OPERON Lateral Flow Reader Instructions for Use

Software Version 3.x

50008141-14

Revision Date: October 2025

Contents

Indication of the introduced modifications

If it's the first time that you use OPERON Lateral Flow Reader, please read the entire document carefully.

If it's not the first time that you use OPERON Lateral Flow Reader and you have used it before, in the table below you can read the indication of the introduced modifications.

Document Revision	Description of changes
14	Updating section 5.4.4 Printer (Administrator or Manager)
	Updating section 7.2 Service Life and Preventive Maintenance

0. Glossary

LFR - Lateral Flow Reader, it is a device such as OPERON Lateral Flow Reader that reads and processes immunochromatographic lateral flow tests.

Administrator - It is the most privileged user and has exclusive access to some options of the LFR.

Manager - It is the second kind of privileged user and can manage users, printers, and network setups of the LFR.

Operator- It is the person designated by the health organization to use the LFR for the intended use.

LFR Configuration - Set of options that determine the behavior and functionalities of the LFR. Most of them are only available by the Administrator user.

Health Organization - It is an institution, company, or other legal entity responsible for operating the LFR together with the cassettes to be used in medical analysis of different nature.

Cassette - It is a device that consists of lateral flow tests and a housing that contains them.

Cassette Processing - The process that analyses lateral flow tests, from inserting a cassette into an LFR, until the results are shown on the screen. This process includes the scan of the cassette.

Cassette Model - It is the cassette housing, with a specific geometry that is adjusted in the slot of a tailored drawer.

Cassette Type - It is the set of a cassette model and specific lateral flow tests contained in its strips.

Cassette Settings - It is a set of parameters that enable the LFR to process and measure a specific batch of specific cassette type. Also referred to as “Test Name”, “Cassette Configuration” and “Cassette Config.”.

Data Matrix - Barcode that contains the full information of one cassette settings. Also referred to as “Configuration Barcode”.

Small-Data Matrix - Barcode that contains the cassette settings code and the batch ID. It is used to confirm that the current cassette matches with current cassette settings. Also referred to as “Small Barcode” and “Confirm Cassette”.

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.

In case a serious incident occurs in relation to the device, it shall be reported to OPERON, S.A. and the competent authority of the Member State in which the user and/or the patient is established.

1.1. Intended Purpose of the OPERON Lateral Flow Reader

The OPERON Lateral Flow Reader is an instrument specifically to be used to provide quantitative, semi-quantitative, and/or qualitative in-vitro determination of photometric immunochromatographic tests defined and marketed by OPERON, S.A.

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 Regulation (EU) 2017/746, OPERON Lateral Flow Reader is classified as CLASS A thus only an EU Declaration of Conformity and CE Marking are required.

1.4. User Management

The OPERON Lateral Flow Reader can be used in three different roles:

- Operator: have access to the features needed when operating.
- Manager: have access to features needed when operating, plus the network and connectivity feature. It can also delete scanned results.
- Administrator: have unlimited access to every feature of the OPERON Lateral Flow Reader Device Description

1.5. Device Description

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

1.6. Contraindications

Not applicable

1.7. General Information

1.7.1. 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.

1.7.2. TECHNICAL ASSISTANCE

At OPERON, S.A. 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, S.A. products. If you have any questions or experience any difficulties regarding the OPERON Lateral Flow Reader or OPERON, S.A. products in general, do not hesitate to contact us.

OPERON, S.A. 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, S.A.. 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, S.A. Technical Service Department, or local distributors.

1.7.3. POLICY STATEMENT

It is the policy of OPERON, S.A. to improve products as new techniques and components become available. OPERON, S.A. 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, S.A. Technical Service with any feedback.

1.7.4. 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, S.A..

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 these 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 the 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, S.A. 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 the 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, S.A.. • After a storage period of 6 months, it is necessary to charge the batteries 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 temperatures 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 loosing of the AC adaptor or the mains power cord, these must be replaced only with the AC adaptors or power cords listed in “Appendix A: Ordering Codes” In case of replacement, this must be ordered to OPERON, S.A..

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, S.A..
- The instrument must not be operated with the cover opened.
- If you suspect any instrument damage, contact OPERON, S.A. Technical Services.

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

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

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/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.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 OSHA[1] ACGIH[2] or COSHH[3] 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 *Biosafety in Microbiological and Biomedical Laboratories*, HHS: https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf See: Section III—Principles of Biosafety Laboratory Practices and Techniques 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 *Biosafety in Microbiological and Biomedical Laboratories*, HHS: https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.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 acetone or disinfectant to clean the surface of the OPERON Lateral Flow Reader instrument. Do not use products containing acetone 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: EU Declaration of Conformity”.
	Type plate on the bottom of the instrument and the external box label[1]	UKCA Mark, Declaration of Conformity, see “Appendix G: UK Declaration of Conformity”.
	Type plate on the bottom of the instrument and the external box label	Medical device manufacturer.
	Type plate on the bottom of the instrument and the external box label	The device is intended to be used as an in vitro medical device.
	Type plate on the bottom of the instrument and the external box label	Date of manufacture.
	Type plate on the bottom of the instrument and the external box label	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	Indicates a carrier that contains unique device identifier information.
	Label on the side of the external box	Temperature limits, see ”Appendix B: Technical Data”.

[1] The UKCA symbol on the external box label will be included only for shipments to the United Kingdom.

Symbol	Location	Description
	Label on the side of the external box	Humidity limits, 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.
	Type plate on the bottom of the instrument	Caution is necessary when operating the device.
	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 LFR Software is an essential part of the LFR and it is not distributed separately.

All the cybersecurity controls are integrated into the SW storage, including SW integrity verification, firewall, and others.

The LFR is designed to operate in the intended environment of use defined by OPERON, S.A.. The LFR’s partner is the legal entity that defines the setup for a specific intended environment of use, including LFR’s setup and operation process. For this purpose, the LFR provides a privileged user (role Administrator) which is the only user that could configure CASSETTE and PREFERENCES tabs.

There is another kind of privileged user (Manager role) that can manage users, printers, and network setups. Only the Administrator and Manager have access to this feature.

The LFR starts with a Login Screen, to introduce the user and password before operating (see section 5.6.1).

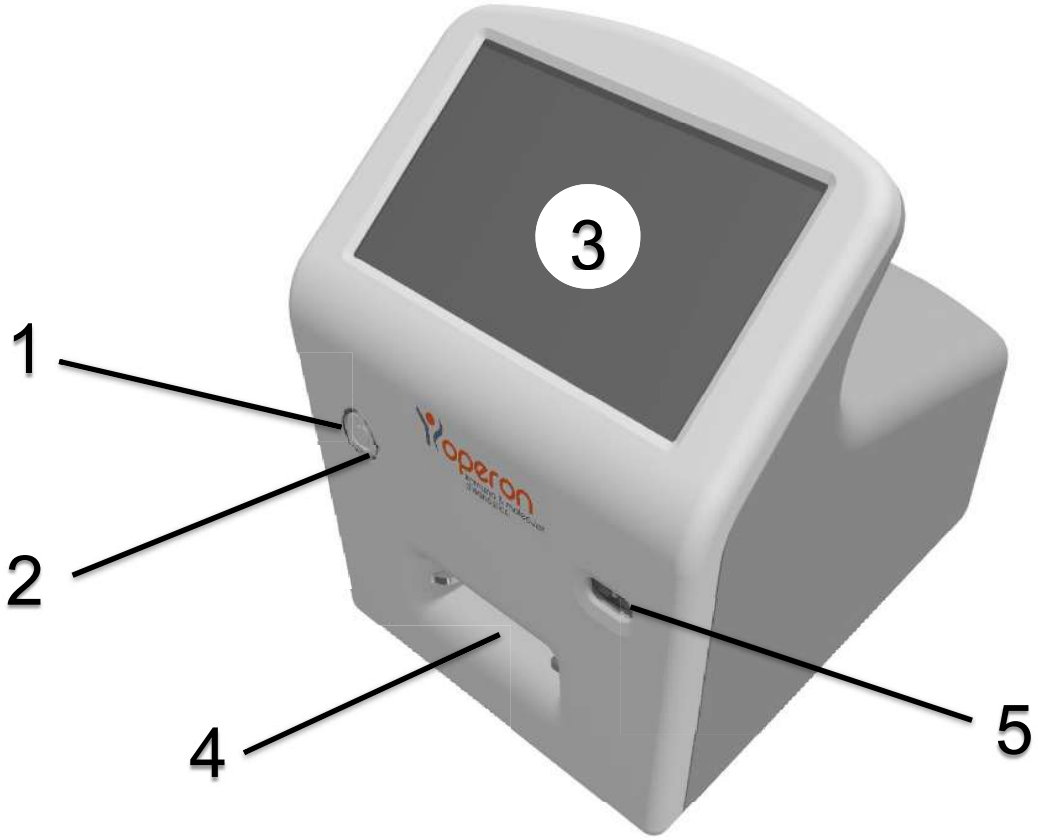
There is an audit trail integrated into the SW to store performed actions involving medical data.

