Urilyzer® Auto

analyticon®

User Manual

Automated Urine Chemistry Analyzer
Software version 3.3

Analyzer for CombiScreen® 11 Auto urine test strips

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1 Introduction

Thank you for choosing Urilyzer Auto automatic urine chemistry analyzer, manufactured by Analyticon Biotechnologies. We hope that you will be satisfied with the analyzer.

1.1 General description of Urilyzer Auto

Urilyzer Auto is designed specifically for professional use in clinical laboratories. It is a fully automated urine chemistry analyzer that meets all the usual requirements indicated by medical laboratories.

Operation of Urilyzer Auto is easy and very efficient. The operator fills the instrument with distilled water, fills up the strip feeder with urine reagent strips and puts the racks with sample-filled test tubes on the rack conveyor. The analyzer takes care of everything else.

To deal with the workload of big laboratories it is a walk-away system offering a unique technology and a new scientific approach to automated urine analysis.

Urilyzer Auto is an automated desktop reflectance photometer designed for high volume urine test strip reading.

Easy operation via touch screen, automatic handling of test strips and test tubes (including sample mixing and precise dosing for each test pad by the pipetting unit), a patented detection technique, and intelligent data management provide maximum efficiency while making urinalysis simple.

The strip results together with the physical parameters from the PMC are stored in the memory of Urilyzer Auto, which is large enough to store 10.000 records.

The Urilyzer Auto urine strip reader is a stand-alone instrument, which can be connected to a microscopy urine sediment analyzer. Together, the two analyzers make up a complete Urine Laboratory System.

	**Biohazard risk** **This analyzer may become infectious in the course of use. Dispose of the analyzer in accordance with the local regulations for biohazardous waste.**

1.2 Methodology of urine testing

Urinalysis is one of the diagnostic methods frequently used by medical doctors in laboratories. The most cost-effective method for screening urine is the use of paper or plastic dipsticks. This micro-chemistry system has been available for many years and allows qualitative and semi-quantitative analysis within one minute by simple but careful visual observation. The color change occurring on each segment of the strip is compared to a color chart to obtain the results. Owing to varying ambient conditions (e.g. external light), however, the results can easily be misread or misinterpreted.

IVD Urine analyzer instruments (urine strip readers) are designed specifically to improve the accuracy and security of urine strip evaluation by automating and standardizing the evaluation process. The analyzers also help in test data handling and report generation by providing data storage and computerized data processing features for medical laboratories.

1.3 Test strips

Good quality dry reagent urine multi-strips are essential for urine analysis. These strips have separate pads for each tested parameter. Pads contain certain chemicals that develop color changes reacting with each tested parameter according to their concentration in urine.

Urilyzer Auto works with CombiScreen 11Auto urine multi-strips that provide accurate results. Tested parameters are as follows:

Billirubin	Urobili-nogen	Ketones	Ascorbic acid	Glucose	Protein	Blood	pH	Nitrite	Leuco-cytes
✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

2 Installation

2.1 Packing list

Urilyzer Auto equipment	1 pc
Power cord	1 pc
Serial cable	1 pc
Waste Container	1 pc
Wash Container	1 pc
Container holder	1 pc
Pipes	3 pcs
Rack mover unit	1 pc
Dropping strip tray	1 pc
Pipetting tray	1 pc
Strip forwarding comb	1 pc
Touch screen pen	2 pcs
Test tubes + cap	100 pcs
Test tube with barcode	1 pc
Racks	10 pcs
Quick Reference Guide	1 pc
Packaging manual	1 pc

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.**

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

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

Urilyzer Auto is shipped in 2 cardboard boxes. Prior to unpacking, clear the area where you would like to operate the analyzer: an 80 x 60 centimeters (31 x 24 inches) size table is needed that is strong enough to support an almost 60 kg (130 lb) analyzer. Refer to the detailed Shipping manual – attached – on how to pack and unpack the analyzer. Please follow the shipping marks on the box while handling.

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

1 Cut off the straps on the wooden shipping box, and remove the lid and the package cushioning. Pull off the outermost packaging shell, and remove the flatpack box on top.

2 Remove the package cushioning and wrapping around the main unit box, then pull off its packaging shell.

3 Remove the 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 small accessories listed in **2.1 Packing list**.

6 Remove both liquid tanks, their tubing, and their bowl and place the tanks in their bowl under the table.

7 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.

8 Unwrap all the accessories, dust them off. Check the completeness of the consignment (☞ **2.1 Packing list**).

⚠ **As the analyzer is quite heavy (about 60 kg (132 lb)), two people are required to move it. Use both hands a grab the analyzer at its bottom corners from underneath each side.**

ⓘ *If the instrument has to be installed in another location, all removable parts have to be removed for transportation and the robot arm has to be fixed with the supplied securing screw and plate. For transportation a trolley might be necessary because of the weight of the analyzer.*

2.3 Installation sequence

1 Remove all remaining package cushioning from inside and around the analyzer.

2 Reaching in from the front of the analyzer, find one extending screw and a metal plate in the middle. The retainer plate secures the pipetting probe of the analyzer during shipping. The retainer plate must be removed before the equipment can be switched on. Unscrew the fixing screw, remove the plate, and fix it with the screw in a screw hole on the top crossbar of the chassis, bored for this purpose.

ⓘ *It is recommended to keep the fixing screw and plate, as you might need them if you need to install the analyzer in a new location.*

3 Find the strip forwarding comb among the accessories and insert it in the appropriate place on the strip forwarder, on the right-hand side inside the unit (☞ **Figure 22**).

4 Find the pipetting tray among the accessories and install it in the appropriate place in the center of the unit (☞ **Figure 22**).

5 Find the drip tray among the accessories and slide it into its slot from the front of the instrument (☞ **Figure 22**).

⚠ **Make sure that one of the openings on the drip tray is aligned with the path of the pipetting probe as it goes down inside the test tubes.**

Figure 1: Dimensions of the analyzer with the rack conveyor attached

6 Link the rack mover unit up with the main unit. Fit the two edges flush against each other and snap the conveyor onto the main unit after fitting their edges push the unit gently until it clicks.

⚠ **Use only rack conveyor units specifically supplied with Urilyzer Auto analyzers.**

7 Connect the power cable first to Urilyzer Auto, then to the mains. For safety reasons Urilyzer Auto can only be connected to grounded outlets.

8 Use the supplied serial cable or USB port to connect Urilyzer Auto to the host PC. Refer to **3.3 Data menu** for information on connecting the analyzer to a host PC.

9 Switch on Urilyzer Auto and wait for the boot sequence to finish.

⚠ **It is important that you remove the retainer plate from the linear robot before you connect the equipment to the mains. When the power is switched on, the instrument is in stand-by mode. When you tap the power button, the system initializes, which includes motion checks. The linear robot may be damaged if the retainer plate does not let it perform the motion checks.**

⚠ **Urilyzer Auto 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 analyzer. Only specially trained service personnel may dismantle the analyzer.

You need to register test strips before you can use the analyzer (☞ 3.5.6 Strip registration).

After you install the analyzer, it is recommended that you review its performance (☞ 3.5.2 Quality Control).

2.3.1 Installation of the fluidic system

1 Lead the two larger size pipes through the two slots of the container cover for waste water. 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 Urilyzer Auto marked “Waste” and “Gravity”.

There is no suction in the gravity tube, so it must be installed so that it slopes downwards all the way to the waste container.

2 Connect the sensor for this container to the D-sub 9 connector on the back of the analyzer marked “WASTE SENSOR”.

3 Fill the other container with **IFW (Instrument Feed 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 slot. One end of the pipe has to be at the bottom of the container held fast by the rubber ring and the other end has to be connected into the “Wash” slot on the analyzer.

4 Connect the sensor for water container to the D-sub 9 connector on the back of the analyzer marked “WASH SENSOR”.

5 Place both containers into their tray and place the tray under the table that supports the assembled analyzer.

2.3.2 Taking Urilyzer Auto out of operation

You do not need to take any special steps to take Urilyzer Auto out of operation. Perform the steps listed below to preserve good condition of the analyzer while it is not in use.

Since urine is a fluid of human origin, it may be infectious and may carry biological risks.

Handle used strips and urine contaminants with care.

Always wear rubber gloves or other protecting clothing when operating Urilyzer Auto.

1 Perform the washing cycle with the disinfectant solution (☞ 3.5.3 Disinfection). Switch off the Urilyzer Auto unit and disconnect it from the mains.

2 Discard both unused strips and all used strips from the waste bin.

3 Remove all fluids from both containers and clean them thoroughly. Let them dry and pack them up, leaving their caps open.

4 Use the supplied securing screw and the retainer plate to secure the linear robot module.

5 Clean Urilyzer Auto carefully and remove all its removable parts (☞ **5 Maintenance**). Let them dry and pack up Urilyzer Auto as it was packaged when it arrived to you.

If you would like to put Urilyzer Auto back into operation, follow the steps described in **2 Installation** *to properly install the analyzer.*

If the instrument has to be installed at another location all removable parts have to be removed for transportation (the strip timer comb, the pipetting tray, the drip tray, and the rack conveyor unit), and the robot arm has to be fixed with the supplied securing screw and plate. For transportation, a trolley might be necessary as the instrument is quite heavy (about 60 kg (132 lbs)).

2.3.3 Tagging test tubes with barcodes

Urilyzer Auto's built-in barcode reader can automatically identify urine samples by barcodes affixed to the side of test tubes.

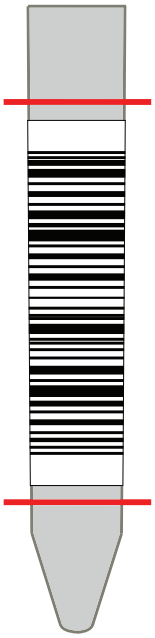


Figure 2: The types of barcodes recognized by the system and illustration of their use

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

Affix barcodes around the middle of the test tubes, between the levels indicated in **Figure 2**. Barcodes above or below these levels might not be identified by Urilyzer Auto. When placing samples with barcodes in the racks, take care that the barcodes face towards the open side of the racks, otherwise the barcode scanner will not be able to scan 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 check the built-in barcode scanner.

3 Menu system

Urilyzer Auto has an easy-to-use, user-friendly menu system. The main menu points are on the right side of the screen; their relevant sub-menus are in the bottom. The menu points can be selected by tapping on the LCD touch screen, clicking with the connected mouse (not accessories) , or selecting them with the arrows of the external keyboard (not accessories). Characters can be entered using the external keyboard or on-screen keypad. Some buttons have more than one state, and their appearance indicates their current status.

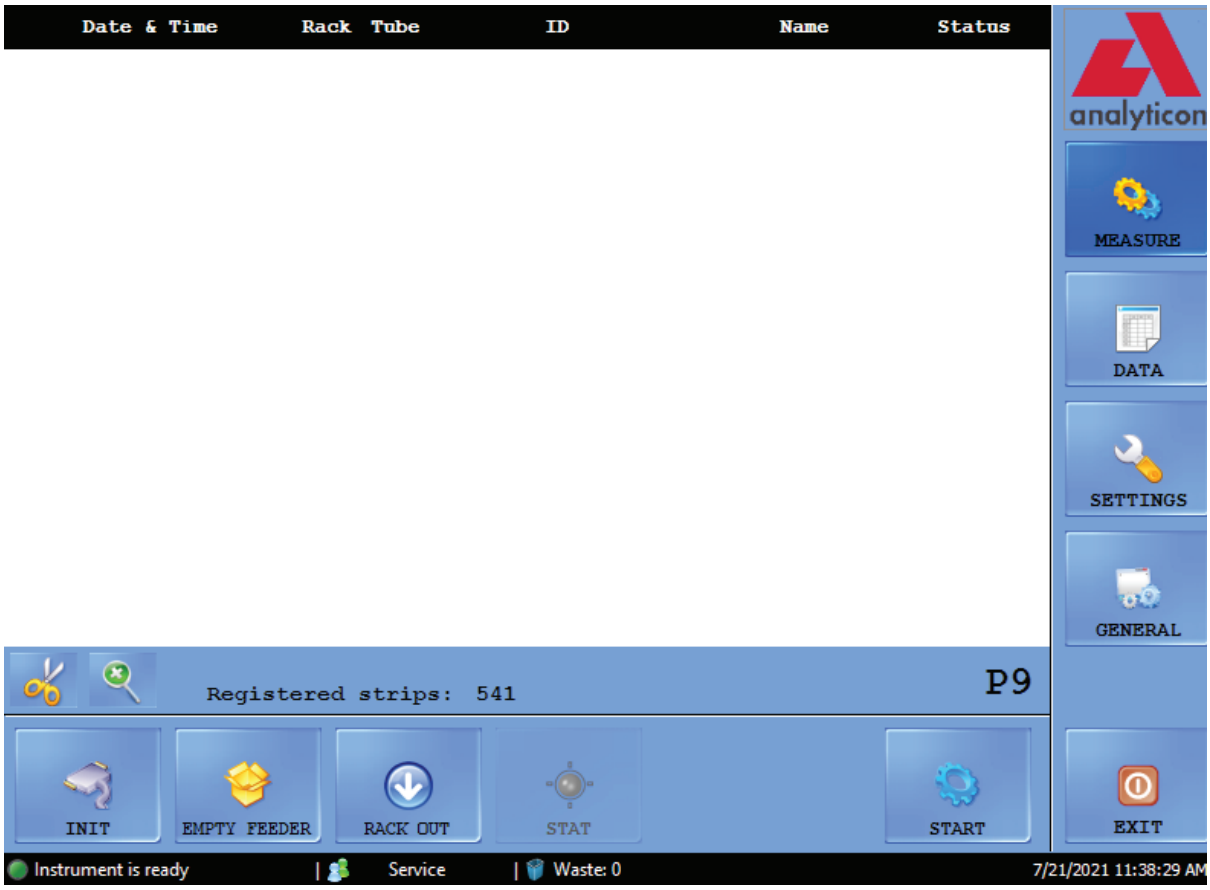


Figure 3: The Measure menu

At the very bottom of the screen, in the status line, the following information is continuously displayed, from left to right:

