

OPERON Lateral Flow Reader Instructions for Use

Software Version 2.3 / 2.4



50008141-08

Revision Date: July 2021

Contents

1. Introduction	4
1.1. Intended Use of the OPERON Lateral Flow Reader.....	4
1.2. Target Population	4
1.3. Product Classification	4
1.4. Device Description.....	4
1.5. General Information	5
1.5.1. Scope of delivery	5
1.5.2. Technical assistance	6
1.5.3. Policy statement	6
1.5.4. Requirements for OPERON Lateral Flow Reader users.....	6
2. Safety Information.....	7
2.1. Proper Use	7
2.2. Electrical Safety.....	8
2.3. Environment	10
2.4. Biological Safety	10
2.5. Chemicals.....	12
2.6. Maintenance Safety	12
2.7. Waste Disposal.....	12
2.8. Symbols on the OPERON Lateral Flow Reader Instrument	13
2.9. Cybersecurity.....	14
3. General Description	15
3.1. Instrument Overview.....	15
3.2. Accessories of the Instrument.....	17
3.2.1. Drawer.....	17
3.2.2. External power supply	17
3.2.3. Power cord	17
4. Installation	18
4.1. Unpack the Instrument.....	18

4.2.	Site Requirements	18
4.3.	Power Cable Connection	18
4.4.	Cassette Requirements	18
5.	Operating Procedures.....	19
5.1.	Login Screen	19
5.2.	Home Screen Overview	20
5.3.	New Scan	21
5.4.	System Menu.....	27
5.4.1.	SYSTEM.....	27
5.4.2.	PRINTER (MANAGER).....	28
5.4.3.	NETWORK	30
5.4.4.	VERSIONS	32
5.5.	Side Menu	33
5.5.1.	Main Menu.....	33
5.5.2.	Cassette Settings.....	33
5.5.3.	Scan Results	35
5.6.	Tools Menu.....	39
5.6.1.	System Menu.....	39
5.6.2.	User Management - CHANGE PASSWORD	39
5.6.3.	User Management - USERS (Manager).....	41
5.6.4.	Logout	42
5.7.	Software Update	43
5.8.	Browser Generic Operations.....	44
6.	Troubleshooting	45
7.	Maintenance	47
7.1.	Cleaning Procedure	47
7.2.	Product Life	47
8.	Appendix A: Ordering Codes.....	48
8.1.	Spare Parts.....	48
8.2.	Optional Accessories	48

9. Appendix B: Technical Data	49
10. Appendix C: Warranty	51
11. Appendix D: Waste Electrical and Electronic Equipment (WEEE)	52
12. Appendix E: EC Declaration of Conformity	53
13. Appendix F: RoHS Statement	54

1. Introduction

Thank you for choosing the OPERON Lateral Flow Reader. We are confident that this instrument will become an integral part of your laboratory.

Before using the OPERON Lateral Flow Reader, it is essential that you read this user manual carefully. Following the instructions and safety information in this user manual will ensure safe operation and maintain the system in a safe condition.

1.1. Intended Use of the OPERON Lateral Flow Reader

The OPERON Lateral Flow Reader is intended for in vitro diagnostic (IVD) use in the detection and/or quantification of target analytes on lateral flow test strips.

The OPERON Lateral Flow Reader is designed to be used only in combination with lateral flow (LF) tests indicated for use with the OPERON Lateral Flow Reader, and only for applications that are described in the respective package inserts of our reader associates.

1.2. Target Population

The OPERON Lateral Flow Reader is intended to be used by trained qualified professional personnel within a hospital setting or in an outpatient setting such as in a physician's office. The intended use does not include the operation of the device in intensive care units or in operating rooms unless all specific hygiene and patient safety requirements of these locations are followed by the user.

1.3. Product Classification

According to Directive 98/79/EC, OPERON Lateral Flow Reader is classified outside of Annex II thus only an CE declaration of conformity is required.

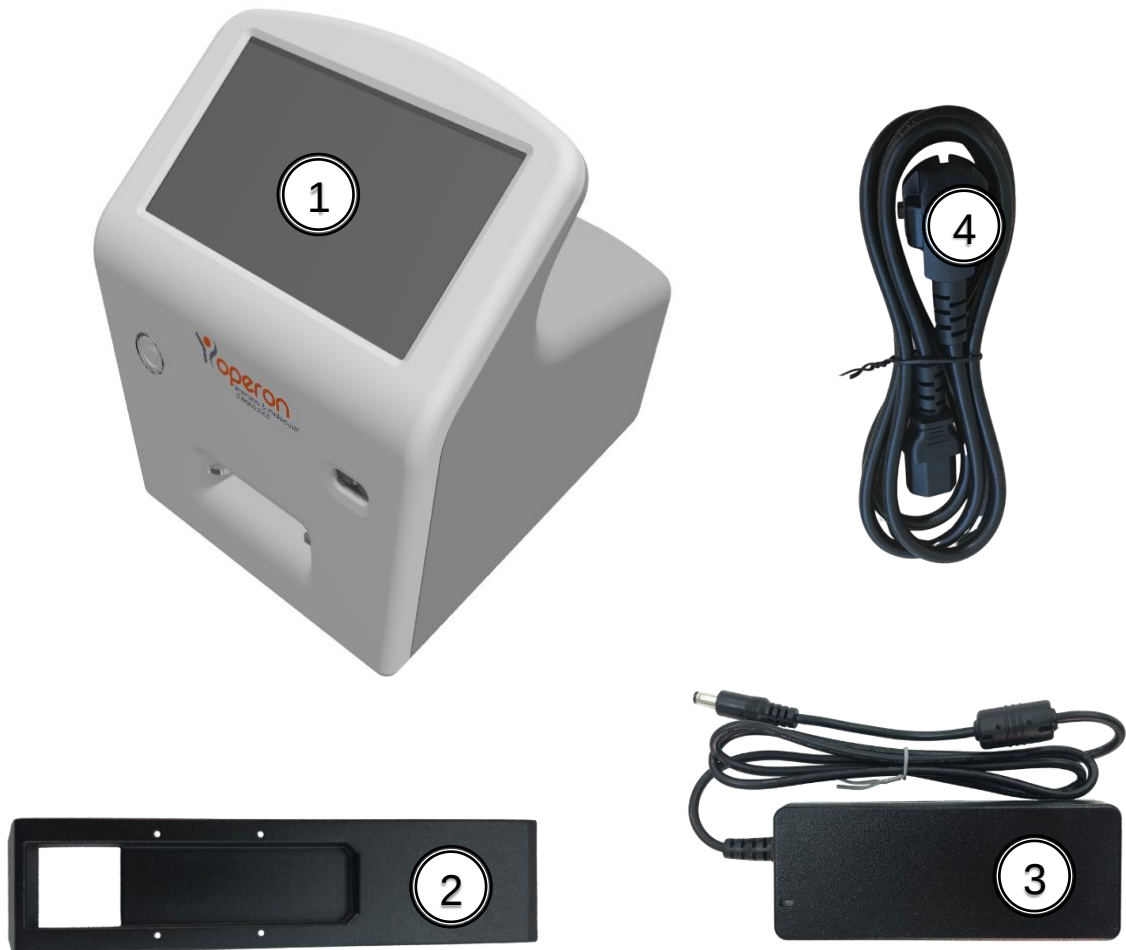
1.4. Device Description

This device is a portable reader of LF tests that will yield qualitative, semi-quantitative, and quantitative results for the lateral flow tests integrated in certain cassette models that are marketed by OPERON.

1.5. General Information

1.5.1. Scope of delivery

The delivery includes the following items:



1. OPERON main unit (Cat.100030000).
2. Drawer (Cat.900013342, Cat.900013435, Cat.900013315 or Cat.900013344).
3. External power supply unit (Cat.900020088).
4. Power cord (Cat.900020077, Cat.900020078, Cat.900020079, Cat.900020081, Cat.900020082, or Cat. 90004873).

See “Appendix A: Ordering Codes” for more information.

1.5.2. Technical assistance

At OPERON we pride ourselves on the quality and availability of our Technical Support. Our Technical Service Department is staffed by experienced technicians with extensive practical and theoretical expertise in the use of OPERON products. If you have any questions or experience any difficulties regarding the OPERON Lateral Flow Reader or OPERON products in general, do not hesitate to contact us.

OPERON customers are a major source of information regarding advanced or specialized uses of our products. This information is helpful to other customers as well as to the researchers at OPERON. We therefore encourage you to contact us if you have any suggestions about product performance or new application and techniques.

For technical assistance, contact OPERON Technical Service Department or local distributors.

1.5.3. Policy statement

It is the policy of OPERON to improve products as new techniques and components become available. OPERON reserves the right to change the specifications of products at any time.

In an effort to produce useful and appropriate documentation, we appreciate your comments on this user manual. Please contact OPERON Technical Service with any feedback.

1.5.4. Requirements for OPERON Lateral Flow Reader users

Table 1 covers the general level of competence for the use and servicing of the OPERON Lateral Flow Reader.

Task	Personnel	Training and experience
Routine use	Laboratory technicians or equivalent	Trained in techniques included in each cassette.
Servicing	Service Specialists only	Trained, certified, and authorized by OPERON.

2. Safety Information

Before using the OPERON Lateral Flow Reader, it is essential that you read this user manual carefully. Following the instructions and safety information in this Instructions for Use will ensure safe operation and maintain the system in a safe condition.

The following types of safety information appear throughout the OPERON Lateral Flow Reader Instructions for Use.

WARNING 	The term WARNING together with the symbol is used to inform you about situations that could result in personal injury to you or other persons. Details about these circumstances are given in a box like this one.
---	--

CAUTION 	The term CAUTION is used to inform you about situations that could result in damage to the instrument or other equipment. Details about these circumstances are given in a box like this one.
---	---

The advice given in this manual is intended to supplement, not supersede, the normal safety requirements prevailing in the user's country.

2.1. Proper Use

WARNING/ CAUTION 	Risk of personal injury and material damage Improper use of the OPERON Lateral Flow Reader instrument may cause personal injury or damage to the instrument. The instrument must only be operated by qualified personnel.
--	--

CAUTION 	Damage to the instrument Avoid spilling water or chemicals onto the OPERON Lateral Flow Reader instrument. Damage caused by water or chemical spillage will void your warranty.
---	---

In case of emergency, switch off the OPERON Lateral Flow Reader with the power button and unplug the power cord from the power outlet.

