INSTRUCTIONS FOR USE

Verséa™ Ophthalmics
4.3” T-POC Lateral Flow Reader

Software Version 3.1

VERSÉA™ Ophthalmics

50008609-00. OPH-007-09252023-v1

Revision Date: October 2023

Contents

INDICATION OF THE INTRODUCED MODIFICATIONS

If this is your first time using the Verséa™ Ophthalmics T-POC Lateral Flow Reader, please read the entire document carefully.

If you have previously used the Verséa™ Ophthalmics T-POC Lateral Flow Reader, in the table below, you can read the indication of the introduced modifications.

Revision	Description of change
00	Initial Version of the document.

0. GLOSSARY

LFR - Lateral Flow Reader, it is a digital device such as the Verséa™ Ophthalmics T-POC Lateral Flow Reader that reads, interprets and processes immunochromatographic lateral flow tests to generate a qualitative, semi-quantitative or quantitative result.

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

Manager - A secondary privileged user whom 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 behaviour and functionalities of the LFR. Most of them are only available to the Administrator.

Health Organization - An institution, company, or other legal entity responsible to operate the LFR together with the cassettes to be used in medical analysis.

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

Cassette Type - A cassette model and specific lateral flow tests contained in its strips.

Cassette Settings - It is a set of parameters that enables the LFR to process and measure a specific batch of a 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 setting. 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 Verséa™ Ophthalmics T-POC Lateral Flow Reader. We are confident that this instrument will become an integral part of your physician office or urgent care laboratory.

Before using the Verséa™ Ophthalmics T-POC Lateral Flow Reader, it is essential that you read these Instructions-for-Use carefully. Following the instructions and safety information in these Instructions-for-Use will ensure safe operation and maintain the system in a safe condition.

In case a serious incident occurs in relation to the device, it should be reported to Verséa Ophthalmics, LLC, and the competent authority of the Member State in which the user and/or the patient is established.

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1.1. Intended Use

The Verséa™ Ophthalmics T-POC Lateral Flow Reader (LFR) is an instrument specifically to be used to provide quantitative, semi-quantitative, and/or qualitative in-vitro determination of a photometric immunochromatographic test defined and marketed by Verséa Ophthalmics, LLC.

The Verséa™ Ophthalmics T-POC LFR is intended to be used only in combination with lateral flow (LF) tests indicated for use with the Verséa™ Ophthalmics T-POC LFR and only for applications that are described in this Instructions-for-Use.

1.2. Target Population

The Verséa™ Ophthalmics T-POC LFR 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 theatres unless all specific hygiene and patient safety requirements of these locations are followed by the user.

1.3. Product Classification

According to US Food and Drug Administration (FDA) requirements, Verséa™ Ophthalmics T-POC LFR is classified as CLASS I and it is exempted from the premarket notification requirement thus only an Establishment Registration and a Medical Device listing are required.

1.4. User Management

The Verséa™ Ophthalmics T-POC LFR can be used in three different roles:

- Operator: have access to the features needed when operating.
- Manager: has access to features needed when operating, plus the network and connectivity feature; can also delete scanned results.
- Administrator: has unlimited access to every feature of the Verséa™ Ophthalmics Device Description

1.5. Device Description

A portable test reader that yields qualitative, semi-quantitative, and quantitative results for the cassettes that are marketed by Verséa Ophthalmics, LLC.

The Verséa™ Ophthalmics Development Software for personal computer enables Verséa™ Ophthalmics to define and assess the settings required to process each cassette supported by the LFR.

