Urilyzer® 500 Pro

analyticon

User Manual

Analyzer for CombiScreen® 11SYS Plus and CombiScreen® 11SYS urine test strips

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If this instrument is used in a manner differently than specified in this manual, the protection provided by the equipment may be impaired.

CE

REF UL0500Pro

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Contents

1. Introduction

1.1 Intended Purpose

The Urilyzer® 500 Pro is a semi-automatic urine test strip analyzer and provides semi-quantitative parameter concentration values in human urine. The analyzer evaluates dedicated CombiScreen® system urine test strips for preliminary screening.

The product is designed for professional use as an in vitro diagnostic medical device.

1.2 Indications for Use

The Urilyzer® 500 Pro urine test strip analyzer is a bench top IVD designed to be used exclusively with CombiScreen® 11SYS PLUS and CombiScreen® 11SYS urine test strips manufactured by Analyticon Biotechnologies GmbH.

CombiScreen® multiparameter urine test strips

The system indicates the pH and Specific Gravity (SG) of the urine samples and performs the semi-quantitative measurement of relevant properties of the following urine analytes:

Bilirubin (Bil), Urobilinogen (Ubg), Ketones (Ket), Ascorbic Acid (Asc), Glucose (Glu), Protein (Pro), Blood (Bld / Ery), Nitrite (Nit), Leukocytes (Leu).

The system provides a screening test for the early detection of the following conditions:

- Liver disease
- Biliary and hepatic obstructions
- Carbohydrate metabolism disorders including Diabetes Mellitus
- Haemolytic disease
- Urological and nephrological diseases associated with haematuria or haemoglobinuria
- Diseases of the kidneys and the urinary tract
- Pathological shifts in the pH value.

ⓘ *For more detailed information about the urine test strips, please refer to the test strip's instructions for use.*

1.3 Limitation of use

Do not use the semi-quantitative results, that the device provides to make diagnostic or therapeutic decisions without additional analysis.

The device was developed and manufactured for human diagnostics use only (original function). The manufacturer excludes all liability arising from or in connection with any use of the device, that is different from its original function.

1.4 How to use this manual

The User Manual contains all instructions to unpack the analyzer, for safely use during daily urinalysis and to keep it in good working condition.

Symbols and formatting conventions

This manual uses the following symbols to highlight important information:

Symbol	Explanation
	CAUTION: This symbol indicates maintenance procedures, operations and other processes that can cause personal harm or equipment malfunction, equipment failure or damage to the equipment if the instructions are not followed carefully. This symbol is also used to highlight situations that can compromise results. **Caution text appears in bold type.**
	BIOHAZARD: This symbol indicates maintenance procedures, operations and other processes where hazardous biological agents are present. Instructions are to be followed carefully to avoid personal injury and/or adversed health effect. **Warning text appears in bold type.**
	NOTE: This symbol indicates important information or useful tips on servicing the device. *Notes appear in italic type.*

1.5 Safety precautions

Before operating the Urilyzer® 500 Pro, it is essential that the operator reads and understands the warnings, cautions, and safety requirements contained in this manual.

⚠ Detailed safety information can be found in ☞*Appendix D: Safety information* section.

⚠ User qualification: Only appropriately trained operators are qualified to operate the analyzer.

⚠ Correct use: Any disregard of the instructions in the User Manual may result in a safety risk. Use the Urilyzer® 500 Pro to analyze urine samples only. It is not intended for any other application.

⚠ Environmental conditions: The Urilyzer® 500 Pro is approved for indoor use only. See ☞ *4. Unpacking & Setup* and the labelling symbols on the exterior of the analyzer for further environmental limitations.

⚠ Handle with care during shipping, the analyzer may be heavy.

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

1.6 Approvals

The Urilyzer® 500 Pro system meets the requirements laid down in:

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

RoHS Restriction of hazardous substances The Urilyzer® 500 Pro system meets the requirements laid down in: Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Compliance with the applicable regulation and directive(s) is provided by means of the Declaration of Conformity.

2. Quickstart

1. Unpack the instrument and place it on an even, hard surface (for detailed installation instructions see ☞ ***4. Unpacking & Setup***). Insert the drop tray, the strip timer rake and the test strip tray.
2. Connect the power supply and turn the analyzer on with the On/Off-switch (See ☞ ***Figure 12: Powering up***). After the first boot-up procedure and self-test the Start-Up Wizard will appear (See ☞ ***6. Start-Up Wizard***). After all further powering on the Measurement screen will show up on the display.

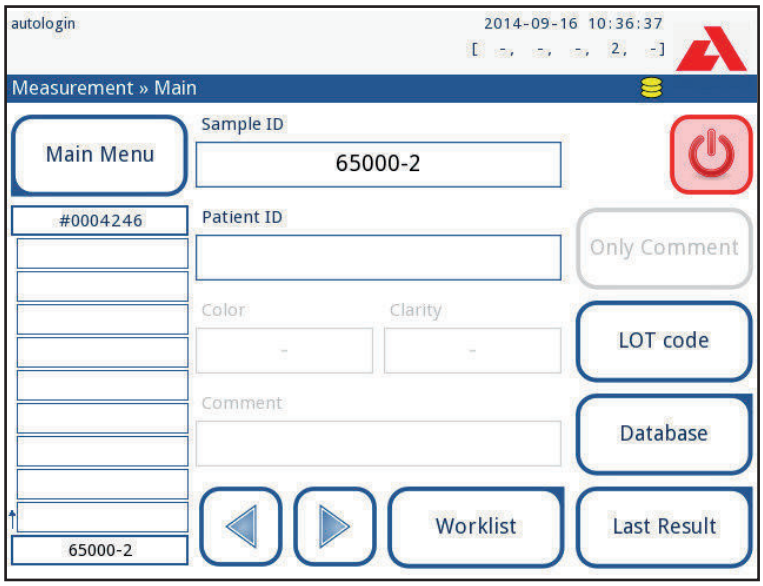


Figure 1: The Measurement menu

3. Dip a CombiScreen® 11SYS Plus or CombiScreen® 11SYS test strip into the urine sample for approximately one second.

⚠ **Do not touch the test pads on the test strip.**

4. Blot by touching the edge of the strip to a paper towel to remove excess urine. Place the strip on the Test Strip Tray in the strip entry area.

⚠ **The instrument automatically detects the placed strip, and the strip timer rake will drag it towards the photometer, starting the measurement cycle.**

5. Repeat steps 3–4 with each of the urine samples. The real-time progress of each of the strips in the list is monitored on the left of the ***Measurement*** screen.
6. The last result can be checked by tapping the Last Result button or by accessing the Database screen.

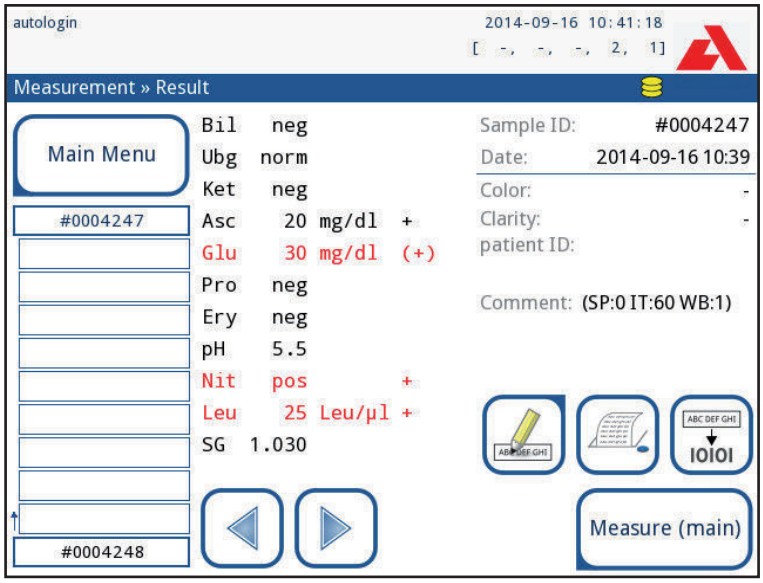


Figure 2: The Result menu

*Refer to **8.5 Further actions with selected items** to delete measurement records.*

– Tap the **Printer** symbol to print the displayed record

– Tap the **Transfer** button to transfer the displayed record to an external analyzer according to the current transfer settings

– Tap the **Measure** button to return to the Measure screen. Start further measurements at any time by placing a test strip dipped in a urine sample.

– Tap the **Edit** button to modify the details of the record

The Edit button is only active if the result has not yet been printed or transferred.

– To access the last test result tap the **Last Result** button on the ***Measurement*** screen.

3. System description

3.1 Principle of operation

The test strip is moved below a moving measurement unit along the test strip tray by the strip timer rake. The photometer unit has an embedded reference pad. The analyzer reads the reference pad, followed by each of the test pads on the strip.

The photometer unit contains four LEDs that emit light at discrete wavelengths. Figure 3 summarizes the electro-optical pad reading process.

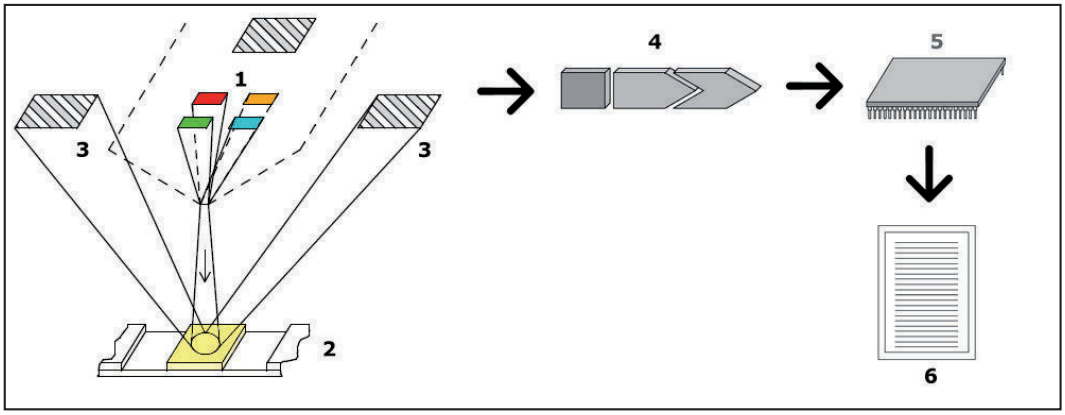


Figure 3: Principle of measurement

Each LED (1) emits light of a predefined wavelength onto the surface of the test pad (2) from directly above the test zone. The test zone is a 3 mm circle in the center of each pad where the reaction is optimal. The light from the LEDs is reflected back from the test zone with more or less intensity. The intensity of the light is directly related to the concentration of the particular analyte in the urine that the pad absorbed. Photodiode detectors (3) positioned at optimum angles pick up the reflected light. The analogue electrical signals from the detectors are first boosted by an amplifier (4) before they arrive at the microcontroller (5). Here the A/D converter in the microcontroller changes the analogue signal into digital values. The microcontroller converts the digital data into an absolute reflectance value by comparing it to a calibration standard. Finally, the system calculates an evaluation value from the reflectance values, compares it to the predefined range limits, and produces a semi-quantitative result (6).

A lead (incubation) time of about 55-65 seconds between the test strips coming into contact with the urine and the start of the measurement produces the most accurate results. The movement pattern of the strip timer rake is calibrated to delay the transport of the strips, and thereby to automatically ensure an optimal lead time.

3.2 Components & Functions

Figure 4: Analyzer front

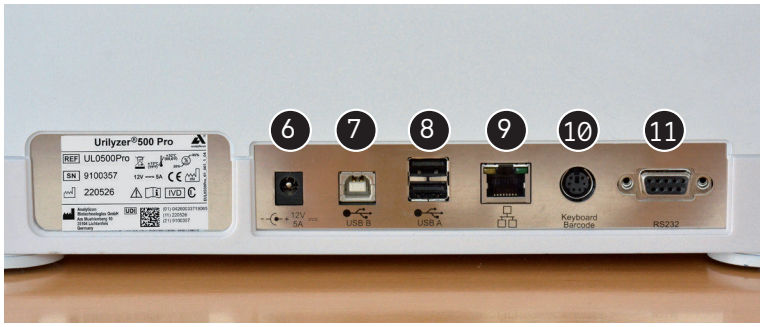


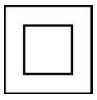
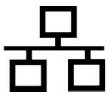
Figure 5: Analyzer back

Component	Function
1. Printer cover	Flips up to receive printer paper
2. Printer cover button	Opens the printer cover when pressed
3. Capacitive touch screen	Serves as interface with the user
4. Test strip tray	Keeps the test strips in position during incubation timing and photometry
5. On/Standby switch	Switches the unit on and off
6. Power socket	Allows connection to the AC adapter
7. Type B USB socket	Allows connection to various USB-B peripherals
8. Type A USB socket	Allows connection to various USB-A peripherals
9. Ethernet socket	Allows connection to an Ethernet network
10. PS/2	Allows connection to a keyboard or a barcode reader
11. Serial interface	Allows connection to a PC or a host computer

⚠ Always connect external devices to their designated connector only. If any external device is connected to a connector it was not intended for, the device or the analyzer may be damaged e. g. because of wrong voltage. Check all cables to make sure they are operational. Verify the proper connection.

3.3 Instrument and Labeling Symbols

The following symbols appear on the device, its AC Adapter and its packaging:

	Double insulated product or transformer. May also identify class 2 equipment (power supply only)		Indoor use only
	Catalogue number		The CE mark indicates that the product complies with the applicable directives of the European Union
	Indicates that 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 includes the same level of testing requirements		Indicates that this equipment is classified as Waste Electrical and Electronic Equipment under the European WEEE Directive. It must be recycled or disposed of in accordance with applicable local requirements
	Indicates that the instrument is listed by Underwriters Laboratories as meeting U.S. and Canadian requirements for safety		Stack no more than four (4)
	Unique Device Identifier		Humidity limitation
	Protect from sunlight and heat		Keep away from rain
	Ethernet port symbol		Caution, consult accompanying documents
	In vitro diagnostic medical device		Consult instructions for use
	Manufacturer		Serial number
	Country of origin of the goods		Date of manufacture
	Handle with care		USB port symbol

	Temperature limitation		DC Adaptor Polarity Centre Positive
	Atmospheric pressure limitation		This way up
	Direct current		Caution, consult accompanying documents
	MAC address		

4. Unpacking & Setup

4.1 Unpacking

⚠ **Read the Urilyzer® 500 Pro User Manual carefully before installation to ensure proper operation of the analyzer from the outset.**

⚠ **Follow the specified installation instructions carefully. Otherwise, inaccurate results or damage to the analyzer may occur.**

Check the carton and instrument for visible signs of damage; if seen, contact the carrier immediately.

Carefully remove the contents of the shipping carton, remove each of the wrappings and check for the following items:

List of delivered parts:

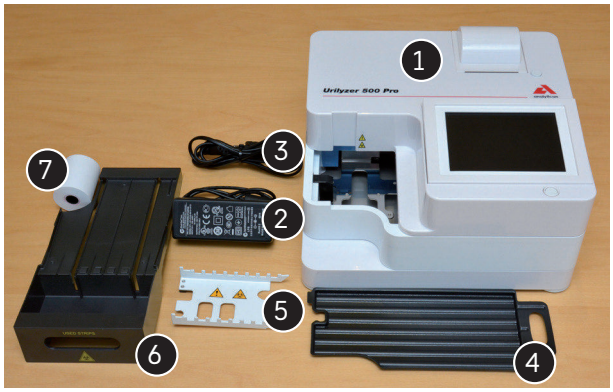


Figure 6: Delivered parts

– Urilyzer® 500 Pro (1)

ⓘ *Urilyzer® 500 Pro is tamper-evident: There is a tamper-evident sticker on a screw on the bottom of the device. Operational elements of the device cannot be accessed without breaking the sticker.*

ⓘ *If the tamper-evident sticker is broken, the warranty your company provides for the device is cancelled. Follow your company's guidelines.*

– Power supply (IN: 100V–240V AC, 50-60Hz, OUT: 12V DC; 5A) (2)

– Power supply cord (3)

ⓘ *If the power cord is not the style needed, contact your service representative*

– Quick Reference Guide

– Drop tray (4)

– Strip timer rake (5)

– Test strip tray/waste bin (6)

– Roll of printer paper (7)

– Grey check strip

⚠ **Do not touch the test area of the check strip. Only touch it by its handle.**

4.2 Setting up

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

- Set up and operate the analyzer on a solid level surface in an environment with fairly constant temperature and humidity.
- Do not operate the analyzer in close proximity to sources of intense electromagnetic radiation (such as unshielded intentional RF sources).
- Do not expose the measuring head to intense light such as direct sunlight.
- Do not set up and operate the analyzer in an environment with vibration sources. Make sure that the strips sit and travel smoothly and stay level on the test strip tray at all times.

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

⚠ **Make sure that there is enough room at the back of the analyzer for easy connection and disconnection of power supply and peripherals.**

⚠ **Do not put anything on top of the analyzer while it is in operation. Objects placed on top of the analyzer may damage the touchscreen and block the printer cover.**

4.2.1 Plugging in the analyzer

Figure 7: Plugging in the analyzer

⚠ **Use only the AC adapter provided and always plug it into a grounded socket.**

1. Plug the cable of the power supply into the power inlet socket located on the rear of the Urilyzer® 500 Pro.
2. Plug the appropriate end of the power cord into the power supply.
3. Plug the other end of the power cord into a readily accessible AC electrical wall outlet.

ⓘ *The instrument is easy to connect and disconnect to the power supply because of the simple standard connectors of the power supply adapter.*

4.2.2 Inserting the drop tray

Handle the drop tray by its handle. Insert the pan with its hollow side up into the opening under the touch screen from the right. Slide the drop tray inside the analyzer until it is held tight by its friction fit flap.

Figure 8: Inserting the drop tray

⚠ **Always insert the drop tray first, before the strip timer rake and the test strip tray/waste bin.**

4.2.3 Inserting the strip timer rake

Figure 9: Inserting the strip timer rake

Touch the strip timer rake by the two fingerholes in the middle, and place it on the metal bracket inside the cavity to the left of the touch screen. Make sure that the tines of the comb are facing up and that the end with the pointed tines is facing towards the LCD touch screen. Position the comb so that it sits snugly on the metal bracket, held tight by the two rubber pins on the bracket.

⚠ **Always insert the strip timer rake before the test strip tray/ waste bin.**

4.2.4 Inserting the test strip tray/waste bin

Figure 10: Inserting the test strip tray

Handle the test strip tray/waste bin by the handle on the right-hand side of the analyzer, below the LCD touch screen. Insert the strip tray with the waste bin cavity facing up into the opening under the LCD touch screen from the right. Push the test strip tray inside the opening until its handle panel is flush with the analyzer casing panel.

⚠ **Make sure that the strip timer rake and its bracket is in a low enough position so that it does not prevent the insertion of the test strip tray. If necessary, push down on the bracket to make room for the test strip tray.**

4.2.5 Loading the printer

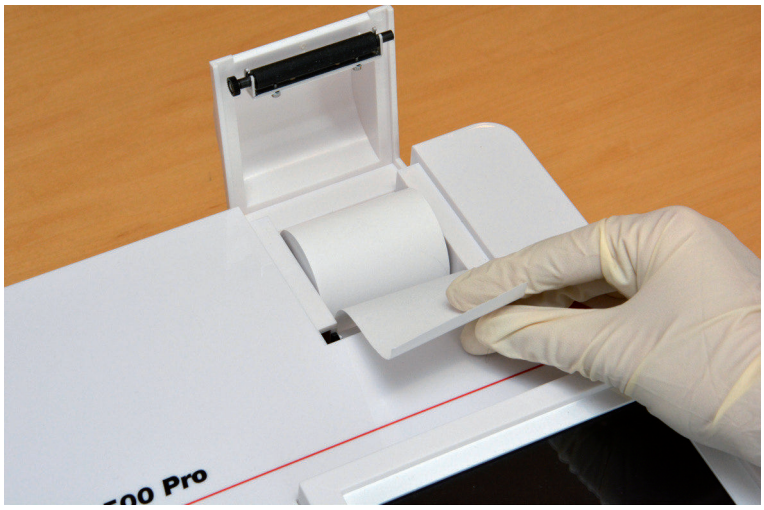


Figure 11: Loading the printer paper

Press the printer cover button to open the printer cover.

⚠ **Do not touch the printer head. It may be hot.**

Place a roll of thermal printer paper into the printer roll compartment. The roll should sit straight inside the depression in the bottom. Position the loose end of the roll so that it comes up towards the printer head, not towards the rear of the analyzer. This should en-

sure that the paper is aligned properly. Let a few centimeters (about an inch) of paper hang over the edge of the compartment, and close the printer cover until click.

To remove the printed test report, tear off the paper by pulling it towards the front across the edge.

The analyzer is set up to print the results automatically (to turn off the automatic print function see ☞ **7.4.2 Customizing the analysis process**

4.2.6 Interfacing with a computer

The instrument can send results to a computer via the serial port located on the back of the analyzer. This requires a D-sub 9-pin serial cable (male on instrument side, female on PC side). It is even possible to transmit data via an Ethernet cable which connector is located on the back of the analyzer.

