

URISED FULLY AUTOMATED URINE SEDIMENT ANALYZER USER MANUAL FOR SW VERSION 2.0.4



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Modification history			
Version	Date	Author	Modification
1.0	13. 05. 2011	Márton Hrubi	First edition
2.0	19. 06. 2012	Márton Hrubi	Second edition
3.0	18. 10. 2012	Márton Hrubi	Third edition – Updated safety symbols
4.0	15. 02. 2013	Balázs Bujna	Complete text and layout overhaul
4.1	02.10.2013	Balázs Bujna	Joint operation with routine urine analyzer section extended

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1 INTRODUCTION

Thank you for choosing UriSed automatic urine analyzer manufactured by 77 Elektronika Kft. in Hungary (EU). We hope that you will be satisfied with the device.

1.1 General description of UriSed

UriSed 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 is easy and very efficient. The operator fills the device with distilled water, places cuvette cartridges onto the rotating cuvette rack, 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 stirs up the urine inside them to make it homogenous using a pipette. UriSed 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 in distilled water to avoid cross-contamination of urine samples. Urine sample holding cuvettes are forwarded into the built-in centrifuge, where they are centrifuged at 2 000 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 pictures through a built-in microscope at several points of the specimen (15 UriSed 2 view fields equal 10 regular microscope view fields). The magnification corresponds to a 400x zoom. All images are evaluated by a high-quality image processing software which is able to detect and further classify the following urine particles: Red Blood Cells (RBC); White Blood Cells (WBC); Hyaline Casts (HYA); Pathological Casts (PAT); Squamous Epithelial Cells (EPI); Non-Squamous Epithelial Cells (NEC); Bacteria (BAC); Yeast (YEA); Crystals (CRY): Calcium-oxalate monohydrate (CaOxm), Calcium-oxalate dihydrate (CaOxd), Uric acid (URI), Triple phosphate (TRI); Mucus (MUC); Sperm (SPRM).

The results and all the images are stored in UriSed's memory, which has a capacity of 5000 records.

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

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

2 INSTALLATION

2.1 Shipping list

UriSed device	1 pc
Power cord	1 pc
FireWire 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 tank	1 pc
Wash tank	1 pc
Container holder	1 pc
Pipes	3 pcs
Rotating cuvette rack	1 pc
Front cuvette guard (positioner for sample injection)	1 pc
Rear cuvette guard (forwarder to microscope)	1 pc
Rack conveyor unit	1 pc
Cuvettes (in cartridges of 50pcs)	12 pcs
Test tubes with caps	100 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 device is shipped with a LabUMat device.

2.2 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.

⚠ Ship and store the device between -20°C and +80°C and between 20–80 % humidity.

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

UriSed is shipped in 2 cardboard boxes. 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 60 kg (130 lbs) device (+ the PC and the LCD monitor). Refer to the detailed Unpacking manual – attached – on how to pack and unpack the device. Please follow the shipping marks on the boxes.

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, the test tubes, 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 [2.1 Shipping list on page 5](#).

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 and LabUMat 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, dust them off, and refer to the Shipping list to check the completeness of the consignment

i As the device is quite heavy (about 60 kg (132 lbs)), two people are required to move it.

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

2.2.1 Installation

1 Lift the acrylic glass door and remove the sponge bolsters.

⚠ You need to remove the pipette securing screw before you can switch on the device.

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

i It is recommended that you keep the fixing screw, as it might be needed if the device needs to be relocated.

3 Find the front cuvette guard among UriSed accessories and install it at the sample injection site to the right of the centrifuge.

4 Find the rear cuvette guard among UriSed accessories and install it next to the microscope, to the left of the centrifuge.

5 Install the rotating cuvette rack onto the shaft next to the front cuvette guard

6 Load the rotating cuvette rack with cuvette cartridges ([Figure 36: Loading the rotating cuvette rack on page 45](#)).

7 Link the rack conveyor unit up with UriSed. Fit the two edges flush against each other and push the unit gently until it clicks. Please note that only the rack conveyor part supplied by the manufacturer is compatible with UriSed.

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

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

10 Connect the supplied monitor, mouse, and keyboard to the operating PC.

11 Connect UriSed to the PC properly with the supplied FireWire cable.

i Note that there is a filter mounted on one end of the FireWire cable. It is important to connect the filter end of the FireWire cable to the UriSed main unit; the other end should be connected to the PC.

12 Connect UriSed to the PC properly with the supplied USB cable.

⚠ It is important to remove the securing screw from the pipette of UriSed before connecting the equipment to the mains. When the power is switched on, the initialization procedure is performed. This includes the motion checks, which may damage the equipment if the securing screw has not been removed.

⚠ UriSed 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 specially trained service personnel may dismantle the device.

2.2.2 Installing the fluidic system

1 Lead the two larger size pipes through the two slots on the waste tank 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 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 tank.

2 Connect the sensor for this container to the D-sub 9 connector of UriSed labeled Waste sensor.

3 Fill the wash tank with distilled water. 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.

4 Connect the sensor for the tank marked Wash container to the D-sub 9 connector of UriSed marked WASH SENSOR.

5 Place both tanks into their bowl, and place the bowl under the table supporting the device.

2.3 Taking UriSed 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.

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

1 Perform the washing cycle with the disinfectant solution. Switch off both the UriSed main unit and the operating PC and disconnect them from the mains.

2 Discard all used cuvettes from the waste bin.

3 Remove all fluids from both containers and clean them thoroughly. Let them dry and pack them up with their cap open.

4 Use the supplied securing screw to secure the pipette-moving robot.

5 Clean UriSed thoroughly, including all of its removable parts ([6 Maintenance on page 55](#)). Let them dry and pack up UriSed as it was packaged when it arrived to you.

i If you would like to put UriSed back into operation, follow the steps described in [2 Installation on page 5](#) to properly install the device.

2.4 Tagging test tubes with bar codes

UriSed's built-in barcode reader can automatically identify urine samples by barcodes affixed to the side of test tubes. UriSed 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 1](#). Bar codes above or below these levels might not be identified by UriSed. 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.

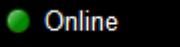
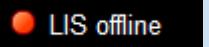
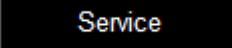


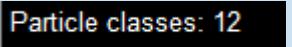
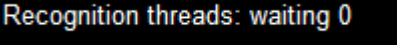
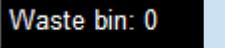
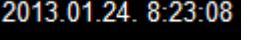
Figure 1: Correct bar code placement

3 THE MENU SYSTEM

UriSed 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 and operating PC  Online	Online Offline Initializing.. Not ready (by HW error)
Status of connection between UriSed and LabUMat  LabUMat offline	LabUMat Online (3.5.7 The LabUMat tab on page 41) LabUMat Offline LabUMat 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

Key to the status bar fields (from left to right)	Possible displayed contents
Number of particles which are evaluated (It can be set in Settings/Evaluation menu up to a maximum of 49. 3.5.4 The Evaluation tab on page 36)  Particle classes: 12	Classes: X
Number of remaining images waiting for evaluation  Recognition threads: waiting 0	Recognition threads: waiting X
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

3.1 User rights

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

i 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 nonoperational unless someone is logged in.

3.1.1 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.

- In the 'By level' user login scheme, each time you run the UriSed 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 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 Right-click into the User rights field of the bottom status line to display the Login pop-up box.

2 Click the pop-up box to display the login window (see [Figure 2](#)).

3a In the 'By user name' user login scheme, type your unique user name and password, then click **OK**. The User rights field of the status bar 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.

3b 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.



Figure 2: The Login window

3.1.2 Changing your password

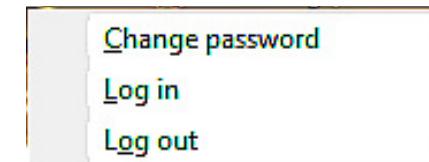


Figure 3: The Login pop-up box for password-protected user accounts

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 3](#)). 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.

3.1.3 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 3](#)). In the 'By level' user login scheme, your access level will automatically revert to Operator.

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

i 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 nonoperational unless someone is logged in.



3.2 The Info button

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



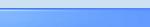
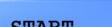
3.3 The Measure menu

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 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.

i 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.

Measure menu buttons	Description
INIT	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.
RACK OUT	Click to remove the rack currently inside the rack passage. This function is disabled while a measurement is in progress.
CLEAR LIST	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.

Measure menu but- tons	Description
 STAT	<p>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:</p> <ol style="list-style-type: none"> 1 The message Wait until the device moves to 1 stat position! is displayed until the measurement in progress is finished and the rack currently inside the rack passage is removed. 2 The rack conveyor moves the racks waiting for measurement backwards to make room for the statim sample. The Insert the urgent sample(s) . message is displayed when the device is ready to measure the statim sample. 3 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. <p>i The STAT button is only active during normal measurement cycles.</p> <p>i Unless the statim sample is tagged with a barcode, STAT measurement records are assigned IDs that start with "ST".</p>
 MANUAL 1/0	<p>Click to toggle between manual and automated modes of measurement (☞ 4.2 Measurement modes on page 45).</p> <p>i The device will start in the measuring mode that was last selected before shutting down.</p>
 START	<p>Click to start, and click again to stop a measurement cycle. (☞ 4.4 A typical daily routine on page 47 for further details. In Manual measurement mode, you will need to set up the measurement before the cycle starts (☞ 4.2 Measurement modes on page 45).</p>

Measure menu but- tons	Description
 EXIT	<p>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 Maintenance for rinsing).</p> <p>⚠ You must perform a rinsing at least once a day, preferably at the end of the workday.</p> <p>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.</p> <p>⚠ The Exit button is disabled while a measurement is in progress.</p>

3.4 The Database menu

i You can manually modify any of the automated evaluation results, as well as manually tag rare or unusual sediment particles on the view field images (☞ [3.4.4 The Sample View Editor \(SVE\) on page 21](#)).

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 view field 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**.

 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.

 Administrator-level users may specify the number and order of the columns displayed in the Sample List ([3.5.2 The Display tab on page 28](#)).

3.4.1 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 ([3.4.3 The Database menu function buttons on page 17](#)).
- Records are identified by the **Date&Time** of measurement, 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 ([3.4.11 Sediment results on page 13](#)).

 The **Sed** column header changes to + / - if the **Chem** column is disabled. [3.5.2 The Display tab on page 28](#)

- The **Chem** column displays the results of the sample's routine urinalysis performed by the interfaced test strip-based urine analyzer ([3.4.12 Chemical results on page 15](#)).

3.4.1.2 Chemical results on page 15).

- 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.

3.4.1.1 Sediment results

After taking the set number of images of the centrifuged urine samples, UriSed evaluates them ([3.5.3.1 Image evaluation on page 31](#)) to modify the number of automatic evaluations and the number of images). Usually, the images can be evaluated without difficulty and UriSed 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 has a range of symbols to display in the **Sed** column to draw attention to results that may require manual processing by a laboratory professional.

- N/A** No sediment results available. The sample was analyzed only with the interfaced routine 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.
- Negative (normal) sample. The sample contains lower levels of each of

- the enabled particle classes than the preset upper limit for those particle classes, except for MUC, SPRM and ART particles. If only MUC or SPRM particles are detected in the sample, it is categorized as negative. See the evaluation section on the Settings menu to enable and disable particle classes and the Category section to 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, and ART particles has no effect on this attribute.
 - ■ For review. Some images are so crowded that it can be difficult to distinguish all the particles present in them. The comment **Review of images is necessary!** is displayed with the quantitative results and in the Sample View Editor for these records, as they require manual re-evaluation ([3.4.4 The Sample View Editor \(SVE\) on page 21](#)). You can choose to hide or display the results of automated evaluation for crowded samples ([3.5.2 The Display tab on page 28](#)). If automated evaluation results are disabled, crowded sample records will display N/A for every particle class as long as the results are not modified manually ([3.4.5 Modifying automated evaluation results on page 23](#)).

 A sample record is marked with a red square even if only one of its view field images is crowded.

- ■ Invalid sample. Samples are indicated as invalid
 - ▶ if the Valid checkbox for all their view field images are manually unchecked;

- ▶ if the status of the sample is manually set to invalid (see [Figure 5](#) and its key);
- ▶ if the Auto evaluate images function is manually turned off ([3.5.3.1 Image evaluation on page 31](#));
- ▶ 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;
 - ▶ zeros (0) are displayed in all of the value fields and **N/A** is displayed in all of the Category fields unless you modify these fields manually ([3.5.1.1 Modifying semiquantitative relative categories on page 27](#));
- ■ Empty cuvette. UriSed can warn the user if an empty cuvette (without injected sample) was measured, to avoid reporting false negative measurements because of missing samples. If this warning message is activated ([3.5.3.2 Warning for empty cuvette on page 31](#)), the **Empty cuvette: [sample ID here]!** warning message window will be displayed.
-  Except for the actual warning messages displayed, samples with the Empty cuvette warning are exported and printed with the same indications as invalid samples.
- ! Low sample level. If the liquid level sensor indicates that the amount

of the sample is below 1 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.

i ↗ [5 Quality control on page 52](#) for the symbols used with QC measurements.

3.4.1.2 Chemical results

i The Chem column is only displayed in the Sample List if it is enabled in the Columns of sample list window (↗ [3.5.2 The Display tab on page 28](#)).

i The test strip pad result window in the Selected Sample screen area is only displayed if the Show chemical data checkbox is checked (↗ [3.5.2 The Display tab on page 28](#)).

How to interpret the Chem column:

- **N/A** Not available, e.g. because sample has been measured with the microscopy but not the routine 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.

3.4.2 The Selected Sample screen area

i 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.

i See ↗ [3.5.6 The Print tab on page 40](#) for the available particle classes.