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

3. General Description

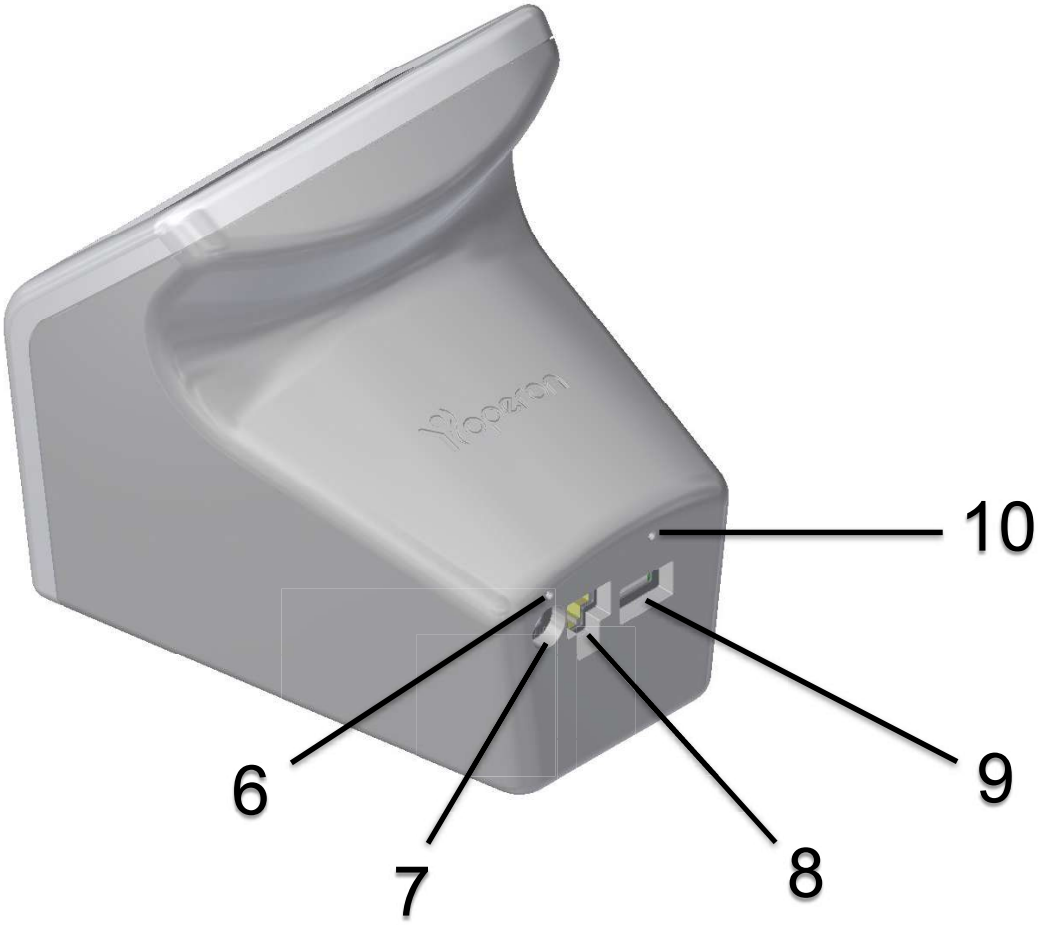
3.1. Instrument Overview

FRONT VIEW:



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

REARVIEW:



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

WARNING 	For proper insertion of a slim 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 the 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 the 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 only with one of the power cords listed in “Appendix A: Ordering Codes” delivered by OPERON, S.A..

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 only with one of the power cords listed in “Appendix A: Ordering Codes” delivered by OPERON, S.A..

3.2.4. ADJUSTMENT DRAWER

The adjustment drawer may be used to readjust the camera parameters.

WARNING 	If the battery level is below 70%, connect the reader to the power supply.

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.

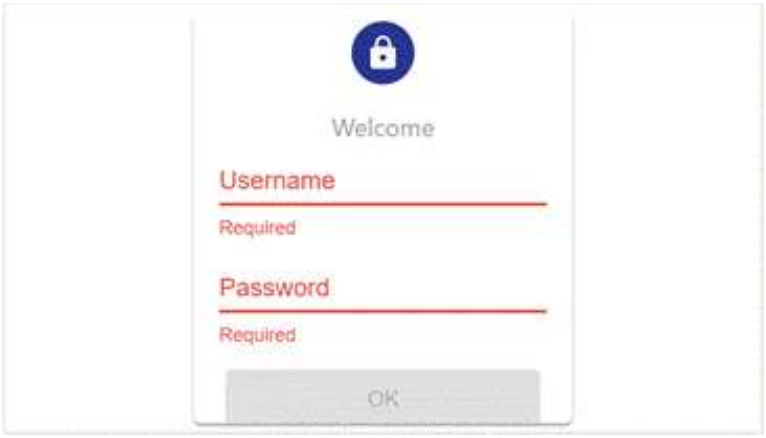
CAUTION	**Do not use expired cassettes.** Review the expiration date of the cassette and do not use it if it is expired.

5. Operating Procedures

CAUTION	Before switching on the reader for the first time or after 6 month 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 and then wait until the boot process ends and the Login Screen is shown:



To enable the instrument, fill properly the 'Username' and 'Password' fields (see yellow and red circles) and then press the '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 the '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**".

CAUTION	Default password MUST be changed to preserve the correct use of the LFR.

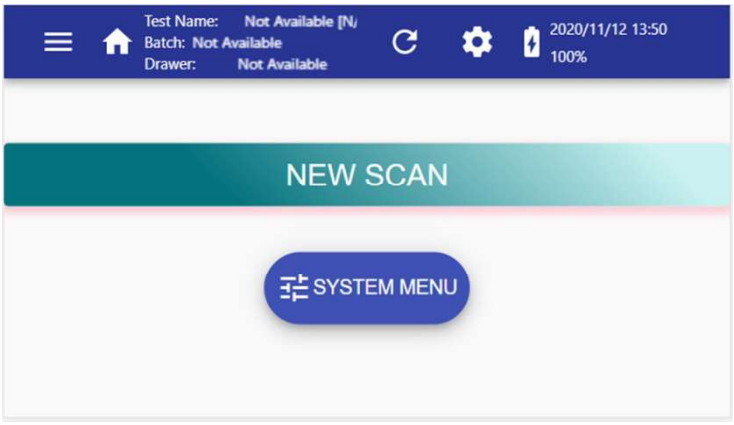
NOTE: If you forget or lose "manager" passwords, contact OPERON, S.A..

NOTE: If you forget or lose your "operator" password, contact OPERON, S.A..

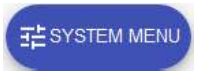
To end the user's session, select 'Logout' on the Tools Menu (see section 5.6.4 for more information) or power off the OPERON Lateral Flow Reader instrument.

5.2. Home Screen Overview

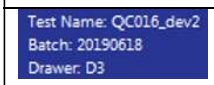
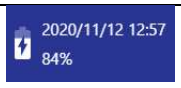
The home screen displays the current cassette configuration, date, time, battery status, the 'NEW SCAN' button, and the "SYSTEM MENU" button.



Home Screen:

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

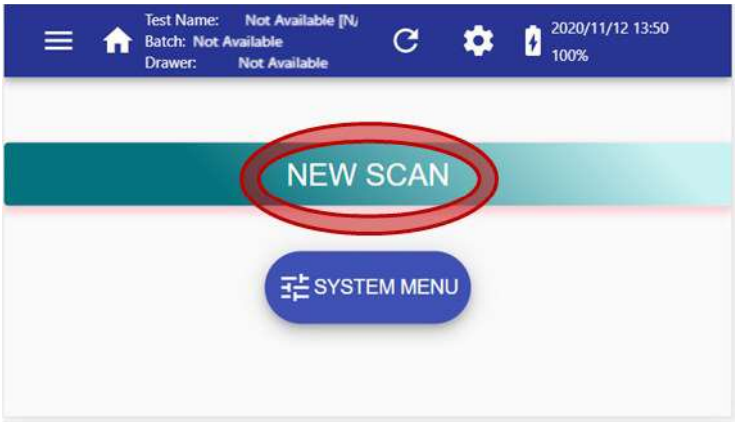
Main Toolbar:

	Shows the drop-Side Menu.
	Return to Home screen.
	Information on 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.
	Remote export icon. Depends on configuration. Only visible when a valid token is checked.