Connections:

Urilyzer® 500 Pro		Host (PC pinout 9-pin)
1		1
2	TxD	2
3	RxD	3
4		4
5	GND	5
6		6
7		7
8		8
9		9

Connected PC must satisfy the electrical safety requirements laid down in EN 60950.

4.2.7 Powering up

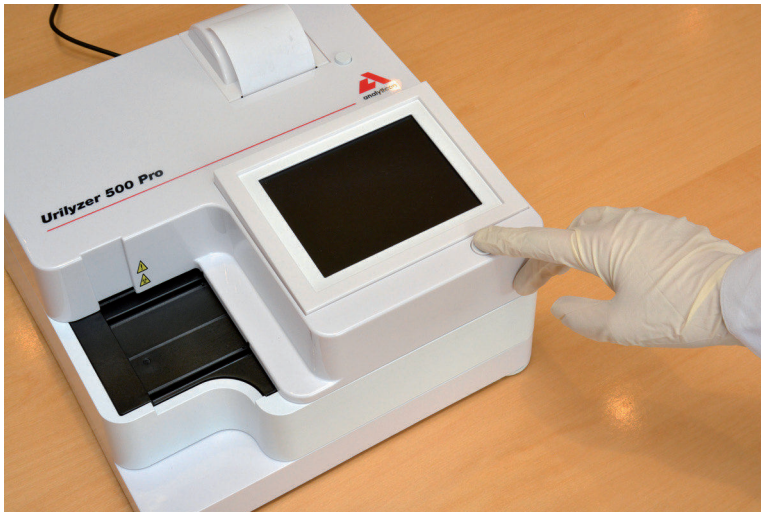


Figure 12: Powering up

To power on the analyzer, firmly press down the ON/Standby button in front of the touch screen. Keep pressing down the button for a few seconds. The system starts up with an audible beep and runs a self-check.

4.2.8 Powering down

Do not remove the power cable while the analyzer is in operation, otherwise the data may be corrupted or the system may be compromised.

Before turning the analyzer off, always ensure that there is no strip on the test strip tray and that the tray is clean.

The analyzer is switched off by tapping the button on the ***Main Menu*** , the ***Measurement*** or on the ***Login*** screen.

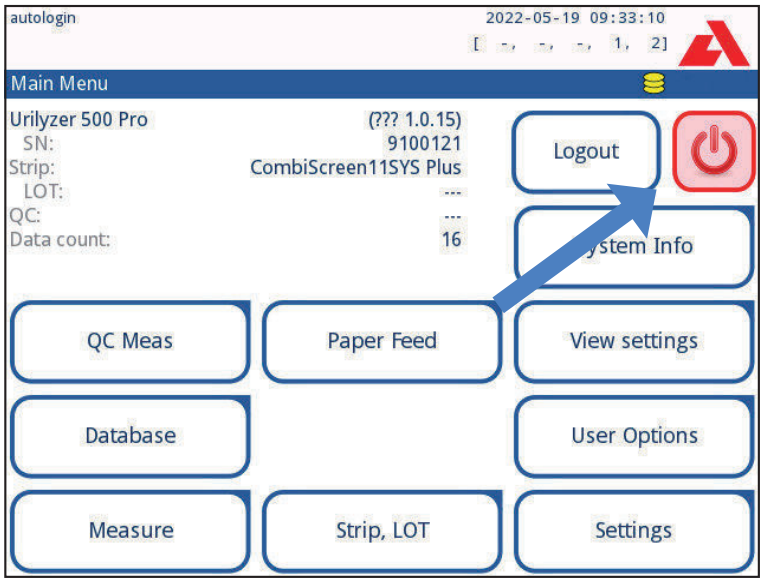


Figure 13: Powering down (1)

We recommend to switch off the analyzer and unplug the mains adapter from the AC wall socket at the end of each day.

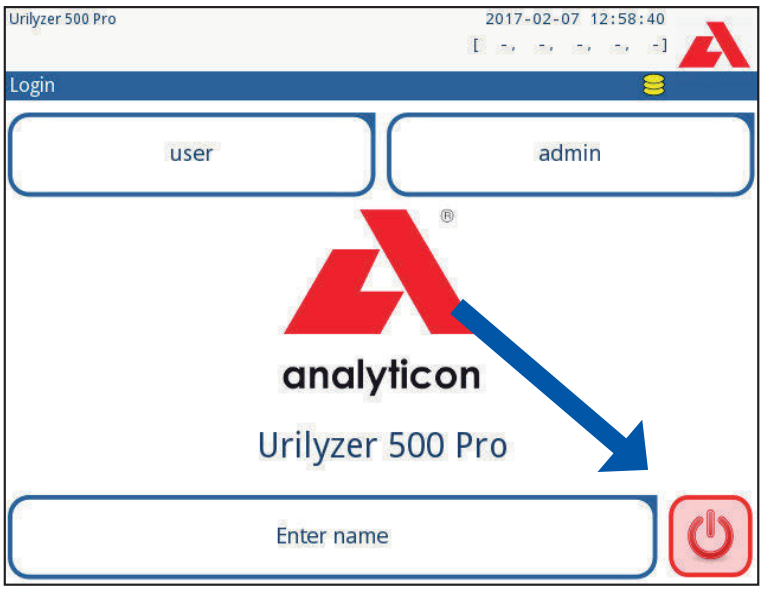


Figure 14: Powering down (2)

4.3 Analyzer software updates

ⓘ *Only Administrator and higher access level operators can run a software update.*

The manufacturer is continuously upgrading the Urilyzer® 500 Pro user software, adding new features and improving usability. From time to time the manufacturer will send a software update for the device. The following sections describe the software update procedure:

ⓘ *The update process will not overwrite or delete the existing database or the active settings on the analyzer.*

4.3.1 Preparation of the USB flash drive

1. Create an 'update' directory in the root folder of the USB flash drive.
2. Unzip the software update package and copy it into the 'update' directory.

⚠ **The device will not be able to access the update files unless they are located in the root folder of the USB flash drive in a folder named 'update'.**

ⓘ *The file names will be similar to these: ur5_x.x.x.tar.gz, ur5_x.x.x.tar.gz.chk (x are replaced with numbers). The file types have to be like this after unpacking the zip-file:* ***.tar.gz*** *and* ***.tar.gz.chk****, otherwise the Urilyzer® 500 Pro device won't be able to recognize the update files.*

4.3.2 Procedure of the software updates

1. Switch on the Urilyzer® 500 Pro and wait until the system is ready.
2. Plug the USB flash drive with the software update into one of the USB A connectors at the back of the analyzer. Wait for a (disk) icon to appear in the top right hand corner of the touchscreen.

ⓘ *The yellow disk icon indicates that the system recognized the USB device.*

3. On the ***Settings » Update*** screen, wait for the **Update** button to light up and tap it to start the automatic update process.

ⓘ*The system detects the software update package and verifies its contents before the Update button becomes active. If no update is detected, the Update button changes to Refresh. Tap it to force the system to check the peripherals again for updates.*

4. Tap **Restart** when the update process is finished and remove the USB flash drive.

⚠**The flash drive can be removed safety by tapping and pressing down for a few seconds on the logo in the top right corner of the display. The logo will turn grey and the disk icon will disappear.**

5. Interacting with the analyzer

5.1 Screens

The system displays messages, instructions and options to choose from the touch screen to operate the analyzer.

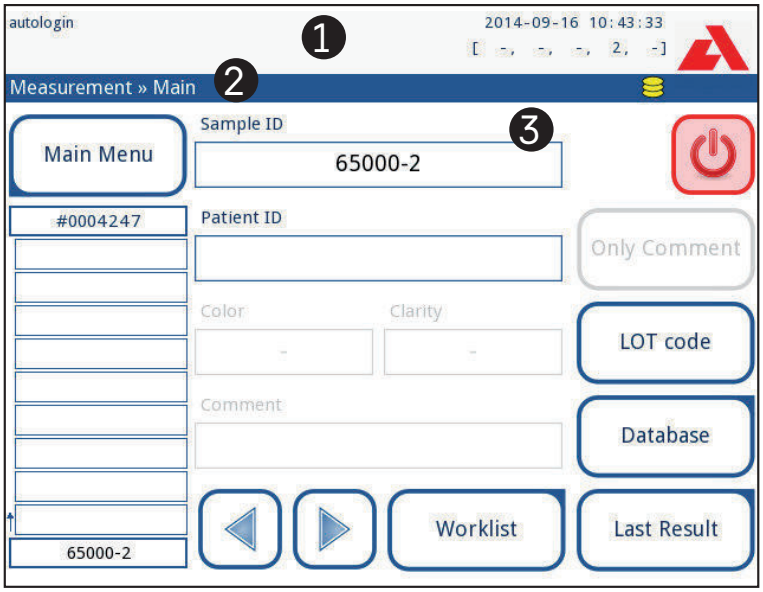


Figure 15: Touch screen layout

The screen layout can be divided into three main areas:

(1) Header: Displays important system information such as the date and time, the current operator ID, queue, and status line messages. The five placeholders below the date and time in the header indicate, from left to right:

- the number of active errors
- the number of records in the printing queue
- the number of records in the transfer output queue
- the number of items on the worklist
- the number of processed test strips in the used strip bin

ⓘ *The background color of the status bar is a basic notification about the system's status. It turns yellow to indicate a warning message and red to indicate an error.*

ⓘ *The active errors and warnings can be listed by tapping the status bar area.*

(2) Content navigation bar: Indicates the current section of the system. The navigation bar shows the track of the location within the menu structure. '»' is the hierarchy separator character.

(3) Content area: The primary operation area of the touch screen.

5.2 Touchscreen operation

How to touch the display

The touchscreen can be operated with bare fingers or gloved fingers. Tap the touch screen gently but firmly in a touch-sensitive area to get a response. Generally, the screen areas that have frames around them respond to tapping: buttons, check boxes, radio buttons, and text boxes.

⚠ **The touch screen display is made of glass. Do not touch the screen if the glass is cracked or shattered. Glass screens are sensitive to drops and mechanical shocks.**

ⓘ *A separate foil layer is attached to screen in order to prevent liquid from leaking into the system.*

ⓘ *Sound effects are enabled by default and the system confirms successful tap events with a short clicking sound.*

5.2.1 Buttons and screen input areas

Buttons

The rectangular buttons are used to trigger actions and to navigate in the menu. The boxed areas vary in size. To show clearly that a button is also used for navigation purposes, it has an additional button indicator.

 Indicator in the bottom left corner: The button closes a screen and moves back to an upper level in the menu hierarchy.

 Indicator in the top right corner: The button opens a new screen and moves down in the menu hierarchy.

Special buttons

 Apply

 Drop

 Inactive buttons are dimmed

Selection buttons

 Up

 Down

 Left

 Right

Up and down buttons are also used to scroll through lists.

Left and right buttons are also used to cycle through values.

Navigation buttons

 Back

 Next

 Drop modifications and Back (Drop & Back)

 Apply modifications and Next (Apply & Next)

To confirm the performed changes on the **User options** or a **Settings** screen first tap **Apply** and leave the screen with the **Back**.


Drop

Changes are still not saved


Apply


Back

No changes or changes are saved

Check boxes

Check boxes are used when an option can be enabled or disabled (e.g. **Autostart**) or the user can select one or more options from a set of alternatives (e.g. QC options: **forced QC, L2, L3**)

Radio buttons

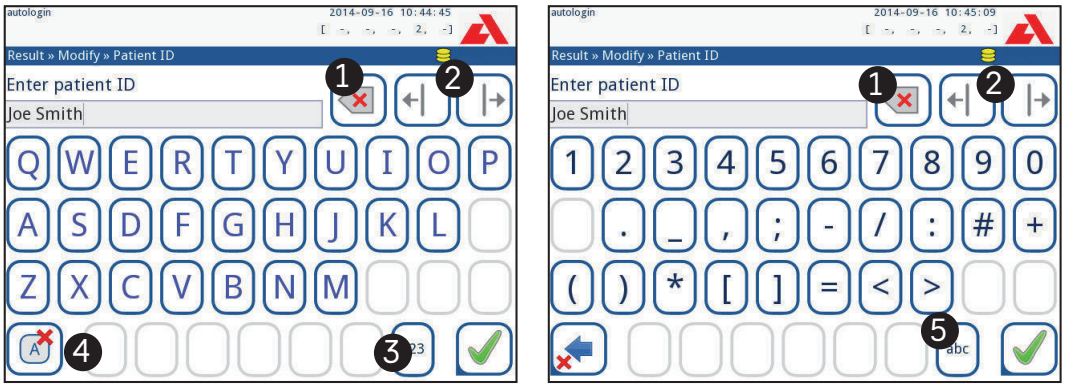
These buttons typically appear on screens that require a selection out of several items. Tap an empty button to select it. A dot in the middle of the button will indicate that it is now the selected option.

5.2.2 Entering data via the touchscreen

The virtual keyboard will be displayed when the user is prompted to enter a user name or password, and when the user taps inside a Sample ID, Patient ID or Comment text box.

The system masks passwords (substitutes all but the character with asterisks) for security.

The virtual keyboard has an alphabetic layout. The user can enter letters, numbers and symbols one at a time. The entered characters are displayed in the input box above the character keys (☞ ***Figure 16***). Tap backspace (❶) to delete the most recently entered character. Use the cursor arrows (❷) to position the cursor, indicated by a grey vertical line, to a specific character in the string. Use the input mode switch keys (❸, ❹, ❺, and ❻) to switch the displayed character set to a numeric, lowercase and uppercase set, respectively. An extended set of punctuation symbols is also available (❼).



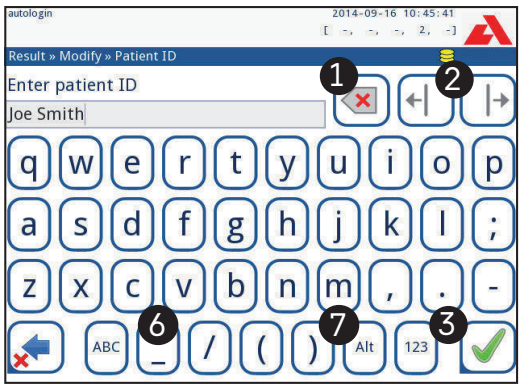


Figure 16: The touch screen keyboard character sets

5.2.3 Entering data via a barcode reader or a keyboard

A barcode reader can not only speed up the sample management process, but the accurate data entry also reduces transcription errors.

Using a barcode reader

⚠ **Make sure that the external barcode reader supports ALT (alternate) mode, and select the ALT input mode before connecting the reader to the analyzer.**

Connect the barcode reader to the PS/2 or USB port at the rear of the device. Barcode readers can be used to enter the following information:

- Operator name during login
- Sample ID
- Patient ID
- QC LOT number
- QC target values
- Test strip LOT number.

ⓘ *No external power is necessary. The barcode reader interface powers the reader.*

The following barcode reader model has been successfully tested with Urilyzer® 500 Pro: Newland HR 3280-S5 2D Imager (Part number: A93025)

Using a standard PC keyboard

Connect the keyboard to the PS/2 or USB port at the rear of the device.

When an input field (Sample ID, Patient ID, Operator ID, and so on) is active, no keyboard shortcut is needed to enter data in the system. Press ‘Backspace’ to delete characters and ‘Esc’ to cancel the input and move back to the previous screen. Press ‘Enter’ to accept the entered value and to move on to the next screen.

A keyboard can also be used to navigate between screens or to perform actions as an alternative to using the touchscreen.

Press ‘Ctrl’ to display the keyboard shortcuts on the screen. The relevant shortcuts will appear in the top left corner of the buttons.

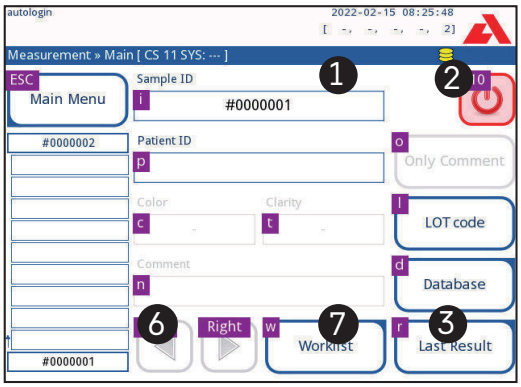


Figure 17: The Main screen with keyboard shortcuts displayed above the onscreen buttons

Another option is to cycle through the onscreen buttons using the ‘Tab’ key. Every time the button ‘Tab’ is used, a crosshairs pointer will move one button to the right, indicating the targeted button. Press ‘Shift’ and ‘Tab’ together to move the crosshairs to the left and ‘Enter’ to select the targeted button or text box.

6. Start-Up Wizard

The first time the Urilyzer® 500 Pro device is switched on, a Start-up Wizard is displayed. Here the user is able to customize the basic options of the device. The Start-up Wizard can be skipped on the second screen.

ⓘ *It is recommended that a supervisor-level user (☞ **11.15 Operators**) should complete the Start-up Wizard and set up the system, so that all the features and functions can be customized.*

The **Start-Up Wizard** will allow the selection of the following settings:

- Language
- Date and time (☞ ***11.2 Date, time***)
- System security (☞ ***11.15.3 Managing security settings***)
- Change 'supervisor' operator password (optional: depends on selected security level)
- Testing workflow (☞ ***7. Analyzing samples***)
- Printout (☞ ***11.3 Printout***)
- QC (☞ ***9.1 QC Options***)
- Add operators (☞ ***11.15.1 Managing operator accounts***) (depending on the level of system security)

ⓘ *Tap **Skip** on the second screen to skip the wizard and configure the settings at a later date.*

ⓘ *For further instructions how to change the settings see ☞ **11. Instrument Settings**.*

When the setup wizard is finished, tap **Start** to exit the wizard.

All active settings can be reviewed on the ***Main Menu » View settings*** screen. All settings, including connectivity (**Output**) can be modified on the ***Main Menu » Settings*** screen.

7. Analyzing samples

Depending on the needs of the laboratory, there are a number of workflows the user can choose from.

– Quick analysis using automatically generated sample IDs (☞ ***7.1 Quick analysis***)

– Analyzing samples using user-entered sample IDs

  • Analyzing individual samples

  • Analyzing samples from a worklist

– Analyzing barcoded samples downloaded from a LIS

The analysis process and the processing of the results itself can be customized individually. (☞ ***7.4 Customizing the analysis workflow***).

⚠ **Follow the European Urinalysis Guidelines (available online at *http://www.escmid.org/fileadmin/src/media/PDFs/4ESCMID_Library/2Medical_Guidelines/ESCMID_Guidelines/EUG2000.PDF*) when handling and preparing urine samples for analysis.**

ⓘ *For more detailed information regarding use and storage of test strips, please refer to the test strip's instructions for use.*

7.1 Quick analysis

After switching on the analyzer displays the ***Measurement*** screen.

ⓘ *The **Measurement** screen is also accessible via the **Main** and the **Database** screens.*

⚠ **The test strip tray, the strip timer rake, and the drop tray have to be correctly loaded into the analyzer to start measurements. Prepare a sufficient number of fresh CombiScreen® 11SYS Plus or CombiScreen® 11SYS test strips, the urine samples and paper towels for blotting excess urine before starting analysis process.**

⚠ **Do not use damaged test strips.**

1. Dip the test strip into the urine sample, wetting all pads. Immediately remove the strip from the urine.

2. Drag the edge of the strip against the side of the sample container.

⚠ **Touch test strips by their handles – do not touch the analyte pads.**

3. Blot by touching the edge of the strip to a paper towel to remove excessive urine.

4. When a continuous green light comes on at the strip delivery zone, place the test strip on the test strip tray, inside the strip delivery zone, with the test pads facing up.

⚠ **Place the test strip inside the strip delivery zone with its handle facing straight away from the back of the analyzer.**

⚠ **Do not place new strips in the strip delivery zone when the LED is red. Wait for the green LED signal to place the next dipped strip.**

⚠ **Do not place more than one (1) test strip at a time anywhere on the test strip tray.**

5. The instrument detects test strips automatically, indicated by the rapid blinking of the green LED in the strip delivery zone and the measurement cycle is started. Repeat steps 1 – 4 until all the samples are processed.

ⓘ *A measurement cycle can be stopped by tapping* **STOP**. *The strip timer rake will sweep all remaining test strips from the test strip tray into the waste bin and the* ***Main menu*** *screen will be displayed.*

ⓘ *During the measurement cycle, while a Sample ID is highlighted in yellow in the measurement queue on the left of the* ***Measurement*** *screen, the user can add Color and Clarity data and comments to the record of the highlighted sample. After the yellow highlighting is moved to another strip, the user can add data to the record by accessing the Database.*

ⓘ *Tap the* **Last Result** *button to display the most recent result that the system processed (it refreshes automatically).*

ⓘ *The analyzer automatically starts the measurement after 60 seconds incubation time.*

7.1.1 Adding Color and Clarity data

– **Color:** To select the visually determined color of the urine sample tap the appropriate button. After selection the next screen is displayed.