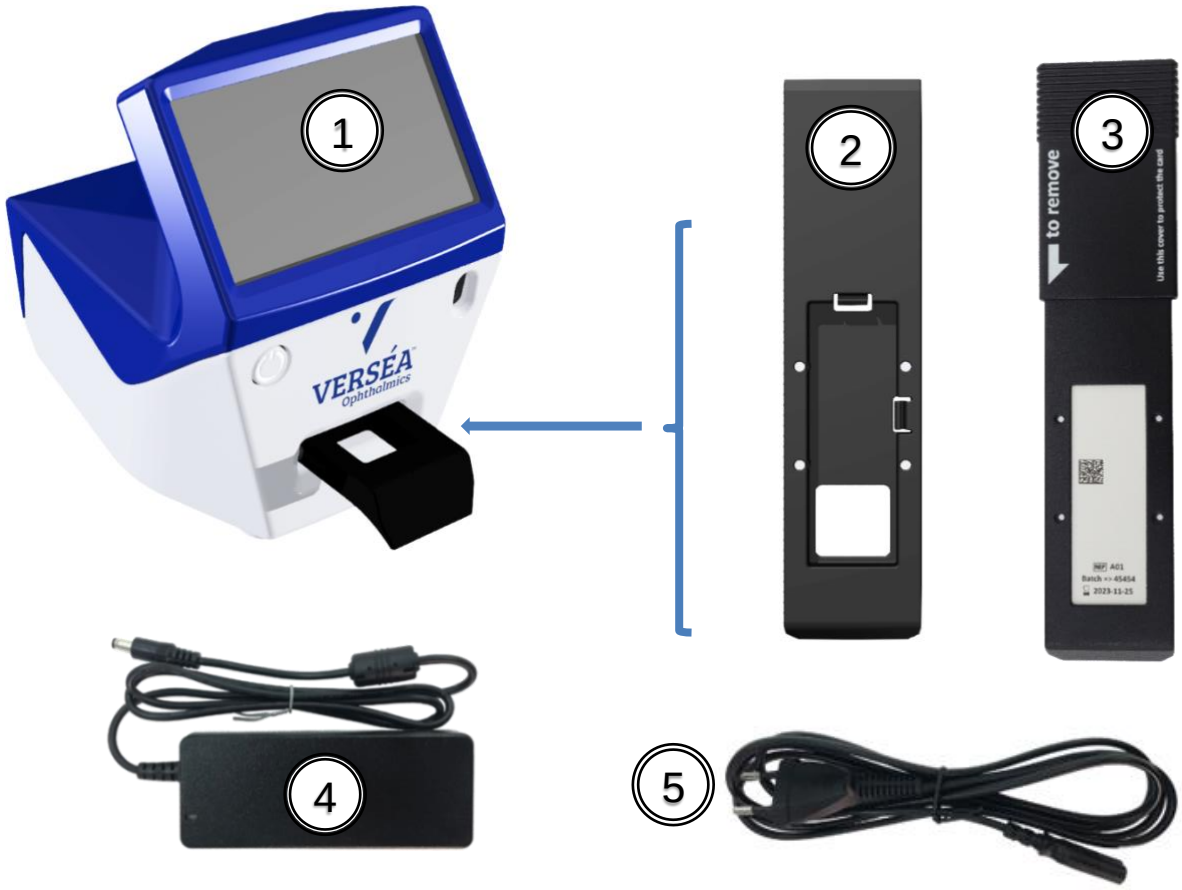
1.6. Contraindications

Not applicable.

1.7. General Information

1.7.1. SCOPE OF DELIVERY

The delivery includes the following items:



1. Verséa™ Ophthalmics 4.3” T-POC Lateral Flow Reader main unit (Cat.100033000)
2. Drawer (Cat. 900014095)
3. Adjustment drawer (Cat.900013732)
4. External power supply unit (Cat. 900020089)
5. Power cord (Cat. 900020078)

See Appendix A “Ordering Codes” for more information.

1.7.2. TECHNICAL ASSISTANCE

Technical assistance is provided by Verséa Ophthalmics, LLC. The Technical Service Department is staffed by experienced technicians with extensive practical and theoretical expertise in the use of Verséa™ Ophthalmics products. If you have any questions or experience any difficulties regarding the Verséa™ Ophthalmics T-POC LFR or other related Verséa™ Ophthalmics products, do not hesitate to contact:

Phone: +1 800-397-0670
Email: ophthalmics@versea.com

Verséa™ Ophthalmics 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 Verséa Ophthalmics, LLC. We, therefore, encourage you to contact us if you have any suggestions about product performance or new applications and techniques.

For technical assistance, contact the Verséa Ophthalmics, LLC Technical Service Department or local distributors.

Email: ophthalmics@versea.com

1.7.3. POLICY STATEMENT

It is the policy of Verséa Ophthalmics, LLC to improve products as new techniques and components become available. Verséa Ophthalmics, LLC 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 these Instructions-for-Use. Please contact Verséa Ophthalmics, LLC Technical Service with any feedback.

1.7.4. REQUIREMENTS FOR VERSÉA™ OPHTHALMICS T-POC LFR USERS

Table 1 covers the general level of competence for the use and servicing of the Verséa™ Ophthalmics T-POC LFR.