3.4.2.1 The particle results window

The results for the particle classes and subclasses that you have enabled on the Settings menu (↗ [3.5.4 The Evaluation tab on page 36](#)) are

Particle	Category	p/HPF	N*	Ref. (p/HPF)
RBC	-	0,50	0,33	0 .. 1,14
.RBC	-	0,50	0,33	0 .. 1,14
.RBCi	-	0,00	0,00	0 .. 1,14
WBC	-	1,50	1,00	0 .. 2,05
CRY	+++	24,00	16,00	0 .. 1,36
.CRY	-	1,00	0,67	0 .. 1,36
.CaOx	-	0,00	0,00	0 .. 1,36
.CaOxm	+++	15,00	10,00	0 .. 1,36
.CaOxd	++	8,00	5,33	0 .. 1,36
.LEU	-	0,00	0,00	0 .. 1,36
HYA	-	0,00	0,00	0 .. 0,45
PAT	-	0,00	0,00	0 .. 0,34
.PAT	-	0,00	0,00	0 .. 0,34
.C-HGR	-	0,00	0,00	0 .. 0,34
NEC	-	0,00	0,00	0 .. 0,45
EPI	-	0,00	0,00	0 .. 1,14
UNC	-	0,00	0,00	0 .. 2,27
YEA	-	0,00	0,00	0 .. 0,68
BAC	+	75,00	50,00	0 .. 29,55
MUC	+	99,00	66,00	0 .. 60

Figure 4: The particle results window in the Selected Sample screen area

displayed in the particle results window (see [Figure 4](#)). 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.
Category	The user-defined (☞ 3.5.1 The Category tab on page 27) semi-quantitative relative category that the quantitative particle result is assigned.
p/HPF	Particle number per High Power Field. This value is generated by multiplying the value in the N° column by 1.5, which is necessary because the view field of the microscope of UriSed has a slightly smaller surface than HPF view field images made using a manual microscope.
N°	The number of particles detected in the view fields of the sample divided by the total number of view field images taken for the sample. You can disable this column (☞ 3.5.2 The Display tab on page 28).
Ref. (p/HPF)	The ranges defined for Semi-quantitative relative category number 1 (which is conventionally the negative category). You can disable this column (☞ 3.5.2 The Display tab on page 28).

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 bearing the name of its parent particle class. The particles that did 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'.

3.4.2.2 The chemical results window

If enabled (see ☞ [3.5.2.2 The Visible settings screen area on page 29](#)), routine urinalysis results transferred from the interfaced test strip-based urine analyzer (see ☞ [4.5 Operating UriSed together with LabUMat on page 49](#) on how to interface the two devices).

3.4.2.3 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 view field image may be marked for review in the following cases:
 - ▶ the image is so crowded with particles that particle detection is restricted (see [Figure 11](#)).
 - ▶ the number of mucus particles in the view field exceeds the pre-defined allowed level of mucus (☞ [3.5.8 The Maintenance tab on page 42](#))
- **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 view field image is accepted as the basis for sample image evaluation. The overall result is based on the averaging of all the valid view fields for a sample.

 By default, every view field image is accepted as valid.

- If the value in the **Error** column is other than zero (0), there is a possible problem with the view field image.

 The Error feature in the Image List is still in a test phase.

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

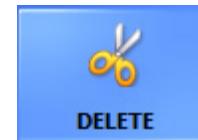
3.4.3 The Database menu function buttons

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.

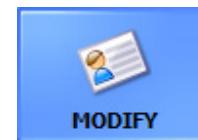


Click to toggle selection of all the records on the Sample List. The button is inactive if there is only one record on the list.



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

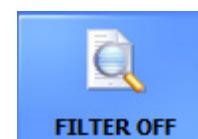
 **The records will be deleted permanently. This is an irrevocable command.**



Click to modify status of the selected sample or the ID or patient name associated with the record using a dialog box (see [Figure 5](#)).

 An empty field is not an acceptable sample ID. The maximum length of the ID and the patient name is the same as that set in the the Display length dialog box ([3.5.2.2 The Visible settings screen area on page 29](#)).

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



Click to toggle the Filter configuration dialog box (see [Figure 6](#)). Records can be filtered by date of measurement, patient name, ID, status, positive or negative result, normal or QC measurement, or sediment or chemistry method.

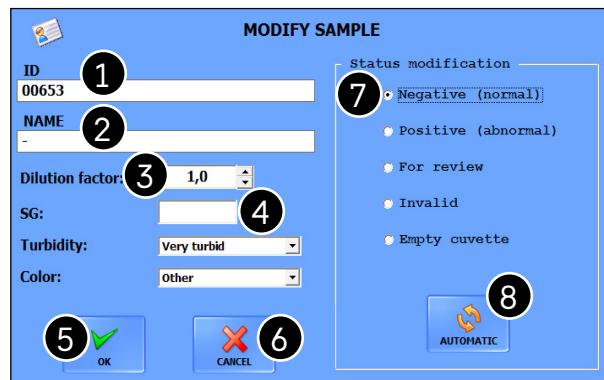


Figure 5: The Modify Sample dialog box (for a sample with both routine and microscopy urinalysis results)

Key to the Modify sample dialog box

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	Physical measurement data Applicable only if the selected sample has been analyzed with the chemical method.

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 (3.5.2.2 The Visible settings screen area on page 29).
8	Click to reset the sample status to that determined by the automated evaluation

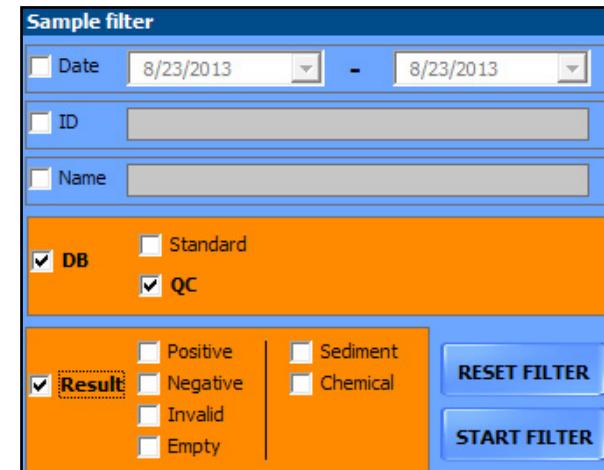
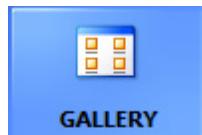


Figure 6: The Sample Filter dialog box

ⓘ Filtering parameters are active only if the check box in their bounding box is checked, indicated by orange highlighting. Click Start filter to display in the Sample List only the records that fit your conditions, and click Reset filter to revert to the full Sample List.



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

Double-click any image in the gallery to enable full-screen viewing. In full-screen mode, press the R, G, and C keys to enable the ruler, the image grid, and automated cell recognition, respectively. Click the **Cancel** button in the bottom right corner of the screen to move back to the Database menu

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

Click to re-evaluate every view field image for the selected records, even the images that have not been evaluated automatically so far for some reason.



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

Click to add comments to the microscopy or routine 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 column of the Database, the Gallery, the Sample View Editor, the exported result, and on the result printout.



i **The button is inactive if more than one record is selected,**

Click to launch the Worklist editor (see [Figure 7](#) 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 [3.5.3 The Measure tab on page 31](#).

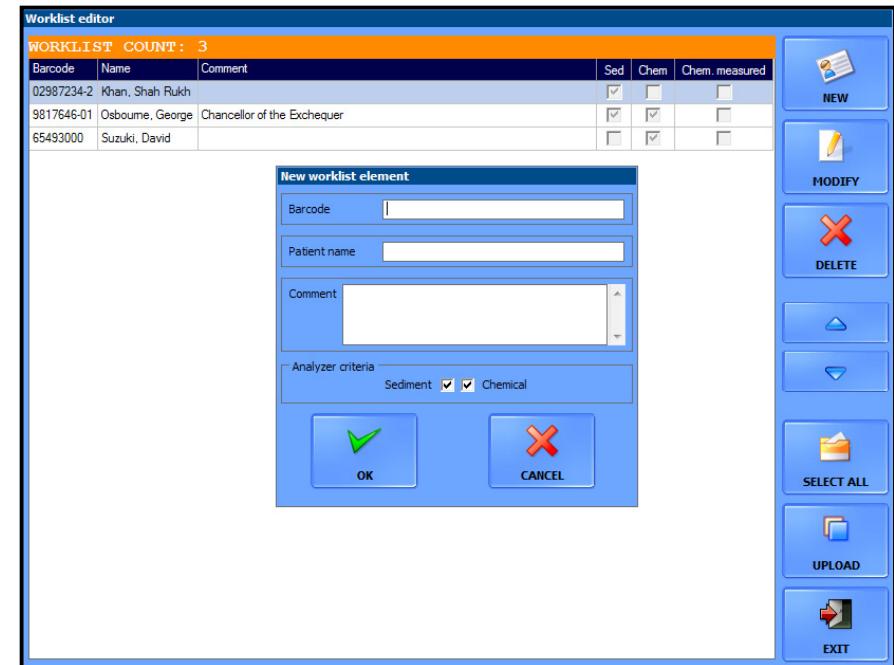
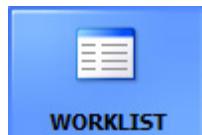
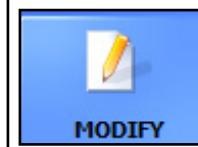


Figure 7: The Worklist editor window with a New worklist element dialog box

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 print-out.) No duplicate barcodes are allowed. If sample measurement is based on worklists and an interfaced routine urinalysis device is enabled, you can choose to measure the the sample with the sediment method, the chemical method, or both ([3.5.7 The LabUMat tab on page 41](#)).



Click to edit the details of the selected worklist element (see [Figure 5](#) and its key).

Key to the Worklist Editor	
	Click to delete the selected worklist element or elements.
	Click to toggle selection of all the records on the Worklist. The button is inactive if there is only one record on the worklist.
	<p>Click to import a Worklist created on an external computer.</p> <p>⚠ 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:</p> <pre><space>W ANALYSER_ID Barcode1^PatientName1^Comment1^Chemical1^Sediment1 Barcode2^PatientName2^Comment2^Chemical2^Sediment2 ... BarcodeN^PatientNameN^CommentN^ChemicalN^SedimentN<Enter></pre> <p>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:</p> <pre>W SN12345 BAR143^Mr. Baker^Comment for Baker^1^1 4444^Mrs. Smith^Comment for Smith^1^0</pre>

Key to the Worklist Editor	
	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 Statim 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 8](#) and its key.)

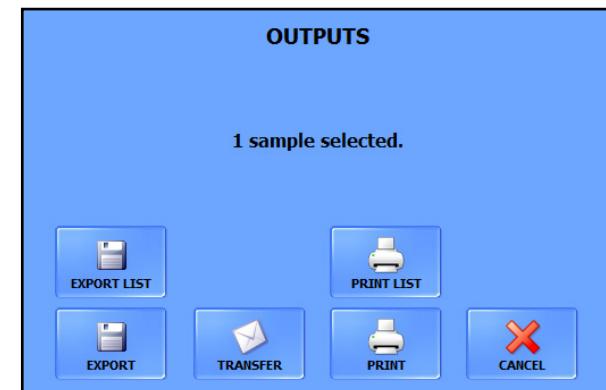


Figure 8: The Transfer options dialog box

Key to the Transfer options



Click to save the selected record and its view field 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 (see [Figure 9](#)). (☞ [3.5.5 The Transfer tab on page 38](#) for further details.)

i The Export button is disabled for subsequent measurements if you enable automatic export on the Transfer tab of the Settings menu.

i Depending on the number of particle types you enabled to be displayed, the exported report might not fit on a single page.



Click to transfer the selected record to a host computer of LIS through the serial port.

i Contact your distributor on how you can set up a transfer protocol.

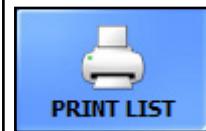


Click to print a combined routine and microscopy urinalysis report with your default printer settings.

i Depending on the number of particle types you enabled to be displayed, the printed 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 the **Print List** button to print a table identical to the HTML table generated by the Export List command.



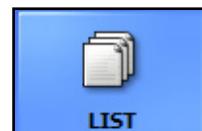
Click to cancel transfer.



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	Quantimetrax Dip and Spin	5/17/2012	0,00	330,00

Figure 9: An example of two normal and one Quality Control measurement, exported as HTML tables



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 20](#) for details.)



Click to validate the selected result as correct. The button is not displayed in the 'By level' user login scheme and is disabled in the 'By user name' user login scheme unless your service person has set up manual validation (☞ [3.5.3.10 Validation on page 35](#)).

⚠ 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.

3.4.4 The Sample View Editor (SVE)

Double-click any of the view field image thumbnails in the Image List in the bottom right corner of the Database menu screen to view it in full screen mode in the Sample View Editor. By default, the device processes

all of the view field images and attempts to identify each of the detected particles in the images, then tags the identified particles. You can review and modify the automatically assigned tags using the SVE. There are essentially two types of view field images:

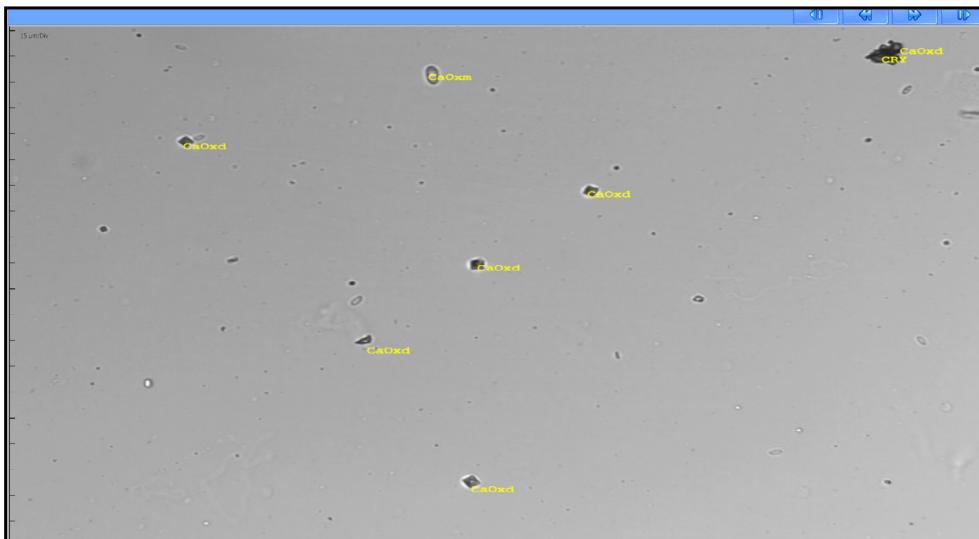


Figure 10: Automatically evaluated and tagged view field image of a Normal image

- View field images that are not crowded with particles are, regardless of whether they are negative or pathological, considered **Normal** (see [Figure 10](#))—they have **No** in their **For review** column in the Image List. The majority of view field images is of this type.