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.

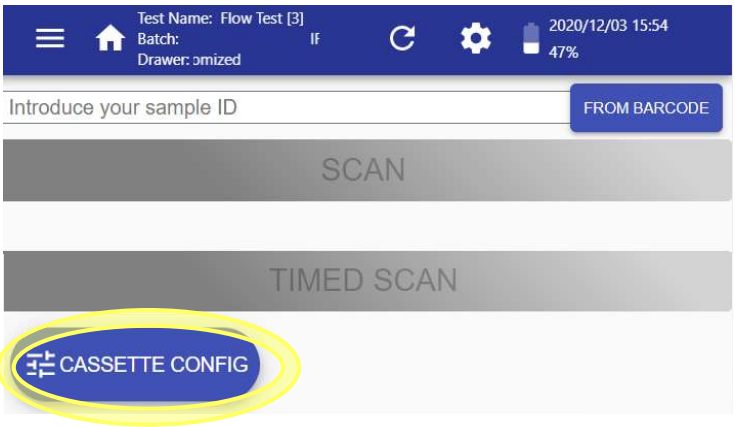


2- Omit this step if the current Cassette Settings is the Cassette Settings to use in the next scan. This step may be required in certain configurations.

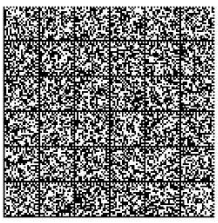
To set the proper Cassette Settings that will be used in the next scan, there are the following options:

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 approximately 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).

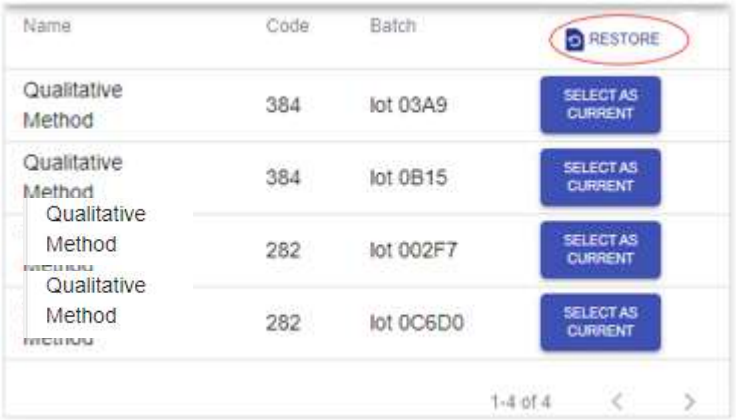
If the barcode is read but does not fit with what is expected, an error message will appear on the screen. Check the exposed barcode and touch the display outside the dialog box to skip the error message and return to the above window.

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

WARNING ⚠	If the barcode hasn't been read correctly, the former Cassette Settings will be the one applied.

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.



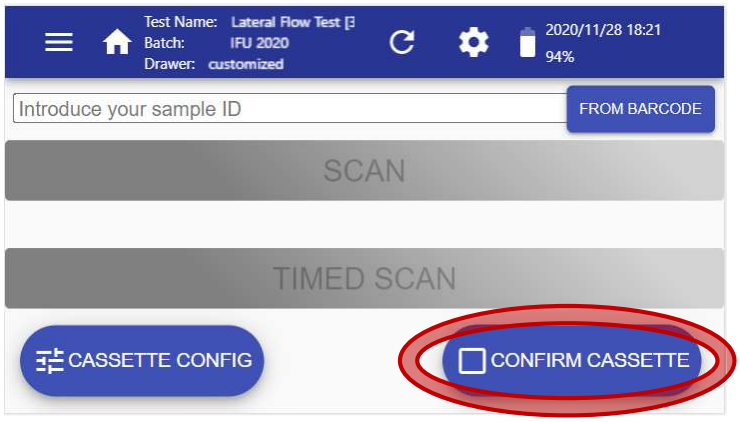
Press the ‘SELECT AS CURRENT’ button to load the Cassette Settings of the row.

CAUTION	By pressing the “Restore” button in red, the cassette settings list will be deleted.

B.2 ‘Barcode Autodetection’ launches directly the scan if the option ‘Barcode Autodetection’ is selected by OPERON, S.A..

CAUTION	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 set, press the ‘CONFIRM CASSETTE’ button (see red circle) to check that the current Cassette Settings match with the cassette to be processed. Depending on the configuration this step may be omitted.



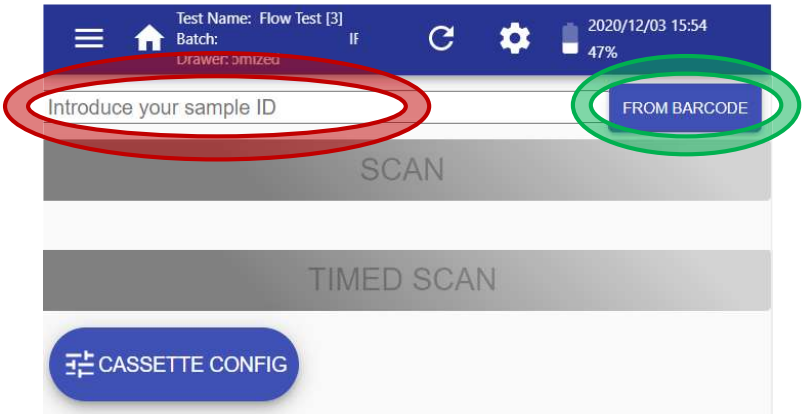
Place the small barcode (Small-Data Matrix) in front of the barcode reader (see section 3.1) at 5 cm of distance approximately.

Press the ‘ACTIVATE BARCODE READ’ button (see yellow circle). The barcode reader starts its reading process using a light. This light disappears when a barcode has been read or after 10 seconds of trying.

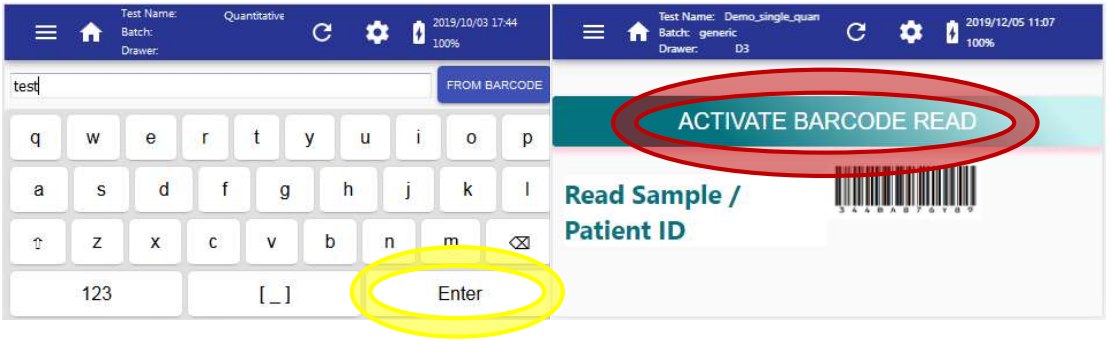
If the Small-Data Matrix does not correspond to the Cassette Settings currently loaded in the LFR, an error message is displayed. In such a case, use a cassette of the proper type, or load another Cassette Settings corresponding to the current cassette.

CAUTION	It is the operator's responsibility to use the Small-Data Matrix (cassette's confirmation barcode) from the current cassette.

4- After reading a Data Matrix, the LFR returns to the scanning screen. Press the 'Introduce your sample/patient ID' field (see red circle) to type the sample/patient identification with the virtual keyboard or press the 'FROM BARCODE' button (see green circle) to read the identification using the barcode reader of the LFR. Depending on the configuration this step is mandatory.



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 following right-side image) and place the barcode in front of the frontal light.

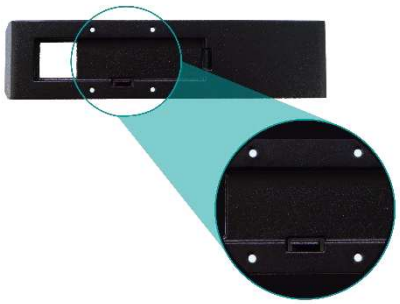


NOTE: Depending on the options of the System Configuration, if the entered reference you enter is already in the OPERON Lateral Flow Reader's stored results, a message is displayed, and scan buttons could be disabled.

