DocUReader 2 PRO

77 ELEKTRONIKA

Urine chemistry analyzer
User Manual (Short version)

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CE IVD

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1 Introduction

1.1 Intended purpose

The DocUReader 2 Pro is a semi-automatic urine test strip analyzer and provides qualitative and semi-quantitative parameter concentration values in human urine. The analyzer evaluates dedicated LabStrip urine test strips for preliminary screening.

The product is designed for professional use and may be used in a near-patient environment as an in vitro diagnostic medical device.

1.2 Indications for use

The DocUReader 2 Pro urine test strip analyzer is a bench top IVD designed to be used exclusively with LabStrip U11 Plus, and LabStrip U mALB/CREA urine test strips manufactured by 77 Elektronika Kft.

LabStrip U11 PLUS multiparameter urine test strips

The system performs the qualitative measurement of relevant properties of Nitrite (Nit) and the semi-quantitative measurement of relevant properties of the following urine analytes of the samples:

Bilirubin (Bil), Urobilinogen (Ubg), Ketones (Ket), Ascorbic Acid (Asc), Glucose (Glu), Protein (Pro), Blood (Bld / Ery), pH, Leukocytes (Leu) and Specific Gravity (SG).

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

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

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

1.3 Limitation of use

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

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

1.4 How to use this manual

This User Manual (short version) contains all essential information and safety instructions to use the analyzer. A detailed description of all system functions and settings is available in the full User Manual, which can be downloaded by the following link or QR-Code.

https://www.en.e77.hu/products/urine-analyzers/docureader-2-pro

1.4.1 Symbols and formatting conventions

This manual uses the following symbols to highlight important information:

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

Caution text appears in bold type.

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

Warning text appears in bold type.

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

Note text appears in italic type.

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

	Double insulated product or transformer. May also identify class 2 equipment (power supply only)		Indoor use only
	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
	Direct current		Caution, consult accompanying documents
	MAC adress		Consult instructions for use
	Manufacturer		Ethernet port symbol
	Power on/off		In vitro diagnostic medical device
	Handle with care		Serial number
	Temperature limitation		Unique Device Identifier
	Atmospheric pressure limitation		USB port symbol
	Suitable for near-patient use		DC Adaptor Polarity Centre Positive
	Keep away from rain		This way up
	Protect from sunlight and heat		Stack no more than four (4)
	Catalogue number		Humidity limitation
	Country of origin of the goods		Date of manufacture

1.5 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 analyzer 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 “12 Maintenance” and “Appendix B Technical specifications” for further environmental limitations.**

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

1.6 Approvals

The DocUReader 2 Pro system meets the requirements laid down in:

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

RoHS Restriction of hazardous substances. The DocUReader 2 Pro system meets the requirements laid down in: Directive 2011/65/EU of the European Parliament and of the Council of 8th June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

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

2 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.

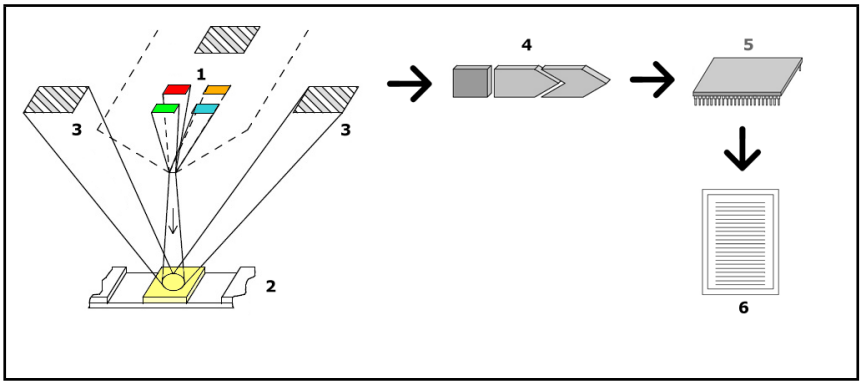


Fig. 1: *Measurement principle*

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

Fig. 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-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 connectors only with their appropriate plugs and operational cables.**

⚠ **Use the On/Off switch to switch off the device only if the normal powering down procedure fails.**

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

3 Device installation

3.1 Unpacking

⚠ **Read the DocUReader 2 Pro User Manual carefully before installation to ensure proper operation of the analyzer from the outset.**

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

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

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

3.2 Parts checklist

- Intact DocUReader 2 Pro analyzer device

ⓘ *DocUReader 2 Pro is tamper-evident: 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.*

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

- Two test strip trays with a clean white reference pad firmly in place
- Grey check strip
- Roll of printer paper
- User Manual (short version)

3.3 Setup considerations

⚠ **Do not use the device outdoors.**

- 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 F 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 B 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.

3.4 Clearance limits

⚠ **Make sure that there is enough room in front of the device for the test strip tray to move in and out 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.**

3.5 Setup

3.5.1 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.
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.

Fig. 3: *Inserting the test strip tray*

3.5.2 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 faces the printer head and not 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.

