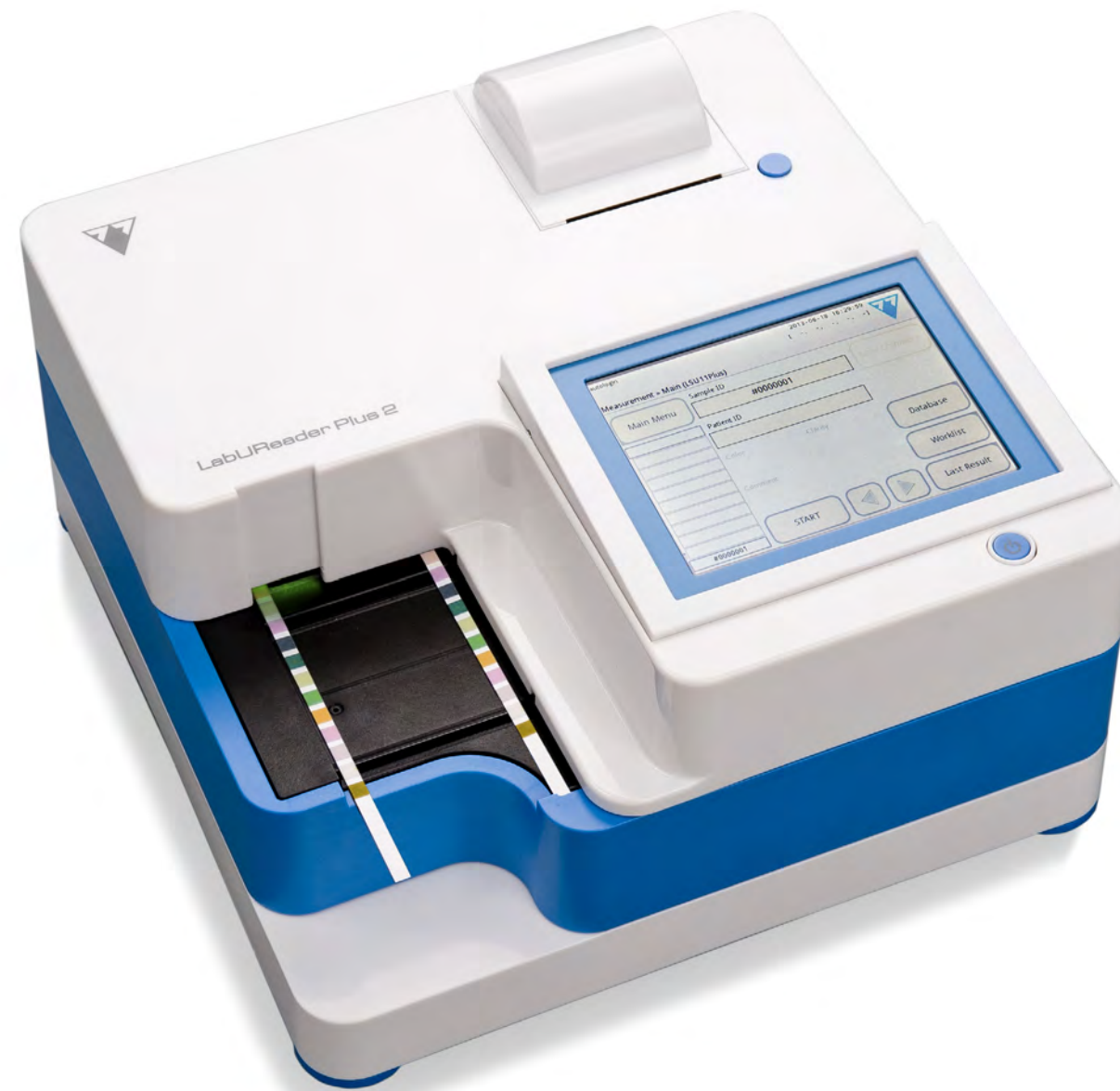


LabUReader Plus 2

Urine Analyzer

sw 1.0.13



Operator's Manual



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REF UA3-9901-2 LabUReader Plus 2

The information in this manual was correct at the time of printing. However, 77 Elektronika Kft. continues to improve its products and reserves the right to change specifications, equipment, and maintenance procedures at any time without notice.

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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.

UA3-9201-2 v4.0 draft 01-2022


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A Introduction

Modification history

Version	SW version	Date	Modification
UD2-9201-1 v2.0	1.0.0	06/2014	First edition
UD2-9201-2 v3.0	1.0.8	01/2019	New features added in software version
UA3-9201-2 v4.0	1.0.13	01/2022	New features added in software version IVDR compliance

 You do not have to calibrate the analyzer in any way before performing measurements. The analyzer software checks the system each time the analyzer is turned on. During testing, the analyzer automatically checks and corrects its performance based on the independent internal sensor.

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

A.1 Intended Purpose

The LabUReader Plus 2 is a semi-automated urine analyzer. It is intended for professional *in vitro* diagnostic use in performing urinalysis testing. It is used as a screening device. The LabUReader Plus 2 uses LabStrip U11 Plus test strips. It is intended for qualitative or semi-quantitative determination of glucose, protein, bilirubin, urobilinogen, pH, blood, ketone, nitrite, leukocytes, ascorbic acid, specific gravity. The analyzer measures urine samples.

A.2 Indications for Use

The LabUReader Plus 2 urine analyzer easy to use, bench top instrument which is intended for *in vitro* diagnostic use with LabStrip U11 Plus reagent strips manufactured by 77 Elektronika. This system performs semi-quantitative detection of the following analytes in urine: Bilirubin, Urobilinogen, Ketones, Ascorbic Acid, Glucose, Protein (Albumin), Blood (Hemoglobin), pH, Nitrite, Leucocytes and Specific Gravity.

The LabUReader Plus 2 urine analyzer is for use in professional facilities and centralized laboratory locations. The analyzer is

intended for use in screening at-risk patients to assist diagnosis in the following areas:

- ▶ Kidney function
- ▶ Urinary tract infections
- ▶ Metabolic disorders
- ▶ Carbohydrate metabolism
- ▶ Liver function

A.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.


A.4 How to use this manual

The Operator's Manual contains the directions you need to unpack the analyzer, safely use it for your daily urinalysis and keep it in good working condition.

A.4.1 Symbols


This manual uses the following symbols to highlight important information and help you navigate the text:


Symbol	Explanation
	CAUTION: Indicates a potentially hazardous situation that if not avoided could result in personal injury or damage to the instrument. This symbol is also used to highlight situations that can compromise results. Caution text appears in bold type.
	BIOHAZARD: Indicates a potentially dangerous situation involving the presence of biohazardous material. All safety precautions must be taken to prevent personal injury or damage to the equipment.
	NOTE: Contains important information or useful tips on using the analyzer. <i>Notes appear in italicized type.</i>


The  symbol indicates a cross-reference within the text. In the manual, you will notice some text is in **bold/italic** or **bold**. The **bold/italic** text identifies screen names, while simple **bold** text identifies a button (touch sensitive area) on the analyzer display.


A.5 Safety precautions

Before operating the LabUReader Plus 2 analyzer, 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** [N.4 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 Operator's Manual may result in a safety risk. Use the LabUReader Plus 2 analyzer to analyze urine samples only. It is not intended for any other application.**

 **Environmental conditions: The LabUReader Plus 2 analyzer is approved for indoor use only. See** [D 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 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.** [N.4.3 Protecting yourself from biohazards](#) **section for more information.**

A.6 Approvals

The LabUReader Plus 2 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 LabUReader Plus 2 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.

B Quickstart

1 Unpack the instrument and place it on an even, hard surface (for detailed installation instructions see [D Unpacking & Setup](#)). Insert the drop tray, the strip timer rake, and the Test Strip Tray.

2 Connect the power supply and turn the reader on with the On/Off-switch (See [Figure 12: Powering up on page 10](#)). After the first boot-up procedure and self-test the Start-Up Wizard will appear (See [F Start-Up Wizard on page 14](#)). After all further powering on the **Measurement** screen will show up on the display.

3 Dip a LabStrip U11 Plus test strip into the urine sample for approximately one second.

 **Do not touch the analyte 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.

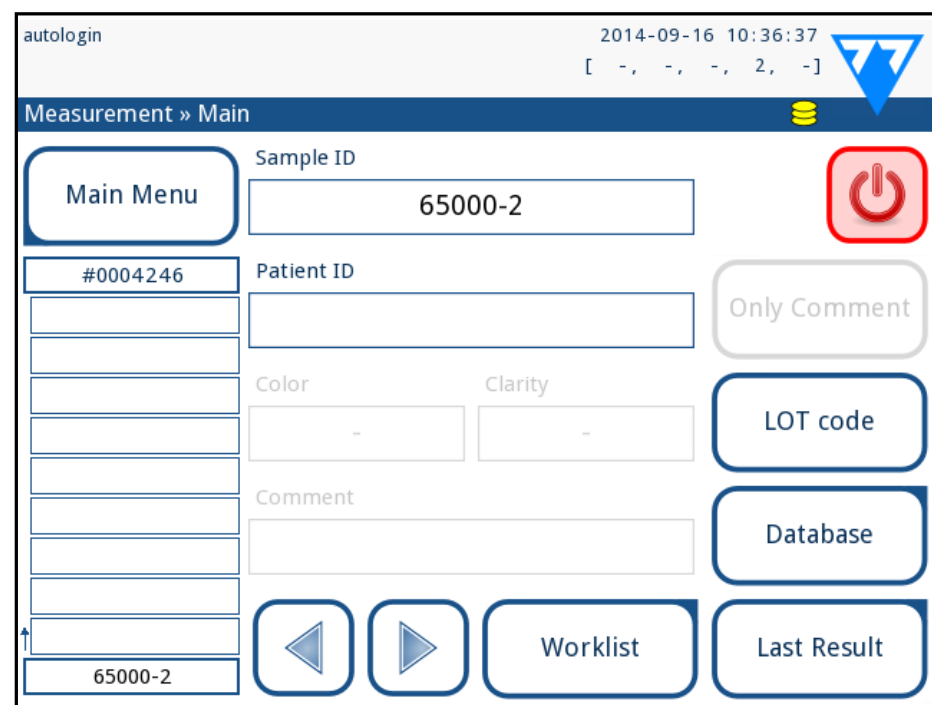



Figure 1: The Measurement menu

 **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 you wish to test. You can monitor the real-time progress of each of the strips in the list 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.

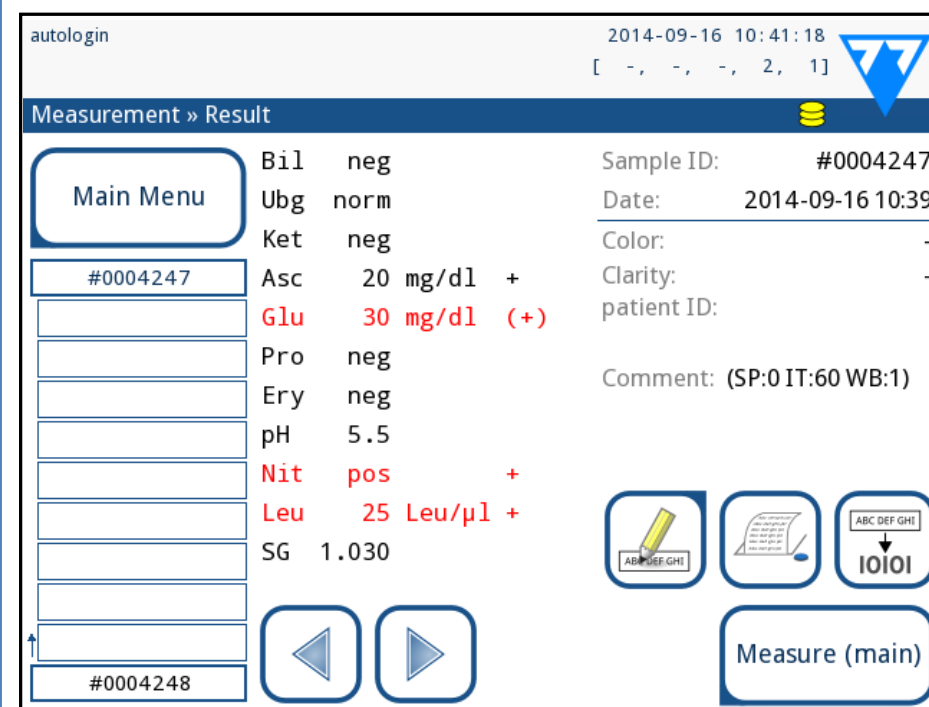


Figure 2: The Result menu

 Refer to [H.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. You can 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



 You cannot modify the details of records that have been printed or transferred to an external database.

▶ You can access the last test result by tapping the **Last Result** button on the **Measurement** screen.

C System description

C.1 Measuring principle

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.

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

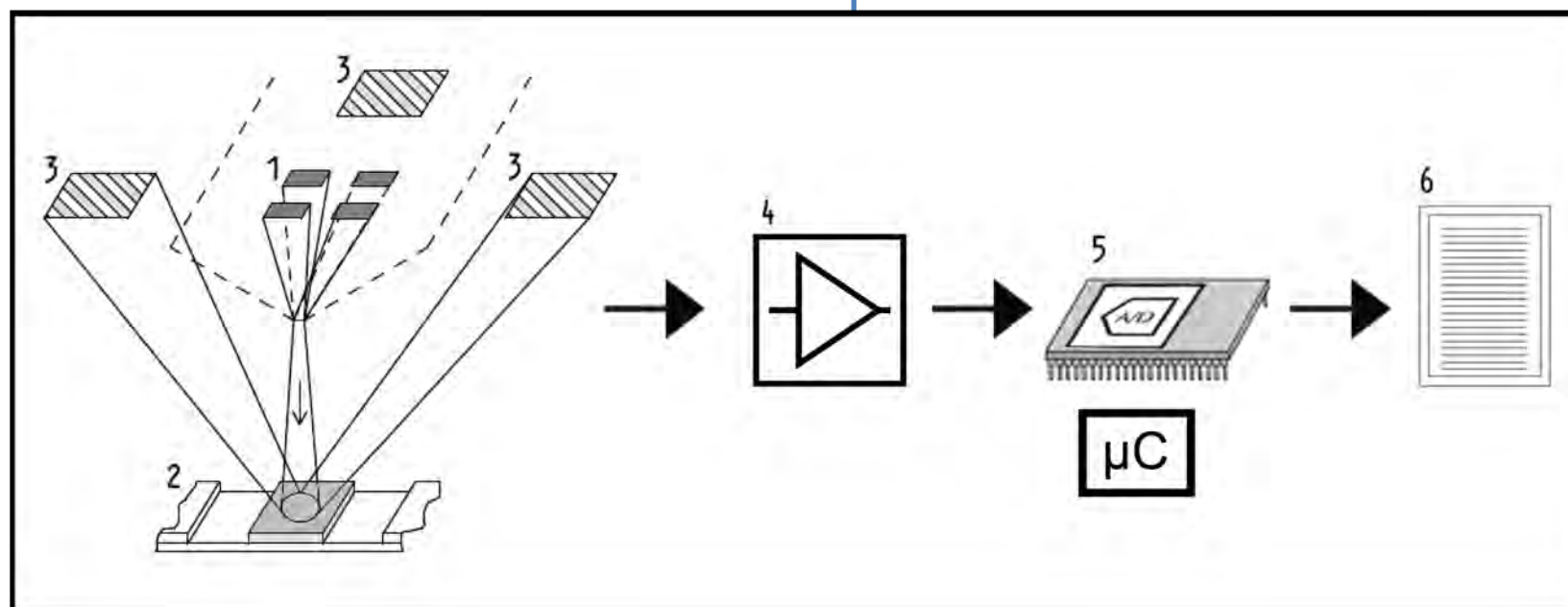


Figure 3: Principle of measurement

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.

C.2 Components & Functions



Figure 4: Analyzer front

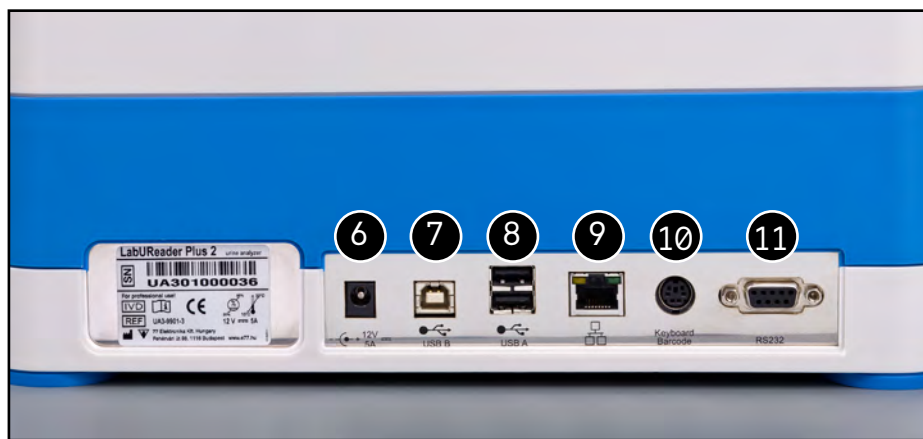







Figure 5: Analyzer back



















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	Receives the AC adapter
7. Type B USB socket	Receives serial USB connector
8. Type A USB socket	Allows connection to various USB peripherals
9. Ethernet socket	Allows connection to an Ethernet network
10. PS/2	Allows connection to a keyboard or a barcode scanner
11. Serial interface	Allows connection to a PC or a host computer

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

C.3 Instrument and Labeling Symbols

This section describes the symbols that appear on the exterior of the LabUReader Plus 2 analyzer, the power supply provided with the instrument, the packaging in which the instrument was delivered and the supplies of reagent strips which you will use with the instrument.