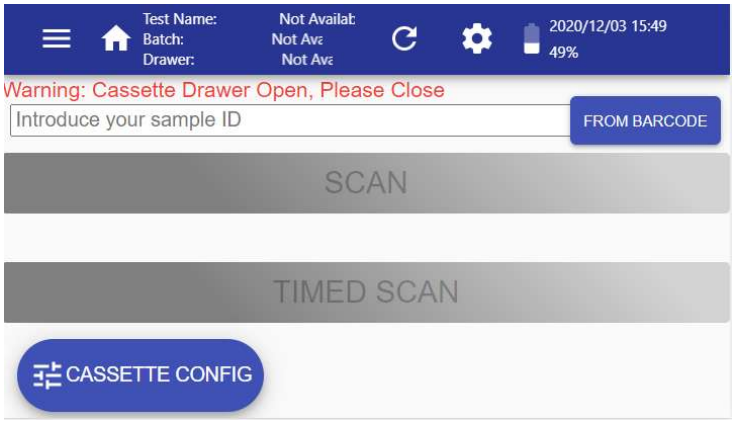
Sample/patient ID using the virtual keyboard: Special characters are not available, and its maximum length is 30.

Sample/patient ID using barcode reader: Special characters are allowed, and the maximum length is 1024. See section 0 to know how IDs are displayed in different scenarios.

5- 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.

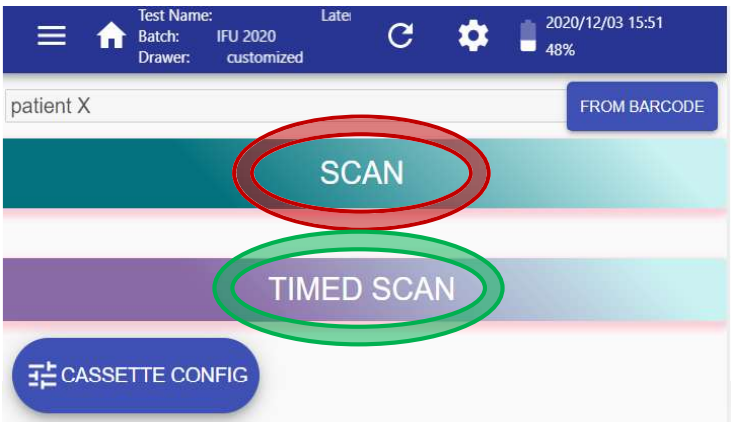
WARNING	**Before launching a scan:** - Ensure that the four (4) white dots (fiducials) on top of the drawer are present, undamaged, clean (see section 7.1), and round (e.g., in its original factory condition).  - Ensure that strips embedded in the cassette are free of impurities such as fiber or dust. Failing to ensure any of the above may lead to an incorrect result.

A warning is shown on the screen to remember to close 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 in the following image:

6- 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.



7- 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 the data (see section 5.5.3 for more information about the results screens and functionalities of its buttons).

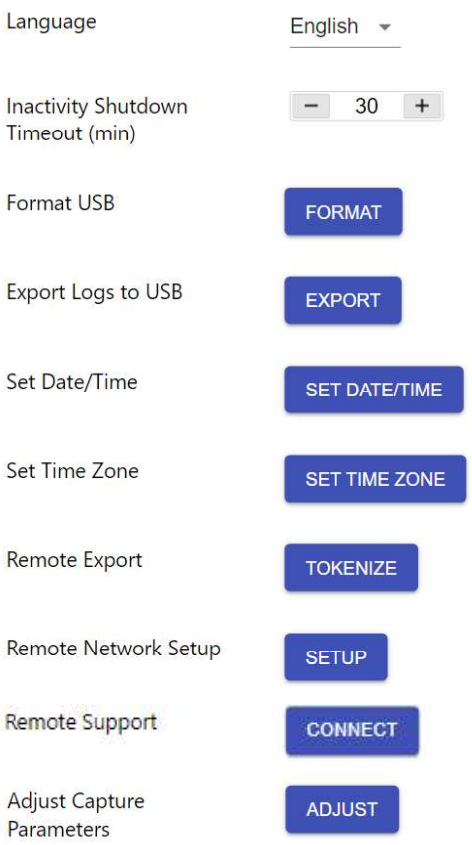
To process another cassette, press the 'NEW SCAN' button on the bottom-right corner.

WARNING	The reader will provide reliable results as long as the tests are running according to by OPERON, S.A.. 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



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 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 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 in diagnosis.
- '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 manufacturing date.

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

WARNING 	After changing the Time Zone, re-start the LFR.

- ‘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.
- Remote Support: Press the ‘CONNECT’ button when receiving technical support.

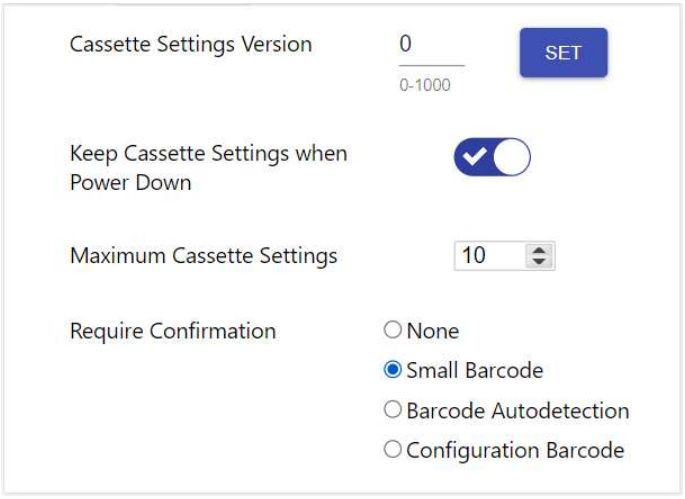
WARNING 	To use the ‘TOKENIZE’ and ‘SETUP’ buttons Internet connection is needed.

- ‘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 if the battery level is below 70%, and press ‘ADJUST’ to start the process.

WARNING 	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. CASSETTE (ADMINISTRATOR ONLY)

Only user “admin” (role Administrator) can access this screen. Parameters related to Cassette Settings are displayed and could be edited:



- Cassette Settings Version: This parameter is used to accept or block some Cassette Settings depending on its configuration. This is an internal parameter of the LFR, but Cassette Settings also have a parameter called Cassette Settings Version. When the value of the LFR is set to “0”, the LFR accepts all Cassette Settings. When the value of the LFR is set to a not “0”, the LFR blocks Cassette Settings with different values, except the value “0”. The value of a Cassette Settings is exported from the iPeak® Development Software. Below are some examples of different combinations:

Value of the Cassette Settings Version in **OPERON Lateral Flow Reader**:	0	0	7	7	3
Value of the Cassette Settings Version in **Cassette Settings**:	0	3	0	3	3
Does the LFR accept the Cassette Settings?:	YES	YES	YES	NO	YES

- Keep Cassette Settings when Power Down: If ON, the current Cassette Settings is kept when the LFR is powered off; otherwise, the current Cassette Settings is lost when the LFR is powered off. By default, it is OFF.
- Maximum Cassette Settings: Number of Cassette Settings that can be stored in the device and available to use (without re-reading its corresponding Data Matrix). The maximum value to set is 20 and the minimum is 1.
- Require Confirmation: Four options are available: ‘None’, ‘Small Barcode’, ‘Barcode Autodetection’, and ‘Configuration Barcode’. By default, Configuration Barcode is applied. Below are details of each option:

  None → It is possible to process samples with current Cassette Settings without restrictions.

Small Barcode → The confirmation barcode (Small-Data Matrix) must be read before each scan, to confirm that the current cassette matches the current Cassette Settings.