Fig. 4: *Loading the printer*

ⓘ *By default, the analyzer prints measurement results automatically. The automatic printing function on the Main » Options » User Options screen can be disabled.*

3.5.3 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:

DocUReader 2 Pro		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.*

3.5.4 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 and runs a self-check.

ⓘ *The device does not require a calibration before performing measurements. The analyzer software checks the system each time the analyzer is turned on. During testing, the analyzer automatically checks and corrects its performance based on the independent internal sensor.*

Fig. 5: *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), switch off the device by pressing the On/Off switch for at least five (5) seconds.*

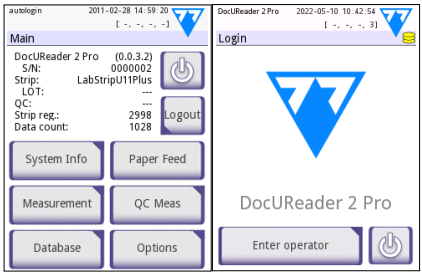


Fig. 6: *Switching off the device*

3.5.5 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 needs to be recalibrated at least once a year. If 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 calibration 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 a 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.

3.6 Software updates

ⓘ *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 the manufacturer will send a software update for the device. The following sections describe the software update procedure:

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

3.6.1 Preparation of the USB flash drive

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

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

ⓘ *The file names will be similar to these: uri2pro_x.x.x.tar.gz, uri2pro_x.x.x.tar.gz.chk (x are replaced with numbers). The file types have to be like this after unpacking the zip-file: .tar.gz and .tar.gz.chk, otherwise theDocUReader 2 Pro device will not be able to recognize the update files*

3.6.2 Procedure of the software updates

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.

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

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

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

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

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

4 Interacting with the device

4.1 Screens

The system displays messages, instructions and options to choose from on the touchscreen to operate the device.

The screen layout can be divided into three main areas:

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

ⓘ *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.*

Fig. 7: *Display layout*

ⓘ *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. The navigation bar shows the track of the 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 "10.4.2 System security settings"), the Measure screen is displayed first. In the work area the user can start a measurement, switch to the LabStrip U mALB/CREA test strip, 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

The touchscreen can be operated with bare fingers, gloved fingers, ballpoint pens with retracted tips, or any stylus-like object. 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.**

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

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

4.2.1 Buttons and screen input areas

Buttons

Tapping rectangular buttons can trigger actions or 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 the user back up one level in the menu hierarchy.

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

Special buttons

 Apply

 Drop

 Left

 Up

 Down

 Right

 Inactive buttons are dimmed

Navigation buttons

 Back

 Next

 Back (Return)

 Forward (More)

 Drop modifications and Back (Drop & Back)

 Apply Modifications and Next (Apply & Next)

Confirming changes

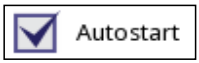
Any changes on User options or Settings screens can be confirmed by tapping **Apply** and leaving the screen with the **Back** button.

Changes are still not saved  Drop&Back  Apply

No changes or changes are saved  Back

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

Check boxes



Check boxes are displayed when there is a selection to enable or disable an option (such as Autostart) or when one or more options from a set of alternatives can be selected (for example the QC options alternatives: Forced QC, L2, L3)

Radio buttons

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

4.2.2 Entering data via the touchscreen

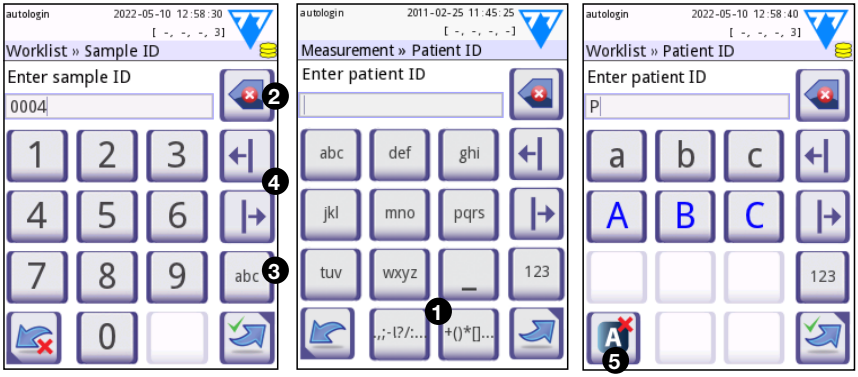


Fig. 8: *Numerical, lowercase, and uppercase input*

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. To enter special characters use the **.,;-!?/:…** or the **+()*[]** buttons (❶) to go to the selection list. To switch between the numeric and alphabetic keyboard, use the **123** and the **abc** buttons respectively (❸).

Erase data with the backspace button (❷). The cursor can be moved with the left and right buttons (❹). To cancel the entry of a character from the current selection, tap the button marked (❺).

4.2.3 Entering data via a barcode reader or a keyboard

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 and target values or test strip LOT number. No external power supply is necessary.

