

DocUReader 2 PRO

Urine chemistry analyzer

User Manual





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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.



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1 INTRODUCTION

1.1 How to use this manual

This Operator's Manual contains all essential information for the user to make full use of the analyzer device. The manual describes system functions and includes step-by-step procedures for the access and use of the system.

For further assistance and feedback, visit <https://www.en.e77.hu/for-distributors>.

1.2 Symbols and formatting conventions

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



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

Caution text appears in bold type.



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

Warning text appears in bold type.



BIOLOGICAL HAZARD: This symbol indicates maintenance procedures, operations, and other processes where hazardous biological agent are present. Instructions are to be followed carefully to avoid personal injury and/or adverse health effect.

Warning text appears in bold type.



NOTE: This symbol indicates important information or useful tips on servicing the device.

Note text appears in italic type.

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

- **Bold grey text** indicates cross-references that point to related parts of the manual or to external hyperlinks.
- **Bold monospace type** indicates text that appears on the display
- **1.** (numbering) within procedures indicates steps that you should perform in sequence.
- Bullet points (•) indicate items on a list or steps that you do not need to perform in sequence.






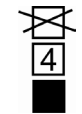








1.2.1 Symbols

The following symbols appear on the device, its AC Adapter, its packaging, and on the packaging of the reagent strip it was designed to read.

	Double insulated product or transformer. May also identify class 2 equipment (power supply only)		Indoor use only
	Indicates that the instrument is listed by Underwriters Laboratories as meeting U.S. and Canadian requirements for safety		The CE mark indicates that the product complies with the applicable directives of the European Union
	Indicates that this product has been tested to the requirements of CAN/CSA-C22.2 No. 61010-1, second edition, including Amendment 1, or a later version of the same standard includes the same level of testing requirements		Indicates that this equipment is classified as Waste Electrical and Electronic Equipment under the European WEEE Directive. It must be recycled or disposed of in accordance with applicable local requirements
	Indicates that 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
			In vitro diagnostic medical device
	Manufacturer		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
	Batch code		Stack no more than four (4)
	The number of items that the contents of the package is sufficient for		Humidity limitation
	Protect from sunlight and heat		Use by date
	Catalogue number		Do not reuse



1.2.2 Abbreviations

This manual uses the following abbreviations:

Abbreviation	Definiton
AC	Alternating Current
A/D	Analog-to-Digital
arb	arbitrary
ASTM	American Society for Testing Material
bps	bits per second
CEE	Commission for Conformity Testing of Electrical Equipment
conv	conventional
csv	comma separated values
DC	Direct Current
def	default
EN	European Standard
FFC	Flexible Flat Cable
GND	Ground (Earth)
ID	identification number
LED	Light Emitting Diode
LIS	Laboratory Information System
N/A	not applicable
neg	negative
nm	nanometer
norm	normal
RxD	Receive data
SI	International System of Units
S/N	serial number
TxD	Transfer data



1.3 Safety information

- ⚠ See “Safety and compliance information” for detailed safety and compliance information.**
- ⚠ Correct use: Any disregard of the instructions in the User Manual may result in a safety risk. Use DocUReader 2 PRO to analyze urine samples only: the device is not intended for any other application.**
- ⚠ Environmental conditions: The DocUReader 2 PRO analyzer is approved for indoor use only. See “3 Device installation & Maintenance” and “Appendix A Technical specifications” for further environmental limitations.**
- ☣ 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 device. Use universal precautions and consult relevant sections of the Centers for Disease Control and Prevention manual, Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition and the World Health Organisation’s Laboratory biosafety manual, Fourth edition.**

1.4 Intended use

The DocUReader 2 PRO urine analyzer is an In Vitro Diagnostic Device (IVDD). It is designed to increase the accuracy and efficiency of routine urinalysis by

- performing semi-quantitative urinalysis using reflectance photometry to read LabStrip U11 Plus/LabStrip U mALB/CREA urine test strips
- displaying, storing, and processing the resulting measurement records.

It is designed for use in professional settings such as hospitals or medical laboratories by qualified clinical personnel under the direction of a physician.

1.5 Indications for use

The DocUReader 2 PRO urine analyzer is a bench top IVDD for professional use designed to be used exclusively with LabStrip U11 Plus/LabStrip U mALB/CREA urine test strips manufactured by 77 Elektronika.

LabStrip U11 Plus

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

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

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

- Liver disease



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

LabStrip U mALB/CREA

The system performs the semi-quantitative measurement of relevant properties of the following urine analytes:

Albumin (mALB), Creatinine (CREA)

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

- Symptoms of beginning nephropathy
- Cardio-vascular diseases

① See the **MedlinePlus Medical Encyclopedia** article on *urinalysis* for further details.

1.6 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.

2 SYSTEM DESCRIPTION

2.1 Principle of operation

A motor moves the test strip tray (a slide with a central channel and an embedded reference pad) that carries the test strip, under a fixed measurement unit. The analyzer reads the reference pad first, then each of the test pads on the strip in turn.

The optical unit contains four LEDs that emit light at various discrete wavelengths.

Figure 1 summarizes the electro-optical pad reading process.

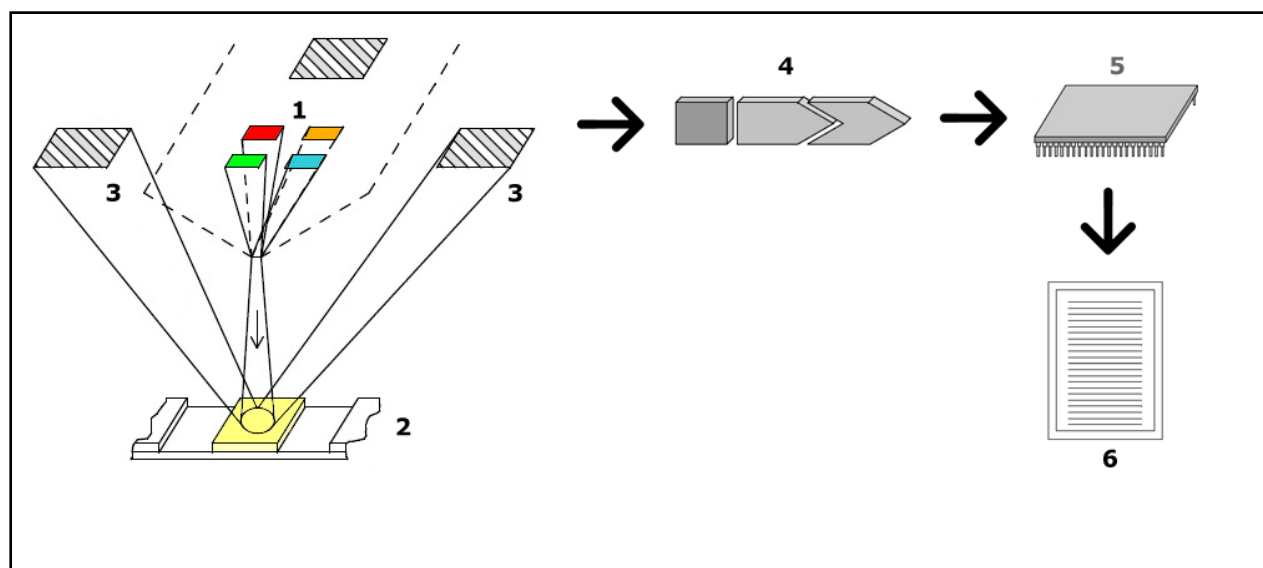


Figure 1: *Measurement principle*

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 test reaction is optimal.

The light from the LEDs is reflected back from the test zone with more or less intensity. The intensity of the reflection is directly related to the concentration of the particular analyte in the urine that the pad absorbed. Photodiode detectors (3) positioned at optimum angles pick up the reflected light. The analogue electrical signals from the detectors are first boosted by an amplifier (4) before they arrive at the microcontroller (5). Here the A/D converter in the microcontroller changes the analogue signals into digital values. The microcontroller converts this 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 produce the most accurate results.



2.2 Components & functions

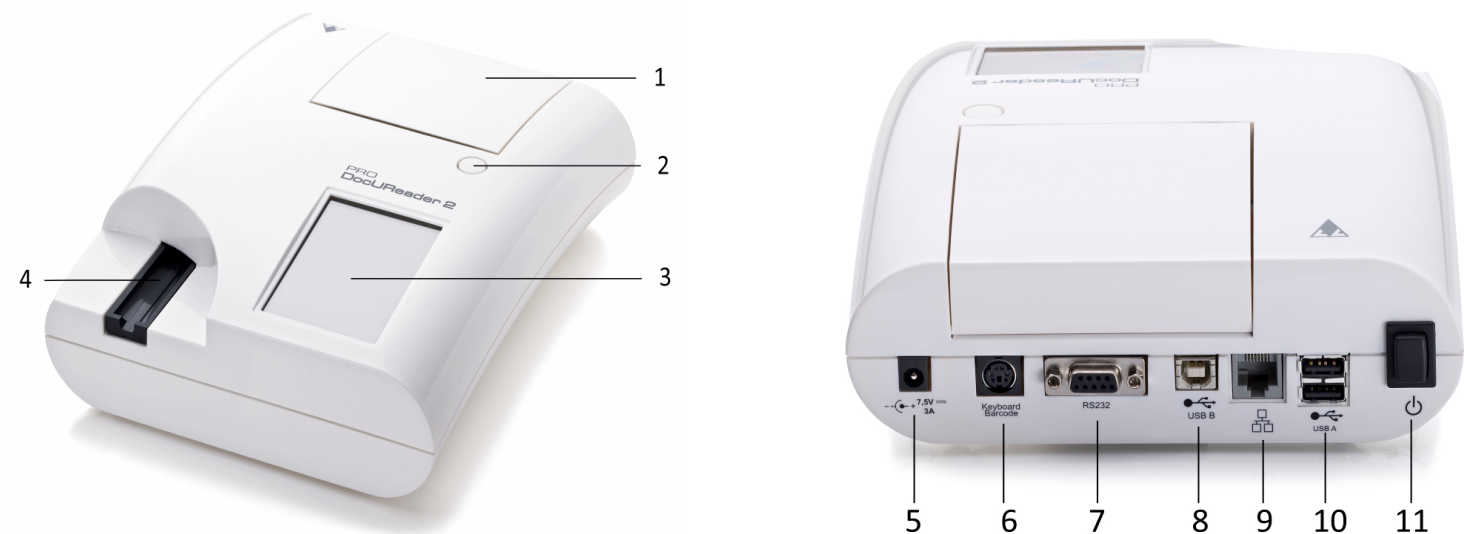


Figure 2: Front and rear view of the analyzer, marked up

Component	Function
1. Printer cover	Flips up to receive printer paper
2. Printer cover button	Opens printer cover when pressed
3. Touchscreen	Serves as an interface with the user
4. Test strip tray	Holds and moves the test strip during the analysis process
5. Power socket	Allows connection to the AC adapter
6. PS/2 socket	Allows connection to a barcode reader or a keyboard
7. Serial interface	Allows connection to a PC or a host computer
8. Type B USB port	Allows connection to a USB A-B cable and other peripheral devices
9. Ethernet socket	Allows connection to an Ethernet network
10. Type A USB port	Allows connection to various USB peripherals
11. On/Off switch	Allows switching the unit on and off. ⚠ Use the On/Off switch to switch off the device only if the normal powering down procedure fails.

⚠ Use the connectors only with their appropriate plugs and operational cables.

i The USB ports are compatible with FAT32, ext2, and ext4 file systems, but not compatible with the NTFS file system.



3 DEVICE INSTALLATION & MAINTENANCE

3.1 Parts checklist

- Intact DocUReader 2 PRO analyzer device

ⓘ *DocUReader 2 PRO is tamper-evident: either there is a silicone seal in one of the four screw holes on the bottom panel, or there is a tamper-evident sticker next to the power socket where the two panels join. Operational elements of the device cannot be accessed without breaking the sticker or removing the silicone seal.*

ⓘ *If you find the tamper-evident silicone seal broken, you may want to cancel the warranty your company provides for the device. Follow your company's guidelines.*

- AC adapter

(Mains requirements: AC 100-240 V, 50/60 Hz, 1.5 A Output: DC 7.5V, 3.0 A)

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

- Mains cable

ⓘ *The shipped mains cable has a CEE 7/16 ('Europlug') plug that can be safely plugged only into a grounded CEE 7/4 socket. If your socket is incompatible with the power plug, use a plug converter or visit <http://www.globtek.com/datasheets/pdfsnew/GTM91120-XXYY-T2T3A.pdf> for a GTM91120-3007.5-T2 AC power supply that suits your socket.*

- Test strip tray with a clean white reference pad firmly in place.

⚠ Do not touch the reference pad.

- Grey check strip, two (2) pieces

⚠ Do not touch the test area of the strip. Hold the strip by its handle.

3.2 Cleaning the device

⚠ It is recommended that you keep the DocUReader 2 PRO device clean and dust free.


3.2.1 Cleaning the analyzer

⚠ Always make sure that the analyzer is switched off before cleaning it.

⚠ Do not turn the analyzer on its side or upside down during cleaning as previously spilled urine or cleaning liquid could run inside the case and damage electrical parts.



 **Make sure that no liquid enters the device.**

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

 **Don't use any sprayer/atomizer for cleaning the device! Use only wet towel dipped in a mild detergent.**

 **Make sure that no liquid enters the printer compartment.**

Wipe the device and the touchscreen with a disposable towel dipped in a mild detergent. Recommended cleaning agents:

- Isorapid (a mixture of 20 g Ethanol, 28 g 1-Propanol, and 0.1 g quaternary ammonium compounds)
- Trigene Advance laboratory disinfectant (at a dilution of 1:100)
- Barrycidal-33 (at a dilution of 2:100)

3.2.2 [Cleaning the test strip tray](#)

Keep the test strip tray clean and free of obstructions. Pay particular attention to the reference pad (1) and the see-through LED window (2).

 **Always wear protective gloves when handling the test strip tray. See "1.3 Safety information" for further details.**

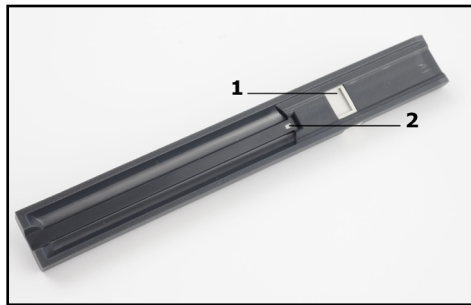


Figure 3: *The test strip tray and its reference pad*



Figure 4: *Rinsing the test strip tray*

Complete the following steps to clean the test strip tray at least once a day :

1. Switch off the device and remove the test strip tray by gently pulling it free from its slot.
2. Rinse the parts that can come into contact with urine under running water. Wipe the tray with a disposable towel dipped in 70% (V/V) isopropyl alcohol.

⚠ Take care not to scratch the white reference pad.

3. Dry the test strip tray with a lint-free wipe.

⚠ Make sure that the test strip tray is completely dry before reinserting it.

4. Reinsert the test strip tray. See “3.4 Setup”.

3.2.3 Cleaning the printer roller

The printer roller can pick up grease and dirt that can cause non-printing white spots or streaks on the printout. It is recommended that you clean the printer roller at least every six months of device operation.

1. Switch off the device and press the printer cover button to expose the printer roller.
2. Hold a lint-free wipe dipped in distilled water to the surface of the roller and use the roller's cog wheel on its left end to turn it. Make sure that you wipe every part of the roller surface.




3.2.4 The reference pad


The white reference pad on the test strip tray behind the test strip channel should not get soiled or discolored during normal operation. Nevertheless, it is recommended that you check that it is intact whenever you clean the test strip tray. If it is soiled or discolored, gently wipe it clean with a disposable towel dipped in distilled water. Replace the reference pad if there are irremovable marks or scratches on its surface.

3.3 Setup considerations

Do not use the device outdoors.

- Make sure that you set up and operate the device on a solid level surface in an environment with fairly constant temperature and humidity.
- Do not operate the device in close proximity to sources of intense electromagnetic radiation (such as unshielded intentional RF sources).

 *The device is certified to meet the EMC requirements of IEC 61326-1:2005 and IEC 61326-2-6:2005. See “**Appendix E Safety and compliance information**” for further details. Do not operate the device in temperatures below 15°C (59°F) or above 32 °C (89.6 °F). See “**Appendix A Technical specifications**” for further environmental considerations.*

 *The device displays a warning message (“**W37**”) if the ambient temperature is out of the operational range.*


- Do not expose the measuring head to intense light such as direct sunlight.

 *The device displays an error message (“**E269**”) if an external light source interferes with the strip reading process.*

- Do not set up and operate the device in an environment with vibration sources. Make sure that the strips sit and travel smoothly and stay level in the test strip tray at all times.

3.3.1 Clearance limits

 **Make sure that there is enough room in front of the device for the test strip tray to move in and out of the machine freely. The DocUReader 2 PRO device can only make accurate measurements if nothing obstructs or touches the test strip tray during the measurement process.**

 **Make sure that there is enough room at the back of the device to operate the On/Off switch. Make sure that there is enough room at the back of the device so that the power supply cable, the USB devices, and the cables of other peripherals are not bent, strained, or twisted.**

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



3.4 Setup

3.4.1 Inserting the test strip tray

⚠ Never touch the top surface of the reference pad on the test strip tray.

1. Handle the test strip tray by the end where the test strip channel opens, opposite the reference pad. Make sure that the test strip channel is facing upwards.



Figure 5: *Inserting the test strip tray*

2. Push the test strip tray into the opening on the front of the device to the left of the touchscreen. Make sure that the serrated edge at the bottom of the tray engages with the stepper motor inside.

3.4.2 Loading the printer

1. Push the printer cover button and open the printer cover.

⚠ Do not touch the printer head; it may be hot.

2. Place a roll of thermal 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 is towards the printer head, not towards the rear of the device. 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.
3. Close the printer cover until click.



Figure 6: Loading the printer

❗ By default, the analyzer prints measurement results automatically. You can turn off the automatic printing function on the **Main » Options » User Options** screen (See “8.3 Recalling QC results”).

3.4.3 Connecting the device to a computer

The device can interface with a computer via the female 9-pin D-sub serial port on its rear panel. The connections are the following:

DocUReader2		Host (PC 9-pin pinout)
1		1
2	TxD	2
3	RxD	3
4		4
5	GND	5
6		6
7		7
8		8
9		9

❗ The connected PC must comply with EN 60950 requirements.



3.4.4 Switching the device on and off

- Connect the device to the electric mains via the AC adapter and switch it on by pressing the On/Off switch at the back. The system starts up with a single beep.



Figure 7:
Switching on the device

- Switch off the device by tapping the  button on the **Main** or the **Login** screen.

⚠ Do not disconnect the power cable while the device is in operation. Doing so can corrupt the data and damage the system.

⚠ Make sure that there is no strip on the test strip tray and that the tray is clean before switching off the device.

ⓘ If necessary (in case the system freezes or the touchscreen fails), you can also switch off the device by pressing down on the On/Off switch for at least five (5) seconds.