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

2. SAFETY INFORMATION

Before using the Verséa™ Ophthalmics T-POC LFR, it is essential that you read this Instructions-for-Use document carefully. Following the instructions and safety information in this Instructions-for-Use document will ensure safe operation and maintain the system in a safe condition.

The following types of safety information appear throughout the Verséa™ Ophthalmics T-POC LFR 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 Instructions-for-Use 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 Verséa™ Ophthalmics T-POC LFR 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 Verséa™ Ophthalmics T-POC LFR instrument. Damage caused by water or chemical spillage will void your warranty.

In case of emergency, switch off the Verséa™ Ophthalmics T-POC LFR with power button and unplug the power cord from the power outlet.

2.2. Electrical Safety

If the operation of the Verséa™ Ophthalmics T-POC LFR 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 Verséa Ophthalmics, LLC Technical Service after such an incident.

WARNING 	**Rechargeable Batteries** The Verséa™ Ophthalmics LFR 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 Verséa™ Ophthalmics. • 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 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 clean. • In case of replacement or loss of the AC adaptor or the mains power cord, these must be replaced only with the AC adaptors or power cords listed on “Ordering Codes” In case of replacement, this must be ordered through Verséa Ophthalmics, LLC.

To ensure satisfactory and safe operation of the Verséa™ Ophthalmics T-POC LFR:

- 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 or power cords than that specified in “Ordering Codes” must be used. In case of replacement, this must be ordered through Verséa Ophthalmics, LLC.
- The instrument must not be operated with the cover removed.
- If you suspect any instrument damage, contact Verséa Ophthalmics, LLC. Technical Service.

If the Verséa™ Ophthalmics T-POC LFR becomes electrically unsafe, prevent other personnel from operating it, and contact Verséa Ophthalmics, LLC Technical Service.

The instrument may be electrically unsafe if:

- The instrument or the external power supply is shown to be damaged.
- The instrument has been stored under unfavorable conditions for a prolonged period.
- A different external power supply or power cord is used other than the one provided by Verséa Ophthalmics, LLC.

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 on the “Ordering Codes” and provided by Verséa Ophthalmics, LLC.

2.3. Environment

Operating conditions

WARNING 	**Explosive atmosphere** The Verséa™ Ophthalmics T-POC LFR is not designed for use in an explosive atmosphere.
CAUTION 	**Direct sunlight** Do not expose the Verséa™ Ophthalmics T-POC LFR to direct sunlight or other powerful lights during operation.
CAUTION 	**High humidity or liquids** Protect the Verséa™ Ophthalmics T-POC LFR from high humidity and contact with liquids.
CAUTION 	**Strong electromagnetic radiation** Do not expose the Verséa™ Ophthalmics T-POC LFR to strong electromagnetic radiation.
CAUTION 	**Strong ultrasonic radiation** Do not expose the Verséa™ Ophthalmics T-POC LFR 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 Verséa™ Ophthalmics T-POC LFR may contain infectious agents. Handle such samples in accordance with the required safety regulations. Always read how to proceed in the cassette's instructions for 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/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.

[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).

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/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.

2.5. Chemicals

WARNING 	**Hazardous chemicals** Some chemicals used with the Verséa™ Ophthalmics LFR 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 Verséa™ Ophthalmics T-POC LFR instrument. Do not use products containing alcohol or other corrosive solvents to clean the Verséa™ Ophthalmics T-POC LFR instrument. Proper maintenance is reviewed in Section 7.
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. Collect and dispose of them following local safety regulations.

All packaging waste from cassettes must be collected and disposed of properly following local environmental regulations.

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

2.8. Symbols on the Verséa™ Ophthalmics T-POC LFR Device

Symbol	Location	Description
	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 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	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.

Symbol	Location	Description
	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 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 “Waste Electrical and Electronic Equipment (WEEE)”.
	Type plate on the bottom of the instrument and the external box label	FCC compliant, Declaration of Conformity, see “EC Declaration of Conformity”.
	Type plate on the bottom of the instrument and the external box label	Caution: Federal law restricts this device to sale by or on the order of a physician.

2.9. Cybersecurity

The LFR Software (SW) 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, or others.

The LFR is designed to operate in the intended environment of use defined by Verséa Ophthalmics, LLC, who 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) whom is the only user that may configure CASSETTE and PREFERENCES tabs.