2.2. Electrical Safety

If operation of the OPERON Lateral Flow Reader is interrupted in any way (e.g., due to interruption of the power supply or a mechanical error), first unplug the power cord from the power outlet, then switch off the instrument using the power button. Contact OPERON Technical Service after such an incident.

WARNING 	Rechargeable Batteries The OPERON Lateral Flow Reader has a battery pack inside that accomplishes the IEC 62133 standard: Secondary cells and batteries containing Alkaline or other Non-Acid Electrolytes – safety requirements for portable sealed secondary cells and for batteries made from them, for use in portable Applications - This WARNING is applicable to routine users as well as to technical service users. • Do not dismantle, open or shred batteries • Keep batteries out of the reach of children • Seek medical advice immediately if a battery has been swallowed • Do not expose batteries to heat or fire. Avoid storage in direct sunlight • Do not remove a battery from its original packaging. • Do not subject batteries to mechanical shock • In event of a cell leaking, do not allow the liquid to come in contact with the skin or eyes. If contact has been made, wash the affected area with copious amounts of water and seek medical advice. • Only use Batteries provided by OPERON. • After extended periods of storage, it may be necessary to charge and discharge the batteries several times to obtain maximum performance.
---	---

WARNING 	Electrical hazard Any interruption of the protective conductor (earth/ground lead) inside or outside the instrument or disconnection of the protective conductor terminal is likely to make the instrument unsafe. This must be checked after service or maintenance. Intentional interruption is prohibited. Lethal voltages inside the instrument This WARNING is applicable to routine users as well as to technical service users. • Risk of electrical shock and energy hazard. All failures should be examined by a qualified technician. Please do not remove the case of the AC adaptor by yourself! • Adaptors should be placed on a reliable surface. A drop or fall could cause damage.
---	--

	• Please do not place the AC adaptor in places with high moisture or near the water. • Please do not place the AC adaptor in places with high ambient temperature or near a fire source. About the maximum ambient temperature, please refer to “Appendix B: Technical Data”. • Disconnect the AC adaptor from the AC power before cleaning. Do not use any liquid or aerosol cleaner. Only use a damp cloth to wipe it. • In case of replacement or a loosening of the AC adaptor or the mains power cord, these must be replaced only with the AC adaptors or power cords listed on “Appendix A: Ordering Codes” In case of replacement, this must be ordered to OPERON.
--	---

To ensure satisfactory and safe operation of the OPERON Lateral Flow Reader:

- The power cord of the external power supply must be connected to a line power outlet that has a protective conductor (earth/ground).
- No other external power supply neither power cords than the specified in “Appendix A: Ordering Codes” must be used. In case of replacement, this must be ordered to OPERON.
- The instrument must not be operated with the cover opened.
- If you suspect any instrument damage, contact OPERON Technical Services.

If the OPERON Lateral Flow Reader becomes electrically unsafe, prevent other personnel from operating it, and contact OPERON Technical Service.

The instrument may be electrically unsafe if:

- The instrument or the external power supply appears to be damaged.
- The instrument has been stored under unfavorable conditions for a prolonged period.
- A different external power supply is used other than the one provided by OPERON.

WARNING 	Risk of electric shock In case of replacement or loss of the external power supply or the power cord, these must be replaced <u>only</u> with the external power supply or power cords listed on “Appendix A: Ordering Codes” and provided by OPERON.
---	---

2.3. Environment

Operating conditions

WARNING 	Explosive atmosphere The OPERON Lateral Flow Reader is not designed for use in an explosive atmosphere.
CAUTION 	Direct sunlight Do not expose the OPERON Lateral Flow Reader to direct sunlight or other powerful lights during operation.
CAUTION 	High humidity or liquids Protect the OPERON Lateral Flow Reader from high humidity and contact with liquids.
CAUTION 	Strong electromagnetic radiation Do not expose the OPERON Lateral Flow Reader to strong electromagnetic radiation.
CAUTION 	Strong ultrasonic radiation Do not expose the OPERON Lateral Flow Reader to strong ultrasonic radiation.

2.4. Biological Safety

Use safe laboratory procedures as outlined in publications such as Biosafety in Microbiological and Biomedical Laboratories, HHS:

<https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF>

WARNING 	Samples containing infectious agents Some samples used with the OPERON Lateral Flow Reader may contain infectious agents. Handle such samples in accordance with the required safety regulations. Always read how to proceed in the LF test's instructions of use. The responsible person(s) (e.g., laboratory manager) must take the necessary precautions to ensure that the workplace is safe and that the instrument operators are suitably trained and not exposed to hazardous levels of infectious agents, as defined in the applicable
---	--

	Safety Data Sheets (SDSs) or OSHA¹ ACGIH² or COSHH³ documents. Venting of fumes and disposal of wastes must be in accordance with all national, state, and local health and safety regulations and laws.
WARNING 	Samples containing infectious agents Use safe laboratory procedures as outlined in publications such as <i>Biosafety in Microbiological and Biomedical Laboratories</i>, HHS: https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF See: Section III—Principles of Biosafety Laboratory Practices and Technique The most important element of containment is strict adherence to standard microbiological practices and techniques. Persons working with infectious agents or potentially infected materials must be aware of potential hazards and must be trained and proficient in the practices and techniques required for handling such material safely. The director or person in charge of the laboratory is responsible for providing or arranging the appropriate training of personnel.
WARNING 	Samples containing infectious agents To avoid hazards in case of cassette break use Primary Barriers and Personal Protective Equipment: Use safe laboratory procedures as outlined in publications such as <i>Biosafety in Microbiological and Biomedical Laboratories</i>, HHS: https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF See: Section III—Principles of Biosafety Safety Equipment (Primary Barriers and Personal Protective Equipment) Safety equipment includes BSCs, enclosed containers, and other engineering controls designed to remove or minimize exposures to hazardous biological materials.

¹ OSHA: Occupational Safety and Health Administration (United States of America).

² ACGIH: American Conference of Government Industrial Hygienists (United States of America).

³ COSHH: Control of Substances Hazardous to Health (United Kingdom).

2.5. Chemicals

WARNING 	Hazardous chemicals Some chemicals used with the OPERON Lateral Flow Reader may be hazardous. Always wear safety glasses, gloves, and a lab coat. The responsible person(s) (e.g., laboratory manager) must take the necessary precautions to ensure that the workplace is safe and that the instrument operators are suitably trained and not exposed to hazardous levels of toxic substances (chemical or biological), as defined in the applicable Safety Data Sheets (SDSs) or OSHA, ACGIH or COSHH documents. Venting of fumes and disposal of wastes must be in accordance with all national, state, and local health and safety regulations and laws.
---	---

2.6. Maintenance Safety

CAUTION 	Damage to the instrument Do not use spray bottles containing alcohol or disinfectant to clean the surface of the OPERON Lateral Flow Reader instrument. Do not use products containing alcohol or other corrosive solvents to clean the OPERON Lateral Flow Reader instrument.
---	---

WARNING 	Risk of electric shock Do not open the panels on the instruments. Risk of personal injury and material damage Only perform maintenance that is specifically described in this Instructions for Use.
---	--

2.7. Waste Disposal

Used consumables, such as cassettes may contain hazardous chemicals or infectious agents. Such waste must be collected and disposed of properly in accordance with local safety regulations.

All packaging waste from cassettes must be collected and disposed properly in accordance with local environmental regulations.

For disposal of waste electrical and electronic equipment (WEEE) see “Appendix D: Waste Electrical and Electronic Equipment (WEEE)”.

2.8. Symbols on the OPERON Lateral Flow Reader Instrument

Symbol	Location	Description
	Type plate on the bottom of the instrument and the external box label	CE Mark, Declaration of Conformity, see "Appendix E: EC Declaration of Conformity".
	Type plate on the bottom of the instrument and the external box label	Legal manufacturer.
	Type plate on the bottom of the instrument and the external box label	The device is an IVD product.
	Type plate on the bottom of the instrument	Date of manufacture.
	Label on the side of the external box	Catalog Number.
	Type plate on the bottom of the instrument and the external box label	Serial Number.
	Label on the side of the external box	Temperature limit, see "Appendix B: Technical Data".
	Label on the side of the external box	Humidity limit, see "Appendix B: Technical Data".
	Only in the cassettes that have a biological hazard (information on the cassettes' instructions for use)	Biological hazard symbol.
	Type plate on the bottom of the instrument and the external box label	Consult instructions for use.

Symbol	Location	Description
	Type plate on the bottom of the instrument and the external box label	Consult caution information in the instructions for use.
	Label on the side of the external box	All components of the instrument are recyclable.
	On the bottom of the drawer	Identify the material the drawer is made of (Polyamide).
	Type plate on the bottom of the instrument and the external box label	Waste Electrical and Electronic Equipment (WEEE), see "Appendix D: Waste Electrical and Electronic Equipment (WEEE)".

2.9. Cybersecurity

The software (SW) of the instrument is an essential part of the instrument and it is not distributed separately. All the cybersecurity controls are integrated in the SW storage, including SW integrity verification, firewall, or others.

To avoid final operator user to manage technical setups there is another kind of privileged user (role Manager) that could manage users, printers, and network setups.

The instrument starts with a Login Screen, to introduce user and password before operating it.