⚠ **Make sure that the used barcode reader supports ALT mode and select this mode of operation before using it with the DocUReader 2 Pro device.**

Fig. 9: *The Measurement screen with keyboard shortcuts displayed above the onscreen buttons*

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

Using a standard PC keyboard:

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

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

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

Press 'Ctrl' to display the keyboard shortcuts on the screen. The relevant short-cuts 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 cross-hairs to the left and 'Enter' to select the targeted button or text box.

5 Start-Up Wizard

The first time the DocUReader 2 Pro device is switched on, a Start-up Wizard is displayed. Here the user is able to customize the basic options of the device. The Start-up Wizard can be skipped on the second screen.

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

- Language
- Date and time
- System security ("11.4.2 System security settings")
- Change the 'supervisor' operator's password*
- Test workflow
- Printout
- Quality control
- Operators* ("11.4.1 Operator access levels overview")

ⓘ ** Optional: Depends on the selected security level.*

At the end of the setup procedure, tap Start to exit the wizard. All settings can be reviewed on the **Options » View** settings screen. All settings can be modified on the **Options » Settings** screens.

6 Testing

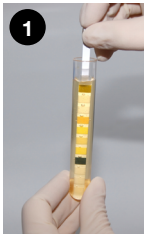
6.1 Measurement process

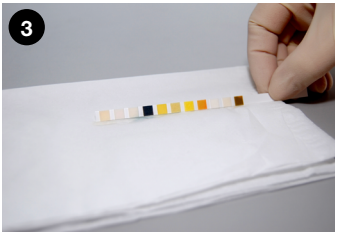
The analyzer can be operated in two different modes:

1. In normal mode, the system automatically waits for the strip to incubate for one 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.

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

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





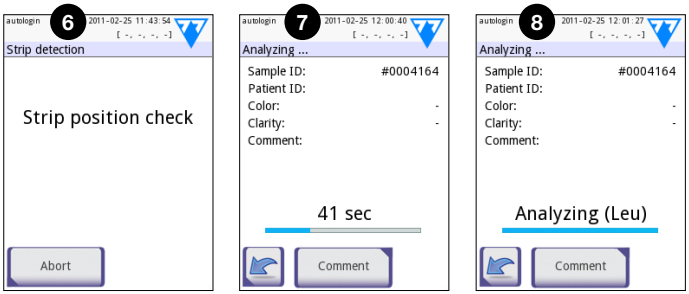
1. Dip the test strip into the urine sample, wetting all pads. Immediately remove the strip from the urine.
2. Drag the edge of the strip against the side of the sample container.
3. Blot by touching the edge of the test strip to a paper towel to remove excessive urine.

4. Place the test strip in the channel of the test strip tray with the test pads facing up.
5. The instrument will automatically detect an applied test 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.**

ⓘ *The DocUReader 2 Pro will perform a sequence of checks (reference pad, strip detection, position of slipped strip, dry strip, etc.) each time a test is run. See "13.1 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.

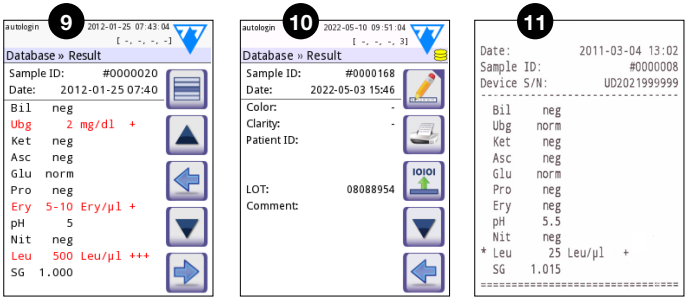
⚠ **To abort a measurement press the Back icon on the Analyzing screen and press Stop/Drop on the Measurement screen.**

⚠ **Comments can be 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 the test strip is removed 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. Than the display will return to the **Measurement** screen (if no error occurred during the readout). If the user touches the display while the circle animation is displayed, the system will not automatically return back.



9. Results Page 1/2
10. Results Page 2/2
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. 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 Select button the result can be selected.
- By pressing the Modify button the result can be modified.
- By pressing the Printer button the result can be printed.
- By pressing the Transfer button the result can be transferred.

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

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

Before performing the next measurement, remove the used test strip and dispose it according to the local standard laboratory procedures. Wipe off the test strip tray insert if necessary.

6.2 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, a connected external keyboard or barcode reader, or automatically by downloading the worklist items from the LIS.

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

Fig. 10: *The Worklist screen with the screen elements labelled*

ⓘ *For more detailed information about the worklist functions, please refer to the full User Manual (See chapter 1.4 How to use this manual).*

7 Recalling Results

The DocUReader 2 Pro device can store up to 3000 measurement records and 1000 QC measurement records. Every result is automatically saved after the analysis in an indexed database. Using the database, results can be searched, reviewed, printed or transferred to an external device.