	Double insulated product or transformer. May also identify class 2 equipment (power supply only)		Indoor use only
REF	Catalogue number	CE	The CE mark indicates that the product complies with the applicable directives of the European Union
C	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
			Do not reuse

LOT	Batch code		Stack no more than 4
	The number of items that the contents of the package is sufficient for		Humidity limitation
	Protect from sunlight and heat		Use by date
	Indicates that this system contains certain toxic or hazardous substances or elements. The environmental protection use period for this system is ten years. The system can be used safely during its environmental protection use period. The system should be recycled immediately after its environmental protection use period has expired.		Caution, consult accompanying documents
			Consult instructions for use
			Ethernet port symbol
		IVD	In vitro diagnostic medical analyzer
	Manufacturer	SN	Serial number
	Power on/off		Do not use if package is damaged
	Handle with care		USB port symbol
	Temperature limitation		DC Adaptor Polarity Centre Positive
	Atmospheric pressure limitation		This way up

D Unpacking & Setup

D.1 Unpacking

⚠ Read the LabUReader Plus 2 Operator's Manual carefully before installation, so as 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**

- ▶ LabUReader Plus 2 analyzer
- ▶ Power supply (AC Adapter 100V–240V, 50-60Hz)
- ▶ Power supply cord

ⓘ If the power cord is not the style you need, contact your service representative

- ▶ Printed Operator's Manual
- ▶ Drop tray

- ▶ Strip timer rake
- ▶ Test strip tray/waste bin
- ▶ Roll of printer paper
- ▶ Grey check strip

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

D.2 Setting up

⚠ The analyzer should only be used indoors.

- ▶ Make sure that you set up and operate the analyzer on a solid level surface in an environment with fairly constant temperature and humidity.
- ▶ Do not operate the analyzer in 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 Touch screen and block the printer cover.

D.2.1 Plugging in the analyzer



Figure 7: **Plugging in the analyzer**

⚠ Only use the power supply adapter included with the unit.

- 1 Plug the cable of the power supply into the power inlet socket located on the rear of the LabUReader Plus 2 analyzer.
- 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.

D.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.

D.2.3 Inserting the strip timer rake



Figure 9: Inserting the strip timer rake

Handle 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.

D.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.

D.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 ensure 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.

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

i The analyzer is set up to print the results automatically (to turn off the automatic print function see [G.6.2 Customizing the analysis process on page 17](#))

D.2.6 Interfacing with a computer

The instrument can send results to a computer via the serialport 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:

LabUReader Plus 2	Host(PC pinout 9-pin)
1	1
2	TxD
3	RxD
4	4
5	GND
6	6
7	7
8	8
9	9

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

D.2.7 Powering up



Figure 12: Powering up

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

D.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.

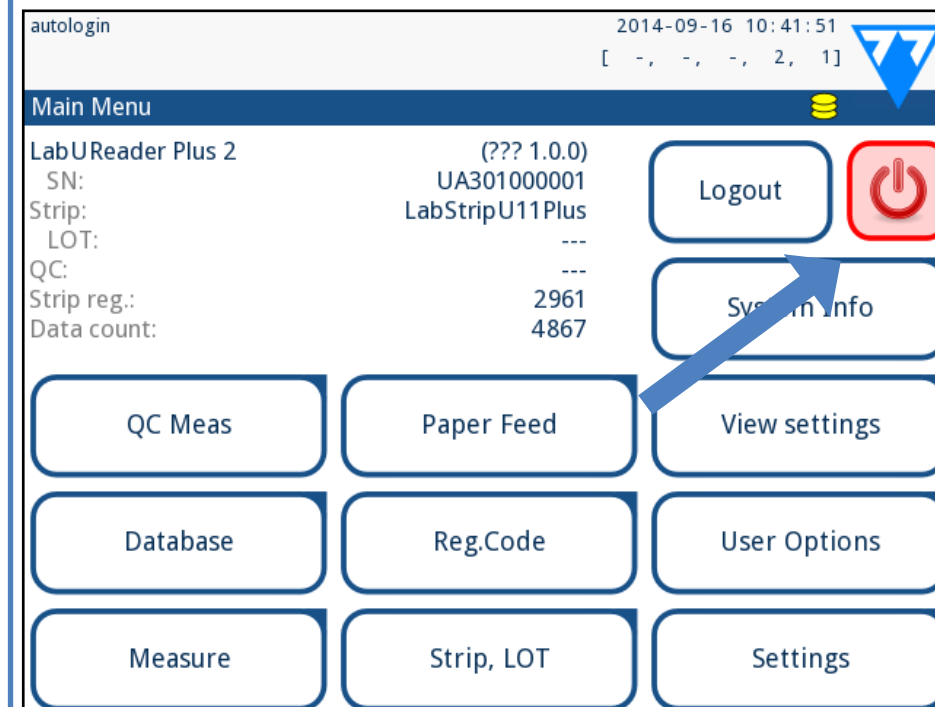


Figure 13: Powering down (1)

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

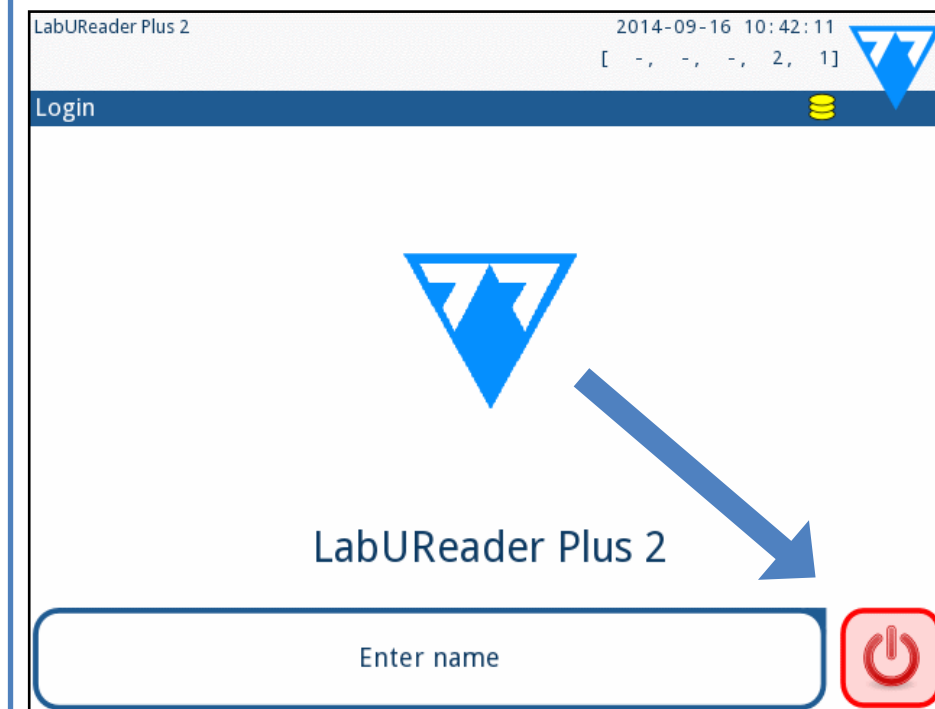


Figure 14: Powering down (2)

D.3 Analyzer software updates

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

The manufacturer is continuously upgrading the LabUReader Plus 2 user software, adding new features and improving usability. From time to time you will be sent a software update package for your analyzer.


The most convenient way to enter software update files into the system is via a USB connection. When a software update package is developed, you will either receive the files via e-mail or as a downloadable, or copied onto a USB flash drive.

The following sections describe the software update procedure in each of the two cases.

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

D.3.1 Using the ready-made USB flash drive

1 Switch on the LabUReader Plus 2 and wait for the System Check to finish.

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 Touch screen.

i The yellow disk icon indicates that the system recognized the USB flash drive.

3 On the **Settings(2)** » **Update** screen, wait for the **Update** button to light up and tap it to start the automatic update process.

i 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.

! You can safely remove the flash drive 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 when you lift your finger or pointing analyzer.

D.3.2 Using the software update package distributed online

i You will need a USB flash drive, a PC or Macintosh to connect it to, and some basic computer skills.

Complete the following steps to copy the software update package you received to an USB flash drive.

1 Create an 'update' directory in the root folder of your USB flash drive.

! In case of existing 'update' directory, the old one should be deleted.

2 Unzip the software update package you received or downloaded and copy it into the 'update' directory you created.

! The analyzer 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'.

3 Complete the steps in [D.3.1 Using the ready-made USB flash drive on page 11](#).

E Interacting with the analyzer

If no barcode reader or keyboard is connected to the analyzer, you can interact with the system using the touch screen only.

E.1 Screens

The system displays messages, instructions, and options to choose from on the touch screen to help you operate the analyzer. You can respond to these by tapping the appropriate area onscreen.

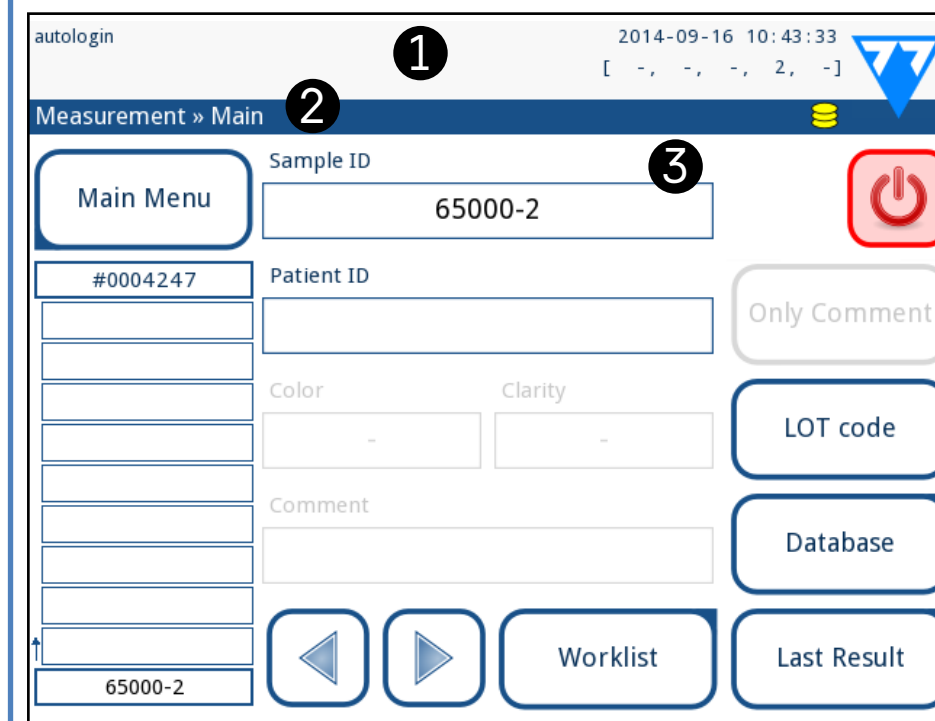


Figure 15: Touch screen layout

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

i 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.

i 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 you are working in. The navigation bar lets you keep track of your location within the menu structure. ‘»’ is the hierarchy separator character.

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

E.2 Touch screen operation

How to touch the display

You can operate the touch screen with bare fingers, rubber gloved fingers, or a capacitive touch screen stylus. 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.


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


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








E.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 Apply	Back
Changes are still not saved	No changes or changes are saved

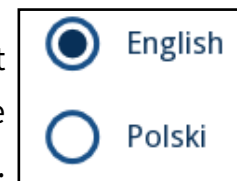
Check boxes

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 from several items. The button with a filled circle is the active selection.



To modify your selection, tap an unfilled circle.

The touch screen keyboard

The virtual keyboard will be displayed when you are prompted to enter your user name or password, and when you tap inside

a Sample ID, Patient ID, or Comment text box.

i The system masks passwords (substitutes all but the character you are currently entering with asterisks) for security.

The virtual keyboard has an alphabetic layout. You can enter letters, numbers, and symbols one at a time. The characters you enter are displayed in the input box above the character keys (Figure 16). Tap backspace (1) to delete the most recently entered character. Use the cursor arrows (2) to position the cursor, indicated by a grey vertical line, to a specific character in the string that you entered. Use the input mode switch keys (3, 4, 5, and 6) to switch the displayed character set to a numeric, lowercase, and uppercase set, respectively. An extended set of punctuation symbols is also available (7).

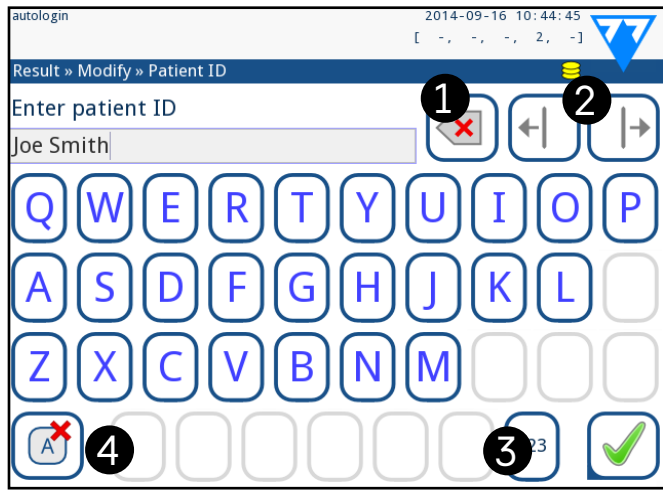
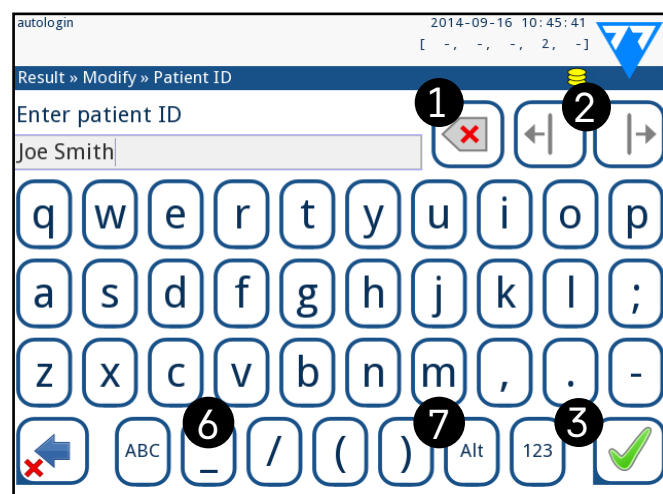
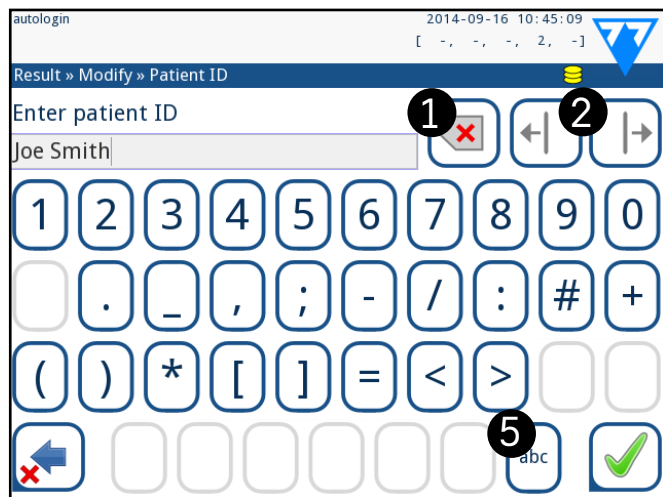


Figure 16: The touch screen keyboard character sets



E.3 Data input via barcode reader

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

Using a barcode reader:

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

You can connect the barcode reader to the PS2 jack or USB port on the rear of the instrument. You can use the barcode reader whenever the analyzer prompts you to enter the following information:

- ▶ Operator name during login

i To speed up barcode-based login, it is recommended that you set up the user account you wish to log into using a barcode so that no password is required for login (see [K.15.4 Customizing security settings on page 33](#)).

- ▶ Sample ID
- ▶ Patient ID
- ▶ QC LOT number
- ▶ Test strip LOT Registration Code
- ▶ Test strip LOT number.

i No external power is necessary—the barcode reader interface powers the scanner analyzer.

i The LabUReader Plus 2 analyzer has been tested with the following barcode scanners:

- ▶ CipherLab CL1000
- ▶ DataLogic QuickScan I QD2100
- ▶ Datalogic Touch 65 Pro
- ▶ Intermec Scanplus 1800 SR

E.4 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. You can also use the keyboard 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.

Another option is to cycle through the onscreen buttons using the 'Tab' key. Every time you press 'Tab', 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.

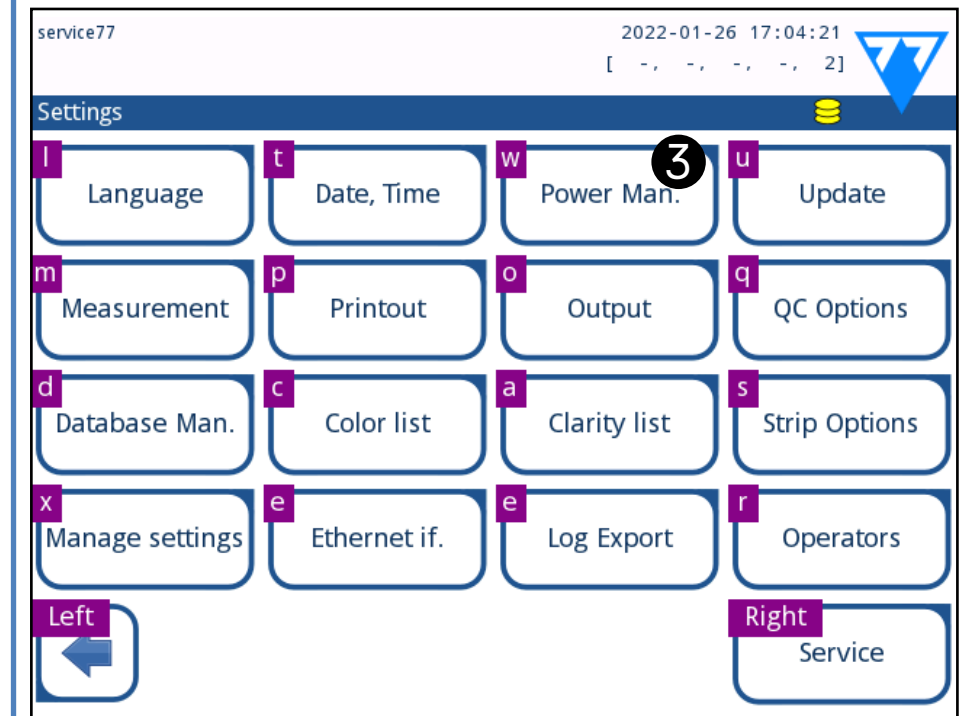


Figure 17: The Settings screen with keyboard shortcuts displayed above the onscreen buttons

F Start-Up Wizard

The first time your LabUReader Plus 2 analyzer is turned on, it will take you through a quick set up procedure. This procedure will allow you to select the basic functions of the analyzer so you can use the analyzer with your choice of settings.

i It is recommended that a supervisor-level user (☞ [K.15 Operators on page 30](#)) 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 you to select the following settings:

- ▶ Language
- ▶ Date and time (☞ [K.2 Date, time on page 25](#))
- ▶ System security (☞ [K.15.3 Managing security settings on page 32](#))
- ▶ Change ‘supervisor’ operator password (optional: depends on selected security level)
- ▶ Testing workflow (☞ [G Analyzing samples on page 14](#))
- ▶ Printout (☞ [“Printout” on page 25](#))
- ▶ QC (☞ [I.1 QC Options on page 21](#))
- ▶ Add operators (☞ [K.15.1 Managing operator accounts on page 30](#)) (depending on the level of system security)

i If you wish to skip the wizard and configure the settings at a later date, tap **Skip** on the second screen.

i If you require further instructions regarding how to change the settings see ☞ [K Instrument Settings on page 24](#).