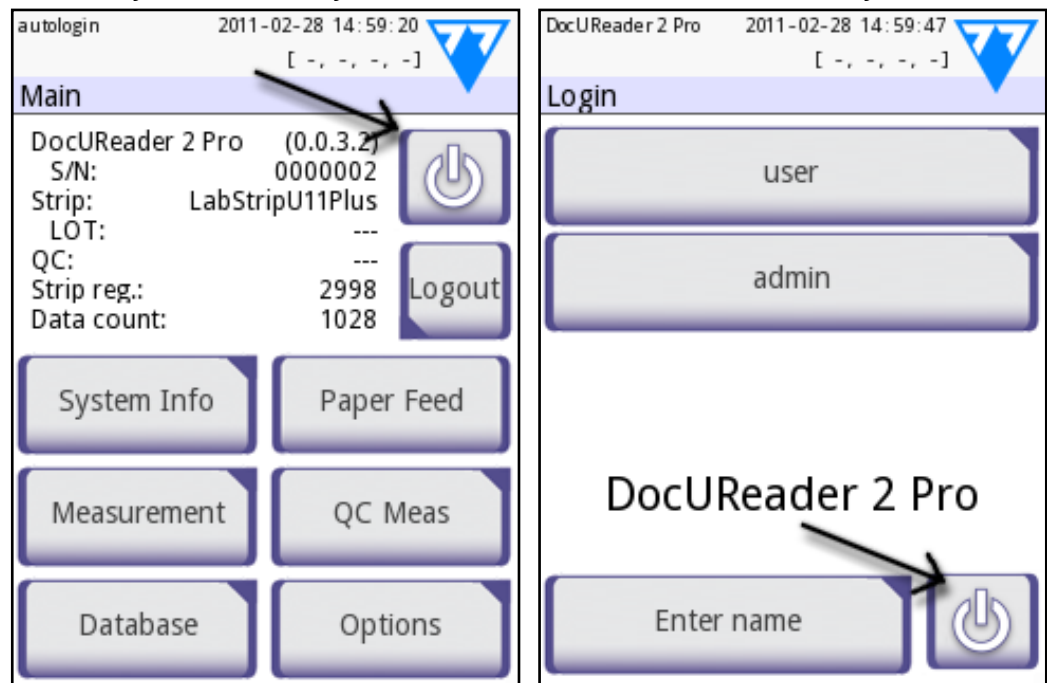


Figure 8: *Switching off the device*



3.4.5 Calibrating the touchscreen

⚠ The touchscreen 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.

The touchscreen of the device is correctly calibrated in the factory, but you may want to recalibrate the display at least once a year. If you notice that the touchscreen is not responding or does not respond accurately, complete the following steps to calibrate it:

1. Switch on or restart the device.
2. While the device is booting, wait for the progress bar at the bottom of the screen to turn green. When it does, keep gently pressing down on the touchscreen until the yellow screen calibration alert screen appears.

⚠ Do not use your finger to calibrate the Touchscreen. Use a pointing device or a pen.

⚠ Do not use a pointing device that could damage the touchscreen such as the tip of a pencil or the extended tip of a ballpoint pen.

3. Wait for the actual black screen calibration screen to appear. Tap the display at the intersection of the crosshairs that appear in the corners and the center of the screen with your pointing device. Try to tap the display as close to the intersections as possible; this practice ensures the best possible alignment between the touchscreen coordinates and the LCD screen behind it.

3.5 Software updates

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

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

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 device.

3.5.1 Using the ready-made USB flash drive

1. Switch on the DocUReader 2 PRO and wait until the system is ready.
2. Plug the USB flash drive with the software update into one of the USB A connectors at the back of the analyzer. Wait for a  (disk) icon to appear in the top



right hand corner of the touchscreen.

① The yellow disk icon indicates that the system recognized the USB device.

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

① 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 device.

3.5.2 Using the online distributed software update package

① 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.

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

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

① The following are the kind of file names you should expect to find in the update package: udr2base_x.x.x.tar.gz; udr2base_x.x.x.tar.gz.chk; iUD2vX, iUD2vX.chk. 'x' and 'X' stand for various numbers. 'pro' replaces 'base' in the file names if you have a DocUReader 2 PRO device.

3. Complete the steps in “3.5.1 Using the ready-made USB flash drive”.

3.5.3 Other ways of updating the software

⚠ If you received your software update package on a microSD card or a code chip, follow the instructions for updating the analyzer software supplied with the media.

① DocUReader 2 PRO can also detect software update files via its microSD or code chip reader slots. You can find these connectors under the printer cover inside the printer roll compartment; on the right if you are facing the touchscreen. The code chip connector is directly above the microSD connector slot.



4 INTERACTING WITH THE DEVICE

If no bar code scanner or keyboard is connected to the device, you can interact with the system via the Touchscreen only.

4.1 Screens

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

The screen layout can be divided into three main areas:

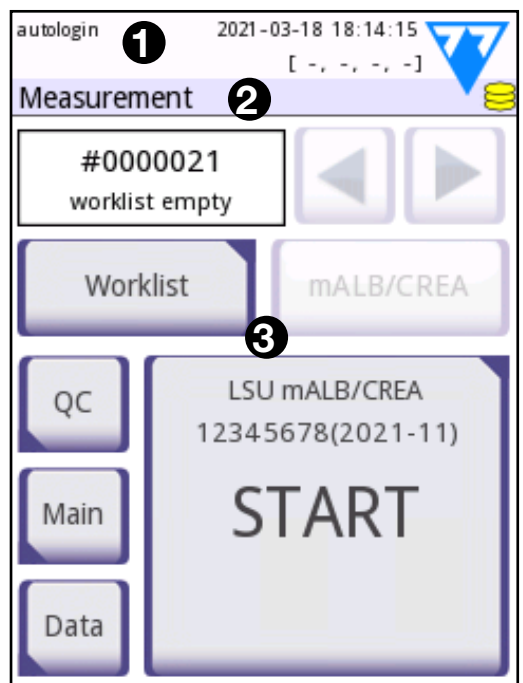


Figure 9: Display layout

❶ Header: Displays important system information, like the date and time, current operator ID queue and status line messages.

The four placeholders below the date and time indicate, from left to right:

- the number of active errors
- the number of records in the printing queue
- the number of records in the output queue
- the number of items in the worklist

❶ *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.*

❶ *Active error and warning messages can be listed by tapping the status bar area.*

❷ 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.

❸ Content area: The primary operation area of the Touchscreen. If the 'autologin' operator is enabled (See "18.15.2 System security settings"), the first main screen you see is the **Measure** screen. In the work area you can start a measurement, review the last result, handle the worklist, cycle through the worklist items and go to the **QC**, **Main** and **Data** screens.

This part of the screen will sometimes also display instructions, feedback, or error messages.



4.2 Touchscreen operation

You can operate the touchscreen with bare fingers, gloved fingers, ballpoint pens with retracted tips, or any stylus-like object. You need to tap the touchscreen 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 touchscreen 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.

① *A separate foil layer is attached to the screen to prevent liquids from leaking into the system.*

① *Sound effects are on by default and the system confirms successful tap events with a short clicking sound.*





INTERACTING WITH THE DEVICE

4.2.1 Buttons and screen input areas

Buttons

You can use rectangular buttons to trigger actions and to navigate menus. Buttons come in several sizes. An indicator in the bottom left or the top right corner of a button indicates whether it has a menu navigation function.

 Indicator in the bottom left corner: Tapping such a button closes a screen and moves you back up one level in the menu hierarchy.

 Indicator in the top right corner: Tapping such a button opens a new screen and moves you one level down in the menu hierarchy.

Special buttons



Apply



Drop



Left



Up



Down



Right



Inactive buttons are dimmed

i You can also use the 'Up' and 'Down' buttons to scroll through lists.

i You can also use the 'Left' and 'Right' buttons to cycle through values.

Navigation buttons



Back



Next



Back (Return)



Forward
(More)



Drop modifications
and Back(Drop &
Back)







Apply Modifications
and Next(Apply &
Next)




Confirming changes

You can confirm any changes you made on **User options** or a **Settings** screens by tapping **Apply** and leaving the screen with the **Back** button.

			
Drop &Back	Apply	Back	
Changes are still not saved		No changes or changes are saved	


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


Check boxes

 Autostart

Check boxes are displayed when you can decide to enable or disable an option (such as **Autostart**, see “9.4 User Options”) or when you can select one or more options from a set of alternatives (for example the **QC options alternatives: Forced QC, L2, L3**, see “8.1 Quality control options”)

Radio buttons

 English

 Deutsch

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

Text boxes

Text boxes are for alphanumeric data input. To edit a value in a text box, tap the input area. A cursor (|) appears in the input area when it is active.



INTERACTING WITH THE DEVICE

4.2.2 Entering data via the touchscreen

When the screen prompts you to enter information, a numeric or alphabetical keyboard appears on the screen.

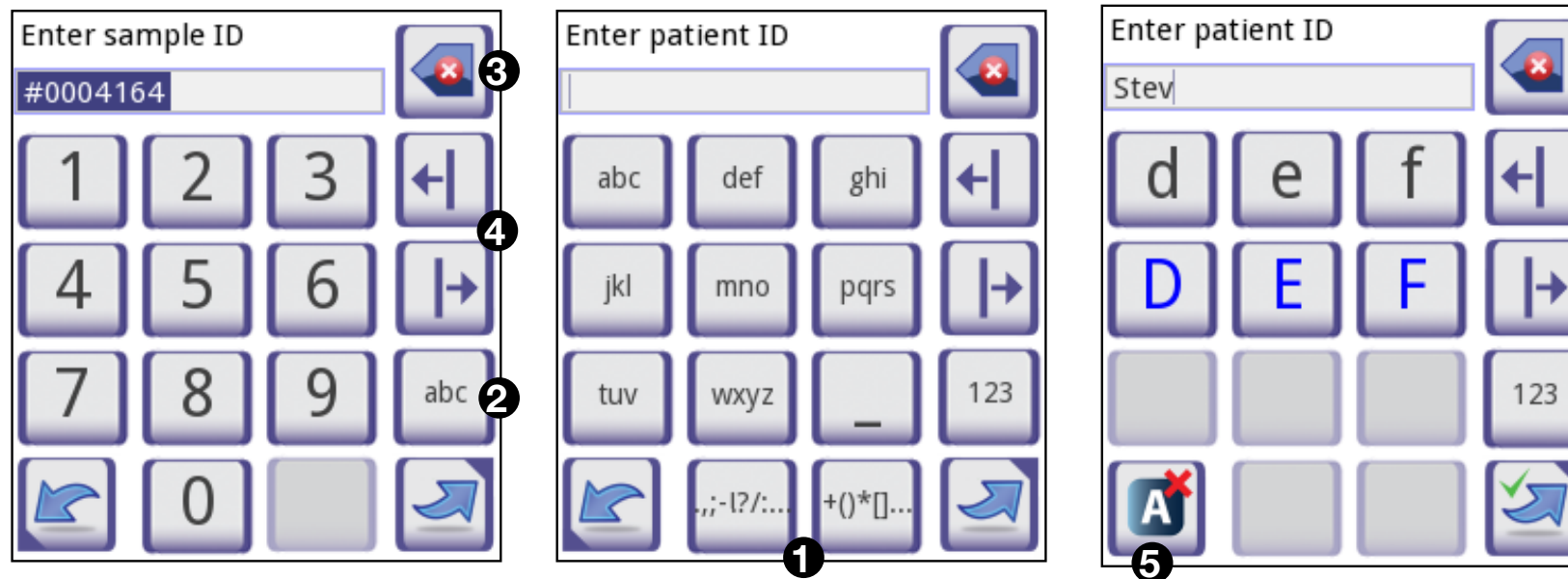


Figure 10: Numerical, lowercase, and uppercase input

Numbers can be entered easily. To enter an alphabetic character first tap the button representing the character group it belongs to, then select the specific lower case or upper case character you want. To enter special characters use the **.,;:-:~*...** or the **()[]** buttons (1) to go to the selection list. To switch between the numeric and alphabetic keyboard, use the **123** and the **abc** buttons respectively (2).

You can erase data with the backspace (3). You can move the cursor with the left and right buttons (4). To cancel the entry of a character from the current selection, tap the button marked 5. When you finish entering the information, tap **Apply** or **Apply&Next**.



INTERACTING WITH THE DEVICE

4.2.3 Entering data via a barcode reader or a keyboard

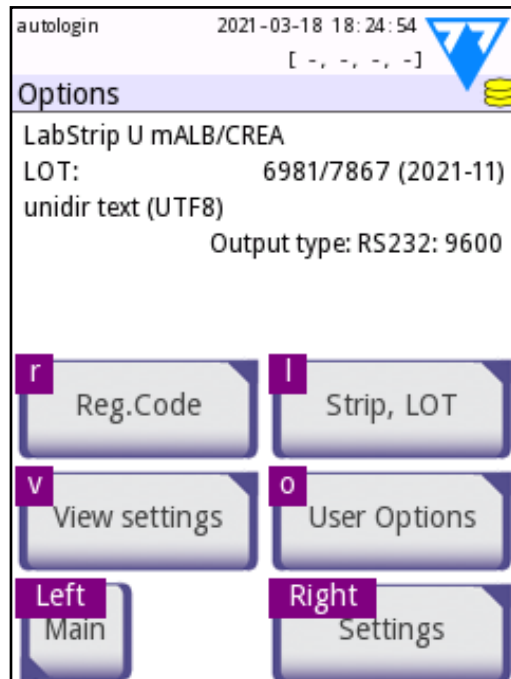


Figure 11:

The Options screen with keyboard shortcuts displayed above the onscreen buttons

Peripherals like a keyboard or a barcode reader can not only speed up the sample management workflow but improve data entry accuracy and reduce transcription errors.

Using a barcode reader:

Connect the barcode reader to the PS/2 or USB port at the rear of the device. Barcode readers can be used to enter the following information: sample ID, patient ID, QC LOT number, registration code, strip LOT number. No external power supply is necessary.

⚠ Make sure that the barcode reader you use supports ALT mode, and select this mode of operation before using it with the DocUReader 2 PRO device.

The following barcode reader models have been successfully tested with DocUReader 2 PRO:

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

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.



5 START-UP WIZARD

The first time you switch on a DocUReader 2 PRO device, you will enter a quick setup procedure. Here you will be able to customize the basic options of the device to suit your needs.

The **Start-Up Wizard** will allow you to specify the following settings:

- Language
- Date and time ("**10.3 Date, time**")
- System security ("**10.16.3 System security settings**")
- Change the 'supervisor' operator's password

① *Optional: depends on the security level you selected.*

- Test workflow ("**10.6 Measurement**")
- Printout ("**10.4 Printout**")
- Quality control ("**8.1 Quality control options**")
- Operators ("**10.16.2 Operator access levels overview**")

① *Optional: depends on the security level you selected.*

① *If you wish to skip the wizard and walk through it at a later time, tap **Skip** on the second screen.*

① *If you require further information about the settings, see "**1 Introduction**".*

At the end of the setup procedure, tap **Start** to exit the wizard.

You can review all settings on the **Options » View settings** screen. All settings, including connectivity (See **9.5**) can be modified on the **Options » Settings** screens.



6 TESTING

The analyzer can be set up to be as simple or sophisticated as you prefer. You may simply insert a dipped urinalysis strip into the analyzer and the result will be reported. By modifying the user options the measurements can be started, printed and transferred automatically.

Alternatively, you have the option to enter the Sample ID, Patient ID, and color, clarity of the specimen manually (See “**6.2 Test features and customization**”). The walkthrough for full testing is found in “**6.3 Full Test**”.

The analyzer can be operated in two different modes:

1. In normal mode, the system automatically waits for the strip to incubate for 1 minute before it reads the first test pad. This is the default mode and the throughput in this mode is approximately 50 strips per hour.
2. In fast mode, which can be selected at User Options, the test strip is measured directly after starting the test. In this case, it is up to the user to time the incubation period outside the analyzer (see “**6.2.1 Features: Autostart, -print, -transfer and fast mode**”).

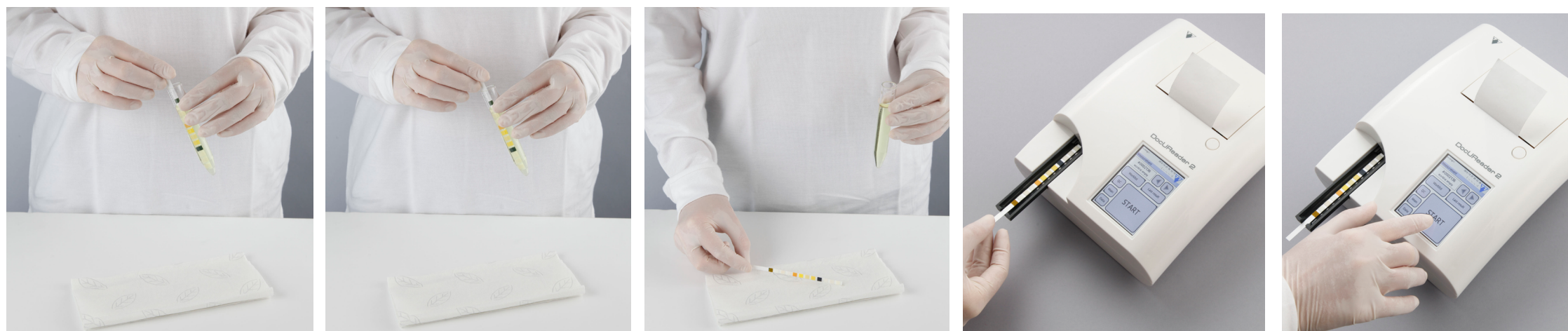
❗ If you require more information regarding use and storage of test strips, please refer to the strip’s instructions of use.

6.1 Quick Test

After switching on the instrument starts with the **Measurement** screen.

① *The Measurement screen can also be directly reached from the **Main** and **Database** screens*

The test strip tray has to be correctly loaded into the reader. Have the test strip, urine sample and paper towel ready too.



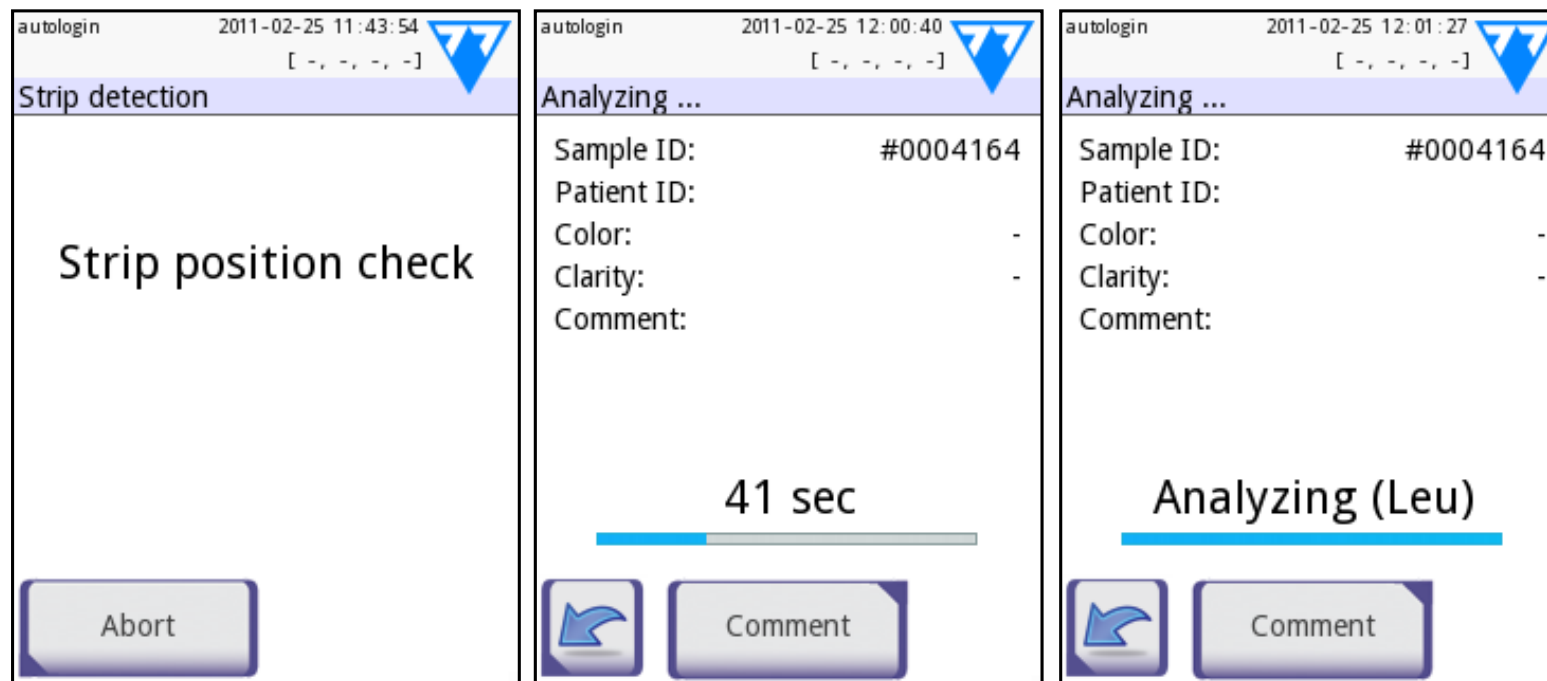
- 1** Dip the reagent strip into the urine sample, wetting all pads. Immediately remove the strip from the urine.
- 2** Drag the edge of the strip against the side of the sample container as you remove it.
- 3** Blot by touching the edge of the strip to a paper towel to remove excess urine.
- 4** Place the reagent strip in the channel of the table with the test pads facing up.
- 5** The instrument will automatically detect an applied strip. The measurement cycle will be started.