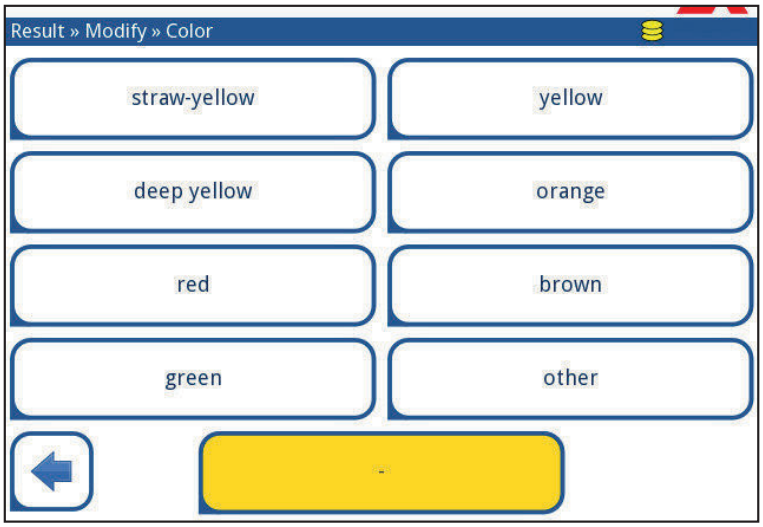


Figure 18: Sample color options

– **Clarity:** To select the visually determined clarity of the urine sample tap the appropriate button. After selection the next screen is displayed.

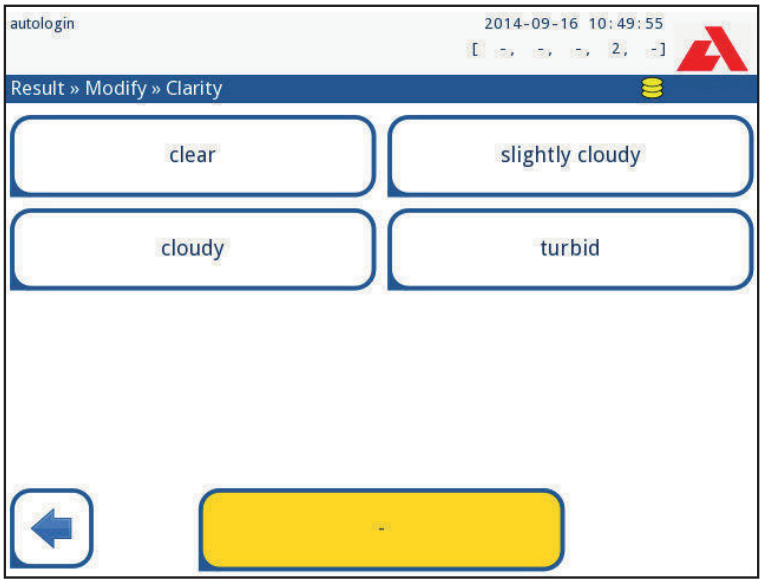


Figure 19: Sample clarity options (Settings»Clarity list)

ⓘ *Only one color and clarity type can be selected for a given urine sample*

ⓘ *The color and clarity selection lists can be customized (☞* ***K.11 Editing the color and clarity list****).*

7.1.2 Strip checking events

Errors in the sample handling and testing procedure may lead to false results. In order to further improve the diagnostic decision-making process, Urilyzer® 500 Pro offers advanced strip-detection features.

The results of mechanical analysis failures fall into three categories:

R1. Measurement has not started

R2. Result is saved with a warning message

R3. Result is saved with an error message

The analyzer automatically recognizes the following events during testing:

Feature	Outcome	Time of action
(partially) dry strip	R2/R3 (based on a user setting ☞)	after testing
upside-down strip	R3	during measurement
background light too strong	R2/R3	during measurement

– If the result is saved with a warning message, the pad values are listed and the code and the description of the flag is inserted into a new comment field of the result. Use the "**with comment**" filter in the database to find results with a warning flag (☞ ***8.6 Filtering: Finding specific results***).

ⓘ *This filter will also return results with comments added by users.*

– No analysis data is stored for records saved with an error message. Use the "**false meas.**" filter in the database to find results with an error code (☞ ***8.6 Filtering: Finding specific results***).

7.2 Analyzing samples with user-entered sample IDs

7.2.1 Analyzing individual samples

1. Prepare the samples (☞ ***7.1 Quick analysis***), dip a test strip into the first urine sample and start a measurement.
2. While the strip timer rake is transferring the dipped test strip towards the measuring head, tap the Sample ID input box and enter a sample ID.

ⓘ *If the samples are barcoded, the barcodes can be scanned at this stage to instantly enter the relevant ID.*

3. Complete steps 1–2 above for each of the samples.

ⓘ *It is possible to add color and clarity data or comments to the samples during the measurement cycle, while a Sample ID is highlighted in yellow in the measurement queue on the left of the* ***Measurement*** *screen.*

7.2.2 Analyzing samples from a worklist

1. Refer to ***7.5.1 Generating a Worklist*** and create a worklist.

ⓘ *Worklists can include only a single sample ID and a Patient ID for each entry on the list. Further information can be added to the entries in the worklist after the worklist has been processed (☞* ***8. Recalling results****).*

2. Prepare the samples from the worklist and make sure to prepare enough fresh CombiScreen® 11SYS Plus or CombiScreen® 11SYS test strips for each of them.
3. Refer to ***7.1 Quick analysis***, dip a test strip into the first urine sample on the worklist and start a measurement by placing the test strip inside the strip delivery zone.

7.3 Analyzing samples downloaded from a LIS

1. On the ***Main Menu » Settings » Output*** menu, select LIS2 (ASTM+) as the active output option.
2. Access the Worklist menu (***Figure 22***) via the ***Measurement » Worklist*** menu and tap the **Download worklist from LIS** button.

*The LIS must comply with the effective LIS2 specification (☞ **11.4.1 Bidirectional protocol (LIS2-A2)**).*

3. Complete steps 2–3 in ***7.2.2 Analyzing samples from a worklist*** to perform the analysis.

7.4 Customizing the analysis workflow

7.4.1 Autoprint and autotransfer

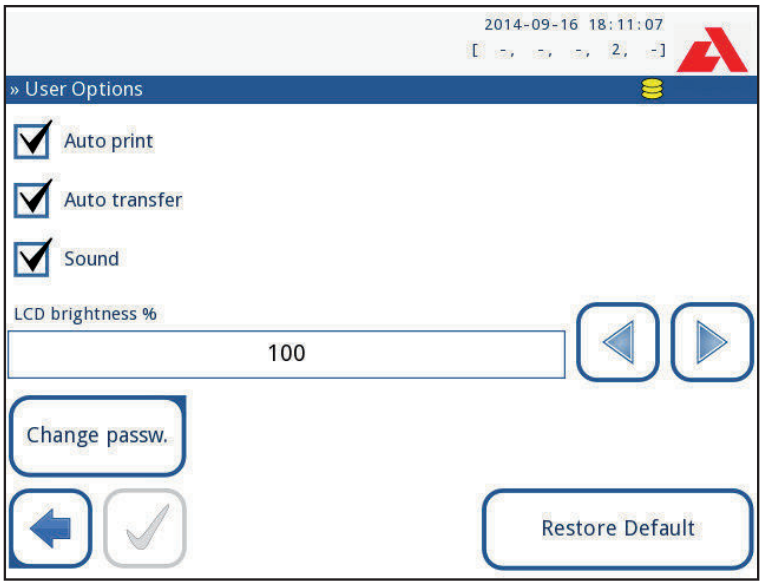


Figure 20: The User Options screen

The measurement features can be modified on the ***Main » User Options*** screen.

– **Auto print:** When enabled, the analyzer automatically prints the report of each measurement.

Auto print is enabled by default.

– **Auto transfer:** When enabled, the analyzer automatically transfers the result to the defined output (i.e. through the serial port to a LIS).

Auto transfer is disabled by default.

These features can be modified by any operator and stored separately for each operator.

– **Change password:** by tapping the **Change password** button the user can modify the password.

7.4.2 Customizing the analysis process

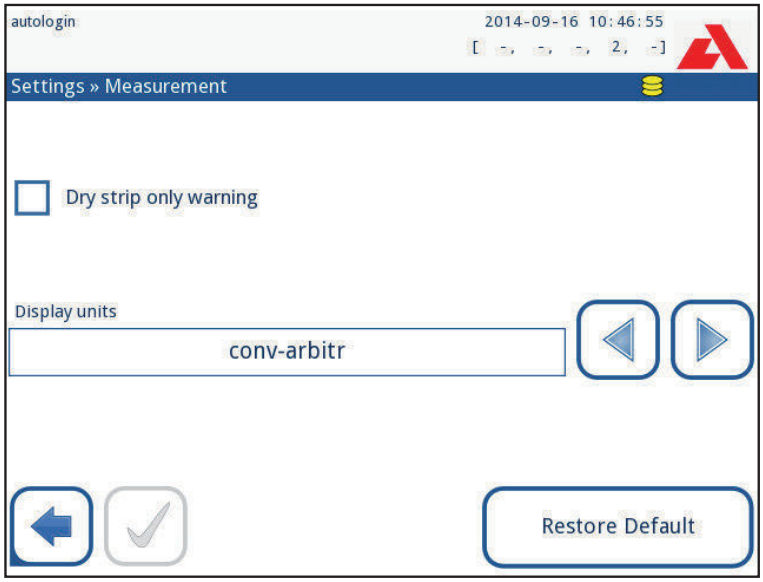


Figure 21: Settings»Measurement

On the ***Settings » Measurement*** screen the user can allow analysis of (partially) dry strips and set the units the results are displayed in.

By default all extra fields are disabled and the display unit is set to conv-arbitr.

Dry strip only warning

If enabled, the result of a (partially) dry strip with pad values is saved in the database with a warning comment. If disabled, an error code is stored in the database for the given record instead of the pad-specific measurement results.

Display units

The default display units can be changed. Available options: conv-arbitr, SI-arbitr, conv, SI, arbitr. Use the **left** and **right** arrows to change the value.

7.5 Worklist management

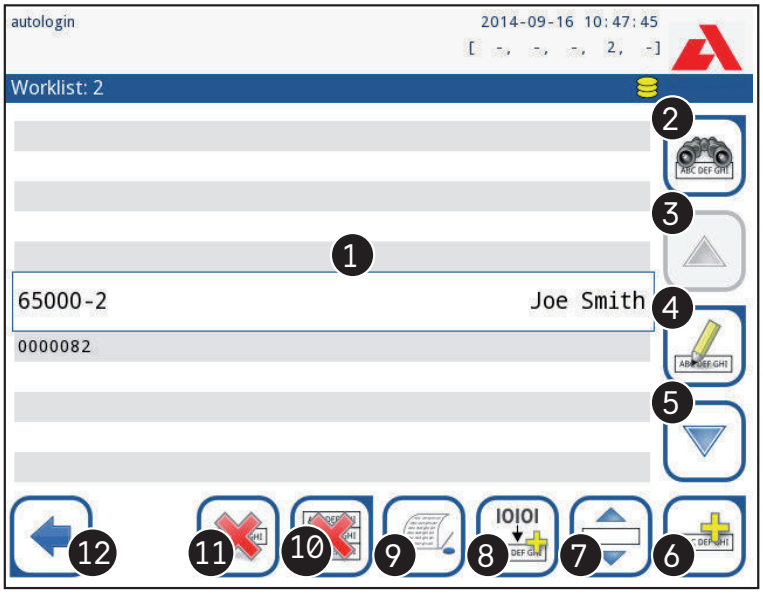


Figure 22: The Worklist menu

The worklist is a predefined sequence of samples and contains the sample IDs and patient IDs in the sequence of planned evaluation.

Tap the **Worklist** button on the ***Measurement*** screen to go to the worklist management.

On the ***Worklist*** menu following settings are available:

- Manually add, modify, delete the worklist items
- Download the worklist from the LIS
- Modify the sequence of the items
- Search for a sample ID in the worklist
- Print the worklist
- Delete the whole worklist

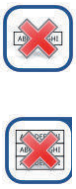
Key to Figure 22:

1. Worklist items
2. Search by sample ID
3. Move up one record in the list
4. Modify item
5. Move down one record in the list
6. Add new item
7. 'Grab' item to move it up or down in the list
8. Download worklist from a LIS
9. Print the record
10. Delete worklist
11. Delete selected record
12. Return to the Measurement menu

If the worklist is empty, only the  *and*  *buttons are active. Other buttons become active if the Worklist contains at least 2 items.*

Use the  **Add item** button to add a new entry to the list. Set the sample and patient ID as described in the testing procedure. By using an external keyboard or barcode reader,

the editing process can be speeded up considerably. The new item will be added to the end of the list. Use the **Modify** button to modify an already existing record.

	**To change the position of the active item** in the list, tap the **Move** button. The button background is changed to orange and the item can be moved up and down in the list by using the arrows on the right side. To finish movement, tap the **Move** button again, so it becomes inactive.
	The **Delete** button removes the current item without confirmation, while the **Delete all** button deletes the whole worklist. The deletion of all items requires user confirmation.

7.5.1 Generating a Worklist

The worklist can be generated:

– Manually through the touch screen, a connected external keyboard or barcode reader,

– Automatically by downloading the worklist items from the LIS.

Sample ID: The sample ID is a numeric string of up to 14 characters. A unique sample ID is assigned by default. To modify the default sample ID, use the touch screen keyboard, the connected keyboard or the barcode reader.

The system does not allow to leave the Sample ID text box empty.

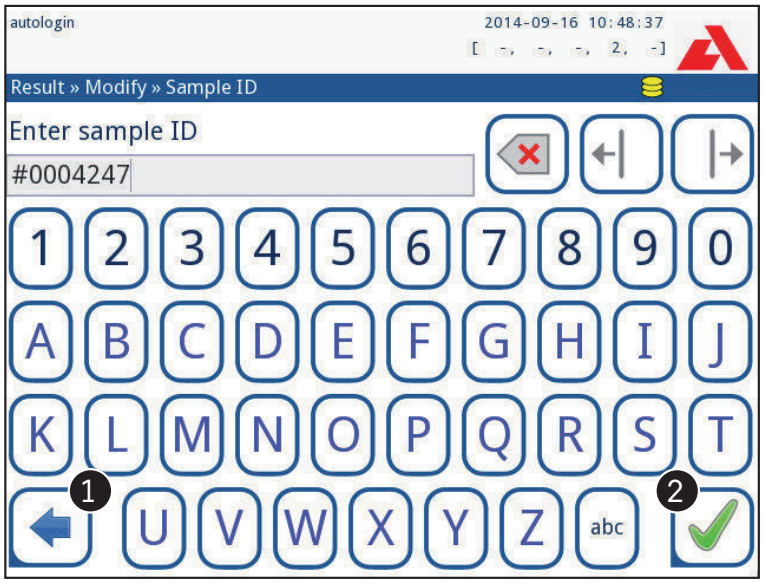


Figure 23: Sample ID input

Once the default Sample ID is modified, the user can either cancel the change by tapping **Drop&Back** (❶ in ***Figure 23***) or store the modified Sample ID with the record by tapping **Apply&Next** (❷ in ***Figure 23***).

– **Patient ID:** The patient ID is a string of up to 32 characters and can contain numeric, alphabetic, or special characters. Use the touch screen keyboard, the attached keyboard or the barcode reader to enter the patient ID. Tap **Next** to leave the Patient ID

field empty. Tap **Apply&Next** after entering the patient ID and proceed to the next screen. To abort and go back to the Sample ID screen, tap **Drop&Back**.

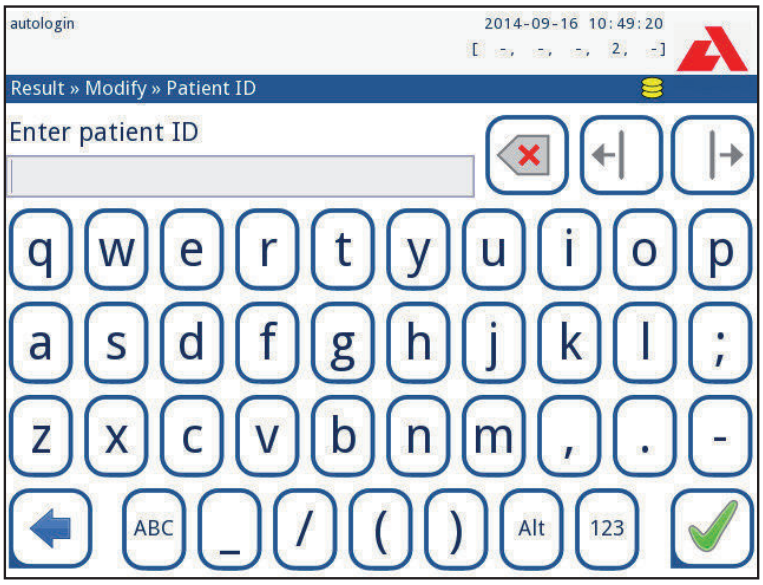


Figure 24: Patient ID input

For further instruction regarding barcode reader usage see ☞ ***5.2.2 Entering data via a barcode reader or a keyboard***

7.5.2 Worklist window in the Measurement menu

By returning to the Measurement screen with the **Back button**, the first worklist item will be active in the list window. The order in the Measurement screen can be changed by using the left and right buttons to cycle through the worklist.

To measure a new sample immediately, which is not in the list, use the left or right arrow to cycle to the beginning or end of the list. An automatically generated sample ID will appear in the window. In this case the (generated) text will appear under the sample ID.

8. Recalling results

The Urilyzer® 500 Pro has memory for 5000 measurements. Every result is automatically saved after the analysis in an indexed database. Using the database, results can be searched, reviewed, printed or transferred to an external device.

By default the analyzer warns the user to free up memory (erase data) 30 records before the limit. The analyzer can also be set up to use circular memory. For more information on database settings see ☞ ***11.7 Database management***

8.1 Last result

If measurements have been performed since switching on the analyzer, tap the **Last Result** button on the ***Measurement*** screen to directly access the most recently processed record.

The Last Result menu is updated in real time to always display the latest processed record.

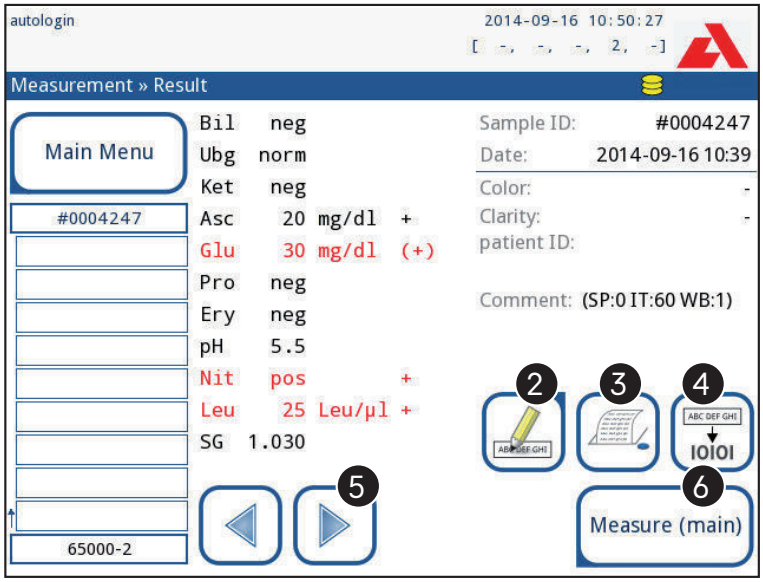


Figure 25: The Last Result menu

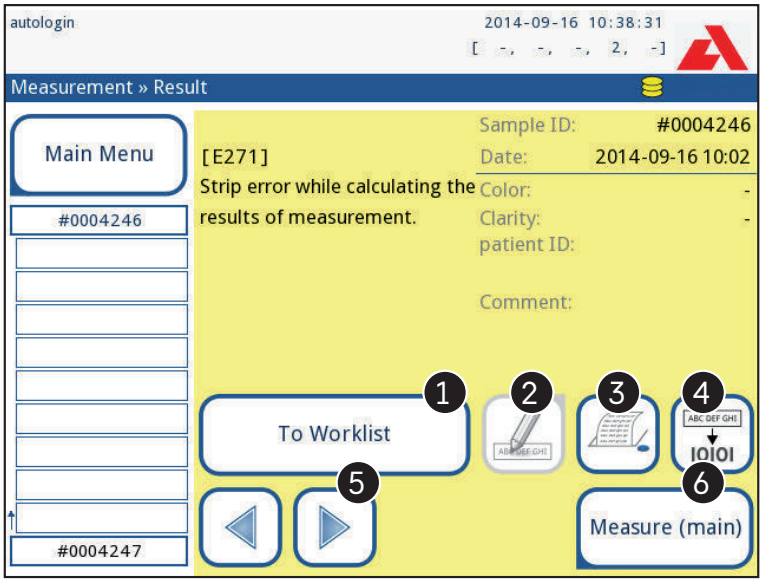


Figure 26: The Last Result menu displaying the record for a failed measurement

If the measurement was successful, all data stored with the record in question is displayed. If the measurement failed for some reason, only the reason for the failure is displayed (usually an error message), and the background of the menu is highlighted in yellow.