When the setup wizard is finished, tap **Start** to exit the wizard. You can review all active settings on the ‘**Main Menu » View settings**’ screen. All settings, including connectivity (‘**Output**’) can be modified on the ‘**Main Menu » Settings**’ screen.

G Analyzing samples

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

- ▶ Quick analysis using automatically generated sample IDs (☞ [G.1 Quick analysis on page 14](#))
- ▶ Analyzing samples using user-entered sample IDs
 - Analyzing individual samples
 - Analyzing samples from a worklist
- ▶ Analyzing barcoded samples downloaded from a LIS

You can further customize some aspects of the analysis process itself, and what happens to the analysis results after the analysis process is finished (☞ [G.6 Customizing the analysis workflow on page 16](#)).

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

i If you require more information regarding use and storage of test strips, please refer to the strip’s instructions of use.

G.1 Quick analysis

After you switch it on, the analyzer displays the **Measurement** screen.

i You can also directly access the **Measurement** screen via the **Main** and the **Database** screens.

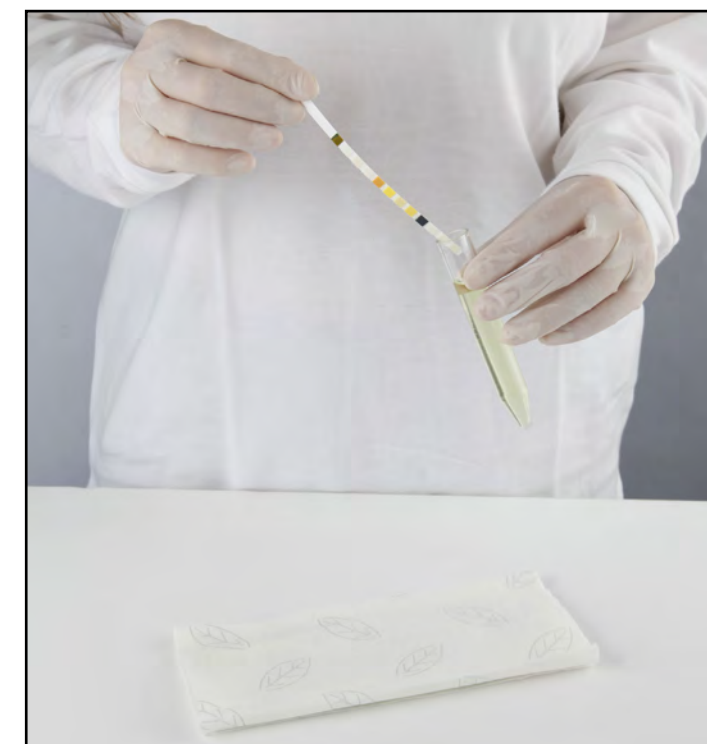
⚠ The test strip tray, the strip timer rake, and the drop tray have to be correctly loaded into the analyzer to start measurements. Prepare a sufficient number of fresh LabStrip U11 test strips, the urine samples you wish to analyze, and paper towels for blotting excess urine before you start the analysis process.

⚠ Do not use damaged strips.

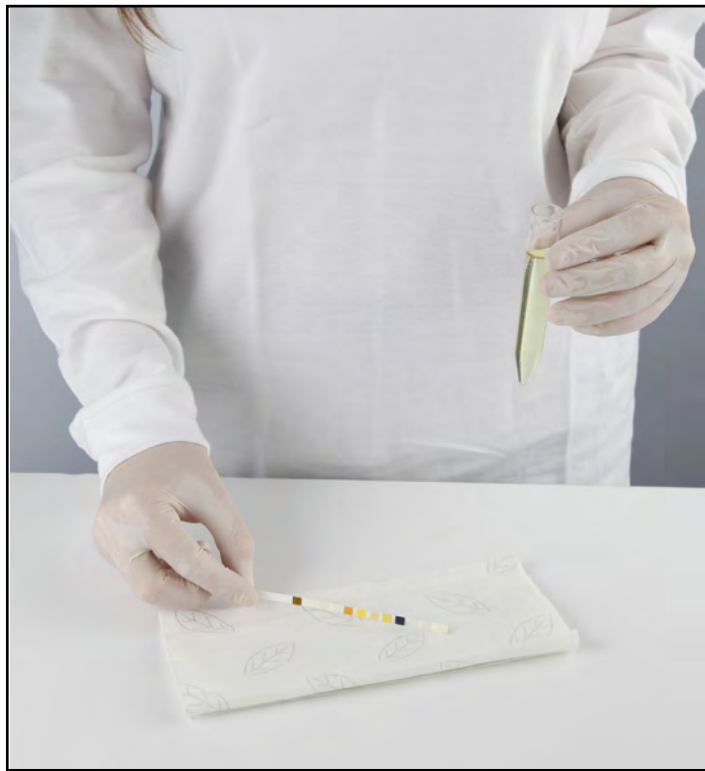


1 Dip the reagent strip into the urine sample, wetting all pads. Immediately remove the strip from the urine.

⚠ Handle test strips by their handles—do not touch the analyte pads.



2 Drag the edge of the strip against the side of the sample container as you remove it.



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



4 When a continuous green light comes on at the strip delivery zone, place the reagent 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 toward you, 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.

i You can abort a measurement cycle 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.

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

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

G.2 Adding Color and Clarity data

► **Color:** To select the visually determined color of the urine sample tap the appropriate button. This will also take you to the next screen.

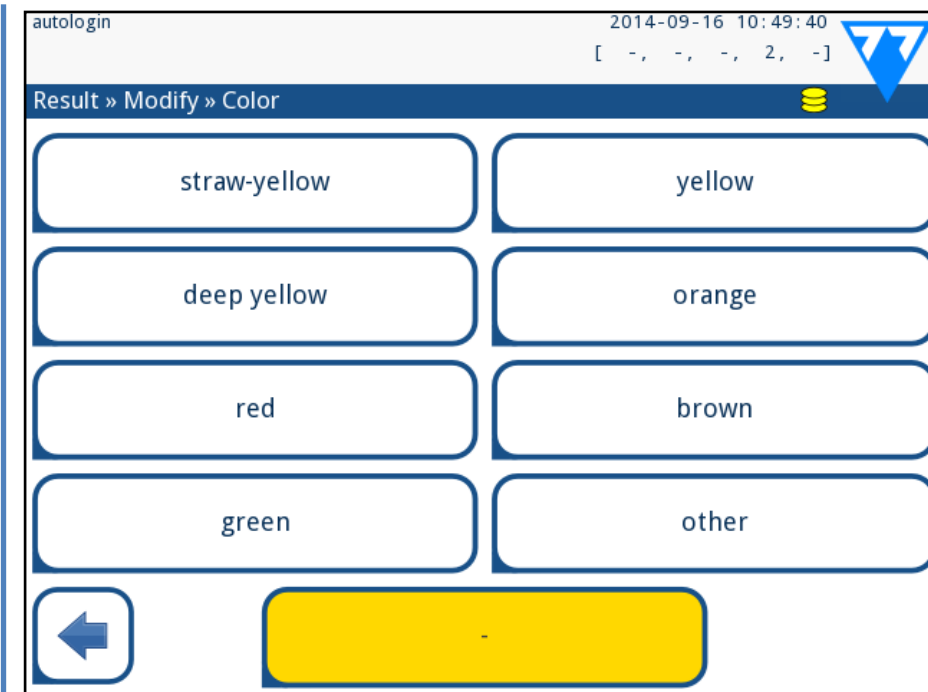


Figure 18: Sample color options

► **Clarity:** To select the visually determined clarity of the urine sample tap the appropriate button. This will also take you to the next screen.

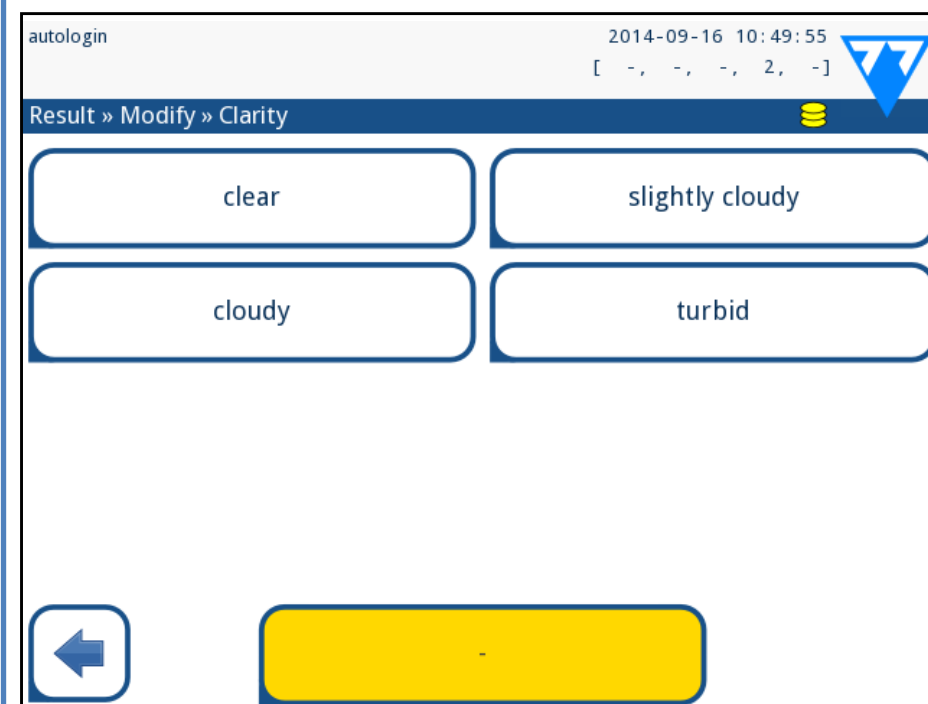


Figure 19: Sample clarity options (Settings»Clarity list

i You can select only one color and clarity type for a given urine sample

i You can customize the predefined color and clarity selection lists (see [K.11 Editing the color and clarity list on page 28](#)).


G.3 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, LabUReader Plus 2 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 ([H.6 Filtering: Finding specific results on page 20](#)).

 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 ([H.6 Filtering: Finding specific results on page 20](#)).

G.4 Analyzing samples with user-entered sample IDs


G.4.1 Analyzing individual samples

1 Prepare the samples Refer to [G.1 Quick analysis on page 14](#), dip a test strip into the first urine sample you wish to analyze, and start a measurement.

2 While the strip timer rake is transferring the dipped test strip towards the measuring head and before you dip and place the next test strip inside the strip delivery zone, tap the Sample ID input box, and enter a sample ID of your choosing.


 If your samples are barcoded, you can scan the bar codes at this stage to instantly enter the relevant ID.

3 Complete steps 1–2 above for each of the samples you wish to analyze.

 If you wish you can 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.

G.4.2 Analyzing samples from a worklist

1 Refer to [G.7.1 Generating a Worklist on page 18](#) and make your worklist.

 Worklists can include only a single sample ID and a Patient ID for each entry on the list. If you want to add further information to the entries on your worklist, you can do so after the worklist has been processed ([H Working with Results on page 18](#)).

2 Prepare the samples that you wish to analyze from the worklist, and make sure that you have enough fresh LabStrip U11 Plus test strips for each of them.


3 Refer to [G.1 Quick analysis on page 14](#), dip a test strip into the first urine sample that you put on your worklist, and

start a measurement by placing the test strip inside the strip delivery zone.

G.5 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»Main** menu and tap the ‘Download worklist from LIS’ button.

 The LIS you are accessing must comply with the effective-LIS2 specification ([K.4.1 Bidirectional protocol \(LIS2-A2\) on page 26](#)).

3 Complete steps 2–3 in [G.4.2 Analyzing samples from a worklist on page 16](#) to perform the analysis.

G.6 Customizing the analysis workflow

G.6.1 Autoprint and autotransfer

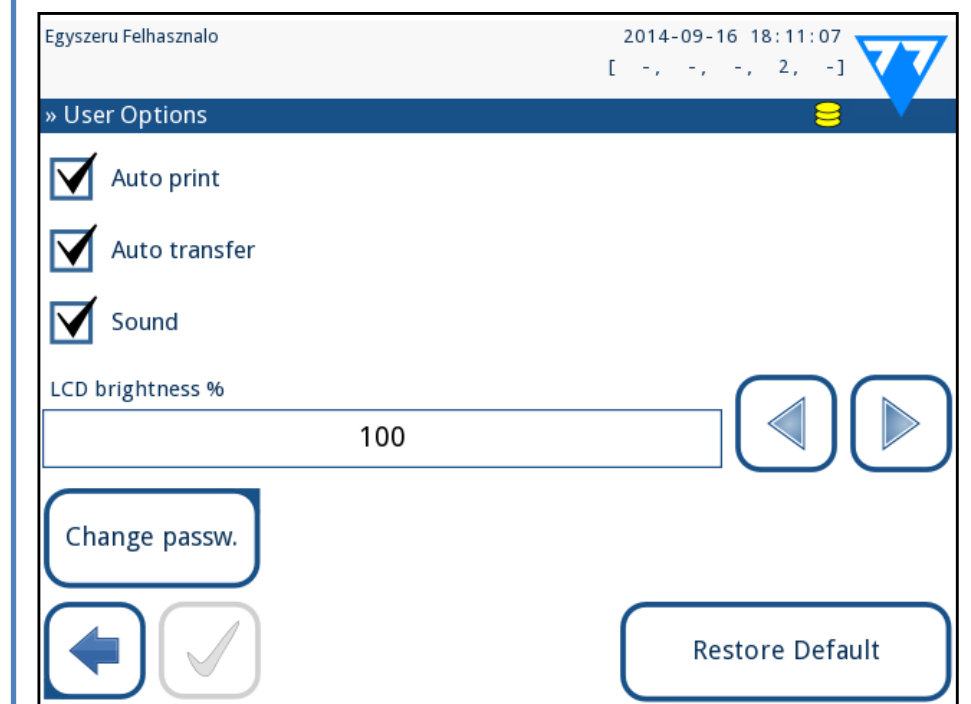





Figure 20: The User Options screen
The measurement features can be modified on the **Main» User Options** screen.

- ▶ **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.

G.6.2 Customizing the analysis process



Figure 21: **Settings»Measurement**

On the **Settings»Measurement** screen you 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

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

G.7 Worklist management

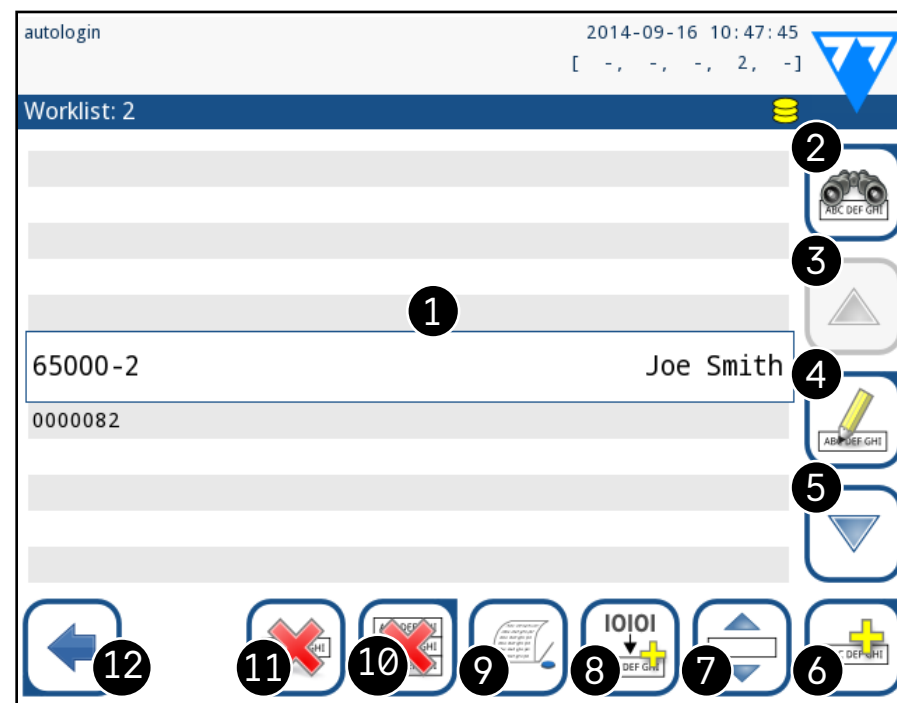


Figure 22: **The Worklist menu**

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 you can:



- ▶ 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.

G.7.1 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.