If the "Autostart" is deactivated, the measurement must be started using the **Start** button.

⚠ **Do not use damaged strips.**

⚠ **Do not push or pull the test strip tray.**

① *DocUReader 2 PRO will perform a sequence of checks (reference pad, strip detections (position of, slipped strip, dry strip, etc.) each time a test is run. See "6.2.3 Strip checking events" for more information.*



- 6 The strip position is checked before measurement.
- 7 A timer will count down the time remaining for analyzing the strip.
- 8 The analysis of the strip pads will begin.

⚠ To abort a measurement press the **Back** icon on the **Analyzing** screen and press **Stop/Drop** on the **Measurement** screen.

⚠ **Comment** can be also added during the countdown time.

After approximately 60 seconds the pad results will be displayed on the screen and the test strip tray is automatically moved out of the analyzer.

⚠ **The buttons remain inactive until the tray is fully moved out.**

- **If Autostart is ON:** The result screen will be displayed until you remove the test strip from the tray. Once the strip is removed, the display automatically returns to the **Measurement** screen.
- **If Autostart is OFF:** The result screen will be displayed for approximately 5 seconds –while displaying a circle animation–, then the display will return to the **Measurement** screen (if no error occurred during the readout). If you touch the display while the circle animation is displayed, the system will not automatically return back.



autologin 2012-01-25 07:43:04
[-, -, -, -]

Database » Result

Sample ID: #0000020
Date: 2012-01-25 07:40

Bil	neg
Ubg	2 mg/dl +
Ket	neg
Asc	neg
Glu	norm
Pro	neg
Ery	5-10 Ery/μl +
pH	5
Nit	neg
Leu	500 Leu/μl +++
SG	1.000

9 Results Page 1/2

autologin 2012-01-25 07:44:14
[-, -, -, -]

Database » Result

Sample ID: #0000020
Date: 2012-01-25 07:40

Color: straw-yellow
Clarity: slightly cloudy
patient ID:


LOT: 5783/6005 (2012-09)
Comment:

10 Results Page 2/2

Date: 2011-03-04 13:02
Sample ID: #0000008
Device S/N: UD2021999999




Bil	neg
Ubg	norm
Ket	neg
Asc	neg
Glu	norm
Pro	neg
Ery	neg
pH	5.5
Nit	neg
* Leu	25 Leu/μl +
SG	1.015

11 Printed results

The pad results are displayed on the first page. Positive findings are clearly marked with red text on the display. To view the remaining test results, touch the **Right**  icon on the screen.

The printout is light-sensitive and may turn yellow when exposed to light during storage. Test results which diverge from negative or normal values are flagged with an asterisk before the parameter concerned. The printout can be fully customized, see “10.4 Printout” for more details. For archiving purposes the printouts should be kept in a dark place (patient file) or as a photocopy.

Functions on the result screen

- By pressing the  **Delete** button the result can be dropped.
- By pressing the  **Printer** button the result can be printed.
- By pressing the  **Transfer** button the result can be transferred.
- To go back to the **Measurement**, press the **Meas.** button.

How to modify the result?

Results can be modified by pressing the **Edit** button on the second result page, before the record is printed or sent.



All fields can be modified except date and pad results, even if the particular field was not available during the acquisition.

Before performing the next measurement

From the test table, remove the used urinalysis strip and dispose of it according to your standard laboratory procedures. Wipe the table insert, if necessary.

6.2 Test features and customization

The testing process can be customized to the need of the laboratory. The measurement feature settings define what activities related to testing process (start) are automatically performed by the instrument. The measurement settings define the activities performed by the analyzer and the collected information.

6.2.1 Features: Autostart, -print, -transfer and fast mode

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

- **Autostart:** if enabled, measurement is automatically started (without further user interaction) if a strip is placed on the test strip tray. By using this feature the instrument can operate “touch-free” (if all the additional data fields are disabled). Default value: enabled.
- **Auto print:** if enabled, the analyzer automatically prints the report of each measurement. Default value: enabled.
- **Auto transfer:** if enabled the analyzer automatically transfers the result to the defined output (i.e. through the serial port to an LIS). Default value: disabled.

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

- **Fast mode** (serial reading): if enabled, the test strip is measured directly after **Measure** is pressed on the **Measurement** screen (note: in fast mode the large start button is renamed to **Measure** and the background is changed to orange). In this case, it is up to the user to time the incubation period outside the analyzer. When working in **Fast Mode**, ensure that you have a foolproof system for matching sequence numbers to samples.

*ⓘ The status of fast mode cannot be saved. After logout or system restart the analyzer always starts in **Normal** mode.*

⚠ When performing serial measurements in Fast Mode, allow the strips to react for approximately 60 seconds before inserting them in the analyzer and pressing MEASURE. False-low or false-negative results may be obtained for some parameters if the reaction time is too short. Likewise, false-high results may be obtained for some parameters if the incubation time outside the analyzer is too long.

The option to enable **Fast mode** only appears on the **User options** screen, if this option is enabled on the **Settings»Measurement** screen.



6.2.2 Customization of testing

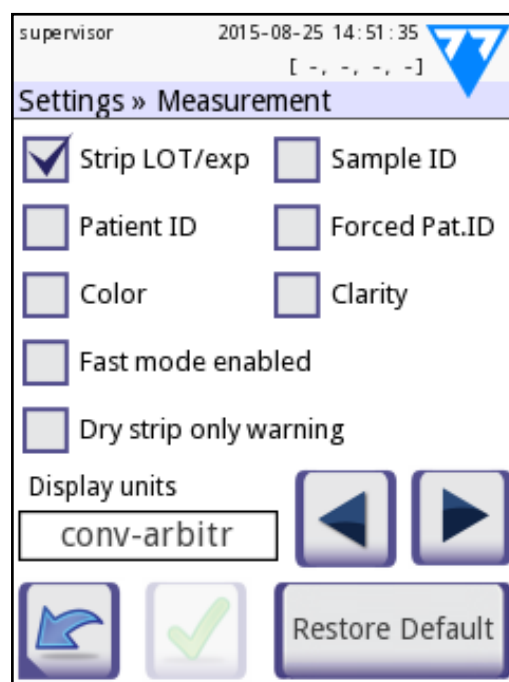


Figure 12: Settings » Measurements

On the **Settings»Measurement** screen you can customize which fields are enabled during acquisition, to disable fast mode at the system level or to allow analysis of (partially) dry strips and modify the settings. You can set the display units here as well.

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

- **Strip LOT/exp:** If you select this box, the system will prompt you to enter the strip LOT number you currently use with the expiry date at every single measurement. The system stores the information and at the next measurement it is enough to confirm the displayed data.
- **Sample ID:** By default the system assigns each reading with a consecutive sequence number of maximum seven (7) digits. If you select this box, the system will prompt you to enter an ID for the sample that you are analyzing.
- **Patient ID:** If you select this box, the system will prompt you to enter an ID for the patient whose urine sample you are analyzing. The system does not assign a default patient ID.
- **Forced Patient ID:** If you select this box, the system will require you to enter an ID for the patient whose urine sample you are analyzing. The measurement will not continue, if the Patient ID textbox is not filled in.
- **Color:** If enabled, you can set the visually observed color of the sample during the test.
- **Clarity:** If enabled, you can set the visually observed clarity of the sample during the test.
- **Fast mode enabled:** If you select this box, the Fast mode button becomes available on the User Options screen (see “9.4 User Options”).
- **Dry strip only warning:** If you select this box, the system will save the full analysis results of a dry strip or partially dry in the database with a warning message. If you leave it unchecked, the system will only save an error message (E261) and no results for dry or partially dry strips.
- **Display units:** You can change the units the system displays the results in. Available options: conv-arbitr, SI-arbitr, conv, SI, and arbitr.

Use   to scroll between the options



6.2.3 Strip checking events

Errors in sample handling and testing procedure may lead to false results. In order to further improve the diagnostic decision making process advanced strip recognition features were introduced in DocUReader 2 PRO.

The outcome of these features is categorized into three groups:

- R1. Measurement is not started
- R2. Result is saved with a warning message
- R3. Result is saved with an error code

The analyzer automatically recognizes the following events during testing:

Feature	Outcome	Time of action
slipped test strip	R3	after third failed check
(partially) dry strip	R2/R3	after testing
upside-down strip	R3	before incubation period
background light too strong	R2/R3	during measurement

If the result is saved with a message, the pad values are listed and the code and the description of the warning is inserted into a new comment field of the result. To search for results with a warning, use the “with comment” extra filter in the database (see “7.3 Setting up filters to find specific results”).

i Please note that this filter will also list results with comments inserted by the user.

If the result is saved with an error, only the error code is visible. To search for results with an error code, use the “false meas.” extra filter in the database.

Slipped strip

The front of the test strip has to be at the leading edge of the test strip tray. Systems check for misposition:

1. Before the incubation time: warning window is displayed with two choices: 1. drop testing and restart with new strip; 2. reposition strip and repeat measurement. Choice is available during the incubation time.
2. Before the measurement: warning window is displayed with two choices, but repeating is limited for 10 seconds. In case of successful repositioning the result will be flagged as ‘Overincubate’ (R2). After 10 seconds only ‘cancel testing’ option is available.
3. After the measurement (R3): result is stored with an error code (‘Measurement error: strip position error’)

Partially dry strip

The evaluation takes place after the measurement based on the reflectance data of the last pad. Based on the configuration settings (see “6.2.2 Customization of testing”) the result is saved either with a flag (R2) or an error code (R3).

6.3 Full Test

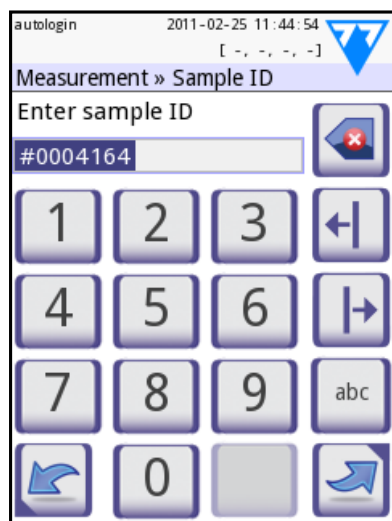
The description of the required preparations and the testing process can be found at “6.1 Quick Test”.

This section only provides additional information on the data input process presuming that all additional fields (sample ID, patient ID, color and clarity) are enabled.

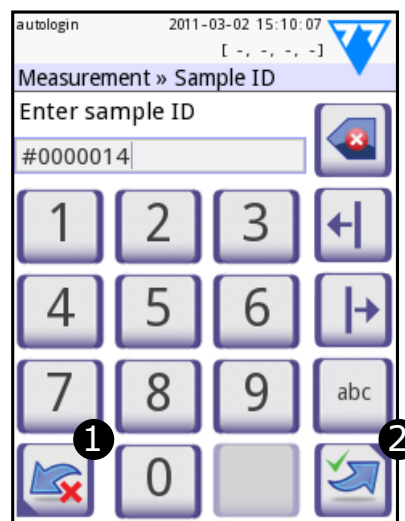
The data input is started after strip position check. The first screen appears when the test strip tray is moved back to the home position.

The sequence of the data input is Sample ID ⇒ Patient ID ⇒ Color ⇒ Clarity.

If a field is disabled at **Settings » Measurement**, the input screen won't appear for it



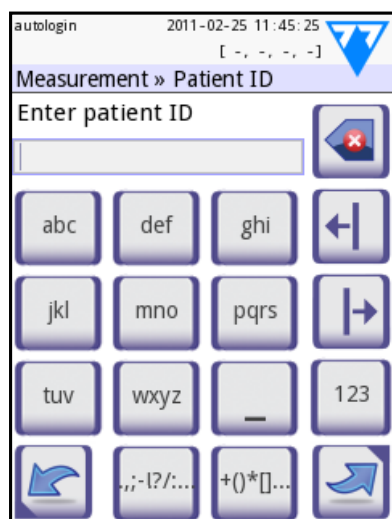
Sample ID: unique sampleID is assigned by default. To change it, use the onscreen keyboard, the attached keyboard or the barcode reader. Maximum 14 characters. Sample ID must not be empty.



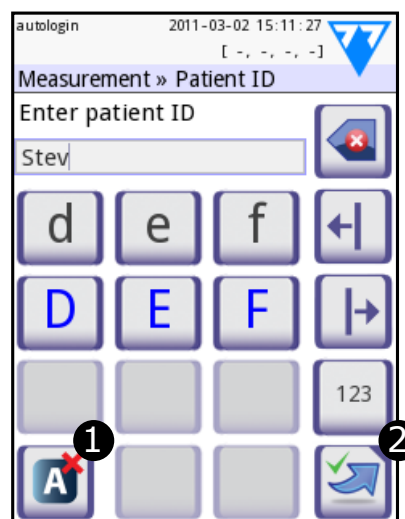
Sample ID: Automatic ID was changed, you can either **1** cancel the change (press **Drop&Back**) or **2** apply it and proceed to the next screen (press **Apply&Next**).

i Reading a sample ID or patient ID with barcode will automatically take you to the next screen.

i If you require further instruction regarding barcode reader or keyboard usage see “4.2.3 Entering data via a barcode reader or a keyboard”.



Patient ID: Use the onscreen keyboard, the attached keyboard or the barcode reader to enter the patient ID. The Patient ID field can be left empty. In this case press Next button at the bottom right corner to move to next screen. Maximum 32 characters.

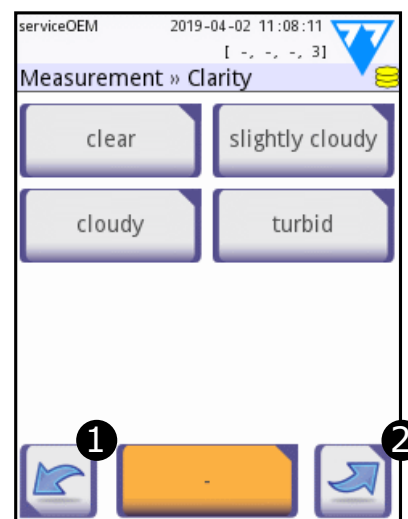


Patient ID: Touch **2** Apply&Next, when you have finished entering the patient ID and proceed to the next screen. To select a new character, press **1**. To abort and go back to the Sample ID screen, press Drop&Back¹.

¹The Drop&Back icon does not appear on the sample screen because the character input is active.



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



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

① You can select only one color and clarity type for a urine sample.

After all data have been entered the next screen displayed will either be:

- Analyzing — if the strip is still being analyzed
- Result — if analyzing the strip has been completed

It is not required to input all data during the incubation time, the system will analyze the strip in the background and move out the test strip tray.

Once you have finished the data input, the **Result** screen will appear.

If Autostart is ON:

The result screen will be displayed until you remove the test strip from the tray. Once the strip is removed, the display automatically returns to the **Measurement** screen.

If Autostart is OFF:

The result screen will be displayed for approximately 5 seconds –while displaying a circle animation– then the display will return to the **Measurement** screen (if no error occurred during the readout). If you touch the display while the circle animation is displayed, the system will not automatically return back.



6.4 Worklist

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. The worklist can be generated manually through the touchscreen, or a connected external keyboard or barcode reader, or automatically by downloading the worklist items from the LIS.



Figure 13: *The Worklist screen with the screen elements labelled*

- 1 Worklist items
- 2 Delete active item
- 3 Delete all items
- 4 Download worklist from LIS
- 5 Search for sample ID
- 6 Move up by one record in the list
- 7 Modify item
- 8 Move down by one record in the list
- 9 Add new item
- 10 Action: select actual item
- 11 Print worklist
- 12 Return to Measurement menu

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



6.4.1 Creating worklist

① If the worklist is empty, only the  and the  buttons are active. The other buttons are active if the worklist contains at least 2 items.

1. Tap the **Main** button on the **Measurement** menu then **Worklist** button on the appearing **Main Menu** screen.
2. Use the **Add new item** button to add a new entry to the list.
3. Set the sample and patient ID and select the reagent strip:
 - **Reagent strip:** It is possible to add multiple reagent strip types for the same sample and patient. They will be listed separately in the Worklist.
 - **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.
Once you have modified the default Sample ID, you can either cancel the change by tapping **Drop&Back** or store the modified Sample ID with the record by tapping **Apply&Next**.

① The system does not allow you to leave the Sample ID text box empty.

- **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**.

① By using 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.

4. When you return the **Measurement** screen with the **Back** button, the sample ID of the first worklist item will be shown in the list window.

6.4.2 Worklist from LIS

1. Tap the **Main** button on the **Measurement** menu then **Worklist** button on the appearing **Main Menu** screen.
2. Use the **Download worklist from LIS** button to download worklist from LIS.

6.4.3 Worklist management

6.4.3.1 Modifying and deleting worklist items

Worklist items can be modified by moving the cursor bar over them using the **Up** and **Down** arrow buttons and tapping **Modify item** button. The appearing input screens let operators making changes.

If a worklist item must be deleted, tap **Delete active item** button when the cursor bar is over it. Tapping **Delete all items** button erases every item on the worklist.



6.4.3.2 Changing the worklist order

New items always added to the end of the list notwithstanding the possible numeric order of the sample IDs. The sequence can be changed with one item at a time.

1. First go to worklist. Using the **Up** and **Down** arrow buttons place the cursor bar over the item you would like to move.
2. Select item by tapping **Select actual item** button. The button turns orange indicating that the selection has been made and you can move the item.
3. Using the **Up** and **Down** arrow buttons move the item on the list notwithstanding the possible numeric order.