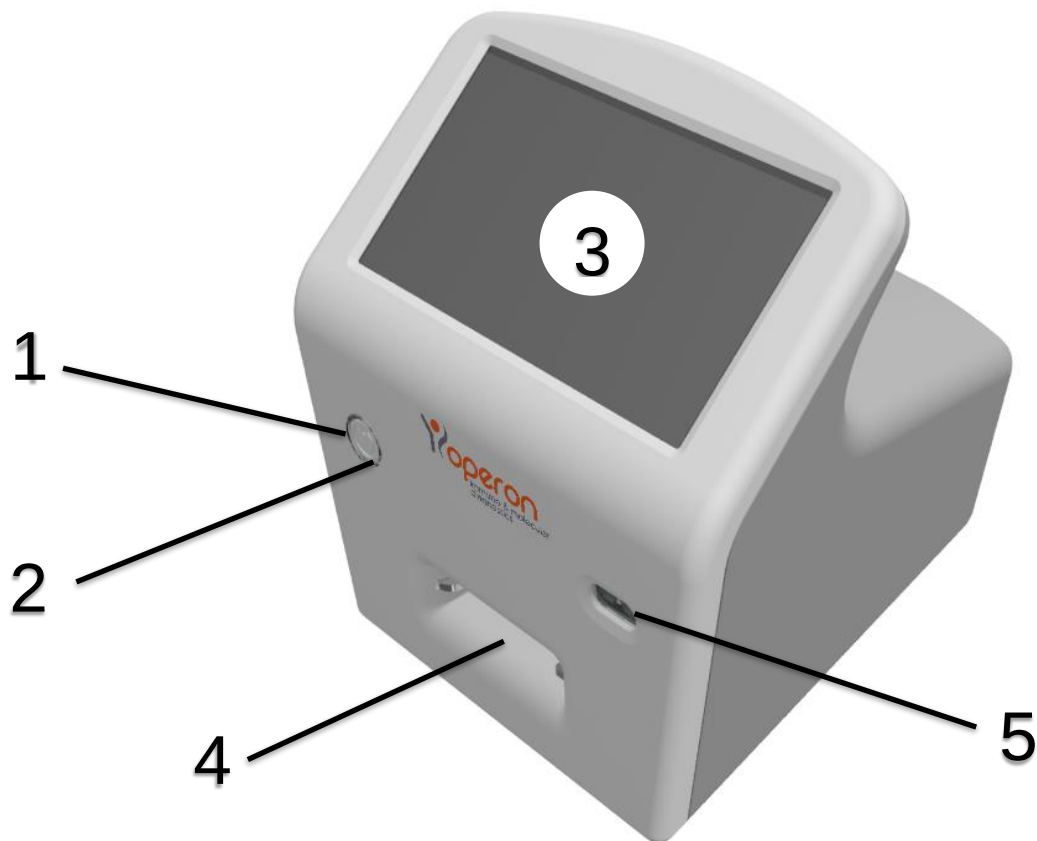
There is an audit trail integrated into the SW to store performed actions involving medical data.

NOTE: Contact with OPERON to request technical specifications of Remote Export and Audit Trail functionalities.

3. General Description

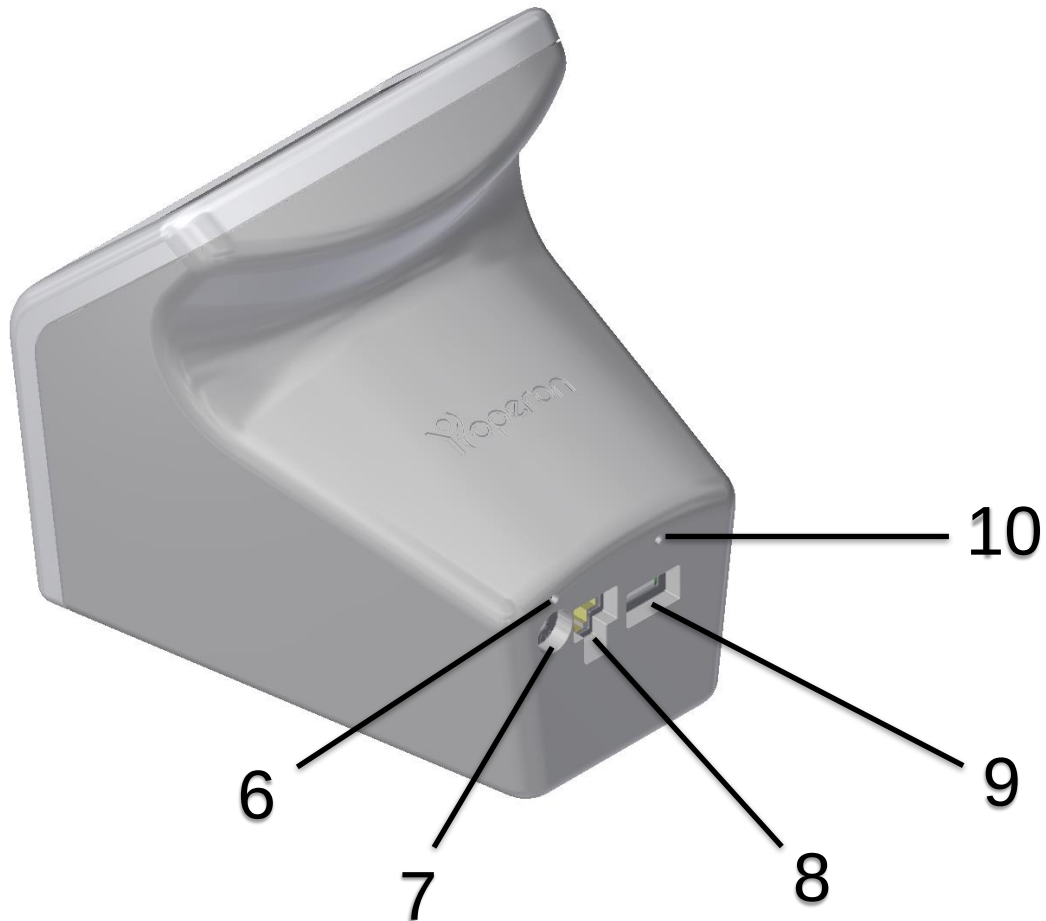
3.1. Instrument Overview

FRONT VIEW:



1. Power button
2. Device ON white LEDs
3. Touchscreen and display
4. Drawer insertion slot
5. Barcode reader

REAR VIEW:



- 6. Battery in charge red LED
- 7. External power supply socket
- 8. Ethernet socket
- 9. USB host port (only accessible for narrow USB memory sticks)
- 10. Software Wipe button hole

ATTENTION: For proper insertion of a narrow USB memory stick, its body section near the connector must be 8,5x16mm or less.

3.2. Accessories of the Instrument

3.2.1. Drawer

The drawer model must fit with the corresponding cassette model for a proper use of the instrument. See “Appendix A: Ordering Codes” to find available models.

3.2.2. External power supply

Connect the external power supply to mains, and the instrument to the external power supply to charge it. The red led above power supply socket should be lit when the power supply is properly connected.

WARNING 	Risk of electric shock In case of replacement or loss of the external power supply, this must be replaced <u>only</u> with one of the power cords listed on the “Appendix A: Ordering Codes” delivered by OPERON.
---	---

3.2.3. Power cord

The instrument is equipped with a power cord with a plug suitable for the destination country. See “Appendix A: Ordering Codes” for details.

WARNING 	Risk of electric shock In case of replacement or loss of the power cord, this must be replaced <u>only</u> with one of the power cords listed on the “Appendix A: Ordering Codes” delivered by OPERON.
---	--

4. Installation

4.1. Unpack the Instrument



The packaging of the OPERON Lateral Flow Reader can be stored for reuse.

CAUTION



Before switching on the reader for the first time or after a long period of inactivity, it is essential to plug it into the mains supply. Failure to do so may cause permanent damage to the unit.

4.2. Site Requirements

Place the OPERON Lateral Flow Reader instrument on a stable surface, far away from powerful lights and near an earthed/grounded electrical outlet.

For a long period of use, kept the OPERON Lateral Flow Reader instrument connected to a power supply.

4.3. Power Cable Connection

The socket for connecting the power cable is on the back of the OPERON Lateral Flow Reader instrument.

When the OPERON Lateral Flow Reader is not in use for a long period of time, we recommend disconnecting the power cable.

4.4. Cassette Requirements

Before using the OPERON Lateral Flow Reader instrument make sure that the cassette has not exceeded its expiration date.

ATTENTION

Do not use expired cassettes

Review the expiration date of the cassette and do not use it if it is expired.

5. Operating Procedures

CAUTION



Before switching on the reader for the first time or after a long period of inactivity, it is essential to plug it into the mains supply. Failure to do so may cause permanent damage to the unit.

5.1. Login Screen

To start the instrument, press the power button on and then wait until the boot process ends and the Login Screen is shown:

To enable the instrument, fill properly 'Username' and 'Password' fields (see yellow and red circles) and then press 'OK' button (see green circle). To edit each field, press on it to access the virtual keyboard (see left image), type suitable text, and press 'Enter' button. No special characters can be used.

- Default Operator username is **“operator”** and its default password is **“pwd”**.
- Default Manager username and password are **“manager”**.

ATTENTION: Default password MUST be changed by authorized users to preserve the correct use of the instrument.

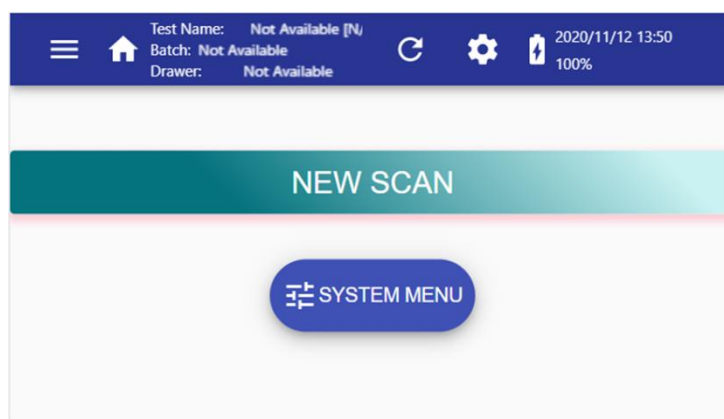
NOTE: If you forget or lose “manager” passwords, contact OPERON.

NOTE: If you forget or lose your “operator” password, contact OPERON.

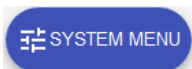
To end the user's session, select 'Logout' on Tools Menu (see section 5.6.4 for more information) or power off the OPERON Lateral Flow Reader instrument.

5.2. Home Screen Overview

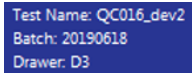
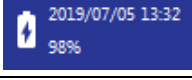
The home screen displays the current cassette configuration, date, time, battery status, 'NEW SCAN' button, and "SYSTEM MENU" button.



Home Screen:

	Press this button to start the process to read and process a new cassette.
	Press this button to enter 'SYSTEM MENU'.

Main Toolbar:

	Shows the drop-Side Menu.
	Return to Home screen.
	Information of the current Cassette Configuration available to be used.
	Press it to refresh the current screen. When a new page or image is loading, the icon spins.
	Shows the dropdown Tools Menu.
	Date, time, and battery status are shown here.
	Airplane icon. Only visible when airplane mode is enabled.