Key to status line information	
Description of displayed information	**Possible displayed contents**
Status of connection between Urilyzer Auto and operating PC	Instrument is ready Instrument is not ok Instrument is initializing
Connection status of the sediment analyzer (if enabled)	sediment analyzer connected sediment analyzer not connected
User rights according to login level or User name	Operator Administrator Service User name
Approx. number of strips in the waste bin	Waste:
Current date and time	Date & time

3.1 User rights

Depending on the login system selected, Urilyzer Auto users can be categorized and identified by their different access levels or by their individual user names (and corresponding access levels). There are three access levels for Urilyzer Auto user accounts: Operator, Administrator and Service with different user rights. Some advanced-level settings are only available to Administrator- or Service-level user accounts, which are always password protected.

Only properly trained and authorized service personnel can log in to Service-level user accounts.

If the access-level based login system is active, the default access level for all users is Operator at the first startup. Operator-level users can perform measurements, manage sample data in the Database, and access the Measure tab on the Settings menu.

3.1.1 Logging in to an Administrator user account

1 Enter Settings Menu and tap the Login button in the bottom left corner. Enter the default user name (“administrator”) and password (“settings”) for the Administrator user account (without the quotation marks).

For security reasons, asterisks (*) will be displayed instead of the characters that you type in the password text box.

2 The user rights–indicator in the status line switches to “Administrator”. Make the changes in the settings that you could not access as an Operator.

3 Enter the Settings menu, navigate to the Measure tab, and tap the Logout button to revert to an Operator-level user.

The user rights of the currently active user are always displayed in the status line. Here it can always be checked whether the current user has Operator, Administrator or Service rights.

3.2 Measure menu

On the Measure menu, a list is displayed in the middle of the screen, containing the date, the time, rack and tube numbers, sample IDs as well as the name of the patient and status icons of the strips that are currently evaluated.

3.2.1 Clear list

Tap this button to remove all finished measurement records from the list displayed in the Measure menu. This function does not remove any records from the database.

3.2.2 Registered strips counter

Displays the number of strips remaining from the last batch of registered strips. When you register a new batch, the Registered strips counter will increase by the number of the newly registered strips.

3.2.3 Init

Tap this button to run the same self-test which runs at each startup. This function checks all independent inner parts and after finishing, it initializes Urilyzer Auto. If you experience any problem while you use the analyzer, it is recommended that you run this self-check as the first step of troubleshooting.

3.2.4 Empty feeder

Tap this button to empty the strip feeder and wait until the icon and the text on the button change. The button is disabled during measurements, unless the number of strips is fewer than 15.

Find the unused strips in the unused strip bin below the strip feeder after emptying the strip feeder module. Unused strips can be used again later. Shake the unused strip bin and pour the strips back into their vial after unscrewing the front cap of the bin after you finished working with Urilyzer Auto. Try to avoid touching unused strips with your hand!

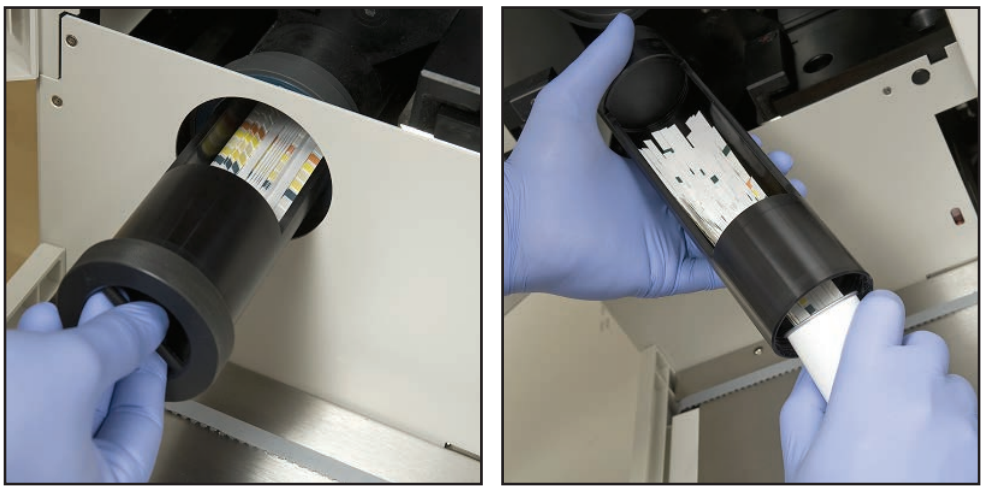


Figure 4: Emptying the unused strip bin back into a test strip vial

⚠ **In total 300 strips can be inserted in the instrument at the same time (2 vials of 150 strips). When filling up the instrument with strips from 2 vials, make sure that they are of the same lot number. Only feed a new vial of CombiScreen 11Auto strips into the analyzer if the number of remaining unused strips inside the instrument has dropped below 15.**

⚠ **Do not store strips in the analyzer. Remove strips from the unused strip bin and put them back into their vials when you stop working with Urilyzer Auto. Strips in the unused strip bin are not properly protected against moisture, and this can significantly reduce their quality.**

3.2.5 Rack out

Tap this button to push out the current rack from the instrument. This button is disabled during measurement.

3.2.6 STAT

This function should be used if there are some urgent samples, which have to be measured urgently before the scheduled ones. STAT button is disabled if there is no running measurement or control measurement is performed and enabled when normal measurements are running. When you tap the STAT button, the analyzer will stop only after it processes the current sample. The message **`Wait until the current measurement is finished`**. is displayed until the analyzer can stop. Then recent rack is pushed out and the rack mover conveyor moves the following not yet measured racks backwards, in order to make room for the extra rack which contains the urgent samples. The message **`Insert the urgent sample(s)`**. indicates that the analyzer is ready to handle the urgent samples, so they you can put them on the rack mover conveyor. When you tap the **`OK`** button in the message window, Urilyzer Auto pulls in the extra rack and measures the samples in it. These measurements will have an extra ID (e.g. ST-01, and so on). However, if there are barcodes on the urgent sample tubes, barcodes will be assigned as IDs. After measuring the extra rack, the interrupted measurements automatically continue.

3.2.7 Start

Tap this button to Start/Stop the measurement. See **4.4 A typical daily routine** for details.

3.2.8 Exit

Tap this button when you have finished working with Urilyzer Auto. When you tap the button, you can choose to start the automatic disinfection rinsing procedure (see **3.5.3 Disinfection**), or skip rinsing and shut down the analyzer directly. You must always perform a disinfection rinsing before you finish working with the analyzer at the end of the day. The software of the instrument shuts down after disinfection, and Urilyzer Auto switches off to stand-by mode. To completely switch off the analyzer, use the main switch at the back of the analyzer. The Exit button becomes active after you stop the measurement cycles. You cannot exit the operating software while a measurement cycle is going on.

3.3 Data menu

Figure 5: The Data menu

You can review, modify, or validate the records for measurements on the Data menu, even while a measurement cycle is still going on. The menu is divided into two parts:

- sample records are listed in the Sample List on the left;
- information about the currently selected sample record is displayed on the right, in two sections:
    - general info on the selected sample is on top;
    - the detailed results for the sample are displayed at the bottom.

Tap the arrow button between the general info and the result list areas to list additional information on the selected result.

3.3.1 The Sample List

The Sample List displays the measurement records for the urine samples in the current measurement cycle. A new measurement record is added to the Sample List every time the system finishes analyzing a sample. To select a record in the Sample List, tap its row. Measurement records include the following information:

Date	The date and time when the urine sample was analyzed. This field is generated by the system, and it is always listed.
ID	The ID that was assigned to the urine sample. If you are not using barcodes on the test tubes to identify samples, the system generates a unique identifier based on the rack's number and the test tube's position in the rack (see **4.3 Identification of test results**).
Name	The name of the patient that supplied the urine sample. This data is optional and is displayed only if you entered a name for the patient (see **3.5.4 Worklist editor** for example).
+/-	This column displays + if the sample was positive (abnormal), or a - if the sample was negative (normal). There are three (3) additional icons that may be displayed to indicate that there was a problem with the measurement
	A red X-mark with or without a subscript index number. See **6.4 Possible measurement errors**.
	 Indicates that the amount of the sample was not enough for proper pad pipetting.
	 Indicates that there was a problem with the PMC part of the measurement for the urine sample, and that the color, clarity, and specific gravity data may be unreliable or missing

3.3.2 Main Features

This section details the general functions that are available across all the tabs via the buttons along the bottom of the display.

If any of the changes you make have an effect on the sample list in the Data menu, the sample list will be automatically refreshed. Depending on the number of records in the database this process can take some time. This is always indicated in the progress bar that is displayed.

3.3.2.1 Transfer

Tap this button to transfer the measurement records of selected urine samples through the serial port to a host computer or LIS.

For further information about transfer protocols, contact your distributor.

3.3.2.2 Print

Tap this button to print the results summary for the selected sample or samples via the connected printer.

3.3.2.3 Export

Tap this button to export selected results to an external USB drive. You

can specify the file path for the export in a dialog box that pops up.

3.3.2.4 Import

Tap this button to import results from an external USB drive. You can specify the file path for the import in a dialog box that pops up.

3.3.2.5 Shift

Tap this button to display the second tier of function buttons.

3.3.2.6 Delete

Tap to delete the selected record. Results for deleted samples are removed from the database. This function is disabled during measurement cycles.

3.3.2.7 Select all/Deselect all

Tap to toggle selection of all the records in the list. This function is inactive if there is only one item in the sample list.

3.3.2.8 Modify

Tap this button to modify the barcode ID, the patient name, or one or more of the physical parameters associated with the selected record, and to add comments. Select the record that you would like to modify. Enter the new ID and patient name with the onscreen keypad and tap the green check mark to save changes or the red X to cancel.

ID text fields may not be left blank.

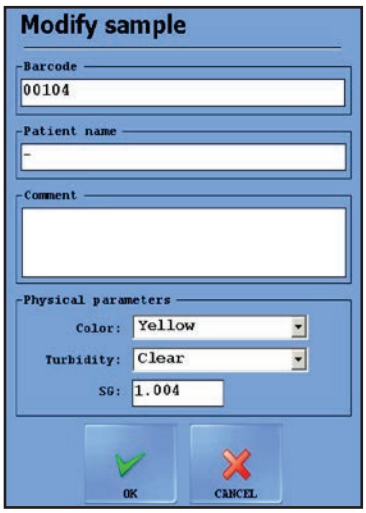


Figure 6: The Modify sample popup window

3.3.2.9 Reeval

Tap this button to evaluate the selected result(s) according to potential changes made to positive sample status, pad visibility, pad sensitivity, trace category and auto validation. See **3.4.3.3 Alternating positive sample status**.

3.3.2.10 Filter

For easy location of one or more sample records, you can filter measurement results based on one or more of the following criteria:

- measurement date

The current date is inserted in both 'from' and 'to' date boxes. Tap the calendar icon next to the date boxes to select different dates.

Select the Last days check box and enter a number in the text box next to the label to filter analysis results that were performed within a given number of days from the current date.

- barcode
- patient name
- name of the operator who performed the measurement

Use the drop-down arrow to select an operator.

- a given LOT number that is registered in the database

Use the drop-down arrow to select a test strip LOT.

This feature is currently only available for Quality Control lots.

- a positive or negative analysis or Quality Control result

Select the QC check box and one of the check boxes under Result to filter positive or negative QC measurements.