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

The LFR starts with a Login Screen, to introduce the username and password before operating. (See sections 5.6.1 System Menu).

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

NOTE: Contact Verséa Ophthalmics, LLC. to request technical specifications of Remote Export and Audit Trail functionalities.

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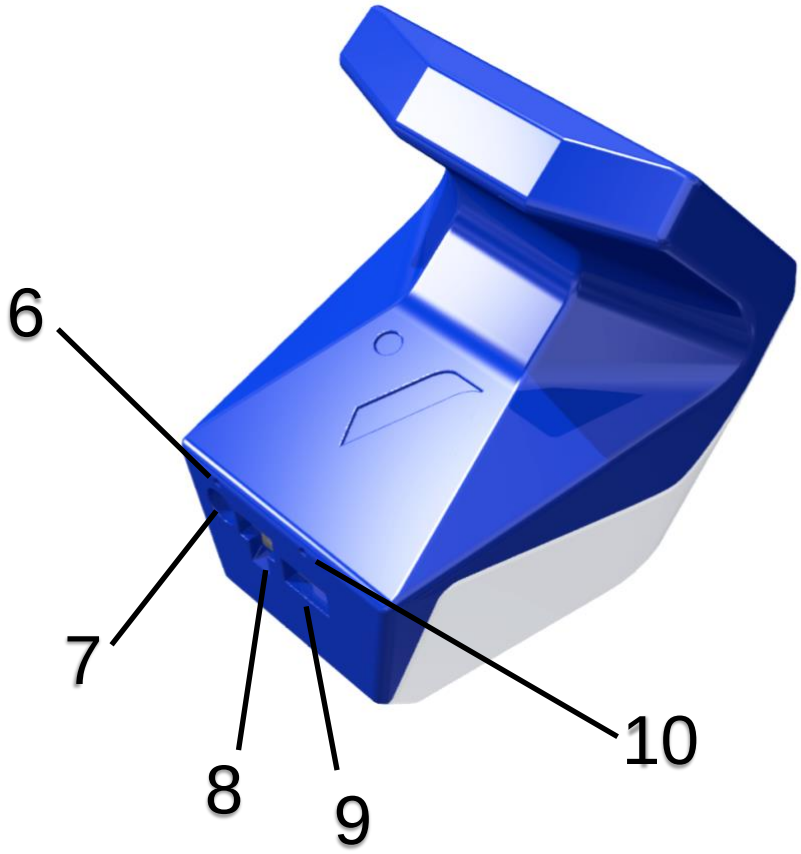
3. GENERAL DESCRIPTION

3.1. Device 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 slim USB memory sticks)
10. Software Wipe buttonhole

ATTENTION: 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 Device

3.2.1. DRAWER

The drawer model must fit with the corresponding Cassette model for proper use of the LFR. See “Ordering Codes” to find available models.

3.2.2. EXTERNAL POWER SUPPLY

Connect the external power supply to main, and the LFR 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 on the “Ordering Codes” delivered by Verséa Ophthalmics, LLC

3.2.3. POWER CORD

The LFR is equipped with a power cord with a plug suitable for the destination country. See “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 on the “Ordering Codes” delivered by Verséa Ophthalmics, LLC

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 Device

The packaging of the Verséa™ Ophthalmics LFR 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 Verséa™ Ophthalmics T-POC LFR device on a stable surface, far away from powerful lights and near an earthed/grounded electrical outlet.

It is recommended to connect the Verséa™ Ophthalmics T-POC LFR device to a power supply when used continuously.

4.3. Power Cable Connection

The socket for connecting the power cable is on the back of the Verséa™ Ophthalmics T-POC LFR device.

When the Verséa™ Ophthalmics T-POC LFR is not in use for a long period of time, we recommend disconnecting the power cable.

4.4. Cassette Requirements

Before using the Verséa™ Ophthalmics T-POC LFR device make sure that the cassette has not exceeded its expiration date.