ⓘ *If measurement is already started, change the sample ID during incubation time on the Measurement»in progress screen. To go through the sample IDs, use the Right and Left arrow buttons next to Sample textbox.*

6.4.3.3 Working outside worklist

When there are items on the worklist, the analyzer recording measurement results using the list, starting with the first sample ID and going down the list. If there is an urgently needed results and items are on the worklist, DocUReader 2 PRO still able to evaluate the new sample. Simply 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.



7 RECALLING RESULTS

The DocUReader 2 PRO device can store up to 3000 measurement records. Every result is automatically saved after the analysis in an indexed database. Using the database, you can search, view, and print analysis records, or transfer them to an external device.

① *By default, the analyzer prompts you to free up memory (erase data) 30 records before reaching maximum database capacity. However, you can modify database settings and instruct the system to use a circular memory.*

① *For more information on database settings see “10.8 Database management”.*

You can access the database

- from the **Measurement** screen by tapping **Data**
- from the **Main** screen by tapping **Database**.



7.1 List view

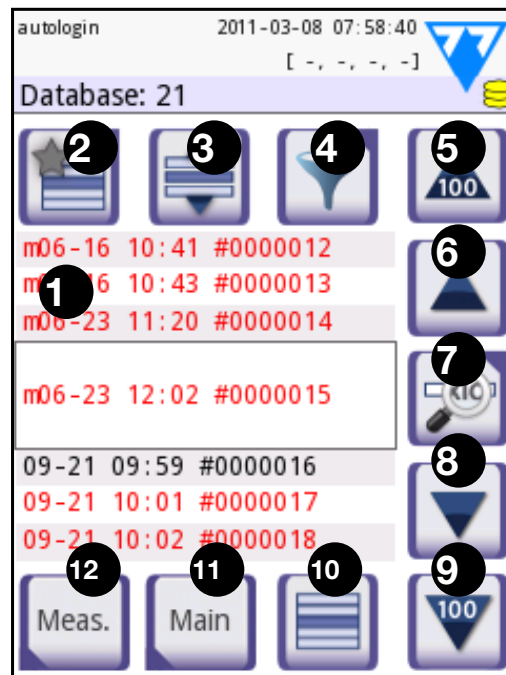


Figure 14: Database - List view

Key to the screen

1. Results list
2. Actions with selected records (**Database** » **Selected** screen)
3. Tap this button to make continuous selections using the up and down buttons on either side of a previously selected record. (This feature is similar to pressing down the 'Shift' key while clicking with the left mouse-key on a PC. See "**Multiple selection 219**")
4. Set up filters to find specific records
5. Move the row cursor up by 100 records in the list
6. Move the row cursor up by 1 record in the list
7. View item (in the case of failed results, their relevant error message will be displayed)
8. Move the row cursor down by 1 record in the list
9. Move the row cursor down by 100 records in the list
10. Select current record
11. Go to the **Main** screen
12. Go to the **Measurement** screen

The records have the following color coding:

Black text: Negative result


Red text: Positive result

Ochre text: Failed result

❗ If you access the database from the **Measurement** screen, an automatic predefined filtering is applied and only the results measured on the current date are displayed. If you access the database from the **Main** screen, no automatic filtering is activated.

❗ The test results belong to LabStrip U mALB/CREA reagent strip is marked with 'm'.

To view details of a urine test result, tap View (number 7 in the key). The first page of the patient's result will be displayed on the screen.

Tap  to see the second page of the selected record.



7.2 Result view

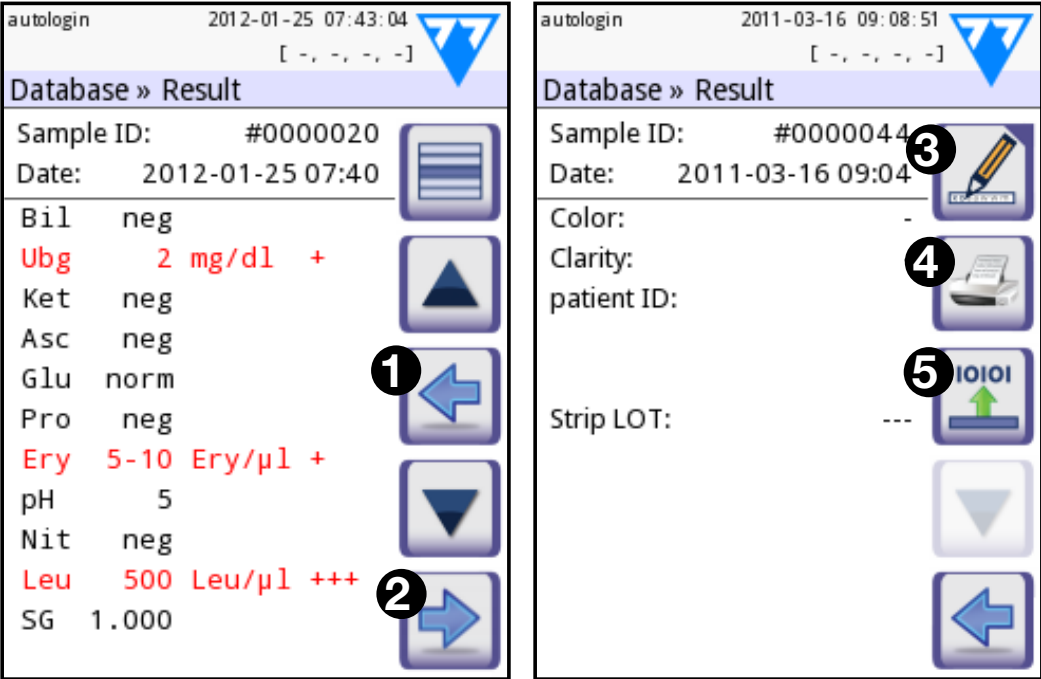


Figure 15: The Results screen page 1 and 2

The results for the reagent pads are listed on the first page. Use the up and down arrows to navigate the results. Tap **1 Return** to go back to list view. To view the second page of the results, tap the **2 More** button. On the second page the action buttons are displayed for the given record: **3 Edit**, **4 Print**, **5 Send for output**.

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



7.3 Setting up filters to find specific results

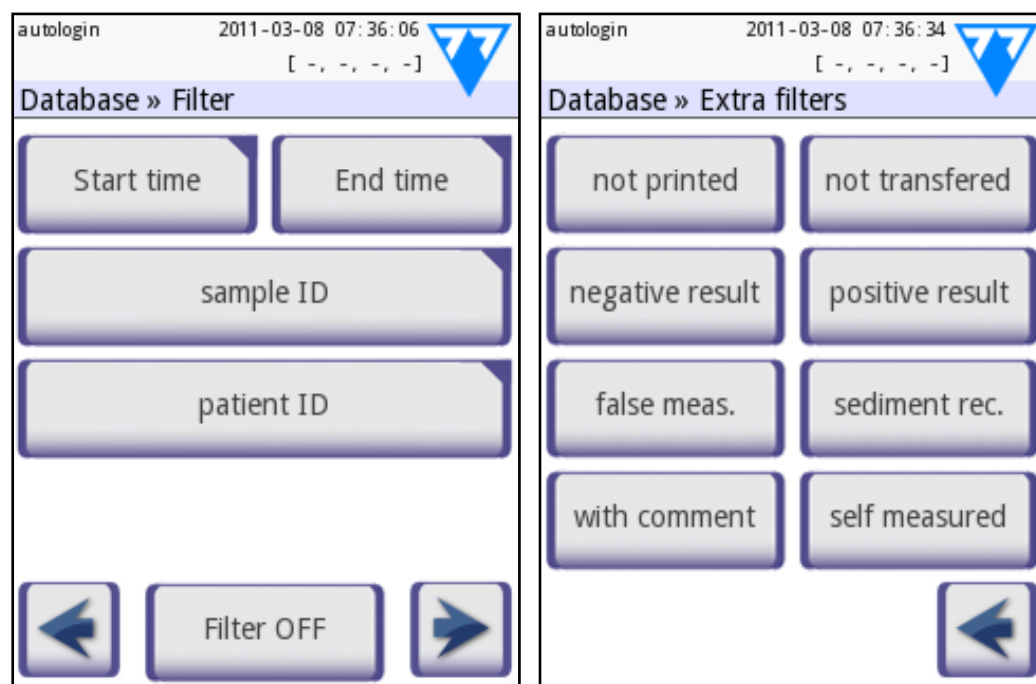


Figure 16: The Database » Filter screens

To narrow down the list of results DocUReader 2 PRO features a sophisticated filtering engine. You can set the following parameters as filtering criteria:

- Date and Time
- Sample ID
- Patient ID
- Status:
 - not printed
 - not transferred
- Additional information:
 - negative
 - positive
 - sediment recommendation
 - false (an error message is returned instead of measurement results)
 - with comment (including warning messages)
 - self measured (records that the operator setting up the filter created).

Tap the corresponding button to activate a filter.

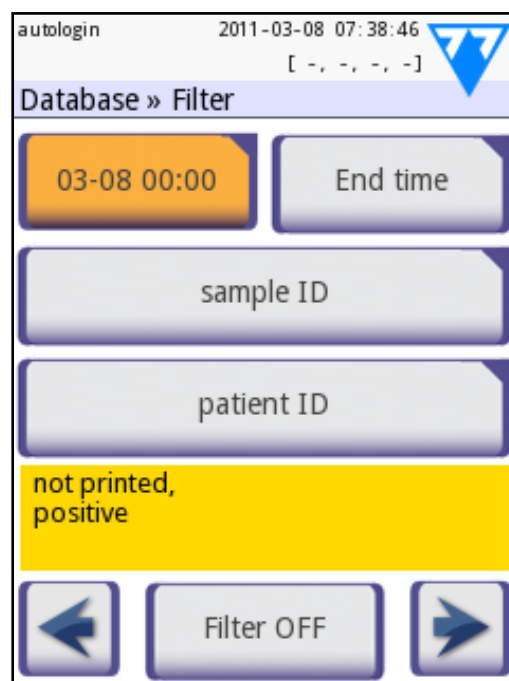


Figure 17: Examples of activated filters

The background of active filter buttons changes to orange. Active filters from the second page appear above the navigation buttons on the first page of the **Filter** screen.





Tap **Filter OFF** to switch off filtering.

Tap **Return** to return to the list of results.



7.3.1 Filtering based on date or time

When setting up filters based on a time period, use the **Filter** » **Start time** and **Filter** » **End time** screens to define the start and the end of the time frame you want to filter, respectively.

By default, the **Day** field is active. Use   to modify the value of the selected field. Use   to move the row cursor.

Tap **Today** to set the beginning or end of the current day.

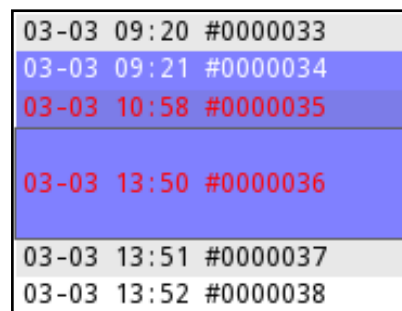
Tap **Switch on** to set the moment the device was last switched on as the start or end of the filtering period.

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

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 filters overview screen.

7.4 Selecting results



03-03	09:20	#0000033
03-03	09:21	#0000034
03-03	10:58	#0000035
03-03	13:50	#0000036
03-03	13:51	#0000037
03-03	13:52	#0000038

Selected records are indicated


- by a blue record entry background in list view
- by the blue Sample ID row background in result view.

In list view, the number of selected results is displayed in parentheses in the navigation bar.



Figure 18: Selected results in a cropped list view

7.4.1 Types of selection

- **Single selection**

Tap  to select/deselect a single record in list view.

- **Multiple selection**

Tap  to activate the 'single-tap continuous selection' feature. When this button is activated  (indicated by an orange background), you can select multiple records on either side (below or above) of a previously selected record. (This feature is similar to pressing down the 'Shift' key while clicking with the left mouse-key on a PC.)

- **Select all**

Tap **Select all** on the **Database** » **Selected** screen to select every record.




- **Invert selection**

Tap **Invert selection** on the **Database » Selected** screen to invert the current selection (deselect currently selected records and select currently deselected records).

- **Clear selection**

Tap **Remove selection** on the **Database » Selected** screen to clear all previous selections.

7.5 Actions with selected items

 *If no record is selected, the action buttons are dimmed.*

- **Delete**

Tap **Delete** on the **Database » Selected** screen to delete selected record or records. A dialog box will appear to confirm the action to prevent accidental loss of data.

- **Print**

Tap **Print** on the **Database » Selected** screen to print the selected record or records.

- **Send for output**

Tap **Output** on the **Database » Selected** screen to send the selected record or records.



8 QUALITY CONTROL TESTING

The performance of the system (analyzer and reagent test strips) should be monitored regularly to that 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, LabStrip U mALB/CREA test strips

i Several commercial controls are available. Control solutions may vary in the number of levels or components, the necessity for reconstitution or readiness for use, or the type and volume of container. 77 Elektronika Kft. recommends Quantimetrix Corporation Dipstick controls as these control solutions provide the necessary color development with LabStrip U11 Plus strips. For quality control of LabStrip U mALB/CREA 77 Elektronika recommends using the CombiScreen Dip Check (Analyticon Biotechnologies AG), the CombiScreen Drop Check (Analyticon Biotechnologies AG) and Microbumin Microalbumin Control / Level 1&2 (Quantimetrix Inc.) Other manufacturers' controls may provide abnormal results due to non-specific colorations of the test pads.

⚠ Verify the performance of the reader with the check strip after every accident (drops, spills, splashes), even if visible damage was not done.

The supplied grey check strip can be used only as a mechanism to confirm the functionality of the analyzer. This is the only QC functionality offered for base model DocUReader 2 PRO devices.

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

- monthly on each previously opened vial
- whenever a new vial of test strips is opened,
- whenever test results are in doubt,
- when new operators are trained on the system.

The urine control solutions are analyzed using a regular urine test strip as if it were a regular patient sample.

Proper quality control is a three-phase process:

1. Configuring the system: specifying urine control levels, setting upforced QC, and QC lockout on the **Options » Settings » QC Options** screen. See "8.1 Quality control options".
2. Setting the urine control LOT number and the acceptance limits. See "8.1.1 Editing QC LOT Information".
3. Performing QC testing at regular intervals. See "8.2 QC Testing".



8.1 Quality control options





Figure 19: The QC options screen

You can configure quality control settings for the device on the **Options » Settings » QC Options** screen

The screen offers the following options:

- enabling/disabling QC lockout
- setting the QC lockout interval in days
- specifying the type of QC lockout (warning or forced)
- specifying the type of control solution used
- editing the QC solutions' LOT data
- deleting the LOT data and acceptance limits set for control solutions not in use (**Cleanup**).

Enabling QC Lockout will make sure that a quality check using the control solutions is performed regularly at the intervals you determine. If QC lockout is enabled, the device will become nonoperational after the time period that is set here is over, unless you perform a quality check.

To enable QC lockout and set the interval before the next QC in days, tap   or tap inside the grey text box and use the numeric input screen.

① *When you apply changes to the QC lockout period, a pop-up window appears with the modified lockout time*

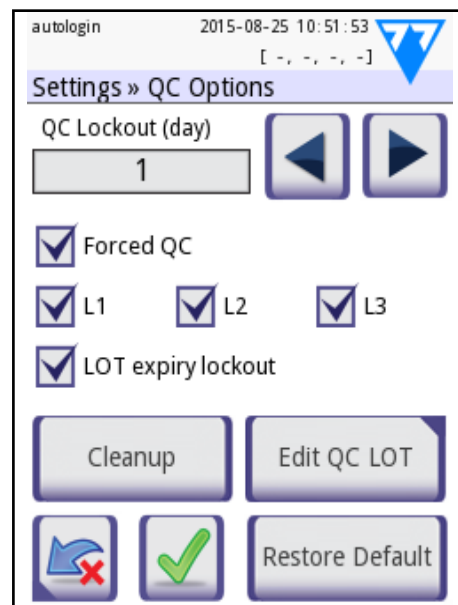


Figure 20: Forced L2 Quality control

You can choose between two lockout modes by checking or unchecking the Forced QC check box.

- Warning ☐ Forced QC
When the QC lockout period is over, the status bar background changes orange and a warning message ("W33") is displayed.
- Forced ☒ Forced QC
In this mode, when the QC lockout period is over, the status bar background changes to red and an error message ("E89") is displayed. With forced QC lockout, the measurement function is disabled until a successful QC check is performed.

The QC check can be set for

- L1: negativ/normal
- L2: positive/abnormal,
- L3: high positive/abnormal

control solution checks, either individually or all together by ticking their checkbox.

① If user security is set high on the system (See "10.16.5 Security settings overview"), normal users will not be able to modify the QC settings, so the QC policy determined by the system administrator will be enforced. For example, only operators with Administrator or higher security level can override the QC lockout and perform a measurement without first doing a quality check.

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.



8.1.1 Editing QC LOT Information

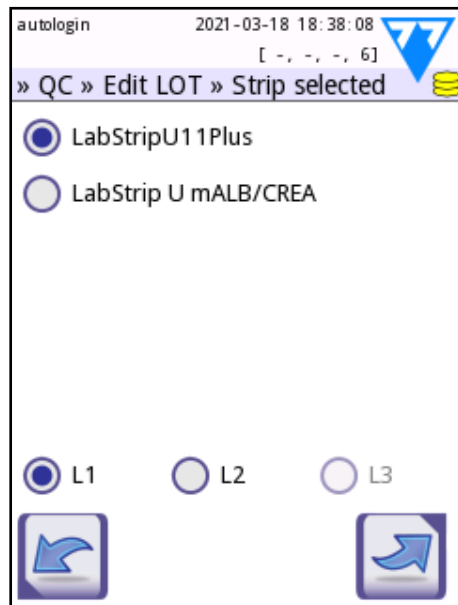




Figure 21: Select QC level

⚠ The QC evaluation relies on manually entered data. Double-check the values before activating them.

1. Tap **Edit QC LOT** on the **QC options** screen to enter the QC Urine Control solution LOT numbers and the acceptance limits for the solutions.
2. Select the type of control solution (L1, L2, L3) you will be using, and tap  **Next**.
3. Enter the solution's LOT code then tap  **Next**. If a LOT code is already stored for the current type of control solution, this will appear in the input field. The input field is otherwise empty.

ⓘ You can also enter the expiry date for the QC solution lot. Separate the expiry date from the lot number by putting it in parentheses. Use two digits for both the year and the month data, and separate the year and the month with a slash (/), a hyphen (-), a dot (.), or an underscore (_).

4. Consult your control solution's package insert and enter the acceptance limits for the type of control solution selected in step 2.

8.1.2 Setting QC solution acceptance limits

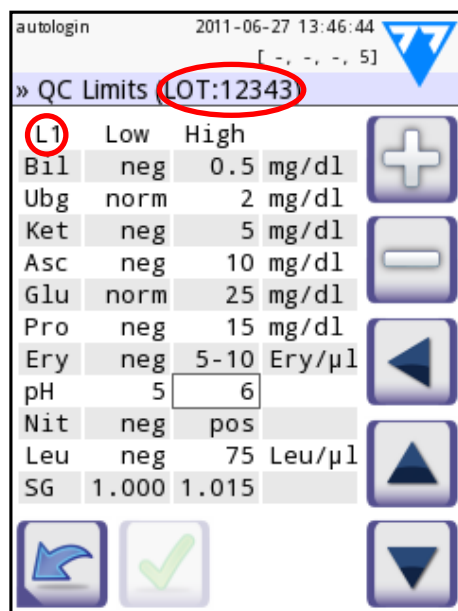





Figure 22: The QC limits screen

The columns of the table are, from left to right: parameter, lower limit, higher limit, unit.