If the measurement failed, the system offers the option to add the record, with all its preset and generated ID to the Worklist.

Key to Figure 25 and Figure 26:

1. Add the record to the Worklist

This function is only available for records of failed measurements. The record will be added to the end of the worklist.

2. Modify the record

The measurement date and the analyte pad results cannot be modified.

3. Print the record
4. Send the record to the LIS
5. Go to the next or previous worklist item.
6. Return to the **Measurement » Main** menu

8.2 List view

Access to the database:

– from the ***Measurement*** menu by tapping the **Database** button

– from the **Main Menu** by tapping the **Database** button.

If the database is accessed from the Measurement screen, an automatic predefined filtering is applied and only the results measured on the current date are displayed.

The Database screen displays the results in chronological order: The most recent test result is displayed at the bottom of the screen.

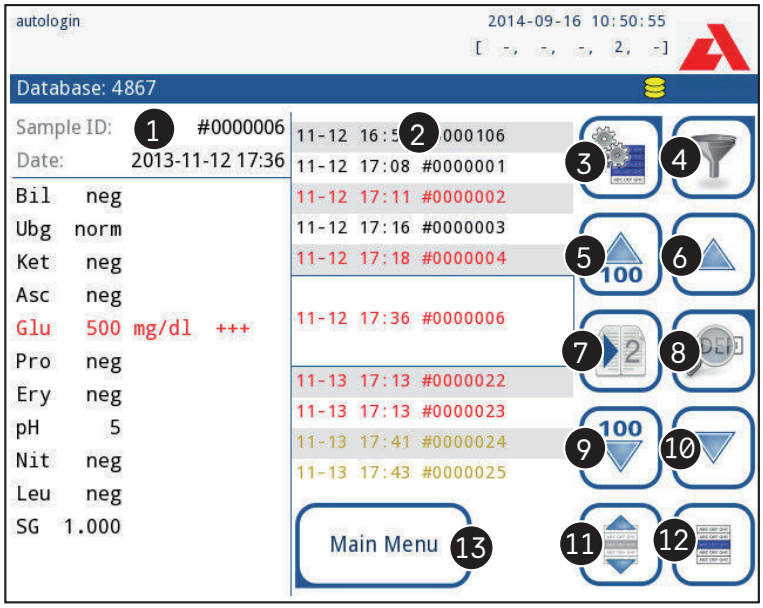


Figure 27: The Database menu

Key to Figure 27

1. Currently selected result details
2. Results list
3. Further actions with selected records
4. Set up filters
5. Move up 100 records in the list
6. Move up 1 record in the list
7. Toggle between the second and first page of the selected record's details
8. Go to the Result view of the selected record

ⓘ *Tap this button to see the measurement data for the selected record. All of the patient's result details will appear (☞ **8.3 Result view**).*

9. Move down 100 records in the list
10. Move down 1 record in the list
11. Toggle continuous selection by movement on/off

ⓘ *Tap this button after the selection of a record (using the button marked 12) to select multiple records below or above the selected record in the list by tapping the down or up arrows, respectively.*

12. Select the record indicated by the line cursor
13. Go to the Measurement menu

Color coding of the results in the list:

Black: Negative result

Red: Positive result

Ochre: Failed result

8.3 Result view

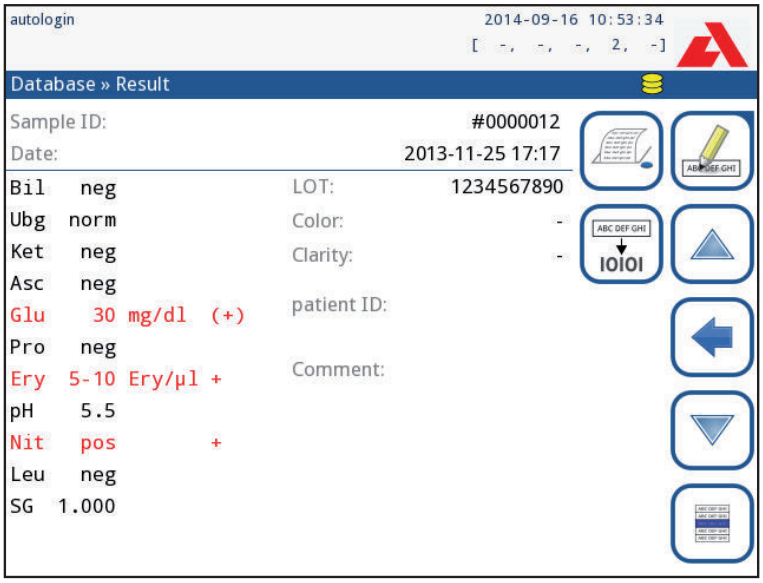


Figure 28: Database»Result menu

Using the buttons in the top right-hand corner of the menu, selected records can be printed, modified and transferred to LIS.

The **Edit** *button is only available if the record has not been printed or transferred yet.*

8.4 Modifying the active selection of results

If a record is selected:

– in list view its background is blue,

– in result view the background of Sample ID's row is blue.

The number of currently selected results is displayed in parentheses in the content navigation bar.

Single selection

Use the button to select/deselect a single record in the list view.

Multiple selection

Tap the button to activate the 'select with movement' feature. If this button is activated (its background changes to orange) the selection state of the records will be reversed (they will be selected or deselected) by moving up and down in the list.

Select all

To select all records listed after filtering tap the **Select** button on the ***Database » Selected*** screen.

Invert selection

To invert the current selection, tap the **Invert selection** button on the ***Database » Selected*** screen.

Remove selection

To remove all selections, tap the **Remove selection** button on the ***Database » Selected*** screen.

8.5 Further actions with selected items

If no record is selected, the action buttons on this menu are dimmed.

Delete

To delete the selected records, tap the **Delete** button on the ***Database » Selected*** screen. In order to prevent accidental deletion, a confirmation dialog appears on the screen.

Output

To send the selected records for output, tap the **Output** button on the ***Database » Selected*** screen.

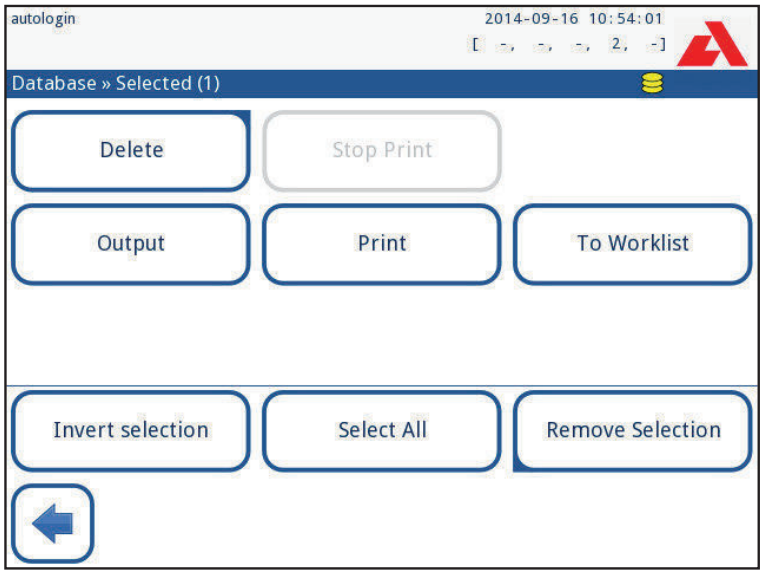


Figure 29: The Database»Selected menu with two records selected, indicated in the status bar

Print

To print the selected records, tap the **Print** button on the ***Database » Selected*** screen.

To Worklist

Tap this button to put the selected measurement records on the Worklist. This feature can be used to repeat failed or doubtful measurements.

Invert selection

Tap this button to invert the selection: Select every record that was not selected, and deselect records that were selected. An information message (“I103: Selection is inverted”) is displayed to confirm the action.

Select all

Tap this button to select all the records in the database. An information message (“I102: All samples are selected”) is displayed to confirm the action.

Remove selection

Tap this button to cancel the selection. The screen will be automatically moved back to the ***Database*** menu.

8.6 Filtering: Finding specific results

To narrow down the list of results Urilyzer® 500 Pro features a sophisticated filtering engine.

The following parameters are available as filtering criteria:

– Date & Time

– Sample ID

– Patient ID

– Status:
  - not printed
  - not transferred

– Values:
  - negative
  - positive
  - sediment recommendation
  - false
  - with comment
  - self-measured

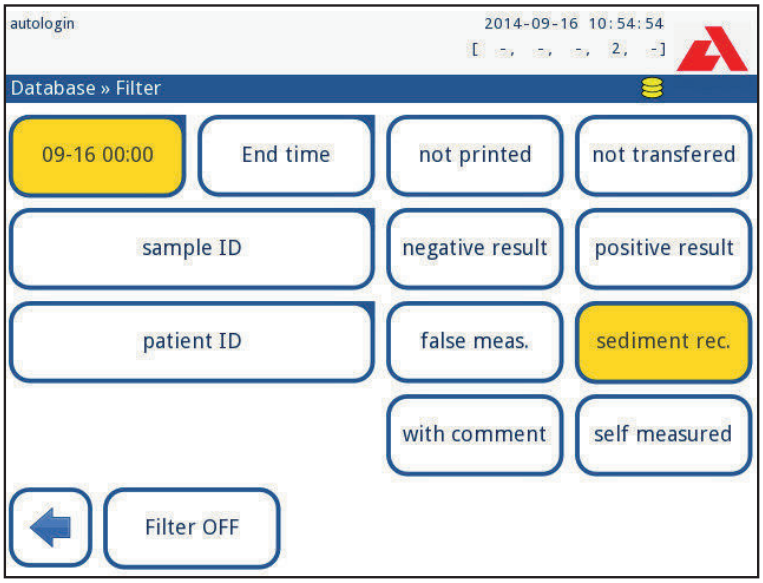


Figure 30: Database » Filter menu with active filters

To activate a filter, tap the desired button.

Active filters are labeled with an orange background.

On the first page of the ***Filter*** screen, the active filters from the second page are listed above the navigation buttons.

To switch off filtering tap the **Filter OFF** button.

To return to the list of results, tap **Return**.

Selecting the Date&Time

To select the filtering period, define the start and end Date&Time separately on the ***Filter » Start time and Filter » End time*** screens.

When entering, the **Day** field is active. To change the value of the active field use **+** and **–** buttons. To modify which field is active use **up** and **down** arrows.

Today button will set the beginning/end of the current day.

Switch on button will set the exact time when the analyzer was switched on.

Tap **Cancel** to discard the changes and return to the filtering overview screen preserving the previous filtering value.

Tap **Apply** to apply the changes and return to the filtering overview screen

Tap **Clear** to clear the start/end filter and return to the filtering overview screen.

9. Quality Control Testing

The performance of the system (analyzer and test strips) should be monitored regularly to ensure reliable results are obtained. To determine the frequency of quality control, consult your facility's quality control policy.

The following possibilities are offered to perform QC tests:

Type	Control
L1, L2 or L3 (One-, two- or three-level) urine control solutions	Urine test strips

ⓘ *Several commercial controls are available. Control solutions may vary in the number of levels or components, the necessity for reconstitution or readiness for use or the type and volume of container. Analyticon Biotechnologies GmbH recommends the use of CombiScreen® Dip Check (Ref.: 93010) or Drop Check (Ref.: 93015) controls as these control solutions provide the necessary color development with CombiScreen® test strips. Other manufacturers' controls may provide abnormal results due to nonspecific colorations of the test pads.*

The use of urine controls is highly recommended particularly in the following situations:

– whenever a new vial of test strips is opened

– whenever test results are in doubt

– when new operators are trained on the system

The urine control solutions are analyzed using a regular urine test strip in an identical manner to a patient sample.

The QC procedure can be divided into 3 phases:

1. Configuring the system: Setting urine control level, forced QC, QC lockout.
2. Setting the urine control LOT number and the acceptance limits.
3. Performing QC testing at defined intervals.

Complete the following steps to perform Quality Control:

1. To configure the system QC settings select ***Main Menu » Settings » QC Options***. ☞ ***9.1 QC Options***

ⓘ *The urine control LOT number and acceptance limits can be set at the same place.* ☞ ***9.1.1 Editing QC LOT Information***

2. The ***QC measurement*** screen can be reached by the **QC Meas** button from the Main Menu. ☞ ***9.2 QC Testing***
3. All QC measurements are stored in a separate database, to reach them tap the **QC results** button on the ***QC measurement*** screen. ☞ ***9.3 Recalling QC results***

9.1 QC Options

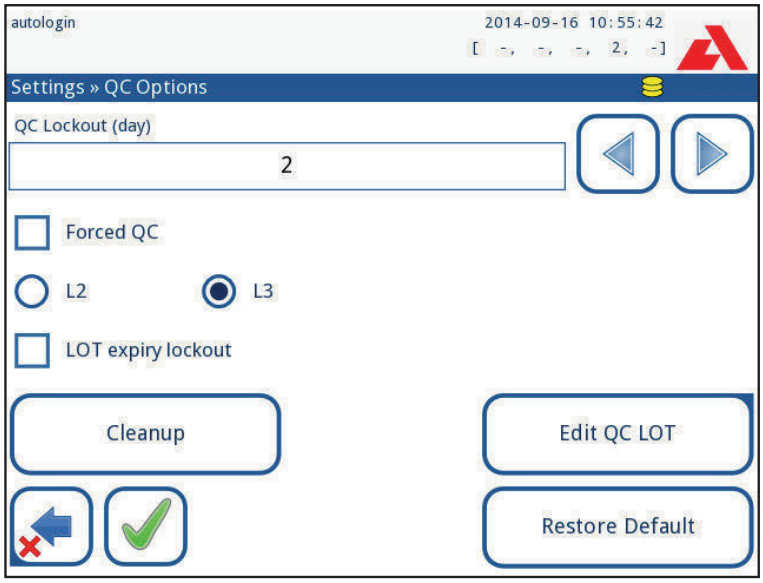


Figure 31: QC Options menu

On the ***Main Menu » Settings » QC Options*** screen the analyzer Quality Control settings can be configured:

- enable/disable QC lockout,
- set the QC lockout interval in days,
- type of QC lockout (warning or forced),
- define the type of control solution (2 or 3 levels),
- edit the QC solutions LOT data.

The **lockout mode** offers the opportunity to ensure a QC-check latest every determined interval using control solutions.

If the lockout mode is activated, the instrument will be released for measurements for the determined timeframe once a successful QC check has been performed.

To enable the QC lockout and set the interval:

- use the right and left arrows, or
- tap inside the grey text box, use the numeric input and apply.

If the QC lockout period is changed, a popup window appears with the modified lockout time.

LOT expiry lockout: If ON, Expiry date must be entered. The system will keep track of the expiry date for each of the QC solution LOT and display an error message whenever an operator attempts to perform a QC measurement using a solution that is past its expiry date.

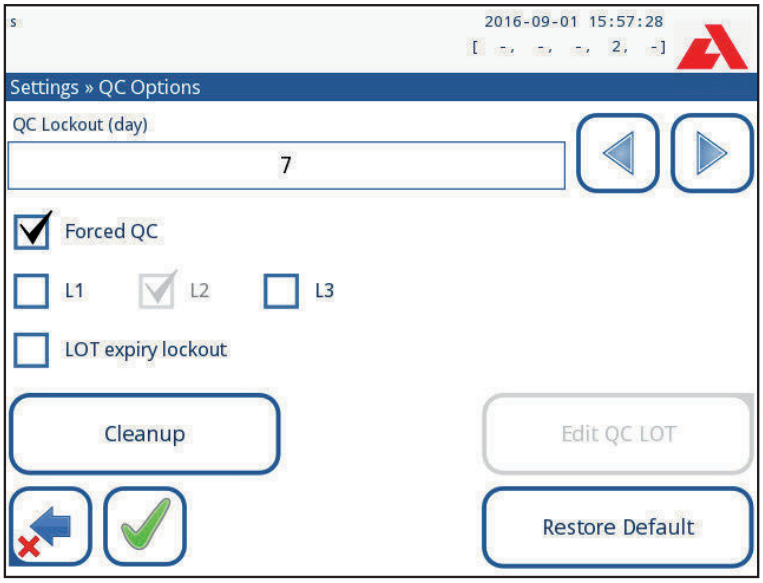


Figure 32: An example of a forced L2 quality check setting

The lockout mode can be

– warning  Forced QC

If the limit is passed, the status bar background is changed to orange and a warning message is displayed.

– forced  Forced QC

If the time limit is exceeded, the status bar background is changed to red and an error message is displayed. In this case the measurement feature will be blocked until a new successful QC check has been performed.

The QC check can be set for

– L1: negative/normal

– L2: positive/abnormal,

– L3: high positive/abnormal

control solution checks, either individually or in any combination by ticking their checkbox.

*If strong user security is applied (☞ **11.15.3 Managing security settings**) the normal users are not able to modify the QC settings, so the QC policy determined by the system administrator will be forced. However if the analyzer is locked out and the user needs to make a measurement immediately without performing the QC check first, the lockout mode can be switched off only by an Administrator.*

9.1.1 Editing QC LOT Information

The QC evaluation relies on the manual data entry. Always double-check the values and ranges before starting the QC procedure.

1. On the ***Main Menu » Settings » QC options*** menu, tap the **Edit QC LOT** button to set the QC Urine Control solutions' LOT numbers and acceptance limits.
2. Select the control level (L1, L2, L3) on the ***Edit LOT » Strip selected*** screen and tap the **Next** button.

3. On the next screen set the LOT code (*and the expiry date)* and tap the **Next** button. If a LOT code is already stored for the current level, its value will be displayed as the default in the input box.
4. On the last screen set the acceptance limits for the selected level of the LOT.

Modifying the limits

The selected level appears in the top left corner of the table. The LOT code is shown in the navigation bar. The columns of the table are: parameter, lower limit, higher limit, unit.

The selected cell is marked with black borders.

Use the arrows to navigate and change the current selection. The value of the lower and higher limit of the selected item can be increased or decreased with the + and − buttons. When the entry is finished, tap the ✓ **OK** button to store the values. The analyzer returns to the ***QC options*** screen.

Repeat the previous steps for all levels.

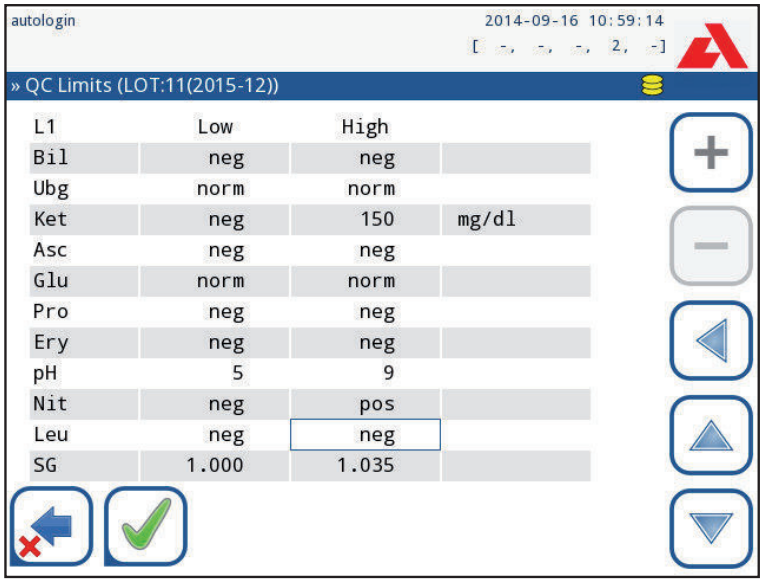


Figure 33: QC Limits menu (accessible via Edit QC LOT)

The target values can also be entered automatically with a barcode reader. Access ***Main Menu » Settings » QC Options***, mark **L1**, press **Edit QC LOT**, select **L1**, press **Next** and scan the barcode of Level 1. Check and confirm with the green tick, press **Edit QC LOT**, select **L2**, press **Next** and scan the barcode of Level 2.

9.2 QC Testing

To perform a quality control measurement go to the ***Main Menu » QC Meas*** screen. The color coding of the QC measurement buttons is the following:

– **QC lockout is disabled:**
  grey: not measured,
  green: valid measurement was performed while in the ***QC Meas*** menu
  red: invalid measurement was performed while in the ***QC Meas*** menu
– **QC lockout is enabled:**
  grey: not measured

green: valid measurement was performed within the time limit
red: invalid measurement was performed within the time limit

The QC can start either with a negative or with a positive control. Apply the control to the strip according to the instructions of the control solutions and the CombiScreen® 11SYS Plus or CombiScreen® 11SYS test strips.

Place the test strip in the strip delivery zone and tap the following button depending on the control level:

– "… Solution 1" for negative control,
– "… Solution 2" for positive control,
– or "… Solution 3" in case of Level 3 for high positive control.

If the QC LOT and its limits were already set at the QC settings, the analyzer offers the QC LOT code. Tap the **Next** button.

ⓘ *The QC LOT code can be modified here as well. If a new LOT code is given, its acceptance limits have to be set as well, so the limits table will appear on the next screen.*

After measurement, the QC result is displayed with the result of the evaluation.