- whether the given sample was recommended for sediment analysis

See **3.4.2.4 Pad reflex**.

To set up a given filter parameter, select one or more of the check boxes.

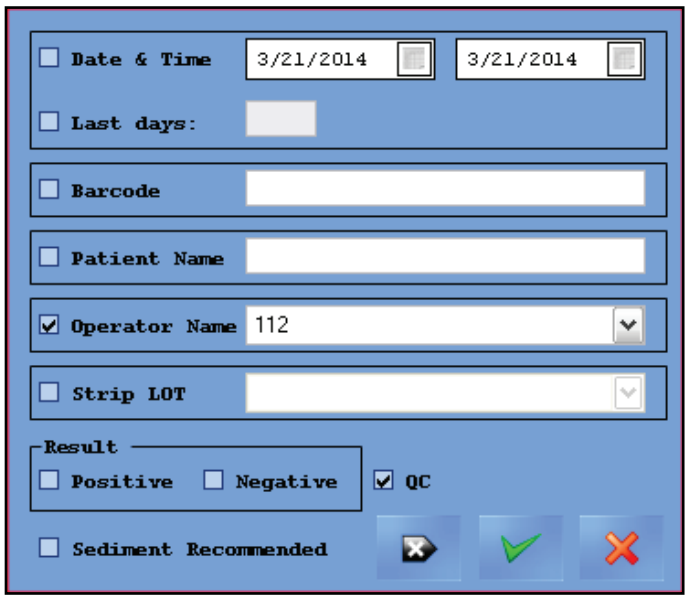


Figure 7: The Filter popup window

When using the Filter function the phrase "with filter" will be appended to the sample count number at the top of the sample list.

3.3.3 Table of displayed results

Arbitrary results: neg or norm, (+) or trace, +, ++, +++, ++++

The trace category can be turned on/off and customized for certain parameters, see **3.4.3 Categories**.

CombiScreen 11Auto Pad names									
Bilirubin Bil	Arbitrary	neg		+	++	+++			
	Conv	neg		1	2	4			mg/dl
	SI	neg		17	35	70			µmol/l
Urobilinogen Ubg	Arbitrary	norm		+	++	+++	++++		
	Conv	norm		2	4	8	12		mg/dl
	SI	norm		35	70	140	200		µmol/l
Ketones Ket	Arbitrary	neg	(+)	+	++	+++			
	Conv	neg	10	25	100	300			mg/dl
	SI	neg	1.0	2.5	10	30			mmol/l
Ascorbic acid Asc	Arbitrary	neg		+	++				
	Conv	neg		20	40				mg/dl
	SI	neg		0.2	0.4				g/l
Glucose Glu	Arbitrary	norm		+	++	+++	++++	+++++	
	Conv	norm		50	100	250	500	1000	mg/dl
	SI	norm		2.8	5.6	14	28	56	mmol/l
Protein Pro	Arbitrary	neg	(+)	+	++	+++			
	Conv	neg	15	30	100	500			mg/dl
	SI	neg	0.15	0.30	1	5			g/l
Blood Bld	Arbitrary	neg		+	++	+++			
	Conv	neg		5-10	~50	~300			Ery/µl
	SI	neg		5-10	~50	~300			Ery/µl
pH	Arbitrary	5	6	6.5	7	7.5	8	9	
	Conv	5	6	6.5	7	7.5	8	9	
	SI	5	6	6.5	7	7.5	8	9	

CombiScreen 11Auto Pad names									
Nitrite Nit	Arbitrary	neg		+					
	Conv	neg		pos					
	SI	neg		pos					
Leukocytes Leu	Arbitrary	neg		+	++	+++			
	Conv	neg		~25	~75	~500			Leu/µl
	SI	neg		~25	~75	~500			Leu/µl

PMC (Physical Measuring Cell) results:	
Turbidity	Clear
	Light turbid
	Very turbid
Color	Pale Yellow
	Yellow
	Amber
	Brown
	Orange
	Red
	Green
	Other
SG (Specific Gravity)	1.000–1.050

3.4 Settings menu

The availability of Settings menu tabs depends on user levels. The Measure tab is accessible to all. Further setting options are only available to Administrator– or Service-level users after they log in until they log out. The Settings button is disabled while a measurement cycle is going on.

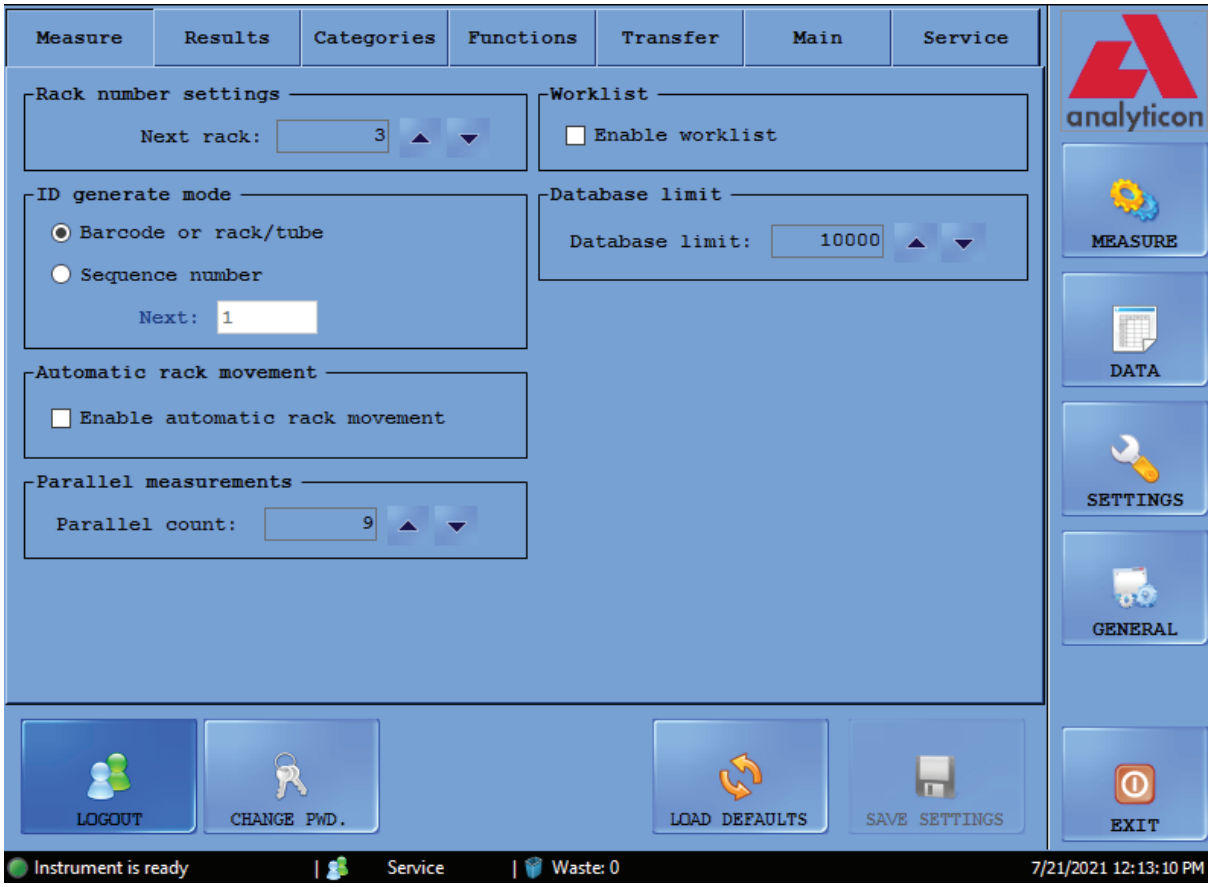


Figure 8: The Measure tab on the Settings menu

3.4.1 Measure settings

In the boxes on this tab, you can set up parameters to do with the measurement process.

3.4.1.1 Parallel measurements

By default, each urine sample is analyzed only once. However, you can set up the analyzer to make more than one measurement for each sample. The system will attempt to process each sample as many times as you specify in this text box.

Measurement records of the same urine sample share an identifyer, but have "-1", "-2", and so on added to the end of the shared ID.

Urilyzer Auto requires at least 2 milliliters of urine sample for accurate analysis results. This amount is enough for approximately two (2) measurements. If you are setting up parallel measurements, make sure that there is enough sample in the test tubes for each measurement.

3.4.1.2 Rack number settings

By default, the first rack in a measurement cycle is assigned the number “1”. In this text box, you can specify what number the system assigns to the next-in-line measurement cycle.

This setting is reset to default at every system restart.

3.4.1.3 Database limit

In this text box, you can set the size of the database and the database warning limit, up to a maximum of 10 000 records. When the number of records reaches the database warning limit, a warning message will be displayed (☞ **6.2.2 Software warning messages**). Check the Overwrite... check box to make the system start overwriting older records when the overall database limit is reached.

If you check the Overwrite... check box, the database warning limit is disabled.

3.4.1.4 Sediment Analyzer

- Check the Working with Sediment Analyzer box to transfer measurement results to a connected sediment analyzer.
- If you select the joint operation checkbox, the Common measurement start option becomes active. If you select this checkbox, the connected sediment analyzer will analyze each and every sample that you measured on the Urilyzer Auto.

For more information about how to operate the Urilyzer Auto with a connected sediment analyzer, ☞**4.5 Operating Urilyzer Auto and a urine microscopy analyzer together***.*

3.4.1.5 Worklist

Check the Enable worklist box to make the system automatically assign the patient names and comments to future measurement records from the worklist you have set up earlier. You can set up worklists in the worklist editor (☞ **3.5.4 Worklist editor**).

You can only enable the worklist if the Parallel count is set to 1.

When Enable Host query activated, the analyzer queries whether the sample that is being identified should be measured or not.

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

3.4.1.6 ID generate mode:

You can specify whether the processed test tubes should be identified based on the sequence in which they arrive or based on the barcodes attached to them. If you selected sequential ID generation, you can also specify the starting number for the test tubes in the Next text box.

3.4.2 Results settings

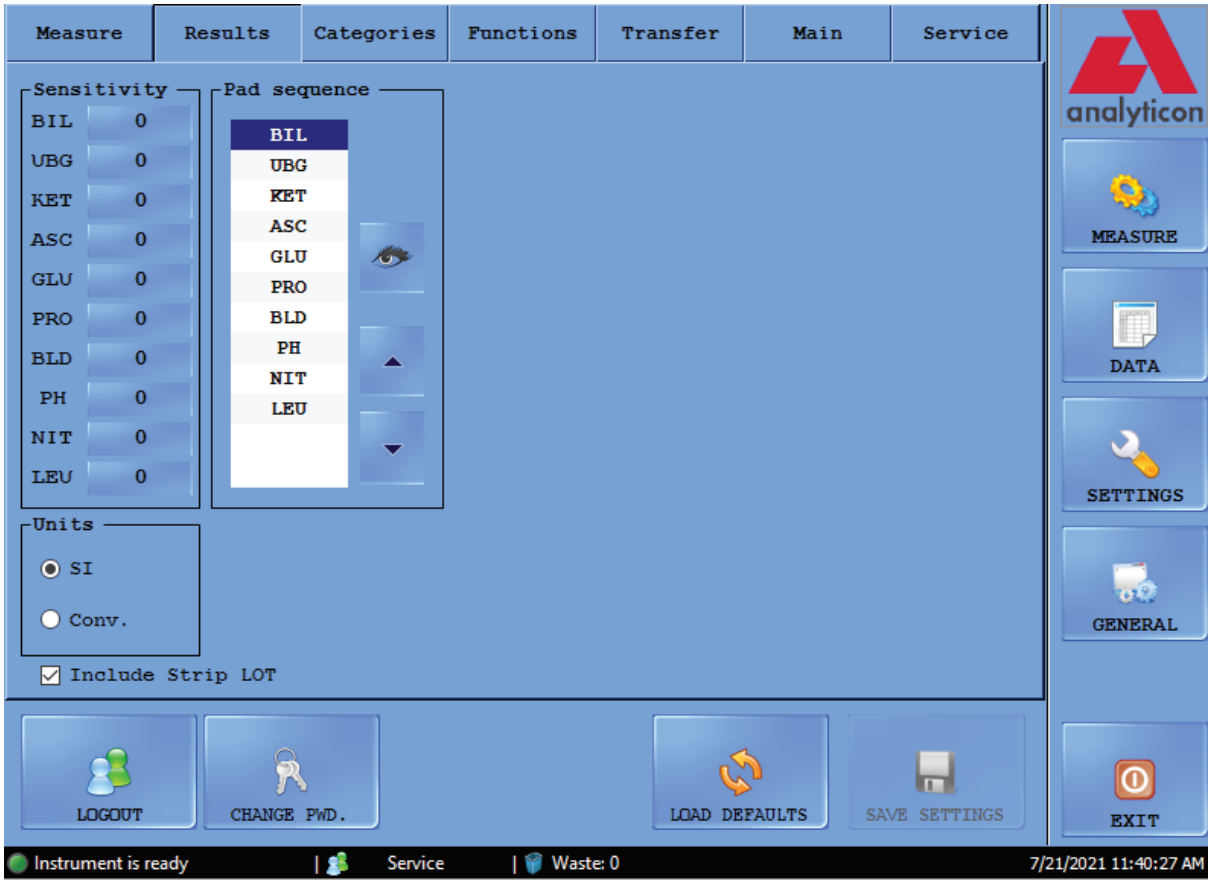


Figure 9: The Results tab on the Settings menu

3.4.2.1 Sensitivity

Lot-specific measurement sensitivity information is in brackets. This sensitivity can be adjusted to up to two levels in either direction (-2, -1, 0, +1, +2) for each individual reagent pad by tapping the number button next to pad labels.

