, Wayne, PA

14 Symbols

Safety labels on the analyzer	
	Protective ground
	General Warning: Indicates a potentially hazardous situation that if not avoided could result in personal injury or damage to the device. This symbol is also used to highlight situations that can compromise results.
	Biohazard: Indicates a potentially dangerous situation involving the presence of biohazardous material. All safety precautions must be taken to prevent personal injury or damage to the equipment.
	Moving parts: This label indicates that there is a danger of moving parts within the vicinity of this label. Keep hands away from moving parts.
	ESD - Electrostatic discharge
	High voltage
	Hot surface
Analyzer and other packaging symbols	
REF	Catalogue number
CE	The CE mark identifies that the product complies with the applicable directives of the European Union
IVD	In vitro diagnostic medical device
	Consult instructions for use
SN	Serial number
EAC	The Eurasian Conformity mark (EAC) is a certification mark to indicate products that conform to all technical regulations of the Eurasian Customs Union.
GTIN	Global Trade Item Number

Symbols

	Manufacturer
	Alternating voltage
	Important note
	Fragile
	This way up
	Keep package out of rain and away from damp conditions
	Do not stack
	Temperature limitation indicating upper and lower limits
	Humidity limitation indicating upper and lower limits