– If the QC measurement is successful, PASSED text is displayed after the QC result ID. Returning back to the main QC screen, the measured solution's button background is changed to green.
– If the QC measurement has failed, red FAILED text is displayed after the QC result ID. Returning back to the main QC screen, the measured solution's button background is changed to red.

Repeat the same procedure with the other solution(s).

After all required solution levels have been successfully measured *(all "…Solution…" buttons are green)*, the analyzer is released until the lockout time is reached and a popup window appears with the modified lockout time.

The remaining lockout time together with the date is displayed in the information windows of the ***Main*** screen.

ⓘ *The maximum displayed negative value is -90. It may mean that more than 90 days has passed since the limit or a successful QC was never performed.*

9.3 Recalling QC results

All QC measurements are stored in the QC memory, which is separated from the memory for the patients' measurements. The Urilyzer® 500 Pro has memory for 5000 QC measurements.

See ☞ ***8. Recalling results*** for more information on how to recall and view results from a database.

ⓘ *Only the additional information specific to the QC database is described in this chapter.*

In the list view the good results have black text, while any failed results have red text.

In the QC result screen PASSED text is displayed after the good QC result ID, while red FAILED text is displayed after the failed QC result ID. For failed QC solution results the out of range pad results are also marked in red.

10. Main Menu options

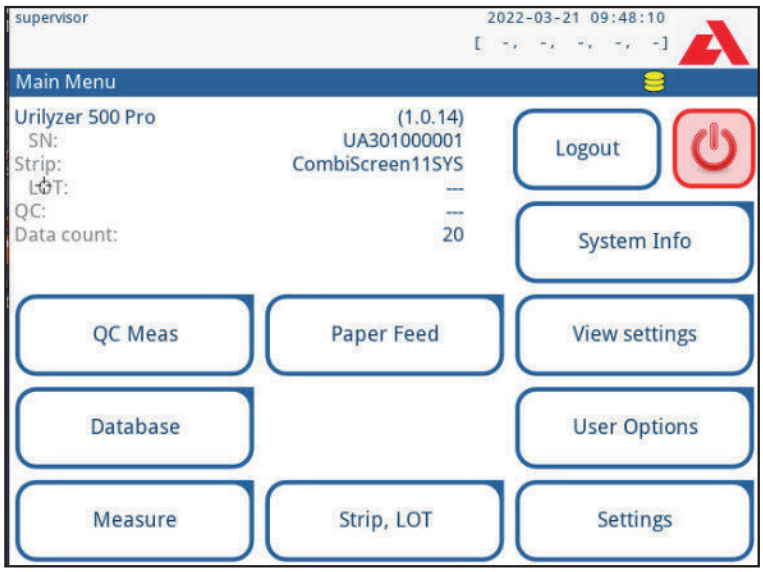


Figure 34: Main Menu options

The Main Menu screen displays the following information:
- Software version
- Serial number
- Test strip type and LOT code information
- QC LOT information
- Data Count

The following functions can also be reached from this screen:
- QC Meas
- Database
- Measure
- Paper Feed
- System Info
- Strip LOT,
- View Settings,
- User Options (auto features, sound, LCD brightness),
- Instrument Settings.

10.1 Strip LOT

Push the Strip LOT button on the Options screen to set the LOT information of the strip. It is also possible to set the expiry date after the LOT code.

The following special characters are allowed for input together with numbers: hyphen '**-**', dot '**.**', forward slash '**/**', space '_' and round brackets '**(**' '**)**'.

This information is stored with every measurement, until it is changed manually.

Please note that the LOT code and expiry date values are semantically not checked by the software. Please double check the LOT code in order to avoid typos.

10.2 View Settings

The ***View settings*** screen shows all settings including user options as well. Use the down and up buttons to scroll through the settings. The analyzer settings can be printed out using the button.

10.3 User Options

Most of the settings on the User options screen are related to the testing procedure except **Sound** and **LCD brightness**.

– **Auto print:** If enabled, the analyzer automatically prints the report of each measurement.

ⓘ *Auto print is enabled by default.*

– **Auto transfer:** If enabled, the analyzer automatically transfers the result to the defined output (i.e. through the serial port to a LIS).

ⓘ *Auto transfer is disabled by default.*

– **Sound:** If enabled, the analyzer confirms the touching actions with a short beep sound.

– **LCD brightness:** Use the left and right buttons to change the brightness of the LCD display or click on the input field to set the LCD brightness value from a numeric keyboard.

– **Change passw.:** The active operator may change the password by tapping the **Change passw.** button. First the system asks for the current password, than the new password has to be repeated twice. The system confirms the successful change.

ⓘ *In case of 'autologin' operator this button does not appear.*

⚠ **The minimum password length is 3 characters.**

ⓘ *These features can be modified by any operator and are stored in the system as part of the operator's account settings.*

11. Instrument Settings

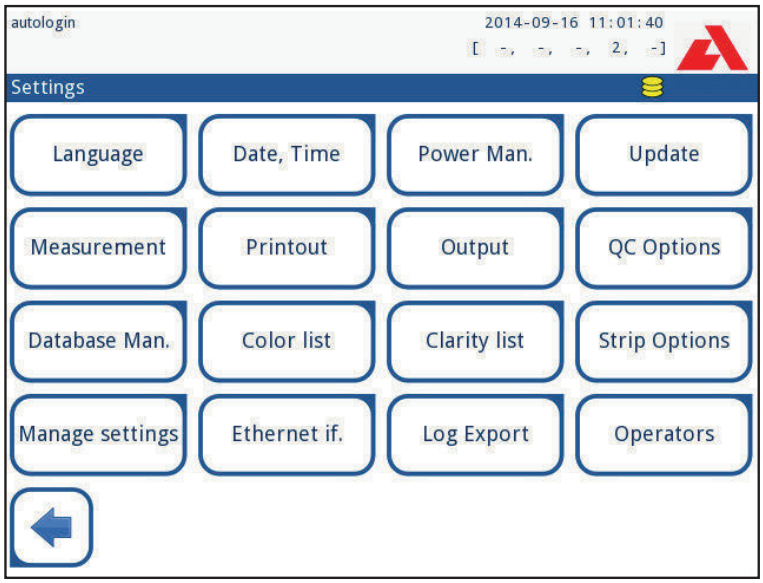


Figure 35: The Settings menu

The Urilyzer® 500 Pro allows to change settings to suit individual workplace requirements. Instrument settings can be reached from ***Main » Settings***.

The list of available settings may vary according to authenticated user level.

To navigate between settings pages use the back and forward arrows.

Confirming changes

To confirm the performed changes on the ***User options*** or ***Settings*** screen first tap **Apply** and leave the screen with **Back**.

No changes or changes are saved

Back & Apply (grayed out)

Changes not yet saved

Drop & Apply

To cancel the modifications simply tap **Drop&Back** before applying changes.

Restoring default values

On each settings screen there is a button (named **Restore Default** or **DEF**.), which can be used to restore the default value(s) for that screen.

To restore ALL settings on the system level go to ***Manage Settings***.

At system level the settings cannot be restored while printing or transfer is in progress.

The settings can be restored based on the settings of supervisor user, if the *'Default by "supervisor" settings'* switch is active on Manage settings page.

Saving and restoring set of settings

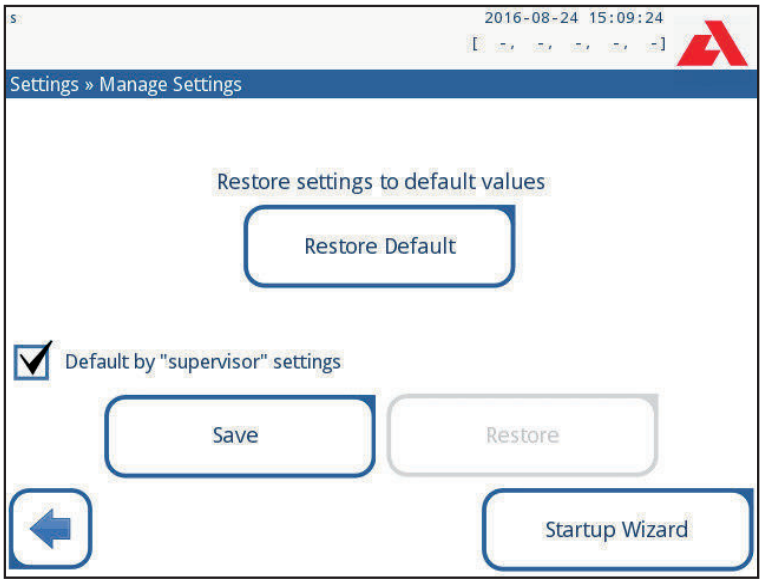


Figure 36: Manage Settings menu

Supervisor level users can download settings to a USB flash drive and upload to one or multiple other analyzer/analyzers with this feature.

1. Enter a USB flash drive into its socket at the back of the analyzer.
2. Go to ***Settings*** » ***Manage Settings*** screen, and click on **Save**. The analyzer saves the actual settings in a .txt format with details of the analyzer and the date.
3. Upload the settings by clicking on the Restore button on the Settings/Manage Settings screen.

ⓘ *The Save and Restore buttons are grayed out when there is no USB flash drive entered or there is no saved settings on it.*

11.1 Language

To change the operating language select the desired language from the list and apply change.

ⓘ *If the translation is partially done in the selected language, the untranslated texts appear in English.*

11.2 Date, time

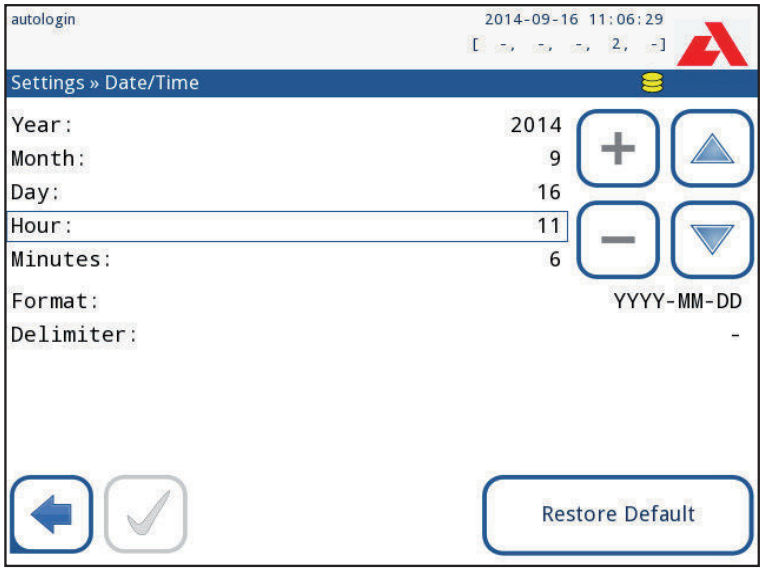


Figure 37: The Date/Time menu

The date and time are displayed on the header and are recorded with the test results.

To Modify which field is active use the **up** and **down** arrows.

To change the value of the active field use the **+** and **–** buttons.

Available date formats:

YYYY-MM-DD (default, ISO 8601 standard)
MM-DD-YYYY (US format)
DD-MM-YYYY (EU format)

Available delimiters: '**-**', '**/**', '**.**'

11.3 Printout

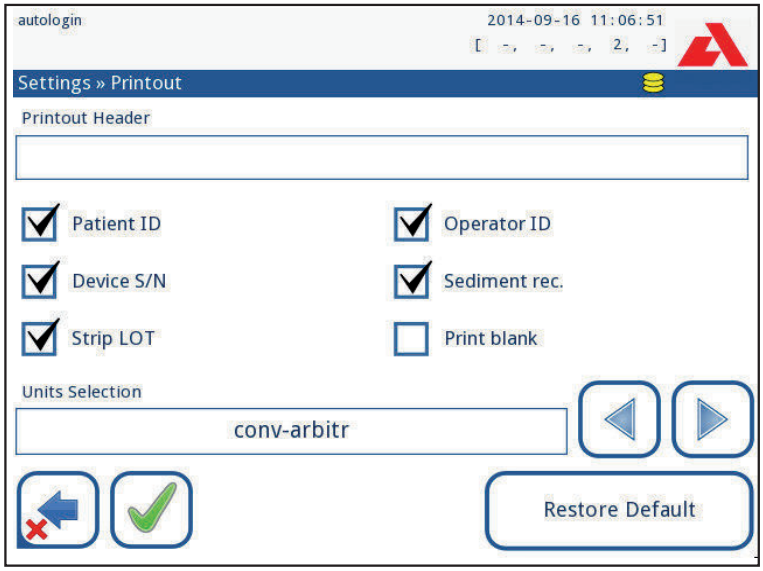


Figure 38: Printout options settings

Printout Header	custom string
Patient ID	If ON, ~ appears on the printout
Operator ID	If ON, ~ appears on the printout
Analyzer S/N	If ON, ~ appears on the printout
Sediment rec:	If ON, sediment recommendation information appears on the printout
Strip LOT	If ON, ~ appears on the printout
Print blank:	If ON, the analyzer prints all the checked fields, even when they are empty.
Units selection:	Changes the display units of the printouts. Available options: conv-arbitr, SI-arbitr, conv, SI, arbitr. Use the left and right arrows to change the value.

11.4 Output (Connectivity: Transfer/Export)

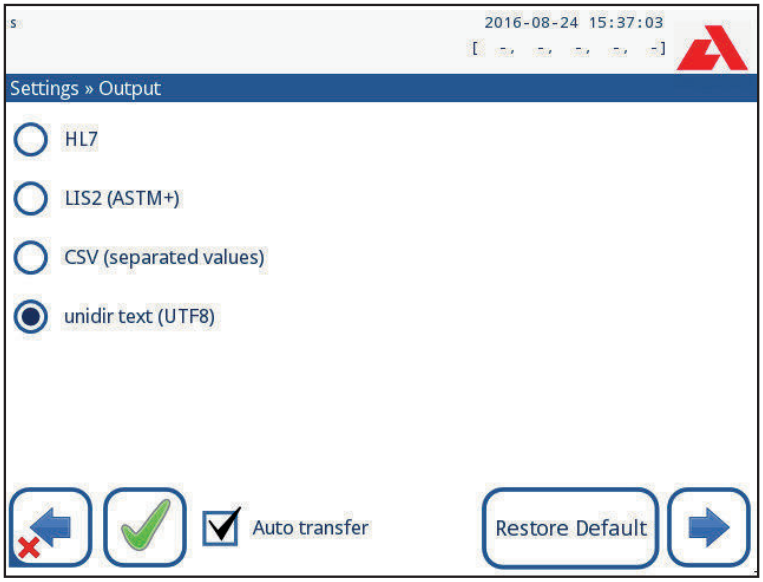


Figure 39: Data transfer settings

At the ***Output*** settings the user can define how the Urilyzer® 500 Pro will connect to other systems or data storage devices.

The analyzer offers several possibilities for transferring the results through an interface (serial, USB or file):

– bidirectional protocol based on the NCCLS LIS2-A2 standard or the HL7 protocol,

– unidirectional protocol, when the data is transferred out in a one-way data flow, either in the CSV or the UTF8 format

The **Output type** input field is used to define the communication port (the available selection is based on the output protocol) on the Output screens. Tap the **Left** and **Right** arrow to scroll through the list.

	Serial (RS232)	TCP/IP Ethernet	File	USB B
Bidir:LIS2 (ASTM+)	⊕	⊕		
Bidir: HL7		⊕		
Unidir: CSV	⊕		⊕	⊕
Unidir: UTF8 text	⊕		⊕	⊕

– For the serial port: The selectable baud rates are 2400, 4800, 9600, 19200, 38400, 57600, and 115200 bits per second. The value defines the speed of the serial communication. The serial interface specification is 1 (one) stop-bit, no parity.

– For **Output:file** option: The transferred data will be saved directly into a file on the root folder of a USB flash drive connected via a Type A USB port. The default file name is udr2(%Y%m%d-%H%M%S). (The placeholder string in parentheses indicates the time of measurement where %Y stands for the year, %m for the month, %d for the day, %H for the hour, %M for the minute, and %S for the second.) The file extension is either .csv or .txt, depending on the selected output protocol.

A path for the saved file can be specified on the USB flash drive by entering the preferred folder name between slashes (/) as the first part of the file name.

Take care that the configuration of the communication ports is correct, otherwise data transfer will not work. If necessary, consult your system administrator to configure the communication ports properly.

– Due to different regulations in laboratories, the analyzer lets operators with Admin or higher level to set up automatic result transfer unchangeably on the ***Settings » Output*** screen. When this **Auto transfer** box is checked, the **Auto transfer** checkbox on the ***User settings*** screen remains checked, grey and out of operation.

11.4.1 Bidirectional protocol (LIS2-A2)

Figure 40: LIS2 transfer settings

The two-way digital transmission protocol of Urilyzer® 500 Pro regarding remote requests and results between Urilyzer® 500 Pro and information systems is base on the NCCLS LIS2A2 approved standard.

It enables Urilyzer® 500 Pro and any standard LIS system, to establish a logical link for communicating text to send results and requests in a standardized and interpretable form.

A custom header can be set and at the **Output type** input field the output type can be defined: Serial, USB B, TCP/IP (Ethernet) the speed of serial communication (only for serial port).

If TCP/IP (Ethernet) is selected, please set the server's IP address and port separated with ':' symbol.

11.4.2 Bidirectional protocol (HL7)

Figure 41: HL7 transfer settings

HL7 stands for Health Level Seven; it is a collective of healthcare informatics standards that allow exchange, integration, sharing, and retrieval of the measurement data over the Urilyzer® 500 Pro and a suitable network.

On this screen, a custom header and the preferred units for the output can be defined. Enter the IP and the port of the server.

Support for the HL7 protocol is in its introductory phase. Contact the manufacturer for the details of the specific HL7 standard or standards that the analyzer supports.

11.4.3 Comma-separated value output

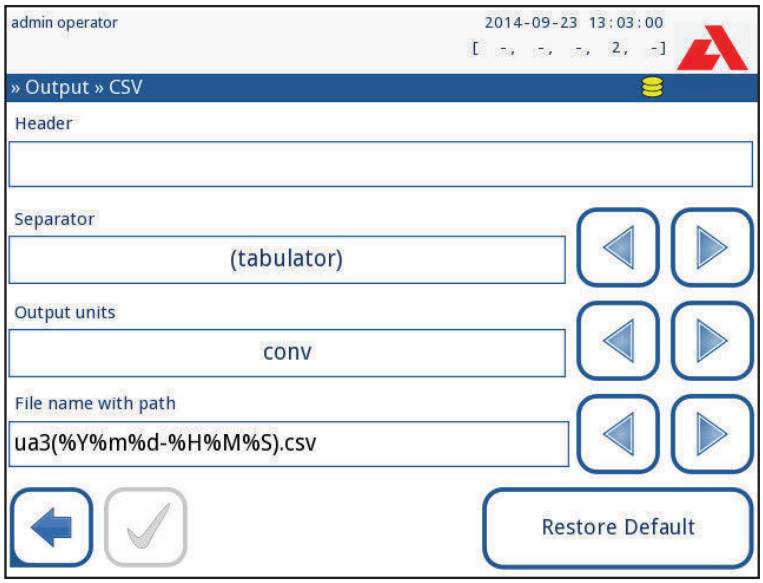


Figure 42: CSV export options

If this output protocol is selected, the system will transfer the analysis results as plain text with a .csv file extension. In the text file, each result record is separated by a line break and each field in a record is separated by a predefined separator character (Options: tabulator, semicolon, comma) The resulting file can be opened by a spreadsheet editor such as Microsoft Excel.

11.4.4 UTF8 unidir text

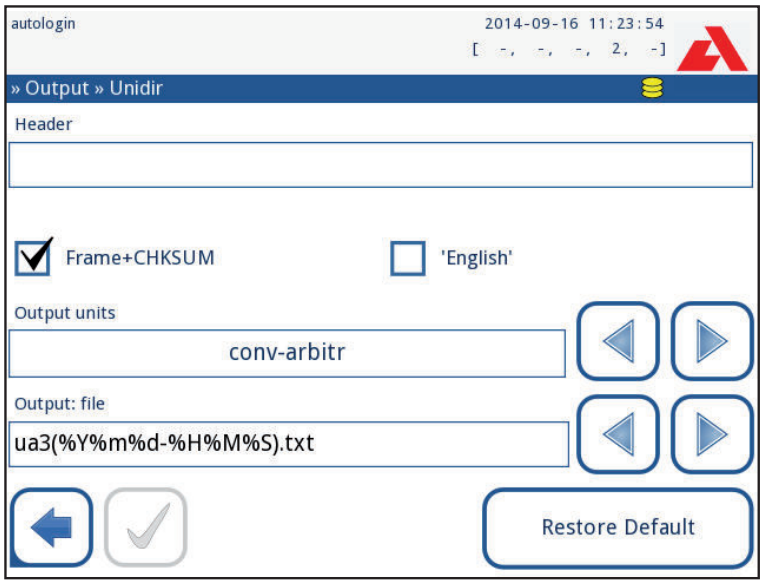


Figure 43: Unidir export settings

If this output protocol is selected, the system will transfer the analysis results encoded as Unicode characters. The options are the same as for the other two protocols. However, the Frame+CHKSUM check box is unique to this screen. If the function is checked, the system will add a ‘start text character’ (STX) at the beginning, and an ‘end text charac-

ter' (ETX) at the end of the transferred string, as well as a two-digit checksum so that the transferred data can be verified.