3.4.2.2 Units

Unit of the results can be set to: SI, Conventional or Arbitrary. Measurement results are evaluated according to the set unit in the result table displayed on the **Data** menu.

3.4.2.3 Pad sequence

You can modify the sequence in which the test strip parameters are shown and transferred.

- Pad parameters are analyzed and transferred in the order in which they are displayed in the list. Tap the pad label you would like to reorder, and tap the arrows next to the list to move the pad parameter up or down on the list.
- To remove a pad parameter from the list, tap the pad label, and then tap the eye icon next to the list. The pad label will be dimmed, and it will not appear in the measurement records or the transferred data.

3.4.2.4 Pad reflex

In this section, you can create custom filters that will select certain but not all samples you want to send to sediment analysis (if you have a sediment analyzer that interfaces with your Urilyzer Auto analyzer). You can specify the conditions for your filters using the measurement results for the individual reagent pads.

Based on the filter you set up the sample will be sent for measurement on the sediment analyzer. Samples meeting the criteria show a checkmark and s symbol. Samples that do not meet the set up criteria are not measured on the connected sediment analyzer and receive skipped status.

- The filter you create will be displayed in the central input window. You can set up the conditions for your filter using the four drop down boxes above this central input window. The drop down boxes and their options are, from left to right:

  1 each parameter of the reagent strip, one at a time

  2 a selection of mathematical symbols (less than, greater than, equal to, not equal.)

  3 the Boolean operators AND, OR, and NOT

  4 the possible results for each parameters in arbitrary units (neg, (+), +, and so on).

- Any parameter, symbol, or arbitrary unit you select will be displayed in the central window. You can combine separate conditions for each individual parameter if you wish to create a single complex filter. For example, to select only measurement records with exactly + Bilirubin results and with Ketone results greater than ++,

  1 select BIL, =, and + from the relevant drop down boxes to set up the Bilirubin condition,

  2 select AND to add the Ketone condition,

  3 select KET, > and ++ in the drop down boxes.

  The selection that you made in the above will be displayed as the string “BIL = + AND KET > ++” in the input window.

Each time you select a parameter, a symbol, an operator, or a unit, it will appear in the window, so you can monitor the creation of your filter.

If you set up invalid conditions, the software displays an error message in red below the central input window, and you will not be able to save the filter until you fix the error.

3.4.3 Categories

Figure 10: The Categories tab on the Settings menu

3.4.3.1 Changing the name of category

You can modify the arbitrary names of result categories that are assigned to each pad to fit the conventions of the testing site.

1 navigate to Settings/Categories screen,

2 click into the text boxes and enter the name that you would like the device to display for the semi-quantitative category,

3 click on Save settings to store changes.

3.4.3.2 Turning trace category on/off

There is a checkbox at the front of every parameter that has trace category. Tick the checkbox to turn the trace category on and untick to turn off. Inactive trace categories are gray.

The trace categories are turned on by default.

3.4.3.3 Alternating positive sample status

The conditions of a positive sample status can be adjusted for every parameters. It works just as a slider. The track is the available category names from neg/norm or the lowest volume to the highest arbitrary category. The ranges of negative/positive sample statuses are marked by their green/red frame. By default, the sample status is

negative if the measurement result whitin the norm/neg category for every parameter except ASC and PH. Use the thumb to extend negative sample status.

3.4.4 Functions settings

You can adjust all the data management properties on this tab.

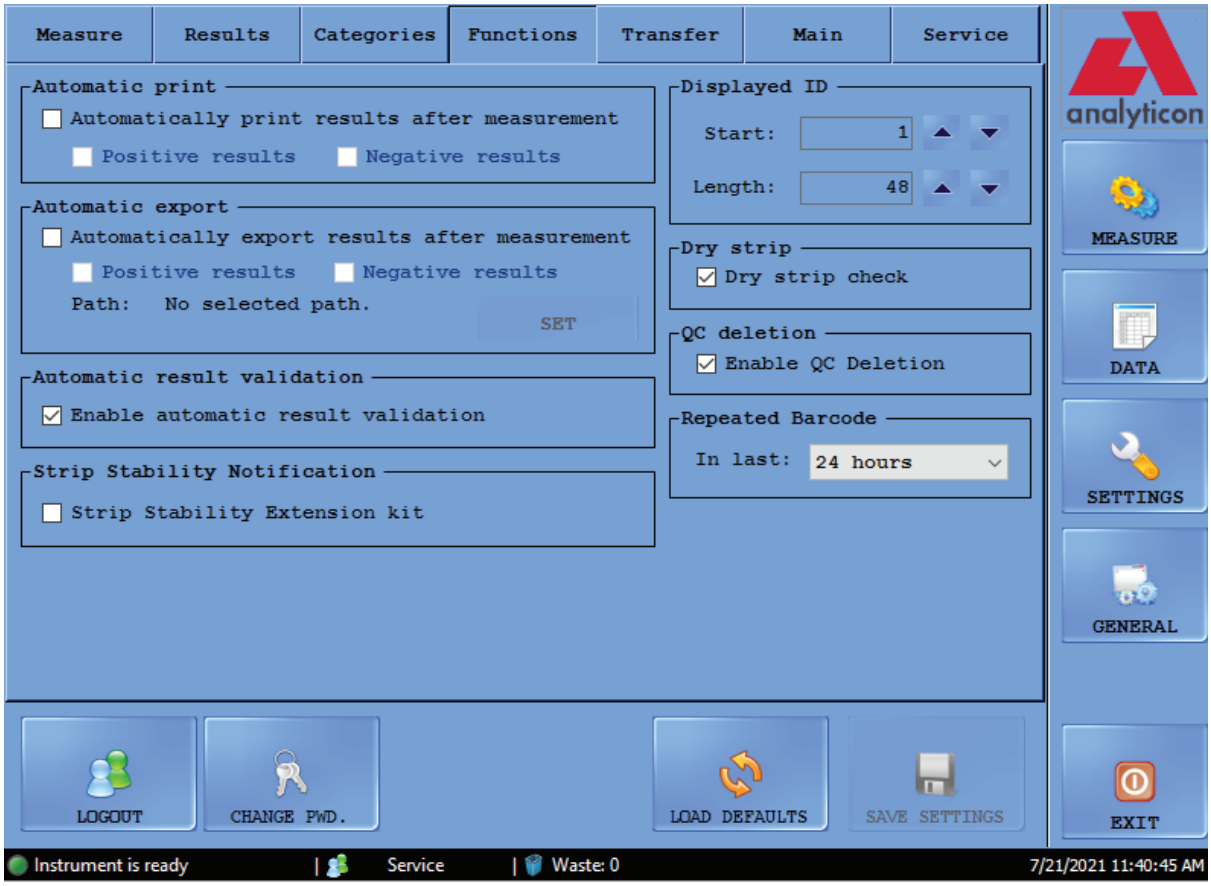


Figure 11: The Function tab on the Settings menu

3.4.4.1 Automatic print

Check this box to make Urilyzer Auto automatically print all measurement records after every finished measurement, regardless of whether the result was positive or negative.

3.4.4.2 Automatic export

Check this box to make the system automatically export all measurement records after every finished measurement, regardless of whether the result was positive or negative. Use the SET button to enter the file path for the export.

3.4.4.3 Displayed ID

Use the Start and Length spin boxes to specify the first character of the barcode that the system recognizes (the default is 1: the complete barcode is processed), and the total number of processed characters in a barcode (up to 32).

3.4.4.4 Dry strip

Check the Dry strip check box to make the system detect whether any of the reagent pads are dry after sample pipetting. If you enable this function, sample records with dry reagent pads will be displayed with X4 status (☞ **6.4 Possible measurement errors**).

3.4.4.5 QC deletion

Check the Enable QC deletion box to allow users to delete QC records from the database.

3.4.4.6 Strip stability notification

Immediately after installing the On-board Stability Kit (see **4.1 Loading strips into Urilyzer Auto**), tick the Strip Stability Extension Kit checkbox. The instrument will send a warning message after one week to check the usability of strips.

The On-board Stability Kit with 100 gramms of desiccant is able to keep the strips stable for maximum14 days at normal room temperature and humidity (20°C, 40% Rh).

3.4.5 Transfer setup

You can set up the properties of the data transfer in this screen area.

- Transfer mode: Select the radio buttons to choose between the unidirectional, bidirectional, LIS2-A2 or HL7 (only available via TCP connection) transfer protocols
- Baudrate: Select the radio buttons to set the speed of the transfer
- TCP settings: Set IP address and port.
- Automatic transfer: Check this box to make the system automatically transfer all measurement records after every finished measurement, regardless of whether the result was positive or negative.
- Allow modification of transferred sample: Check this checkbox to be able to modify results after they were sent to LIS.

Contact your distributor for more information about data transfer protocols.

Transfer setup is only available if you leave the Sediment analyzer box on the Measure tab unchecked.

3.4.6 Main settings

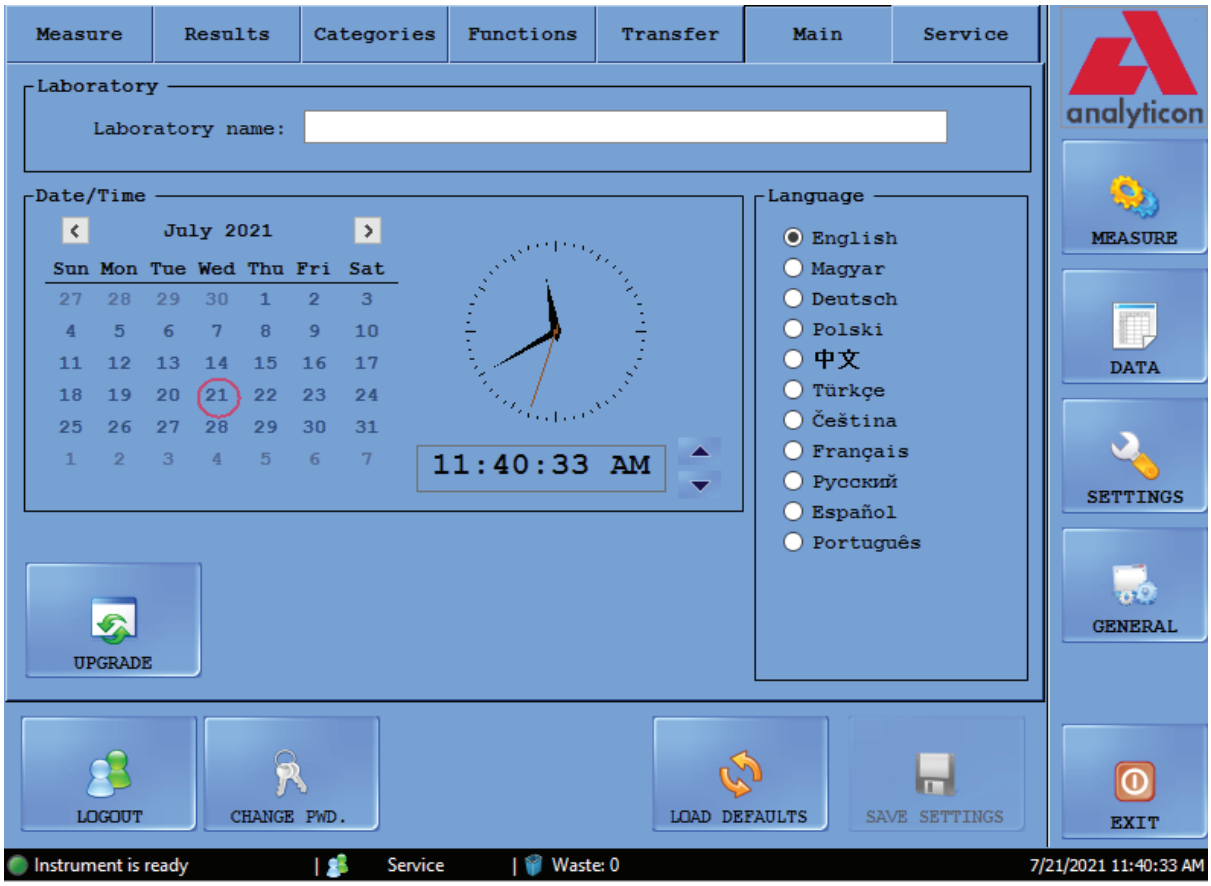


Figure 12: The Main tab on the Settings menu

3.4.5.1 Laboratory

The text you enter into this text box is displayed as laboratory identification on printed reports, in unidir transfer data, and on exported sample reports.