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

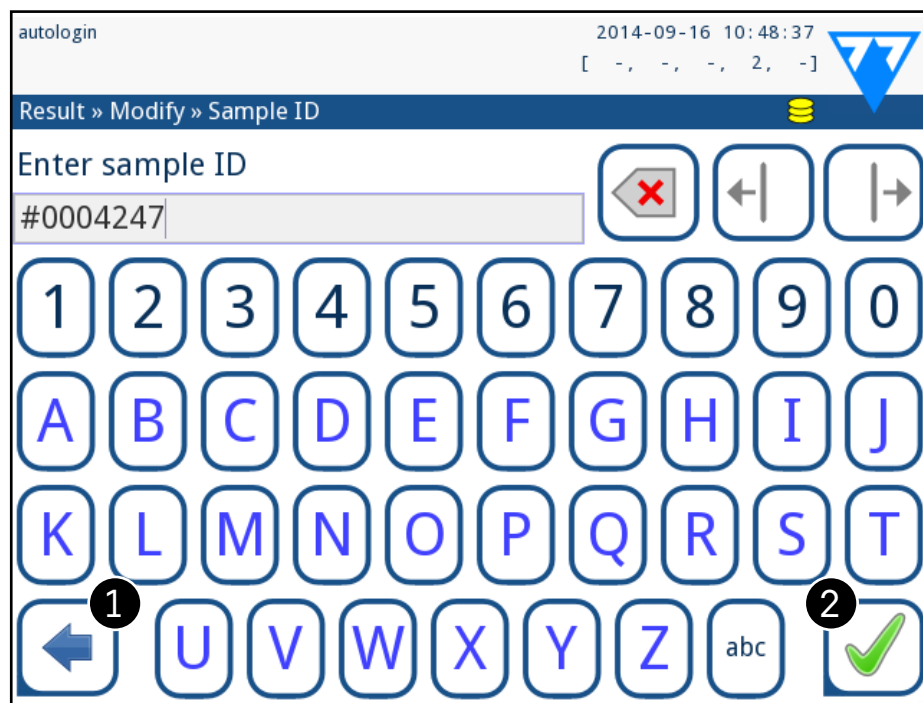


Figure 23: Sample ID input

Once you have modified the default Sample ID, you can either cancel the change by tapping **Drop&Back** (1 in Figure 23) or store the modified Sample ID with the record by tapping **Apply&Next** (2 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** when you

have finished entering the patient ID and proceed to the next screen. To abort and go back to the Sample ID screen, tap **Drop&Back**.

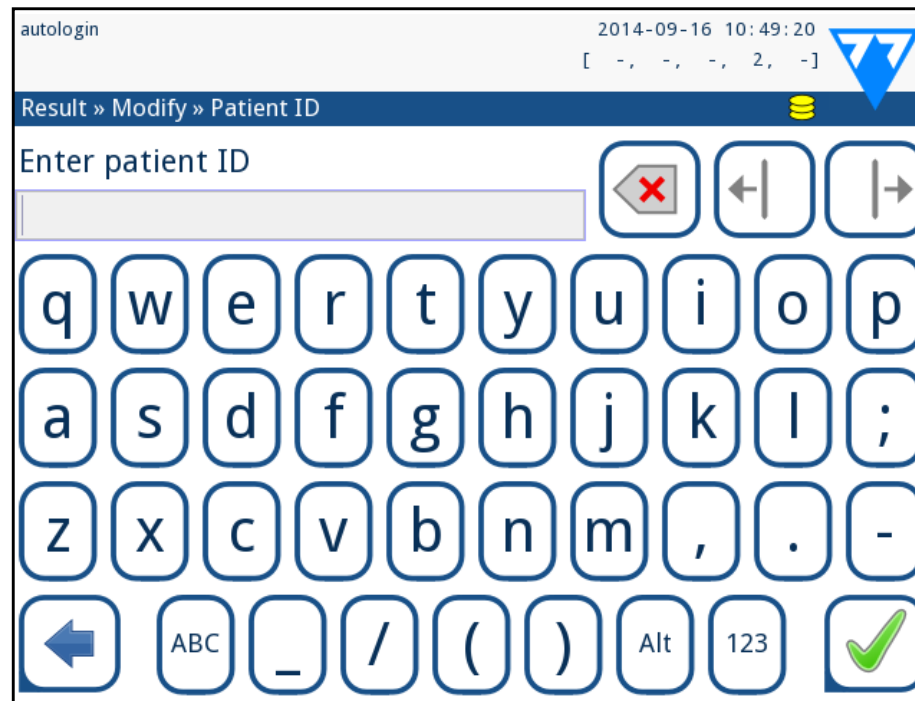


Figure 24: Patient ID input

i If you require further instruction regarding barcode reader usage see [E.3 Data input via barcode reader on page 13](#)

G.7.2 Worklist window in the Measurement menu

When you return the Measurement screen with the **Back** button, the first worklist item will be active in the list window. If you need to manually change the order in the Measurement screen, use the left and right buttons to cycle through the worklist.

If you also have 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, so an automatically generated sample ID will appear in the window. In this case the (generated) text will appear under the sample ID.

H Working with Results

The LabUReader Plus 2 has memory for 5000 measurements. Every result is automatically saved after the analysis in an indexed database. The database enables you to search, view, edit, print, and transfer patient test results.

i 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 [K.7 Database management on page 28](#)

H.1 Last result

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

i The Last Result menu is updated in real time to always display the latest processed record. It is, however, not reset when you switch off the analyzer.

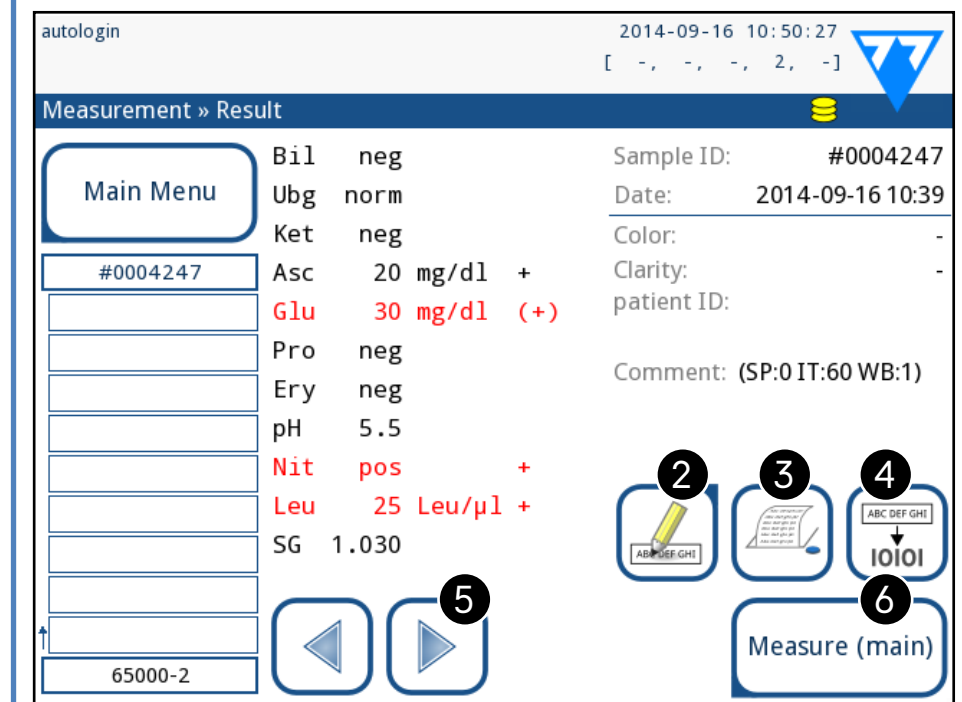


Figure 25: The Last Result menu

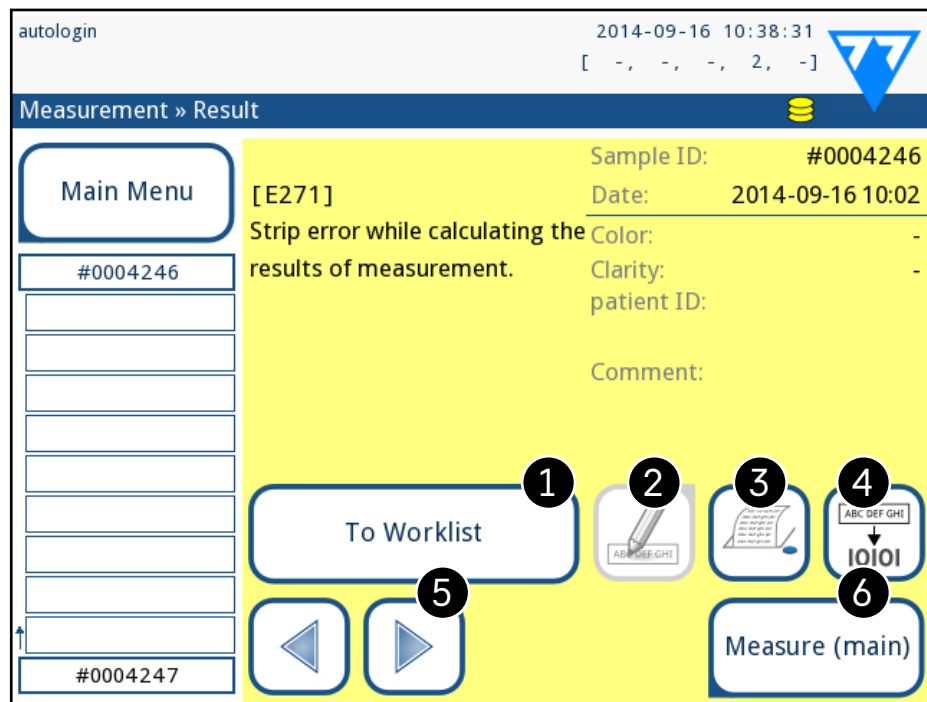


Figure 26: The Last Result menu displaying the record for a failed measurement

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.

i 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
- i** 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
- i** You cannot modify the measurement date and the analyte pad results.
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

H.2 List view

You can access the database

- ▶ from the **Measurement** menu by tapping the **Database** button
- ▶ from the **Main Menu** by tapping the **Database** button.

i If you enter from the **Measurement** screen, an automatic predefined filtering is applied and only the results measured after the last powering up are listed. If you enter from the main menu, no automatic filtering is applied.

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

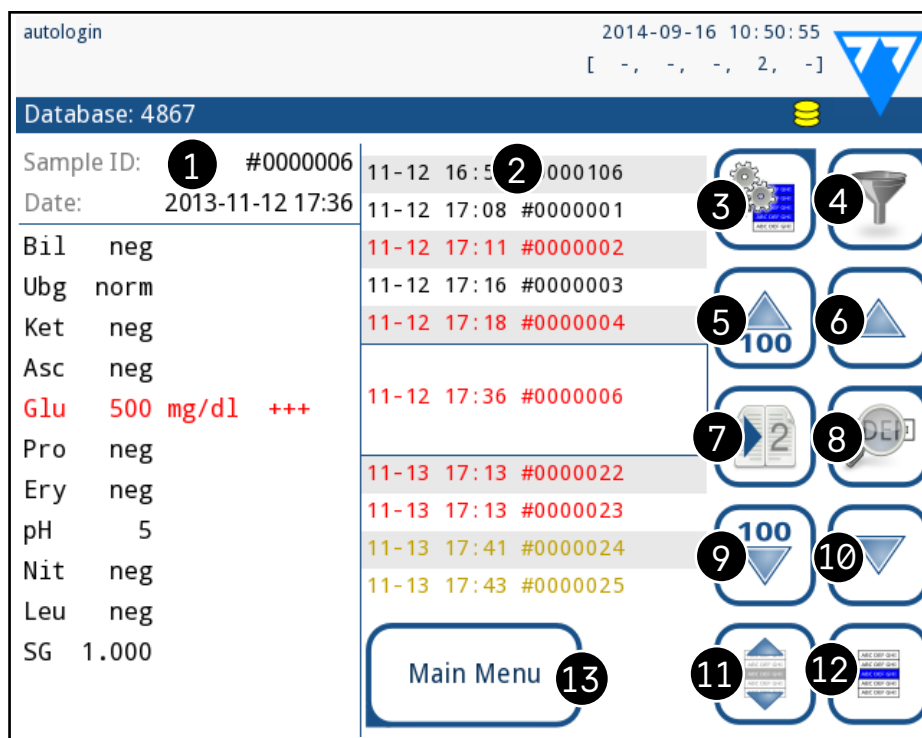


Figure 27: The Database menu

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 by 100 records 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

i Tap this button to see the measurement data for the se-

lected record. All of the patient's result details will appear (see **H.3 Result view on page 19**).

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

i Tap this button after you select 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 (see **Multiple selection on page 20**).

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

H.3 Result view

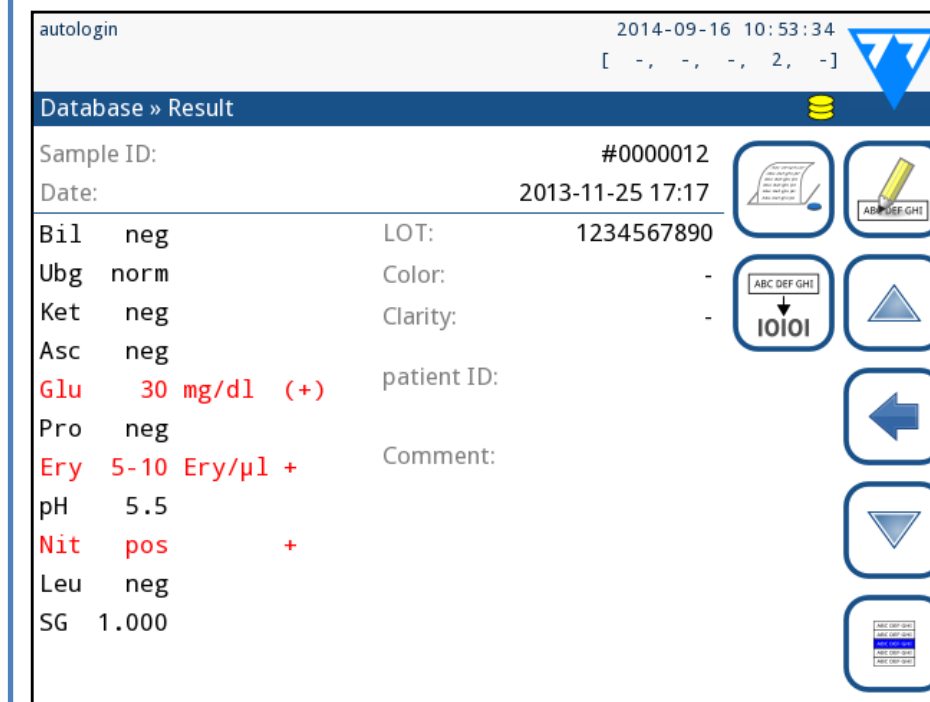


Figure 28: Database»Result menu

Using the buttons in the top right-hand corner of the menu, you can print, modify, or transfer the selected record to LIS.

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


H.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 (breadcrumb).

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.

H.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.

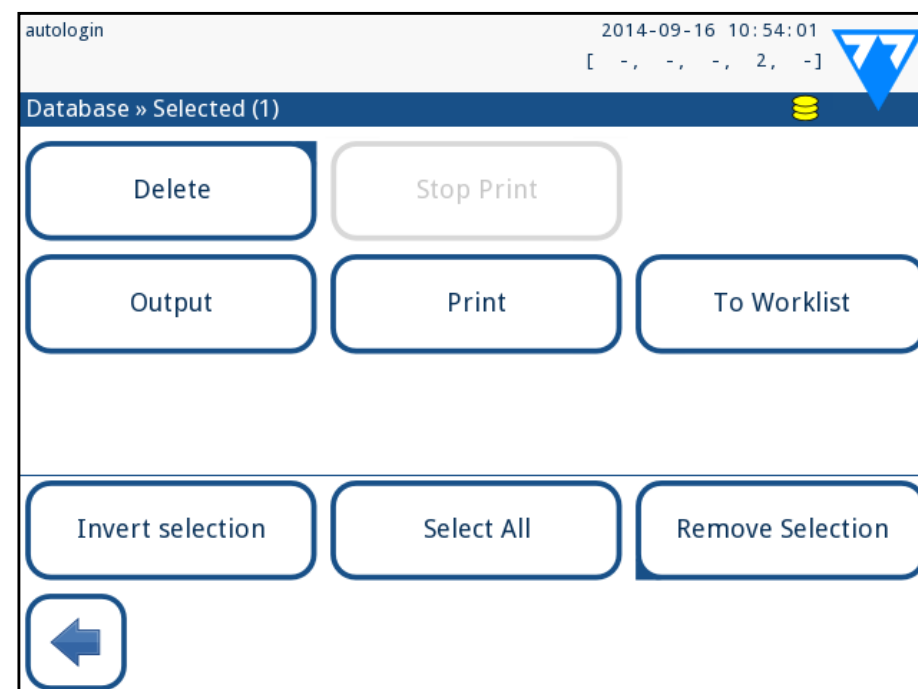


Figure 29: The **Database»Selected** menu with three records selected, indicated in the status bar

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. You can use this feature to repeat failed or doubtful measurements.

Invert selection

Tap this button to invert the selection you made in the previous menu: Select every record that was not selected, and deselect records that were selected. An information message ("1103: 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 ("1102: All samples are selected") is displayed to confirm the action.

Remove selection

Tap this button to cancel the selection you made in the previous menu. You will be automatically moved back to the **Database** menu.

H.6 Filtering: Finding specific results

To narrow down the list of results LabUReader Plus 2 features a sophisticated filtering engine.