5.3. New Scan

To perform a new scan, the next steps should be followed:

- 1- Push the 'NEW SCAN' button on the Home screen (see red circle) to enter the scanning screen.

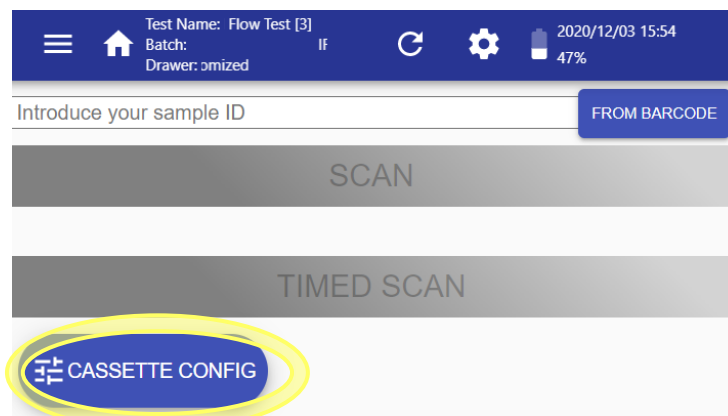


- 2- Omit this step if the current Cassette Settings is the Cassette Settings to use in the next scan. This step may be required in certain configurations.

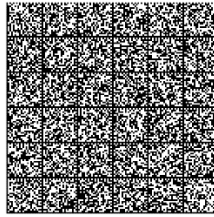
To set the proper Cassette Settings that will be used in the next scan, there are the following options:

Option A: to load a new Cassette Settings through the barcode reader.

To load a new Cassette Settings, press the 'CASSETTE CONFIG' button (see yellow circle).



Take the Cassette Configuration barcode which is supplied along with the cassette box:



Place it in front of the instrument's barcode reader (see section 3.1).at 5 cm of distance approximately. Press on the 'ACTIVATE BARCODE READ' (see red circle). The barcode reader will start the scanning using a light that will disappear when the barcode has been read or after 10 seconds of trying.



NOTE: If a barcode cannot be read, check and clean the window of the barcode reader (see section 3.1).

If the barcode is read but does not fit with which is expected, an error message will appear on the screen. Check the exposed barcode and touch the display outside the dialog box to skip the error message and return to the above window.

In the new screen, the new Cassette Configuration data are shown in the Tab bar.

Option B: select an available Cassette Settings from the list.

B.1 Select from the 'Cassette Settings' list. If the Cassette Settings was previously uploaded, it is not required to upload the Cassette Settings again. Go to the Side Menu, press 'Cassette Settings', and the list of Cassette Settings is displayed.

Name	Code	Batch	
Qualitative Method	384	lot 03A9	SELECT AS CURRENT
Qualitative Method	384	lot 0B15	SELECT AS CURRENT
Qualitative Method	282	lot 002F7	SELECT AS CURRENT
Qualitative Method	282	lot 0C6D0	SELECT AS CURRENT

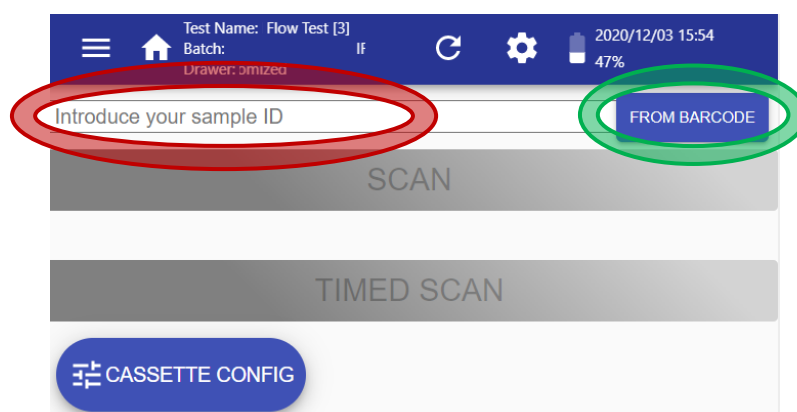
1-4 of 4 < >

Press the 'SELECT AS CURRENT' button to load the Cassette Settings of the row.

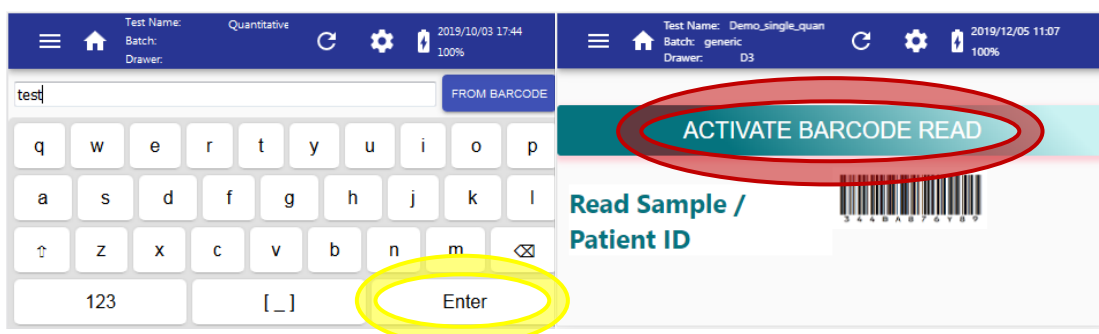
B.2 'Barcode Autodetection' launch directly the scan if the option 'Barcode Autodetection' is selected by the IUL's partner.

ATTENTION: The LFR will automatically load the proper Cassette Settings if it is stored (Cassette Settings list), the current cassette has a Confirmation Barcode embedded in it and some valid (not expired) Cassette Settings are shown on the Top Bar.

- 3- Once the proper Cassette Settings is uploaded, press on the text 'Introduce your sample/patient id' (see red circle) to type the identification with a virtual keyboard or press on the 'FROM BARCODE' button (see green circle) to scan the identification using the barcode reader of the device. This step may be compulsory or not depending on the options selected in the System Menu.



After typing an identification text on the virtual keyboard, press the 'Enter' button (see the yellow circle on the left-side image) to proceed. To load the identification text from a barcode, press the 'ACTIVATE BARCODE READ' button (see the red circle on the right-side image) and place the barcode in front of the reader's light.



NOTE: Depending on the options of the System Configuration, if the entered reference you enter is already in the OPERON Lateral Flow Reader's stored results, a message is displayed, and scan buttons could be disabled.

Sample/patient ID using the virtual keyboard: Special characters are not available and its maximum length is 30.

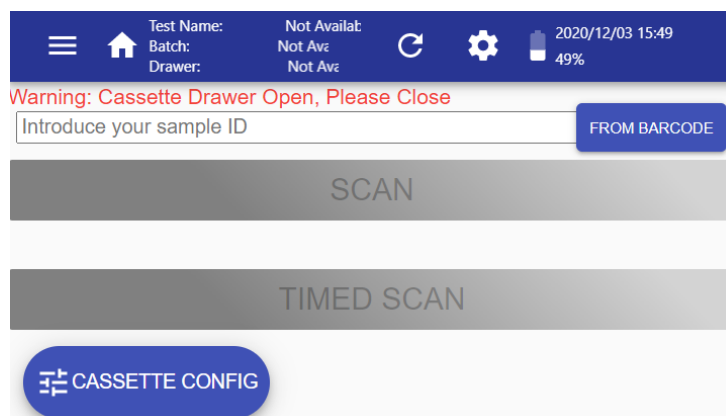
Sample/patient ID using barcode reader: Special characters are allowed and the maximum length is 1024. See section 5.5.3 to know how IDs are displayed in different scenarios.

- 4- Insert the cassette into the corresponding drawer; ensuring that the code in the drawer bottom (see yellow circle) agrees with the drawer code displayed along with the cassette configuration at the top bar. Be sure that the cassette and the drawer surfaces are leveled; then push the drawer inside the reader.

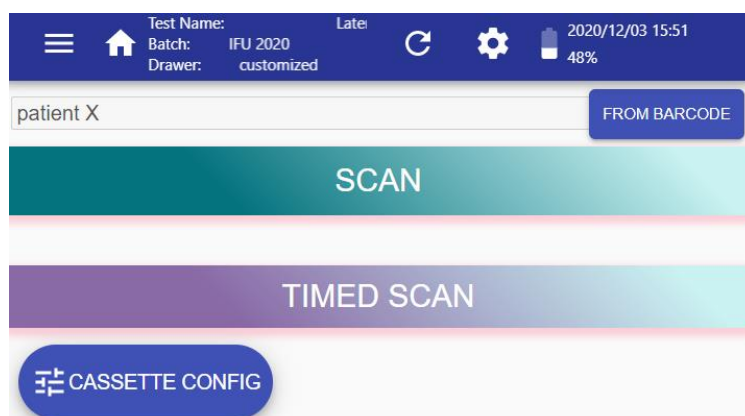


NOTE: Ensure that the strip embedded in the cassette is free of impurities such as hair or dust.

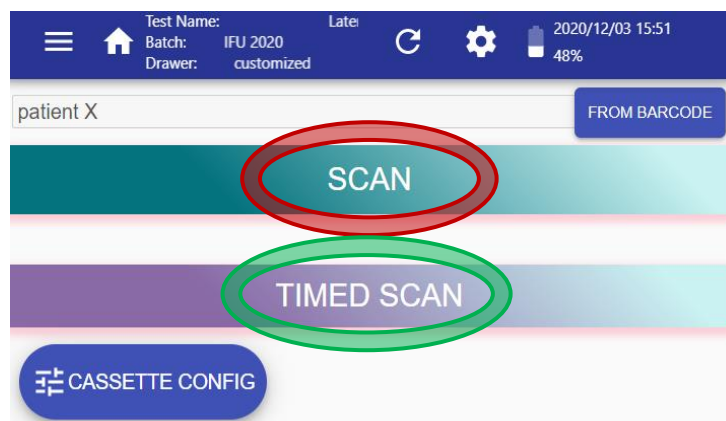
A warning is shown on the screen to remember closing the drawer (see next image). Place the drawer properly inside the reader to remove the warning.