3.4.5.2 Date/Time

Set the current time and date, and your preferred time and date format.

3.4.5.3 Language

Select the radio buttons to set your preferred user interface language. The setting will take effect after you tap SAVE SETTINGS.

3.4.5.4 Upgrade

If a software upgrade is available for Urilyzer Auto, your distributor will send you the new software version. To upgrade the software of Urilyzer Auto, insert the USB stick you received from your distributor in one of the USB ports of the instrument and tap this UPGRADE button. No further user action is required. The upgrade process may take several minutes, after which the system will restart.

The upgrade process will not affect your personal settings.

⚠ **When you first switch on your instrument after upgrading, do not tap any buttons until the "Successful software upgrade!" message is displayed.**

3.4.5.5 Logout

Tap this button to revert to an Operator user account with limited user rights. Operator-level users only have access to the Measure tab of the Settings menu.

After logging out, you will need to enter a valid password to log in as an Administrator-level user.

3.4.5.6 Change password

Tap this button to modify the currently valid password for the user account you are currently logged in to. Only users logged in as Administrators can change the Administrator password. In the popup window that appears, enter the original password, then the new password, twice, for security, and tap OK.

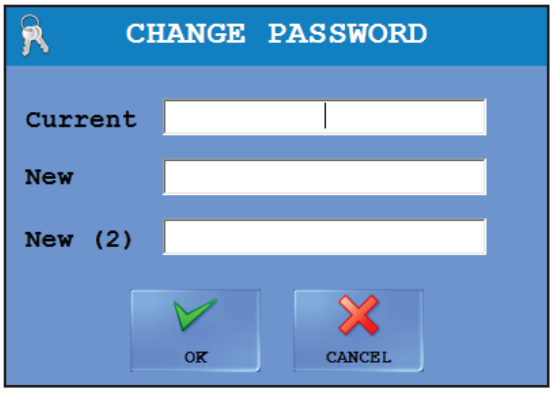


Figure 13: The password change popup window

3.4.5.7 Load defaults

Tap this button to reset all the settings and values you have modified across the complete system to their defaults.

3.4.5.8 Save settings

Tap this button to save the changes you made.

3.5 General

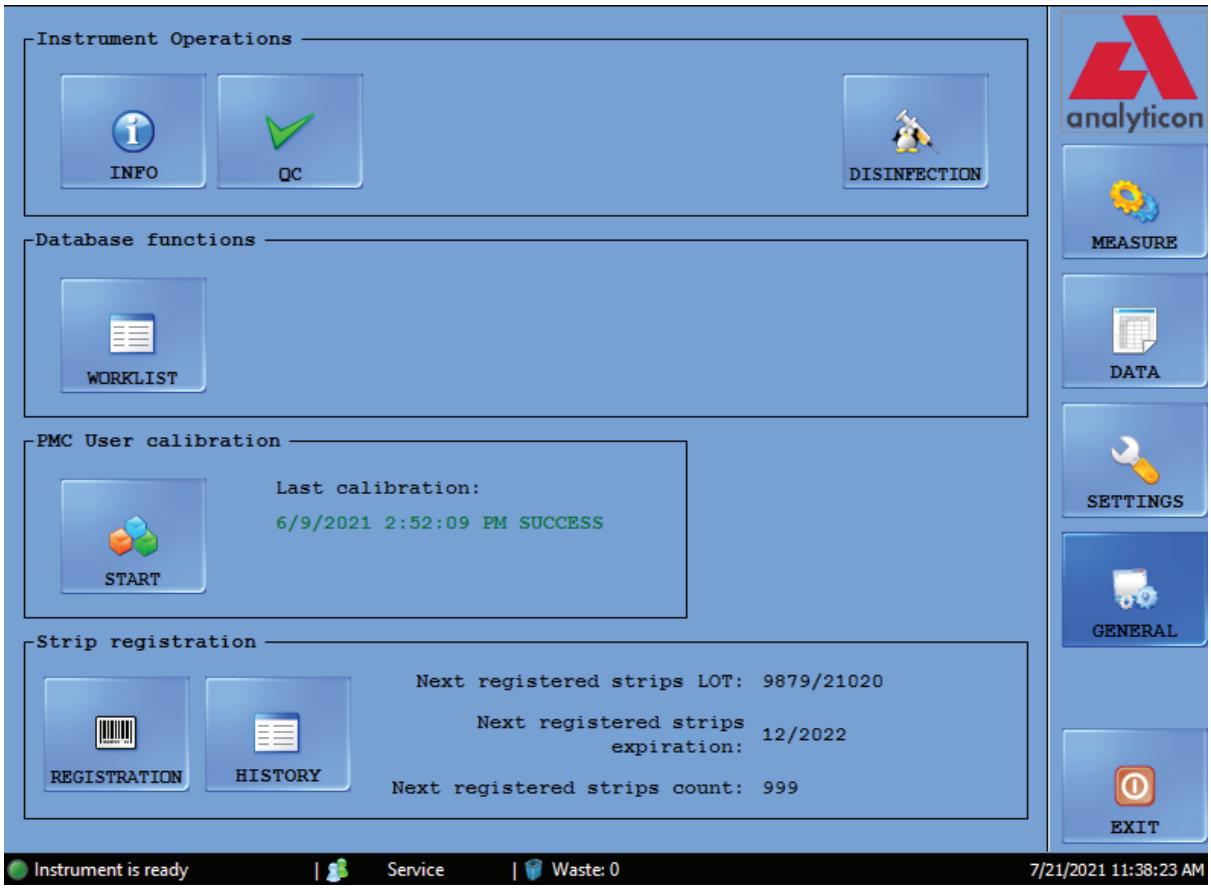


Figure 14: The General menu

3.5.1 Info

This window gathers all software-, and firmware version numbers of different modules currently presented in your Urilyzer Auto.

3.5.2 Quality Control

You can monitor the performance of your Urilyzer Auto using the integrated quality control procedure. All information and parameters concerning quality control measurements are collected on this menu. Tap the QC button to access the quality control settings discussed in the following.

3.5.2.1 Overview of QC

There are two types of control solution within a set: a solution to mimic a normal (Low level) and an abnormal (High level) urine sample. Normal control solutions do not contain any chemical components that the analyzer can detect, while an abnormal control solution – like abnormal urine – contains chemical analytes in a given concentration. During quality control the instrument analyzes first the normal, then the abnormal control solution, and compares the results to the preset analyte concentrations for the given control solution lot. Quality control measurements of Low level and High level control solutions are successful if all of checked parameters are within the set values specified in the limit tables.

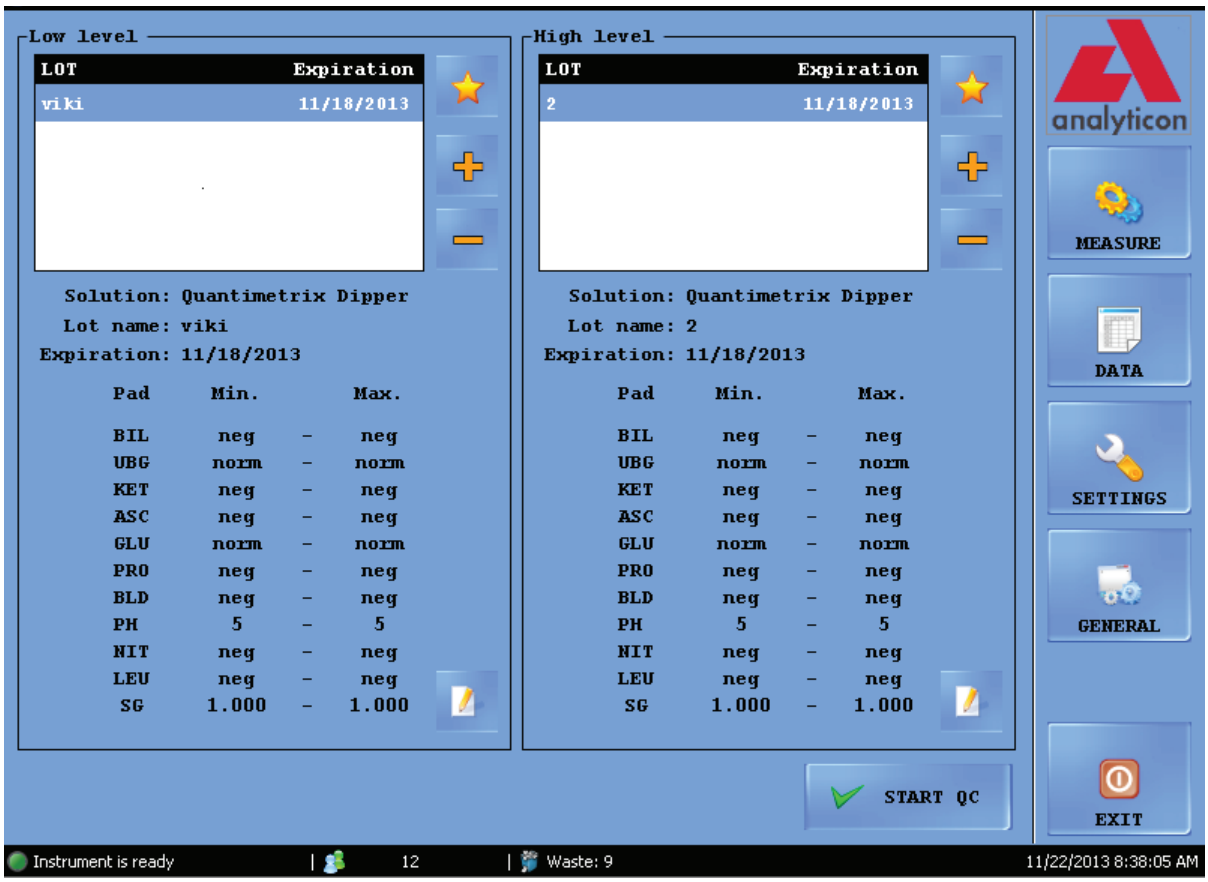


Figure 15: The Quality Control setup menu

3.5.2.2 Quality Control settings

The QC settings menu lets you collect and manage all your quality control solutions in a single place.

1 Tap the  button in the Low Level screen area to start entering the details for a normal control solution in the popup window that appears.

2 Select the type of control solution you are using in the drop-down menu (only the listed control solutions can be used).

3 Find the lot number and the expiration date on the solution packaging or on the package insert, and enter these details.

4 Refer to the acceptance ranges listed on the package insert and enter the minimum and maximum arbitrary values for each of the parameters of the given Low Level solution lot by tapping the spin buttons in the Min. and Max. columns.

The maximum value cannot be lower than the minimum value for any parameter.

5 Save your changes by tapping the green check mark, and complete steps 1–4 for your abnormal control solution.

6 Use the  (edit) and the  (delete) buttons to manage your control solution lots.

If you delete a control lot, all its related quality control records will also be deleted from the database.

3.5.2.3 Starting a QC measurement

The following quality control solutions are compatible with the system:

CombiScreen Dip Check
Quantimetrix Dip and Spin
Quantimetrix Dropper
Bio-Rad Liquichek
Hycor Kova Liqua-Trol

1 Pour at least 2 milliliters of both control solutions two separate test tubes and put them in a rack on the rack conveyor.

2 Select the control solution lot you wish to use in the list. Tap the  button to enable the selected lot. Tap the START QC button.

3 The system will prompt you to insert the test tube filled with the Low level (Level 1) control solution. Then it will prompt you to insert the the test tube containing the High level (Level 2). Insert the rack with the control solutions you prepared and tap OK in the dialog box.

4 The analyzer will switch to the Measure menu and perform the control measurements, identical to urine sample analysis. The records of the two control measurements are named and stored in the database as QC_LOW and QC_HIGH, respectively.

5 When the control measurements are finished, a message will be displayed about whether the control was successful or not. Successful and failed QC measurements are labeled  and  in the sample list, respectively. The success or failure of the QC tests is also listed in their comments.

3.5.3 Disinfection

Disinfection: You can start the disinfection rinsing process with this button. For details, please refer to the **5 Maintenance** chapter.