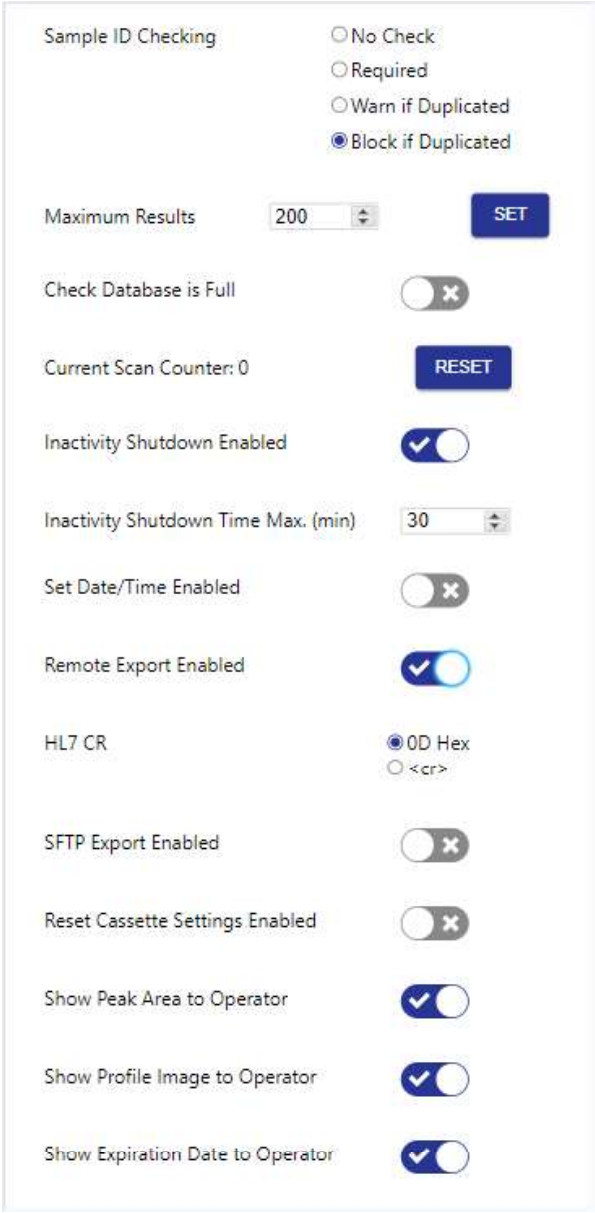
Barcode Autodetection → After launching a scan (with 'SCAN' or 'TIMED SCAN' buttons), the device tries to find the Cassette Settings that match with one of the Cassette Settings in the list, reading the barcode embedded on the cassette. Using this option you can also use the Small-Data Matrix to confirm the cassette.

WARNING 	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.

Configuration Barcode → It is necessary to load proper Cassette Settings before each scan.

5.4.3. PREFERENCES (ADMINISTRATOR ONLY)

Only user “admin” (role Administrator) can access this screen. Some parameters are displayed and could be edited:



- Sample ID Checking: Four ID checking levels are available: ‘No Check’, ‘Required’, ‘Warn if Duplicate’, and ‘Block if Duplicate’. By default, ‘Warn if Duplicate’ is applied.

  No Check → There are no restrictions or warnings.

  Required → A value is mandatory.

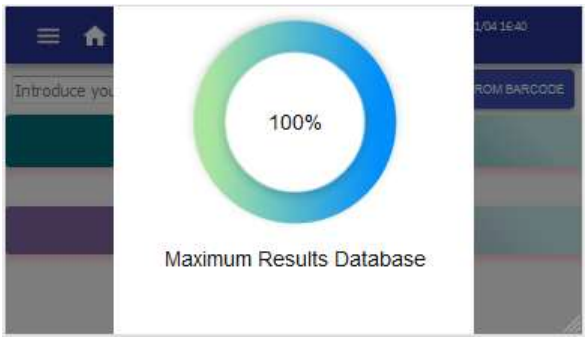
  Warn if Duplicate → A value is mandatory, and a warning is displayed if the current value is in the LFR’s stored results.

  Block if Duplicate → A value is mandatory and scan buttons are disabled if the current value is in the LFR’s stored results.

- Maximum Results Database: Set the maximum number of results that are stored in the LFR (up to 200). When the limit is exceeded, the oldest data is overwritten.

WARNING 	To avoid losing older results, before decreasing the Max Results Database, an Export Results procedure must be performed (see section 0).

- Check Database is Full: When the database reaches 80% of its capacity, a warning message is shown when the LFR is powered on and when a new Cassette Processing is started. When the message shows 100% like the below image, the oldest result is overwritten if a new scan is performed. Disable this option if it does not care to keep the results stored.



- Current Scan Counter: Displays the number of scans that have been performed since the last reset. Press the RESET button to reset this counter.
- Inactivity Shutdown Enabled: If ON, the LFR turns off automatically when the prescribed time is surpassed without any activity detected.
- Inactivity Shutdown Time Max. (min): Maximum value that the operator can set if the inactivity shutdown is enabled.
- Set Data/Time Enabled: If ON, it is possible to set Date/Time in the SYSTEM tab.
- Remote Export Enabled: If ON, remote export functionalities are active. The 'TOKENIZE' button is accessible (see section 5.4.1).
- HL7 CR: Selects the separator for HL7 segments, and two options are available:

  OD Hex → It is the non printable character for carriage return. For 'Remote Export' functionality, the data will be encoded in base64 to prevent issues with https comunications. For the 'SFTP Export' functionality, the data will be not encoded.
  <cr> → These four characters "<cr>" will be used as segments separator

- SFTP Export Enabled: If ON, after each scan the SFTP export service tries to send the result to its configured SFTP server. If an error is found a pop-up dialog shows its description. To configure the remote network, access the

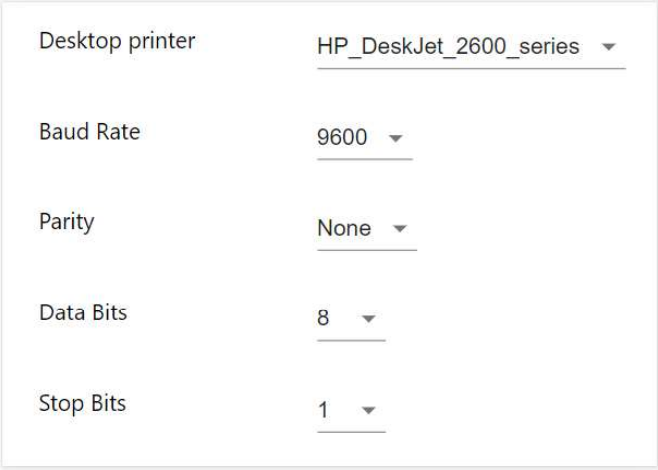
"System" tab and click the 'SETUP' button in the "Remote Network Setup" field (see section 5.4.1). When SFTP export is enabled, the Scan Results list displays an SFTP status for each scan and a 'RETURN SFTP' button when necessary (see section 0).

- Reset Cassette Settings Enabled: If ON, users with the Operator role can restore the Cassette Settings to their factory default settings. If no factory cassette settings are provided in the reader, the list will be cleared/emptied.
- Show Peak Area to Operator: If ON, users with the Operator role will see the peak area displayed in brackets within qualitative results. When set to OFF and the logged user is an Operator, this parameter will be hidden when the result is displayed or exported (ticket, PDF report and CSV file).
- Show Profile Image to Operator: If ON, users with the Operator role will be able to view the profile image in the Image tab of the results. When set to OFF and the logged user is an Operator, the profile image will not appear on the result views neither in the exported PDF reports.
- Show Expiration Date to Operator: If ON, users with the Operator role will have visibility of the expiration date of the cassette settings introduced in the reader. When set to OFF and the logged user is an Operator, this parameter will be hidden when the result is displayed or exported (ticket, PDF report and CSV file).

NOTE: Contact OPERON, S.A. to request technical specifications of Remote Export or SFTP Export functionalities:

5.4.4. PRINTER (ADMINISTRATOR OR 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.



Both the desktop printer and ticket printer must be connected to the OPERON Lateral Flow Reader USB host port (see section 3.1).

- Desktop printer: Allows to select the supported template for printing reports in PDF format.

- Ticket printer: Enter the Baud Rate, Parity, Data Bits and Stop Bits that correspond to the configuration of the receipt printer to be used.
- Baud rate: Data rate, in bits per second, of the serial communication with the ticket printer.
- Parity: Method for detecting errors in the transmission of serial communication with the ticket printer.
- Data bits: Number of bits per character, of the serial communication with the ticket printer.
- Stop bits: Number of stop bits sent at the end of each character of the serial communication with the ticket printer.