A cursor box indicates which cell is selected (In **Figure 22** this is the High pH limit cell.)

1. Use the arrows to navigate the cells and the plus and minus   buttons to increase or decrease the values.
2. When you have finished, tap **OK**  to store the values. You will be returned to the **QC options** screen.
3. Repeat the previous steps for each type of control solution.

ⓘ QC limit definition is not possible for ACR and ACR interpretation.



8.2 QC Testing

The QC measurement buttons are color coded:

- **If QC lockout is disabled,**
 - grey means no measurement is stored,
 - green means a valid measurement was made while in the **QC Measurement** menu, and
 - red means an invalid measurement was made while in the **QC Measurement** menu.
- **If QC lockout is enabled,**
 - grey means no measurement is stored,
 - green means a valid measurement was made within the time limit, and
 - red means an invalid measurement was made within the time limit.


① *The strip type of the given QC measurement is marked in the header.*

1. Go to the **Measurement » QC** or the **Main » QC Meas** screen.

2. Apply the negative (Low) or the positive (High) solution to the test strip following the instructions in the control solution and the test strip package inserts.

① *The solution button text is changed to „Stip LOT” and disabled on QC Measure screen when LOT expiry is enabled but no valid solution LOT is registered in the instrument.*

① *For quality control of LabStrip U11 Plus, 77 Elektronika recommends using the Dipper, the Dropper or the Dip&Spin control solution kits from Quantimetrix Inc. For quality control of LabStrip U mALB/CREA 77 Elektronika recommends using the CombiScreen Dip Check (Analyticon Biotechnologies AG), the CombiScreen Drop Check (Analyticon Biotechnologies AG) and Microbumin Microalbumin Control / Level 1&2 (Quantimetrix Inc.) Control solutions of other manufacturers may provide abnormal results because of non-specific colorations of the test pads.*

3. Place the strip on the tray and tap **...Solution 1** for a negative control solution, **...Solution 2** for a positive control solution, or **...Solution 3** for a 'High positive' control solution, if you are using a three-level control solution kit. If you have previously entered a LOT number and acceptance limits for the given solution type on the **QC Options** screen, the system will display this LOT number on the LOT input screen. If the LOT number is correct, tap Next .

⚠ If you enter a new LOT code on the numeric input screen, you will also have to set new acceptance levels after tapping Next.

① *If the quality check is successful, the system displays 'PASSED' next to the QC result ID. The button background for passed QC tests changes to green. If the QC measurement has failed, red FAILED text is displayed after the QC result Id. The button background for failed QC tests changes to red.*

4. Repeat the previous steps for each control solution.

5. After all required solution levels have been successfully measured (that is, every **Start measure...** button on the **QC Measurement** screen turned green), the analyzer is released for testing until the lockout time limit is reached once again. A pop-up window appears with the modified lockout time limit. The remaining lockout time and the date is displayed in the information windows of the **Main** screen.

① *The maximum negative value that can be displayed is -90. If you see this value, either more than 90 days have passed since reaching the limit, or a successful QC has never been performed.*



8.3 Recalling QC results


① See “7 Recalling Results” for detailed information on how to recall and view results from system databases. Only information specific to the quality check database is discussed in this section.

All quality check measurements are stored in the QC memory, a database separate from the memory used for urine test results. The DocUReader 2 device can store 1000 quality check results.

In list view, results that have passed the quality check appear in black; failed results appear in red.

On the **QC Result** screen ‘PASSED’ is displayed next to passed QC result IDs, while ‘FAILED’ in red is displayed next to failed ones.

In case of failed QC solution results, the out-of-range pad results also appear in red.

Tap **Forward**  to move to the second page of the QC Result screen, which lists the active QC limits for each parameter.

① The QC results belong to LabStrip U mALB/CREA reagent strip is marked with ‘m’.



9 THE OPTIONS MENU

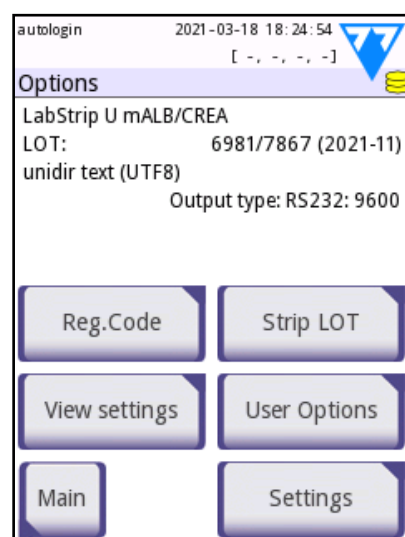


Figure 23:

The Options screen

The **Options** screen displays the following information:

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

You can access the following options from this screen:

- Registration Code,
- Strip LOT,
- View Settings,
- User Options (auto features; fast mode; sound; LCD brightness),
- Instrument Settings (See “10 Instrument Settings”).

9.1 Registration Code

The system uses the registration code to precisely control the analysis process. The following strip-related information is incorporated in the registration code:

- the expiry date of the current LOT of test strips
- calibration information for the current test strip LOT

i *The strip manufacturer may or may not enable sensitivity adjustments for the individual test strip pads.*

- the number of test strip measurements still available with the currently registered LOT.

⚠ Calibration is required for every test strip vial that you open to obtain correct results.

When you open a new shipment or vial of test strips, find the registration/calibration card in the package. The unique registration code is attached to the registration card and it is valid for one (1), ten (10), or twenty (20) vials.

To enter the numeric registration code on the card tap the **New Registration Code** button. You can enter the 15-digit code manually via the touchscreen, via an external keyboard connected to the device, or automatically, using a barcode reader. After a successful registration the available tests counter is reset to the number defined by the new registration code.

i *If there are available test strip measurements remaining from the previous registration code when you enter a new one, these will not be lost. You can resume using a registration code that you entered previously by re-entering it.*



9.2 Strip LOT




Tap the **Strip LOT** button on the **Options** screen to set the LOT information of the test strips. You can also set the expiry date for the LOT that you enter.

You can use the following special characters together with numbers: hyphen '-', period (full stop) '.', forward slash '/', space '_' and parentheses '(' ')'.

The LOT code and the expiry date data are stored with every measurement until you manually change them.

ⓘ The software does not check LOT code and expiry date entries. Because the registration code does not include the strip LOT code, the software cannot check whether the LOT code is correct. It is recommended that you double-check the code that you enter to prevent errors.

9.3 View Settings

Tap **View settings** to review every currently active setting including user-specified options. Use the   buttons to scroll through the settings. You can print the list of active settings by tapping the  button.

9.4 User Options

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

- **Autostart:** If you check this box, measurement starts automatically whenever you place a test strip on the test strip tray. If automatic printing and automatic transfer is also enabled, this option allows 'touch-free' operation. The box is checked by default.
- **Auto print:** If you check this box, the device automatically prints the report for each measurement. The box is checked by default.
- **Auto transfer:** If you check this box, the device automatically transfers the result to the defined output (See "**10.5 Output (Connectivity: Transfer/Export)**" for output configuration). The box is unchecked by default.

Every operator can access the user options. The system stores the user options for each operator separately.

- **Fast mode** (serial reading): If fast mode is enabled on the **Settings » Measurement** screen (See "**10.6 Measurement**"), the **Fast mode** button becomes available on this screen. If the box is checked, the test strip is measured directly after you tap **Measure** on the **Measurement** screen.

*ⓘ In fast mode the large **Start** button on the **Measurement** screen is renamed **Measure** and the background changes to orange.*

⚠ When performing serial measurements in Fast Mode, allow the strips to react for approximately 60 seconds before you insert them in the device and tap MEASURE. A too short reaction time can cause False-low or false-negative results. Similarly, a too long incubation time can cause false-high results.

ⓘ Enabling fast mode is valid for only a single measurement session. After you log out or when the system restarts, the device will start up in Normal mode.

- **Sound:** If you check this box, the device confirms successful tapping events with a short clicking sound.
- **LCD brightness:** Use the left and right buttons to change the brightness of the LCD display or tap the text box to set the LCD brightness value with the numeric keyboard.



- **Change passw.:** The active operator can change the password by tapping the **Change passw.** button. The system prompts the user for the current password, and twice for the new password. The system will then confirm the new password.

① *The **Change passw.** button appears only if an operator with a password is logged in to the system. An 'autologin' operator will not see this button.*

⚠ **The minimum password length is three (3) characters.**



10 INSTRUMENT SETTINGS

The DocUReader 2 PRO device allows you to change settings to suit the specific workplace requirements. You can modify the system settings on the **Main » Options » Settings** screen.

ⓘ The list of available settings may vary according to operator access level.







Figure 24: The Settings screen page 1 and 2

ⓘ Use the back and forward arrows to navigate between the settings pages.

- **Confirming changes**

Tap **Apply**, then leave the screen with **Back** to confirm your changes on the **User options** or a **Settings** screen first

No changes or changes are saved	 
Changes not yet saved	 

Tap **Drop & Back** before applying changes to cancel them.



- **Restoring default values**

There is a button on every settings subscreen (named **Restore Default** or **DEF.**) which can be used to restore the default value or values for the given screen.

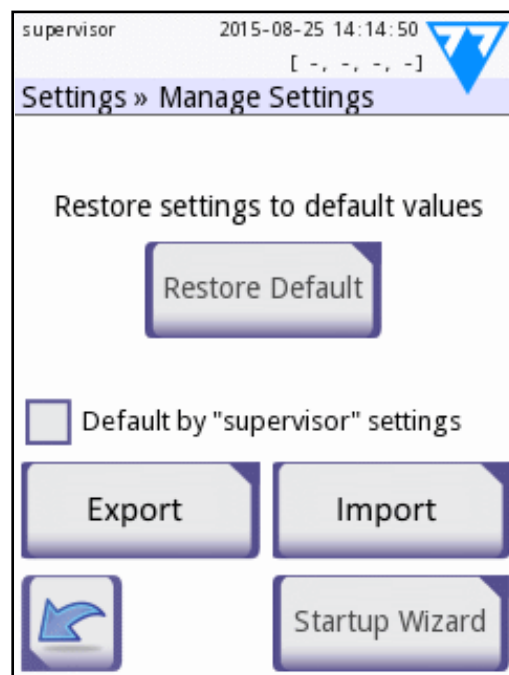
10.1 Manage settings

10.1.1 Default settings

If you check the **Default by “supervisor” settings** check box on the **Settings » Manage Settings** screen, the **Restore Default** button on the same screen reverts system-level settings to those specified by the ‘Supervisor’-level user,

❗ *The settings cannot be restored at the system level while printing or data transfer is in progress.*

10.1.2 Exporting and importing settings



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

Figure 25: The Settings » Manage Settings screen

10.2 Language

To change the operating language select the desired language from the list and tap **Apply**.

❗ *If the translation of screen elements is only partially completed in the language you selected, the untranslated screen texts will appear in English.*



10.3 Date, time

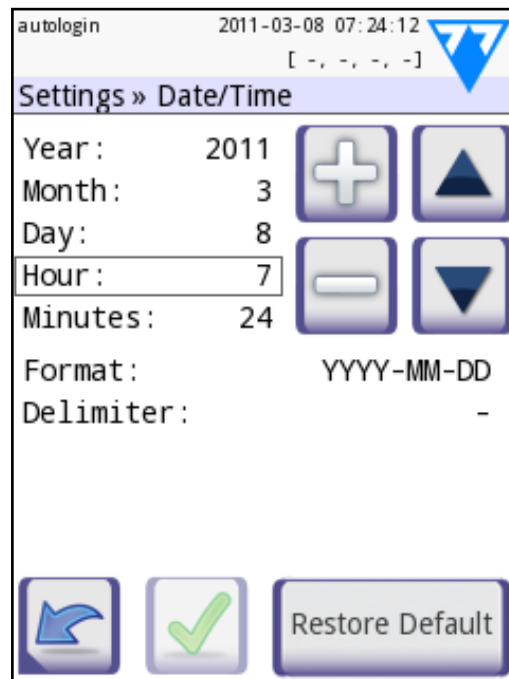


Figure 26: The Settings » Date/Time screen

The date and time you set is displayed on the display header and is recorded with the test results. Use to modify the value of the selected field.

Use to move the row cursor.

The format and delimiter settings determine how the system displays and prints date information.

- Available date formats:
YYYY-MM-DD (ISO 8601 standard), MM-DD-YYYY, and DD-MM-YYYY

① Where 'Y' stands for the year, 'M' for the month, and 'D' for the day of the date.

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



10.4 Printout

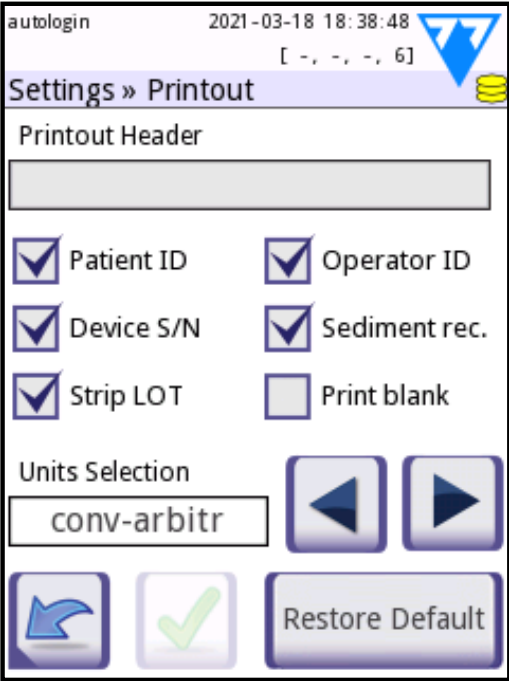


Figure 27: The Settings » Printout screen

Printout Header	Custom string
Patient ID	If enabled, ~ appears on the printout
Operator ID	If enabled, ~ appears on the printout
Device S/N	If enabled, ~ appears on the printout
Sediment rec	If enabled, the printout will indicate whether sediment analysis was recommended for the record
Strip LOT	If enabled, the ~ appears on the printout
Print blank	If enabled, the fields that are checked will always be printed, even if they are empty
Units selection	You can change the default units that appear on the printout. The options: conv-arbitr, SI-arbitr, conv, SI, arbitr. Use the left and right arrows to toggle between options.



10.5 Output (Connectivity: Transfer/Export)

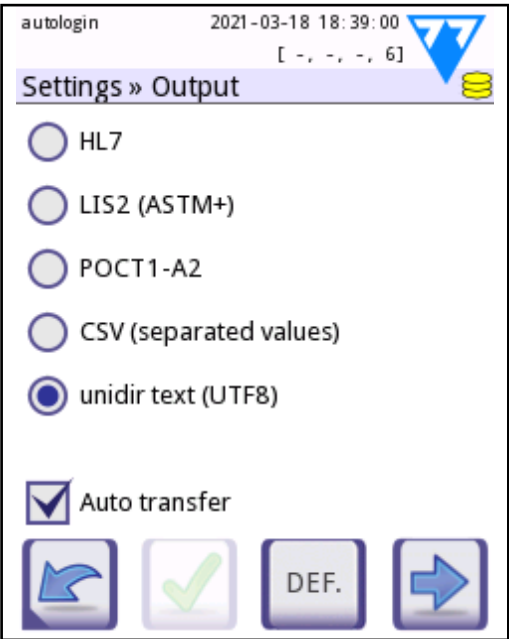





Figure 28:
The Settings » Output screen

You can configure how the DocUReader 2 PRO device connects to other systems or storage devices by defining the Output settings.


The system supports two protocols to transfer the analysis results through an interface:

- bidirectional (two-way) protocol based on the NCCLS LIS2-A2 standard protocol, the POTC1-A2 or the HL7 protocol
- unidirectional protocol, when the data are sent out as a one-way data flow, either formatted
 - as comma-separated values (CSV),
 - or as UTF8 text.

The **Output type** text box (available after you select any of the three output protocols and tap ) is used to define the communication port (available options are based on the output protocol). Tap   to scroll through the list.

	Serial (RS232)	TCP/IP Ethernet	File	USB B
Bidir:LIS2 (ASTM+)	⊕	⊕		⊕
Bidir: HL7		⊕		
Bidir: POCT1-A2		⊕		
Unidir: CSV	⊕		⊕	⊕
Unidir: UTF8 text	⊕		⊕	⊕

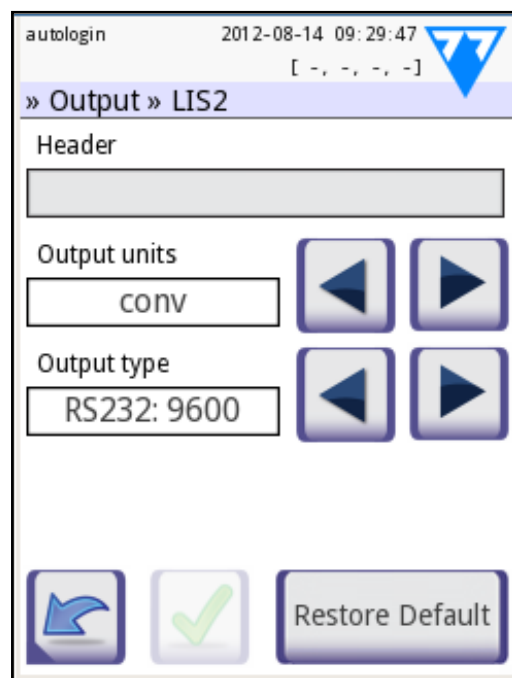
- For the serial port the selectable baud rates are 2400, 4800, 9600, 19200, 38400, 57600, and 115200 bits per second. The value defines the speed of the serial communication. The serial interface specification is 1 (one) stop-bit, no parity.
- If you select the **Output: file** option, the transferred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

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

 **Make sure that you configure the communication ports properly, otherwise data transfer will not work.**



10.5.1 Bidirectional protocol (LIS2-A2)

**Figure 29:**

The Settings » Output » LIS2 screen

The two-way digital transmission protocol of the DocUReader 2 PRO device regarding remote requests and results between the analyzer and external information systems is based on the NCCLS LIS2A2 approved standard.

The standard enables DocUReader 2 PRO and any standard LIS system to establish a logical link for communicating text to send results and requests in a standardized and mutually interpretable form. On this screen you can enter a custom header for the output, and, using the **Output type** text box, you can configure

- the output type (serial (RS232 or USB B), or TCP/IP (Ethernet))
- the speed of the serial communication in bits per second (in case you select the RS232 port).

⚠ If you select TCP/IP (Ethernet) as your output, you will need to enter the server's IP address and port number, separated with a colon (':').



10.5.2 HL7 bidirectional protocol

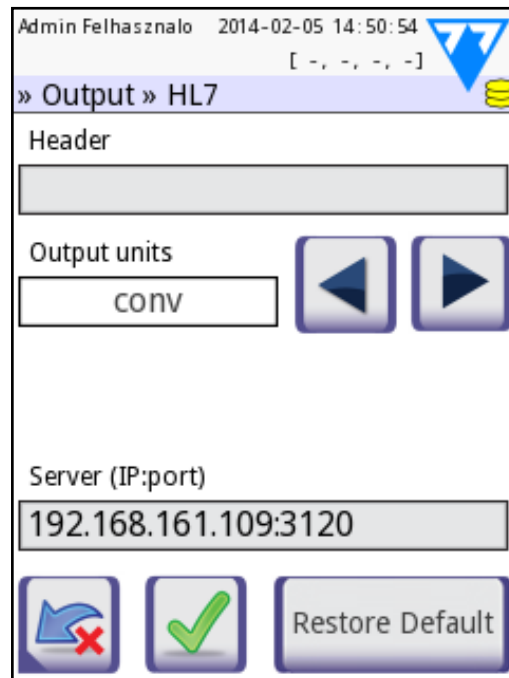


Figure 30:

The Settings»Output»HL7 screen

HL7 stands for Health Level Seven; it is a collective of healthcare informatics standards that allow exchange, integration, sharing, and retrieval of the measurement data over the DocUReader 2 PRO device 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.