Disinfection rinsing will completely drain the fluidic system. If you would like to go on working with the analyzer after you perform a disinfection rinsing, make sure that you initialize the system first.

3.5.4 Worklist editor

Worklist: In worklist editor names of the patients can be entered in a list before starting the measurement. During measurement Urilyzer Auto takes the names from the worklist one by one and automatically assigns them to test results according to the names sequence in the list or according to identifying barcodes if this function is enabled. To launch the worklist editor, tap the Worklist button.

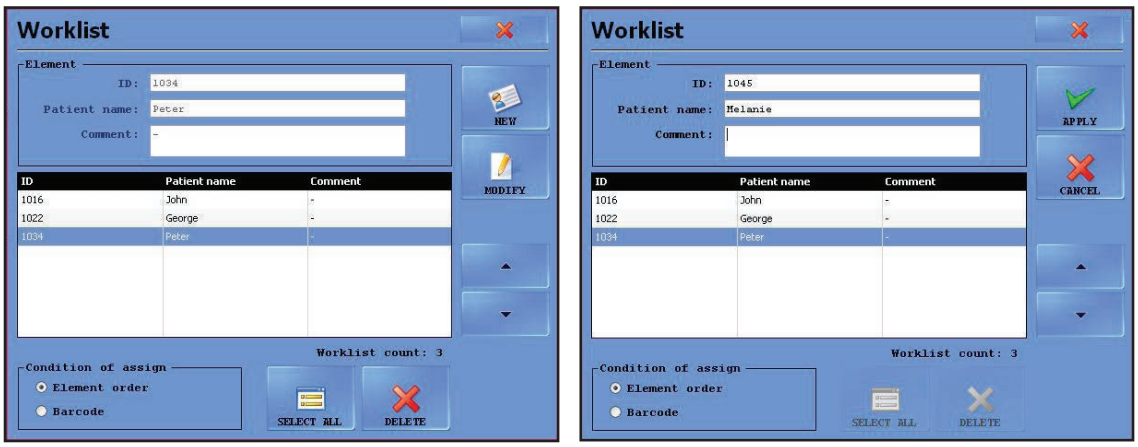


Figure 16: The Worklist popup window with all its function buttons

Key to Figure 16:

- New: New barcode and patient name can be added to the worklist with this button.
- Modify: Selected worklist item can be modified with this button.
- Apply/Cancel: Modifications can be accepted or cancelled.
- Select all: Tap this button to select every item on the list.
- Delete: Tap this button to delete the selected items from the worklist. It can also be set on this panel whether patient names should be assigned to measurement results according to their sequence in the list or according to identifying barcodes. Desired way of assignment has to be selected by the radio buttons.

  Scrolling among the elements can be done exactly the same way as in the data menu. Selection of the elements is also similar.

3.5.5 PMC User calibration

It is recommended to perform PMC User Calibration once a month. Tap the start button to perform calibration on the Physical Measurement Cell using IF water

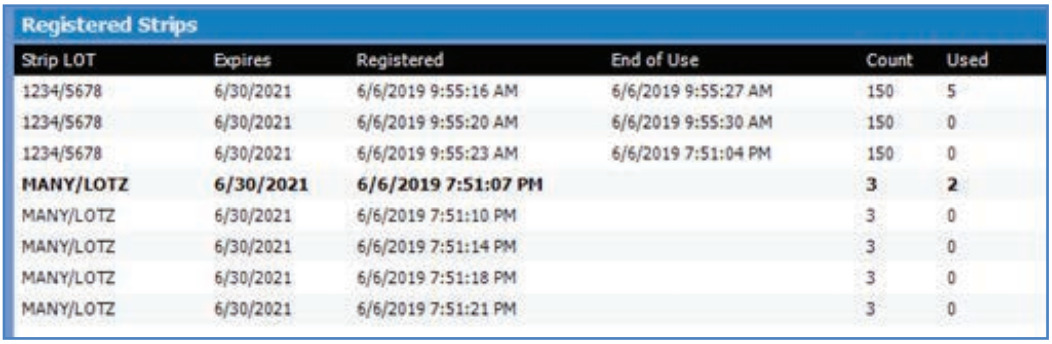
⚠ **Make sure that both liquid tanks are connected to the system before you start the PMC calibration process.**

Tap the START button. The system will measure the specific gravity of the water, compare it to a factory preset, and if calibration is successful, modify its default calibration.

⚠ **If user calibration fails, contact your distributor's technical support.**

3.5.6 History

Tap on **History** button to display the list of registered strips with LOT number, date of expiry, date of registration, last registered strip count and number of used strips.



Registered Strips

Strip LOT	Expires	Registered	End of Use	Count	Used
1234/5678	6/30/2021	6/6/2019 9:55:16 AM	6/6/2019 9:55:27 AM	150	5
1234/5678	6/30/2021	6/6/2019 9:55:20 AM	6/6/2019 9:55:30 AM	150	0
1234/5678	6/30/2021	6/6/2019 9:55:23 AM	6/6/2019 7:51:04 PM	150	0
MANY/LOTZ	**6/30/2021**	**6/6/2019 7:51:07 PM**		**3**	**2**
MANY/LOTZ	6/30/2021	6/6/2019 7:51:10 PM		3	0
MANY/LOTZ	6/30/2021	6/6/2019 7:51:14 PM		3	0
MANY/LOTZ	6/30/2021	6/6/2019 7:51:18 PM		3	0
MANY/LOTZ	6/30/2021	6/6/2019 7:51:21 PM		3	0

Figure 17: Details of registered strips

4 Operation

4.1 Loading strips into Urilyzer Auto

Urilyzer Auto operates with single-use reagent urine strips. Strips are supplied in vials, each holding 150 strips. Before you can start a measurement cycle, you have to load strips into the instrument. You can load up to two vials of strips into the instrument at one time.

On-board stability: The quality of the test strips that you loaded into the analyzer but did not use up is preserved for 24 hours under operational circumstances (☞8 Technical data).

Open up the doors of the unit and take out the strip loader container of Urilyzer Auto by turning it left and pulling out as shown in the pictures below.

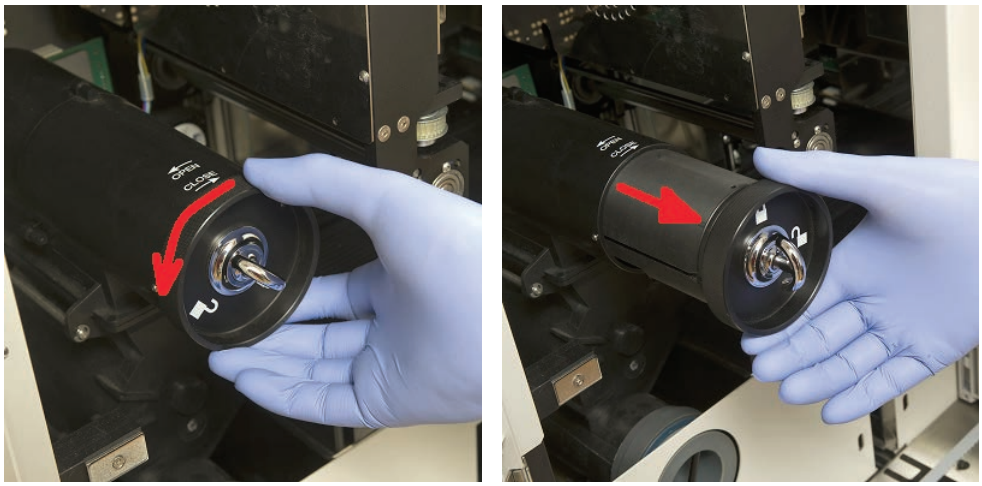


Figure 18: Removing the strip loader cylinder

After removing the strip loader container open the latch by turning it to the right. Pull out the cap.

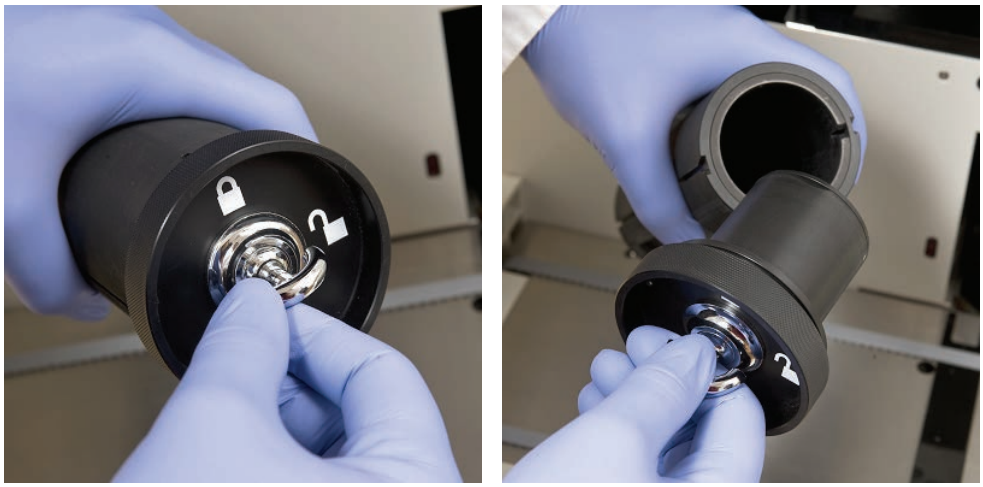


Figure 19: Opening the strip loader cylinder

Pour in the strips from the vial. Place the top of the vial into the cap so the desiccant in it protects the strips from air humidity. Close the container by locking the latch turning it to the left.

Figure 20: Loading test strips and desiccant into the strip loading cylinder

Push back the strip loading cylinder to its original position and turn it to the right to close. (There is only one possible orientation for putting it back and closing it properly.) At the same time the strips are transported from the cylinder onto the strip feeder drum.

⚠ **Do not throw away the strip vial as unused strips should be put back at the end of measuring with Urilyzer Auto.**

- Using the On-board Stability Kit:

  A new spare part for Urilyzer® Auto allows the user to increase the on-board stability of test strips up to 2 weeks. The On-board Stability Kit consist a locking cap and a desiccant holder. Desiccant packs are also needed and are available to order from Analyticon Biotechnologies. The new holder is larger than the one that is part of the instrument and allows the user to place more desiccant into it.

Figure 21: The On-board Stability Kit with desiccant

If you want to use it, finish the strip loading procedure that is described above. After you closed the cap, and the strips fell onto the feeder drum, load new desiccant into the new onboard stability kit's extended desiccant holder. Place the new cap onto it. Unlock and remove the loading cylinder, and open and remove the cap. Replace the regular cap with the new On-board Stability Kit with the desiccant and push the cylinder back to its place and close it. With the use of 100 g of desiccant (2 packs) at room temperature the strips are stable for 14 days.

Later, for the strip loading procedure only, you can use the new cap without the desiccant holder.

The analyzer can be operated only using test strips designed specifically for Urilyzer Auto, and supplied by the manufacturer of the analyzer.

Strips are for single use only. Never re-use test strips.

Do not touch fresh unused strips: contamination can influence the evaluation.

Since urine is a fluid of human origin, it may be infectious and carry biological risks. Handle used strips and urine contaminants with care. Always wear rubber gloves or other protecting equipment when operating Urilyzer Auto.

4.2 Measurement

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

We removed manual measurement mode, thanks to the solution of not to discard 2 strips.

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

Urilyzer Auto requires at least 2 mL of urine sample for accurate analysis results. This amount is enough for approximately two (2) measurements. If you are setting up parallel measurements, make sure that there is enough sample in the test tubes for each measurement.

4.3 Identification of test results

Test results can be identified either by automatically generated ID numbers, by barcodes affixed to test-tubes or by sequence numbers. All identifications can be changed later by renaming records in the “Database” menu using the “Modify” option (i.e. if the barcode was missed or not read properly). Attributes of the possible identifications are concluded as follows:

- Automatically generated IDs: Urilyzer Auto identifies samples by their position. The first three digits of the ID encode the number of the rack, while the second two digits encode the position of the measured sample in the rack. Numbering of the racks can be seen on the racks themselves.
- Identification by barcode: Urine samples can be identified by barcodes if barcodes are affixed to test-tubes. On what type of barcodes can be used and on how they should be applied on test tubes, please refer to the chapter titled “Placing barcodes on test tubes”.
- Sequence numbers: Patient urine samples could be identified as well in the order of the sample tubes put into the racks by a running sequence number. Starting sequence number can be adjusted in Settings/Measure.

4.4 A typical daily routine

It is very easy to operate Urilyzer Auto after it has been set up for normal operation, strips have been loaded into the instrument and the wet system is properly installed. Just follow the instructions listed below to finish your laboratory work without any effort.