The following parameters are available as filtering criteria:

- ▶ Date & Time
- ▶ Sample ID
- ▶ Patient ID
- ▶ Status:
 - o not printed
 - o not transferred
- ▶ Values:
 - o negative
 - o positive
 - o sediment recommendation
 - o false
 - o with comment
 - o self-measured

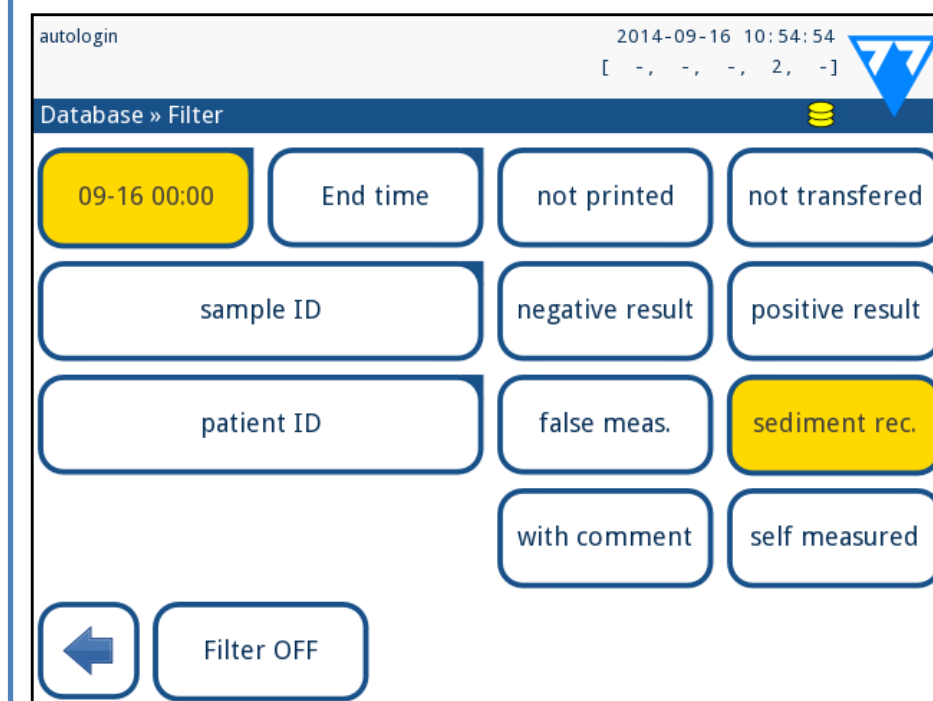


Figure 30: Database»Filter menu with active filters

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, you can 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.

Quality Control Testing

The performance of the system (analyzer and reagent 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
Check strip	Analyzer
L1, L2 or L3 (One-, two- or three-level) urine control solutions,	LabStrip U11 Plus test strips

i Several commercial controls are available. Controls may vary in number of levels or components, necessity for reconstitution or ready to use, type and volume of container. 77 Elektronika Kft. supports the use of Quantimetrix Corporation Dipstick Controls as these controls provide the necessary color development with LabStrip U11 Plus strip. Other manufacturers' controls may provide abnormal results due to non-specific colorations of the test pads.

⚠ After the occurrence of an accidental event (drops, spills, splashes), even if visible damage is not seen, verify the performance of the reader with the check strip.

The supplied check strip can be used only as a mechanism to confirm the functionality of the analyzer.

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

- ▶ monthly on each open bottle,
- ▶ whenever a new bottle of test strips is opened,
- ▶ whenever test results are in doubt,
- ▶ whenever 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**. [I.1 QC Options on page 21](#)

i The urine control LOT number and acceptance limits can be set at the same place. [I.1.1 Editing QC LOT Information on page 22](#)

2 The **QC measurement** screen can be reached by the **QC Meas** button from the **Main** screen. [I.2 QC Testing on page 22](#)

3 All QC measurements are stored in a separate database, to reach them tap the **QC results** button on the **QC measurement** screen. [I.3 Recalling QC results on page 23](#)

I.1 QC Options

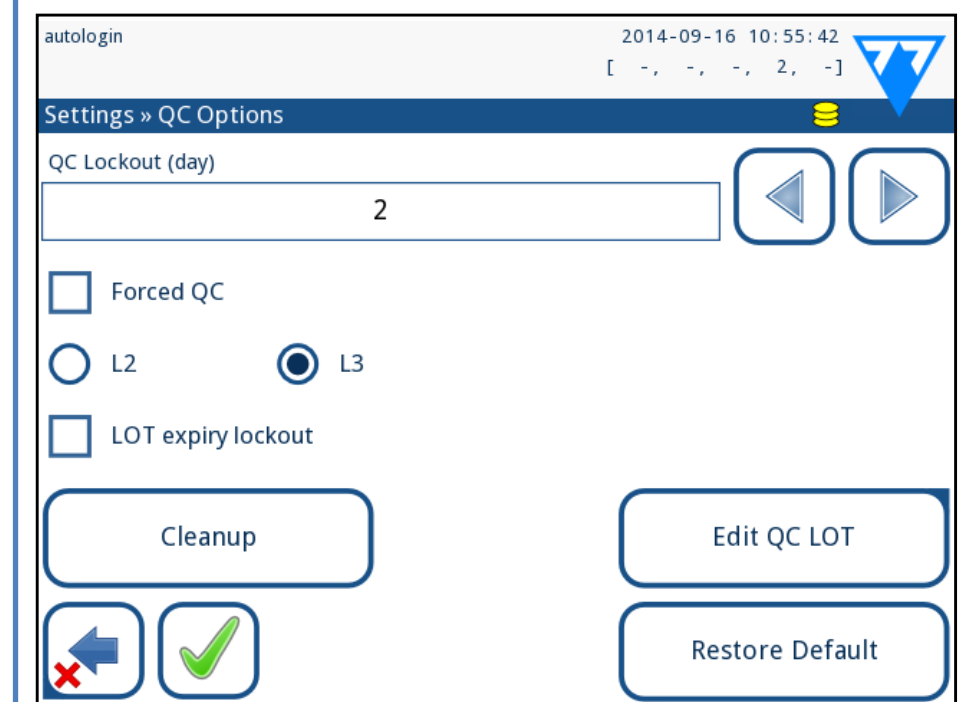


Figure 31: QC Options menu

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.
- i** If you apply changes to the QC lockout period, a popup window appears with the modified lockout time.

LOT expiry lockout: If ON, Expiry date must be entered. In case of entering LOT and a date after it in brackets, it is going to be the expiry date. It works with solution and strip LOT, too.

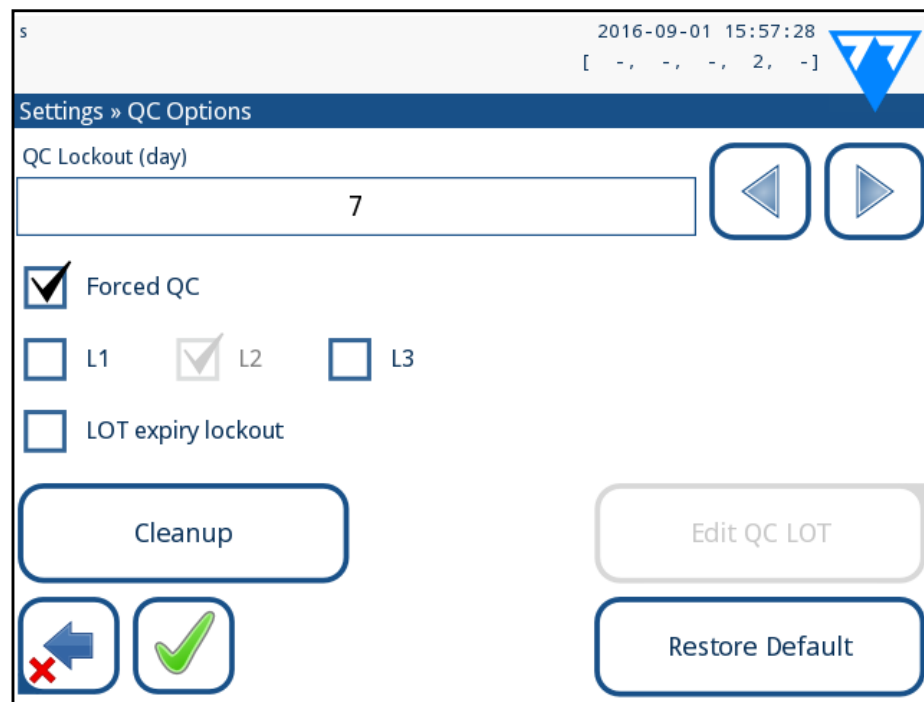


Figure 32: An example of a forced L2 quality check setting

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: negativ/normal
- ▶ L2: positive/abnormal,
- ▶ L3: high positive/abnormal

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

i If strong user security is applied (see [K.15.3 Managing security settings on page 32](#)) 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 you need to make a measurement immediately without performing the QC check first, the lockout mode can be switched off only by an Administrator.

1.1.1 Editing QC LOT Information

⚠ The QC evaluation relies on the data that you input manually. 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 On the **Edit LOT»Strip selected** screen that displays, select the control level (L1, L2, L3) and tap the **Next** button.
- 3 On the next screen set the LOT code (you may also include 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 you have finished, tap the **OK** button to store the values. The analyzer returns to the **QC options** screen.

Repeat the previous steps for all levels.

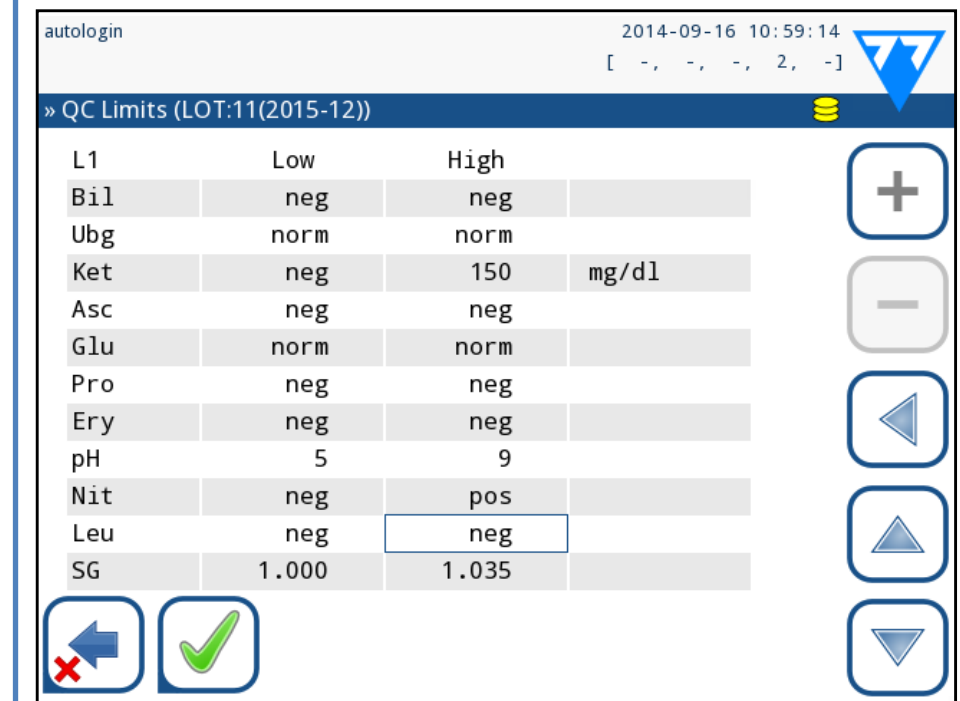


Figure 33: QC Limits menu (accessible via Edit QC LOT)

1.2 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:
 - o grey: not measured,
 - o green: valid measurement was performed while in the QC Meas menu
 - o 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

You 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 LabStrip U11 Plus test strips.

i We recommend using the Dipper, the Dropper or the Dip&Spin control solution kits from Quantimetrix Inc. to carry out the QC-Check. Controls of other manufacturers may provide abnormal results due to non-specific colorations of the test pads.

Place the strip on the tray and tap

- ▶ “... Solution 1” for negative control,
- ▶ “... Solution 2” for positive control,
- ▶ or “... Solution 3” in case of Level 3 for high positive control, depending on the control you are currently testing.

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.

i 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.

i 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.

I.3 Recalling QC results

All QC measurements are stored in the QC memory, which is separated from the memory for the patients’ measurements. The LabUReader Plus 2 has memory for 5000 QC measurements. See **H Working with Results on page 18** for more information on how to recall and view results from a database.

i Only the additional information specific to QC the 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.

J Main Menu options

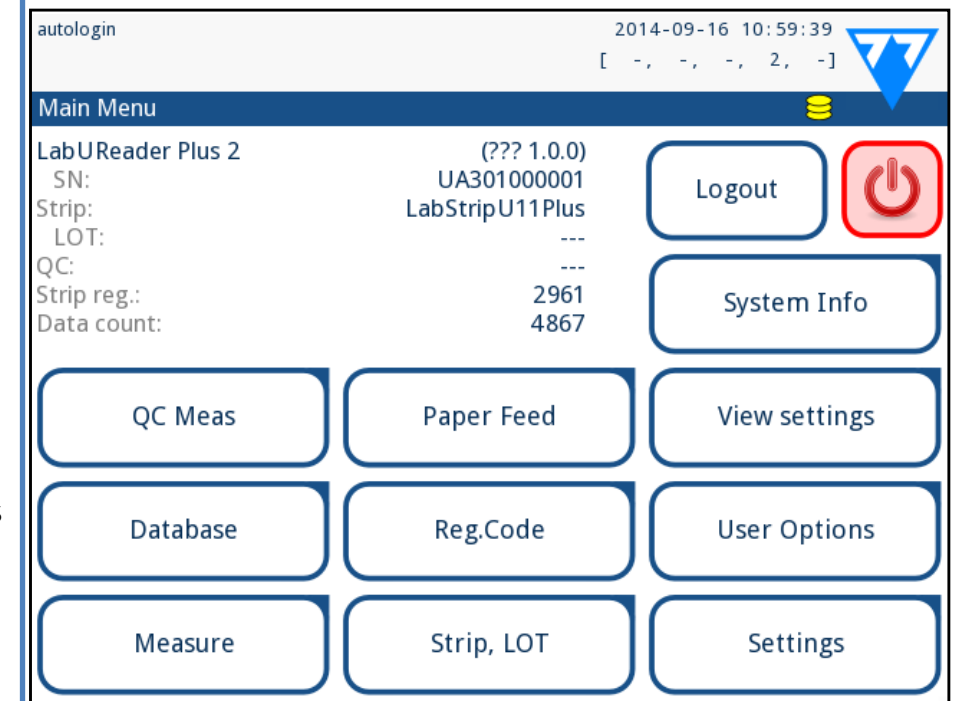


Figure 34: Main Menu options

The **Main Menu** screen displays the following information:

- ▶ strip type and LOT code information,
- ▶ output settings.

The following functions can also be reached from this screen:


- ▶ Registration Code,
- ▶ Strip LOT,
- ▶ View Settings,
- ▶ User Options (auto features; sound; LCD brightness),
- ▶ Instrument Settings.

J.1 Registration Code

The encoded registration code contains strip related information allowing the LabUReader Plus 2 analyzer to control the evaluation precisely:

- ▶ expiry date of LOT,
- ▶ calibration information for the particular LOT (possible sensitivity adjustment for each pad determined by the manufacturer),
- ▶ maximum counts of measurements allowed with the given calibration.


 **Calibration is required to obtain proper results.**

 **Please note that a vial of test strips and calibration are co-related.**

The **Registration Code** screen shows the expiry date and the remaining counts.

When opening a new shipment or a vial of strip, the registration/calibration card can be found in the package. The unique registration code is affixed to the registration card and it is valid for 1/10/20 vials.


To enter the numeric code on the card tap the **New Registration Code** button. Either type in the 15 digit number or input the information using a barcode reader. After successful registration the number of available tests is set to the value of the registration code.

 *Newly registered test strips are not added to the number of unused test strips left over from a previous registration. The number of test strips left over from a previous registration will be reset. You can, however, re-register a previously entered registration code to use the unused test strips in the corresponding batch.*

J.2 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. Also as the registration code does not contain the strip LOT code, the software cannot check if the LOT code is correct. Please double check the LOT code in order to avoid typos.*


J.3 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.


J.4 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.*

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

▶ **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.**

K Instrument Settings

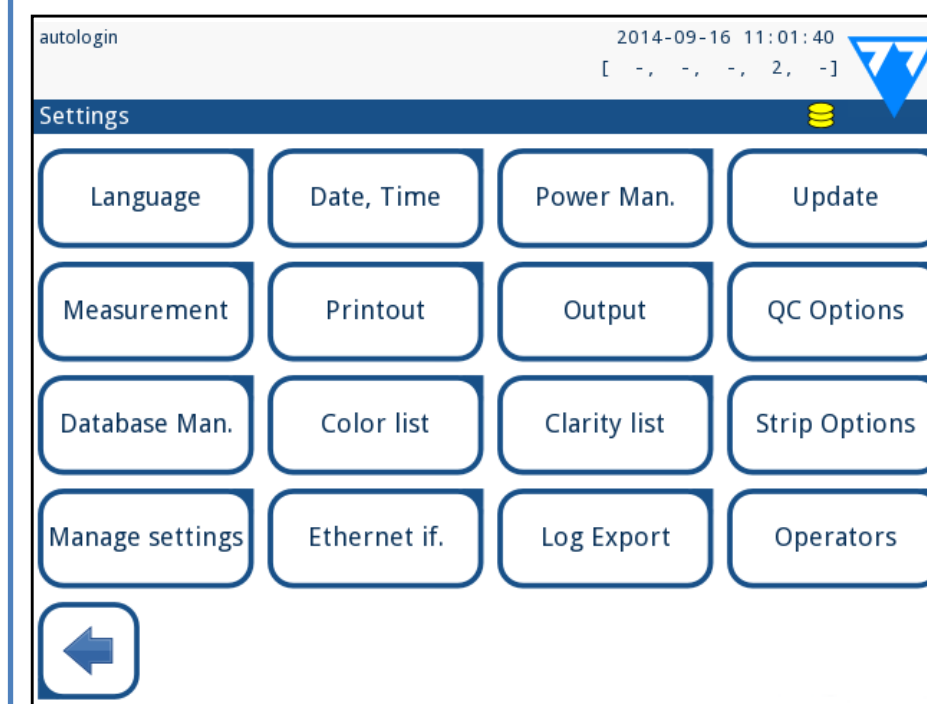




Figure 35: The Settings menu

Your LabUReader Plus 2 analyzer allows you to change settings to suit your 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 a **Settings** screen first tap **Apply** and leave the screen with **Back**.