11.5 Measurement

The detailed description of the ***Measurement*** screen can be found in ☞ ***7.4.2 Customizing the analysis process***

11.6 Strip options

The strip options screen shows the available strip types and the various analyte pads on the strips.

Selection of a pad is indicated by a black row cursor.

– Use the up and down arrows to change the active pad

– Tap [+] or [−] to increase or decrease the sensitivity of the selected pad.

Sensitivity can be set between -2 and +2 from the user interface.

– Tap the **SED** button to assign a sediment analysis recommendation to the selected pad. If the pad is labeled with **SED**, all results containing positive value of the selected pad will receive a "sediment examination is recommended" flag in the database. The information may also be displayed on the printout. The flag value is stored in the database, so the database may be filtered for this option as well (See ☞ ***8.6 Filtering: Finding specific results***).

Modifying the displayed pad order:

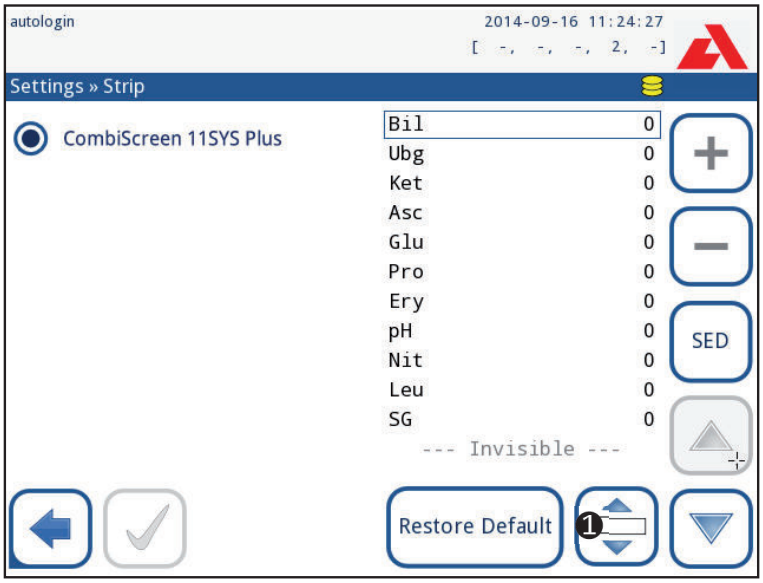


Figure 44: Strip options menu with an example of an invisible pad

1. Select the pad.
2. Tap the **Move (1)** button. It will be active and its background will be changed to orange.
3. Use the up and down arrows to move the position of the selected pad. If it is at the desired position, tap the **Move (1)** button to deactivate the movement and re-

lease it. To exclude a specific pad from the results view, move the pad below the —Invisible— line. The pads below this line will not be listed in the results.

The system will only measure and store results for invisible analytes when they are restored above the ---Invisible--- line.

11.7 Database management

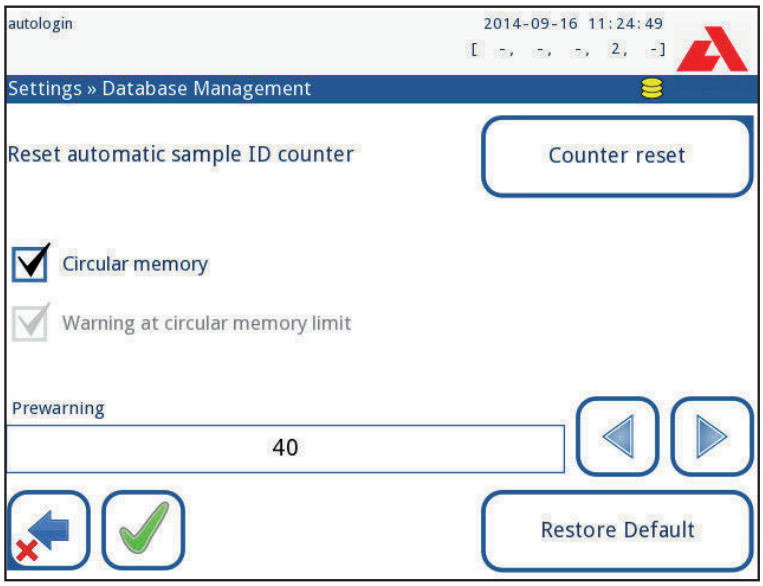


Figure 45: The Database management menu

On the ***Database management*** screen the user can define how the Urilyzer® 500 Pro manages the storage of the records.

The following settings can be specified:

- The automatic Sample ID counter can be reset by tapping the Counter reset button. The execution requires confirmation.
- Circular memory on or off: Circular memory on will continuously record, writing over old data when memory is full. Circular memory off will stop recording when memory is full.
- Warning at…: If it is on, the device displays a warning before old data is overwritten.
- Pre-warning: Define the amount of records when the device displays a warning before the memory is full. Adding new records is still possible but it is not required to free up database memory by erasing data.

11.8 QC Options

The detailed description of the QC options screen can be found in ☞ ***9.1 QC Options***

11.9 Power management

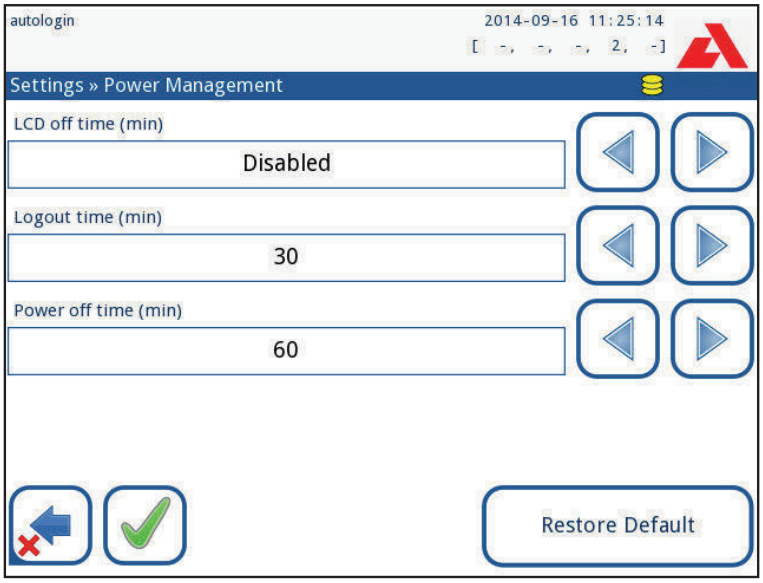


Figure 46: The Power management menu

On the Power Management screen the following options can be enabled and set:

- LCD off time (starts screensaver)
- Logout time (logs out the active user)
- Power off time (switches off the analyzer)

The analyzer will perform these activities if it has been inactive for the given time.

Use the **left**, **right** arrows to change the values:

- LCD off time:
  Disabled, 5, 10, 15, …, 60
- Logout time:
  Disabled, 10, 20, 30, …, 120
- Power off time:
  Disabled, 20, 40, 60, …, 180

The screensaver mode and the automatic power-off feature helps to reduce the unnecessary power usage, thus reducing the economic footprint of the analyzer.

11.10 Log export

To export the log files, analyzer settings and version information for diagnostic purposes:

1. Plug the USB flash drive into one of the USB A connectors on the back of the analyzer. Wait until the disk icon appears in the status line. The icon shows that the USB flash drive was recognized by the system.
2. Push the **Log Export** button in the ***Settings*** screen.
3. An information window appears *(Log export is in progress. Please wait.)*. The information disappears, when the log export is finished.
4. Remove the USB flash drive.

Always export and send log files to service in case of unresolvable errors.

11.11 Editing the color and clarity list

The Urilyzer® 500 Pro units allow the possibility to customize the urine color and clarity list values according to standard lists determined by your facility's policy.

The color list can be edited at the ***Settings » Color list*** screen, while the clarity list can be edited at the ***Settings » Clarity list*** screen.

To modify a value:

1. Tap the item's button (e.g. straw-yellow or clear),
2. Edit the text,
3. When the new name is entered, tap the **OK** button, which takes the user back to the list.

The modified items will be marked with an orange background. To accept the changes, tap the **Apply** button. To restore the original list, tap the **Restore Default** button.

11.12 Ethernet interface configuration

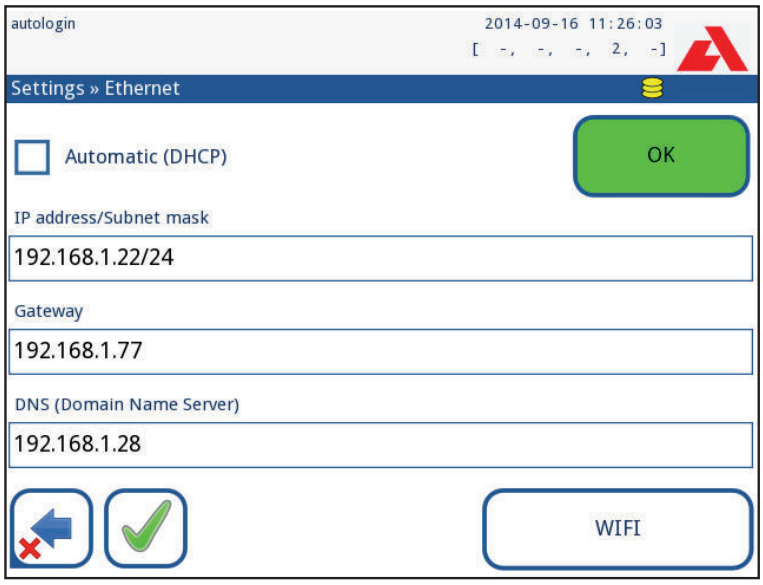


Figure 47: The Ethernet connection setup menu

To connect the Urilyzer® 500 Pro to the network via Ethernet interface through TCP/IP, the user has to configure the Ethernet interface.

Ask for these values from your facility's IT system administrator.

Wi-Fi button appears only if a USB Wi-Fi adapter known by the analyzer is connected.

The configuration can be performed:

– automatically (DHCP),

– manually.

For automatic configuration select the **Automatic (DHCP)** checkbox. By using DHCP, TCP/IP configuration is done dynamically and automatically when the analyzer is started. Dynamic configuration requires a properly configured DHCP server on your network.

For manual configuration uncheck the **Automatic (DHCP)** checkbox and manually assign

- the IP address / subnet mask
  (i.e. 192.168.1.5/24 or 192.168.1.5/255.255.255.0),
- the gateway,
- the DNS server.

To confirm the changes, tap the **Apply** button after modification.

11.13 Update

Refer to ***4.3 Analyzer software updates*** for details of the software update process.

11.14 Wi-Fi settings

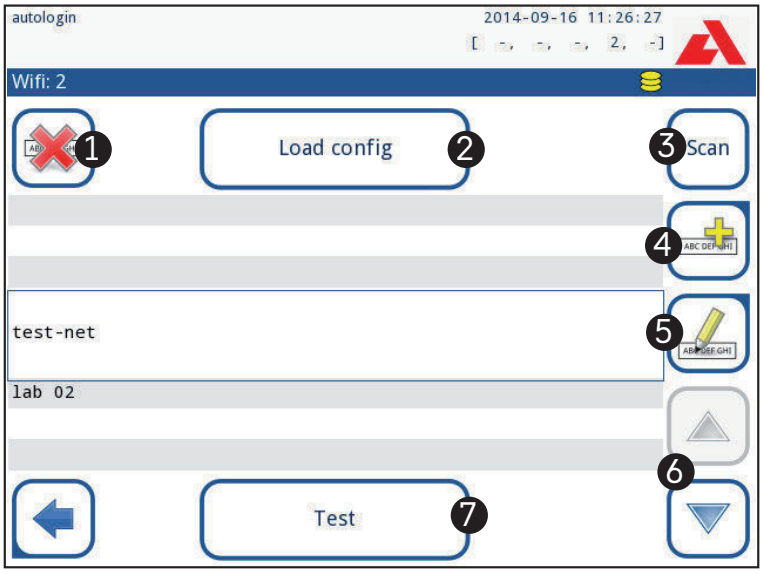


Figure 48: The Wi-Fi screen (available from the Ethernet configuration screen)

11.14.1 Connect to an existing network

1. Insert a USB Wi-Fi adapter into one of the USB sockets at the back of the analyzer. Access the ***Main » Settings » Ethernet interface*** screen. Tap the **WIFI** button.
2. Tap the **Scan** button. The system displays all the networks that are within range, listed by descending signal strength. Use the **Up** and **Down** arrow buttons (numbered 6 in ***Figure 48***) to position the cursor over the network and tap the **Add element** button (numbered 4 in ***Figure 48***). On the keyboard screen that is displayed, enter the Password for the selected network, and tap **OK**.
3. Tap the **Scan** button once again to toggle it off. Use the **Up** and **Down** arrow buttons (numbered 6 in ***Figure 48***) to position the cursor over the network and tap the **Test** but-

ton. A status text will be displayed below the name of the network. When the status tet reads **COMPLETE**, the analyzer is connected to the selected wireless network.

For functional bidirectional data transfer, a receiving server is needed.

11.14.2 Add a new connection

1. Insert a USB Wi-Fi adapter into one of the USB sockets at the back of the analyzer. Access the ***Main » Settings » Ethernet interface*** screen. Tap the **WIFI** button.
2. Tap the **Add element** button (numbered 4 in ***Figure 48***). On the keyboard screen that is displayed, enter the ESSID (the name), and then the Password for the new wireless network.

A valid password is between 8 and 63 characters long.

3. Use the **Up** and **Down** arrow buttons (numbered 6 in ***Figure 48***) to position the cursor over the network and tap the **Test** button (numbered 7 in ***Figure 48***). A status text will be displayed below the name of the network. When the status text is **COMPLETE**, the analyzer is connected to the selected wireless network.

11.14.3 Load preconfigured networks and advanced authentication protocols

The Urilyzer® 500 Pro system software includes a utility (the wpa_supplicant utility) that can be used to configure advanced wireless network options. To set up the preferred options, the user needs to supply the wpa_supplicant utility with the required configuration information in a text file.

1. Look up online the documentation on the proper format for wpa_supplicant configuration information. Create and bundle a 'wpa_supplicant.conf' file, and, if necessary, a 'certificate' and a 'key' file in a zip file that is named **wpa_supplicant.conf.zip**. Include the string **/usr/local/WIFI/** in the pathname for the files. Do not put the files inside folders before zipping them.

Examples of properly named certificate and key files:
ca_cert="/usr/local/WIFI/ca.pem"
client_cert="/usr/local/WIFI/user.pem"
private_key="/usr/local/WIFI/user.prv"

2. Copy the zipped file to the root directory of a USB flash drive. Insert the USB flash drive into a USB socket at the back of the analyzer.
3. Insert a working USB Wi-Fi adapter into a USB socket at the back of the analyzer. Access the ***Main » Settings » Ethernet interface*** screen. Tap the **WIFI** button.
4. Tap the **Load config** button (numbered 2 in ***Figure 48***) to load the zipped configuration files from the USB flash drive. The system unzips and saves the files on the USB flash drive in the **/usr/local/WIFI** folder.
5. Exit and re-enter the **WIFI** screen to enable the modifications.

11.14.4 Edit or delete an existing wireless network

1. Insert a USB Wi-Fi adapter into one of the USB sockets at the back of the analyzer. Access the ***Main » Settings » Ethernet interface*** screen. Tap the **WIFI** button.
2. Use the **Up** and **Down** arrow buttons (numbered 6 in ***Figure 48***) to position the cursor over the network.

3. Tap the **Delete** or the **Edit** button (numbered 1 and 5, respectively, in ***Figure 48***), as necessary. Follow the instructions and messages that are displayed.

11.15 Operators

The Operators screen is used to manage the system security settings and to manage the active operators.

No user can operate the analyzer without a unique operator account. There are four (4) levels of operator accounts, each with its associated user rights.

Operator account level	User rights
Disabled	Disabled operators cannot log in or perform any tasks
User	This is the default access level. Users with User-level operator accounts can perform the following routine tasks: manage worklists perform analysis perform quality control tests print and export records modify user options (that are stored for each operator account)
Admin	Users with Administrator-level operator accounts can perform every user-level task, plus the following: modify system settings manage operator accounts install software updates
Supervisor	Users with Supervisor-level operator accounts can perform all of the above tasks, and also modify global security settings.

11.15.1 Managing operator accounts

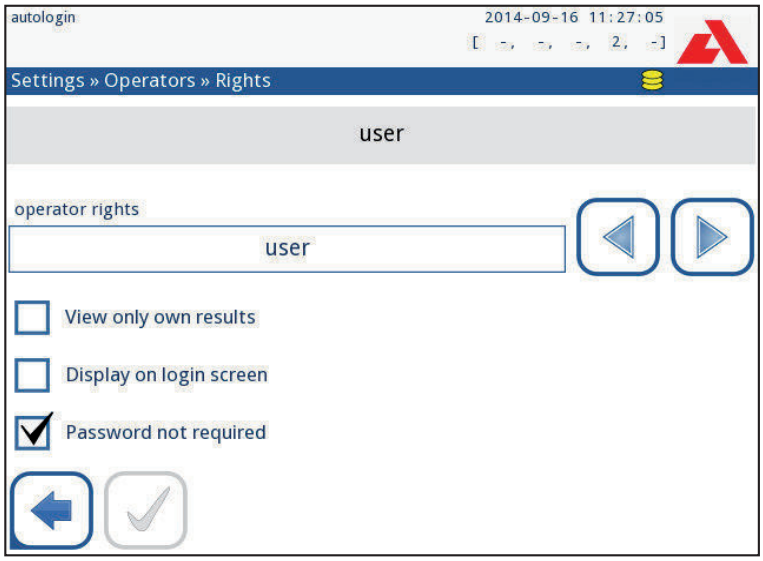


Figure 49: The operator account management menu

Adding operator accounts

Only users with administrator- and supervisor-level operator accounts can add new operator accounts.

1. On the Operators menu, tap the Add new operator button.
2. Use the touch screen keyboard to enter an Operator ID for the account and tap Next.
3. Set the level of the operator account and edit the additional settings (☞ ***Customizing operator accounts***).

No user can assign an account level higher than that of their own to an operator account they are creating.

Setting passwords for operator accounts

If a password is required for an operator account (determined by global security settings and operator account customization), the user using that account has to set a password the first time they log in to that account. The system will prompt the user to confirm the new password, and will display the login screen after the password is successfully set.

Deleting operator account passwords

1. Select an operator account on the list, and enter its ***Settings » Operators » Rights*** menu (☞ ***Figure 49***).
2. Tap the **Clear password** button to delete the password associated with the operator account.
3. Confirm the command by tapping the **Apply** button.

If the user wants to assign a new password to an operator account with a deleted password, enable the "Password not required" setting, save the modification, then disable the "Password not required setting", and save the account again. The next time a user attempts to log in to the operator account, the user will be prompted to set a password.

Customizing operator accounts

Apart from the user rights associated with them, operator accounts can be further customized by users with administrator- and supervisor-level operator accounts on the **Settings » Operators » Rights** menu (☞ ***Figure 49***).

The following additional settings are available for each operator account:

– View only own results – users logged in to this operator account can only access records for measurements they themselves have performed on the analyzer

ⓘ *Operator accounts with this setting enabled are displayed in the list of operators with an "(S)".*

– Display on login screen – the user name for this operator account is displayed on the login screen, so that the user is only required to tap the user name and enter the account password (if any) to access the analyzer

ⓘ *Up to eight (8) operator accounts can be displayed on the Login screen. Operator accounts with this setting enabled are displayed in the list of operators with a "(D)".*

ⓘ *Supervisor-level operator accounts cannot be listed on the login screen.*

– Password not required – users logging in to this operator account are not prompted for a password

ⓘ *If this setting is enabled for an operator account that already has a password associated with it, it is not necessary to clear the password for the account before this setting becomes active.*

ⓘ *Operator accounts with this setting enabled are displayed in the list of operators with an "(L)".*

Data exchange

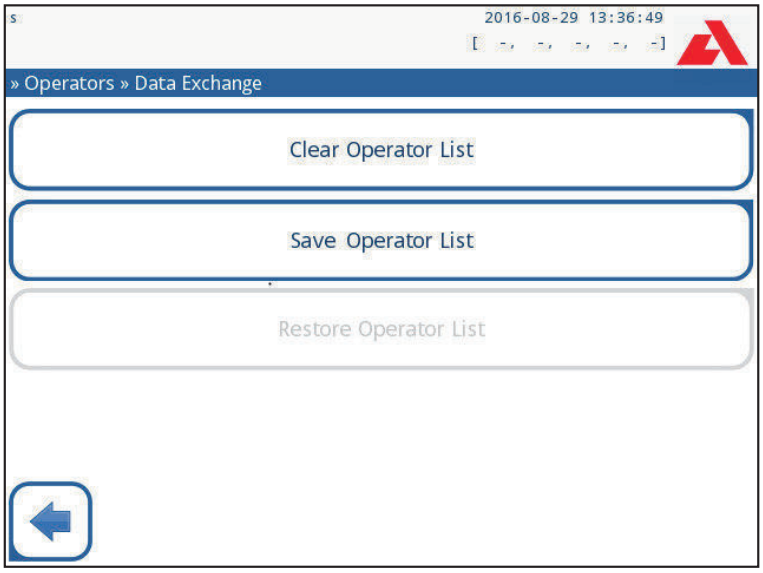


Figure 50: The Data Exchange menu

Supervisor level users can download operator list to a USB flash drive and upload to one or multiple other analyzer/analyzers with this feature.