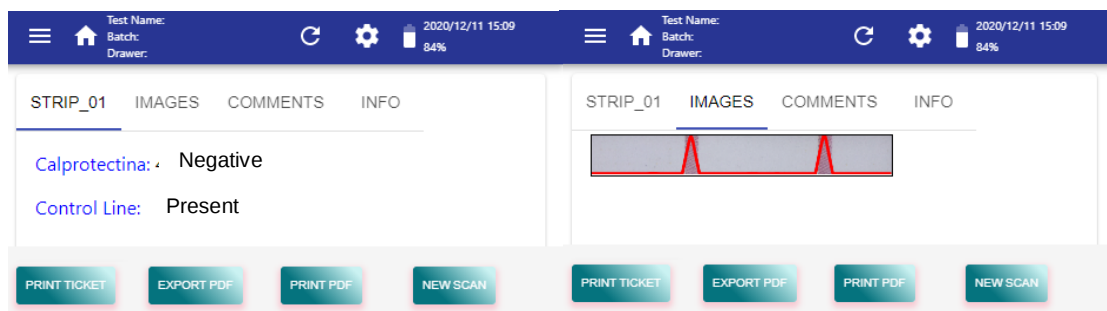
The scan buttons ('SCAN' and 'TIMED SCAN') remain in grey until a valid Cassette Settings is loaded, an ID is set (if required), and a drawer is placed inside the reader. Depending on the reader's configuration a cassette's confirmation barcode could be also required. When all conditions are reached the scan buttons turn coloured, as the following image:



- 5- Two options are available to scan a cassette: (1) If you have already waited the prescribed time after inoculating the sample into the cassette, press the 'SCAN' button (see red circle) to scan the cassette immediately. (2) If you have just inoculated the sample into the cassette, press the 'TIMED SCAN' button (see green circle) to defer the scan to the prescribed waiting time. When the second option is selected a countdown is shown until the scan starts.



- 6- The results of the scan will be displayed when the process ends. Drag up and down on the touchscreen, and press on the different tabs to see all data (see section 5.5.3 for more information). See section 5.5.3 for more information about the functionalities of its buttons.



To process another cassette, press the 'NEW SCAN' button on the bottom-right corner.

WARNING 	The reader will provide reliable results as long as the tests are running according to the IUL's partner specifications, the control and test lines are differentiated from the background, as well as the cassette does not present artifacts or impurities such as hair or dust.
---	---

5.4. System Menu

Set the configuration through this menu. Different tabs are available, depending on the user's role.

5.4.1. SYSTEM

Language	English ▾
Inactivity Shutdown Timeout (min)	– 30 +
Format USB	FORMAT
Export Logs to USB	EXPORT
Set Date/Time	SET DATE/TIME
Set Time Zone	SET TIME ZONE
Remote Export	TOKENIZE
Remote Network Setup	SETUP
Adjust Capture Parameters	ADJUST

NOTE: Depending on the configuration some items are not displayed.

- 'Language': Select one language among those that are already installed in the reader.
- 'Inactivity Shutdown Timeout (min)': Time in minutes since the last interaction with the reader, and the system powers-down itself to save battery. The default value is 30 minutes. Contact to your Manager to increase this value.
- 'Format USB': Press this button to format a slim USB memory stick and then be able to use it to export CSV and PDF results, write logs, and to update the reader software.
- 'Export Logs to USB': Writes some internal files to a slim USB memory stick plugged into the USB host port, in order to send them to the Technical Service to aid for diagnose.
- 'Set Date/Time': Allows defining the current date and time. This parameter has configurable access.

NOTE: The instrument is not ready to work with dates before the manufacture's date.

- 'Set Time Zone': Allows defining the current time zone.

ATTENTION: After changing Time Zone re-start the reader.

- 'Remote Export': Press the 'TOKENIZE' button to claim the server for a token update. This parameter has configurable access.
- 'Remote Network Setup': Press the 'SETUP' button to load available SFTP setup, including network domain: Ethernet, WLAN, airplane mode. The reader's Manager is responsible for defining a proper SFTP and network setup for a specific domain. This parameter has configurable access.

ATTENTION: To use 'TOKENIZE' and 'SETUP' buttons Internet connection is needed.

- 'Adjust Capture Parameters': To readjust the camera parameters insert the Self-adjusting light Drawer (optional accessory Cat.900013732), connect the reader to the power supply, and press 'ADJUST' to start the process.

ATTENTION: The adjustment drawer must be in good condition, otherwise the process could misadjust the device. To improve the adjustment process avoid direct illumination on the drawer slot.

5.4.2. PRINTER (MANAGER)

Users with the role of Manager can access this screen. A desktop printer model could be selected, and communication parameters for a ticket printer are displayed and could be edited.

Desktop printer	HP_DeskJet_2600_series ▼
Baud Rate	9600 ▼
Parity	None ▼
Data Bits	8 ▼
Stop Bits	1 ▼

- Desktop printer: To select a desktop printer model.
- Baud rate: Default value is "9600".
- Parity: Default value is "even".
- Data bits: Default value is "8".

- Stop bits: Default value is “1”.

Both desktop printer and ticket printer must be connected to the reader USB host port (see section 3.1).

Introduce Baud rate, Parity, Data bits, and Stop bits that corresponds with configuration of the used ticket printer.

The ticket printer **MUST** support ESC/P control language, and there are two options:

- A-** Ticket printer with serial port, and an external USB to serial port adaptor.
- B-** Ticket printer with USB port, internally emulating serial port.

To use the ticket printer Cat.90003069 (see 8.2 section), you should also order the USB adapter cable Cat.90004874.

5.4.3. NETWORK

Users with the role of Manager can edit the parameters of this screen. Users with the Operator's role only Airplane Mode is able to set. Network communications parameters are displayed.

Airplane Mode	☐
Ethernet	SET
Status	On
Mode	DHCP Client
IP	192.168.10.100
Mask	255.255.255.0
Broadcast	192.168.10.255
Gateway	192.168.10.1
WLAN	SET
Status	On
Mode	Access Point
SSID	lfr_2037
IP	192.168.138.1
SFTP	SET
Server	localhost
Port	22
HL7 path	LFR/data
PDF path	LFR/reports
Username	H-manager
Delete	Delete

- 'Airplane Mode': If ON, Wi-Fi connections are disabled, and an airplane icon is shown in the Top Bar.

- 'Ethernet': Displays current Ethernet configuration. Press on its SET button to configure it. With option 'DHCP Client' (default), the network server will assign network parameters to reader. If the option 'Static' is selected the connection parameters must be set on (specifically: IP, Mask, and Gateway).

The image shows two side-by-side screenshots of the Ethernet configuration interface. The left panel shows the 'DHCP Client' mode selected, with 'CLOSE' and 'SAVE' buttons at the bottom. The right panel shows the 'Static' mode selected, with input fields for IP, Mask, and Gateway, and 'CLOSE' and 'SAVE' buttons at the bottom.

- 'WLAN': Displays current Wi-Fi network configuration. Press on its SET button to configure it. With option 'Access Point' (default), its SSID and password should be set but also a subnet selected from available ones. With option 'DHCP Client' it is possible to connect the reader to a Wi-Fi net if proper SSID and password are set.

The image shows two side-by-side screenshots of the WLAN configuration interface. The left panel shows the 'Access Point' mode selected, with input fields for SSID, Password, and Subnet, and 'CLOSE' and 'SAVE' buttons at the bottom. The right panel shows the 'DHCP Client' mode selected, with input fields for SSID and Password, and 'CLOSE' and 'SAVE' buttons at the bottom.

NOTE: WLAN Password field must contain between 8 and 63 characters (IEEE 802.11i-2004 compliant).

- 'SFTP': Displays current SFTP configuration. Press its SET button to configure it. It could be set remotely and loaded with an internet connection (see section 5.4.1).

5.4.4. VERSIONS

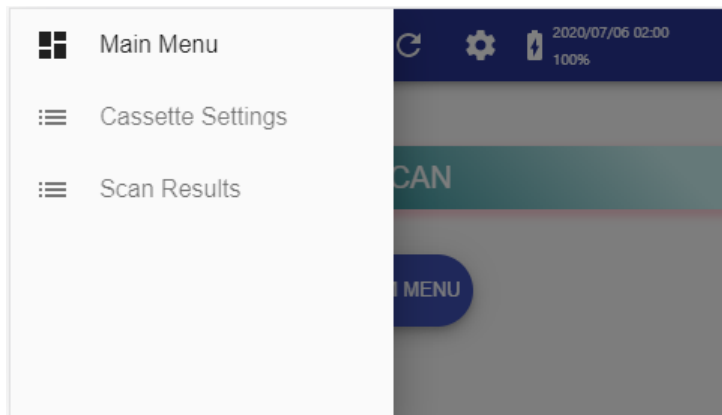
Displays a list of information related to the instrument and its software.

Model	operon
Serial Number	100030000/00000
Current SW Version	2.3
Hardware Version	6.0
Product Image Version	lfr-operon
Wipe Clean SW Version	2.0.2
Factory SW Version	2.3

- 'Model': It is related to product number (see bottom label). Determines the compatibility of cassette settings and it is related with Cassette Settings Version functionalities.
- 'Serial Number': Unique number for each instrument (see bottom label).
- 'Current SW Version': Software version of the instrument.
- 'Hardware Version': Hardware version
- 'Product Image Version': Name of image file burn-in current SD.
- 'Wipe clean SW Version': Software version if a wipe clean is performed.
- 'Factory SW Version': Software version used when manufacturing.

5.5. Side Menu

By pressing the menu symbol on the left of the top bar, a drop side menu is displayed with the following features:

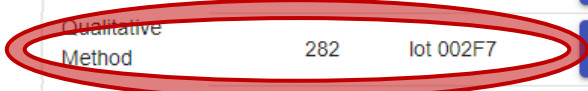


5.5.1. Main Menu

The device returns to the Home screen.

5.5.2. Cassette Settings

The available Cassette Settings list is displayed. After pressing one 'SELECT AS CURRENT' button (see yellow circle) the corresponding Cassette Configuration will be displayed on the Top Bar and it will be ready to use. Press on a row (see red circle) to access each Cassette Settings screen.