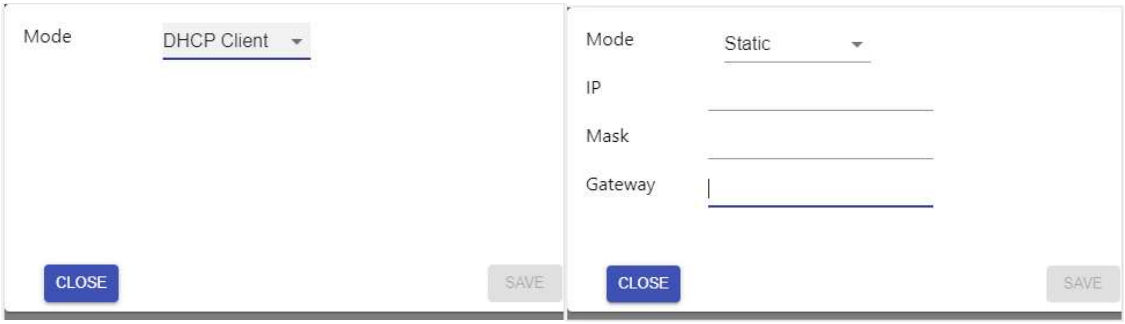
The ticket printer MUST support ESC/POS control language, and there are two options:

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

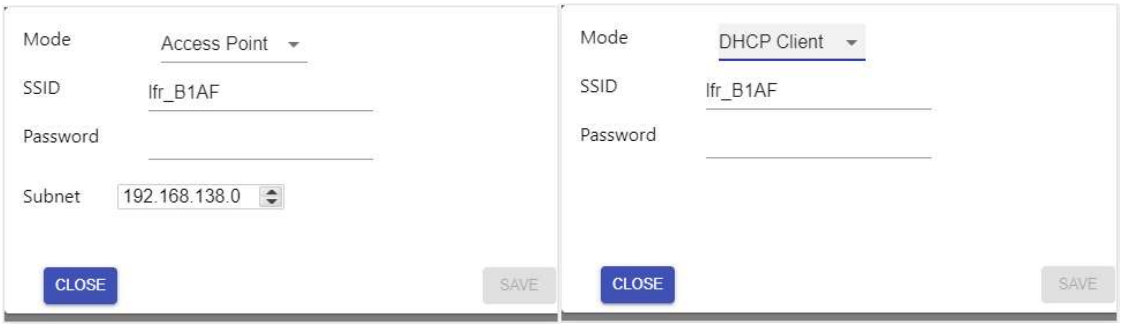
5.4.5. NETWORK (ADMINISTRATIOR OR MANAGER)

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

- '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 the option 'DHCP Client' (default), the network server will assign network parameters to the reader. If the option 'Static' is selected the connection parameters must be set on (specifically: IP, Mask, and Gateway).



- ‘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 the option ‘DHCP Client’ it is possible to connect the reader to a Wi-Fi net if proper SSID and password are set.



NOTE: The SSID field must contain between 1 and 32 characters and the Password field must contain between 8 and 63 characters (IEEE 802.11i-2004 compliant). To edit the WLAN configuration, the Airplane Mode must be disabled.

‘SFTP’: Displays current SFTP configuration. Press its SET button to configure it.

5.4.6. VERSIONS

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

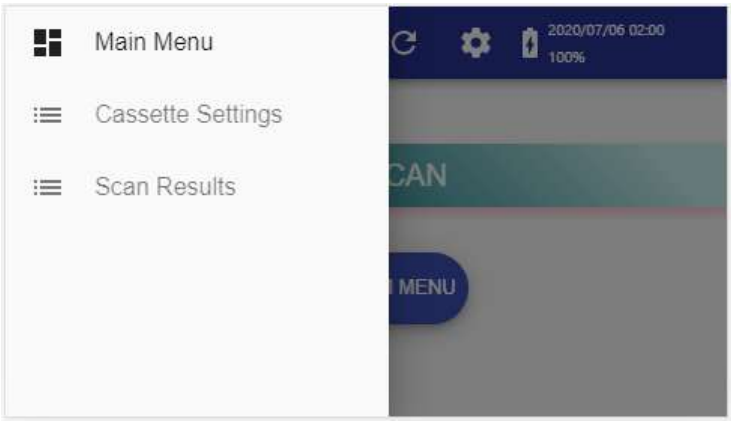
Model	Operon
Serial Number	100030000/99999
Current SW Version	3.2
Hardware Version	5.0
Product Image Version	lfr-operon-3.2-s.img
Wipe Clean SW Version	3.0
Factory SW Version	3.2

- ‘Model’: It is related to the product number (see bottom label). Determines the compatibility of cassette settings and it is related to 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.

NOTE: The maximum number of Cassette Settings that the reader stores could be set between 1 and 20. Depending on the configuration.

After selecting one row the following screen is reached:

Press ‘DELETE’ (see yellow circle) to delete this Cassette Settings from the available list.

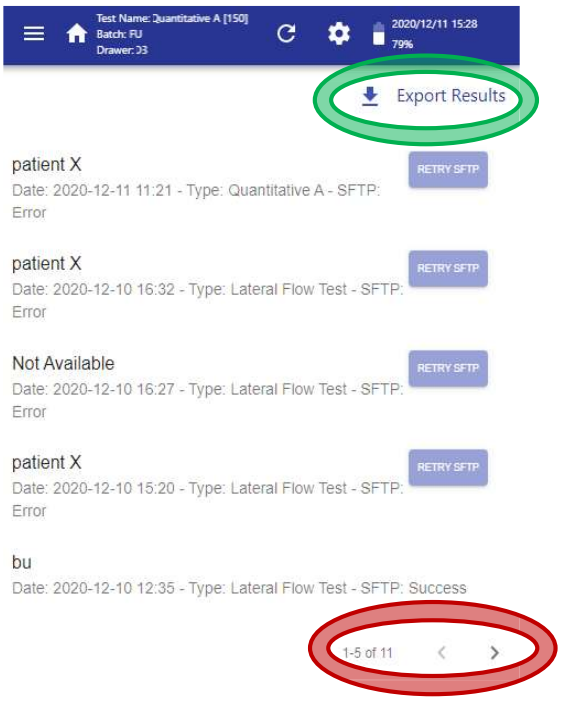
Drag up on the screen and select each tab to visualize all data related to this Cassette Settings:

Available tabs:

- LINES: List of test lines included on this Cassette Configuration and grouped strips.
- BATCH: Information related to 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.



WARNING 	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.

NOTE: The results sent successfully can't be sent again through SFTP.

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 the Administrator's or 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.

WARNING ⚠	In the Images tab, ensure that the images are aligned, focused, and not distorted. These may lead to an incorrect result.

- COMMENTS: Open space to add comments to this scan result.
- INFO: Displays data related to the scan process.

Available buttons:

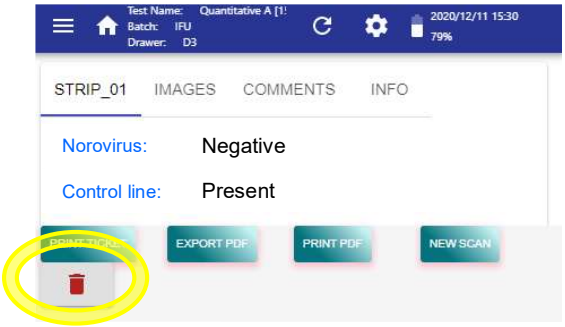
- PRINT TICKET: If a ticket printer is connected and properly configured, press the PRINT TICKET button to obtain a ticket/label containing the identification data and the summary results of the scan. See section 5.4.4 to connect and configure a ticket printer.

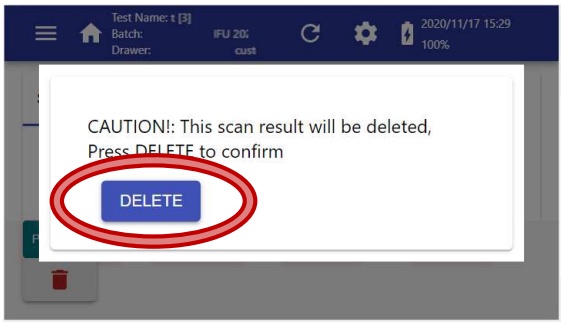
```
2020-11-16  16:51:23 (CET)
ID: test
Qualitative (3)
Lot: IFU 2020
Expiration: 2022-02-22 01:00:00 (CET)
Reader: 100030000/99999
Username: Operator
Comment:

>strip_01
  Control Line: Present (750)
  Test Line: Positive (531)
```

- 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) to the reader's USB host port and press the 'EXPORT PDF' button.