No changes or changes are saved



Changes not yet saved



To cancel the modifications simply tap **Drop&Back** before ap-

plying 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**.

i 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

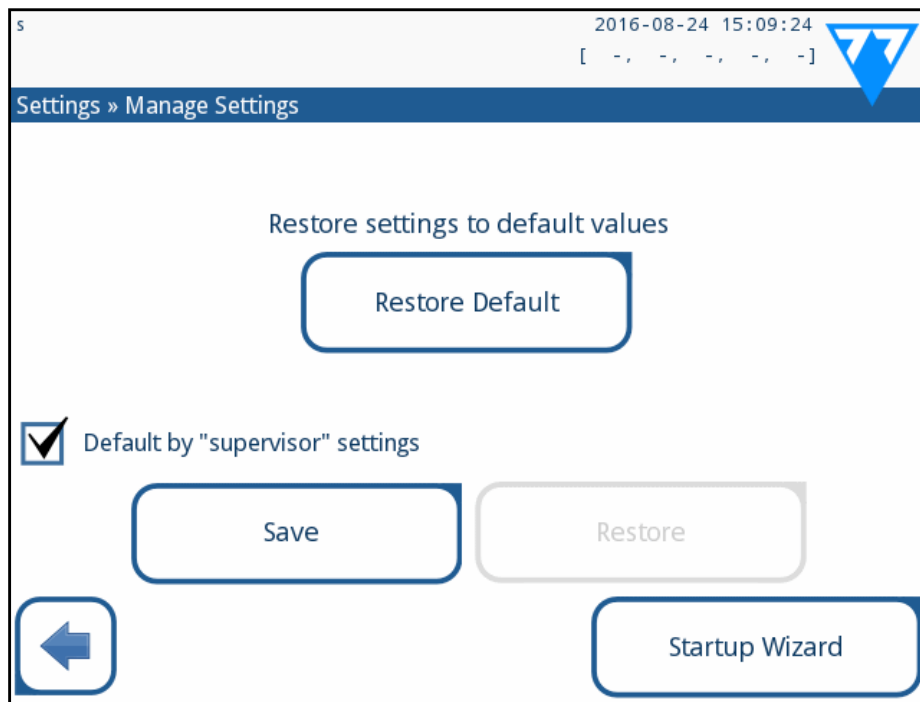


Figure 36: **Manage Settings menu**

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.

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

K.1 Language

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

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

K.2 Date, time

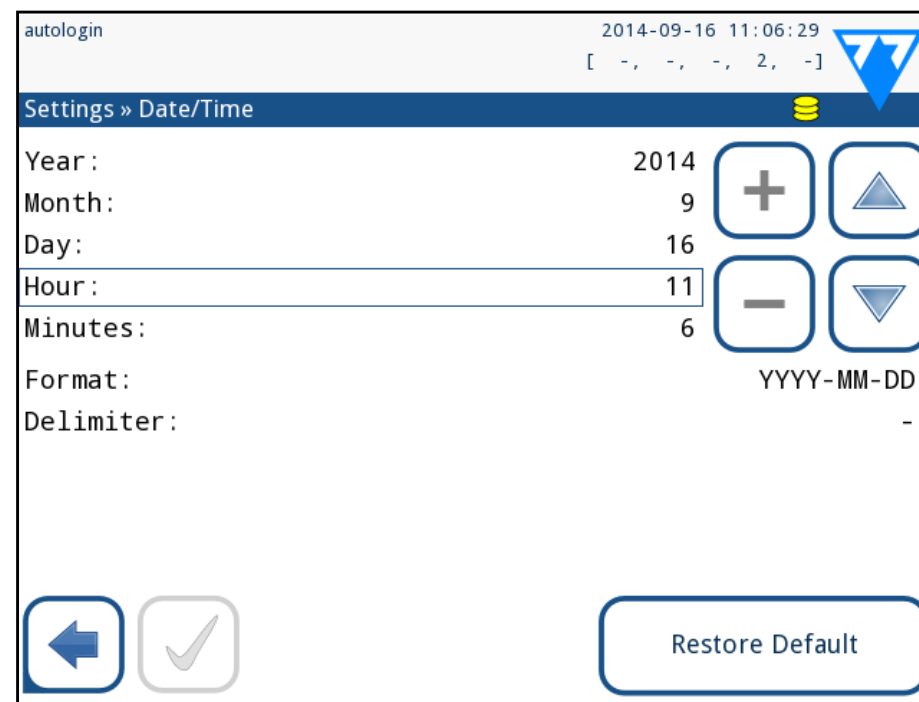


Figure 37: **The Date/Time menu**

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: '-', '/', '.'

K.3 Printout

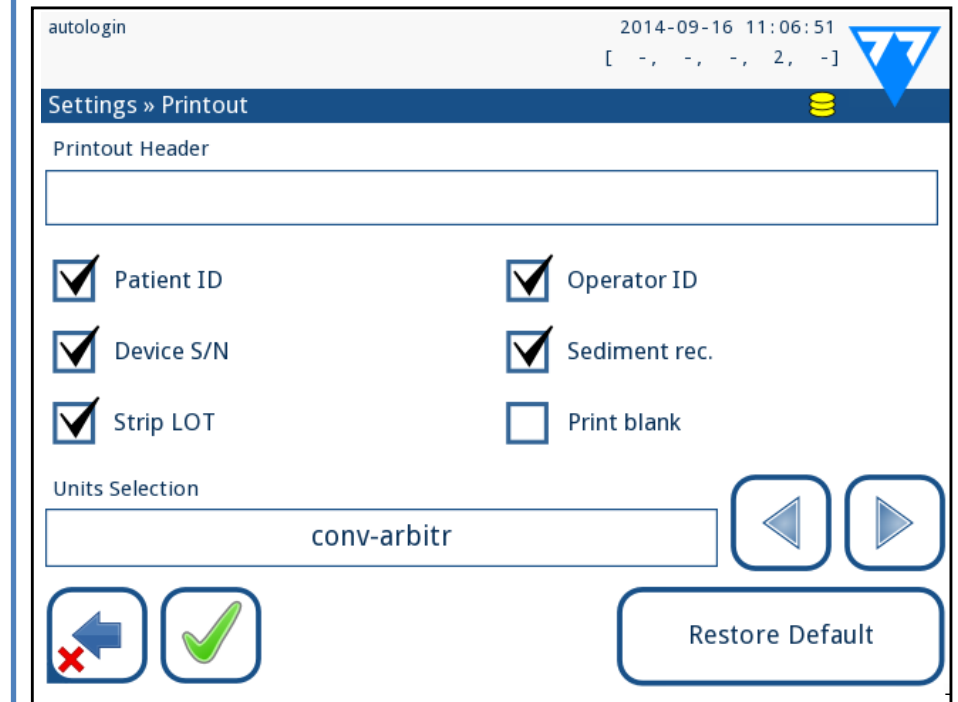


Figure 38: **Printout options settings**

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 print-out
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.

K.4 Output (Connectivity:Transfer/Export)

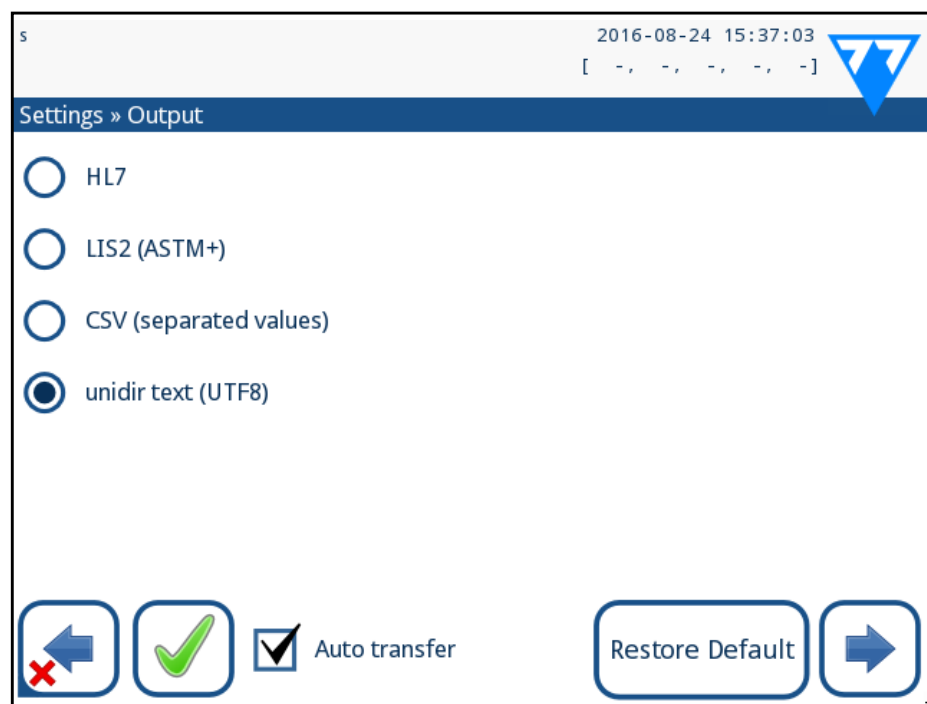


Figure 39: Data transfer settings

At the **Output** settings you can define how the LabUReader Plus 2 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 CVS 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 speci-

fication is 1 (one) stop-bit, no parity.

- If you select the **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 output protocol you selected.

i You can specify a path for the saved file on the USB flash drive by entering your preferred folder name between slashes (/) as the first part of the file name.

⚠ Make sure that you configure the communication ports properly, 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.

K.4.1 Bidirectional protocol (LIS2-A2)



Figure 40: LIS2 transfer settings

The two-way digital transmission protocol of LabUReader Plus 2 analyzer regarding remote requests and results between LabUReader Plus 2 and information systems is based on the NCCLS LIS2A21 approved standard.

It enables LabUReader Plus 2 and any standard LIS system, to establish a logical link for communicating text to send results and requests in a standardized and interpretable form.

You can set a custom header and at the **Output type** input field you can define

the output type: serial, USB B, TCP/IP (Ethernet)

1. 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.

K.4.2 Bidirectional protocol (HL7)

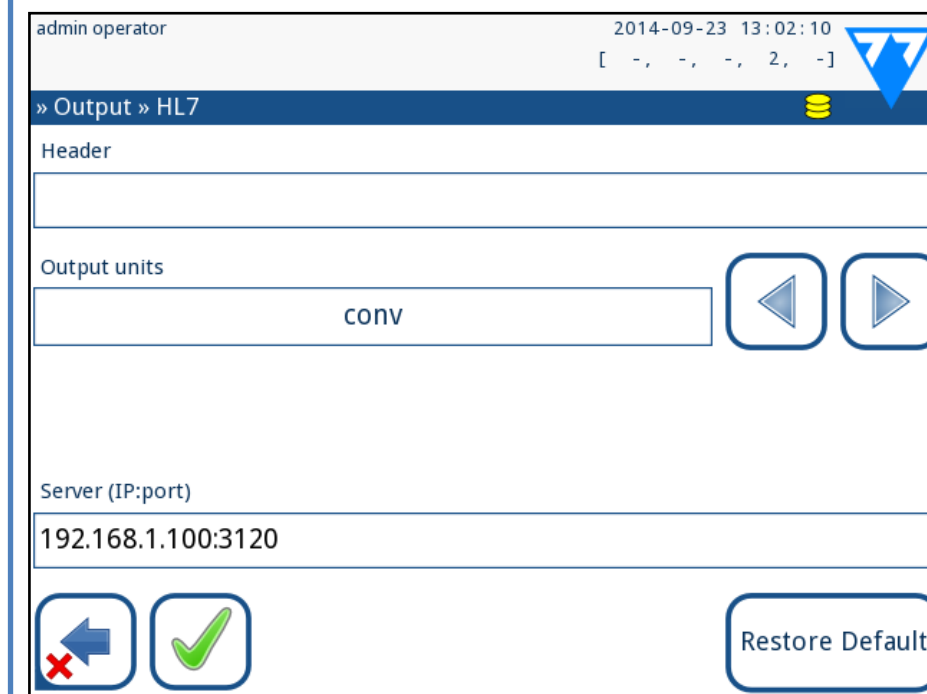


Figure 41: HL7 transfer settings

HL7 stands for Health Level Seven; it is a collective of healthcare informatics standards that allow exchange, intergration, sharing,

1 NCCLS LIS2-A2: Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems; Approved Standard—Second Edition (Volume 24 Number 33)

and retrieval of the measurement data over the LabUReader Plus 2 analyzer and a suitable network.

On this screen, you can set up a custom header and the preferred units for the output, and enter the IP and the port of the server that you are using.

i 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.

K.4.3 Comma-separated value output

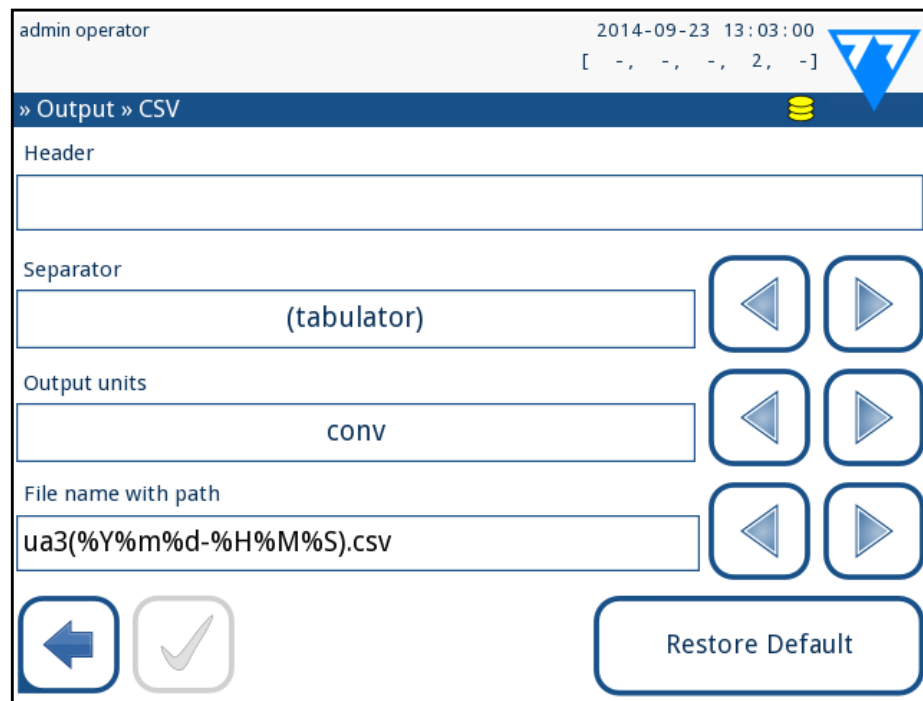


Figure 42: CSV export options

If you select this output protocol, 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 (You have the option to choose a tabulator, a semicolon, or a comma as the separator character.) The resulting file can be opened by a spreadsheet editor such as Microsoft Excel.

K.4.4 UTF8 unidir text

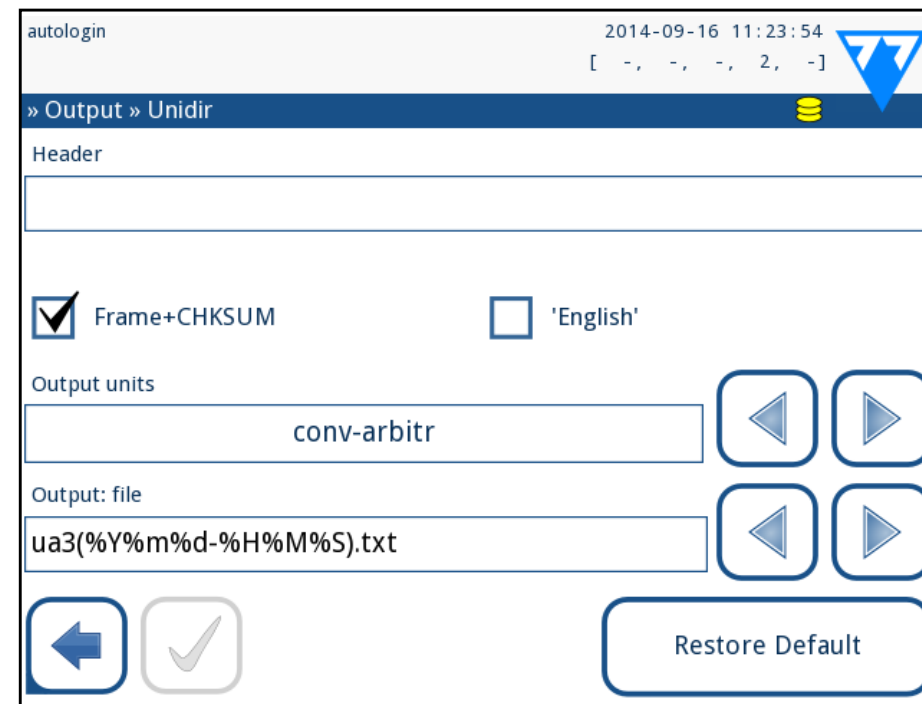


Figure 43: Unidir export settings

If you select this output protocol, 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 you leave it checked, the system will add a 'start text character' (STX) at the beginning, and an 'end text character' (ETX) at the end of the transferred string, as well as a two-digit checksum so that the transferred data can be verified.

K.5 Measurement

The detailed description of the **Measurement** screen can be found in [G.6.2 Customizing the analysis process on page 17](#)

K.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.

i Sensitivity can be set between -2 and +2 from the user in-

terface.

- ▶ 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 print-out. The flag value is stored in the database, so the database may be filtered for this option as well (See [H.6 Filtering: Finding specific results on page 20](#)).