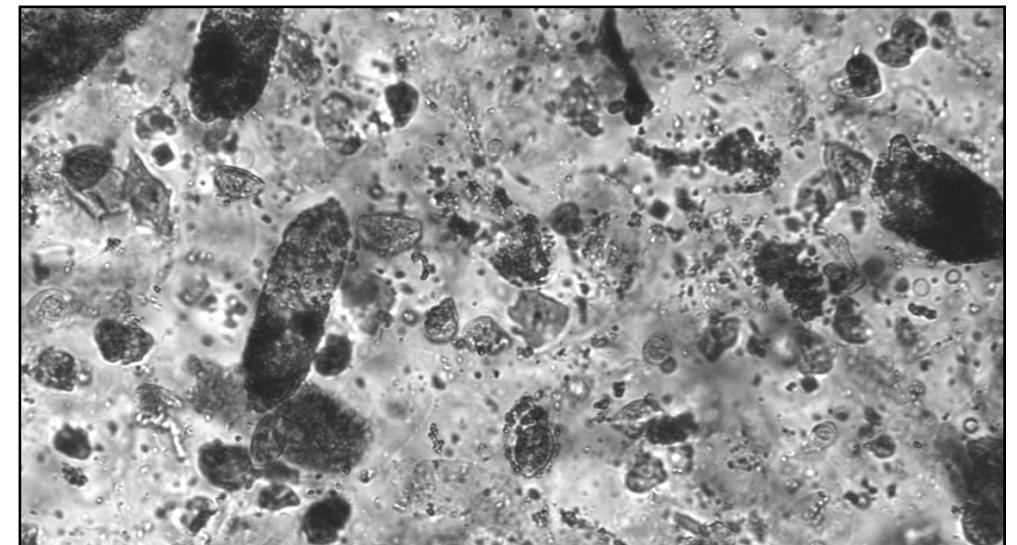


Figure 11: A crowded view field image without automatic tags added

- View field images that are so crowded with particles that it is difficult to distinguish between various elements are considered **Images for review** (see [Figure 11](#))—they have **Yes** in their **For review** column in the Image List, and the message **Review of images necessary!** is displayed in red in the SVE header.

Keyboard shortcuts: C—toggles all the particle tags ('captions') in the image; R—toggles a ruler running along the sides of the screen (see [Figure 10](#)); G—toggles a grid over the image for the better estimation of particle size (see).

Breakdown of the elements of the SVE:

- The sample to which the enlarged view field image belongs is identified in the header of the SVE by its results summary.
- The number of the current view field image out of all the view field images available for the given sample is displayed in the top right corner.

- Use the buttons to scroll through the view field images of a single sample; use the and to scroll through all the sample records in the database.
- A table summarizing the particle classes and their number found in the currently displayed view field image is displayed on the right. Each of the particle classes that was 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 view field images applies to every other view field image in the series for the current sample, but not to the view field images of other samples. For example, if you hide WBC (White Blood Cell) tags for one of the images, no WBC tags will be displayed in any of the view field images for the selected sample.



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



Click to re-evaluate the currently displayed view field image.

i All manual modifications will be lost when the image is re-evaluated.



Click to toggle a fixed-size window (see) over the current view field image that displays a digitally magnified view of the area around the mouse cursor in real time and with a pre-selected zoom factor between 2–8.

i Drag the zoom window by its header to re-position it over the view field image.

i The zoom window does not affect the editing of images.



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

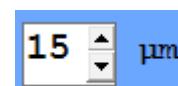


Click to print a urinalysis report of the current sample with the default printer settings.



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

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



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



Click to save the current view field image as displayed (with or 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.

3.4.5 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 overridden.

UriSed 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.

3.4.5.1 Modifying microscopy results in the Database

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

- 1 In the summarized microscopy urinalysis report, double-click on the row of the particle you wish to modify.
- 2 Enter the desired value in the dialog box that pops up (see [Figure 12](#)). The system will automatically apply the change you made in one of the text boxes to both text boxes.

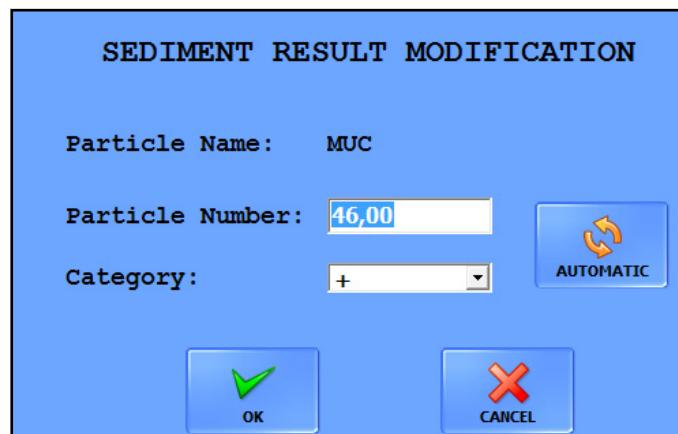


Figure 12: A dialog box to modify a microscopy urinalysis result

⚠ If you change the semi-quantitative result category, the quantitative result will be reset to the middle of the range

of the new category.

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

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

i 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.

3.4.5.2 Modifying routine urinalysis results in the Database

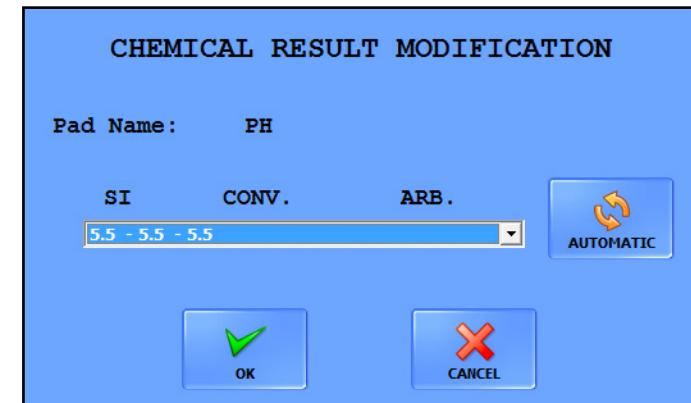


Figure 13: A dialog box to modify a routine urinalysis result

1 In the summarized routine urinalysis report, double-click on the row of the analyte result you wish to modify to display the modification dialog box (see [Figure 13](#)).

2 Choose the desired result in the dialog box.

3 Click **OK** to save the changes, or **Cancel** to discard the changes.

3 Click **Automatic** to undo the changes and revert to the original evaluation.

 Modified records will be displayed in blue in the report.

3.4.5.3 Adding new particles in the Sample View Editor:

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

1 Click any area of the view field image to display the list of available particle classes (see [Figure 14](#)).

⚠ 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 ([3.5.4 The Evaluation tab on page 36](#)).

2 Click a particle class to display its available subclasses. Double-click on the desired particle class or subclass to add it to the view field image in the specified spot. Double-click **EXIT** on the list to cancel the modification.

 The software will take the new particle into consideration when generating the microscopy report.

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

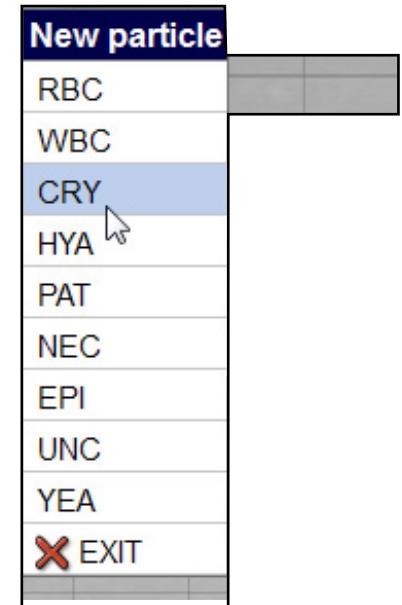


Figure 14: The default list of available particle classes

3.4.5.4 Modifying particles in the Sample View Editor

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

- 1 Move the cursor above the tag you wish to modify. Right-click the tag to display the **Modify particle** dialog box (see [Figure 15](#)).

⚠ 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 (☞ [3.5.4 The Evaluation tab on page 36](#)).

- 2 Click a particle class to display its available subclasses. Double-click the desired particle class or subclass to replace the original tag with the new one. Double-click **EXIT** on the list to cancel the modification.

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

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

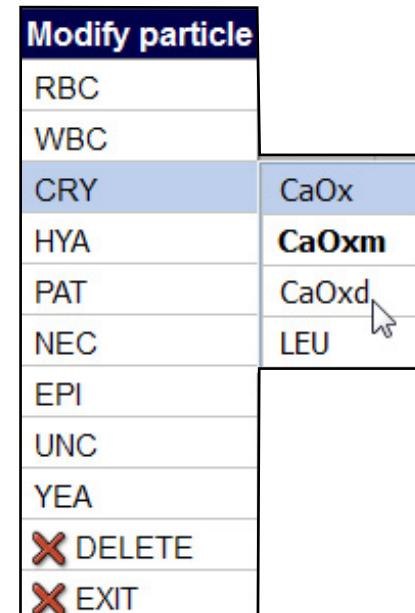


Figure 15: The default particle class modification dialog box

3.4.5.5 Deleting particles in the Sample View Editor

- 1 Move the cursor above the tag that you want to remove. Right-click on the caption to display the Modify particle dialog box (see [Figure 15](#)).
- 2 Double-click on **DELETE** to remove the tag.

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

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

3.4.5.6 Modifying analysis results with the Modify button

See [Figure 5](#) and its key.

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



3.5 The Settings menu

i The Settings menu is available only to users logged in as Administrator- or Service-level operators (☞ [3.1 User rights on page 9](#)).

i 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.

3.5.1 The Category tab

Particle	1. category	2. category	3. category	4. category	5. category	Particle name
RBC	- .. 1,14	.. 9,09	++ .. 34,09	+++ .. 56,82	++++ .. <	Red Blood Cells
.RBC1	- .. 1,14	.. 9,09	++ .. 34,09	+++ .. 56,82	++++ .. <	Isomorphic RBC
WBC	- .. 2,05	.. 11,36	++ .. 45,45	+++ .. 90,91	++++ .. <	White Blood Cells
CRY	- .. 1,36	.. 4,09	++ .. 13,64	+++ .. 30	++++ .. <	Crystals
.CaOx	- .. 1,36	.. 4,09	++ .. 13,64	+++ .. 30	++++ .. <	CRY - Calcium-oxalate
.CaOxm	- .. 1,36	.. 4,09	++ .. 13,64	+++ .. 30	++++ .. <	CRY - Calcium-oxalate monohydrate
.CaOxd	- .. 1,36	.. 4,09	++ .. 13,64	+++ .. 30	++++ .. <	CRY - Calcium-oxalate dihydrate
.LEU	- .. 1,36	.. 4,09	++ .. 13,64	+++ .. 30	++++ .. <	CRY - Leucine
HYA	- .. 0,45	.. 0,91	++ .. 1,36	+++ .. 1,82	++++ .. <	Casts - Hyalin
PAT	- .. 0,34	.. 0,57	++ .. 0,91	+++ .. 1,36	++++ .. <	Casts - Pathological
.C-HGR	- .. 0,34	.. 0,57	++ .. 0,91	+++ .. 1,36	++++ .. <	Casts - Hyalin-granular
NEC	- .. 0,45	.. 0,91	++ .. 1,36	+++ .. 1,82	++++ .. <	Non Squamous Epithelial Cells
EPI	- .. 1,14	.. 5,60	++ .. 17,05	+++ .. 27,27	++++ .. <	Squamous Epithelial Cells

Figure 16: 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.

i By default, the Category tab displays only the default set of particle classes and subclasses (☞ 1.1 General description of UriSed on page 4). The Category tab will only display the additional particle classes and subclasses that are

specified on the Evaluation tab (☞ 3.5.4 The Evaluation tab on page 36), and only if the Enable added particle categories check box is checked on the Category tab.

3.5.1.1 Modifying semiquantitative relative categories

i The names of the particle classes and sub-classes cannot be modified.

1 Double-click on the particle class row that you wish to modify to display the Category modification dialog box (see Figure 17)

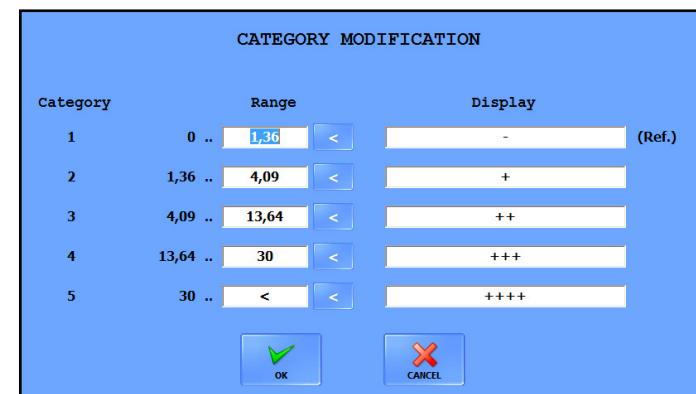


Figure 17: The Category modification dialog box

2 Enter the upper cutoff for the quantitative ranges of the semi-quantitative relative categories. The upper cutoff for a category will automatically be entered as the lower cutoff for the next category so that overlapping is prevented.