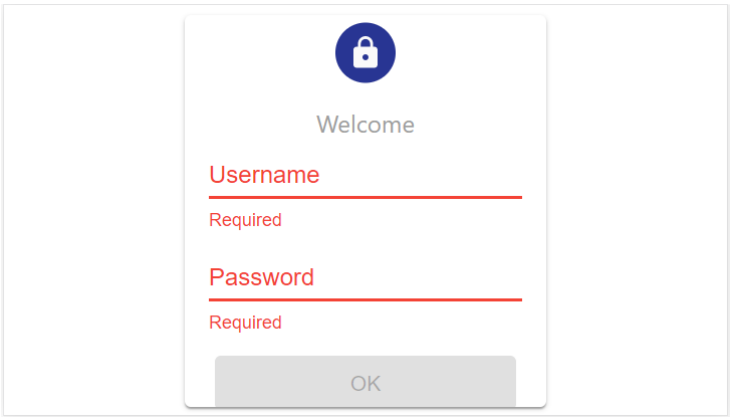
ATTENTION: Do not use expired cassettes. Review the expiration date of the cassette and do not use it if it is expired.

5. OPERATING PROCEDURES

CAUTION	Before switching on the reader for the first time or after a 6 month period of inactivity, it is essential to plug it into the main supply. Failure to do so may cause permanent damage to the unit.

5.1. Login Screen

To start the LFR, press the power button (see section 3.1) and wait until the Login Screen is shown:



To enable the LFR, 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 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**".

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

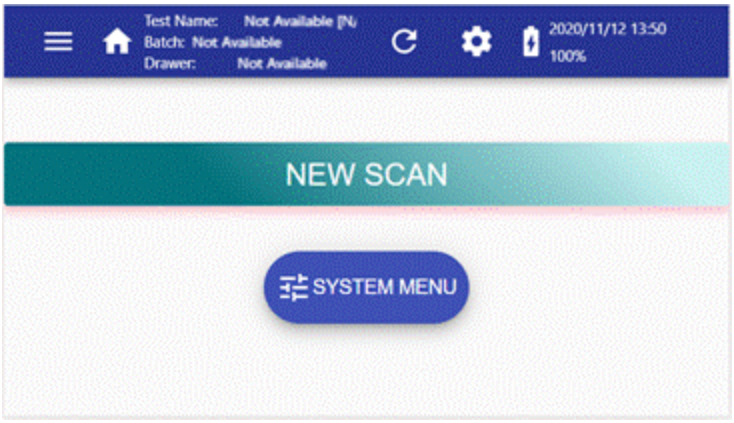
See section 5.6.2 for explanations on how to change passwords. Retain the new password in a secure location.

NOTE: If you forget or lose your password, contact your LFR's Manager.

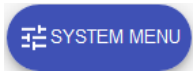
To end the user's session, select 'Logout' on Tools Menu (see section 5.6.4 for more information) or power off the LFR.

5.2. Home Screen Overview

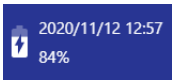
The Home screen displays the current Cassette Settings, date, time, battery status, 'NEW SCAN' button, and 'SYSTEM MENU' button.



Main Screen:

	Press this button to start a new Cassette Processing.
	Press this button to enter the System Menu.

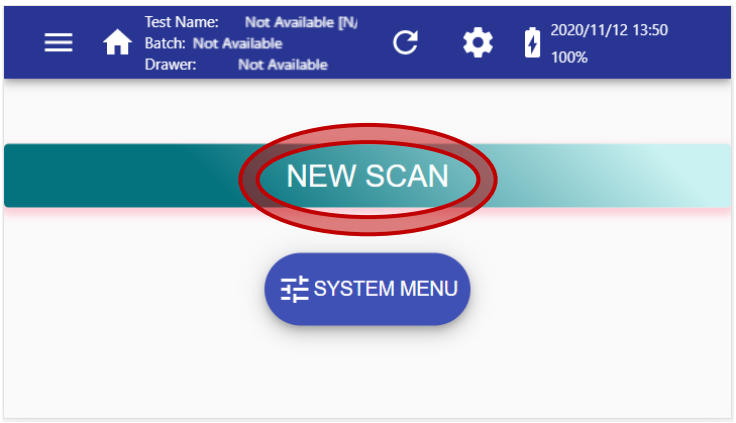
Top Bar:

	Shows the Drop-Side Menu.
	Return to Home screen.
	Information on the current Cassette Settings available to be used.
	Press it to refresh the current screen. When a new page or image is loading, the icon spins.
	Shows the drop-down 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. Cassette Processing

To process a cassette, the next steps should be followed:

1- To start a new cassette scan, press the ‘NEW SCAN’ button on the Home screen (see red circle).