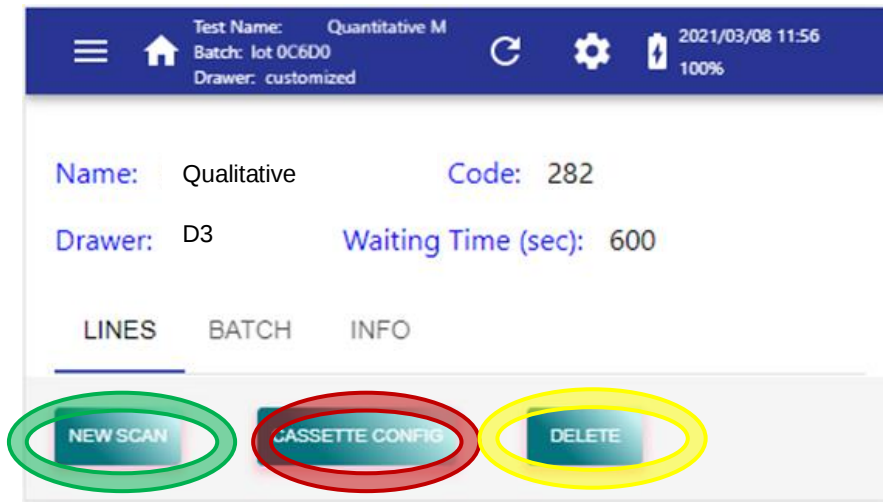
Name	Code	Batch	
Qualitative Method	384	lot 03A9	 SELECT AS CURRENT
Qualitative Method	384	lot 0B15	SELECT AS CURRENT
 Qualitative Method	282	lot 002F7	SELECT AS CURRENT
Qualitative Method	282	lot 0C6D0	SELECT AS CURRENT

1-4 of 4 < >

NOTE: The maximum number of Cassette Configuration that reader stores could be set between 1 and 10. Depending on the configuration.

After selecting one row the following screen is reached:

Press 'NEW SCAN' (see green circle) to start a new Cassette Processing. Press 'CASSETTE CONFIG' (see red circle) to load a Cassette Configuration through barcode reader. Press 'DELETE' (see yellow circle) to delete this Cassette Settings from the available list.



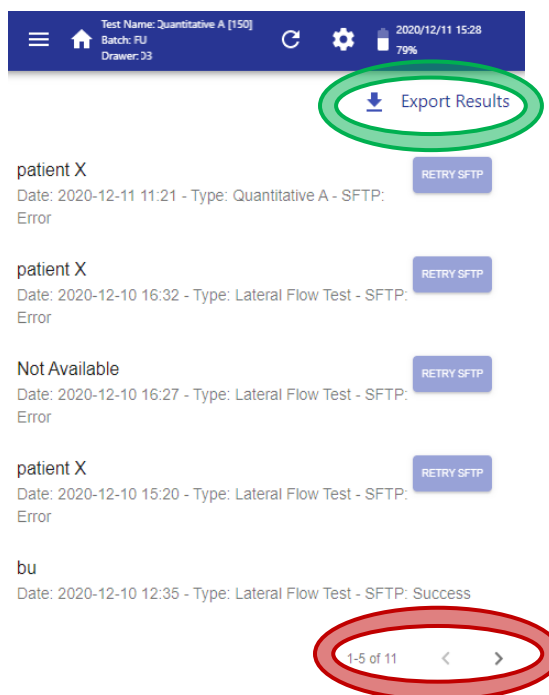
Drag-up on the screen and select each tab to visualize all data related to this Cassette Settings:

Available tabs:

- LINES: List of test lines included on this Cassette Configuration and grouped strips.
- BATCH: Information related with the batch of this Cassette Configuration.
- INFO: Informative text included in Cassette Configuration.

5.5.3. Scan Results

Access the list of stored scan results. The list is ordered with the most recent scan on top. Maximum 5 results are shown on each page. Drag up and down on the touchscreen to displace the list of the current page. On the bottom of each page there are back and forward buttons (see red circle) to change pages. On the upper-right corner, there is an 'Export Results' button (see green circle) to export **ALL** stored results.



ATTENTION: According to OPERON's configuration 200 results are kept. If you do not want to lose your old results before archiving this number export the results.

For each scan in the list, the following information is displayed:

- Sample/Patient reference ID (only first 30 characters displayed)
- Date and time of the scan
- Cassette type
- SFTP state (only in case of enabling SFTP service)

Each SFTP state could have the following values:

- Pending: Sending data is ongoing. As well as if the scan was performed with the SFTP service disabled.
- Success: Scan data has been properly sent.
- Error: Scan data has not been properly sent. A RETRY SFTP button is shown next to the item.

NOTE: After pressing the 'RETRY SFTP' button refresh the screen to ensure that the SFTP state has properly been updated.

A. RESULT VIEW

Select a scan result to explore its information and print it as a ticket, as a report, or export a report (a trash icon  appears in Manager's users to delete the scan result).



Available tabs:

- **STRIP** (tab's name depends on Cassette Configuration): If the control line is present, result values for each test line and control line are shown. If not, only the control line review is displayed. There is one STRIP tab for each strip defined in the Cassette Configuration used for this scan.
- **IMAGES**: Shows processed pixels of each test line with the peak area curve profile over it. It contains one image for each strip defined on the Cassette Settings used for this scan.
- **COMMENTS**: Open space to add comments to this scan result.
- **INFO**: Displays data related to the scan process.

Available buttons:

- **PRINT TICKET**: If a ticket printer is connected and properly configured, press **PRINT TICKET** button to obtain a ticket/label containing the identification data and the summary results of the scan. See section 5.4.2 to connect and configure a ticket printer.

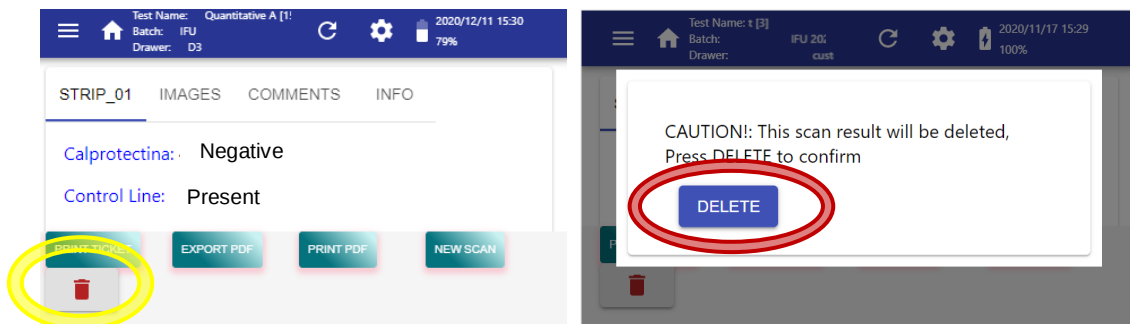
```
2020-11-16 16:51:23 (CET)
ID: test
Qualitative (3)
Lot: IFU 2020
Expiration: 2022-02-22
Reader: 100033000/99999
Comment:

>strip_01
Control: Present
Test Line: Negative
```

- **EXPORT PDF:** To export the results data into a PDF report file, connect a slim USB memory stick (previously formatted as described in section 5.4.1) into the reader's USB host port and press the 'EXPORT PDF' button.

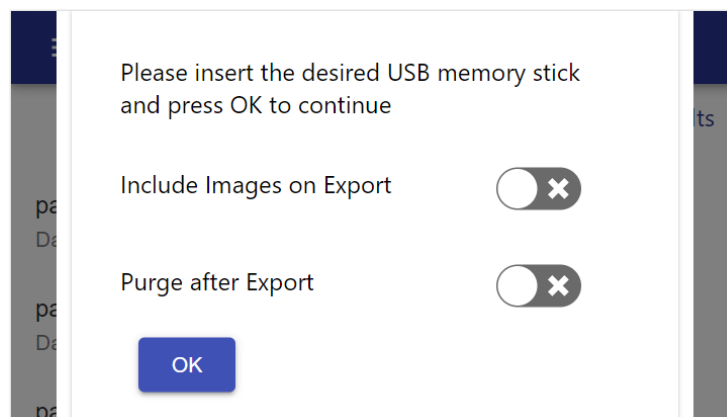
NOTE: PDF report filename contains a maximum of the 228 first characters from Patient/sample ID followed by a timestamp. Special characters are removed from the file name, spaces replaced by dashes, and uppercases replaced by lowercases.

- **PRINT PDF:** If a desktop printer is connected and properly configured, press PRINT PDF button to print the scan result report.
- **NEW SCAN:** To start a new Cassette Processing.
- **DELETE** (only available for Manager): When the trash icon (see yellow circle) is pressed a pop-up dialog asks for deleting confirmation. Press the DELETE button (see red circle) to remove the scan result from the database.



B. EXPORT RESULTS BUTTON

After pressing on the 'Export Results' button from the Scan Results screen a pop-up dialog is displayed to select export options. Before pressing on 'OK' button a slim USB memory stick (previously formatted as described in section 5.4.1) should be plugged into the USB host port (see section 3.1).



The export process creates a folder in the root of the USB, named as current timestamp (YYYYMMDD_hhmmss) to store exported file/s. Scan Results data are transferred as a CSV file, which can be later opened with a spreadsheet application on a computer. Depending on selected options the process performs some extra actions or not:

- Include Images on Export: If ON, captured images from each scan are also exported in PNG format. Image file names are composed with Sample/patient ID, an underscore, and the uuid of the scan.
- Purge after Export: If ON, the reader's results database is removed after successful exportation.

About the exported CSV file:

- File extension is .CSV
- Field separator/delimiter is character TAB, and numeric decimal separator is always character FULL STOP ".". Consider this when importing the .CSV file into a spreadsheet application.
- The first row contains the headers/titles of the fields.
- For each cassette processing result, there are as many rows as lines (Control+Test) in all the strips of the cassette. For instance, in the case of one cassette with 2 strips, and each strip having 1 Control line and 2 Test lines, will have 6 rows of results in the .CSV.
- In the case of a strip where no Control line was found, then there will be no rows corresponding to Test lines (because they cannot be evaluated if the Control line is missing).