⚠ Semiquantitative relative category number 1, topmost in the dialog box, is displayed as reference for each of the particle classes in the particle result window on the Database menu. You can disable the display of this reference range on the Display tab of the Settings menu (☞ 3.5.2 The Display

[tab on page 28\).](#)

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

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

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

4 Click **OK** to store your changes or **Cancel** to discard the changes.
Click SET on the Category tab screen to save your modifications.

The system will 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.

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

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

3.5.2 The Display tab

3.5.2.1 Grid, ruler and particle font properties

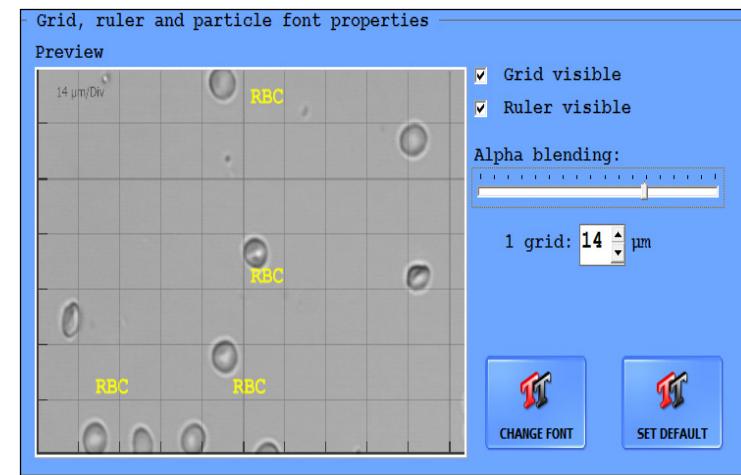


Figure 18: The Grid, ruler, and particle font properties window

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

- Toggle the grid and the ruler overlay in the SVE screen with the **Grid visible** and **Ruler visible** check boxes, respectively ([☞ SVE Keyboard shortcuts on page 22.](#))
- 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 demonym to modify the display language of the system.



You will need to restart the device for the language settings to take effect.

3.5.2.2 The Visible settings screen area

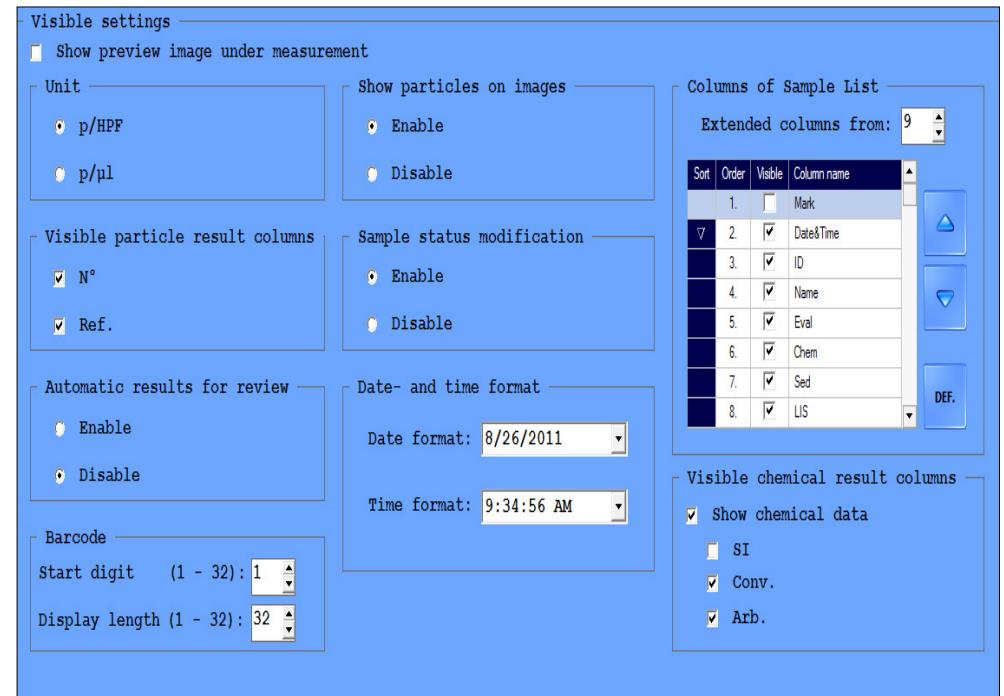


Figure 19: The Visible settings window

- Check the **Show preview image under 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.
- 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 reactively recalculate all the measurement results for every sample in the database.

- Click the radio buttons in the Visible particle result columns dialog box to enable or disable the N° and Ref. columns in the results summary ([Key to the particle results window on page 16](#)).
- Click the radio buttons in the **Automatic results for review** dialog box to enable or disable attempts to evaluate view field images that are marked **For review** ([3.4.2.3 The Image List on page 16](#)).

i If this function is disabled, all the results associated with samples marked **For review** will be displayed as N/A (not applicable).

- Use the arrow keys next to the text boxes in the **Barcode** dialog box to specify which part of the bar codes you would like the device to use: **Start digit** indicates the first character of the sample ID where bar code reading begins; **Display length** indicates the number of characters considered following the starting digit.

i If the **ID generate mode** is set to **Sequence number** ([3.5.3 The Measure tab on page 31](#)), the text boxes will not respond to the arrow keys.

- In the **Show particles on images** dialog box, click the radio buttons to enable or disable the automatic tagging of particles in the view field images.
- Check the check boxes in the **Sample status modification** dialog box to enable or disable manual modification of the status of samples ([Status modification options on page 18](#)).
- 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:

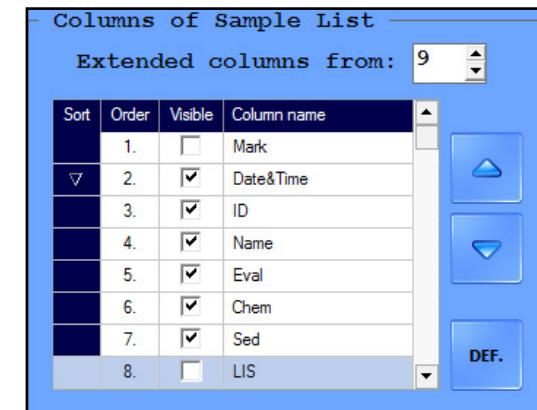


Figure 20: The Sample List will display 8 columns in compact view; chemical urinalysis results will be omitted; the samples in the list will be sorted by date in descending order

- 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 20](#));
- specify how many columns are displayed in the compact view of

the Sample List by increasing or decreasing the number in the **Extended columns from** text box (for example, if the number in the box is 9, columns up to 9 (that is, 1–8) will be displayed in compact view;

- ▶ and revert to the default Sample List setup by clicking **DEF**.
- If a routine urinalysis device is interfaced to your UriSed device, use the check boxes in the **Visible chemical result** column to enable the display of the chemical measurement results and set up their display units

3.5.3 The Measure tab

Use this tab to define measurement-related settings.

3.5.3.1 Image evaluation

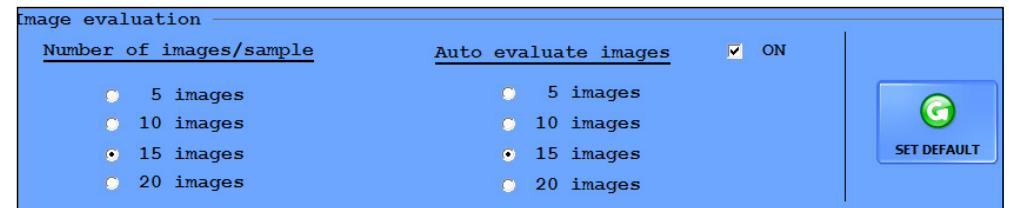


Figure 21: The Image evaluation window

- Click the radio buttons on the **Number of images/sample** list to set the number of view field images the device should make for each sample.
- Check or uncheck the **Auto evaluate images** check box to enable or disable automatic analysis of view field images, and click the radio buttons in the list to specify the number of view field images out of the total that the device should evaluate.
- Click the **SET DEFAULT** button to revert to the default settings of 15 view field images per sample, all of which are automatically evaluated (see [Figure 21](#)).

3.5.3.2 Warning for empty cuvette

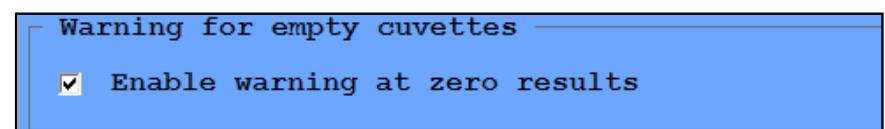


Figure 22: The Warning for empty cuvettes

- Check this check box to enable the empty cuvette warning message, which will prevent false negative results that occur because of a missing sample ([3.4.1.1 Sediment results on page 13](#)).

⚠ Samples with an empty cuvette-warning are nearly identical in their result output to invalid samples. The only difference is the warning symbol that the system assigns to them.

3.5.3.3 Repeated barcode checking

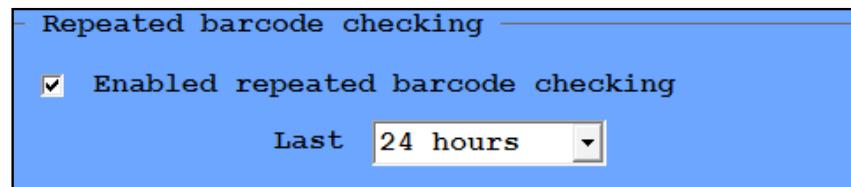


Figure 23: The repeated barcode checking window

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

3.5.3.4 Parallel count

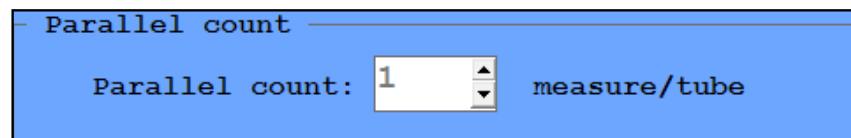


Figure 24: The Parallel count window

i 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.

i 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.

⚠ Parallel measurements can be set up in both Auto and Manual measurement modes.

⚠ If you have set up the device to interface with a routine urinalysis device and measurements are performed according to a worklist ([3.5.7 The LabUMat tab on page 41](#)), the Parallel count text box becomes disabled.

3.5.3.5 Worklist

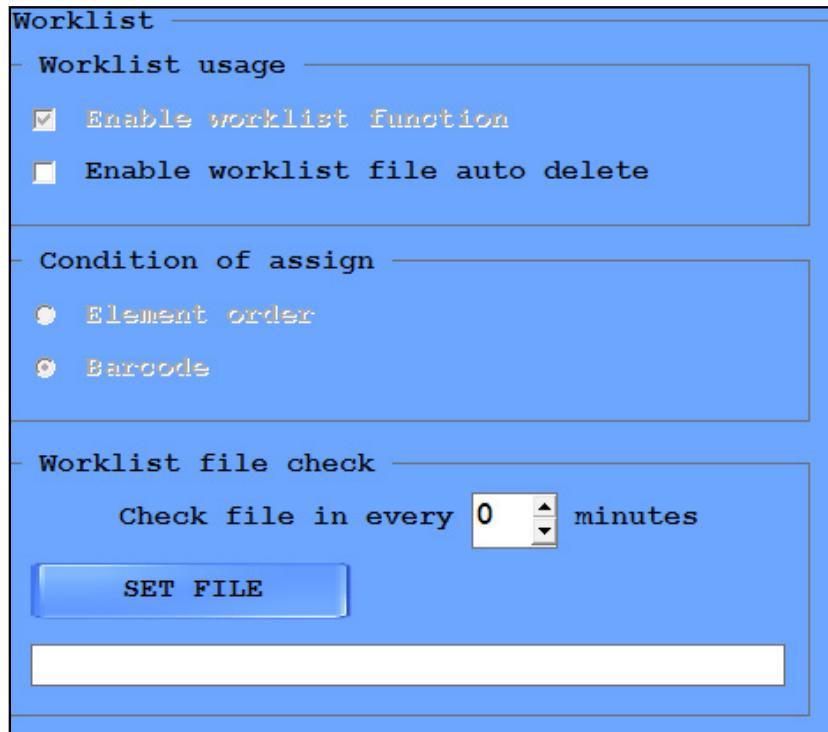


Figure 25: The Worklist window



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 7](#) 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 on page 20](#)), 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 routine urinalysis device and measurements are performed according to a worklist (☞ [3.5.7 The LabUMat tab on page 41](#)), the **Enable worklist** check box becomes checked and disabled by default.

- Condition of assign

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

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

⚠ If you have set up the device to interface with a routine urinalysis device and measurements are performed according to a worklist (☞ [3.5.7 The LabUMat tab on page 41](#)), the **Barcode** radio button becomes selected and the **Condition of assign** dialog box becomes disabled by default.

- Worklist file check

If you wish to import a worklist (☞ [Importing a Worklist on page 20](#)) click **SET FILE** to display a dialog box to define the path for the worklist file. If you would like to continually update the worklist based on the

imported worklist file, **Check file in every X minutes** text box to specify how often the system should refresh the worklist based on potential changes in the external worklist file.