Modifying the displayed pad order:

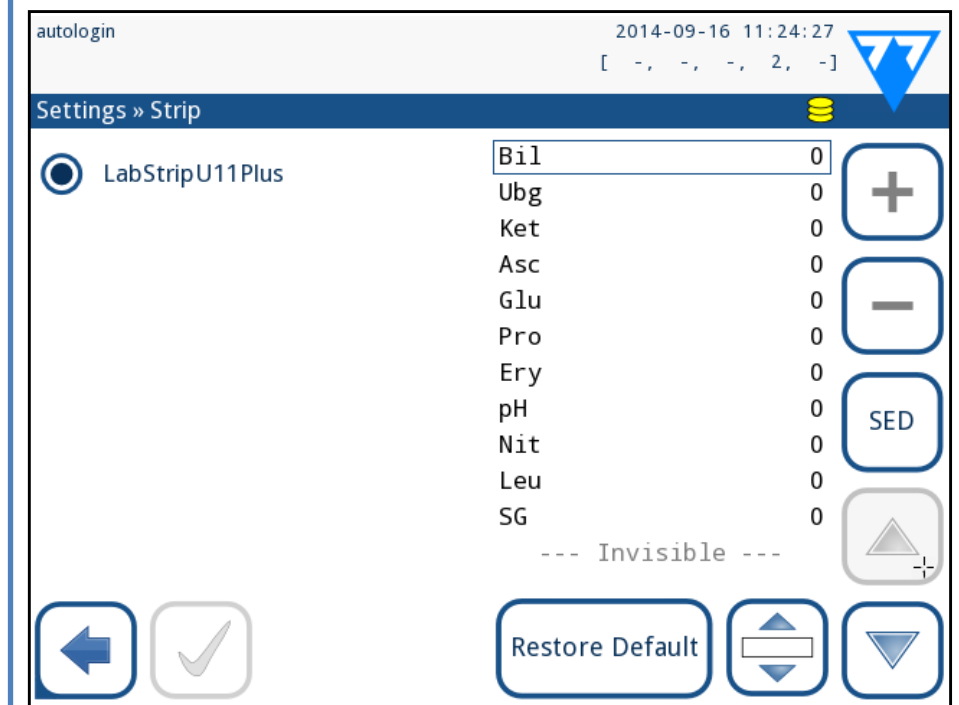


Figure 44: Strip options menu with an example of an invisible pad

- 1 Select the pad.
- 2 Tap the **Move** 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** button to deactivate the movement and release it. If you want 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.

i The system will only measure and store results for invisible analytes after you have restored them above the ---Invisible--- line.

K.7 Database management

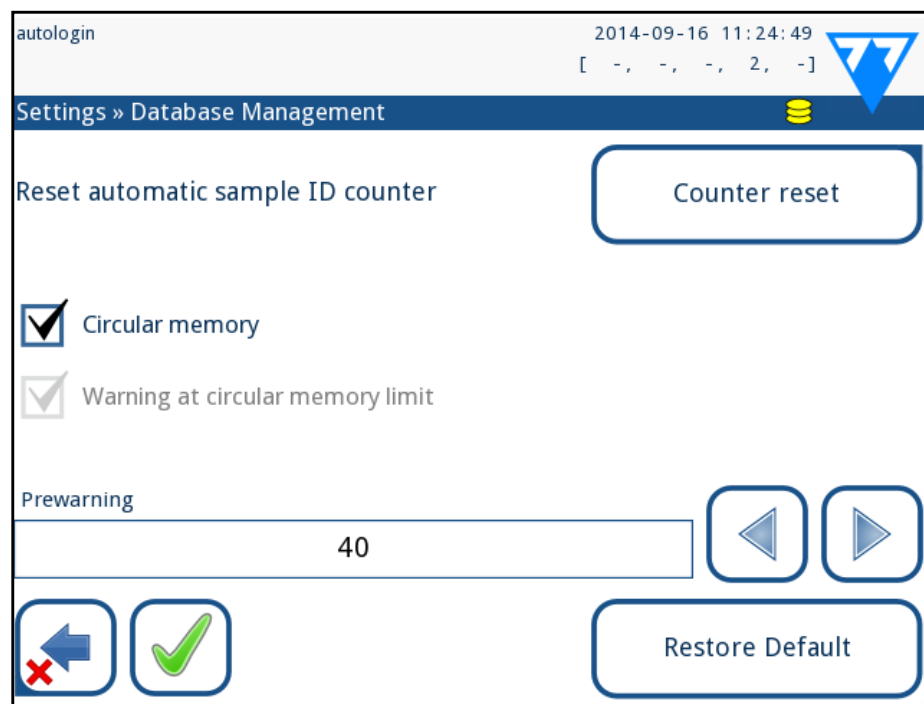


Figure 45: The Database management menu

On the **Database management** screen you can define how the LabUReader Plus 2 manages the storage of the records.

You can specify the following:

- ▶ The automatic Sample ID counter can be reseted 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, you receive a warning before old data is overwritten.
- ▶ Pre-warning: define the amount of records when you receive warning before the memory is full. Adding new records is still possible but you are advised to free up database memory by erasing data.

K.8 QC Options

The detailed description of the QC options screen can be found in [I.1 QC Options on page 21](#)

K.9 Power management

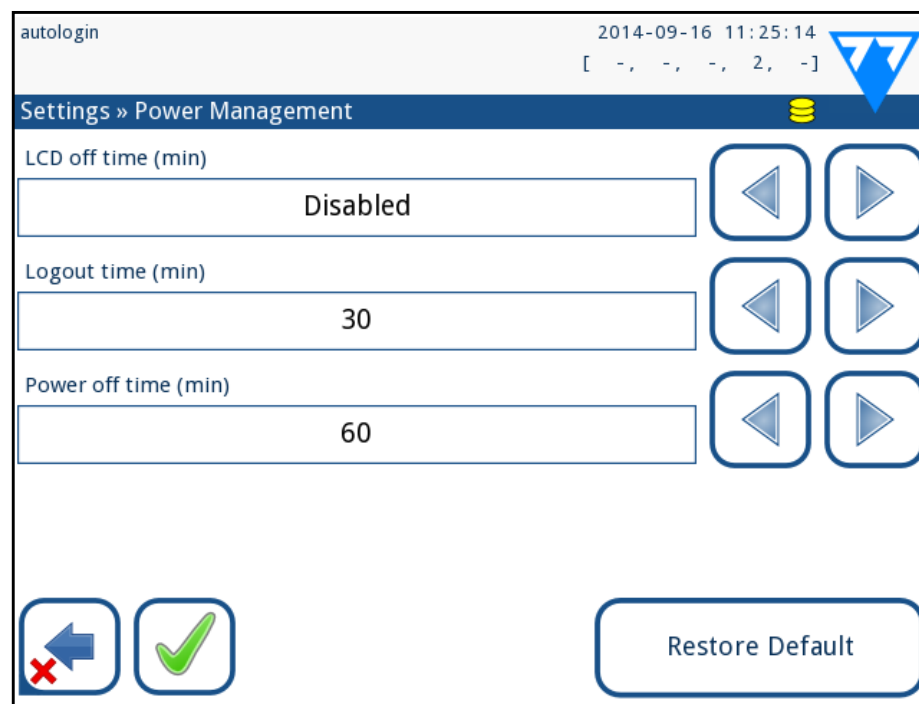


Figure 46: The Power management menu

At the Power Management screen you can enable and set the value in minutes for the following options:

- ▶ 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.

K.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 (2)** 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.

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

K.11 Editing the color and clarity list

The LabUReader Plus 2 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 you set the new name, tap the **OK** button, which takes you 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.

K.12 Ethernet interface configuration

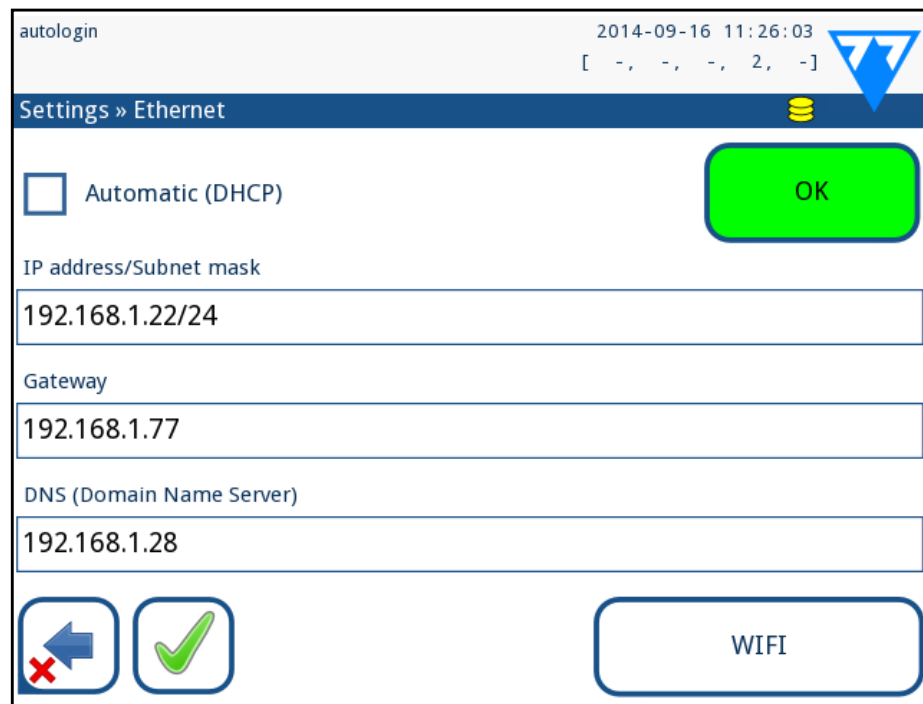


Figure 47: The Ethernet connection setup menu

To connect the LabUReader Plus 2 Pro analyzer to the network via Ethernet interface through TCP/IP, you have to configure the Ethernet interface.

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

i 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 **auto (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 auto (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.

K.13 Update

Refer to [D.3 Analyzer software updates on page 11](#) for details of the software update process.

K.14 Wi-Fi settings

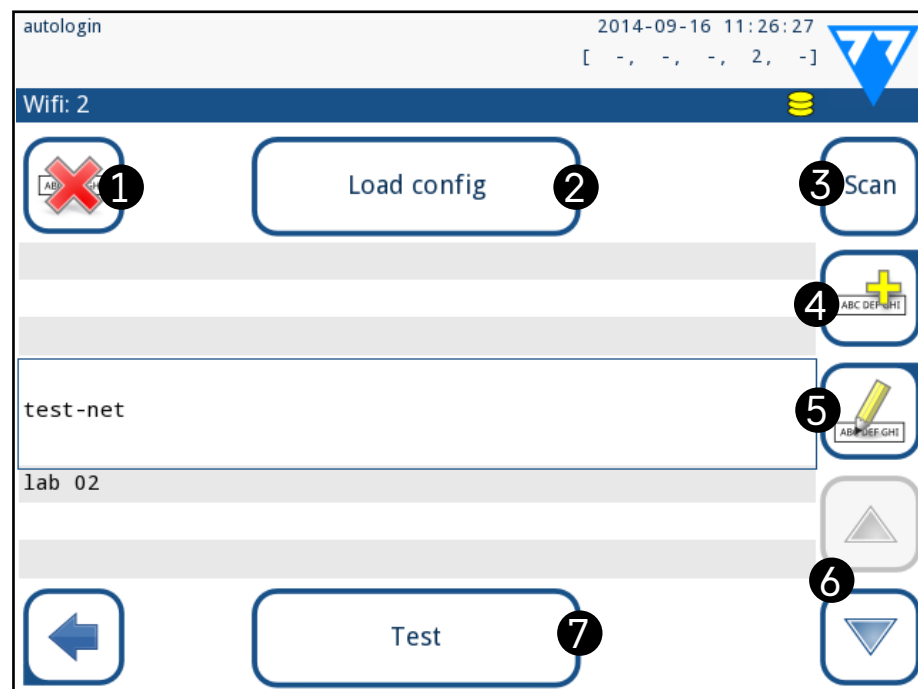


Figure 48: The Wi-Fi screen (available from the Ethernet configuration screen)

K.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»Options»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 that you would like to connect to, 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 po-

sition the cursor over the network that you are connecting to, and tap the **Test** button. A status text will be displayed below the name of the network. When the status text reads **COMPLETE**, the analyzer is connected to the selected wireless network.

i For functional bidirectional data transfer, you also need to have a receiving server set up.

K.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»Options»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.

i 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 that you are connecting to, 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.

K.14.3 Load preconfigured networks and advanced authentication protocols

The LabUReader Plus 2 system software includes a utility (the wpa_supplicant utility) that you can use to configure advanced wireless network options. To set up your preferred options, you need 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 you name **wpa_supplicant.conf.zip**. Include the string **/usr/local/WIFI/** in the pathname for the files. Do not put the files inside folders before you zip them.

i 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 that you set up in step 1 above 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.

K.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»Options»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 that you would like to modify or delete.

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.

K.15 Operators

You can manage user authentication settings and system security settings on the **Operators** menu.

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.

K.15.1 Managing operator accounts

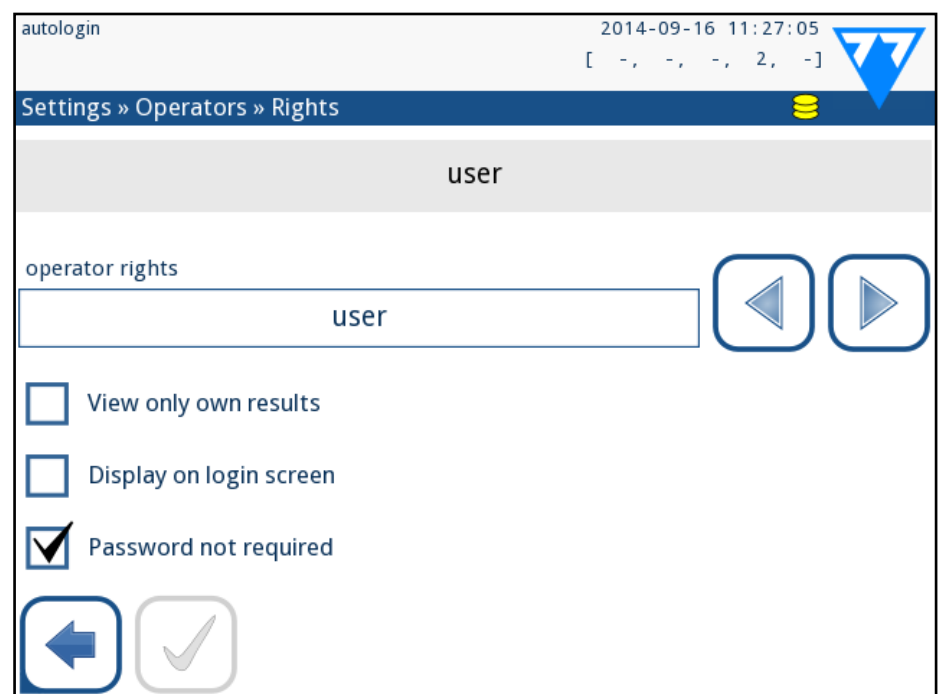


Figure 49: The operator account management menu

Adding operator accounts

i 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 on page 30](#)).

i 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 50](#)).
- 2 Tap the **Clear password** button to delete the password associated with the operator account.
- 3 Confirm the command by tapping the Apply button.

i If you want 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 into the operator account, he or she 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 50](#)).

The following additional settings are available for each operator account:

- ▶ View only own results—users logged into this operator account can only access records for measurements they themselves have performed on the analyzer

i 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

i 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)”.

i 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

i If you enable this setting for an operator account that already has a password associated with it, you don't have to clear the password for the account before this setting becomes active.

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

Data exchange

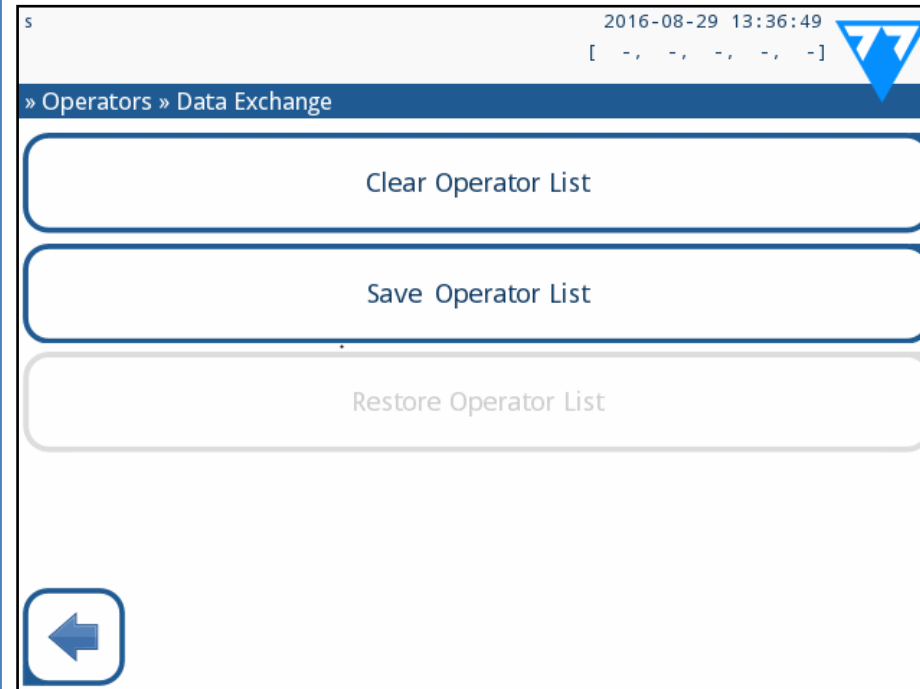


Figure 50: The Data Exchange menu

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.

i If you have 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.

i 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.