ⓘ 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 device supports.



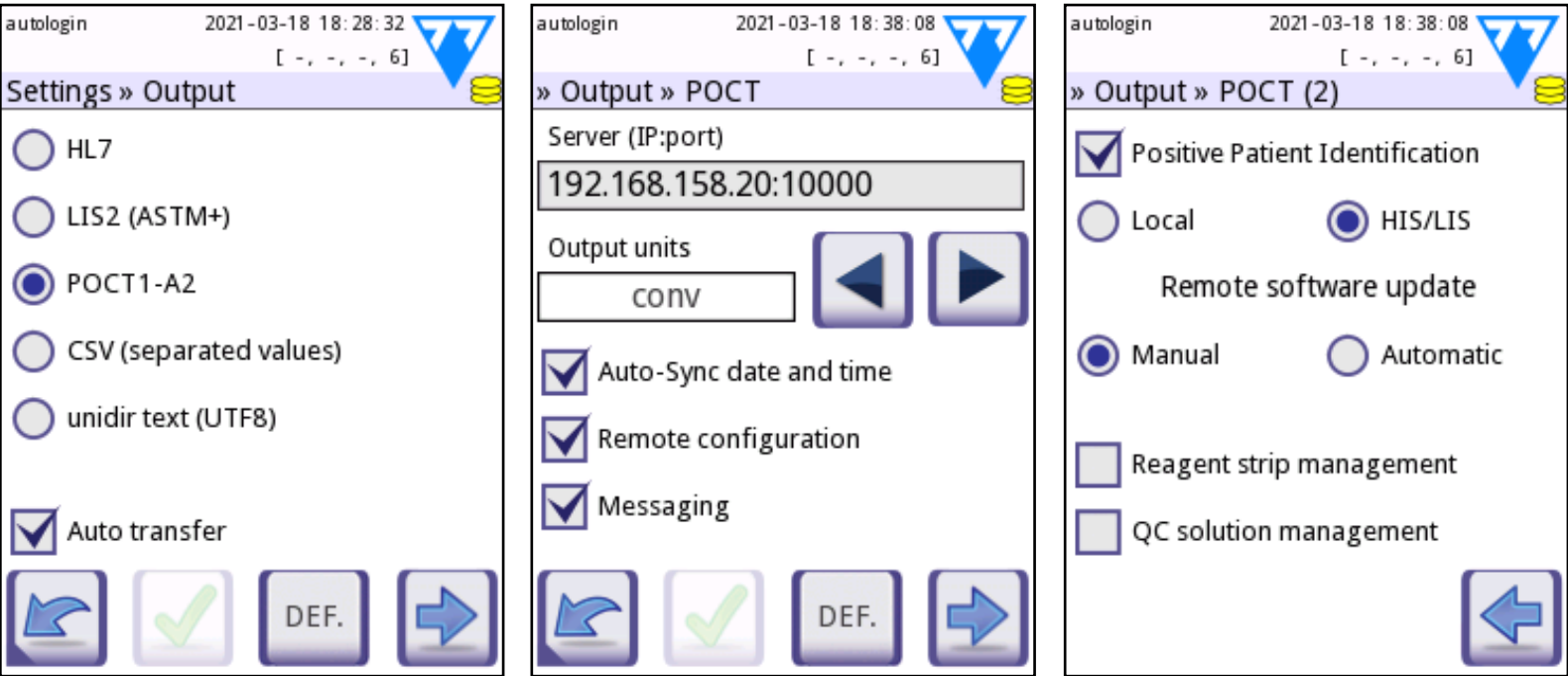
10.5.3 POCT1-A2 bidirectional protocol

The POCT1-A2 standard protocol allows bidirectional communication in Point-of Care environments with near-patient testing and is intended to be applied between the DocUReader 2 PRO and data managers (middleware). POCT features provided by the instrument are described in detail in the next sections. The POCT1-A2 protocol is specified in detail in the Interface description, which is available upon request and provides information to middleware developers or data manager developers to facilitate the attachment of DocUReader 2 PRO to a local laboratory information system (LIS).

DocUReader 2 PRO supports POCT1-A2 communication protocol through TCP/IP network connection. Before activating POCT1-A2, it needs to be clarified and set from the ethernet menu if automatic (DHCP) or static IP address is used.

POCT1-A2 can be selected from the **Main»Options»Settings(1)»Output** menu and related settings are available as shown in **Figure 31**.

Type the server and port number in the Server (IP:port) field. Please separate the server IP and the port number with a “:”, as shown in picture 2.



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. The resulting file can be opened by a spreadsheet editor such as Microsoft Excel.

Available separator characters: tabulator, semicolon (;), comma (,).

The options you can specify are almost identical to those in **Figure 73** with the exception of the TCP/IP (Ethernet) interface that is unavailable with CSV.

Figure 31: Examples of POCT1-A2 output settings



10.5.4 Comma-separated value output

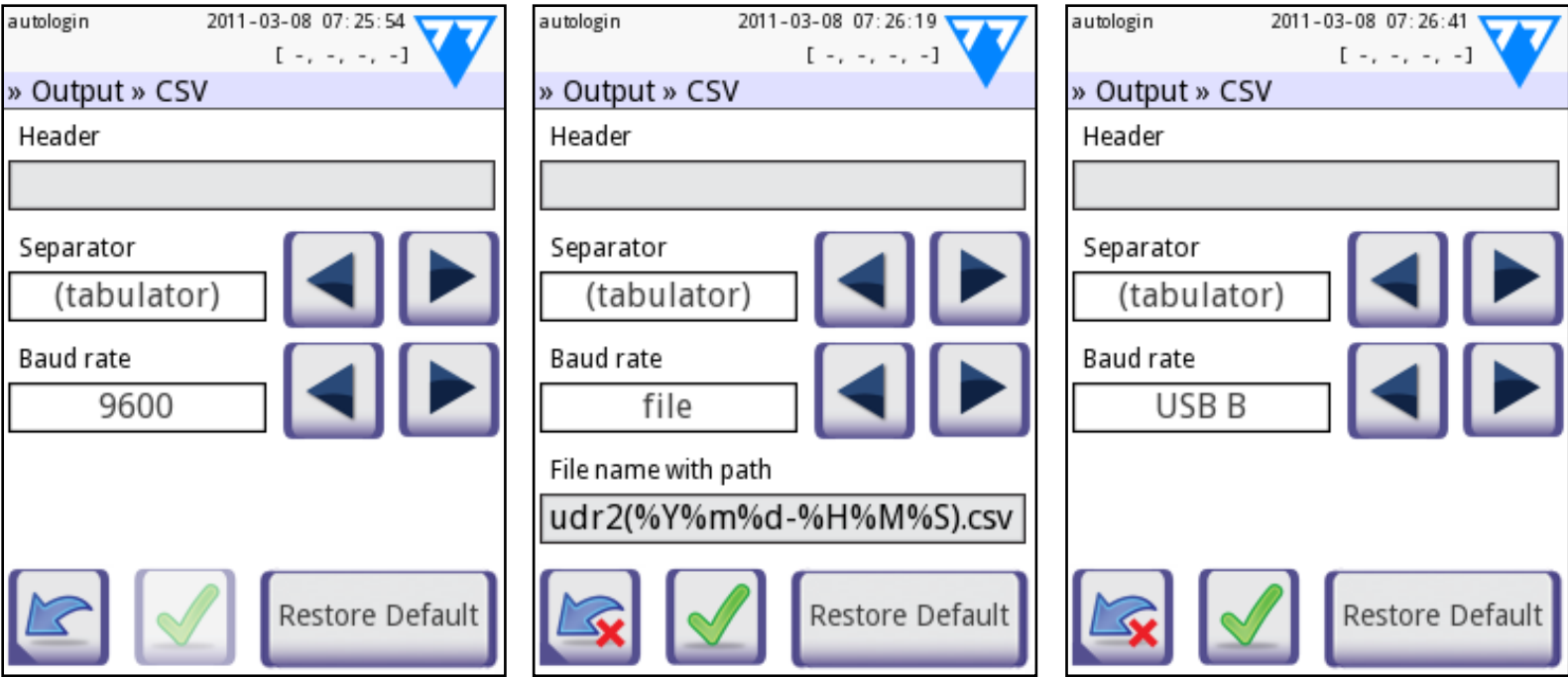


Figure 32: Examples of Comma-separated output settings

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. The resulting file can be opened by a spreadsheet editor such as Microsoft Excel.

Available separator characters: tabulator, semicolon (;), comma (,).

The options you can specify are almost identical to those in **Figure 73** with the exception of the TCP/IP (Ethernet) interface that is unavailable with CSV.



10.5.5 UTF8 unidir text

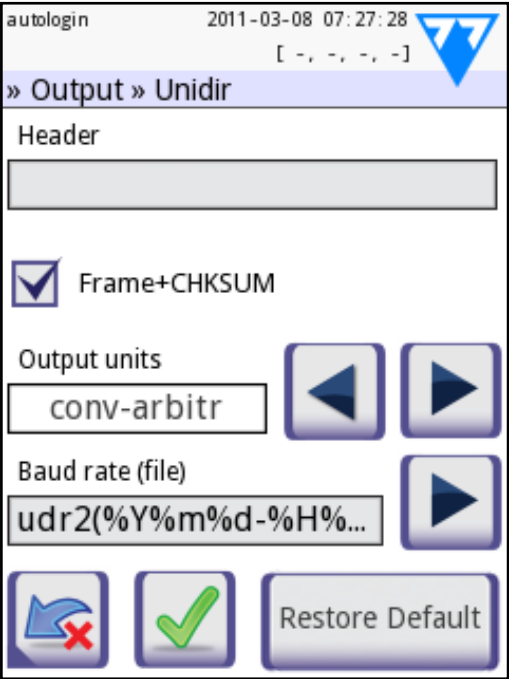


Figure 33: *The Settings » Output » Unidir screen*

If you select this output protocol, the system will transfer the analysis results encoded as Unicode characters. The options you can specify are identical to those in **Figure 32**. However, the a **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.

The following table is an example of UTF-8 output with every parameter set to visible and the with the frame and checksum option enabled.

[STX] Date:		2014-02-11 13:56	
Sample ID:		#0000020	
Patient:		Guaraldi, V.	
Device S/N:		6100074	
Operator ID:		Ed 02	
Strip LOT:		lot-13.06.2014	
<hr/>			
	BiI	neg	
	Ubg	norm	
	Ket	neg	
	Asc	neg	
	Glu	norm	
	Pro	neg	
	Ery	neg	
<hr/>			
	pH	6.5	
*	Nit	pos	+
<hr/>			
	Leu	neg	
	SG	1.020	
	Color:		-
<hr/>			
	Clarity:		-
<hr/>			
[CR] [ETX]AC[CR]			



10.6 Measurement

The detailed description of the Measurement screen can be found in “6.2.2 Customization of testing”.

10.7 Strip options

The main strip options screen shows the available strip types. To modify the strip settings select the strip type you are using and tap **order**, **sensitivity**.

The **Settings » Strip » Pads** screen will appear, that lists the pads on the strip corresponding to each analyte that is measured. (See “1.5 Indications for use” for a key to analyte abbreviations.) The selected pad is marked with a row cursor.

Tap to change the selection. Tap to increase or decrease the sensitivity of the selected test pad. You can modify the sensitivity between -2 and +2.

For LabStrip U mALB/CREA reagent strip, setting sensitivity for ACR and ACR interpretation is not available.

Tap **SED** to tag the selected test pad for additional sediment analysis. If the pad is tagged ‘SED’, all results of the selected pad with a positive value will get a “sediment examination is recommended” tag when stored in the database. The tag may also appear on the printout. Because the tag is stored in the database, you can create a filter to only return such tagged records (See “7.3 Setting up filters to find specific results”).

10.7.1 Reordering the test pads

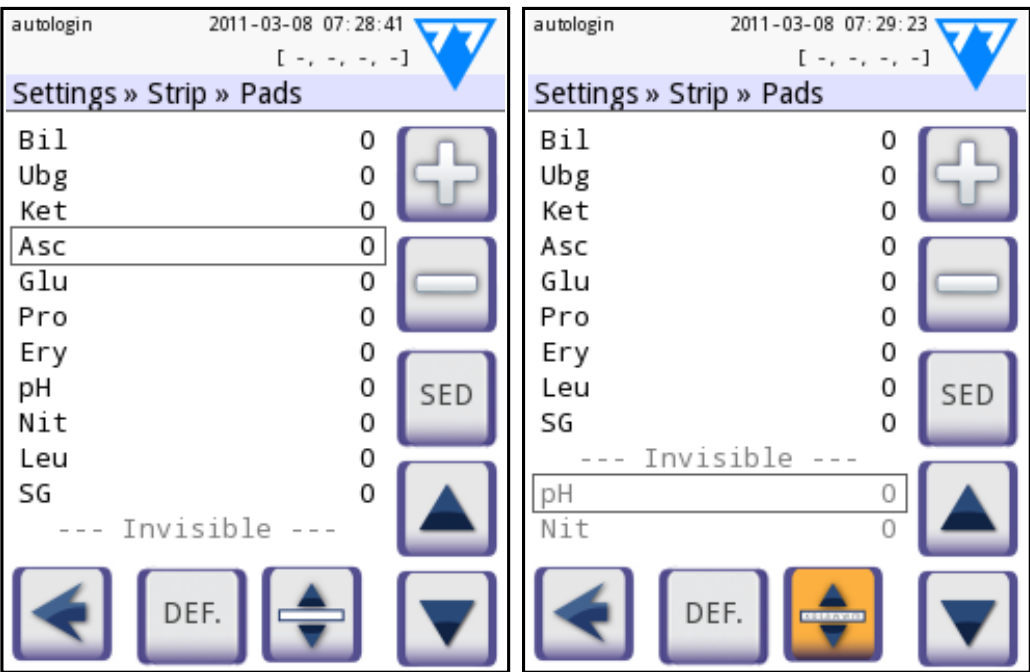


Figure 34: The Settings » Strip » Pads screen with an example of invisible analytes

1. Select the pad with the row cursor.
2. Tap **Move to ‘grab’ the selected pad**. Its background will change orange to indicate that it is active.
3. Use to move the selected analyte pad. When it is in the position you want it, tap **Move** once again to release it.

You can exclude any analyte from the results view if you move it below the ---Invisible--- line. The analyte pads in this area will not appear on the printout or in the database.

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



10.8 Database management

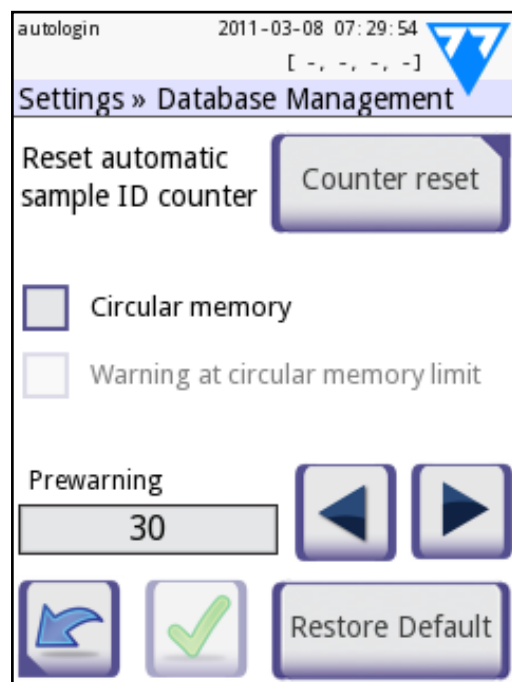


Figure 35: The Settings » Database management screen

On the **Database management** screen you can define how the DocUReader 2 PRO device manages the storage of the records.

The screen offers the following options:

- Resetting the automatic sample ID counter by tapping **Counter reset**. A confirmation screen will appear to prevent accidental data loss.
- Switching **Circular memory** on or off. When switched on, the system will start writing over older data when the memory is full. If this box is unchecked, the system will stop recording when memory gets full.
- Switching **Warning at...** on or off. When this option is on, the system will display a warning before old data is overwritten.
- Specifying the **Prewarning** limit. You can specify the number of records below the maximum database capacity at which the system should prompt you to free up space in the database. You will still be able to add new records past this point, but it is recommended that you erase some old data to free up database space.

10.9 QC Options

See “8.1 Quality control options” for a detailed description of the **QC Options** screen.



10.10 Power management

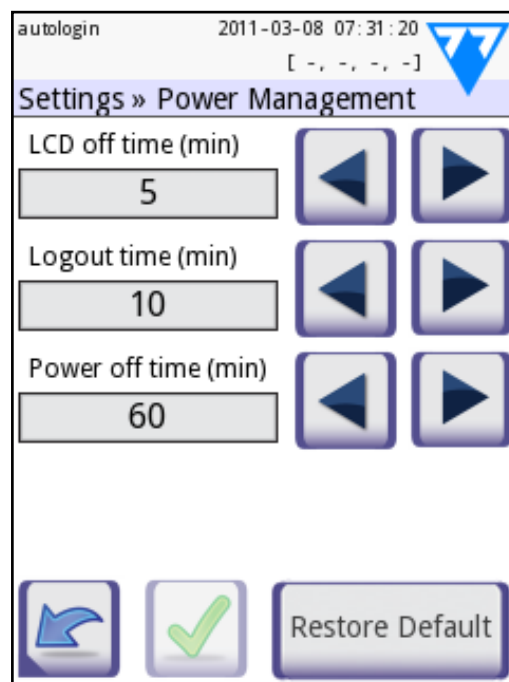




Figure 36: The Settings » Power management screen


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

- **LCD off time** (the screen saver starts)
- **Logout time** (the active operator is logged out)
- **Power off time** (the analyzer switches off)
- The device will perform these actions if it has been idle for the specified time. Tap   or tap inside the grey text box and use the numeric input screen to define the power management periods.

The screensaver mode and the automatic power-off feature help to reduce unnecessary power use and so reduce the ecological footprint of the device. The automatic logout feature offers an additional layer of security.

10.11 Log export

On this screen you can export log files, analyzer settings, and version information for diagnostic purposes. Complete the following steps.

1. Plug in the USB flash drive into one of the Type A USB ports on the back of the device. Wait until the  disk icon appears in the status line. The icon indicates that the system recognized the USB flash drive.
2. Tap the **Log Export** button on the **Settings (2)** screen. An information message will appear ("I111"). When the information message disappears, the log export is finished.

i A warning message ("W135") will appear if you try exporting a log file when no USB flash drive is connected. You will need to tap this warning screen to make it disappear.

3. Remove the USB flash drive.





10.12 The color and clarity list

DocUReader 2 PRO analyzers offer you the option of customizing the urine color and clarity list values so that the device can conform to any medical facility's in-house standards.

You can edit the color list on the **Settings » Color list** screen. You can edit the clarity list on the **Settings » Clarity list** screen.