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

3.5.3.6 Database full

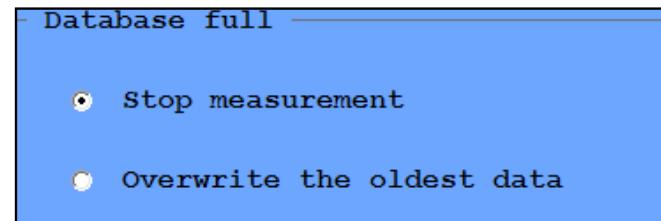


Figure 26: The Database full window

Select the radio buttons to specify whether you would like the device to stop when the database reaches its maximum capacity, or whether you would like to start overwriting the oldest data for uninterrupted operation.

⚠ If you select the overwriting of old data, the Database Warning limit text box is disabled.

3.5.3.7 Database sample limit

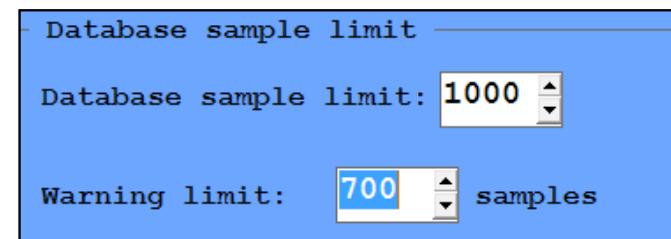


Figure 27: The Database sample limit window

- Use the **Database sample limit** text box to specify the size of the results database between 1000 and 5000 records.
- Use the **Warning limit** text box to specify how many measurements the device should perform before it prompts you to free up space in the database.

3.5.3.8 ID generate mode

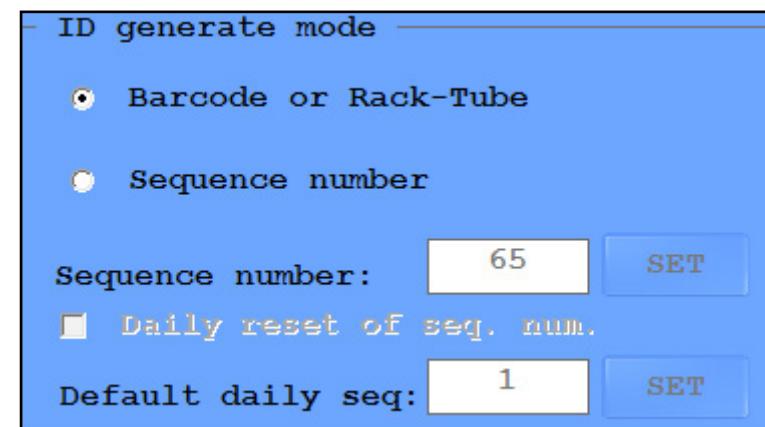


Figure 28: The ID generate mode window

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 bar codes on the test tubes, or, in case bar codes are missing, automatically assign a 5-digit, slash-delimited identifier based on the rack and tube number of the given sample. (For example, a sample in the fifth tube of the second rack would be assigned the ID **002/05**.)

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

! The rack-tube ID assignment sequence is reset to **001/01** every time you start the device and the date has changed since you last shut down the system.

i 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

i 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.

i [4.3 Test result identification on page 46](#) for further details.

3.5.3.9 Rack counter settings

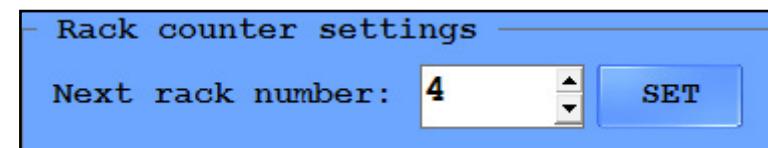


Figure 29: The Rack counter settings

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**.

3.5.3.10 Validation



Figure 30: The Validation window

! This feature is only available if you are using the 'By user' user login scheme.

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

Use the radio buttons to specify whether samples are validated automatically or whether manual validation is required.

3.5.4 The Evaluation tab

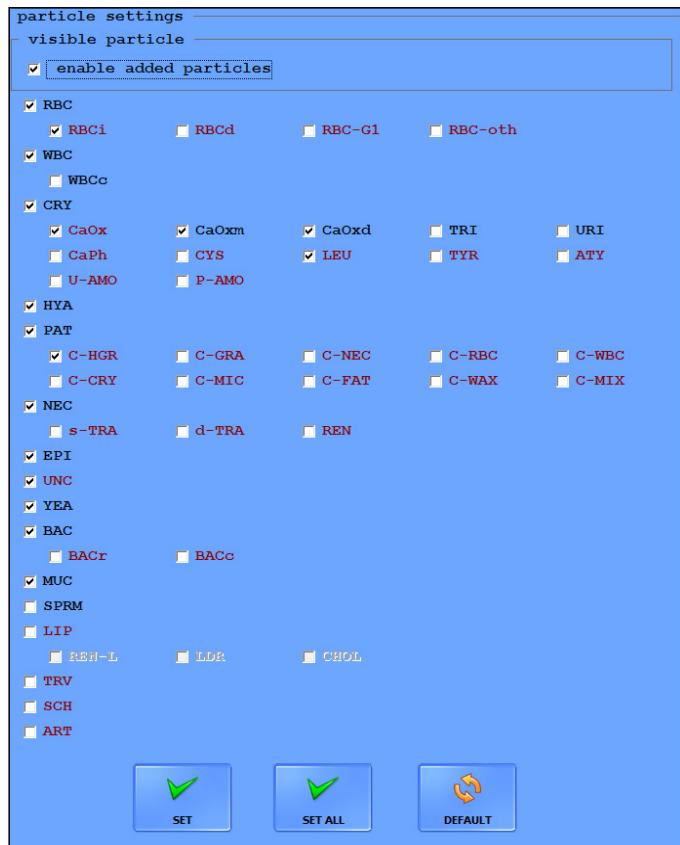


Figure 31: The Particle settings window on the Evaluation tab

On this tab, you can specify which sediment particles you would like the

device to identify in the view field 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.

⚠ You will need to check the enable added particles 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 ([3.4.5 Modifying automated evaluation results on page 23](#)). However, if you enable the 'added particles' and check any of them, the system will reevaluate all the previous view field images and retroactively assign the newly enabled tags where necessary.

3.5.4.1 Using the Evaluation tab

- 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.
- Click the **SET ALL** button to enable all of the particle classes and subclasses. An alert dialog box will pop up prompting you to confirm the action.

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

3.5.4.2 Particle setting defaults

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

	✓: Enabled	✗: Disabled
RBC	✓	URI ✗
WBC	✓	TRI ✗
NEC	✓	YEA ✓
EPI	✓	BAC ✓
PAT	✓	MUC ✓
HYA	✓	SPRM ✗
CRY	✓	UNC ✗
CaOxm	✓	
CaOxd	✓	

3.5.4.2 Full list of evaluated particles

Class	Subclass	auto	added
Red Blood Cells		RBC	
	Isomorphic RBC	RBCi	
	Dismorph RBC		RBCd
	G1 RBC (Acanthocyte)		RBC-G1
White Blood Cells	RBC others		RBC-oth
		WBC	
	White Blood Cells Clumps		WBCc

Class	Subclass	auto	added
Squamous Epithelial Cells		EPI	
Non Squamous Epithelial Cells		NEC	
	Superficial Trans. Epithelial Cells	s-TRA	
	Deep Transitional Epithelial Cells		d-TRA
	Renal Epithelial Cells		REN
Lipids		LIP	
	Lipids - Oval Fat Bodies	REN-L	
	Lipids - Free Droplets		LDR
	Lipids - Cholesterol Crystal		CHOL
Casts - Hyalin		HYA	
Casts - Pathological		PAT	
	Casts - Hyalin-granular	C-HGR	
	Casts - Granular		C-GRA
	Casts - with Renal Tubular Cells	C-NEC	
	Casts - RBC		C-RBC
	Casts - WBC	C-WBC	
	Casts - Crystal		C-CRY
	Casts - Microorganism	C-MIC	
	Casts - Fatty		C-FAT
	Casts - Waxy		C-WAX
Casts - Mixed		C-MIX	

Class	Subclass	auto	added
Crystals		CRY	
	CRY - Calcium-oxalat		CaOx
	CRY - Calcium-oxalate monohydrate	CaOxm	
	CRY - Calcium-oxalate dihydrate	CaOxd	
	CRY - Triple-phosphate	TRI	
	CRY - Uric acid	URI	
	CRY - Calcium-phosphate	CaPh	
	CRY - Amorphous		AMO
	CRY - Cystine		CYS
	CRY - Leucine		LEU
	CRY - Tyrosine		TYR
	CRY - Atypical		ATY
Yeast		YEA	
Bacteria		BAC	
	Bacteria Rods	BACr	
	Bacteria Cocci		BACc
Mucus		MUC	
Spermatozoa		SPRM	
Unclassified particles			UNC
Trichomonas			TRV
Parassites - Schistosoma Haematobium			SCH
Artifacts			ART

3.5.5 The Transfer tab

The Transfer tab lets you adjust the data management settings.

3.5.5.1 The Transfer screen area

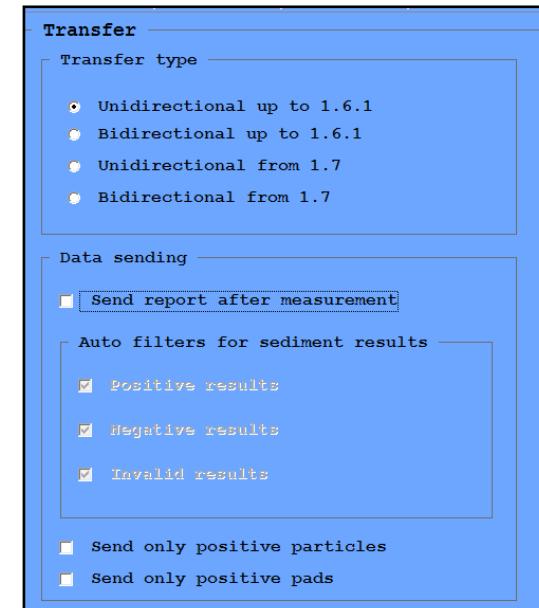


Figure 32: The Transfer screen area on the Transfer tab

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

- Click the radio buttons to select unidirectional or bidirectional transfer.
- ⚠ Contact your distributor to determine which transfer type you require.**
- Check the **Send report after measurement** check box to enable the automatic transfer of the results table of each processed sample through the serial port.

- ▶ Check or uncheck the check boxes in the **Auto filters for sediment results** dialog box to enable or disable the filters for positive, negative, or invalid results to specify which results should automatically be transferred through the serial port.

⚠ The filters are available only if automatic transfer is enabled.

i If you enable all three filters, every measurement result will be transferred automatically.

- ▶ Check or uncheck the two other check boxes in the **Data sending** screen area to enable or disable the editing of the measurement results when transferring them: you can decide to leave out particle classes and subclasses or test strip pads (if routine urinalysis results are available) with negative results to reduce the size of transferred data.

i 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.

3.5.5.2 The Export screen area

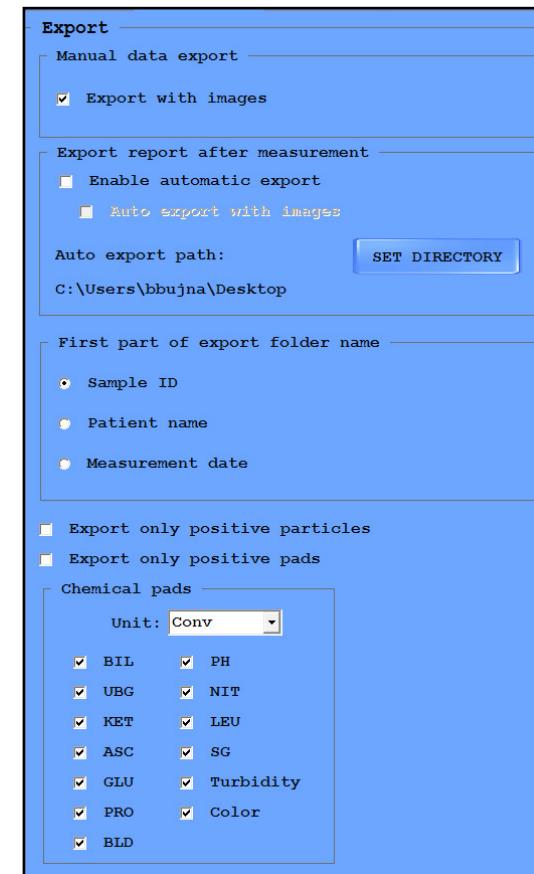


Figure 33: The Export screen area on the Transfer tab

- Check the **Export with images** check box to include view field images with the results tables when exporting results manually.
- In the **Export report after measurement** dialog box, check the check boxes to enable the automatic export of each processed sample, with or without view field images, to a folder on the PC you can specify by clicking the **SET DIRECTORY** button. Results are exported as html

tables and separate folders for each of the samples is generated inside the folder you specify.

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

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

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

- Check or uncheck the **Export only positive particles** or the **Export only positive pads** check boxes to enable or disable the editing of the measurement results when exporting them: you can decide to leave out particle classes and subclasses or test strip pads (if routine urinalysis results are available) with negative results to reduce the size of transferred data.
- In the **Chemical pads** dialog box, use the text box to specify the default units for the exported routine urinalysis results, and use the check boxes to control which test pad analyte results and which physical measurement results are exported with the routine urinalysis results.