ⓘ *By default, the analyzer prompts the user to free up memory (erase data) 30 records before reaching maximum database capacity. However, the database settings can be set up to a circular memory.*

Access to the database:

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

7.1 List view

Key to the screen

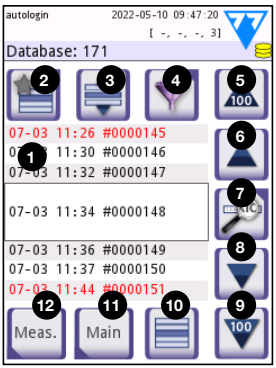


Fig. 11: *Database - List view*

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.
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 single record
11. Go to the Main screen
12. Go to the Measurement screen

The records have the following color coding for Patient and QC measurements:

Black text: Negative result

Red text: Positive result

Ochre text: Failed result

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

ⓘ *The results that belong to LabStrip U mALB/CREA test strips are marked with 'm'.*

7.2 Setting up filters to find specific results

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

- 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 measured by the operator, who setting up the filter).

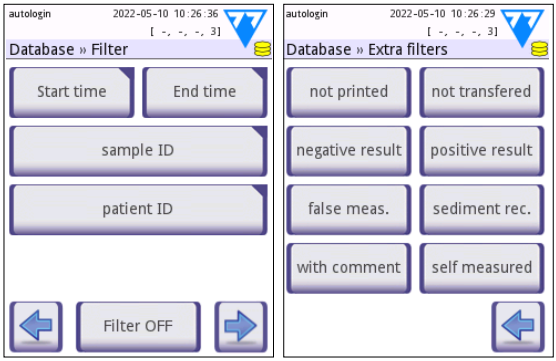


Fig. 12: *The Database » Filter screens*

Tap the corresponding button to activate a filter.

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.

ⓘ *For more detailed information about the database and filter functions, please refer to the full User Manual (See chapter 1.4 How to use this manual).*

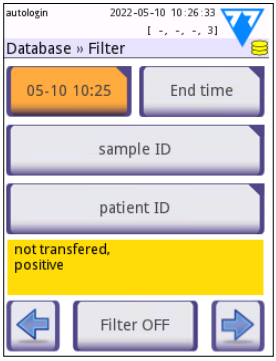


Fig. 13: *Examples of activated filters*

7.3 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 urine test strips) should be monitored regularly to ensure reliable results are obtained. To determine the frequency of quality control, consult your facility's quality control policy.

The following possibilities are offered to perform QC tests:

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

ⓘ *Several commercial controls are available. Control solutions may vary in the number of levels or components, the necessity for reconstitution or readiness for use or the type and volume of container. 77 Elektronika Kft. recommends the use of CombiScreen® Dip Check (Ref.: 93010) or Drop Check (Ref.: 93015) controls as these control solutions provide the necessary color development with LabStrip test strips. Other manufacturers' controls may provide non-specific colorations of the test pads.*

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

⚠ **Verify the performance of the device with the grey check strip after every accident (drops, spills, splashes), even if visible damage was not done. Do not touch the test area of the grey check strip. Hold the strip by its handle.**

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

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

Proper quality control is a three-phase process:

1. Configuring the system: Specifying urine control levels and setting the QC options on the **Options » Settings » QC Options** screen.
2. Setting the urine control LOT number and the acceptance limits. See "9.1 Editing QC LOT Information".

3. Performing QC testing at regular intervals. See “9.3 QC Testing”.

ⓘ *For more detailed information about the Quality control options, please refer to the full User Manual (See chapter 1.4 How to use this manual).*

8.1 Editing QC LOT Information

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) 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.

ⓘ *The expiry date of the QC solution LOT can also be entered. 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 (_).*

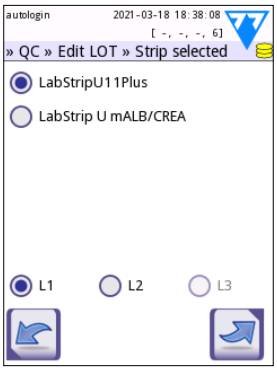


Fig. 14: *Select urine test strip*

Consult the control solution’s instruction of use and enter the acceptance limits for the type of control solution selected in step 2.

8.2 Setting QC solution acceptance limits

The columns of the table are from left to right: parameter, lower limit, higher limit, unit. A cursor box indicates which cell is selected.

Use the arrows to navigate the cells and the plus and minus buttons to increase or decrease the values.

Tap **OK** to store the values. The device will return to the QC options screen.

Repeat the previous steps for each level of control solution.

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

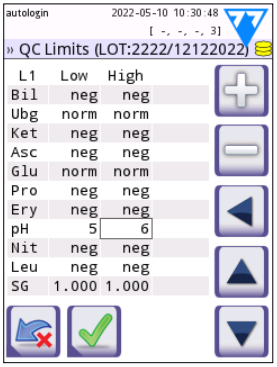


Fig. 15: *The QC limits screen*

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

8.3 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.

ⓘ *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.

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

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 a three-level control solution kit is used. If a LOT number and the acceptance limits for the given solution type are already entered 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 a new LOT code is entered on the numeric input screen, new acceptance levels must be set after tapping Next.**

ⓘ *If the quality check is successful, the system displays 'PASSED' next to the QC result. The button background for passed QC tests changes to green. If the QC measurement has failed, the system displays 'FAILED' next to the QC result. 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, 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.