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

⚠ **Always wear rubber gloves or other protecting clothing when operating Urilyzer Auto.**

1 Check Waste container and empty, if necessary. Check Wash container and fill with IF water, if necessary. Remove all racks from the rack mover part and switch on Urilyzer Auto with the start button on it right side. User software of Urilyzer Auto starts up, the self-diagnostic procedure is automatically performed and the “Measure” menu appears on the screen.

2 Load test strips into the analyzer. Register the strips, if necessary. Prepare urine test samples in test tubes and put the test tubes in the supplied racks. If your test-tubes are identified by barcode, make sure that the barcodes face the open side of the racks, otherwise the barcode reader will not be able to identify test tubes.

3 Put the racks with test-tubes containing urine samples on the rack mover unit to the right of the little black pins on the right side of test tube driving hole. Take care to place racks on the rack mover unit by facing their open side to the right. Urilyzer Auto automatically ensures correct rack angle right before the rack reaches the test tube driving hole.

⚠ **Fill test tubes with at least 2.0 ml of urine. For the measurement only ~1 ml urine is aspirated, however, bigger amount is needed for performing sampling properly.**

⚠ **If you have not set up the analyzer to automatically export or transfer the measurement results (☞ 3.4.4.2 Automatic export and 3.4.4.6 Transfer setup), you can connect a external printer.**

4 Now Urilyzer Auto is ready to operate. Tap the Start button to start the measurement cycle.

ⓘ *During measurement, the measuring process can be followed on the screen: the date, time, sample position, ID, name and the status of each strip is continuously displayed. The results of the measurements can be studied in the Data menu.*

5 When you are finished, tap the Stop measurement button.

ⓘ *The analyzer will not stop immediately. The test strips that were already pipetted, or were about to be pipetted when you tapped Stop measurement will be processed before the measurement cycle stops.*

6 If the last rack remains inside the test-tube driving hole after finishing measurements, tap the Rack out button to remove the rack.

⚠ **Do not try to remove the racks manually from inside the analyzer.**

7 Tap Empty feeder button and empty the unused strips back to their original tubes and close the tube with its cap. Open the used strip bin on the right side of the analyzer and empty it. It is also recommended to rinse it at the end of each day.

8 To switch the instrument into stand-by mode, tap the Exit button.

⚠ **A disinfectant rinsing procedure is required before you switch off the analyzer at the end of each day (☞3.5.3 Disinfection).**

9 Switch off the analyzer with the main switch on the bottom right casing panel. Clean the instrument at the end of each day (☞5 Maintenance).

4.4.1 Basic operation-related troubleshooting

⚠ **The analyzer will not start or will automatically stop if...**	**...there are no more test tubes to measure.**
	...the database is full.
	...it runs out of strips
	...it runs out of IF water.
	...the used strip bin is full.
	...the waste container is full.
	...the worklist is enabled and all the worklist elements have been processed.
	...the rack mover is full.

⚠ **Urilyzer Auto can be operated only with its dedicated strips supplied by the manufacturer of the instrument.**

⚠ **Never touch the rack mover part during operation if there are racks with test tubes on it.**

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

⚠ **The measuring process is suspended if any problem arises during operation. In case of a failure ☞ 6 Error messages, troubleshooting for advice.**

⚠ **Never switch off the instrument with the main switch on the bottom right casing panel while a measuring process is going on. Always exit the software by tapping the `Exit` button before you switch off the analyzer completely.**

⚠ **Always perform a disinfection procedure before you switch off the analyzer at the end of the day.**

Do not reach into the analyzer under the front doors while it is in operation! Moving parts might be dangerous and could cause injuries (automatic strip-feeder, automatic probe and pipette) if disregarded!

Do not touch the parts of the analyzer that are marked with the ESD (Electrostatic discharge) symbol.

4.5 Operating Urilyzer Auto and a urine microscopy analyzer together

There are a number of advantages of operating a routine urinalysis analyzer such as Urilyzer Auto, together with a compatible microscopy urinalysis analyzer. The most commonly used benefit is that you can immediately have a more detailed analysis of the samples that the routine urine chemistry analysis found problematic.

⚠ **Before you can start operating the two analyzers as a unit, their rack conveyors need to be connected, and their databases need to be linked. Consult your service person if you need advice on how to connect the analyzers or how to maintain the link between the two systems.**

⚠ **Before you can start operating the two analyzers as a unit, you need to link the databases of the two analyzers (☞ 3.4.1.4 Sediment Analyzer and the relevant section of the instructions for use of the sediment analyzer). Make sure that you select the relevant settings on both systems.**

5 Maintenance

In order to prevent contamination Urilyzer Auto must be cleaned adequately. 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 carry biological risks. Handle used strips and urine contaminants with care. Always wear rubber gloves or other protective equipment when operating Urilyzer Auto.

To keep Urilyzer Auto in perfect condition, complete the following steps at the end of each workday:

1 Before switching off the instrument at the end of the day, fill 6 mL of 2 % NaOCl (sodium hypo chlorite) solution into a test tube. Remove all remaining racks with test tubes from the rack conveyor unit and place the test tube with NaOCl solution into a rack all by itself. Tap the Exit button, confirm the automatic rinsing process, and wait until it is finished. This should take about 2 minutes.

2 Switch off the analyzer. Pull out the used strip bin on the right side of the equipment, and empty it. It is recommended that you rinse it with a 2 % NaOCl solution, and then with water at the end of each day.

In case of an extreme clogging (for example because the device had been misused) fill a 5 % NaOCl (sodium hypochlorite) solution instead of a 2 % one.

No measurement can be started while the used strip bin is full.

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

4 Remove the rack conveyor unit 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 it. Nevertheless, immersing the rack mover unit in water is not recommended as flooding damages the bearings inside.

5 Remove the strip pipetting stage and the strip timer comb. Both can be easily removed from inside of the unit.

6 Remove the measuring stage under the measurement head.

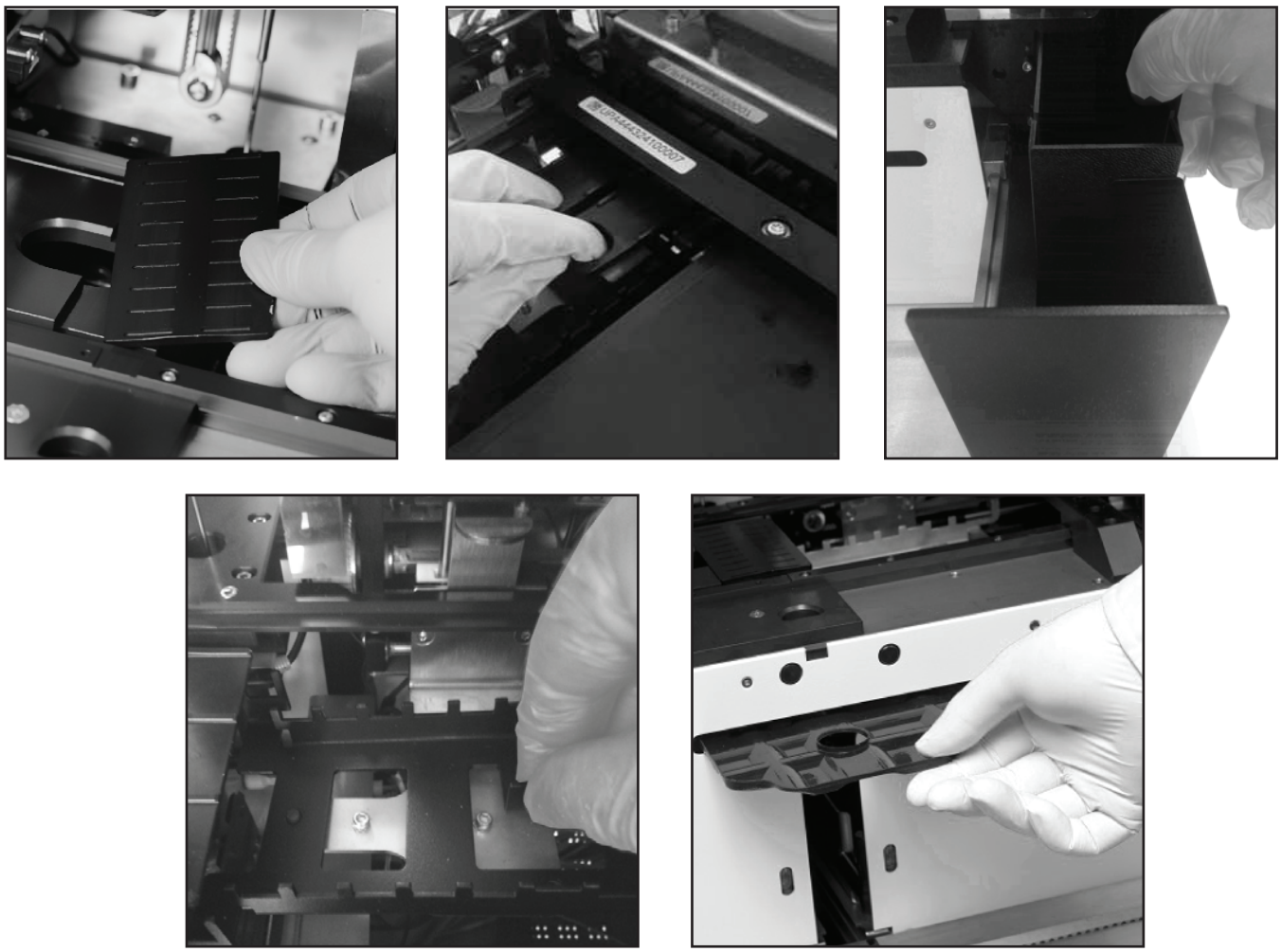


Figure 22: Removing (clockwise) the pipetting stage, the measuring stage, the used strip bin, the drip tray, and the strip timer comb for cleaning

7 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, you can also rinse removable parts in an alcohol– or sodium hypochlorite solution.

⚠ **Do not spray inside the analyzer. Remove removable parts from the analyzer before you spray them. Use a moistened piece of cloth to clean internal parts.**

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

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

8 Pull out and clean the tray under the strip forwarder unit easily with a cloth dipped in a disinfectant solution.

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

⚠ **Never switch off the analyzer with the main switch at the back before the automatic cleaning process is finished.**

6 Error messages, troubleshooting

6.1 Info messages

If an info message from the following list appears follow the troubleshooting instructions and tap “OK”. Some messages disappear immediately if their reasons are resolved.

Find complete list of hardware warning messages in the table below:

Error code	Software info message	Info description
1	There are no logs available.	-
2	Data transfer successful.	-
3	Password has been successfully modified.	-
4	You can open the unused strip bin.	-
5	N/A	-
6	Hardware diagnostic finished.	-
7	Strip registration successful.	-
8	Insert stat sample.	-
9	Level 1 QC measurement passed.	-
10	Level 2 QC measurement passed.	-
11	Attention! Air humidity may damage the test strips in the container. Check test strip performance before doing further measurments!	-
12	sample(s) successfully exported.	-
13	sample(s) successfully transfered.	-
14	sample(s) successfully printed.	-
15	Cannot locate the installer.	-
16	The QC solution is expired	-
17	Don't forget to check the pad reflex rule after changing the trace category options.	-
18	X QC sample(s) are not deleted.	-
19	The specified QC solution isn't supported by the sediment instrument.	-
20	The new QC LOT is expired.	-

6.2 Warning messages

If a warning message from the following list appears follow the troubleshooting instructions and tap “OK”. Some messages disappear immediately if their reasons are resolved.

6.2.1 Hardware warning messages

Error code	Hardware warning message	Warning detail / corrective action
14	Feeding tube not present	Please insert the loading bin! You cannot start the measurement.
16	Unused strip bin not present	Please insert the empty bin! You cannot start the measurement.
19	Feeder is empty.	Please insert strips to the feeder!
22	Water tank warning	Please take care of the washing liquid!
23	Water tank empty	Please fill up the washing bin! You can not start the measurement.
25	Waste tank warning	Please take care of the waste liquid!
26	Waste tank full	Please empty the waste bin! You can not start the measurement.
32	Rack conveyor at maximum capacity	Please empty the measured samples! You can not start the measurement.
33	No rack.	Please prepare a new rack to the rack mover.
36	Door open	Please close the left door! You can not start the measurement.
38	Door open	Please close the right door! You can not start the measurement.
41	Drawer (plate) is out.	Please insert the drawer (plate)! You can not start the measurement.
48	N/A	N/A
49	N/A	N/A
63	Strip timer comb not present	Please insert comb!
64	Pipetting stage not present	Please insert pipetting stage!
79	Excess light at photometer	-
80	LED error in photometer.	-
127	Not enough washing liquid.	
129	Strip not found on pipetting plate.	
139	STAT measurement finished. Please, remove the STAT rack then press OK.	
140	Unsupported measuring head detected.	