Complete the following steps to edit the list items.


1. Tap the item's button (for example **straw-yellow** or **clear**). A virtual keyboard will be displayed. Modify the text as necessary.
2. Tap the **OK**  button when you are done to move back to the **Color list** screen. The item you modified will be marked with an orange background.
3. Tap the **Apply**  button to accept the changes. Tap the **Restore Default** button to cancel the changes and revert to the original list.

10.13 Ethernet interface configuration

To connect your DocUReader 2 PRO analyzer to the network via an Ethernet interface through TCP/IP, you have to configure the Ethernet interface.

 *Ask your IT system administrator for the necessary data.*

The configuration can be performed:

- automatically (DHCP): 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.
- manually: uncheck the auto (DHCP) checkbox and manually assign
 1. the IP address / subnet mask
(i.e. 192.168.1.5/24 or 192.168.1.5/255.255.255.0),
 2. the gateway
 3. the DNS server.
 4. Tap the **Apply**  button after modification.



10.14 Wi-Fi settings

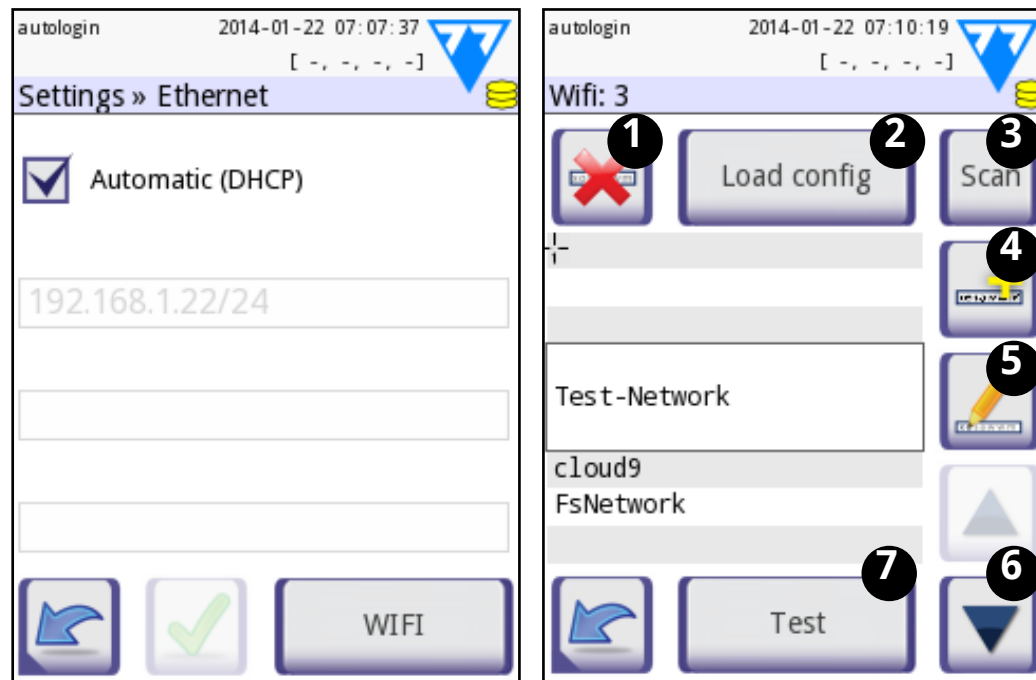


Figure 37: The Ethernet and the Wifi screens

10.14.1 Connect to an existing network

1. Insert a USB Wi-Fi adapter into one of the USB sockets at the back of the device. Access the **Main»Options»Settings(2)»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 81**) to position the cursor over the network that you would like to connect to, and tap the **Add element** button (numbered 4 in **Figure 81**). 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 81**) to position 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 device is connected to the selected wireless network.

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



10.14.2 Add a new connection

1. Insert a USB Wi-Fi adapter into one of the USB sockets at the back of the device. Access the **Main»Options»Settings(2)»Ethernet interface** screen. Tap the **WIFI** button.
2. Tap the **Add element** button (numbered 4 in **Figure 81**). 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 81**) to position the cursor over the network that you are connecting to, and tap the **Test** button (numbered 7 in **Figure 81**). A status text will be displayed below the name of the network. When the status text is **COMPLETE**, the device is connected to the selected wireless network.

10.14.3 Load pre-configured networks and advanced authentication protocols

The DocuRedear 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 device.
3. Insert a working USB Wi-Fi adapter into a USB socket at the back of the device. Access the **Main»Options»Settings(2)»Ethernet interface** screen. Tap the **WIFI** button.
4. Tap the **Load config** button (numbered 2 in **Figure 2**) 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.



10.14.4 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 device. Access the **Main»Options»Settings(2)»Ethernet interface** screen. Tap the **WIFI** button.
2. Use the **Up** and **Down** arrow buttons (numbered 6 in Figure 2) 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 2**), as necessary. Follow the instructions and messages that are displayed.

10.15 Update

See “**3.5 Software updates**” for a detailed description of the system software updates.



10.16 Operators



Figure 38: The Settings » Operators screen with its function buttons labelled

You can manage the system security settings and the active operators on this screen.0

① 'User' refers to anyone using the device. 'Operator' is a user with an account (login name plus password) recognized by the device. Therefore, each user has at least one associated operator.

① You can modify the access levels separately for each operator. The system stores operator data in the database.

1. The list of operators
2. Delete selected operator (requires confirmation to prevent accidental data loss)
3. Data Exchange
You can: Clear, Import and Export Operators Lists here
(available only to Supervisor and Service level operators)
4. Filter
5. Access system security settings
(available only to Supervisor and Service level operators)
6. Move row cursor up one row
7. Edit the access level of the selected operator
8. Move row cursor down one row
9. Add new operator
10. Activate/deactivate operator reordering
- ① You can reorder the operators that will be displayed on the **Login** screen with the **Move** button. The button will only become active if there is at least one operator listed that has the '**Display on login screen**' option checked (See "**10.16.3 System security settings**" and **Figure 39**). The button will only become functional if there are at least two (2) such items.
11. Print operators list
12. Go back to the **Settings** screen





10.16.1 Navigating the Operators screen

The number of operators recognized by the system appears in the content navigation bar. A row cursor indicates the selected operators on the screen. The entries for administrator or higher level operators are displayed in red. The access level of selected operators is also displayed, followed by some additional information about them in parentheses:

- S indicates that the operator can only access the results for measurements that he or she performed
- L indicates that the operator can log in without a password
- D indicates that the operator's ID may be displayed on the **Login** screen

i Like the other Operator settings options, the option to allow or disable operator IDs to appear on the Login screen has a security function. You may not want users of the device to know any of the other users' data, especially if no password is required and anybody can access the device with a valid operator ID.

A blue entry background indicates operators that can be displayed on the **Login** screen. (If the **Operators on login screen** check box is checked. See 9.16.2). Tap the  **Move**  button to 'grab' the selected blue-background operator and move it higher or lower on the **Login** screen with the arrow buttons.


10.16.2 Operator access levels overview

Operator access level	User rights
Disabled	Disabled operators cannot log in or perform any tasks.
User	This is the default access level. User-level operators can perform the following routine tasks: <ul style="list-style-type: none"> • worklist management • testing • quality control • printing and exporting results • editing user options.
Admin	Administrator-level operators can perform all user-level tasks, plus the following: <ul style="list-style-type: none"> • editing settings • managing operators • installing software updates.
Supervisor	Supervisor-level operators can perform all of the above actions and modify the system security settings.
Service	Service operators can perform all of the above actions, and have access to the Service screen.

i Users at a specific operator access level can only see other operators up to and including their own access level.



10.16.3 System security settings

Supervisor- and service-level operators have access to the **Operators » Security** screens by tapping the  button on the **Operators** screen. On these screens, you can select any of the five (5) pre-programmed security schemes with the up and down arrows, or configure your own customized security policy.

The available security schemes, in order of increasing level of security, are the following:

- **Open system**

Logging in is automatic; no identification or password is required. Tests can be performed and settings can be freely modified by anyone using the 'autologin' operator that has an Administrator operator access level.

- **Anonymous usage**

Logging in is automatic; no identification or password is required. Tests can be performed but settings cannot be modified. Users can create operators for themselves; these operators will have a 'user' operator access level.

- **Self-add**

Logging in requires an Operator ID but no password. Tests can be performed but settings cannot be modified. Users can create operators for themselves; these operators will have a 'user' operator access level.

- **Self-add with password**

Logging in requires both an Operator ID and a password, however, users are free to create 'user'-level operators for themselves as long as they also set a password. The system keeps an audit trail of operator activities.

- **Secure**

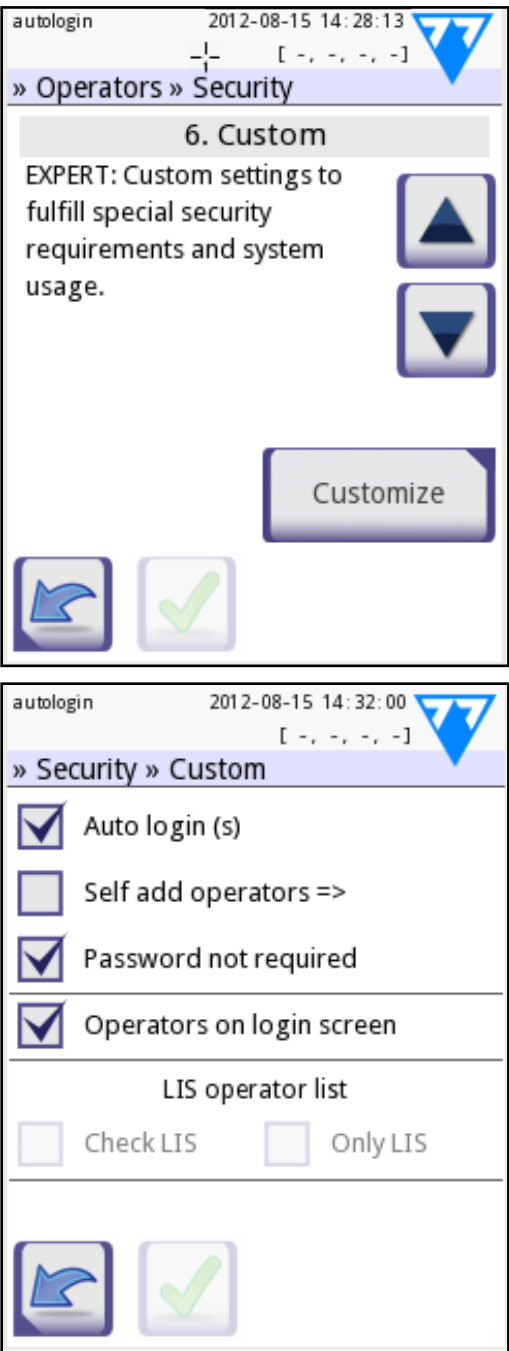
Only registered operators can log in; operators can only be registered by operators with an operator access level of Administrator or higher. The system keeps an audit trail of operator activities.

- **Custom security settings**

Tap **Customize** on the sixth **Security** screen to access the **Operators » Security » Custom** screen. You can check or leave unchecked any or all of the check boxes on this screen to specify a customized device security scheme to fit your facility's needs or preferences.



10.16.3.1 Key to the custom security options check boxes



- **Auto login**
Checking this check box activates the preprogrammed 'autologin' operator. Users logging in as 'autologin' operators are never prompted for a password. As a Service level operator, you can assign any operator access level to the 'autologin' operator. The abbreviation of the current operator access level is indicated in parentheses next to the check box when it is checked. 'autologin' operators do not need to enter an Operator name on the **Login** screen but can simply tap **Apply** to access the device at the operator access level granted to them.
 - **Self add operators**
Checking this check box allows users to create operators for themselves with any operator ID they choose. When you check this check box, you can specify what operator access level the operators that users create will automatically have. You can also decide whether they will need a password to log in, and whether they will be displayed on the **Login** screen. The current user access level and the relevant optional settings are indicated next to the check box when it is checked.
 - **Password not required**
Checking this check box makes sure that the system will not require a password from newly added operators. This is a global setting that applies to every operator—however, if a password has previously been set for an operator, the user will still have to enter the password to access the device.
 - **Operators on login screen**
Checking this check box has the effect that maximum four (4) operators' IDs are displayed on the **Login** screen. You can specify the order in which the operators that you allow to appear on the **Login** screen are displayed on the **Settings > Operators** screen (See "10.16.3.1 Key to the custom security options check boxes"). This is a global setting—if you uncheck it, the **Display on login screen** check box will not appear on any **Operators > Rights** screen (See "10.16.6 Managing operators").
 - **Check LIS**
Checking this check box has the effect that operators that are set up on the LIS2 connected to the device can also log in to the system.
 - **Only LIS**
Checking this check box will limit the number of operators that can log in to the system to the operators that are set up on the LIS2 connected to the device.
- ⚠ **When you check this check box, the following check boxes on this screen will automatically become unavailable: Auto login, Self add operators, and Password not required.**

Figure 39: The sixth Security screen and the Operators»Security»Custom screen

ⓘ The LIS options only become active when the device is connected to a LIS2.



10.16.4 Preprogrammed operators

- 'autologin': See "10.16.3 System security settings"
- 'self add': See "10.16.3 System security settings"
- 'supervisor': Supervisor-level operators can modify system security settings. The operator name is 'supervisor' (all lower-case, without the inverted commas), and the default password is '1234'. Supervisor-level operators can never be displayed on the **Login** screen.
- 'service': Service-level operators can access the **Service menu** screen. See 3.6 for further details.
- 'Full database and config clear.': If you enter this string (as is, without the inverted commas, but with a capitalized first word and a period (full stop) at the end) as the Operator name on the **Login** screen, the system will perform a full database clear.

❗ Full clear is a final, irrevocable command. Use it only when necessary. It is recommended that, for future reference, you perform a "Log export 255" before a Full clear.

10.16.5 Security settings overview

	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 (def password)	supervisor (def password)	supervisor (def password)	supervisors	supervisors
add user	N/A	anyone	anyone	anyone	admins
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



10.16.6 Managing operators

10.16.6.1 Adding operators


1. Tap the  button on the **Operators** screen to access the **Settings » Operators » Add** screen.
2. Enter the Operator ID using the alphabetic character selection and tap **Apply** to move on to the **Settings » Operators » Rights** screen.
3. Use the left and right arrows to specify the new operator's access level.
4. Use the check boxes to specify additional security settings for the operator you are creating. See "10.16.3.1 Key to the custom security options check boxes" for an explanation of these check box options.



Figure 40: The Operators » Add and the Operators » Rights screens

ⓘ Based on the global security settings, some or all of these check boxes can be disabled or unavailable.

10.16.6.2 Data exchange

1. Tap Data exchange button on the Operators screen to access the **Settings » Operators » Data Exchange** screen.
2. **a**, If you want to delete the list of operators tap **Clear Operator List**.
b, If you want to import a list of operators, insert a USB flash drive into to analyzer with the operators list on it, and tap **Import Operator List**.
c, If you want to export the list of operators onto other analyzers, insert a USB memory stick and tap **Export Operator List**.



10.16.6.3 Editing operator settings

1. Select the operator whose settings you wish to edit with the row cursor on the **Settings » Operators** screen.
2. Tap the button marked '5' on the key to the **Settings » Operators** screen.
3. See "**10.16.6 Managing operators**" for further information about the **Operators » Rights** screen.

10.16.6.4 Passwords

i *The system encrypts all passwords and so not even Service-level users can recover lost passwords. It is recommended that you clear passwords that the user has lost and set a new one for the associated operator.*

- Setting passwords

When an operator is created and the security settings require a password, the system prompts the user for a password at the first login attempt. Valid passwords are at least three (3) characters long. The system will prompt the user to confirm the password. After the password is set up, the user is returned to the Login screen and has to enter the Operator name and the new password.

- Resetting passwords

You can reset operator passwords on the **Settings » Operators » Rights** screen. If there is an active password associated with the operator, the **Clear passw.** button is displayed on the screen.

1. Tap **Clear passw.** The button background will change to orange to indicate that it is active.
2. Tap **Apply** to confirm the password reset or tap **Clear passw.** again to cancel the action.

i *The system will prompt the operator with a cleared password to enter a new password at the next login attempt.*



11 TROUBLESHOOTING

To help you diagnose what is wrong with your DocUReader 2 PRO device, this section lists the most common problems and their suggested remedies.

11.1 Abnormal analysis results

If the device consistently provides false positive or false negative results, you need to take action as soon as possible. If you think that the readings are inaccurate, you first have to determine whether the measuring head or the test strips are responsible for the problem. You will need:

- an unopened lot of LabStrip U11 Plus/LabStrip U mALB/CREA test strips before its expiry date
- previously analyzed urine samples that are definitely positive or negative regarding one or more of the analyte properties DocUReader 2 PRO measures
- at least two grey check strips
- Optional: a second, functioning DocUReader 2 PRO device that passed a quality check with a grey check strip

Complete these steps to help you decide:

1. Open a new lot of test strips. Use the fresh strips to test one or more urine samples that are either definitely positive or definitely negative regarding one or more of the analyte properties the device measures. Print or otherwise record the measurement results.	⇒ If the results you get match the results of the previous analysis of the sample, the test strips you used earlier were probably defective. If not, it is the measuring head that is probably defective. Call your service representative.
2. Run three or four (3–4) quality checks with as many grey checks strip as you have available. (See “ Quality control options ”)	⇒ If the device passes the check strip quality check, the measuring head is probably working correctly. If the device repeatedly does not pass the check strip quality check, the measuring head is almost certainly defective. Call your service representative.
3. Run a quality check with the recommended control solutions, using the fresh test strips you opened in step 1. (See “ Quality control options ”)	⇒ If you get the expected values indicated in the package insert of the control solutions, the test strips you used earlier were probably defective. If not, it is the measuring head that is probably defective. Call your service representative.
4. Use the urine samples you used in the previous steps and test them using the lot of fresh test strips you opened in step 1. Read the test strips visually by comparing the pads to the color chart on the test strip tube. Consult the LabStrip U11 Plus/LabStrip U mALB/CREA user manual at https://www.en.e77.hu/for-distributors for further details. Record the results.	⇒ If the results you read match the results you got in step 1, the test strips you used earlier were probably defective. If not, it is the measuring head that is probably defective. Call your service representative.
5. Optional: Use the grey check strips, the lot of fresh test strips, and the urine samples you used in the previous steps, and test them again with a second DocUReader 2 PRO device. Print or otherwise record the measurement results.	⇒ If the results you get do not match those you got with the first device, the measuring head of the device is probably defective. Call your service representative.



11.2 Troubleshooting chart

When you encounter problems with the device, it is recommended that you first of all remove the casing (10.2). With the top casing panel off, check whether all the internal cables are properly plugged in and that they are not damaged. If the cables are all properly connected and intact, but the problem or problems persist, consult the Troubleshooting chart.