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

9 The Options menu

The Options screen displays the following information:

- Registration Code
- Strip type and LOT code information,
- Output settings.

Following options are available from this screen:

- Strip LOT
- View Settings: Review and print settings
- User Options (Auto features, fast mode, sound, LCD brightness)
- Instrument Settings (See “11 Instrument Settings”).

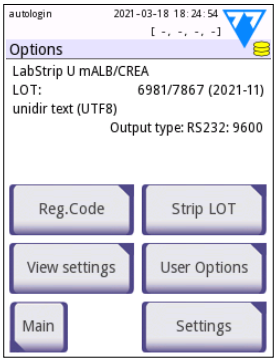


Fig. 16: *The Options screen*

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

ⓘ *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.

ⓘ *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 and the expiry of the test strips. 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.

ⓘ *The software does not check LOT code and expiry date entries. It is recommended to double-check the entered codes.*

ⓘ *For more detailed information about the Options menu and User options, please refer to the full User Manual (See chapter 1.4 How to use this manual).*

10 Instrument Settings

The DocUReader 2 Pro device offers several settings to suit the specific workplace requirements. System settings can be modified on the **Main » Options » Settings** screen.

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

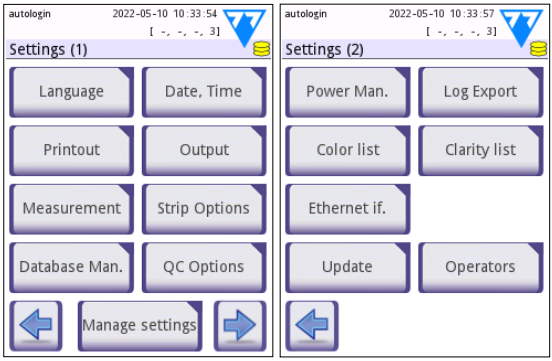


Fig. 17: *The Settings screen page 1 and 2*

ⓘ *For more detailed information about the instrument settings, please refer to the full User Manual (See chapter 1.4 How to use this manual).*

10.1 Output (Connectivity: Transfer/Export)

The DocUReader 2 Pro device can be connected 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 any of the three output protocols is selected and ▶ is tapped) is used to define the communication port (available options are based on the output protocol). Tap ◀ ▶ to scroll through the list.

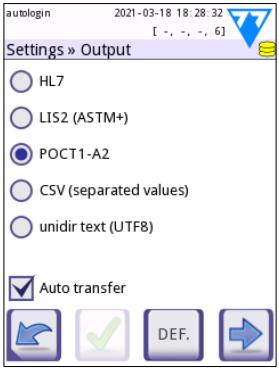


Fig. 18: *The Settings » Output screen*

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

ⓘ *For more detailed information about the output settings, please refer to the full User Manual (See chapter 1.4 How to use this manual).*

10.2 Strip options

The main strip options screen shows the available test strip. To modify the strip settings select the strip type 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 “2.1 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. The sensitivity can be modified between -2 and +2.

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

Tap **SED** to enable 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.

10.2.1 Reordering the test pads

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 correct position, tap Move once again to release it.

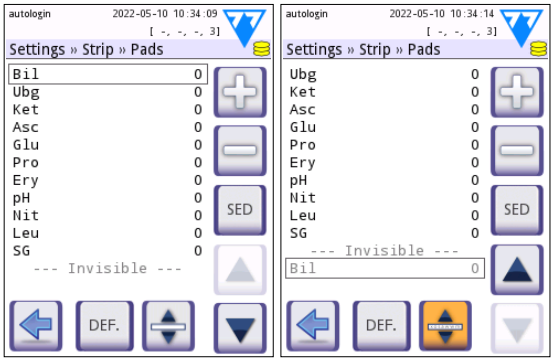


Fig. 19: *The Settings » Strip » Pads screen with an example of invisible analytes*

Any analyte can be excluded from the results view if it is moved 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 when they are restored above the ---Invisible--- line.*

10.3 Power management

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

- **LCD off time** (the screen saver starts)
- **Logout time** (the active operator is logged out)
- **After measurement logout**
- **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.

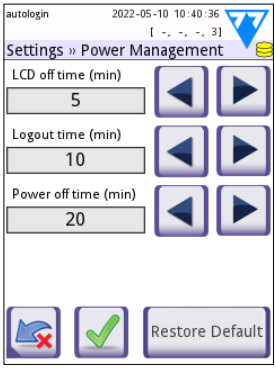


Fig. 20: *The Settings » Power management screen*

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.

10.4 Operators

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

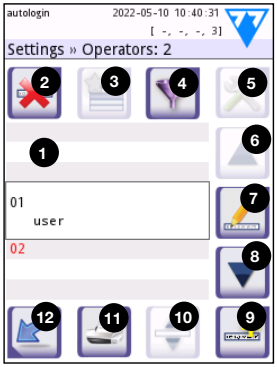


Fig. 21: *The Settings » Operators screen with its function buttons labelled*

Legend:

1. The list of operators
2. Delete selected operator (requires confirmation to prevent accidental data loss)
3. Data Exchange: 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

ⓘ *The order of the operators that will be displayed on the* **Login** *screen can be changed 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.*

11. Print operator list
12. Go back to the Settings screen

ⓘ *For more detailed information about the operator settings, please refer to the full User Manual (See chapter 1.4 How to use this manual)*

10.4.1 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: • worklist management • testing • quality control • printing and exporting results • editing user options.