3.5.6 The Print tab

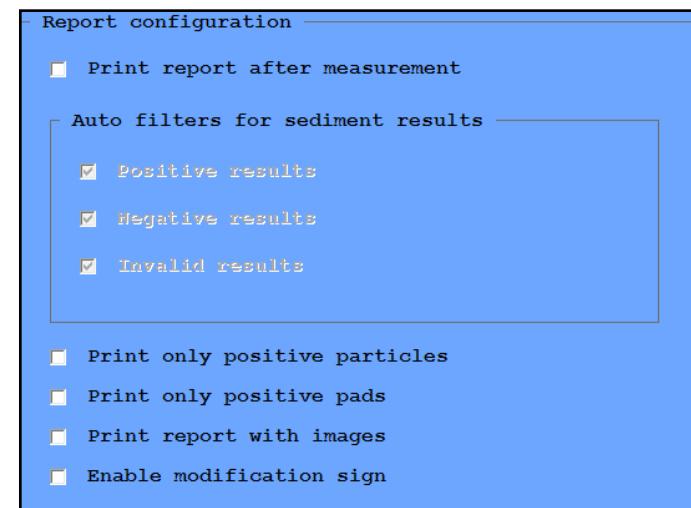


Figure 34: The Report configuration dialog box on the Print tab on the Settings menu

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

- Check the Print report after measurement check box to enable the automatic printing of each processed sample.
 - Check or uncheck the check boxes in the **Auto filters for sediment results** dialog box to enable or disable the filters for positive, negative, or invalid results to specify which results should be printed automatically.

i If you enable all three filters, every measurement result will be transferred automatically.

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

- Check or uncheck the **Print only positive particles** or the **Print only positive pads** check boxes to enable or disable the editing of the measurement results when exporting them: you can decide to leave out particle classes and subclasses or test strip pads (if routine 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 view field images when printing results.

 By default, view field images are not printed.

- Check the **Enable modification sign** 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.

3.5.7 The LabUMat tab

 This section details the setup options for interfaced UriSed and LabUMat devices. For information on how you can connect the two devices, [4.5 Operating UriSed together with LabUMat on page 49](#).

UriSed microscopy urinalysis devices can be interfaced with LabUMat

- Check the **Working with LabUMat function is enabled** check box when interfacing UriSed with a LabUMat device. If the function is enabled, UriSed will attempt to connect to the LabUMat device during initialization. When the link is established, the message **LabUMat online** will be displayed in the bottom status bar. Check the **Worklist synchronization at LabUMat start** check box if you want to use the worklist on the microscopy device with the interfaced chemistry analyzer device.
- Click the radio buttons in the **Criteria of sample measuring** dialog box to set up certain filters for samples arriving to UriSed 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 measurement cycle the samples that tested negative on LabUMat
 - Select **Measure samples according to worklist** to exclude from the UriSed measurement cycle samples that you have not entered on the worklist
 - Select **Measure chemically filtered samples** to exclude

from the UriSed measurement cycle the samples that do not fall inside the filter ranges that you can set up on LabUMat for each of the test strip analytes separately.

- Use the **Expired barcode time interval** text box to set up the maximum delay, in hours, between a bar code-identified sample to be measured by UriSed after it was processed by LabUMat. If a sample arrives from LabUMat to UriSed outside the specified time frame, its bar code will not be identified by UriSed.

3.5.8 The Maintenance tab

3.5.8.1 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.

3.5.8.2 Diagnostic report

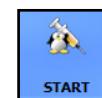
Click the **CREATE** (in case no routine urinalysis device is connected), or the **LabUMat** (in case UriSed is interfaced with a chemical analyzer) button in the dialog box to generate a status report of the software and driver versions, and the current settings of one or the other device, saved in 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.

3.5.8.3 Washing



- Click the **START** button in the **Washing** dialog box to start a daily rinse cycle that is identical to the 'daily washing cycle' that the device prompts you about each time you exit the software.

3.5.8.4 Database



- Click to optimize the device database size and speed up database management.



Depending on the size of the database, compression may take up to several hours. It is recommended that you run a database compression at least once a month.

 Every time you upgrade the device software, a database compression will automatically start. Because of this, the first bootup time after a software upgrade will probably take longer than usual.

 Do not switch off the device while data compression is in progress.

3.5.8.5 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.

3.5.8.6 Exit

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

3.5.8.7 Enable QC result deleting

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

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

3.5.8.8 Users

Administrator- and Service-level users can manage (create, modify, or delete) user accounts in this dialog box by selecting the accounts and clicking the relevant buttons (see [Figure 35](#)).

⚠ The default password for newly created user accounts is the same as the user name, which needs to be changed at the first login (☞ [3.1.2 Changing your password on page 10](#)).



Figure 35: The Users dialog box

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

⚠ No user can delete his or her own account.

3.5.8.9 MUC for review flag trigger level

Set a percentage value in the text box and check **Enabled** in the dialog box to enable the automatic highlighting (with a red square) of samples with a Mucus particle level that exceeds the set percentage value. The status of these samples will automatically be changed to **For review**.

 The default setting is enabled. The default percentage level is 30%, that corresponds to a +++ Mucus reading.

3.5.8.10 Tube type

Click the radio buttons in the **Tube type** dialog box to specify how the device mixes the sample before aspirating the 200 µl required for evaluation. Select **Normal** to use the high-performance air pump to mix the samples, or **Narrow** to use the aspirating pump for mixing that is less likely to cause the sample to splash out of the test tube.

3.5.8.11 Auto log out

Enter a number other than zero (0) in the **Auto log out after** text box 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.

4 OPERATION

4.1 Loading cuvettes into UriSed

⚠ UriSed 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 contamination might frustrate the microscopic evaluation.

UriSed operates with single-use disposable cuvettes. Cuvettes are supplied in cartridges of fifty (50) cuvettes. Before starting the measurement cuvettes should be loaded into the device.

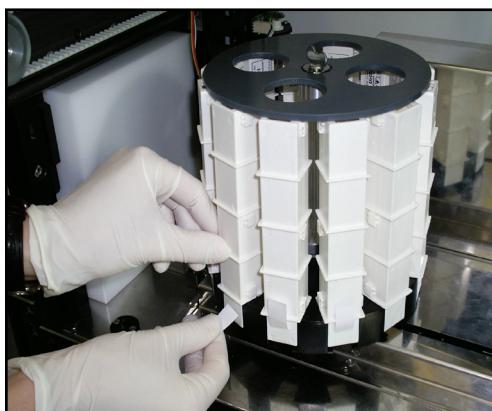


Figure 36: Loading the rotating cuvette rack

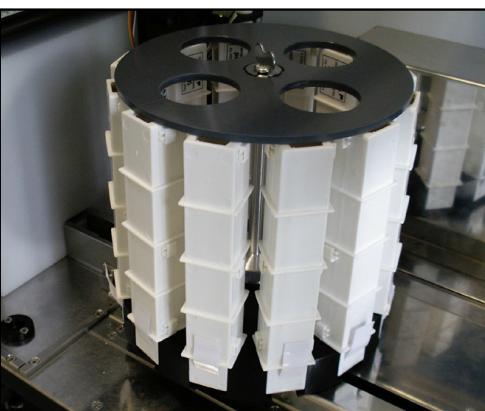


Figure 37: A fully loaded rotating cuvette rack

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

i The asymmetric shape of the cartridge makes sure that the cartridge is aligned properly in the rotating cuvette rack.

2 After placing the cartridge into the rotating cuvette rack, remove the sticker from the bottom of the cartridge by simply pulling it off (see [Figure 36](#)).

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

⚠ Only remove the sticker from the cuvette cartridge after you have inserted it into the slot of the rotating cuvette rack. 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 rack is fully loaded (see [Figure 37](#)).

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

4.2 Measurement modes

You can select your preferred measuring mode on the Measure menu by clicking the measure mode selection button. It displays the current measurement mode and so either reads **Auto** or **Manual**. The default measurement mode is automatic.

⚠ When in Auto measurement mode, the device performs measurements continuously and stops only when there are no more samples on the rack conveyor, or when the device runs out of cuvettes, or when the operator clicks the Stop measurement button.

i When the device stops in Auto measurement mode because

there are no more samples on the rack conveyor, a single empty cuvette will remain loaded into the sampling position. If you do not start a new measurement cycle, this cuvette will be forwarded into the used cuvette bin when you switch off the device.

In Manual measurement mode, the device performs exactly as many measurements in a cycle as you specified in the Manual mode measurement setup dialog box (see [Figure 38](#)), that is displayed when you click the **START** button in Manual mode.

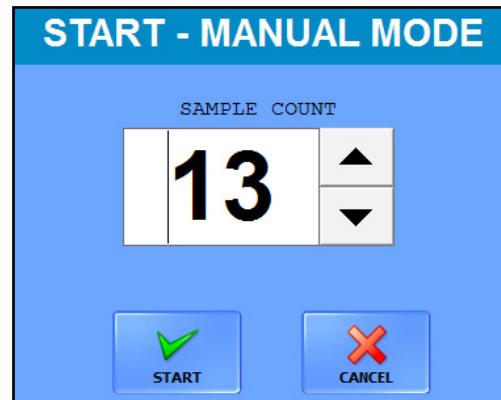


Figure 38: The measurement setup dialog box in Manual mode

Enter the desired number of measurements in the **Sample Count** text field. Click **START** to start the measurement cycle or **CANCEL** to exit the dialog box.

⚠ The device will measure the number of separate samples that you specified in the Sample Count field. The device will only stop before the specified number of measurements were completed if it runs out of cuvettes or distilled water, if the waste tank is full, if there are fewer samples on the rack conveyor than the specified number, or if the operator clicks the Stop measurement button.

⚠ The measurement cycle is suspended if any problem

arises during operation. If this should happen, consult [7 Error messages, troubleshooting on page 57](#) for advice.

Whenever a new measurement cycle is started, the number of measurements will always revert to zero (0). You can make parallel (multiple) measurements of the same samples [3.5.3.4 Parallel count on page 32](#). The parallel measurement count setting applies to both Automatic and Manual measurement modes.

⚠ 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.

4.3 Test result identification

i For further information [3.5.3.8 ID generate mode on page 34](#).

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 **001/01** if the date changes between a system shutdown and the following system restart.
- Bar codes attached to the test-tubes
 - ▶ Urine samples can be identified by bar codes if you tag each test tube with a unique bar code. For further information about the types of bar codes the system can read and how to attach them to the test tubes [2.4 Tagging test tubes with bar codes on page 8](#).

- 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 ([3.5.3.8 ID generate mode on page 34](#)).

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

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

4.4 A typical daily routine

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

UriSed 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 ([2 Installation on page 5](#)). 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 protecting clothing when handling fluids or any part of the device.**

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



A self-diagnostic procedure is automatically performed and the **Measure** menu is displayed. You will not need to leave the **Measure** menu during normal operation.

- 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 bar code 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 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.**

 **If you reuse supplied test tubes, wash them thoroughly after each use. Soiled test tubes can frustrate test results. If possible use only single-use tubes! Do not reuse single-use tubes!**

- 4 Select the measurement mode (Auto or Manual). If you selected Manual mode, specify the number of samples you would like to analyze ([4.2 Measurement modes on page 45](#)). If you selected Auto, simply 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 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 ([3.4.1 The Sample List screen area on page 13](#)).

5 When you are finished, click the **STOP** button.

 The device will not stop immediately. The cuvette that was already loaded into the sampling position when you clicked **STOP** will be processed before the measurement cycle is stopped.

6 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.

7 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.

8 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 red 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 ([6 Maintenance on page 55](#)).

9 Switch off the device hardware with the red power switch on the right 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 ([3.5.8.6 Exit on page 43](#)), you will not need to shut down the PC manually.

4.4.1 Basic operation-related troubleshooting

 In both Auto and Manual measurement modes, the device will not start, or will automatically stop if...	...there are no more test tubes to measure.
	...the database is full.
	...it runs out of cuvettes.
	...it runs out of distilled water.
	...the used cuvette bin is full.
	...the waste tank is full.
	...the worklist is enabled and all the worklist items have been processed.
	...the rack conveyor is full.

4.5 Operating UriSed together with LabUMat

UriSed can be connected with LabUMat, a fully automated urine chemistry analyzer from the same manufacturer. The two devices together provide a complex solution in urinalysis, offering both routine and microscopy urinalysis results in a single package.

4.5.1 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) between the two devices and connect it to both devices. Fit the two left-hand side feet of LabUMat and the two right-hand side feet of UriSed 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 to UriSed with the supplied serial cable.
- 5** On LabUMat, enter the Settings menu. In the Sediment analyzer window on the Measure tab, enable the **Working with Sediment Analyzer** feature. On UriSed, enter the Settings menu, and on the

LabUMat tab, enable the Working with LabUMat feature ([3.5.7 The LabUMat tab on page 41](#) [tab on page <?>](#)).

 When you enable or disable the connection with the external analyzer, UriSed automatically refreshes the connection status

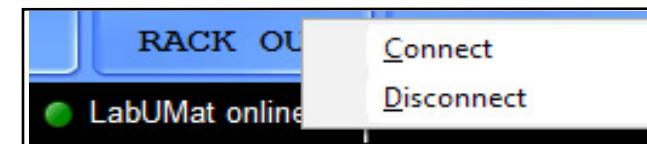


Figure 39: The Connection status indicator field after a single right-click

- 6** If the connection has been successfully established, it is indicated on the interfaced chemical analyzer and the message **LabUMat online** in the UriSed status bar ([Key to the status bar fields on page 9](#)). 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. Right-click on the Connection status indicator field on the status bar to disconnect or reconnect the two devices.

 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's rack conveyor, and tap **Start measurement** on its touch screen. Depending on your settings, the samples will be analyzed chemically by LabUMat, forwarded to UriSed, and analyzed again.

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

Measurement results of LabUMat and UriSed are matched either based on the bar codes of the samples or on their rack and tube-based identifying IDs. Results only appear in the joint urinalysis report if bar codes or generated IDs are used on both devices ↪ [3.5.3 The Measure tab on page 31](#)



The measurement settings of the routine urinalysis device override those of the microscopy device. (For example, if 2 manual measurements are specified on LabUMat, 2 manual measurements will be performed by UriSed also).