– To download the list enter a USB flash drive into its socket at the back of the analyzer. Go to ***Settings*** » ***Operators*** » ***Data Exchange*** screen, and click on **Save**. The analyzer saves the operator list in a .txt format with details of the analyzer and the date.
– Click on **Clear Operator List** button to delete all existing operators.
– To upload the list click on the **Restore** button on the ***Settings*** » ***Operators*** » ***Data Exchange*** screen.

If there are operator accounts on the analyzer with the same ID as in the list on the USB flash drive, the one on the USB flash drive overwrites the existing operators rights.

The Save Operator List and Restore Operator List buttons are grayed out when there is no USB flash drive entered or there is no saved operator list on it.

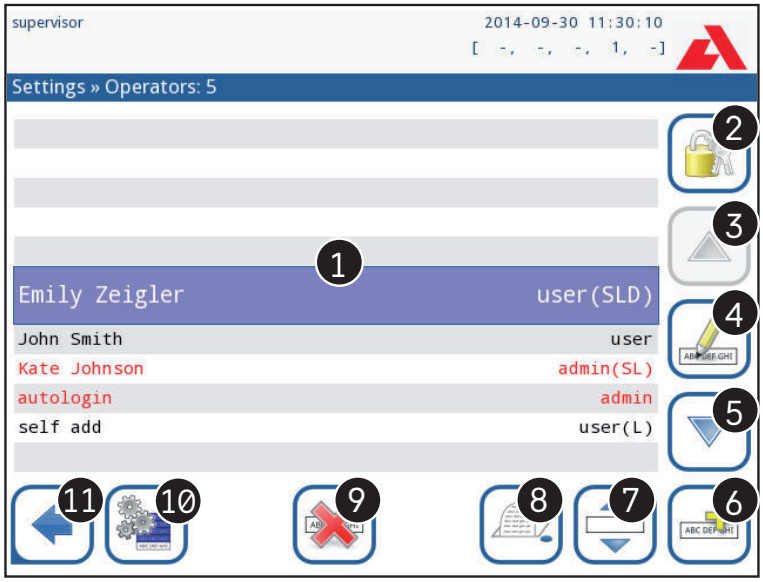


Figure 51: The Operators menu

Key to Figure 51:

Administrator- and supervisor-level operator accounts are displayed in red.

1. List of operators
2. Access the Security settings menu

This feature is only available to supervisor-level operators.

3. Move the line cursor selection up
4. Modify and manage the selected operator's accounts
5. Move the line cursor selection down
6. Add new operator
7. Toggle enabling the reordering of operators on the list

This function is only available when an operator is selected that is displayed on the login screen (☞ ***11.15.1 Managing operator accounts***), and if there are at least two such operators. The operators are displayed on the login screen in the order that is specified on this list.

The button turns orange to indicate that the function is enabled.

8. Print the current list of operators
9. Delete the selected operator account
10. Go to the ***Data Exchange*** menu
11. Go back to the ***Settings*** menu

11.15.2 Predefined operator accounts

⚠ **The user rights of the “autologin” and the “self add” operators can be modified only by users with a supervisor-level operator account.**

autologin:

The ‘autologin’ operator is a special predefined operator without either a user name, or a password. If enabled, any user can operate the analyzer logging in with the ‘autologin’ operator account.

To login with ‘autologin’ operator, leave blank the login name field (“Enter Operator name”) and tap the Apply button.

self add:

The ‘self add’ operator rights define what kind of rights an operator created by a user will receive, when the ‘self add operators at login’ feature is enabled. All self-added operators will inherit the right of the ‘self add’ operator.

supervisor:

The ‘supervisor’ operator is not listed in the operator list. The user can login to it by typing the login name from the login screen. The supervisor’s default password is ’1234’. Currently its password cannot be reset, do not forget the password. Later there will be a special user which can be used to reset the whole system (erase users, DB). The service user will also have the right to reset the supervisor password.

Full database and config clear.:

Special user to reset the whole system.

Can be used in case of system lock-out (i.e. lost supervisor password), corrupted database or to create a fresh system.

If this name is entered in the login name field, the software will erase all data, settings and operator accounts. Make sure to include the full stop at the end of the sentence “Full database and config clear.” The system will ask to confirm the command.

⚠ **Make sure that all previously collected data is already archived before erasing. This step will erase all existing information from the system.**

11.15.3 Managing security settings

ⓘ *Security settings are only available to users with Supervisor-level operator accounts.*

The global security setting level can be set on the ***Settings » Operators » Security*** menu (☞ ***Figure 52***).

Urilyzer® 500 Pro offers 5 different preset security levels, and a fully customizable ‘Expert’ level where various security settings can be enabled or disabled to best suit the laboratory workflow.

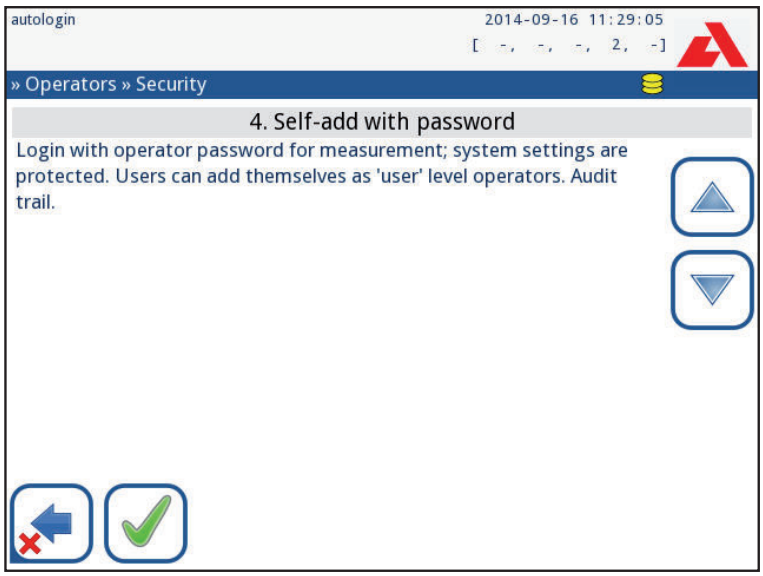


Figure 52: The Self-add with password preset security level screen

1. Open system

Automatic login without identification or password, free modification of settings. No security applied: Anyone can perform tests and modify the settings using the ‘autologin’ operator.

2. Anonymous usage

Automatic login without identification and password for measurement; system settings are protected. Users can add themselves as ‘user’ level operators.

3. Self-add

Users can add themselves as ‘user’ level operators at login.

4. Self-add with password

Login with operator password for measurement; system settings are protected. Users can add themselves as ‘user’ level operators at login, and a password is required for each account. An audit trail logging user activities is enabled.

5. Secure

Full security applied: only registered users may login. Users can be registered by administrators (‘admin’). An audit trail logging user activities is enabled.

	1 Open system	**2** Anonymous usage	**3** Self-add	**4** Self-add with password	**5** Secure
auto login	☑ On	☑ On	☐ Off	☐ Off	☐ Off
auto login rights	admin	user	N/A	N/A	N/A
self add	☐ Off	☑ On	☑ On	☑ On	☐ Off
self add rights	N/A	user	user	user	N/A
password not re-quired	☑ On	☑ On	☑ On	☐ Off	☐ Off
perform test	anyone (anonymous)	anyone (anonymous)	anyone	anyone	registered users
modify settings	anyone	admins	admins	admins	admins
modify security	supervisor	supervisor	supervisor	supervisors	supervisors
add user	anyone	admin	admin	admin	admin
login	autologin	autologin	self-regis-tered users w/o passw	self-regis-tered users with passw	admin-regis-tered users with passw
user man-agement	N/A	admins	admins	admins	admins
identifica-tion	not forced	not forced	forced	forced	forced
password usage	not forced	not forced	not forced	yes	yes
real audit trail	no	no	no	yes	yes

11.15.4 Customizing security settings

To enable full customization for security settings select **Custom** on the **Seetings » Operators » Security** screen and tap the **Customize** button, which takes the user to the ***» Operators » Custom*** screen.

The following options can be set independently of each other for full control over system security and user authentication:

Auto login:

Check this box to enable the autologin preset operator account (☞ ***11.15.2 Predefined operator accounts***)

Self add operators:

If this option is enabled, the ‘self add’ special operator account is enabled: Users can freely create a new operator account when logging in to the analyzer (if the login name

does not already exist in the database). When this option is enabled, the account level can be set for all such self-added operator accounts, as well as customize them (☞ ***Customizing operator accounts***).

Password not required:

If this option is enabled, users are not prompted to enter passwords when setting up new operator accounts.

ⓘ *If a password is already associated with an operator account, users can only access the account if they provide the password.*

Operators on login screen:

If this option is enabled, the "Display on login screen" option becomes available for operator account customization (☞***11.15.1 Managing operator accounts***).

Check LIS:

If active, the operators defined on the LIS can be used.

Only LIS:

If active, only the operator accounts defined on the LIS can be used (except for supervisor-level operator accounts). If this option is enabled, the "Auto login" , "Self add operators", and "Password not required" options automatically become disabled.

ⓘ *If enabled, the 'login without password' and 'operators on login screen' can be separately modified for each operator.*

12. Cleaning & Maintenance

As a general preventive action, always keep the outside of the Urilyzer® 500 Pro clean and free of dust.

12.1 Cleaning the analyzer

When the analyzer is turned off, wipe the outside (including the display) with a damp (not wet) cloth and a mild detergent. Make sure that no liquid enters the analyzer.

⚠ **Do not use any type of solvent, oil, grease, silicone spray or lubrication on the analyzer.**

⚠ **Make sure that no liquid enters the device and printer compartment.**

⚠ **In case of excessive contamination, clean the analyzer immediately.**

ⓘ *Recommended and tested cleaning agents: Isorapid (20 g Ethanol, 28 g 1-Propanol, 0.1 g Quaternary ammonium compounds), Trigene Advance Laboratory 0.5, 1% solution, Barrycidal 33 2%*

12.2 Cleaning the internal elements

Figure 53: Rinsing the test strip tray

Figure 54: Rinsing the strip timer rake

Figure 55: Rinsing the drip tray

The parts of the analyzer that may come into contact with urine samples must be cleaned regularly.

⚠ **Always wear protective gloves when handling the test strip tray, the strip timer rake or the drop tray.**

⚠ **Blot by touching the edge of the strip to a paper towel to remove excessive urine to avoid unnecessary amount of evaporating urine in the strip entry area.**

At the end of each day, clean the internal elements using the following procedure:

1. Turn off the Urilyzer® 500 Pro and take out the internal elements.
2. Rinse the test strip tray, the strip timer rake, and the drop tray under running water and then clean them with 70 % isopropyl alcohol.
3. Dry the elements with a lint-free wipe and reinsert them into the analyzer (☞ ***4.2 Setting up***).

⚠ **Make sure that the elements are completely clean and dry before reinserting.**

13. Troubleshooting

The Urilyzer® 500 Pro will operate properly if the directions for using and cleaning the instrument are followed.

Advisory messages will be displayed when the user's attention is required on any disorder or result of a performed action.

The user interface messages can be categorized into the following groups:

1. Error messages
2. Warning messages
3. Information messages

The active errors and warnings can be listed by tapping the status bar area on any screen.

Error messages

If an error prevents the instrument from being used, certain selection areas on the screen will be disabled and testing procedure cannot be started. The background of the status bar changes to red. Performing the displayed corrective action will remove the error and allow the user to use the instrument and enable testing.

Warning messages

Less severe errors trigger warning messages. These kinds of errors do not prohibit testing, but may limit certain functionality (i.e. transfer, printing) of the system. The background of the status bar changes to yellow. These errors do not compromise the testing and the measurement performance of the system. The resolution of these errors may include the restart of the system. When the corrective action are taken, the message will be removed from the system.

Information messages

Provides feedback about the successful execution of an action and/or provides additional information for the operator.

Based on the presentation the display type of the messages are the following:

1. Status line: Appears permanently in the status bar
2. Timed pop-up window: A pop-up window is displayed only for a few seconds, then disappears automatically without operator interaction
3. Pop-up window: A pop-up window requiring confirmation by the operator.
4. Result view: Message appears on the standard content area.

Key for the table of Error messages	
Categories (C)	**Type (T)**
E Error message	S Status line
W Warning messages	TP Timed pop-up window
I Information messages	P Pop-up window
	R Result view

13.1 Troubleshooting chart

In case of an error, try to solve it according to the below troubleshooting guide first. If the failure remains, please contact your service representative. The certified service personnel is allowed to perform further troubleshooting, repair serviceable parts and configure the system according to the service manual.

Problem	Cause	Corrective action
1. The device does not respond to the On/Off switch	1.1 The mains cable or the AC adapter is not plugged in correctly.	Check that the adapter is connected to the analyzer and that the mains cable is plugged into the wall socket. Make sure that the blue light on the AC adapter lights up when it is plugged in.
	1.2 The mains cable or the AC adapter is defective.	Check the mains cable and AC adapter for external signs of damage. If the cable or adapter is damaged, contact your certified service personnel.
	1.3 The On/Off switch is defective or it has lost its connection to the PCB	Contact your certified service personnel.
	1.4 The microSD memory card is defective.	
	1.5 The Mainboard is defective	
2. The device switches on, but the touchscreen does not light up.	The Touchscreen is not connected properly to the Mainboard or the touchscreen is defective	Contact your certified service personnel.
3. The touchscreen is very dim or does not respond.	3.1 The LCD brightness is set too low.	Set the LCD brightness higher on the Main Menu»Settings»User Options screen.
	3.2 The touchscreen is defective.	Contact your certified service personnel
4. Measurement results are consistently below or above standard ranges.	The used test strips or the measuring head is defective	Repeat the measurement with a new vial of test strips or perform a QC measurement to check the test strip performance. Contact your certified service personnel, if the QC fails.
5. The strip timer rake does not move or move irregular / slow.	5.1 The test strip or strip timer rake is contaminated by dried urine.	Clean the test strip tray and strip timer rake as described in 12.2 Cleaning the internal elements
	5.2 The mechanic is defective	Contact your certified service personnel

Problem	Cause	Corrective action
6. The system does not recognize one or more external connectors	6.1 The affected connector or connectors lost the connection with the connector board.	Contact your certified service personnel.
	6.2 The connector panel is defective	
7. The green LED at the strip delivery zone does not light up or it is very faint	The LED is blocked by dirt or dried urine build-up.	Clean the strip delivery zone. If problem persists, contact your certified service personnel
8. Results are not printed or the printout is very faint.	8.1 Autoprint is not enabled.	Check the Autoprint function on the Main Menu»Settings»User Options screen.
	8.2 The paper loaded is not compatible with the printer.	Make sure that the correct thermal printer paper is loaded into the paper compartment.
	8.3 The thermal paper is too old; the heat-sensitive layer deteriorated.	Load the printer with a fresh roll of thermal paper.
	8.4 The printer is defective	Contact your certified service personnel.
	8.5 Paper is out or printer cover is not closed	Refill paper and close printer cover.
8. There are white spots or streaks on the printout where results are not printed.	The grease and dirt accumulated on the printer roller prevents uniform printing.	Clean the printer roller. If the problem persists, contact your certified service personnel.
9. The date or time displayed in the display header is incorrect	9.1 The date or time settings have been changed.	Go to Settings » Date/Time and tap Restore Default to reset the system to the current date and time..
	9.2 The real-time clock battery on the Mainboard is dead or lost its connection to the board.	Contact your certified service personnel.

13.2 Error messages

Message ID	C.	T.	Status line text	Full text	Recommended action
E99	E	S	Head HW	Head hardware error. Please call Service.	Contact your service representative
E98	E	S	Printer HW	Printer hardware error. Please call Service.	Contact your service representative.
E97	E	S	Head voltage	Head voltage value is out of range. Please call Service.	Contact your service representative.
E96	E	S	Power voltage	Power voltage value is out of range. Please call Service.	Contact your service representative.
E95	E	S	Mechanic HW	Mechanical hardware error. Please call Service.	Contact your service representative.
E90	E	S	Reference pad	Failure of reference pad check. Reference pad value is out of range. See User's Manual for further instructions.	The photometry reference pad is contaminated or damaged. Contact your service representative to replace the reference pad, and recalibrate the analyzer.
E89	E	S	QC lockout	Go to "QC measurement" to perform QC check.	Perform QC check measurements to remove the QC lockout.
E88	E	S	Memory limit	Database limit exceeded, please delete results to free up space.	Free up memory by erasing old data!
E87	E	S	Strip tray	Strip tray out. Please insert it	Make sure that the test strip tray is firmly in place.
E86	E	S	Drop tray	Drop tray out. Please insert it	Make sure that the drop tray is firmly in place.
E85	E	S	Rake out	Rake out. Please insert it.	Make sure that the strip timing comb is in place and that it is oriented correctly.
E84	E	S	Power switch	Power switch off. Please insert 'Strip tray' (again).	Switch off the analyzer and after that insert the 'Strip tray' again.
W69	W	S	Output port	Output port not open. Please restart the system!	Restart the analyzer.
W68	W	S	Output internal	Output internal error. Please restart the system!	Restart the analyzer.
W67	W	S	Output init	Output not inited. Please restart the system!	Restart the analyzer.
W66	W	S	Output closed	Output closed. Please restart the system!	Restart the analyzer.
W65	W	S	Output memory	Not enough memory for output. Please restart the system!	Restart the analyzer.
W64	W	S	Output write	Cannot write output. Please change file name or (re)insert USB pendrive.	Use alphanumeric characters only, and ensure that the USB flash drive is connected properly and recognized by the system. If required, re-initialize the USB port by tapping the Analyticon logo in the top right corner.

Message ID	C.	T.	Status line text	Full text	Recommended action
W63	W	S	Output aborted	Output aborted. Please start again.	Restart transfer.
W62	W	S	Output limit	Output reached internal limit. Please check protocol.	Check and verify output settings.
W61	W	S	Output protocol	Protocol failure. Please check connection type.	Check and verify output settings.
W60	W	S	Output failure	Output failure. Please wait and try again in a minute. In case of repeated failure please check connection type.	The system continuously tries to deliver the output. If it succeeds, the error will automatically disappear. If the error persists, check and verify output settings.
W59	W	S	Output busy	Output line busy. Please wait and try again in a minute.	The system continuously tries to deliver the output. If it succeeds, the error will automatically disappear. If the error persists, check and verify output settings.
W58	W	S	Output file	Output file not open. Please change file name or insert pendrive.	Change the file name / destination and ensure that the USB flash drive is connected properly and recognized by the system. If required, re-initialize the USB port by tapping the Analyticon logo in the top right corner.
W57	W	S	Output link	Output link lost. Please wait a minute. In case of persistent failure please check connection and connection parameters.	The system continuously tries to deliver the output. If it is successful, the error will automatically disappear. If the error persists, please verify the connections and the presence/status of the destination
W56	W	S	Output connect	Output port cannot connect to server. Please check ethernet cable, ethernet configuration in settings and server IP address and port number.	The system continuously tries to deliver the output. If it succeeds, the error will automatically disappear. If the error persists, please verify the connections and the presence/status of the destination.
W38	W	S	Head version	Measure head SW version is unknown. Please call Service.	Contact your service representative.
W37	W	S	Temperature	Temperature out of allowed range.	Ensure the proper environmental conditions.
W35	W	S	Data lost (limit)	Database limit exceeded. Earlier results will be dropped.	To free up memory in the database, delete unused data. (Circular memory is active, so old data will be overwritten by new data).
W34	W	S	Memory near full	Database counter is reaching its limit. Please delete some results.	To free up memory in the database, delete unused data.
W33	W	S	QC lockout	Go to „QC measurement” to perform QC check.	Perform QC check measurements to remove the QC lockout.