Operator access level	User rights
Admin	Administrator-level operators can perform all user-level tasks, plus the following: • 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.

10.4.2 System security settings

The main security settings of the analyzer can be modified on the **Operators » Security** screen. This screen is only accessible for the Supervisors.

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.

Preprogrammed operators

- 'autologin': See "11.4.2 System security settings"
- 'self add': See "11.4.2 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.
- 'Full database and config clear.': If this string is entered (as is, without the inverted commas, but with a capitalized first word and a period (full stop) at the end) as an 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 to perform a "Log export 255" before a Full clear.*

10.4.3 Security settings overview

	1 Open system	**2 Anonymous usage**	**3 Self-add**	**4 Self-add with password**	**5 Secure**
auto login	☑ On	☑ On	☐ Off	☐ Off	☐ Off
auto login rights	admin	user	N/A	N/A	N/A
self add	☐ Off	☑ On	☑ On	☑ On	☐ Off
self add rights	N/A	user	user	user	N/A
password not required	☑ On	☑ On	☑ On	☐ Off	☐ Off
perform test	anyone (anonymous)	anyone (anonymous)	anyone	anyone	registered users
modify settings	anyone	admins	admins	admins	admins
modify security	supervisor (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

11 Maintenance

11.1 Cleaning the analyzer

⚠ **It is recommended to keep the DocUReader 2 Pro device clean and dust free.**

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

⚠ **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 and printer compartment.**

⚠ **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.**

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)

11.2 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 “2.4 Safety information” for further details.**

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 “4.5 Setup”.

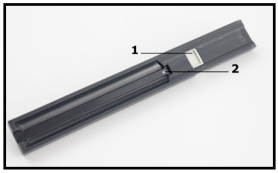


Fig. 22: *The test strip tray and its reference pad*

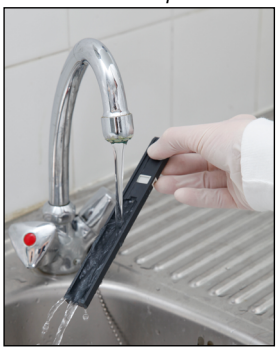


Fig. 23: *Rinsing the test strip tray*

11.3 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 to 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 to wipe every part of the roller surface.

11.4 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 to check that it is intact whenever during cleaning 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. If the device is routinealy operated at or close to peak throughput, the reference pad may need more frequent replacement.

12 Troubleshooting

12.1 Strip checking events

Errors in sample handling and testing procedure may lead to false results. In order to 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 “8.2 Setting up filters to find specific results”).

ⓘ *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, the result is saved either with a flag (R2) or an error code (R3).

12.2 Troubleshooting chart

Problem	Cause	Corrective action
1 The device does not respond to the On/Off switch.	1.1 The mains cable or the AC adapter is not plugged in correctly.	Check that the adapter is connected to the analyzer and that the mains cable is plugged into the wall socket. Make sure that the blue light on the AC adapter lights up when it is plugged in.
	1.2 The mains cable or the AC adapter is defective.	Check the mains cable and AC adapter for external signs of damage. If the cable or adapter is damaged, contact your certified service personnel.
	1.3 The On/Off switch is defective or it has lost its connection to the interface board.	Contact your certified service personnel.
	1.4 The microSD memory card is defective.	
	1.5 The Mainboard is defective.	
2 The device switches on, but the touchscreen does not light up.	The touchscreen is not connected properly to the Mainboard or the touchscreen is defective	Contact your certified service personnel.
3 The touchscreen is very dim.	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.	Calibrate the touchsreen as descriped in chapter 3.5.5 Calibrating the touchscreen
	4.2 The touchscreen is defective.	Contact your certified service personnel.
5 Measurement results are consistently below or above standard ranges.	The used test strips or the Optical module is defective	A) Repeat the meaurement with a new vial of test strips B) Perform a QC and Grey strip measurement to check the test strip and device performance. Contact your certified service personnel if the QC fails.

Problem	Cause	Corrective action
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 the device.
	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.
	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 function on the Main»Options»User Options screen.
	10.2 The paper loaded is not compatible with the printer.	Make sure that the correct 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. 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.

12.3 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.

12.3.1 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, there are two categories:

- Error messages (E): Indicating 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): 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 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.

ID	C	T	Short text	Full text	Corrective action
E90	E	S	Reference	Failure of reference pad check. Reference pad value of the tray is out of range. See User Manual for further instructions.	See “13.3.2 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
W67	W	S	Output init	Output not inited. 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 77 Elektronika 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.