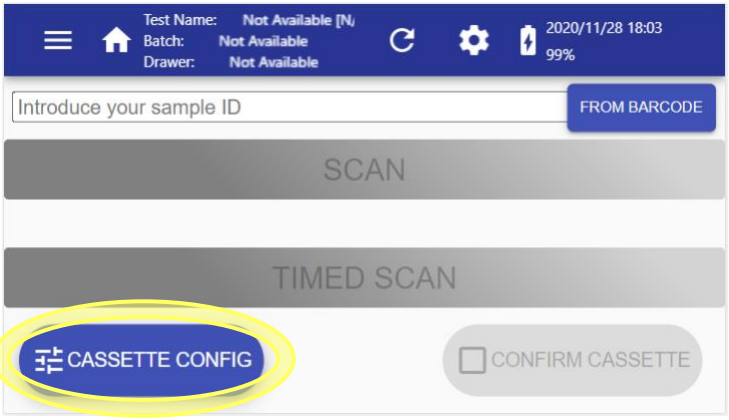


2- Omit this step if the Cassette Settings on the Top Bar is the Cassette Settings to use in the next scan. This step may be required in certain configurations.

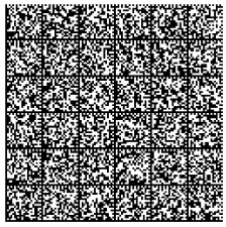
To set the proper Cassette Settings that will be used in the next scan, there are the following options:

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 Data Matrix of proper Cassette Settings, which is supplied along with the cassette box:



Place it in front of the LFR's barcode reader (see section 3.1) at 5 cm (2 inches) of distance approximately. Press the 'ACTIVATE BARCODE READ' button (see green 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.

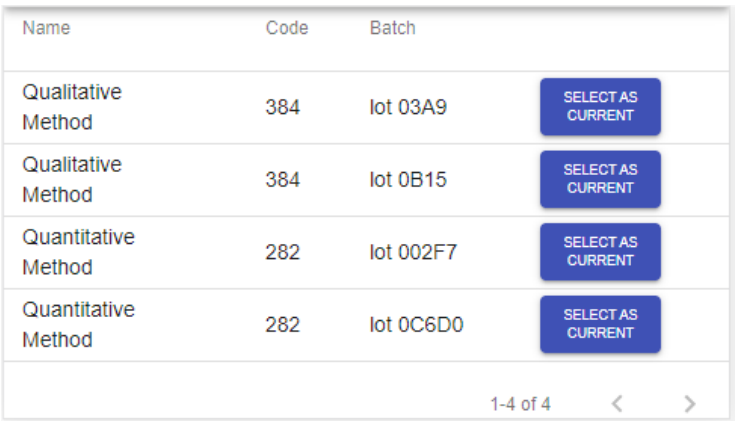
NOTE: If a barcode cannot be read, check and clean the window of the barcode reader (see section 3.1).

If the barcode is read but does not fit with the expected features, an error message is shown on the screen. Check the exposed barcode and touch the display outside the dialog box to skip the error message and return to the previous screen.

After proper reading, the new Cassette Settings data is shown on the Tab bar.

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

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

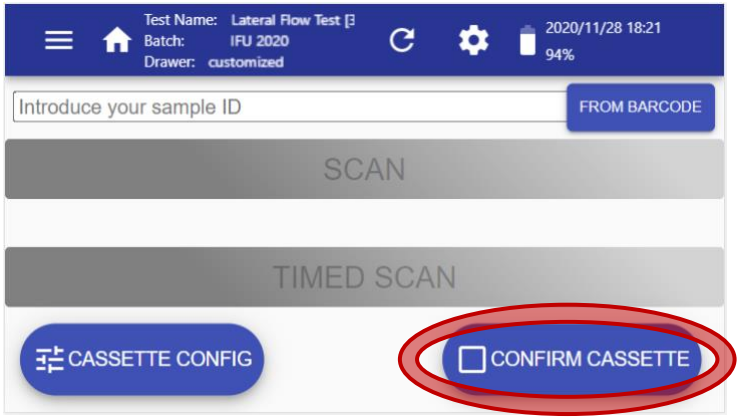


Press the ‘SELECT AS CURRENT’ button to load the Cassette Settings of the row.

B.2 ‘Barcode Autodetection’ launches the scan directly if the option ‘Barcode Autodetection’ is selected.