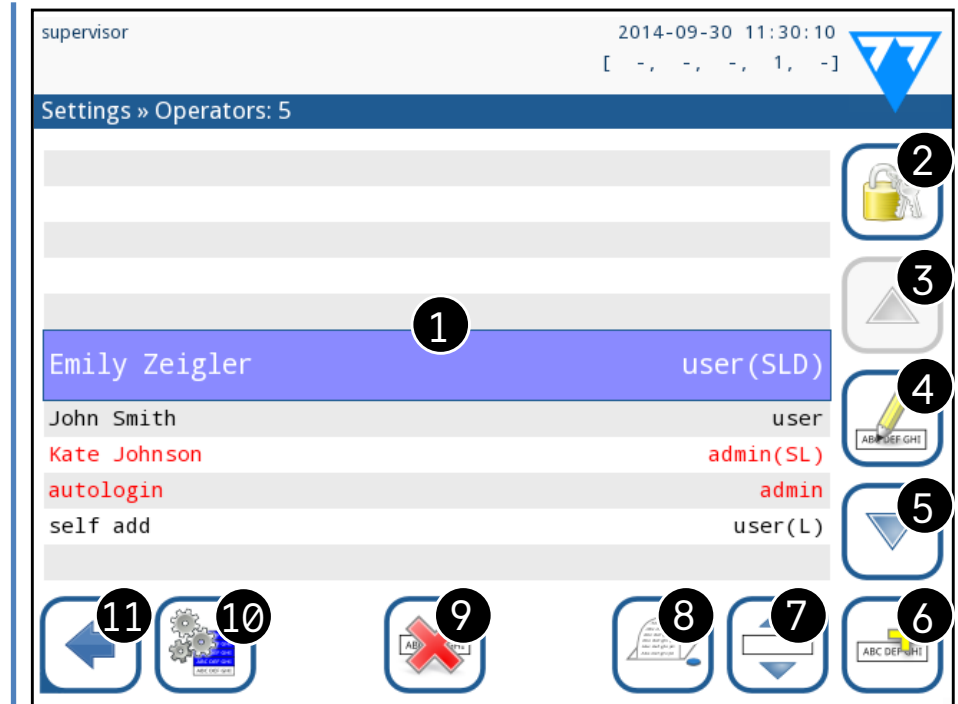


Figure 51: The Operators menu

Key to Figure 51:

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

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

i 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

i This function is only available when you select an operator that is displayed on the login screen (☞), and if there are at least two such operators. The operators are displayed on the login screen in the order that you specify on this list.

i 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

K.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 currently not listed in the operator list, however you login 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 you enter this name in the login name field, the software will erase all data, settings, and operator accounts (except test strip registration codes you have entered). Make sure that you include the full stop at the end of the sentence “Full database and config clear.” The system will prompt you to confirm the command.

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

K.15.3 Managing security settings

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

You can set the global security setting level on the **Settings»Operators»Security** menu (see [Figure 51](#)).

LabUReader Plus 2 offers 5 different preset security levels, and a fully customizable ‘Expert’ level where you can enable or disable various security settings to best suit your laboratory workflow.

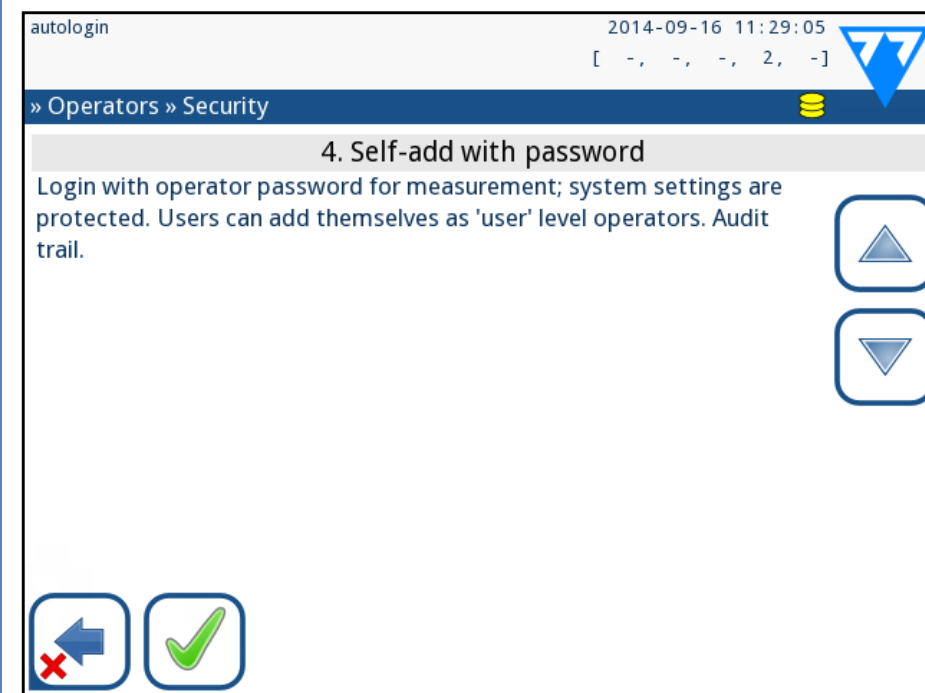


Figure 52: **The Self-add with password preset security level screen**

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	<input checked="" type="checkbox"/> On	<input checked="" type="checkbox"/> On	<input type="checkbox"/> Off	<input type="checkbox"/> Off	<input type="checkbox"/> Off
auto login rights	admin	user	N/A	N/A	N/A
self add	<input type="checkbox"/> Off	<input checked="" type="checkbox"/> On	<input checked="" type="checkbox"/> On	<input checked="" type="checkbox"/> On	<input type="checkbox"/> Off
self add rights	N/A	user	user	user	N/A
password not required	<input checked="" type="checkbox"/> On	<input checked="" type="checkbox"/> On	<input checked="" type="checkbox"/> On	<input type="checkbox"/> Off	<input type="checkbox"/> 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-registered users w/o passw	self-registered users with passw	admin-registered users with passw
user management	N/A	admins	admins	admins	admins
identification	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

K.15.4 Customizing security settings

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

You can set the following options 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 (👉 [K.15.2 Predefined operator accounts on page 32](#))

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 you enable this option, you can set the account level for all such self-added operator accounts, as well as customize them (👉 [Customizing operator accounts on page 30](#)).

Password not required:

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

i 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 (👉)

Check LIS:

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

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.

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

L Cleaning & Maintenance

As a general preventive action, always keep the outside of the LabUReader Plus 2 analyzer clean and free of dust.

L.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.**

⚠ **Care should be taken to avoid liquid entering the printer compartment.**

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

ⓘ **Recommended, 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%*

L.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 excess 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 LabUReader Plus 2 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 (↪ [D.2 Setting up on page 8](#)).

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

M Troubleshooting

Your LabUReader Plus 2 analyzer will operate properly if you follow the directions for using and cleaning the instrument.

Advisory messages will be displayed when your 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 you 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 you have taken the corrective action, the message will be removed from the system.

Information messages

Provides a 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 operation to clear up disappears after the confirmation of the operator

4. Result view: message appears on the standard content area.

M.1 List of Errors and Information Messages

In case of an error, try to solve it according to the below trouble-shoot 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.

Irregular or slow movement of test strip tray

If movement of the test table is irregular or slow, this may be caused by the heavy buildup of dried urine on the test table. Clean the test strip tray and insert as described in

[L.2 Cleaning the internal elements on page 34](#)

Analyzer does not switch on

Only use the power supply adapter included with the unit.

Check all power connections:

the DC plug is correctly inserted into the analyzer,

- a) the AC plug is correctly inserted into the external power supply (the blue LED is switched on).

The reader does not print or the printout is not visible

- ▶ Paper is out (error: W30) or paper cover is not closed (error: W31): Replace paper and close paper cover.
- ▶ Wrong paper (not thermal paper) is loaded: Insert the right type of paper correctly

Legend 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

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 of the tray 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.
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 initied. 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 77E logo in the top right corner.
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 77E 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 succeeds, the error will automatically disappear. If the error persists, please verify the connections and the presence/status of the destination
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.
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.

Message ID	C.	T.	Status line text	Full text	Recommended action
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.
W32	W	S	Stripholder	Stripholder error. Can't go to home position. Please check it!	Check if the test strip tray is placed properly in the housing or remove any obstacles from the path (See D.2.2 Inserting the drop tray on page 9).
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.: on page 32
E198	E	P		DB failure: cannot modify result. Please call Service!	Contact your service representative or do a Full database and config clear.: on page 32
E197	E	P		DB failure: cannot delete result. Please call Service!	Contact your service representative or do a Full database and config clear.: on page 32
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.: on page 32
E195	E	P		Worklist DB failure: cannot write new item.	Contact your service representative or do a Full database and config clear.: on page 32
E194	E	P		Worklist DB failure: cannot insert or modify item.	Contact your service representative or do a Full database and config clear.: on page 32
E193	E	P		Worklist DB failure: cannot delete item.	Contact your service representative or do a Full database and config clear.: on page 32
E181	E	P		Load config error: read details from “wpa_suppllicant.conf.err” file on PENDRIVE	The system encountered a problem in the wpa_suppllicant.con.zip file, and has saved an error report on the connected USB stick. Refer to the WPA Suppllicant documentation to deal with the issue.
E180	E	P		Load config error: USB drive or wpa_suppllicant.con.zip file not exists.	Make sure that the wpa_suppllicant.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 Wastebin.
E177	E	TP		Length of password must be between 8 and 63 characters.	The password that you entered is too long or too short. Enter a new password.
E175	E	TP		Length 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’.
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 77E 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 operator name that you entered 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.

Message ID	C.	T.	Status line text	Full text	Recommended action
W156	W	TP		Cannot connect to server for output.	Check output server settings.
W142	W	P		Wastebin near full. Please empty it.	Empty Wastebin.
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, empty, and replace the waste bin. Tap inside the message window to reset the used strip counter.
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 77E 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.
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.)	You have successfully increased the active QC lockout time.
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
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 K.15.3 Managing security settings on page 32)
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

Message ID	C.	T.	Status line text	Full text	Recommended action
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

M.1.1 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	Strip tray 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.
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 K.6 Strip options on page 27). 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.

ID	C.	T.	Status line text	Full text	Testing: Error Source & Action
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

M.1.2 Software Update: List of Errors and Information Messages

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.

N Appendices

N.1 Appendix A: Results table

The LabUReader Plus 2 analyzer prints the results in the following gradation of concentration:

Parameter	Conventional Units (Conv.)	SI Units (SI)	Arbitrary
BIL (Bilirubin)	neg	neg	neg
	0.5 mg/dl	8.5 µmol/l	(+)
	1 mg/dl	17 µmol/l	1+
	3 mg/dl	50 µmol/l	2+
	6 mg/dl	100 µmol/l	3+
UBG (Urobilinogen)	norm	norm	neg
	2 mg/dl	35 µmol/l	1+
	4 mg/dl	70 µmol/l	2+
	8 mg/dl	140 µmol/l	3+
	12 mg/dl	200 µmol/l	4+
KET (Ketone)	neg	neg	neg
	5 mg/dl	0.5 mmol/l	(+)
	15 mg/dl	1.5 mmol/l	1+
	50 mg/dl	5 mmol/l	2+
	150 mg/dl	15 mmol/l	3+
ASC (Ascorbin)	neg	neg	neg
	20 mg/dl	20 mg/dl	1+
	40 mg/dl	40 mg/dl	2+
	100 mg/dl	100 mg/dl	3+
GLU (Glucose)	norm	norm	norm
	30 mg/dl	1.7	(+)
	50 mg/dl	2.8	1+
	150 mg/dl	8	2+
	500 mg/dl	28	3+
PRO (Protein)	neg	neg	neg
	15 mg/dl	0.15 g/l	(+)
	30 mg/dl	0.3 g/l	1+
	100 mg/dl	1 g/l	2+
	500 mg/dl	5 g/l	3+

Parameter	Conventional Units (Conv.)	SI Units (SI)	Arbitrary
ERY (Erythrocytes)	neg	neg	neg
	5-10 Ery/µl	5-10 Ery/µl	1+
	50 Ery/µl	50 Ery/µl	2+
	300 Ery/µl	300 Ery/µl	3+
pH		5	
		5.5	
		6	
		6.5	
		7	
		7.5	
		8	
		8.5	
		9	
NIT (Nitrite)	neg	neg	neg
	pos	pos	+1
LEU (Leukocytes)	neg	neg	neg
	25 Leu/µl	25 Leu/µl	1+
	75 Leu/µl	75 Leu/µl	2+
	500 Leu/µl	500 Leu/µl	3+
SG (Specific Gravity)		1.000	
		1.005	
		1.010	
		1.015	
		1.020	
		1.025	
		1.030	
		1.035	

N.2 Appendix B: Specifications

Type:	reflectance photometer with 4 discrete wavelengths: 505, 530, 620, 660nm
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)
Power supply:	IN: 100...240V AC, 50/60Hz

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

Interfaces:

PS2 (external keyboard, barcode reader)
 serial RS232
 USB Type B
 USB Type A
 Ethernet

Expected lifetime:

5 years or 100000 measurements

N.3 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: LabStripU11Plus
 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 you restore the default settings.

N.4 Appendix D: Safety information

LabUReader Plus 2 was designed and manufactured to comply with the international regulations listed in this section, and left the factory in a safe condition. To keep the analyzer in a safe condition, you must observe all instructions and warnings included in this manual.

The instrument complies with the protection requirements of IEC 61010-1:2010, IEC 61010-2-101:2002 and IEC 61326-1:2005, IEC 61326-2-6:2005.

This analyzer was designed and manufactured to comply with the following international regulations “Safety requirements for electrical equipment for measurement, control and laboratory use” and left the factory in a safe condition. In order to keep the analyzer in a perfect and safe condition, it is up to the user to observe all instructions and warnings included in this manual.


 Complies with the provisions of the applicable EU regulations.

Per IEC 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 analyzer will perform as intended.

Do not use this analyzer 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 analyzer.

This equipment has been designed and tested to CISPR 11 Class A. The analyzer must be operated only with the prescribed power supply unit (Class II protection).

Opening covers or removing parts of the instrument, except where this can be achieved manually without the use of any tools, may expose voltage-carrying components. Connectors can be live, too.

 **Do not attempt to maintain or repair an open instrument which is carrying voltage.**


If you suspect that the instrument can no longer be operated safely, turn it off and take steps to ensure that no one will subsequently attempt to use it. Make sure that only trained members of staff operate the LabUReader Plus 2 analyzer.

Any personal computer to which the analyzer is connected must meet the EN 60950, UL 60950/CSA C22.2 No. 60950 requirements

for data processing equipment.

Only connect the intended external analyzers 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 analyzers or the analyzer.

If the instrument is to be taken out of operation entirely and disposed of, it must be disposed of in conformity with the relevant legal regulations and in co-ordination with your local authority, if appropriate. Please note that the instrument may potentially be infectious. Equipment must be decontaminated before repair, maintenance, or removal from the laboratory.


 **The data and information contained in this manual are accurate at the time of printing. Any substantial changes will be incorporated in the next edition. In case of conflict between this manual and information given in package inserts, the package inserts shall take precedence.**


N.4.1 Incident reporting

Inform your 77 Elektronika Kft. service representative and your local competent authority about any serious incidents which may occur when using this product.

N.4.2 Disposal of the analyzer

 **You must not dispose of your used DocUReader 2 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 (see an NHS example), but you must follow local waste management guidelines and regulations.**


 77 Elektronika will accept DocUReader 2 PRO devices that you no longer want to use, if you disinfect or sterilize the device before mailing it as written below. Before mailing the disinfected device to H-1116 Budapest, Fehérvári út 98., Hungary, make sure that you

1. Sign in to the Helpdesk in the For Distributors section of our website (www.e77.hu) using your 77 Elektronika account user name and password.

2. Click the RMA button and follow the instructions.

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 make sure that you 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).

N.4.3 Protecting yourself from biohazards


This information summarizes the established guidelines for handling laboratory biohazards. Use this summary for general information only. It is not intended to replace or supplement your laboratory or hospital biohazard control procedures.

Urine specimens should be handled at Biosafety Level 2 as recommended for any potentially infectious material in the Centers for Disease Control and Prevention manual, *Biosafety in Microbiological and Biomedical Laboratories*, 2009². Universal (or standard) precautions may apply if the urine is contaminated with blood or if required by the infection control policy of your facility. To prevent accidental contamination in a clinical laboratory, strictly adhere to the following procedures:

- ▶ Wear gloves to protect hands from exposure to hazardous materials. Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary. Do not wash or reuse disposable gloves.
- ▶ Remove gloves and wash your hands after working with potentially hazardous materials and before leaving the laboratory.
- ▶ Wear personal protective laboratory equipment, such as coats, gowns, smocks, or uniforms when working with possible hazardous contaminants. Remove protective clothing before leaving for non-laboratory areas

² <http://www.cdc.gov/biosafety/publications/bmbl5/>

- ▶ Wear eye and face protection when splatter or aerosol formation are possible.
- ▶ Do not eat, drink, smoke, handle contact lenses, apply cosmetics or store food while in the laboratory.
- ▶ Do not pipette any liquid by mouth; use only mechanical pipetting analyzers.
- ▶ Always handle sharp items with precautions.
- ▶ Perform procedures carefully to minimize the creation of splashes or aerosols.
- ▶ Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.
- ▶ Dispose of contaminated materials including used personal protective equipment according to your laboratory's biohazard control procedures. Potentially infectious materials must be placed in a durable, leak proof container during collection, handling, processing, storage, or transport within a facility.
- ▶ The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures.
- ▶ During service work, keep your hands and fingers away from your mouth, nose and eyes.
- ▶ Wash your hands after working.
- ▶ Waste material should be handled or disposed of in accordance with the local safety regulations.

 *Be sure to read and understand the safety warnings and symbols in this manual.*

N.5 Support & ordering

Support

77 Elektronika offers full service support for its products. Feel free to contact us if you encounter any problem with the LabUReader Plus 2 device that consulting this manual does not or only partially solve. There are several channels of communication available, listed below.

By phone or e-mail

You can reach qualified 77 Elektronika service staff during office hours at the service hotline and the service staff e-mail address:

+36 1 371 0546
service@e77.hu

The number and the address are also listed on our website (www.e77.hu) in the 'For Distributors' section.

Through the Helpdesk

Sign in to the Helpdesk in the For Distributors section of our website (www.e77.hu) using your 77 Elektronika account user name and password.

Press the New Issue button in the top left corner.


In the Description text box, provide as much information about the problem as you can. You can also include photos or video clips that highlight the problem as attachments.

When you are done, press Send at the top of the screen. You will get status update notification e-mails as the reported issue is processed.

Ordering

You can order any replaceable part, accessories and consumables of the device directly from 77 Elektronika.

- Grey check strip (2 pcs) S-UD21150002
- Labstrip U 11 Plus ANA-9901-1

 *Do not use the phone to place orders. Use the written forms of contact listed below and always include the article number of the part or parts you are requesting.*

Send your order by fax to

+36 1 206 1481

or by e-mail to

service@e77.hu.

Our service staff will get in touch with you to confirm your order as soon as possible.