Message ID	C.	T.	Status line text	Full text	Recommended action
W31	W	S	Door open	Printer door is open. Please close it!	Check if the paper roll is correctly loaded in the printer bay and close the printer door.
W30	W	S	Paper out	Paper out. Please replace the printer paper!	Open printer door and load a fresh paper roll in the printer.
E199	E	P		DB failure: cannot write result. Please call Service!	Contact your service representative or do a ***Full database and config clear.***
E198	E	P		DB failure: cannot modify result. Please call Service!	Contact your service representative or do a ***Full database and config clear.***
E197	E	P		DB failure: cannot delete result. Please call Service!	Contact your service representative or do a ***Full database and config clear.***
E196	E	P		DB failure: configuration is corrupted. Please check the configuration settings.	Contact your service representative or do a ***Full database and config clear.***
E195	E	P		Worklist DB failure: cannot write new item.	Contact your service representative or do a ***Full database and config clear.***
E194	E	P		Worklist DB failure: cannot insert or modify item.	Contact your service representative or do a ***Full database and config clear.***
E193	E	P		Worklist DB failure: cannot delete item.	Contact your service representative or do a ***Full database and config clear.***
E181	E	P		Load config error: read details from “wpa_supplicant.conf.err” file on PENDRIVE	The system encountered a problem in the wpa_supplicant.con.zip file, and has saved an error report on the connected USB stick. Refer to ***the WPA Supplicant documentation*** to deal with the issue.
E180	E	P		Load config error: USB drive or wpa_supplicant.con.zip file not exists.	Make sure that the wpa_supplicant.con.zip file is properly saved on the connected USB flash drive.
E179	E	P		Mechanic error.\nPlease remove ‘strip tray’, view inside, check rake and remove lost strip.\n\n(Touch to confirm).	Remove ‘strip tray’, view inside, check rake and remove lost strip.
E178	E	P,S		Wastebin full. Please empty it.	Empty waste of teh test strip bin.
E177	E	TP		Length of password must be between 8 and 63 characters.	The entered password is too long or too short. Enter a new password.
E175	E	TP		Lenght of LOT+expiry is more than 32 character.	Enter a LOT expiry shorter than 32 character.
E174	E	TP		Format of entered expiry is failed.\nFormat of expiry is ‘YEAR/MONTH’.	Enter expiry in format: ‘YEAR/MONTH’.

Message ID	C.	T.	Status line text	Full text	Recommended action
E173	E	TP		Format of entered LOT is failed.\nFormat of expiry is '(YEAR/MONTH)' with brackets.	Enter LOT expiry in format: '(YEAR/MONTH)' with brackets.
E172	E	TP		Time is expired.	Start it again.
E171	E	TP		Cannot export log.	Ensure the USB flash drive is connected properly and recognized by the system. If required, re-initialize the USB port by tapping the Analyticon logo on the top right corner.
E170	E	TP		Sample ID already exists, please change it.	Verify and repeat the input or use another Sample ID!
E169	E	TP		Registration Code is already used.	Verify and repeat the input or use another RegCode.
E168	E	TP		Registration Code is not valid.	Verify and repeat the input or use another RegCode.
E167	E	TP		Operator ID already exists, please change it.	Enter another Operator ID.
E166	E	TP		Password check failed, please try again.	Enter the valid password
E165	E	TP		Password is too short, please try again! (minimum length is 3 characters)	Enter a new password that is at least 3 characters long.
E164	E	TP		Password does not match, please try again.	Re-enter the password.
E163	E	TP		Operator does not exist, please try again.	The entered operator name is not on the operator list. Enter another Operator ID.
E162	E	TP		Password check failed, please try again.	Enter the valid password
E161	E	TP		Sample ID required. Please set it.	Enter a Sample ID.
E160	E	TP		LOT Code required. Please set it.	Enter a LOT Code
W169	W	TP		Cannot open serial port for output!	Check the serial port connection.
W158	W	TP		Cannot open file for output!	Check the output port and that the output storage is present.
W156	W	TP		Cannot connect to server for output.	Check output server settings.
W142	W	P		Wastebin near full. Please empty it.	Empty waste of the test strip tray.
W141	W	P		Please empty wastebin. (Touch to clear wastebin counter.)	The number of processed test strips has reached the capacity of the waste bin (max 200 strips). Remove the waste of the test strip tray. Tap inside the message window to reset the used strip counter.

Message ID	C.	T.	Status line text	Full text	Recommended action
W140	W	P		Due to changes lockout time was decreased to %d day(s). (Touch to confirm.)	Tap inside the message window to confirm the new QC lockout period.
W139	W	TP		Previous “strip pads” settings lost. Tap “OK” (apply) before strip change.	Tap the Apply button to save changes, otherwise the special strip settings (pad order, sediment rec., etc.) will not be saved.
W138	W	P		Server IP address or mask format not right. (ex.: 192.168.1.12:4130)	Check and correct server IP address or mask input.
W137	W	P		IP address or subnet mask format is not correct. (i.e. 192.168.1.5/24 or 192.168.1.5/255.255.255.0)	Check and correct the analyzer’s IP address or mask input.
W136	W	P		IP address format is not correct. (i.e. 192.168.1.12)	Check and correct the analyzer’s IP address.
W135	W	TP		Cannot export log, because USB drive does not exists. Please insert it.	Make sure that the USB flash drive is connected properly and recognized by the system. If required, re-initialize the USB port by tapping the Analyticon logo in the top right corner.
W134	W	P		Worklist DB failure: possible data loss! Trying to repair. May take some minutes, please wait.	Database failure. The system is trying to repair itself. This may take a few minutes.
W134	W	P		Worklist DB failure: possible data loss!	Possible data loss, check worklist. If problem occurs multiple times, contact your service representative.
W133	W	P		Config DB failure: possible data loss! Trying to repair. May take some minutes, please wait.	Data loss probably occurred. The system is trying to repair itself.
W133	W	P		Config DB failure: possible data loss!	Possible configuration loss, check database. If problem occurs multiple times, contact your service representative.
W132	W	P		Config DB is recreated. Previous configuration is lost!	System settings are regenerated. Set the configuration options again. If problem occurs multiple times, contact your service representative.
W131	W	P		DB failure: possible data loss! Trying to repair. May take some minutes, please wait.	Data loss probably occurred. System is trying to repair itself.
W131	W	P		DB failure: possible data loss!	Possible data loss, check database. If problem occurs multiple times, contact your service representative.

Message ID	C.	T.	Status line text	Full text	Recommended action
W130	W	P		DB is recreated. All previous data is lost!	All existing data was lost. If problem occurs multiple times, contact your service representative.
I117	I	P		Due to changes lockout time was increased to %d day(s). (Touch to confirm.)	The active QC lockout time is increased successfully.
I117	I	P		Successful QC check. Lockout time was increased to %d days(s). (Touch to confirm.)	The QC lockout time was restarted because of the successful QC measurement.
I116	I	TP		Reminder: Last day before lockout.	There is only one day left to perform a successful QC measurement before the QC lockout is activated.
I115	I	TP		Measure head SW update in progress. May take some seconds, please wait.	N/A
I114	I	TP		Connection is in progress. Please wait.	N/A
I113	I	TP		Output is paused while in “Settings » Ethernet” screen.	N/A
I112	I	TP		Log exported.	N/A
I111	I	TP		Log export in progress. Please wait.	N/A
I110	I	TP		Output paused while navigating in settings menu.	N/A
I109	I	TP		Unused QC LOTs and limits deleted.	N/A
I107	I	TP		No password set. Please set your password on login!	N/A
I106	I	TP		Operator added.	N/A (Applicable in ‘self-add’ and ‘self-add with password’ system security levels ☞ ***11.15.3 Managing security settings***)
I105	I	TP		Selection was sent for printing.	N/A
I104	I	TP		Selection was sent for output.	N/A
I103	I	TP		Selection is inverted.	N/A
I102	I	TP		All samples are selected.	N/A
I101	I	TP		Sample ID was not found, please try again or cancel the search.	N/A

13.2.1 Testing/Measurement Result Errors

These error codes are stored together with the results in the database permanently and are also displayed after the testing procedure.

ID	C.	T.	Status line text	Full text	Testing: Error Source & Action
E299	E	R	Head HW error: defective LEDs	Head HW error: some LEDs may be defective. Please call Service.	Head hardware error. Contact your service representative.
E298	E	R	Head HW error: voltage out of range	Head HW error: voltage out of range. Please call Service.	Head hardware error. Contact your service representative.
E297	E	R	Head HW error: check failed	Head HW error: software check failed. Please call Service.	Head hardware error. Contact your service representative.
E296	E	R	Head communication error	Head communication failed. Please restart the system.	Communication with the head failed after the measurement. Restart the analyzer and repeat the test with a new test strip. If the error persists, contact your service representative.
E282	E	R	DB error: corrupted item	Database error. Stored item is corrupted. Please delete item from database.	Corrupted data. Restart the analyzer and repeat the test with a new test strip. If the error persists, contact your service representative.
E281	E	R	DB error: missing configuration data	Database error. Missing strip configuration data. Please delete item from database.	Corrupted data. Restart the analyzer and repeat the test with a new test strip. If the error persists, contact your service representative.
E280	E	R	DB error: configuration corrupted	Configuration error. System configuration (or database) failed.	Corrupted data. Restart the analyzer and repeat the test with a new test strip. If the error persists, contact your service representative.
E270	E	R	Measurement error: reference pad out of range	Reference pad error. Measured value is out of acceptable range.	Repeat the last measurement. If the error persists, contact your service representative.
E269	E	R	Measurement error: too strong backlight	Backlight is too strong. Measurement is not possible!	External light was too strong during testing. Reduce the intensity of the external light or do not expose the tray directly with a strong light source (i.e. direct sunlight or lamp). Repeat the test with a new test strip.
E268	E	R	Measurement error: mechanical error	Mechanical error. Strip timing comb cannot go to home position.	Make sure that the test strip tray and the strip timing comb is correctly inserted. If the error persists, contact your service representative.

ID	C.	T.	Status line text	Full text	Testing: Error Source & Action
E267	E	R	Mechanical error: home position error	Home position error. Strip failure detected after measurement	Contact your service representative.
E266	E	R	Measurement error: strip type mismatch	Strip type mismatch while calculating the results of measurement.	Not the proper test strip type was used. Make sure that the strip used was of the type that was set (See ☞ ***11.6 Strip options***). Repeat the test with a new test strip.
E264	E	R	Measurement error: strip position error	Strip position error. Strip position check failed after the measurement.	The test strip moved from its initial position during testing. Repeat the test ensuring the strip is correctly positioned on the test strip tray: slide strip to the end of the channel.
E263	E	R	Measurement error: temperature out of range	Temperature was out of allowed range during measurement.	Test was performed outside the operation range. Ensure the proper environmental conditions. Repeat the test using a new test strip
E262	E	R	Measurement error: flipped strip	Flipped strip error. Strip is put backside top on stripholder.	Test strip was placed with its wrong side up. Repeat the test ensuring the strip is correctly positioned on the test strip tray with the test pads facing up.
E261	E	R	Measurement error: dry strip	Strip is (partially) dry.	Strip was (partially) dry. Repeat the test ensuring that the new strip including the pad closest to the handle (the last pad) has been in contact with the sample.
E260	E	R	Measurement error: no strip	No strip is present. Storing commented item without real values.	No strip was detected during measurement. The result is only saved to enable comment input.
E 265	E	R	Measurement error: pad values are out of range	Measured value out of valid range for one or more pads.	Measurement error: pad values are out of range

13.2.2 Software Update Errors

SW Update ID	C	T	Full text	Corrective action
E596	E	U	Update was failed.	Check and verify the software update sources on the media. Restart update.
E597	E	U	Internal configuration failure! (Please call Service)	Restart update.
E572	E	U	Failed install: ……	Corrupted or missing files. Check and verify the software update sources on the media. Restart update.
E562	E	U	Failed backup: ……	Restart update.
E561	E	U	Missing: ……	Corrupted or missing files. Check and verify the software update sources on the media. Restart update.
I502	I	U	The system is already up to date.	N/A
I503	I	U	SW update is not found. Please insert USB drive with SW package.	Follow the message text instructions.
I504	I	U	Software update package was found. Tap “Update” button to start process.	Follow the message instructions.
E5XX	E	U	Package error: ……	Corrupted or missing files. Check and verify the software update sources on the media. Restart update.
E5XX	E	U	Internal error: ……	Restart update.
E5XX	E	U	Missing source: ……	Check and verify the software update sources on the media. Restart update.
E5XX	E	U	Source check failure: ……	Corrupted or missing files. Check and verify the software update sources on the media. Restart update.

Appendices

Appendix A: Results table

The Urilyzer® 500 Pro prints the results in the following gradation of concentration:

Parameter	Conventional Units (Conv.)	SI Units (SI)	Arbitrary Units (Arb.)
BIL (Bilirubin)	neg 1 mg/dl 2 mg/dl 4 mg/dl	neg 17 µmol/l 35 µmol/l 70 µmol/l	neg 1+ 2+ 3+
UBG (Urobilinogen)	norm 2 mg/dl 4 mg/dl 8 mg/dl 12 mg/dl	norm 35 µmol/l 70 µmol/l 140 µmol/l 200 µmol/l	neg 1+ 2+ 3+ 4+
KET (Ketone)	neg 10 mg/dl 25 mg/dl 100 mg/dl 300 mg/dl	neg 1.0 mmol/l 2.5 mmol/l 10 mmol/l 30 mmol/l	neg (+) 1+ 2+ 3+
ASC (Ascorbic acid)	neg 20 mg/dl 40 mg/dl	neg 0.2 g/l 0.4 g/l	neg 1+ 2+
GLU (Glucose)	norm 50 mg/dl 100 mg/dl 250 mg/dl 500 mg/dl 1000 mg/dl	norm 2.8 mmol/l 5.6 mmol/l 14 mmol/l 28 mmol/l 56 mmol/l	norm 1+ 2+ 3+ 4+ 5+
PRO (Protein)	neg 30 mg/dl 100 mg/dl 500 mg/dl	neg 0.3 g/l 1 g/l 5 g/l	neg 1+ 2+ 3+
ERY (Erythrocytes)	neg 10 Ery/µl 50 Ery/µl 300 Ery/µl	neg 10 Ery/µl 50 Ery/µl 300 Ery/µl	neg 1+ 2+ 3+
pH	5 6 6.5 7 7.5 8 9	5 6 6.5 7 7.5 8 9	5 6 6.5 7 7.5 8 9
NIT (Nitrite)	neg pos	neg pos	neg pos
LEU (Leukocytes)	neg 25 Leu/µl 75 Leu/µl 500 Leu/µl	neg 25 Leu/µl 75 Leu/µl 500 Leu/µl	neg 1+ 2+ 3+
SG (Specific Gravity)	1.000 1.005 1.010 1.015 1.020 1.025 1.030	1.000 1.005 1.010 1.015 1.020 1.025 1.030	1.000 1.005 1.010 1.015 1.020 1.025 1.030

Appendix B: Specifications

Type:	reflectance photometer with 4 discrete wavelengths: 505, 530, 620, 660 nm
Throughput:	maximum 500 strips/hour
Display:	5.7” LCD VGA capacitive touch-screen (resolution: 640x480)
Memory:	5000 test results / 5000 QC results
Printer:	internal thermo printer (roll diameter max. 60mm)
Dimension:	30 x 30 x 18 cm (W x D x H)
Weight:	6.6 kg
Power supply:	IN: 100...240V AC, 50/60 Hz OUT: 12V DC ; 5A
Operational conditions:	Temperature: +15˚C to +32˚C Relative humidity: 20% to 85% (without condensation) Atmospheric pressure: 70 kPa to 106 kPa
Storage:	Temperature: +5˚C to +40˚C Relative humidity: 10% to 85% (without condensation) Atmospheric pressure: 70 kPa to 106 kPa
Transportation:	Temperature: -25˚C to +60˚C Relative humidity: 10% to 85% (without condensation) Atmospheric pressure: 70 kPa to 106 kPa
Altitude:	3000 m
Interfaces:	PS2 (external keyboard, barcode reader) serial RS232 USB Type B USB Type A Ethernet / Wi-Fi
Expected lifetime:	5 years or 100000 measurements

Appendix C: Analyzer Default settings

User options:

Autostart:	ON
Auto print:	ON
Auto transfer:	OFF
Sound:	ON
LCD brightness (%):	100

Measurement:

color:	OFF
clarity:	OFF
Set Sample ID:	OFF
Set Patient ID:	OFF
Display units:	conv-arbitr
Strip:	CombiScreen® 11SYS Plus

Bil	0
Ubg:	0
Ket:	0
Asc:	0
Glu:	0
Pro:	0
Ery:	0
pH:	0
Nit:	0
Leu:	0
SG:	0

Printout:

Operator ID:	ON
Patient ID:	ON
Analyzer S/N:	ON
Sediment rec.:	ON
Strip LOT:	ON
Empty always:	OFF
Printout units:	conv-arbitr
Output:	unidir text (UTF8)
Header:	empty
Frame+CHKSUM:	ON
Output units:	conv-arbitr
Baud rate:	9600

QC options:

QC Lockout (day):	0
L1:	ON
L2:	ON
L3:	OFF
LOT expiry lockout:	OFF

Power management options:

LCD off time (min):	5
Logout time (min):	10
Power off time (min):	60

Database management options:

Circular memory:	OFF
Warning at circ.mem. limit:	OFF
Prewarning:	30

Authent. general settings:

Auto login:	OFF
Self add operators at login:	OFF
Login without password:	OFF
Operators on login screen:	OFF
LIS operator list check:	OFF
LIS operator list only:	OFF

ⓘ *Authentication general settings do not change when restoring the default settings.*

Appendix D: Safety information

The Urilyzer® 500 Pro device was designed and manufactured to comply with the following international regulations, and left the factory in a safe condition. Follow the instructions and pay attention to the warnings in this manual to keep the analyzer in a safe condition.

The device complies with the protection requirements of IEC 61010-1:2010, IEC 61010-2-101:2015, IEC 61326-1:2012 and IEC 61326-2-6:2012.

CE Complies with the provisions of the applicable EU regulations.

According to EN 61326-2-6, it is the user's responsibility to ensure that a compatible electromagnetic environment for this instrument is provided and maintained in order that the device will perform as intended. Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper operation. The electromagnetic environment should be evaluated prior to operation of device.

This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case you may want to reduce the interference.

The analyzer must be operated only with the prescribed power supply unit (Class II protection).

Personal computers that are connected to the device must meet the EN 60950, UL 60950/CSA C22.2 No. 60950 requirements for data processing equipment.

Only connect the intended external devices with safety low voltages to the corresponding interfaces (serial, PS2, USB, Ethernet) to avoid the risk of electrical shock or the risk of damaging the devices or the analyzer.

Please note that the instrument may potentially be infectious. Disinfect or sterilize all equipment before repair, maintenance or removal from the laboratory (See "Appendix D.2 Disposal information")

D.1 Incident reporting

Inform Analyticon Biotechnologies GmbH service representative and your local competent authority about any serious incidents which may occur when using this product.

D.2 Disposal information

⚠ Do not dispose of an used Urilyzer® 500 Pro device or any of its parts as municipal solid waste.

⚠ Without disinfection or sterilization the device and any of its parts are considered infectious clinical waste (EWC code 180103*). Untreated infectious waste is typically incinerated. Follow the local waste management guidelines and regulations to dispose the device and its parts.

Disinfect or sterilize all the disassembled parts:

- Immerse the parts in a germicidal bath of chlorine bleach (5:100 Sodium hypochlorite solution) for two (2) minutes at room temperature (20°C or 68°F)

⚠ **Wear protective rubber gloves and protective goggles when handling chlorine bleach and work in a well-ventilated room.**

- Sterilize the parts (according to DIN EN ISO 1764) in an autoclave for 7 minutes at 132 °C (270 °F) or for 20 minutes at 121 °C (250 °F).

Appendix E: Support & ordering

E.1 Support

Analyticon Biotechnologies GmbH offers full service support for its products. Feel free to contact our service staff by phone during office hours at the service hotline or at the support e-mail address

Phone: +49 (0) 6454 / 7991 0
Fax: +49 6454 7991 - 71
e-mail address: support@analyticon-diagnostics.com.

E.2 Ordering

Any replaceable part, accessories and consumables of the device can be ordered directly from your local distributor:

Part name	Part number	Pack size / amount
CombiScreen® 11SYS PLUS	94100 / 94150	100 / 150 strips
CombiScreen® 11SYS	93100 / 93150	100 / 150 strips
CombiScreen® Dip Check	93010	2x 15 ml (Level 1 + 2)
CombiScreen® Drop Check	93015	2x 5 ml (Level 1 + 2)
Test strip stray/waste bin	S-UA34402004	1
Strip timer rake	S-UA34409341	1
Drop tray	S-UA30501522	1
Printer paper	A93010	1
Power supply cord	S-1AGT4113	1
Power supply adapter	S-UA34600021	1
Barcode Reader	A93025	1

Appendix F: Modification history

Version	Software Version	Changes
1.0 (01.05.2017)	1.0.10	First release
1.1 (01.11.2017)	1.0.10	Implementation of CombiScreen 11SYS
1.2 (01.01.2018)	1.0.10	Implemenation of the Reference number on page 86
1.3 (01.08.2018)	1.0.10	Korrektur der Tabelle in Anhang A (Seite 81)
IU500_GB_26_001_01.04_20191205 (1.4)	1.0.10	Implementation of CombiScreen Dip und Drop Check, harmonisationg of CS 11SYS Plus und CS 11SYS
IU500_GB_26_001_05.01_20211213	1.0.15	Change of the legal form (GmbH)
IU500_en_26_001_06.01_20220215	1.0.15	Implementation of IVDR requirements
IU500_en_26_001_07.01_20220520	1.0.15	Content-related correction to “IU500_ en_26_001_06.01_20220215”