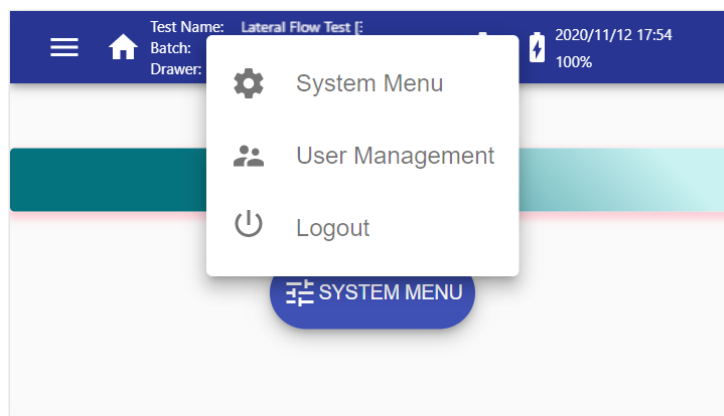
Parameters included in the results (for each processed line):

- reference: Sample/patient id (maximum length 2024 characters).
- uuid: Unique identifier of the scan (also included in the captured image name).
- timeStamp: UTC time of the scan.
- comments: Comments added after the scan.
- cassette type: Name of Cassette Configuration Settings.
- cassette code: Code of Cassette Configuration Settings.
- batch ID: Batch id of the cassette.
- due date: Expiring date of cassette batch.
- NormError: Processing parameter.
- lineError: Processing parameter.
- line warnings: Processing parameter.
- strip name: Name of the strip from a cassette.
- line name: Name of the line from a strip.
- result qualifier: Qualification result of the scan.
- quantification: Quantification result of the scan (decimal separator ".").

- quantification units: Units of the quantification result.
- peak area: Measured intensity of the line (decimal separator “.”).
- base line: Processing parameter.
- peak height: Processing parameter.
- peak position [mm]: Processing parameter.
- drawer intensity: Processing parameter.
- wb_factors: Processing parameter.
- applied thresholds: Cassette Configuration Settings parameter.
- fiducials: Processing parameter.

5.6. Tools Menu

By pressing the gear symbol  on the center-right of the top bar a dropdown menu is displayed, where the following functions will be shown.



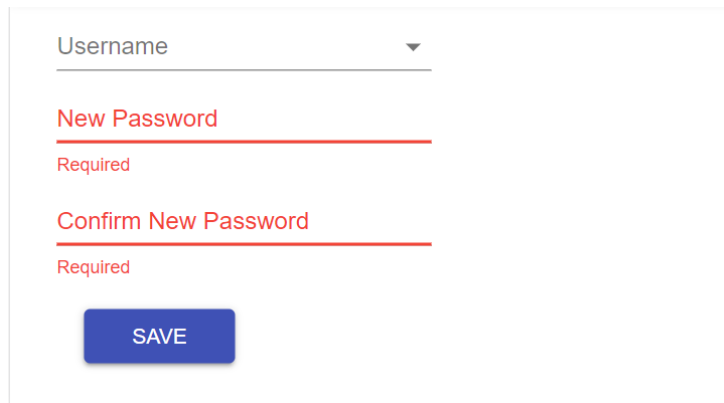
5.6.1. System Menu

Explained in section 5.4.

5.6.2. User Management - CHANGE PASSWORD

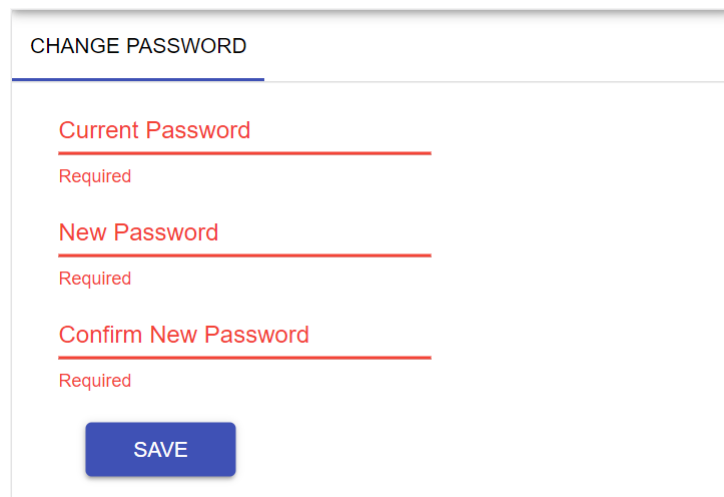
This screen allows password changing.

If you are the Manager, a 'Username' must be selected, and a new password must be typed in both 'New Password' and 'Confirm New Password' fields.



A form for a Manager to change their password. It features a dropdown menu labeled 'Username' with a downward arrow. Below it are two text input fields: 'New Password' and 'Confirm New Password'. Each field has a red underline and the word 'Required' in red text below it. At the bottom of the form is a blue button with the text 'SAVE' in white.

If you are an Operator to change the password, type the current password in the 'Current Password' field and type the new password in both the 'New Password' and the 'Confirm New Password' fields.



A form titled 'CHANGE PASSWORD' for an Operator. It contains three text input fields: 'Current Password', 'New Password', and 'Confirm New Password'. Each field has a red underline and the word 'Required' in red text below it. At the bottom of the form is a blue button with the text 'SAVE' in white.

After editing all fields, press 'SAVE' button:

- If the reader displays the green message: 'Password Changed!', the password is replaced successfully.
- If the reader displays the red warning: 'Password Not Match!', the 'New Password' field and the 'Confirm New Password' field are not equal.
- If the reader displays the red warning: 'Authentication failed' the 'Current password' field is not correct.

5.6.3. User Management - USERS (Manager)

Press 'USERS' tab to create, edit and delete user accounts. This screen is only accessible for users with the role or Manager.

To see available users press the drop-down menu 'Usernames'. Only user "admin" can edit its own account. Only user "Manager" can edit its own account.

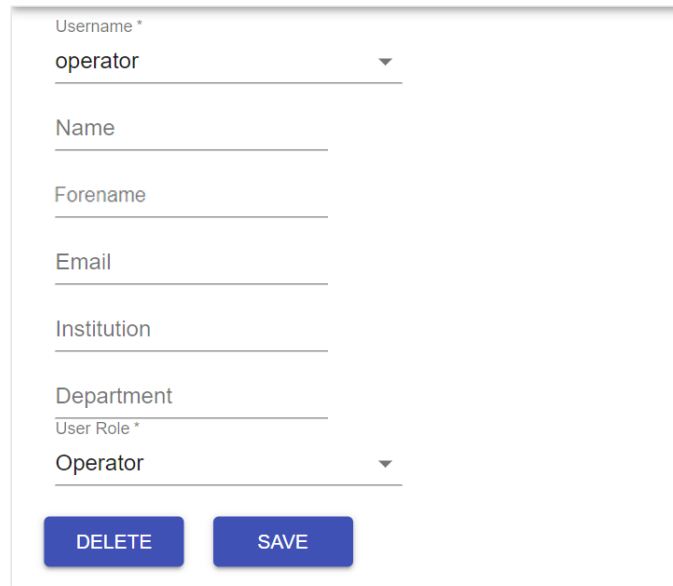
A. CREATE NEW USER

To create a new user, select the first item of the 'Username' list, '*Create new user*', and fill the fields available. Only the 'Username', 'Password', and 'User Role' fields are mandatory.

Press the 'SAVE' button and then the 'CONFIRM' button from the pop-up dialog to store the new user account.

B. EDIT or DELETE AVAILABLE USER

To edit or delete a user account, select the user on the 'Username' drop-down list.



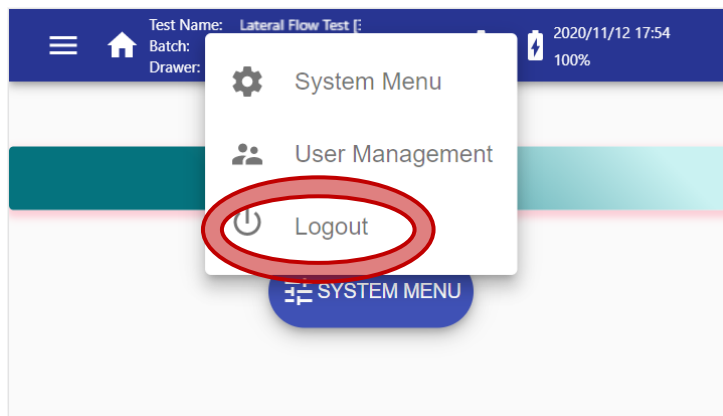
A form for editing or deleting a user account. It contains the following fields: 'Username *' (a dropdown menu with 'operator' selected), 'Name' (a text input field), 'Forename' (a text input field), 'Email' (a text input field), 'Institution' (a text input field), 'Department' (a text input field), 'User Role *' (a dropdown menu with 'Operator' selected), and two buttons at the bottom: 'DELETE' and 'SAVE'.

Press each field to edit its value using a virtual keyboard. To save changes press the 'SAVE' button and then the 'CONFIRM' button from the pop-up dialog.

To delete the selected user, press the 'DELETE' button and then the 'CONFIRM' button from the pop-up dialog.

5.6.4. Logout

Selecting this option (see red circle) disables the current user's session and shifts to Login Screen. A new login must be performed to enable the instrument.



See section 5.1 for an explanations about the login process.

5.7. Software Update

CAUTION 	Run this procedure under Technical Support advice and with a full charge of the battery and plug the OPERON Lateral Flow Reader instrument to the mains supply.
CAUTION 	Do not update a LFR with software version 2.x using an update package 1.x. Do not update a LFR with software version 1.x using an update package 2.x.

To update the Software, follow these steps under OPERON.supervision:

- Power off the the OPERON Lateral Flow Reader instrument.
- Plug the memory stick into the USB port of the reader with the new software version according to OPERON.supervision.
- Power on the reader and wait until the process ends, and a reset message is displayed.
- Press the power button (see section 3.1) for 10 seconds until the reader turns off.
- Remove the slim USB memory stick. The reader is ready.