ID	C	T	Short text	Full text	Corrective action
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 77 Elektronika 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.	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.
W38	W	S	Head version	Measure head SW version is unknown. Please call Service.	Contact your certified service personnel.
W37	W	S	Tempera-ture	Temperature out of allowed range.	Ensure the proper environmental conditions. See 3.3 Setup considerations.
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.
W30	W	S	Paper out	Paper out. Please replace the printer paper!	Open printer door and load a fresh paper roll in the printer.
E199	E	P		DB failure: cannot write result. Please call Service!	Contact your certified service personnel.
E198	E	P		DB failure: cannot modify result. Please call Service!	Contact your certified service personnel.
E197	E	P		DB failure: cannot delete result. Please call Service!	Contact your certified service personnel.
E196	E	P		DB failure: configuration is corrupted. Please check the configuration settings.	Contact your certified service personnel.
E195	E	P		Worklist DB failure: cannot write new item.	Contact your certified service personnel.
E194	E	P		Worklist DB failure: cannot insert or modify item.	Contact your certified service personnel.
E193	E	P		Worklist DB failure: cannot delete item.	Contact your certified service personnel.
E181	E	P		Load config error: read details from \"wpa_ supplicant.conf.err" file on PENDRIVE.	The system encountered a problem in the wpa_supplicant. con.zip file, and has saved an error report on the connected USB flash drive. Refer to the WPA Supplicant documentation to deal with the issue.
E180	E	P		Load config error: USB drive or "wpa_supplicant. con.zip" file not exists.	Make sure that the wpa_ supplicant.con.zip file is properly saved on the connected USB flash drive.
E177	E	T		Length of password must be between 8 and 63 characters	The password 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 the expiry date is separated from the QC LOT number with parentheses.

ID	C	T	Short text	Full text	Corrective action
E172	E	T		Time is expired	The expiry date of the QC solution LOT 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 77 Elektronika 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.
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 is not on the operator list. Enter another Operator ID.
E162	E	T		Operator disabled, please try again.	The operator name 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 The system does not recognize one or more external connectors (USB, RS232, Ethernet, and so on).” of the Troubleshooting chart.
W158	W	T		Cannot open file for output!	Check the output port and presence of the output storage.

ID	C	T	Short text	Full text	Corrective action
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 exist. 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 77 Elektronika 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. 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.

ID	C	T	Short text	Full text	Corrective action
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.
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

ID	C	T	Short text	Full text	Corrective action
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

12.3.2 Handling of failure of reference pad check (E90)

1. Remove the test strip tray and clean it paying particular attention to the reference pad.
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 the reference pad or test strip tray in case there is an available spare part.
5. If E90 remains after replacing the reference pad with a new one, please call service.

12.3.3 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.	Contact your certified service personnel.
E297	E	R	Head HW error: software check failed. Please call Service.	Contact your certified service personnel.
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.	Delete item from the database. If problem persists, contact your certified service personnel.

ID	C	T	Full text	Testing: Error Source & Corrective Action
E280	E	R	Configuration error. System configuration (or database) failed.	Delete item from the database. If problem persists, contact your certified service personnel.
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.	A) Check if the test strip tray is properly inserted and remove any obstacles from its path. B) Clean the test strip tray.
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. 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 test strips designed for automatic evaluation are used and that they are positioned correctly on the test strip tray.
E265	E	R	Measured value out of valid range for one or more pads.	A) Unrealistic data was collected. Make sure that the correct test strips are used. B) Check the test strips' date of expiry. Discard expired strips and open a new LOT of test strips.
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 ("4.3 Setup considerations") and repeat the test with a fresh strip.

ID	C	T	Full text	Testing: Error Source & Corrective Action
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 to add a comment.

12.3.4 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 text 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.

SW Update ID	C	T	Full text	Corrective action
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

13 Appendices

Appendix A Results table

The DocUReader 2 Pro analyzer prints the results in the following gradation of concentration using LabStrip urine test strips:

Parameter	Conventional Units (Conv.)	SI Units (SI)	Arbitrary
BIL (Bilirubin)	negative 0.5 mg/dl 1 mg/dl 3 mg/dl 6 mg/dl	negative 8.5 µmol/l 17 µmol/l 50 µmol/l 100 µmol/l	negative
UBG (Urobilinogen)	normal 2 mg/dl 4 mg/dl 8 mg/dl 12 mg/dl	normal 35 µmol/l 70 µmol/l 140 µmol/l 200 µmol/l	negative 1+ 2+ 3+ 4+
KET (Ketone)	negative 5 mg/dl 15 mg/dl 50 mg/dl 150 mg/dl	negative 0.5 mmol/l 1.5 mmol/l 5 mmol/l 15 mmol/l	negative (+) 1+ 2+ 3+
ASC (Ascorbic acid)	negative 20 mg/dl 40 mg/dl 100 mg/dl	negative 20 mg/dl 40 mg/dl 100 mg/dl	negative 1+ 2+ 3+