The current LabUMat 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 when the device is disconnected from UriSed.

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

4.5.2 Joint operation considerations

When joint measurements are started, you should specify the following settings on the LabUMat device:

- ▶ the measurement mode (auto or manual)
- ▶ and the number of parallel (multiple) measurements you would like to make on each sample.

⚠ These settings will override UriSed system settings during joint operation, but not the other way around.

4.5.2.1 Measurement modes and joint operation

There are certain limitations on how you can combine Auto and Manual measurement modes when operating LabUMat and a UriSed as a unit—essentially, while a measurement cycle with Auto measurement mode is in progress, you can only start another Auto measurement cycle. The following table summarizes the possible as well as the non-functional combinations.

Measurement mode of the measurement cycle started on the LabUMat device	Measurement mode of separate measurement cycle on UriSed (while the first measurement cycle is still in progress)	Is this a valid combination of measurement modes?
Manual	Manual	YES
Manual	Manual with parallel measurements	YES
Manual	Auto	YES
Manual	Auto with parallel measurements	YES

Measurement mode of the measurement cycle started on the LabUMat device	Measurement mode of separate measurement cycle on UriSed (while the first measurement cycle is still in progress)	Is this a valid combination of measurement modes?
Auto	Manual	NO
Auto	Manual with parallel measurements	NO
Auto	Auto	YES
Auto	Auto with parallel measurements	NO
Manual with parallel measurements	Manual	YES
Manual with parallel measurements	Manual with parallel measurements	YES
Manual with parallel measurements	Auto	YES
Manual with parallel measurements	Auto with parallel measurements	YES
Manual with X number of parallel measurements	Manual with Y number of parallel measurements	YES
Auto with parallel measurements	Manual	NO
Auto with parallel measurements	Manual with parallel measurements	NO
Auto with parallel measurements	Auto	NO
Auto with parallel measurements	Auto with parallel measurements	YES
Auto with X number of parallel measurements	Auto with Y number of parallel measurements	NO

UriSed will reject joint measurement cycles that you initiate in LabUMat 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 or if its system has not initialized yet ([4.4.1 Basic operation-related troubleshooting on page 48](#) for further possible causes.)

If UriSed is performing an Auto mode measurement cycle started separately, directly in UriSed. Wait for the currently running Auto mode measurement to stop or stop it manually.

If UriSed is performing a joint Auto mode measurement cycle that was started in LabUMat and the new joint measurement cycle that you are initiating in LabUMat is either a Manual mode measurement cycle, or an Auto mode measurement cycle with a parallel measurement count that differs from the parallel measurement count of the currently running Auto mode measurement. Wait for the currently running Auto mode measurement to stop or stop it manually.

4.5.2.2 Basic joint operation-related troubleshooting

5 QUALITY CONTROL

Measuring the performance of UriSed can be checked 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 40](#)).



Figure 40: The Quality Control menu

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 diluted elements (RBC-and WBC-like particles) can be found at the concentration that was set for that particular control solution lot. Low level and High level control solutions pass Quality control analysis if both analyzed particles (WBCs and RBCs) are within the values you specify in [5.1](#).

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

5.1 Setting up Quality Control 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.

i 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 is compatible with the following quality control solutions:

- Quantimetrix QuanTscopics
- Quantimetrix Dip and Spin
- Hycor 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 Modify the values of acceptance ranges in the Quality Control menu by entering the expected limits in the relevant boxes according to the lot-specific ranges given in the control solution package inserts. Click the **SAVE** button to save your changes.

Ranges that correspond to UriSed evaluation

With the Hycor KOVA control solution, use the ranges listed under "Microscopic quality control cell counts", "Quantitative", and "Swing Rotor".

With the Biorad Liquichek control solution, use the ranges listed under the "KOVA system" rows in the package insert.

With the Quantimetrix control solutions, use the ranges listed for UriSed/sedi-MAX.

⚠ Corrective factors (accessible only to Service-level users) are displayed next to the limit text boxes. These are automatically taken into consideration by UriSed to fine-tune control solution analysis. This is necessary because cells might be slightly deformed in the solutions and therefore have a somewhat different texture than their natural appearance. Because of this, some particles might not be detected in the control solutions even if the microscope is set up and the device is calibrated properly. Compensating factors define the acceptable limits that UriSed should detect compared to the ranges declared in the control solution

package inserts.

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 view field 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.

5.2 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 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 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 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.

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 41](#)). Click the **Labels on/off** button to toggle

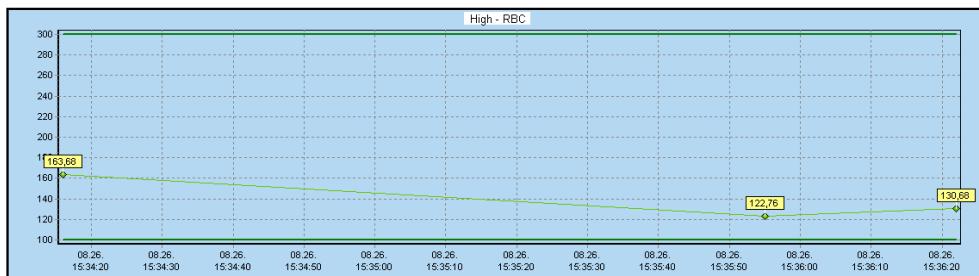


Figure 41: An example of a Quality Control diagram. The x-axis represents the time period; the y-axis represents the measurement result values.

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.

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

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

i The QC Lot data above the diagrams is listed for identification and statistical information purposes (CV%, SD) and also

indicate specific color and measurement count for the Lot.

Buttons on the Quality Control menu	
	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).
	<p>QC reports can be exported along with diagrams. This function will create 6 files in the folder you designate.</p> <p>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</p>
	Click to close the Quality Control menu and return to the previously active menu window (either the Measure or the Database menu).

6 MAINTENANCE

In order to prevent infection, you must make sure that your UriSed device is properly and regularly cleaned. Use alcohol-based cleaning agents and aldehyde-free disinfectant (bactericide, fungicide, viricide) solutions.

⚠ 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 in perfect 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 the NaOCl solution test tube into a rack all by itself. Remove the front cuvette guard and click the **Exit** button. Confirm the automatic rinsing process and wait for it to finish. This should take about 5 minutes.

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

⚠ In case of an extreme mechanical obstruction (for example because the device had been misused) 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.

i **No measurement can be started when the waste bin is full.**

3 Empty the waste tank and clean it with a 2% sodium hypochlorite solution, and then rinse it with water.

i **No measurement can be started when the waste tank is full.**

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 rear cuvette guard, the centrifuge cover and the centrifuge arm.

i **You will need to remove the front cuvette guard to access the centrifuge cover. Pull back the black 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.

⚠ Dry removed parts before replacing them.

 Take particular care to clean out-of-reach surfaces.

7 Before replacing the front and the rear cuvette guards, 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.

8 Without loosening its securing screw, turn the cuvette holder 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 cuvette holder 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.

9 If necessary, use a wet piece of cloth to clean the covering panels as well.

⚠ Do not forget to place a test tube filled with disinfectant onto the rack conveyor before clicking the "Exit" button.

⚠ Never switch off UriSed by clicking the main switch before the automatic cleaning process is finished.

7 ERROR MESSAGES, TROUBLESHOOTING

7.1 Information messages

If an info 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 information messages the system may display.

Error code	Hardware Warning message	Info description
100	Now you can switch off the Hardware..	The automatic rinsing is finished. You can replace the front cuvette guard and switch off the device.
101	Password successfully changed!	The new password is now valid.
102	Registration code accepted!	
103	There is not enough sample in tube! (Barcode: X)	The sample amount in the test tube indicated was insufficient. Please pour at least 2mL of sample into each tube.
104	No particles detected - please validate X!	
105	Diagnostic report file created successfully.	The diagnostic file has been properly created in the designated location.
106	Empty cuvette: X!	There were no particles detected in the given sample. Please measure again and/or verify with manual microscopy.
107	Quality control (Low level) passed!	

Error code	Hardware Warning message	Info description
108	Quality control test (High level) passed!	
109	Place control solutions! First for Low level then for High level!	
110	Chemical diagnostic file is received successfully.	The diagnostic file from LabUMat was sent to UriSed.

7.2 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.

Error code	Hardware Warning message	Warning elimination
1	No cuvette front-line!	Replace the front cuvette guide.
2	No cuvette back-line!	Replace the rear cuvette guard.
3	No cuvette!	Load the rotating cuvette rack with cuvette cartridges.
9	Waste full!	Empty the waste tank. If it is already empty, check the waste cable and its connection.

Error code	Hardware Warning message	Warning elimination
10	No washing liquid!	Fill distilled water into the distilled water tank. If the container is full, checkwash cable and its connection.
19	Front cover open!	Close the left door.
26	No rack!	Put a rack on the rack conveyor.
27	Rack mover full!	Remove the processed racks from the rack conveyor.
33	Please close cuvette waste bin!	Close the waste bin.
41	Please close centrifuge door!	Replace the centrifuge housing.
151	Cuvette waste bin full!	The waste bin is full, so the measurement stopped. Empty the waste bin to start measurement.
155	The next rack number didn't change, because the device is not ready!	
160	Database sample count limit is coming!	Delete some unused data to free up space in the database.
161	Database full, measuring stopped! Please delete unused data!	At measurement start: Delete the unused data so you can start a new measurement.
162	The new limit is not correct. Please delete some samples, before you set this limit!	Delete results from the database in order to reduce the number of elements in the database below the set limit.

Error code	Hardware Warning message	Warning elimination
163	Database full, measuring stopped! (Delete error!) Please delete unused data!	
165	ID contains illegal character(s)!	The ID doesn't contain ' character at filter.
166	Name contains illegal character(s)!	The Name doesn't contain ' character at filter.
172	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 solution. Repeat the measurement.
173	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 solution. Repeat the control measurement.
175	Wait until the device moves to STAT position!	When the current measurement is finished, the rack will be pushed out and you can place the STAT rack into the first rack position.
176	Empty Lot number! Please fill in!	Please enter the Lot number.
177	Empty liquid type! Please choose one!	No liquid type was selected for the quality control solution. Choose a liquid type.
178	The selected Low level Lot does not exist in database. Please select another Lot!	Select a Low level Lot from the list.
179	The selected High level Lot does not exist in database. Please select another Lot!	Select a High level Lot from the list.

Error code	Hardware Warning message	Warning elimination
181	Invalid user name or password, login failed!	Enter the correct password to log in.
183	Old password incorrect!	At password change the original password was given incorrectly. Enter the original password correctly.
184	You can not delete yourself!	It is not possible to delete your user name by yourself. It can only be deleted by another user of the same or higher level.
185	The user name must be at least 2 characters long!	Change the user name to contain at least 2 characters.
186	The user is not Service user, login failed!	You can only login as Service user. Use the proper name and password to login as Service user.
187	The user name already exists!	The user name that you entered is already in use by another person. Please choose another user name!
190	Worklist elements are consumed!	The measurement cannot be started because all the samples on the worklist have been completed. Enter new worklist items or disable this function.
191	Existing barcode!	An existing bar code was entered in the worklist. Enter a new unique bar code.
193	In this common reflex mode the chemical parallel count must be 1!	Set the parallel count to 1 on the interfaced chemical analyzer device.
194	If you use worklist function the chemical parallel count must be 1!	Set the parallel count to 1 on the interfaced chemical analyzer device.
195	There is no actual user!	
196	Device is not ready!	

Error code	Hardware Warning message	Warning elimination
197	Sample X have not been saved as Database limit would be exceeded!	
198	Sample X have not been saved as Database limit would be exceeded! Measuring stopped, please delete unused data!	
199	Database full! Please delete unused data!	
200	Hardware diagnostic report can not open!	Click the Init button, and try to restart the diagnostic report.
201	Hardware diagnostic failed!	Click the Init button, and try to restart the diagnostic report.
202	DAILY WASHING PROCEDURE Please 1. INSERT washing liquid 2. REMOVE the cuvette frontline then click OK!	This message is displayed before the daily rinsing procedure.
203	Please remove the cuvette frontline then click OK!	This message is displayed before the daily rinsing procedure if you click OK in the first dialog box without removing the front cuvette guard.
204	Init is needed!	
205	No more sample!	
206	Repeated barcode: X!	

Error code	Hardware Warning message	Warning elimination
207	QC measurement is running!	
208	Please set the correct serial number!	
209	Delete is not available, because QC result deleting is not enabled!	☞ 3.5.8.7 Enable QC result deleting on page 43
210	Name contains illegal character(s)!	The Name can not contain '& / \ : * ? " < > ^ ~ characters at Sample Data Modifying.
211	ID contains illegal character(s)!	The ID can not contain '& / \ : * ? " < > ^ ~ characters at Sample Data Modifying.
212	Comment contains illegal character(s)!	The Comment can not contain '& ^ ~ characters at Comment changing.
213	Worklist name contains illegal character(s)!	The Name can not contain '& / \ : * ? " < > ^ ~ characters at Worklist elements.
214	Worklist ID contains illegal character(s)!	The ID can not contain '& / \ : * ? " < > ^ ~ characters at Worklist elements.
215	Worklist comment contains illegal character(s)!	The Comment can not contain '& ^ ~ characters at Worklist elements.
216	Category display contains illegal character(s)!	The Category display can not contain '& ^ ~ characters at Category definition settings.
217	Lot number contains illegal character(s)!	The Lot number can not contain '& ^ ~ characters at QC settings.
220	X sample(s) have not been exported!	Validate the sample and retry exporting!
221	X sample(s) have not been sent!	Validate the sample and retry sending!
222	X sample(s) have not been printed!	Validate the sample and retry printing!