CAUTION 	The software update procedure takes some time (around 20 minutes), during which the reader may seem unresponsive. Do not power off the reader until the procedure is completed.
---	---

5.8. Browser Generic Operations

Here some tips to browse this instrument:

- Return to the previous screen swiping left.
- Remove an error message from the screen, touching the screen outside the error.
- Depending on the selected field, the virtual keyboard is displayed:

For Username(user), Password(user), Sample/patient ID, Comments, Name, Surname and Department:

a / A	d / D	g / G	j / J	m / M	p / P	s / S	v / V	y / Y	1	4	7
b / B	e / E	h / H	k / K	n / N	q / Q	t / T	w / W	z / Z	2	5	8
c / C	f / F	i / I	l / L	o / O	r / R	u / U	x / X	0	3	6	9

For SSID, Password(WLAN), Email, Institution, Server, HL7 path, PDF path, Username(SFTP) and Password(SFTP):

0 ... 9				a ... b				A ... B		
space	!	"	#	\$	%	&	'	(	)	=
*	+	,	-	.	/	:	;	<	>	^
?	@	[	]	\	_	`	'	{	}	~

For IP, Mask and Gateway:

1	4	7	0
2	5	8	.
3	6	9	

For Cassette Settings Version:

1	4	7	0
2	5	8	
3	6	9	

6. Troubleshooting

Symptom	Probable cause	Recommended action
The unit cannot turn ON	Battery discharged	Plug the Power supply unit to recharge
The unit cannot turn ON or Turn OFF	Damage in the ON/OFF button	Contact the Technical Service for repair
The unit switches-off spontaneously (a message has been displayed for a while before switching off)	Too much time of inactivity elapsed	Increase the inactivity time in the 'SYSTEM MENU'
The unit switches off spontaneously (a message has been displayed for a while before switching-off)	Mains cord unplugged and battery getting too low	Plug the mains supply and let the battery fully charge
Battery in charge red LED is blinking	Not correct charger / charger damaged / battery damaged / electronic component damaged	Ensure the charger is proper one / ensure charger wiring is well connected / Contact the Technical Service for repair
The unit cannot perform as expected	Old version of SW	Upgrade the SW
The unit cannot storage the actual time	Internal battery discharged	Contact the Technical Service for repair
The unit Wi-Fi does not appear in the computer	The wireless range is out of range	Situate the unit near the wireless connection
After reading barcode for Cassette Settings or for confirmation, an error message is shown	The barcode type is different than the expected one	If you are loading the Cassette Settings, show the big Data Matrix (configuration barcode). If you are confirming the cassette, show the Small-Data Matrix
The unit cannot read the Ethernet device	The Ethernet is not right connected	Correctly connect the Ethernet device
The Ethernet is not detected	Damage in internal connection in the Ethernet port.	Contact the Technical Service for repair
The barcode reader light is on, but the barcode cannot be read	The barcode is incorrectly placed in front of the barcode reader.	Move slightly the barcode forward-backward and tilting, until the barcode is read
The barcode reader light is on, but the barcode cannot be read	The barcode is damaged or the wrong type	Replace the barcode with a correct one
The barcode reader light is on, but the barcode cannot be read	There is dirtiness on the barcode reader window	Clean it with an antistatic cloth or a brush.
The unit cannot read the USB device	Damage in internal connection in the USB port	Contact the Technical Service for repair
The unit cannot access the USB memory stick	The USB stick is too wide, preventing its proper full insertion into the socket	Use a narrow width USB memory stick
The unit cannot access the USB memory stick	The USB is not properly formatted	Format the USB memory stick using the option in the System options

Symptom	Probable cause	Recommended action
The unit cannot access the USB memory stick	The USB is not right connected	Correctly connect the USB device
It is not possible to perform a scan and the following message is displayed "Please fit drawer and cassette properly"	Some obstacle prevents the drawer from being completely inserted / The drawer is damaged	Remove the obstacle / Replace the drawer
When launching scan, the device shows a message: "cassette not present"	The operator forgot to place the cassette in the drawer	Place the cassette in the drawer
When launching scan, the device shows a message: "image normalization failed. White balance factors out correction range"	The camera is incorrectly adjusted	Perform the adjustment process following the steps of section 5.4.1.
When launching scan, the device shows a message: "fiducial not found"	The white spots of the drawer are dirty or damaged	Clean or replace the drawer
When displaying results, the Control line says: Absent or Invalid, and no results for test lines are shown	The control line is absent or too weak	Correctly inoculate the cassette. Wait the prescribed time or use the Timed Scan feature
The screen displays the message "RTC CRITICAL FAILURE. Please contact Technical Service"	Real Time Clock battery is damaged	Send the LFR to Technical Service
After pressing the Remote Export 'TOKENIZE' button, an error message is displayed	No internet connection	Review network connection and read whole error message for more options
After pressing the Network Remote Setup 'UPDATE' button, an error message is displayed	No internet connection	Review network connection and read whole error message for more options
After performing a scan, the screen displays the error message "Error trying to export results to SFTP server..."	No internet connection	Review network connection and read whole error message for more options
The unit cannot reset to defaults	Damage in the Software Wipe buttonhole.	Contact the Technical Service for repair

If you contact the Technical Service for other malfunctions beyond those described above, they might ask you to send the log files. Use the 'Export Logs to USB' option of the System Menu (see section 5.4.1) and send the files by e-mail to the Technical Service.

7. Maintenance

7.1. Cleaning Procedure

To clean the OPERON Lateral Flow Reader instrument use a lightly moistened cloth or an antistatic cloth.

CAUTION



Damage to the instrument

Do not sprinkle inside the instrument or close to the drawer slot.

7.2. Product Life

The product life of the OPERON Lateral Flow Reader device is 5 years.

8. Appendix A: Ordering Codes

8.1. Spare Parts

Product	Contents	Cat. #
Drawer D1	1 unit	900013342
Drawer D2	1 unit	900013435
Drawer D3	1 unit	900013315
Drawer D4	1 unit	900013344
External power supply	1 unit	900020088
Power cord Schuko	1 unit	900020077
Power cord (USA / Japan)	1 unit	900020078
Power cord (UK)	1 unit	900020079
Power cord (Argentina)	1 unit	900020081
Power cord (China / Australia)	1 unit	900020082
Power cord (India & South Africa)	1 unit	90004873

8.2. Optional Accessories

Product	Contents	Cat. #
Ticket printer (serial interface, 40 columns)	1 unit	90003069
CP2102 USB RS232 to DB25 adapter cable	1 unit	90004874
Self-adjusting light Drawer	1 unit	900013732

9. Appendix B: Technical Data

OPERON reserves the right to change specifications at any time.

Specifications

Process time	from 15 seconds
Camera sensor	8 Mpixel
Touch screen	4,3"
Operating system	Linux
USB sockets	1 host port

Connectivity

Ports	Wi-Fi, Ethernet and slim USB
Export results	HL7 v2.8 compliant. Connections https with SSL TLSv1 TLSv1.1 TLSv1.2 TLSv1.3. Authentication: transport level 2 with token key management
Audit trail	HL7 v2.8 compliant. Connections https with SSL TLSv1 TLSv1.1 TLSv1.2 TLSv1.3. Authentication: transport level 2 with token key management
SFTP	The reader can export to an external SFTP server

Operating conditions

Power range	12V +/-5%. (it is supplied with an external power supply unit that can be used in 100V-240V)
Frequency range	D.C. (it is supplied with an external power supply unit that can be used in 50Hz-60Hz)
Maximum power	40 W
Overvoltage category	II

Air temperature	15 ~ 30 °C
Relative humidity	10 ~ 75 % (non-condensing)
Altitude	Up to 2000 meters (6500ft.)
Place of operation	For indoor use only
Pollution level	2

Transportation conditions

Air temperature	5°C ~ 40°C (41°F ~ 104°F) In manufacturer's packaging
Relative humidity	Maximum 75 % (non-condensing)

Storage conditions

Air temperature	5°C ~ 40°C (41°F ~ 104°F) In manufacturer's packaging
Relative humidity	Maximum 75 % (non-condensing)

Dimensions and Weight

Dimensions (WxHxD)	145 x 126.5 x 140 mm / 5.7 x 4.98 x 5.51 in
Weight	0.60 Kg / 1.32 lb

10. Appendix C: Warranty

The OPERON instrument has a 12-month warranty period.

The warranty is void when misuse of the equipment can be proved. Damage or faults caused by impacts, chemical or corrosive products, liquids, damp, or other external factors, such as radiation, fire, or inadequate transport are not included.

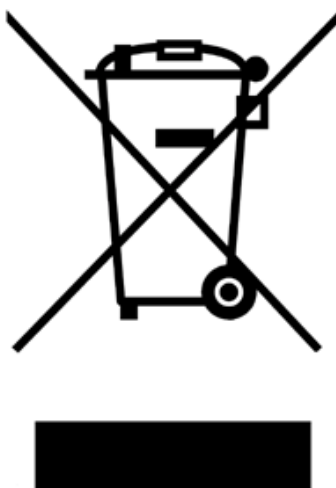
In addition, the warranty will not apply if the equipment has been handled, repaired, or modified by not qualified or specifically designated personnel.

11. Appendix D: Waste Electrical and Electronic Equipment (WEEE)

This section provides information about the disposal of waste electrical and electronic equipment by users.

The crossed-out wheeled bin symbol (see below) indicates that this product must not be disposed of with other waste; it must be taken to an approved treatment facility or to a designated collection point for recycling, according to local laws and regulations.

The separate collection and recycling of waste electronic equipment at the time of disposal helps to conserve natural resources and ensures that the product is recycled in a manner that protects human health and the environment.



12. Appendix E: EC Declaration of Conformity

Manufacturer:

IUL, SA - Carrer de la Ciutat d'Asunción, 4 08030 Barcelona Spain



Declares that the product Name:

OPERON Lateral Flow Reader

Catalog Number:

900030000SD1D3

900030000UKD1D3

900030000USD1D3

Classification:

NOT LIST A OR B, ARTICLE 9 – SELF DECLARATION

Conformity assessment route:

IN VITRO MEDICAL DEVICE DIRECTIVE 98/79/EC, ANNEX III (SELF DECLARATION)

Conforms the Council Directives:

- Directive [98/79/EC](#) of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

Barcelona, July the 1st 2021



A handwritten signature in blue ink, appearing to read 'V. Font', written over a horizontal line.

Vicenç Font
(IVD Technical Manager)

A handwritten signature in blue ink, appearing to read 'D. Guerrero', written over a horizontal line.

David Guerrero
(Quality Manager)

13. Appendix F: RoHS Statement

13. Appendix F: RoHS Statement

The following information has been made available to comply with The Restriction of Hazardous Substances Directive, (RoHS2 & RoHS 3), short for Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment.



Notes