Parameter	Conventional Units (Conv.)	SI Units (SI)	Arbitrary
GLU (Glucose)	normal	normal	normal
	30 mg/dl	1.7 mg/dl	(+)
	50 mg/dl	2.8 mg/dl	1+
	150 mg/dl	8 mg/dl	2+
	500 mg/dl	28 mg/dl	3+
	1000 mg/dl	56 mg/dl	4+
PRO (Protein)	negative	negative	negative
	15 mg/dl	0.15 g/l	(+)
	30 mg/dl	0.3 g/l	1+
	100 mg/dl	1 g/l	2+
	500 mg/dl	5 g/l	3+
ERY / BLD (Blood)	negative	negative	negative
	5-10 Ery/µl	5-10 Ery/µl	1+
	50 Ery/µl	50 Ery/µl	2+
	300 Ery/µl	300 Ery/µl	3+
pH	5 / 5.5 / 6 / 6.5 / 7 / 7.5 / 8 / 8.5 / 9		
NIT (Nitrite)	negative	negative	negative
	positive	positive	1+
LEU (Leukocytes)	negative	negative	negative
	25 Leu/µl	25 Leu/µl	1+
	75 Leu/µl	75 Leu/µl	2+
	500 Leu/µl	500 Leu/µl	3+
SG (Specific Gravity)	1.000 / 1.005 / 1.010 / 1.015 / 1.020 / 1.025 / 1.030		

Parameter	Conventional Units (Conv.)	SI Units (SI)	Arbitrary
mALB	10 mg/l	10 mg/l	norm
	30 mg/l	30 mg/l	+
	80 mg/l	80 mg/l	++
	150 mg/l	150 mg/l	+++
	500 mg/l	500 mg/l	++++
CREA	10 mg/dl	0.9 mmol/l	10
	50 mg/dl	4.4 mmol/l	50
	100 mg/dl	8.8 mmol/l	100
	200 mg/dl	17.7 mmol/l	200
	300 mg/dl	26.5 mmol/l	300

Parameter	Conventional Units (Conv.)	SI Units (SI)	Arbitrary
ACR	-	-	-
	<= 30 mg/g	<= 3.4 mg/mmol	norm
	31 - 299 mg/g	3.5 -33.8 mg/ mmol	+
	>= 300 mg/g	>= 33.9 mg/ mmol	++
ACR>	Recollect sample*	Recollect sample*	Recollect sample*
	Normal	Normal	Normal
	Abnormal	Abnormal	Abnormal
	High abnormal	High abnormal	High abnormal

* mALB 10 mg/l + CREA 10 mg/dl (0.9 mmol/l)

Appendix B 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		
Environmental conditions	Temperature	Relative humidity	Altitude
Operating	+15˚C to +32˚C	30–80% (non-condensing)	3000 m (above sea level)
Storage	+5˚C to +40°C	10–85%	
Transportation	–25˚C to +60°C	75% at 30˚C	
Interfaces	PS2 (external keyboard, bar code scanner)		
	Serial RS232 (with transmission speeds 1200–115200 bps)		
	USB Type B		
	USB Type A		
	Ethernet / Wi-fi		
Expected lifetime	5 years or 50000 measurements		

Appendix C 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: **LabStrip U11 PLUS**

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

Printout:

Operator ID: ..... ON
Patient ID: ..... ON
Analyzer S/N: ..... ON
Sediment rec.: ..... ON
Strip LOT: ..... ON
Empty always: ..... OFF
Printout units: ..... conv-arbitr

Output:

unidir text (UTF8)

Header: ..... empty

Frame+CHKSUM: ..... ON

Output units: ..... conv-arbitr

Baud rate: 9600

QC options:

QC Lockout (day): 0

L1: ..... ON

L2: ..... ON

L3: ..... OFF

LOT expiry lockout: ..... OFF

Power management options:

LCD off time (min): 5

Logout time (min): 10

Power off time (min): 60

Database management options:

Circular memory: ..... OFF

Warning at circ.mem. limit: ..... OFF

Prewarning: 30

Authent. general settings:

Auto login: ..... OFF

Self add operators at login: ..... OFF

Login without password: ..... OFF

Operators on login screen: ..... OFF

LIS operator list check: ..... OFF

LIS operator list only: ..... OFF

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

Appendix D Support & ordering

D.1 Support

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

Phone: **+36 1 206 14 80**

Fax: **+36 80 27 77 77**

e-mail: **service@e77.hu**

D.2 Ordering

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

Part name	Part number	Pack size / amount
Labstrip U11 PLUS	ANA-9901-1	150 strips
Labstrip U mALB/CREA	ACR-9902-1	25 strips
Test strip tray	S-UD24406001	1
Grey strip	S-UD21150002	2
Printer paper	S-612EPL19	1
Power supply cord	S-35200307	1
Power supply adapter	S-1AGTM911	1

Appendix E Disposal information

⚠ **Do not dispose of an 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. Follow the local waste management guidelines and regulations to dispose the device and its parts.**

Disinfect or sterilize all the disassembled parts:

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

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

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

Appendix F Safety and compliance information

The 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.

CE Complies with the provisions of the applicable EU regulations.

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

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

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

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

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

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

F.1 Incident reporting

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

Appendix G Modification history

Version	Software	Modification
UD2-920102-1	2.2.3	First version: Short manual according to IVDR requirements

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