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

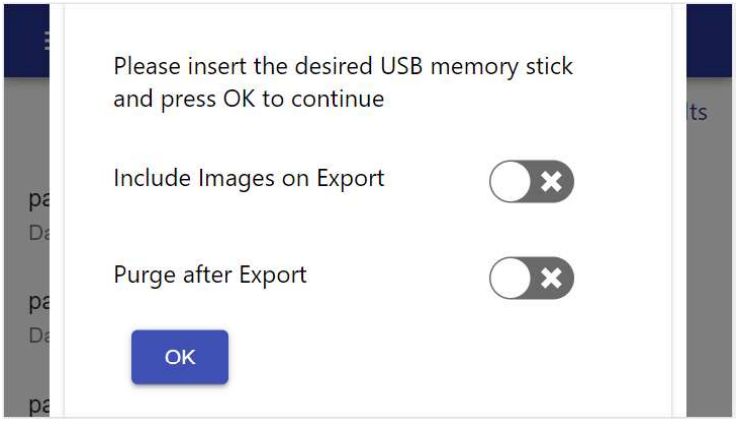
- PRINT PDF: If a desktop printer is connected and properly configured, press the PRINT PDF button to print the scan result report.
- NEW SCAN: To start a new Cassette Processing.
- DELETE (only available for Manager): When the trash icon (see yellow circle) is pressed a pop-up dialog asks for deleting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

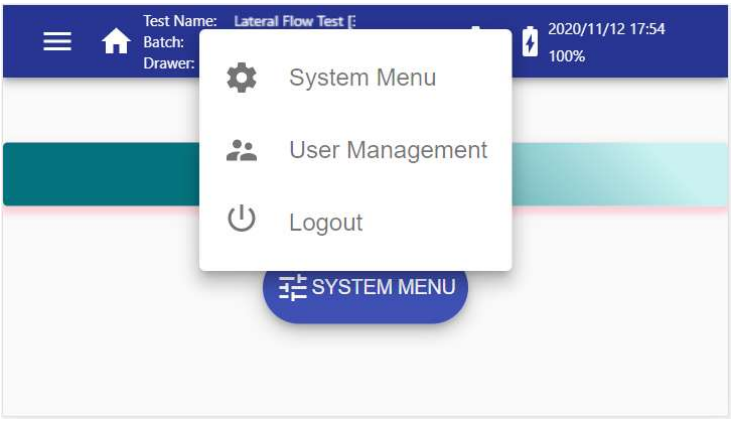
Parameters included in the results (for each processed line):

NOTE: Some fields will not appear if you have logged in with Manager or Operator role.

- 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.
- username: Username of the session where the scan is performed.
- 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 position [mm]: 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.



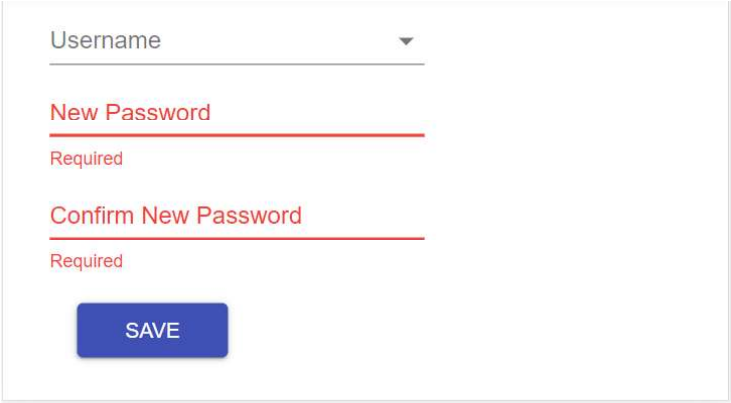
5.6.1. SYSTEM MENU

Explained in section 5.4.

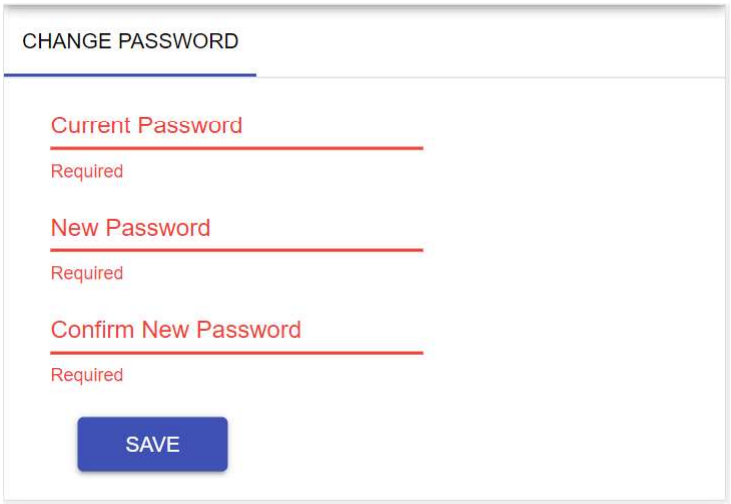
5.6.2. USER MANAGEMENT – CHANGE PASSWORD

This screen allows password change.

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



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.

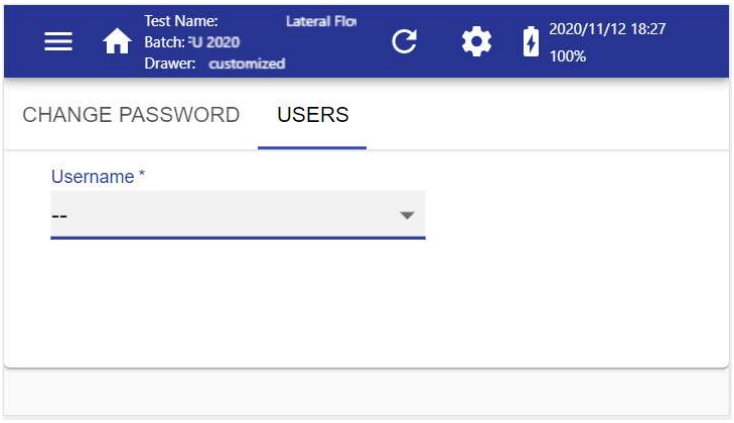


After editing all fields, press the 'SAVE' button:

- 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 (ADMINISTRATOR OR MANAGER)

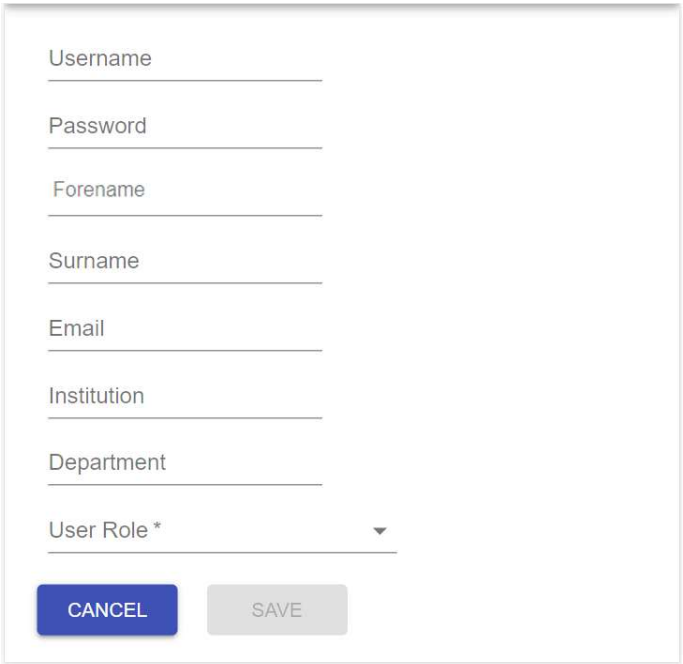
Press the 'USERS' tab to create, edit, and delete user accounts. This screen is only accessible for users with the role of Manager.



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

A. CREATE NEW USER

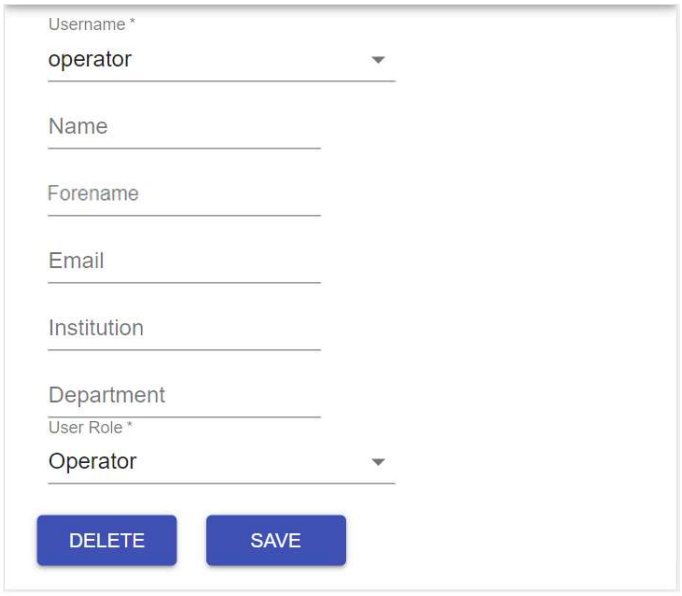
To create a new user, select the first item of the 'Username' list, '*Create new* user', and fill in the fields available. Only the 'Username', 'Password', and 'User Role' fields are mandatory.



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.