Error code	Hardware Warning message	Warning elimination
223	Invalid SG parameter!	
224	Please check the front rail!	
225	Wrong dilution factor!	Set the correct dilution factor (1-100) with correct decimal separator.
226	The ID must be at least 1 characters long!	
227	Low disk space, less than X MB!	
228	If you use sequence number in sediment analyzer, the chemical parallel count must be 1!	
229	Waiting for rack of chemical analyzer!	
231	Invalid start parameters!	
232	The sediment analyzer is busy!	
235	The LIS is busy, try to change transfer type later!	Try to change transfer type later!
240	There is no diagram. Please, set an other filter!	Make filter settings that generate a diagram.
241	There is no Low level Lot. Please add a new one!	No Low level Lot has been saved. Enter new Low Level data.

Error code	Hardware Warning message	Warning elimination
242	There is no High level Lot. Please add a new one!	No High level Lot has been saved. Enter new High Level data.
243	There is no Low level Lot selected. Please select one!	Select a Low level Lot from the list.
244	There is no High level Lot selected. Please select one!	Select a High level Lot from the list.
245	Existing Lot number!	The Lot number already exists. Please fill in another Lot number.
250	N/A	N/A
251	There is no chemical diagnostic file!	
252	Error while writing the chemical diagnostic file!	

7.3 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.

Error code	Hardware error message	Recommended corrective action (CLICK INIT AFTER EVERY ERROR MESSAGE)
0	Arm base position error!	Check if there is no cuvette in the arm way and click Init. Check that the arm can move to base position.
1	Arm robot position error!	Check if there is no cuvette in the arm way and click Init. Check that the arm can move to base position.
2	Arm centrifuge position error!	Check the centrifuge door place. Check if there is no cuvette in the arm way and click Init. Check if the arm can move to base position.
3	Arm microscope position error!	Check if there is no cuvette in the arm way and click Init. Check if the arm can move to microscope position.
4	Rotor position error!	Moving it manually, check if the rotor can rotate and if there is no cuvette between the rotor and the front cuvette guard. The arm must be in base position.
5	Cuvette checking error!	Check if there is anything obstructing the laser beam's path to the cuvette.
8	N/A	N/A
9	N/A	N/A
16	X robot wash position error!	The Y Robot must be in upper position. Check if there is no object in the X Robot way. Moving the robot manually, check if the robot can be moved above the washer.
17	X robot cuvette position error!	The Y Robot must be in upper position. Check if there is no object in the X Robot way. Moving the robot manually, check if the robot can be moved above the cuvette.
18	X robot tube position error!	The Y Robot must be in upper position. Check if there is no object in the X Robot way. Moving the robot manually, check if the robot can be moved above the test tube.

Error code	Hardware error message	Recommended corrective action (CLICK INIT AFTER EVERY ERROR MESSAGE)
19	Y robot upper position error!	Check if there is no object in the Y Robot way. Click Init to check the Robot movement.
20	Y robot cuvette position error!	Check if there is no object in the Y Robot way. Click Init to check the Robot movement.
21	Y robot tube position error!	Check if there is no object in the Y Robot way. Click Init to check the Robot movement.
22	Y robot wash position error!	Check if there is no object in the Y Robot way. Click Init to check the Robot movement.
23	Sample holder error!	Check if there is no object in the sample holder way.
24	Rack backend position error!	Check if there is no object in the rack puller arm way.
25	Rack frontend position error!	Check if there is no object in the rack puller arm way.
27	Rack position error!	Check if you are using the correct rack, and that the rack conveyor and the rack puller arm are in the proper position.
28	Rack aligner opening error!	Check the unobstructed movement of the rack aligner and that the rack conveyor is in the correct position.
29	Rack aligner closing error!	Check the unobstructed movement of the rack aligner and that the rack conveyor is in the correct position.
30	Missing barcode reader error!	Turn off the device and exit the program. Turn on the device and start the program and a measurement.

Error code	Hardware error message	Recommended corrective action (CLICK INIT AFTER EVERY ERROR MESSAGE)
32	Microscope table position error!	Check if there is a blockage in the microscope table movement.
33	Linear motor base position error!	Check if there is a blockage in the microscope table movement.
34	Linear motor outer position error!	Check if there is a blockage in the microscope table movement.
35	Focus motor base position error!	Turn off the device and exit the program. Turn on the device and start the program and a measurement.
48	Card1 communication error!	Check if the device is switched on and that the USB cable is functional and properly connected.
49	Card2 communication error!	Check if the device is switched on and that the USB cable is functional and properly connected.
50	Card3 communication error!	Check if the device is switched on and that the USB cable is functional and properly connected.
51	Card4 communication error!	Check if the device is switched on and that the USB cable is functional and properly connected.
52	Card5 communication error!	Check if the device is switched on and that the USB cable is functional and properly connected.
53	Card6 communication error!	Check if the device is switched on and that the USB cable is functional and properly connected.

Error code	Hardware error message	Recommended corrective action (CLICK INIT AFTER EVERY ERROR MESSAGE)
54	Card7 communication error!	Check if the device is switched on and that the USB cable is functional and properly connected.
55	Chem. analyzer communication error!	Check that the interfaced routine urinalysis device is properly connected and that shared operation is settings on both devices. If it is not connected, uncheck the Working with LabUMat function is enabled check box on the LabUMat tab of the Settings menu (3.5.7 The LabUMat tab on page 41).
56	Missing serial port error!	Turn off the device and exit the program. Turn on the device and start the program and a measurement.
62	Too many serial port error!	Turn off the device and exit the program. Turn on the device and start the program and a measurement.
63	UriSed 2 Connection error!	Check the microscopy urinalysis device and its connection.
64	LabUMat connection error!	Turn off the device and exit the program. Turn on the device and start the program and a measurement.
65	LIS connection error!	Turn off the device and exit the program. Turn on the device and start the program and a measurement.
69	Camera init error!	
70	Camera init error!	
71	Camera init error!	
72	Focus init error!	
73	Focus init error!	

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

Error code	Miscellaneous error message	Recommended corrective action
150	Initialization error: ARM!	Check the arm movement and if there is no cuvette in the arm way.
151	Initialization error: WASH!	Turn off the device and exit the program. Turn on the device and start the program and a measurement.
152	Initialization error: ROBOT!	Check if the robot fixing screw is removed and that the robot movement is
153	Initialization error: RACK!	Check the movement of the rack puller arm and the position of the rack conveyor.
154	Initialization error: MICROSCOPE!	Check the microscope table and arm movement.
155	Initialization error: CENTRIFUGE!	Check if there is a cuvette stuck in between the centrifuge arm and the front cuvette guard.
160	Modify sample error!	Database connection error, exit the program and restart.
161	Edit sample comment error!	Database connection error, exit the program and restart.
162	Database error! The modification cannot be saved!	An error occurred during the save of chemical result modification into the database. Database connection error, exit the program and restart.
163	Database error! The modification cannot be saved!	An error occurred during the save of sediment result modification into the database. Database connection error, exit the program and restart.
164	The particle number is bigger than 99999.9!	At sediment result modification the given particle number can not be more than 99999.9. Give a smaller number.

Error code	Miscellaneous error message	Recommended corrective action
165	Cannot change modification! The min. range is bigger than max.!	In QC menu at range setting: Give correct values.
166	Not a proper number format! Use " " decimal character.	Change the decimal character in the number you entered. (Sample mod.)
170	Delete error!	Database connection error, exit the program and restart.
172	Invalid strip on LabUMat! (Barcode: xxx)	
173	Late strip on LabUMat! (Barcode: xxx)	
174	Bad strip position on LabUMat! (Barcode: xxx)	
175	Color problem on LabUMat! (Barcode: xxx)	
176	Lost strip on LabUMat! (Barcode: xxx)	
177	Grey strip test failed on LabUMat! (Barcode: xxx)	
178	Control measurement failed on LabUMat! (Barcode: xxx)	
180	Sample count exceed sample limit! Please delete unused data!	There is not enough free space in the database for the results of the measurement that you started. Delete unused data and try again.

Error code	Miscellaneous error message	Recommended corrective action
181	Compatibility issue!	
182	Flipped strip on LabUMat2! (Barcode: xxx)	
183	No strip under the head on LabUMat2! (Barcode: xxx)	
184	Dry strip under the head on LabUMat2! (Barcode: xxx)	
185	Horizontal flipped strip on LabUMat2! (Barcode: xxx)	
190	New passwords are not the same!	At password change the new password must be entered twice: Enter the new password twice correctly.
191	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.
192	You can not change the password to the default password!	Change the password to a different one from default password.
193	The password must be at least 5 characters long!	Change the password to contain at least 5 characters.
202	X. category definition is not correct!	At category modification: Maximum value is less than minimum value. Enter correct values.
203	Empty X. category display strings!	At category modification: Enter the category name.

Error code	Miscellaneous error message	Recommended corrective action
204	Same category display strings!	At category modification: Existing category name. Enter another name.
206	The end of the category definition is missing!	At category modification: Close the last category definition with this sign: "<" .
207	Minimum and maximum range are equal in "" . category definition!	Please increase X. category definition, because it is the same as the previous one.
208	Not a proper number format! Use " " decimal character.	Change the decimal character in the typed number. (Cat def.)
209	Empty X. maximum range!	Please fill in the maximum range.
210	The directory ... does not exists !	Select an existing directory.
212	Directory ... create error !	Do not use the following characters in folder names: ' & / \ : * ? " < > ^ ~
213	Cannot save/overwrite the html file, because the access is denied!	
215	Database compact is failed!	There is not enough space on hard disk for compact database. Please delete fbk file from Database directory and make at least as much free space on hard disk as the size of current database.
217	N/A	N/A

Error code	Miscellaneous error message	Recommended corrective action
218	There is no connection with the Printer!	
220	LabUMat disconnected! Please check LabUMat status and reinit!	Check the interfaced chemical analyzer settings.
230	N/A	N/A
231	N/A	N/A
232	LIS communication error!	Check the Host settings and the Host program. Check the soundness and connections of the communication cable.
233	LIS connection is offline!	Check the Host settings and the Host program. Check the soundness and connections of the communication cable.
240	Not a proper number format! Use " " decimal character.	Change the decimal character in the typed number. (QC)
245	N/A	N/A
246	N/A	N/A
247	N/A	N/A
248	N/A	N/A
249	N/A	N/A
250	N/A	N/A

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.

8 ANALYTICAL PERFORMANCE

The data evaluation was performed based on a 2x2 contingency table with Manual (reference) microscopy or UriSed-based urinalysis, and pathological or normal results as the two variables. For the investigated sediment particles the following indexes were determined as describing the diagnostic results:

Sensitivity: the number of samples indicated pathological by the test / the total number of pathological samples

Specificity: the number of samples indicated normal by the test / the total number of non-positive samples

The following table lists basic sensitivity and specificity values obtained from a clinical evaluations of 500 samples:

Particle	Sensitivity [%]	Specificity [%]
RBC	85	80
WBC	85	80
NEC	70	90
EPI	85	85
PAT	60	70
CaOx	70	90
YEA	70	90

The above data have been generated on a database which was planned to check the sensitivity of the system, so the number of pure negative samples was very low. The reference method in the clinical evaluation was the Standard Manual Microscopy Method (described in the European Urinalysis Guidelines – ECLM and [GP16-A2 Urinalysis and Collection](#),

[Transportation, and Preservation of Urine Specimens; Approved Guideline – Second Edition](#)).

9 DEVICE SUPPORT

9.1 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.
- The latest documentations concerning certain versions of the device should be obtained from the manufacturer.

9.2 Ordering information

Consumable:

URS-9961-1	PACKED CUVETTE (600 PCS)
UAZ-1105-1	SPECIAL NARROW TEST TUBE (100 PCS)
UAZ-1106-1	TEST TUBE CAP (100 PCS)

Accessories:

UAZ-4439-3	RACK FOR UriSed (10 PCS)
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10 TECHNICAL DATA

General	
Throughput	Up to 90 samples/hour (depending on the number of set images)
Memory	5000 measurements (with all the recorded images)
Dilution factor	1-100 setting available
Main unit dimensions	
Size	600 X 650 X 600 mm
Weight	60 kg
Main unit interfaces*	
Firewire	IEEE 1394
USB	USB Type B
Power	
Main Unit	100-240 VAC, 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 8A L
Circumstances of operation	
Op temperature	15-30 °C
Op humidity	20-80 %
Circumstances of storage	
Storing temperature	(-20)-(+80)°C
Storing humidity	20-80 %
Bar code scanner	
Identified bar code 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
Urine homogenization	Stirring by sample liquid mixing
Height (if tube is conical)	100-110 mm
Height (if tube bottom is linear)	100-105 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	green
Focus depth	±5 µm
Camera	
Chip size	8.8 mm x 6.6 mm

UriSed images	
Number of images per sample	5, 10, 15 or 20 (15 by default)
Positions of images	Not overlapping fields near each other in the middle of the cuvette
Magnification	Corresponds to ~400x magnification microscopic image
Image size	1280x960 pixels
UriSed viewfield volume	0.16 µL native urine
Washing system	
Washing liquid in container	Distilled water
Volume of containers	5 liters
Washing liquid consumption	min. 300 measurements can be performed with 5L distilled water
Washing solution used for daily cleaning of UriSed	Min. 6 mL, 2% NaOCl solution in one test tube
Waste bin	
Waste bin size	app. 400 measurements

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

11 SYMBOLS

	The CE mark identifies that the product complies with the applicable directives of the European Union
	In vitro diagnostic medical device
	This product has been tested to the requirements of CAN/CSA-C22.2 No. 61010-1, second edition, including Amendment 1, or a later version of the same standard incorporating the same level of testing requirements
	Consult instructions for use
	Serial number
	Manufacturer
	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
	ESD - Electrostatic discharge
	Laser radiation warning (Class 2)
	High voltage

	Important note
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