Problem	Cause	Corrective action
1/a The device does not respond to the On/Off switch.	1.1 The mains cable or the AC adapter is not plugged in correctly.	Check that the adapter is connected to the analyzer and that the mains cable is plugged into the wall socket. Make sure that the blue light on the AC adapter lights up when it is plugged in.
	1.2 The mains cable or the AC adapter is defective.	Check the mains cable and AC adapter for external signs of damage. If the cable or adapter is damaged, contact your certified service personnel.
	1.3 The On/Off switch is defective or it has lost its connection to the Interface board.	Contact your certified service personnel.
	1.4 The microSD memory card is defective.	
	1.5 The Mainboard is defective.	
1/b The device does not respond to the On/Off switch.	1.6 A bit of jagged solder fragment on the Mainboard punctured the touchscreen FFC, causing a short circuit.	Contact your certified service personnel.
2 The device switches on, but the touchscreen does not light up.	2.1 The touchscreen is not connected to the Mainboard, or it is not connected properly.	Contact your certified service personnel.
	2.2 The touchscreen is defective.	Contact your certified service personnel.
3 The touchscreen is very dim.	3.1 The LCD brightness is set too low.	Set the LCD brightness higher on the Main»Options»User Options screen.
	3.2 The touchscreen is defective.	Contact your certified service personnel.
4 The touchscreen does not respond to tapping, or the wrong area of the screen is activated.	4.1 The touchscreen is not calibrated correctly.	Contact your certified service personnel.
	4.2 The touchscreen is defective.	Contact your certified service personnel.



Problem	Cause	Corrective action
5 Measurement results are consistently below or above standard ranges.	The test strips used or the Optical module is defective.	See “11.1 Abnormal analysis results”
6 The test strip tray does not move.	6.1 The serrated edge of the test strip tray does not engage with the stepper motor cogs.	Carefully push the test strip tray farther inside the device until it locks firmly into the stepper motor cogs.
	6.2 The stepper motor is defective.	Contact your certified service personnel.
7 The movement of the test strip tray is slow or jerky.	7.1 A buildup of dried urine is obstructing the passage of the tray.	Clean the top casing panel underneath the test strip tray and the test strip tray itself. Pay close attention to the serrated edge on the bottom of the test strip tray. Clean the slot that the test strip tray slides into in the Optical module. (3.2)
	7.2 The stepper motor that moves the test strip tray is defective.	Contact your certified service personnel.
8 The system does not recognize one or more external connectors (USB, RS232, Ethernet, and so on).	8.1 The affected connector or connectors lost the connection with the Interface board.	Contact your certified service personnel.
	8.2 The Interface board is defective.	
9 The green LED under the test strip tray does not light up or it is very faint.	9.1 The LED's transparent plastic cover is blocked by dirt or dried urine build-up.	Clean the test strip tray and the top casing panel underneath the test strip tray. (3.2)
	9.2 The LED board is defective.	Contact your certified service personnel.
10 Results are not printed or the printout is very faint.	10.1 Autoprint is not enabled.	Check the Autoprint box on the Main»Options»User Options screen.
	10.2 The paper loaded is not compatible with the printer.	Make sure that thermal printer paper is loaded into the paper compartment.
	10.3 The thermal paper is too old; the heat-sensitive layer deteriorated.	Load the printer with a fresh roll of thermal paper.
	10.4 The printer is defective.	Contact your certified service personnel.
11 There are white spots or streaks on the printout where results are not printed.	The grease and dirt accumulated on the printer roller prevents uniform printing.	Clean the printer roller (3.2.3). If the problem persists, contact your certified service personnel.



Problem	Cause	Corrective action
12 The date or time displayed in the display header is incorrect.	12.1 The Date/Time settings have been changed.	Go to Settings » Date/Time and tap Restore Default to reset the system to the current date and time.
	12.2 The real-time clock battery on the Mainboard is dead or lost its connection to the board.	Contact your certified service personnel.



11.3 Error messages

This section lists all the messages the DocUReader 2 PRO system uses to communicate with the operator and the relevant corrective actions where necessary.

- ① *The status bar (the top part) of the display turns yellow to indicate that a warning message is active. The status bar will turn red to indicate that an error message is active. Tap the status bar when it is yellow or red to see the full text of the warning- or error message.*

11.3.1 General error-, warning-, and information messages

Key to the system messages table

The DocUReader 2 PRO system displays messages when the user's attention is required. In decreasing order of severity, the two categories are:

- Error messages (E), indicating that a malfunction occurred that prevents normal operation
- Warning messages (W), indicating that although normal operation is possible, some functionality of the system is lost
- Information messages (I) that provide feedback or additional information.

The system displays these messages in the following ways:

- Status line (S): the message appears in the status bar without a time limit
- Timed pop-up window (T): the message appears for a few seconds in a pop-up window.
- Pop-up window (A): the message appears in a pop-up window that disappears at the end of the process or event.
- Pop-up window (P): the message appears in a pop-up window that requires user confirmation to disappear.
- In-result message (R): the message is appears in the content area of the display.

ID	C	T	Short text	Full text	Corrective action
E99	E	S	Head HW	Head hardware error. Please call Service.	Contact your certified service personnel.
E98	E	S	Printer HW	Printer hardware error. Please call Service.	Contact your certified service personnel.
E97	E	S	Head voltage	Head voltage value is out of range. Please call Service.	Contact your certified service personnel.
E96	E	S	Power voltage	Power voltage value is out of range. Please call Service.	See point "1" of the Troubleshooting chart.
E90	E	S	Reference	Failure of reference pad check. Reference pad value of the tray is out of range. See User's Manual for further instructions.	See "11.3.2 Handling of failure of reference pad check (E90)" .
E89	E	S	QC lockout	Go to "QC measurement" to perform QC check.	Perform QC check measurements to lift 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
W69	W	S	Output port	Output port not open. Please restart the system!	Restart the device
W68	W	S	Output internal	Output internal error. Please restart the system!	Restart the device



ID	C	T	Short text	Full text	Corrective action
W67	W	S	Output init	Output not initied. Please restart the system!	Restart the device
W66	W	S	Output closed	Output closed. Please restart the system!	Restart the device
W65	W	S	Output memory	Not enough memory for output. Please restart the system!	Restart the device
W64	W	S	Output write	Cannot write output. Please change file name or (re)insert USB flash drive.	Use alphanumeric characters only and make sure that the USB flash drive is connected properly and is detected by the system. If necessary, 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. When it can successfully display the output, the error message 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. When it can successfully display the output, the error message 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 flash drive.	Change the file name or its destination. Make sure 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. When it can successfully display the output, the error message will automatically disappear. If the error persists, check and verify output settings.
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.	
W38	W	S	Head version	Measure head SW version is unknown. Please call Service.	Contact your certified service personnel.
W37	W	S	Temperature	Temperature out of allowed range.	Ensure the proper environmental conditions. See 3.3
W35	W	S	Data lost (limit)	Database limit exceeded. Earlier results will be dropped.	Free up memory by erasing old data (circular memory option is enabled, 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.	Free up memory by erasing old data.
W33	W	S	QC lockout	Go to „QC measurement“ to perform QC check.	Perform QC check measurements to remove the QC lockout. See “Quality control options”.



ID	C	T	Short text	Full text	Corrective action
W32	W	S	Strip-holder	Stripholder error. Can't go to home position. Please check it!	Check if the test strip tray is properly inserted and remove any obstacles from its path (See " Clearance limits ")
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. (3.4.2)
W30	W	S	Paper out	Paper out. Please replace the printer paper!	Open printer door and load a fresh paper roll in the printer. (3.4.2)
E199	E	P		DB failure: cannot write result. Please call Service!	Contact your certified service personnel.
E198	E	P		DB failure: cannot modify result. Please call Service!	
E197	E	P		DB failure: cannot delete result. Please call Service!	
E196	E	P		DB failure: configuration is corrupted. Please check the configuration settings.	
E195	E	P		Worklist DB failure: cannot write new item.	
E194	E	P		Worklist DB failure: cannot insert or modify item.	
E193	E	P		Worklist DB failure: cannot delete item.	
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 flash drive. 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.
E177	E	T		Length of password must be between 8 and 63 characters	The password that you have entered is either too short or too long. Enter another password.
E174	E	T		Format of entered expiry is failed. Format of expiry is YEAR/MONTH	Enter the QC LOT expiry date again. Do not use parentheses
E173	E	T		Format of entered LOT is failed. Format of expiry is (YEAR/MONTH)	Enter the QC LOT number and the expiry date again. Make sure that you separate the expiry date from the QC LOT number with parentheses.
E172	E	T		Time is expired	The expiry date of the QC solution lot that you are trying to register is already past. Register a lot of QC solution that is still valid.
E171	E	T		Cannot export log.	Make sure that the USB flash drive is connected properly and that the system detects it. If required, re-initialize the USB port by tapping the 77E logo in the top right corner of the touchscreen display.
E170	E	T		Sample ID already exists, please change it.	Verify and repeat the input or use another Sample ID.
E169	E	T		Registration Code is already used.	Verify and repeat the input or use another RegCode.
E168	E	T		Registration Code is not valid.	Verify and repeat the input or use another RegCode.
E167	E	T		Operator ID already exists, please change it.	Enter another Operator ID.
E166	E	T		Password check failed, please try again.	Enter the valid password.



ID	C	T	Short text	Full text	Corrective action
E165	E	T		Password is too short, please try again! (minimum length is 3 characters)	Enter a new password that is at least three (3) characters long.
E164	E	T		Password does not match, please try again.	Re-enter password.
E163	E	T		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	T		Operator disabled, please try again.	The operator name that you entered has been disabled. Enter another Operator ID.
E161	E	T		Sample ID required. Please set it.	Enter Sample ID.
E160	E	T		LOT Code required. Please set it.	Enter LOT number from the test strip package.
W169	W	T		Cannot open serial port for output!	Check serial port connection. See point "8" of the Troubleshooting chart.
W158	W	T		Cannot open file for output!	Check the output port and presence of the output storage.
W156	W	T		Cannot connect to server for output.	Check output server settings.
W140	W	T		Due to changes the lockout time has been expired.	Perform a QC measurement to lift the lockout.
W139	W	T		Previous "strip pads" settings lost. Press "OK" (apply) before strip change.	Tap the Apply button to save changes, otherwise the special strip settings (pad order, sediment rec., and so on) 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 92.168.1.5/255.255.255.0)	Check and correct server IP address or mask input.
W136	W	P		IP address format is not correct. (i.e. 192.168.1.12)	Check and correct server IP address or mask input.
W135	W	T		Cannot export log, because USB drive does not exists. Please insert it.	Make sure that the USB flash drive is connected properly and that the system detects it. If required, re-initialize the USB port by tapping the 77E logo in the top right corner of the touchscreen display.
W134	W	A		Worklist DB failure: possible data loss! Trying to repair. May take some minutes, please wait	Check the worklist to see if any data was lost. Clear the database (See 9.16.4). If problem persists, contact your certified service personnel.
W134	W	P		Worklist DB failure: possible data loss!	Database failure. The system is trying to repair the problem. This may take a few minutes.
W133	W	A		Config DB failure: possible data loss! Trying to repair. May take some minutes, please wait.	Data was probably lost. The system is trying to repair itself.
W133	W	P		Config DB failure: possible data loss!	Possible configuration loss, check database. Contact your certified service personnel.
W132	W	P		Config DB is recreated. Previous configuration is lost!	System settings are regenerated. Set the configuration options again. Contact your certified service personnel.
W131	W	A		DB failure: possible data loss! Trying to repair. May take some minutes, please wait	Data was probably lost. The system is trying to repair itself.



ID	C	T	Short text	Full text	Corrective action
W131	W	P		DB failure: possible data loss!	Check the worklist to see if data was lost. Contact your certified service personnel.
W130	W	P		DB is recreated. All previous data is lost!	All existing data was lost. Contact your certified service personnel.
I117	I	P		Due to changes lockout time was increased to X day(s).	You have successfully increased the active QC lockout time.
I117	I	P		Successful QC check. Lockout time was increased to X day(s).	The QC lockout time was restarted because of the successful QC measurement.
I116	I	T		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	A		Measure head SW update in progress. May take some seconds, please wait.	N/A
I114	I	A		Connection is in progress. Please wait.	N/A
I113	I	T		Output is paused while in Settings » Ethernet screen.	N/A
I112	I	T		Log exported.	N/A
I111	I	T		Log export in progress. Please wait	N/A
I110	I	T		Output paused while navigating in settings menu.	N/A
I109	I	T		Unused QC LOTs and limits deleted.	N/A
I107	I	T		No password set. Please set your password on login!	N/A
I106	I	T		Operator added.	N/A
I105	I	T	.	Selection was sent for printing	N/A
I104	I	T		Selection was sent for output.	N/A
I103	I	T		Selection is inverted.	N/A
I102	I	T		All samples are selected.	N/A
I101	I	T		Sample ID was not found, please try again or cancel the search	N/A



11.3.2 Handling of failure of reference pad check (E90)

1. Remove the test strip tray and clean it paying particular attention to the reference pad.

⚠ Use one of the prescribed cleaning agents. See 3.2.1.

2. After cleaning the reference pad make sure that there is not any apparent disorder on its grey surface.
3. Put back the test strip tray and check if E90 fixed.
4. If E90 remains, replace reference pad in case there is an available spare part. If you do not have spare reference pad, please call service.
5. If E90 remains after replacing the reference pad with a new one, please call service.

11.3.3 Testing- and Measurement error logs

The system displays the following error messages when a malfunction occurs during analysis. These are permanently stored in the database with the measurement results and will also be printed.

ID	C	T	Full text	Testing: Error Source & Corrective Action
E299	E	R	Head HW error: some LEDs may be defective. Please call Service.	Contact your certified service personnel.
E298	E	R	Head HW error: voltage out of range. Please call Service.	
E297	E	R	Head HW error: software check failed. Please call Service.	
E296	E	R	Head communication failed. Please restart the system.	Communication with the head failed after the measurement. Restart analyzer and repeat the test with a new test strip. If the problem persists, contact your certified service personnel.
E282	E	R	Database error. Stored item is corrupted. Please delete item from database.	Delete item from the database. If problem persists, contact your certified service personnel.
E281	E	R	Database error. Missing strip configuration data. Please delete item from database.	
E280	E	R	Configuration error. System configuration (or database) failed.	
E270	E	R	Strip tray reference pad error. Measured value out of acceptable range!	The reference pad is contaminated or damaged. Clean the test strip tray and the reference pad Replace the reference pad or the test strip tray if the problem persists contact your certified service personnel.
E269	E	R	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 to a strong light source (for example to direct sunlight or a lamp).
E268	E	R	Mechanical error. Stripholder can't go to home position.	Check if the test strip tray is properly inserted and remove any obstacles from its path. Clean the test strip tray (3.2.2).
E267	E	R	Home position error. Step failure detected after measurement.	Position count check failed after testing. Check if the test strip tray is properly inserted and remove any obstacles from its path (See "3.3.1") Make sure that you do not push or pull the tray during its movement.
E266	E	R	Strip type mismatch while calculating the results of measurement.	Make sure that only LabStrip U11 Plus or LabStrip U mALB/CREA test strips are used and that they are positioned correctly on the test strip tray.



ID	C	T	Full text	Testing: Error Source & Corrective Action
E265	E	R	Measured value out of valid range for one or more pads.	Unrealistic data was collected. Make sure that the right test strips are used. Check the test strips' date of expiry. Discard expired strips and open a new lot of test strips. If problem persists, see "11.1 Abnormal analysis results" .
E264	E	R	Strip position error. Strip position check failed after the measurement.	Strip moved from its initial position during testing. Make sure that the strip is correctly positioned on the test strip tray.
E263	E	R	Temperature was out of allowed range during measurement.	The ambient temperature was out of the operating range during the test. Maintain proper environmental conditions ("3.3 Setup considerations") and repeat the test with a fresh strip.
E262	E	R	Flipped strip error. Strip is put backside top on stripholder.	Test strip was placed downwards. Repeat the test ensuring the strip is correctly positioned on the test strip tray with the test pads facing up.
E261	E	R	Strip is (partially) dry.	Strip was (partially) dry. Repeat the test with a fresh strip. Make sure that every pad on the strip is immersed in the urine.
E260	E	R	No strip is present. Storing commented item without real values.	The system did not detect a strip during measurement. The result is saved only so you can add a comment.

11.3.4 Software update error- and information messages

SW Update ID	C	T	Full text	Corrective action
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. Press "Update" button to start process.	Follow the message instructions.
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.
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.
E5XX	E	U	Unpack failed:	Corrupted or missing files. Check and verify the software update sources on the media. Restart update.
I5XX	I	U	N/A
O5XX	I	U	N/A



12 APPENDICES

Appendix A Technical specifications

Type	reflectance photometer with 4 discrete wavelengths (505,530, 620, 660nm)		
Throughput	maximum 50 strips/hour (in normal mode)		
Display	3.5" QVGA touch-screen LCD (resolution: 240x320)		
Memory	3000 test results / 1000 QC results		
Printer	thermal line dot printer paper width: 58 millimeters		
Dimensions	Width 190 mm (7.4 inches)		
	Depth 236 mm (9.2 inches)		
	Height 77 mm (3 inches)		
Weight	1255 grams (2.767 pounds) including the AC adapter, the power cord, and a new roll of printer paper		
Power supply	100–240V AC ± +10% -15%, 50/60Hz ± 5% external mains adapter		
Operating conditions	Temperature	Relative humidity	Altitude
Optimum	20–26°C	35–55% (non-condensing)	3000 m (9842 feet)
Operating	15–32°C	20–80%	
In storage	–10–+60°C	20–85%	
Interfaces	PS2 (external keyboard, bar code scanner)		
	serial RS232 (with transmission speeds 1200–115200 bps)		
	USB Type B		
	USB Type A		
	Ethernet / Wi-fi		
	microSD card holder		



Appendix B Default factory 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
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i Authentication general settings do not change when you restore the default settings.



Appendix C Support & ordering

C.1 Support

77 Elektronika offers full service support for its products. Feel free to contact us if you encounter any problem with the DocUReader 2 PRO 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

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. Press the **New Issue** button in the top left corner.
3. 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.
4. 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.

C.2 Ordering

You can order any replaceable part of the device directly from 77 Elektronika.

❗ *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.



Appendix D Disposal information

⚠ 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.

i 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 per step 4 in F.1. 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.

D.1 Disassembly and disposal of the device

1. Disconnect the device from the power supply and unplug all electrical wires.
2. Clean the device thoroughly (See “3.2 Cleaning the device”).
3. Remove the top casing panel and all the printed circuit boards, including the Optical module.
4. 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).
5. Dispose of the following components separately:
 - the AC adapter and power cable: contact the manufacturer for disposal information (See “3.1 Parts checklist”) or **find a recycling center online**
 - the electrical wires: **find a recycling center online**
 - the casing panels: follow the local guidelines and regulations for Acrylonitrile butadiene styrene (ABS) disposal
 - the printed circuit boards (PCBs), including the Optical module and the touchscreen: find a specialized recycling firm (**see a UK example**)
 - the CR2032 real-time clock battery on the Mainboard: follow local regulations and guidelines for lithium battery disposal
 - metallic elements (such as the stepper motor and the connector plugs): follow local guidelines and regulations for metal disposal
 - silicone supports: dispose of these as municipal waste



Appendix E Safety and compliance information

Your DocUReader 2 PRO device was designed and manufactured to comply with the following international regulations, and left the factory in a safe condition. Follow the instructions and pay attention to the warnings in this manual to keep the analyzer in a safe condition.

The device complies with the protection requirements of IEC 61010-1:2001, IEC 61010-2-101:2002, IEC 61326-1:2005 and IEC 61326-2-6:2005.

The instrument is certified as meeting the EMC requirements and safety specifications of the In Vitro Diagnostic Directive (98/79/EC). According to EN 61326-2-6, it is the user's responsibility to ensure that a compatible electromagnetic environment for this instrument is provided and maintained in order that the device will perform as intended. Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper operation. The electromagnetic environment should be evaluated prior to operation of device.

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

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

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

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

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