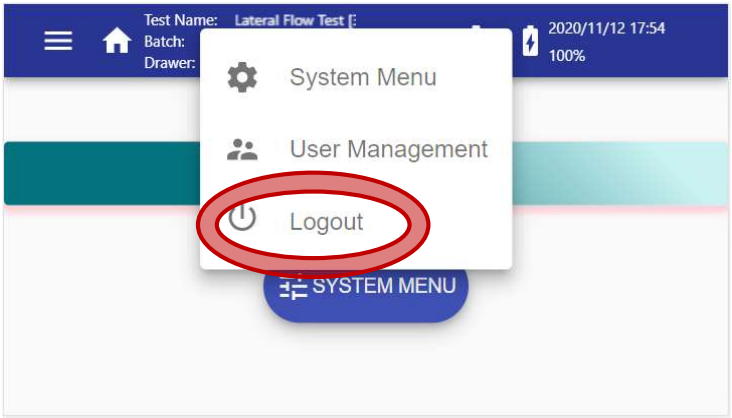


Press each field to edit its value using a virtual keyboard. To save changes press the 'SAVE' button and then the 'CONFIRM' button from the pop-up dialog.

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 the Login Screen. A new login must be performed to enable the instrument.



See section 5.1 for an explanation of 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 into the mains supply.
CAUTION 	Do not update an OPERON Lateral Flow Reader with software version 3.x using an update package 2.x or 1.x.

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

- Format a slim USB memory stick in the 'SYSTEM' tab from the System Menu of the LFR (see section 5.4.1).
- Download the proper update package under OPERON, S.A. supervision into a computer and unzip it.
- Copy the update package (file .upd) from the computer to the ROOT of the slim USB memory stick.
- Power off the LFR.
- Plug the memory stick into the USB port of the LFR with the new software version according to by OPERON, S.A.. supervision.
- Power on the LFR 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 OPERON Lateral Flow Reader turns off.
- Remove the slim USB memory stick. The LFR is ready.

CAUTION 	The software update procedure takes some time (around 40 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 are some tips to browse this instrument:

- Return to the previous screen by swiping left.
- Remove an error message from the screen, by 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 LFR cannot turn ON or Turn OFF	Damage to 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 Options menu
	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	Ensure the charger is proper one
	The charger or power cord is not properly plugged	Ensure that all charger wiring is well connected
	The charger or power cord is damaged	Replace it with a new one
	The battery or other electronic component is damaged	Send the device to Technical Service
The unit cannot perform as expected	Old version of SW	Upgrade the SW
The Wi-Fi SSID of the LFR does not appear on the computer	The wireless signal is out of range	Situate the unit near the wireless connection
	The Wi-Fi device is damaged	Contact the Technical Service for repair
The Ethernet is not detected	The Ethernet is not right connected	Correctly connect the Ethernet device
	Damage to Ethernet socket or its internal connection port	Contact the Technical Service for repair
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 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 is damaged or the wrong type	Replace the barcode with a correct one
	There is dirtiness on the barcode reader window	Clean it with an antistatic cloth or a brush
The unit cannot access the USB memory stick	The USB stick is too wide, preventing its proper full insertion into the socket	Use a slim 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	Damage to USB socket or its internal connection port	Contact the Technical Service for repair
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 or the cassette from being completely inserted	Remove the obstacle
	The drawer is damaged	Replace the drawer
	No drawer has been inserted in the LFR	Place the cassette in the drawer correctly
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”	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: Normalization error: fiducial not found	The white spots on 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 LFR cannot reset to defaults	The internal button is not properly pressed	Ensure the activation of the button during start-up
	Damage in the Software Wipe internal button	Contact the Technical Service for repair
The device restarts itself	Electrostatic discharge on the touchscreen	Wait until reboot process ends
The device does not respond	Electrostatic discharge on the touchscreen	Press and hold the power button for 10 seconds. Press power button again to power on the device

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 with 70% ethanol dilution or 10% bleach dilution.

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

To clean the drawers, use a slightly moistened cloth or an antistatic cloth with 70% ethanol dilution or 10% bleach dilution.

CAUTION 	**Damage to the drawer** Clean the 4 white dots very carefully to avoid damaging them.

7.2. Service Life and Preventive Maintenance

The OPERON Lateral Flow Reader does not have a predefined expiration date. However, to ensure continued safe operation and optimal performance over time, the manufacturer establishes a mandatory preventive maintenance program.

The OPERON Lateral Flow Reader is guaranteed to operate safely for five (5) years from the manufacturing date without requiring maintenance during that period. After this initial period, preventive maintenance must be performed every two (2) years, provided that critical components remain available and unaffected by obsolescence. Maintenance may include, where applicable, functional checks, software updates, cleaning, readjustment, or the replacement of wear-sensitive parts. Use of the OPERON Lateral Flow Reader beyond the five-year period without performing the required maintenance compromises its conformity and is entirely at the user's own risk. The manufacturer is not liable for performance, safety, or regulatory issues resulting from missed maintenance.

The OPERON Lateral Flow Reader is intended to be used as part of a broader diagnostic system. It must be integrated and validated by the system developer or test manufacturer. The OPERON Lateral Flow Reader manufacturer is not responsible for the regulatory compliance or performance of the overall system.

NOTE: This service life and maintenance guidance applies only to the main instrument. It does not affect the separate shelf life, storage conditions, or expiration dates of any consumables, reagents, control cassettes, or third-party components provided by IUL or its partners, which remain subject to their respective specifications and regulatory markings.

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
External power supply (US)	1 unit	900020089
Power cord Schuko	1 unit	900020077
Power cord (USA / Japan)	1 unit	900020080
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	90004875
Self-adjusting light Drawer	1 unit	900013732

9. Appendix B: Technical Data

The manufacturer 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
Coefficient of variation (CV)	< 5% [1]

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 ºC
Relative humidity	10 ~ 75 % (non-condensing)
Altitude	Up to 2000 meters (6500ft.)

[1] In lines with an intensity around the center of the dynamic range of IUL's Quality Control pattern.

Place of operation	For indoor use only
Pollution level	2

Transportation conditions

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

Storage conditions

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

Dimensions and Weight

Dimensions (WxHxD)	126.5 x 145 x 140 mm / 4.98 x 5.71 x 5.51 in
Weight	0.60 Kg / 1.32 lb

10. Appendix C: Warranty

The OPERON Lateral Flow Reader 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.

As part of this warranty, all shipping costs to OPERON, S.A.'s Technical Service are the responsibility of the Buyer.

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: EU Declaration of Conformity

Manufacturer:

IUL, SA – C/ Ciutat d'Asunción, 4 08030 Barcelona (Spain)

Single Registration Number (SRN): ES-MF-000000861

Product Name:

OPERON Lateral Flow Reader

Catalog Number:

900030000SD1D3

900030000UKD1D3

Basic UDI-DI:

8437022431LFR8L

Intended Purpose:

The OPERON Lateral Flow Reader is an instrument specifically to be used to provide quantitative, semi-quantitative, and/or qualitative in-vitro determination of photometric immunochromatographic test defined and marketed by OPERON, S.A.

Classification:

According to Rule 5(b) of Annex VIII, the product is classified as CLASS A.

Statements:

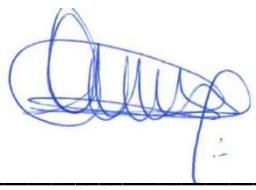
- EU declaration of conformity is issued under the sole responsibility of the manufacturer.
- The product that is covered by the present declaration is in conformity with Regulation (EU) **2017/746** of the European Parliament and of the council of 5 April 2017 on in vitro diagnostic medical devices.

Barcelona, June the 7th 2022

CE

Vicenç Font

(IVD Technical Manager)



David Guerrero

(Quality Manager)

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.

14. Appendix G: UK Declaration of Conformity

Manufacturer:

IUL, SA – C/ Ciutat d'Asunción, 4 08030 Barcelona Spain

UK Responsible Person:

CMC Medical Devices Ltd. – Office 32 19-21 Crawford Street, W1H 1PJ London, United Kingdom

Product Name / Catalog Number:

OPERON Lateral Flow Reader / 900031000UKD6

Basi UDI-DI:

8437022431LFR8L

Intended Purpose:

The declared product is an instrument specifically to be used to provide quantitative, semi-quantitative, and/or qualitative in-vitro determination of photometric immunochromatographic test defined and marketed OPERON, S.A..

Classification:

NOT LIST A or B, ARTICLE 9 – GENERAL IVD DEVICES

Conformity assessment route:

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

Statements:

- This declaration of conformity is issued under the sole responsibility of the manufacturer
- The product that is covered by the present declaration is in conformity with the UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended)

UK Designated Standards:

- EN ISO 13485:2016 & EN ISO 13485:2016/AC:2018 - Medical devices - Quality management systems - Requirements for regulatory purposes
- EN 61010-2-101:2002 - Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
- EN 61326-2-6:2006 - Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2- 6: Particular requirements - In vitro diagnostic (IVD) medical equipment
- EN 62304:2006 - Medical device software - Software life-cycle processes

Barcelona, October the 24th 2022

UK CA

Vicenç Font
(IVD Technical Manager)

David Guerrero
(Quality Manager)

Notes