6.2.2 Software warning messages

Error code	Software warning message	Warning detail / corrective action
0	Measurement rejected by the sediment analyzer	Make sure that the number of parallel measurements set for the urine sample is the same for both devices
1	Worklist empty	Populate the worklist or disable its use
2	All worklist items completed	Populate the worklist or disable its use
3	Database warning limit is reached.	Free up disk space in the database or enable circular memory
4	Not enough disk space on the removable drive	Free up disk space on the removable drive
5	No removable device present	Connect a USB drive or HDD
6	Auto export path not selected	Select the path for auto export or disable the feature
7	Auto export path does not exist	Define a path for auto export or disable the feature
8	Sediment analyzer not ready	Check the interfaced sediment analyzer
9	Invalid start parameter delivered to the sediment analyzer	Check the interfaced sediment analyzer
10	Sediment analyzer busy	Check the interfaced sediment analyzer
11	Sediment analyzer waste tank full	Check the interfaced sediment analyzer
12	Sediment analyzer out of distilled water	Check the interfaced sediment analyzer
13	Sample count has exceeded the sample limit on the sediment analyzer	Check the interfaced sediment analyzer
14	Cuvette registration required on the sediment analyzer	Check the interfaced sediment analyzer
15	Sediment analyzer cuvette waste bin full	Check the interfaced sediment analyzer
16	All sediment analyzer worklist items completed	Check the interfaced sediment analyzer
17	The current reflex mode setting does not support parallel measurements	Check the interfaced sediment analyzer

Error code	Software warning message	Warning detail / corrective action
18	When the worklist is enabled, no parallel measurements are allowed on the sediment analyzer	Check the interfaced sediment analyzer
19	No user is logged in on the interfaced sediment analyzer	Check the interfaced sediment analyzer
20	When the worklist is enabled, no parallel measurements are allowed	Disable the worklist feature or set the number of parallel measurements to 1
21	At least 1 pad must be enabled	Enable one or more pads in the pad sequence setup
22	Parallel measurements are not supported for generated sample Ids	Set the number of parallels measurements to 1
23	Sediment analyzer busy with QC measurement	Check the interfaced sediment analyzer
25	No LOT activated for every QC level	Activate a LOT number for each QC level
26	All activated QC LOTs must be of the same solution type	Make sure that the active QC LOT numbers come from the same solution type
27	No QC LOT activated	Activate a QC LOT number
28	QC LOT already in use	Set a different QC LOT number
29	Waste bin warning reached	Empty the waste bin
30	QC deletion is not avaiable!	One or more selected items contain QC measurement results. Enable QC result deletion in the User software on the Settings/ Functions tab
31	Low disk space	
32	Device serial number missing	Set a valid device serial number
33	Invalid pad reflex condition setting	Set an applicable and valid pad reflex
34	Parallel measurements are not supported when the sediment analyzer is using sequenced sample IDs	Disable automatic sample ID generation on the sediment analyzer or set the number of parallel measurements to 1
35	Strip registration necessary	Register new strips in the User software on the General menu
36	Level 1 QC measurement failed	
37	Level 2 QC measurement failed	

Error code	Software warning message	Warning detail / corrective action
38	Sample has not been validated yet!	
39	The measured value of the REF pad is reached the warning limit!	Please, clean the reference pad!
40	SG is invalid. (Measure ID: X)	The SG result for the sample is positive while the sample it self is negative. Inspect the results and repeat the measurement if necessary.
41	The category names cannot be the "_" string.	
42	You must initialize the instrument.	
43	The failed sample (X) cannot be validated.	
44	The failed sample (X) cannot be transferred.	
45	The failed sample (X) cannot be printed.	
46	The failed or not validated sample (X) cannot be exported.	
47	The barcode “X” already has a measurement result.	
48	The reevaluation on the following barcodes were rejected: “X”	
49	Low disk space for Diagnostics.	
50	PAD reflex settings are inconsis-tent.	
51	Active QC lot configuration syn-chronization failed.	
52	Measure ID generation modes are inconsistent.	
53	The specified IP address is not valid.	
54	The host IP port is not valid.	
55	Two category names are the same on a pad.	

6.3 Error messages

During operation a control program checks the operational conditions needed for proper execution of each functions. If checking ends with indication of a problem, an error message will be displayed. Error messages are either hardware-related or software errors.

6.3.1 Hardware-related error messages

If a hardware-related error message appears, tap the Init button in Measure window. In some cases this will automatically solve the problem by initializing Urilyzer Auto. If not, try switching the analyzer off and on again – a hardware reset may help to eliminate the problem.

If the error persists, note the Error code of the message and the exact words of the message as they are displayed, and contact product support for assistance.

6.3.2 Software error messages

Error code	Software error message	Error detail / corrective action
0	LIS connection error	Check the LIS system and the connecting cables
1	Error at LIS connection open	Check the LIS system and the connecting cables
2	Upgrade command error	Reboot the application. If reboot is unsuccessful, upgrade the module PCBs in the Service software on the Card setup menu.
3	Flash erase error	Reboot the application. If reboot is unsuccessful, upgrade the module PCBs in the Service software on the Card setup menu.
4	Upgrade file (mhx) error	Reboot the application. If reboot is unsuccessful, upgrade the module PCBs in the Service software on the Card setup menu.
5	Flash memory error	Reboot the application. If reboot is unsuccessful, upgrade the module PCBs in the Service software on the Card setup menu.
6	Upgrade file (mhx) not found	Reboot the application. If reboot is unsuccessful, upgrade the module PCBs in the Service software on the Card setup menu.
7	No processor	Reboot the application. If reboot is unsuccessful, upgrade the module PCBs in the Service software on the Card setup menu.
8	Upgrade flash write error	Reboot the application. If reboot is unsuccessful, upgrade the module PCBs in the Service software on the Card setup menu.
9	File IO error.	Make sure that the removable device is working properly and is not write-protected.
10	Login failed. Incorrect username or password	Login using the correct username and password
11	Database full!	Free up disk space in the database or enable circular memory
12	Cannot export next sample	Make sure that the connected USB device is recognized and that there is available disk space on it
13	Username and password must differ	Choose another password
14	Incorrect previous password	Enter the correct previous password
15	Minimum password length is five (5) characters	Choose a password of at least 5 characters for higher security

Error code	Software error message	Error detail / corrective action
16	Re-entered password does not match new password	Retype the new passwords
17	This username is already in use	Choose another username
18	Username too short	Usernames must be at least 2 characters
19	This username is already in use	Please enter another user name!
20	Username too short	Usernames must be at least 2 characters
21	You may not delete your own account	You can't delete yourself!
22	LIS connection error!	Check the connection to the LIS
23	Quality Control database full	Delete QC data
24	File IO error during logs copying	Check the connected USB device
25	Waste bin full	Empty the waste bin
26	File IO error!	Check the removable device
27	Diagnostic error	Retry the diagnostic
28	Measurement ID is in use	
29	File IO error!	
30	Strip registration code has expired	Register a new code
31	Unrecognized registration code	
32	Registration code not detected	Retry the registration
33	Invalid registration code	Registration code already in use. Use a different code
34	The measured value of the REF pad is reached the error limit!	Please, change the measuring head module!
38	Error on barcode reading!	An error occured during reading the barcode.
39	N/A	N/A
40	The new password must be different from the old one.	
41	Software error during re-evaluation	
42	The worklist item is empty.	
43	The operation cannot be completed, because the instrument is in service mode.	

Error code	Software exception message	Error detail / corrective action
0	Software exception	Reboot the analyzer. If the error persists, contact product support.
1	Database compact failed	Reboot the analyzer. If the error persists, contact product support.
2	Card upgrade error	Reboot the analyzer. If the error persists, contact product support.
3	Invalid measure head	
4	N/A	
5	Failed to create the database.	
6	Unable to connect to the database.	
7	Failed to prepare the database.	
8	Failed to clear the database.	
9	Failed to sweep the database.	
10	Failed to initialize the database module.	

If you cannot solve the problem, or any other error message is displayed, contact product support for assistance. The instrument should be repaired only by specially trained service personnel.

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

6.4 Possible measurement errors

While performing measurements, Urilyzer Auto displays the status of the strips in the Status column on the Measure menu. If the analyzer could not carry out the complete measurement process of a sample for some reason, a red “X” will be displayed in the Status column, with an explanatory code number. Repeat these measurements to get reliable results.

Measurement error code	Error description
X1	Reverse pad order The test strip was loaded into the feeder drum the wrong way around. Repeat the measurement with a properly oriented test strip.
X2	No strip detected Strip lost after sample dispensing.
X3	Strip misaligned The strip lays oblique under the measuring head. Clean the strip clamps, the strip timer comb and the strip measuring plate.
X4	Dry strip or inadequate colour of strip pads
X5	Strip flipped over The strip flipped during the feeding, sample dispensing, or timing process.
X6	Strip not recognised
X7	Overexposed strip
Xt	Quality control measurement failed (control measurement result is out of the set range). Repeat theh QC measurement.
X	Measurement stopped by user / HW or other undefined error

7 Instrument support

7.1 Servicing

- Only qualified and trained experts may repair the analyzer.
- Only original parts which are recommended by the manufacturer can be used as replacement.
- Before you remove the cover of the analyzer for any reason, switch off the analyzer and unplug the power cable.
- Right to make changes is reserved by the manufacturer, therefore slight variances can occur between the description and reality.
- The latest documentations to the certain variants should be obtained from the manufacturer.

8 Technical data

General	
Evaluated parameters	Bilirubin, Urobilinogen, Ketones, Ascorbic acid, Glucose, Protein, Blood, pH, Nitrite, Leucocytes using CombiScreen 11Auto test strips; Specific gravity, Color, Turbidity using the built-in PMC (Physical Measurement Cell) module
Technology	reflectance photometer (wavelengths: 505, 530, 620, 660nm)
Throughput	240 tests/hour
Memory capacity	10 000 results
Dimensions of main unit	
Size	600x560x640 mm (WxDxH)
Weight	55 kilograms
Interfaces*	USB, RS232 serial port, PS2, DVI, Display port
Display	800x600 TFT color touch screen
Power	
Main Unit	100-240V ~ max. 3A, 50-60Hz
Fuse	2xT8A 250V
Operational conditions	
Temperature	+15 °C to +32 °C
Relative humidity	30 % to 80 % (without condensation)
Atmospheric pressure	106 kPa to 70 kPa (equates to an altitude of app. 0–3,000 m)
Storage conditions	
Temperature	+5 °C to +40 °C
Relative humidity	10 % to 85 % (without condensation, limited through the lower and upper limit of the absolute humidity: 0.1 g/m^3 and 25 g/m^3
Atmospheric pressure	106 kPa to 70 kPa (equates to an altitude of app. 0–3,000 m)
Transportation conditions	
Temperature	–25 °C to +60 °C
Relative humidity	max 75 % at 30 °C (24 h)
Atmospheric pressure	106 kPa to 70 kPa (equates to an altitude of app. 0–3,000 m)
Barcode reader	
Identified barcode types	CODE 39, CODE 128, EAN-13, EAN-8, INTERLEAVED 2/5, CODABAR
Min height of identified barcodes	20 mm
Rack	Only racks provided by the manufacturer can be used
Tube	
Min sample volume in tube	2 ml (checked by liquid level sensor)
Urine homogenization	Stirring by sample mixing
Height (if tube is conical)	70–110 mm
Height (if tube bottom is linear)	70–105 mm

Diameter at the top of tube	16–17.5 mm
Max. diameter at the top of rack (56 mm above bottom of tube)	16.5 mm
Type	CombiScreen 11Auto

Parameters	Bilirubin, Urobilinogen, Ketones, Ascorbic acid, Glucose, Protein, Blood, pH, Nitrite, Leucocytes
Package	150 pcs/vial
Max. strip load	300 pieces (2 vials)
Washing system	
Washing liquid in container	IFW (Instrument Feed Water) Maximum microbial content: 1000 CFU/mL Maximum conductivity: 1 µS/cm (25 °C) Maximum silicate content: 0.1 mg/L CLSI standard: July 2006 (C3-A4 Vol. 26 No. 22)**
Volume of containers	5 liters
Washing liquid consumption	min. 300 measurements can be performed with 5 l Instrument feed water (IFW)
Washing solution for daily cleaning of Urilyzer Auto	Min. 6 ml, 2 % NaOCl solution in one test tube
Waste bin	
Waste bin size	app. 300 measurements

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

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

9 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
	Date of manufacture
	Manufacturer
	Warning: Indicates a potentially hazardous situation that if not avoided could result in personal injury.
	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
	Caution: Indicates a potentially hazardous situation, that, if not avoided, could lead to damage to the instrument or compromised analysis results.
	Indicates important information or useful tips on the proper use of the analyzer.