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- Depending on the configuration this step may be omitted. 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.

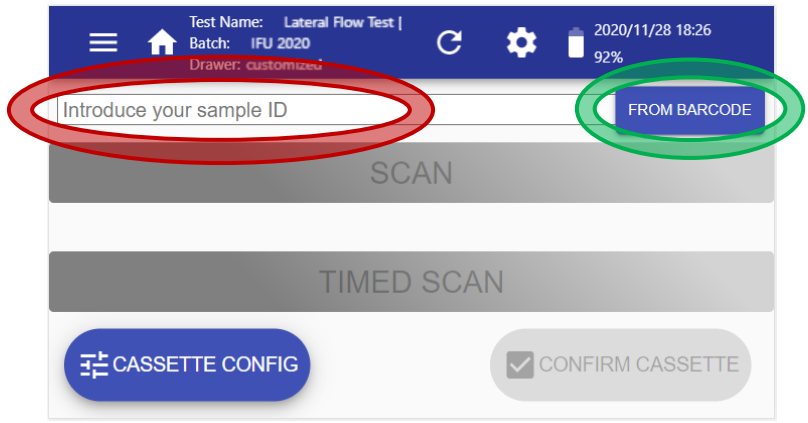


Place the small barcode (Small-Data Matrix) in front of the barcode reader (see section 3.1) at 5 cm of distance approximately. Press the ‘ACTIVATE BARCODE READ’ button (see yellow circle). The barcode reader starts its reading process using a light. This light disappears when a barcode has been read or after 10 seconds of trying.

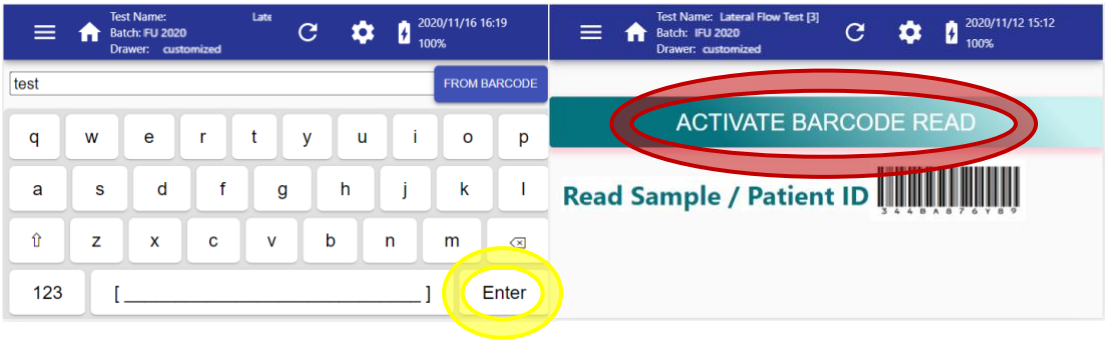
If the Small-Data Matrix does not correspond to the Cassette Settings currently loaded in the LFR, an error message is displayed. In such a case, use a cassette of the proper type, or load another Cassette Settings corresponding to the current cassette.

ATTENTION: 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 LFR's configuration, if the reference you enter is already in the LFR's stored results, a message is displayed, and scan buttons could be disabled.

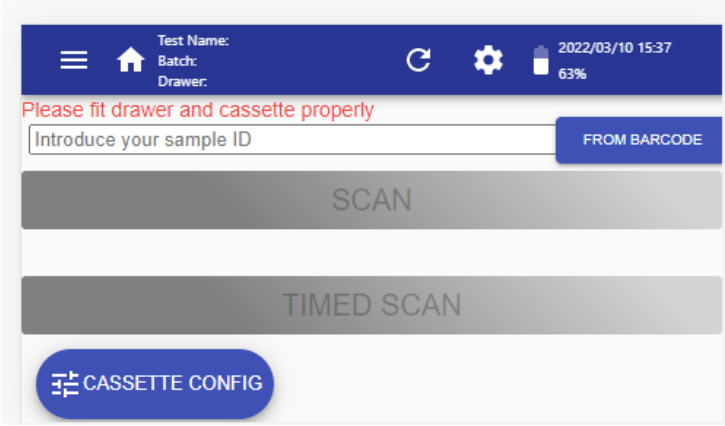
Sample/patient ID using the virtual keyboard: Special characters are not available and its maximum length is 30.

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.

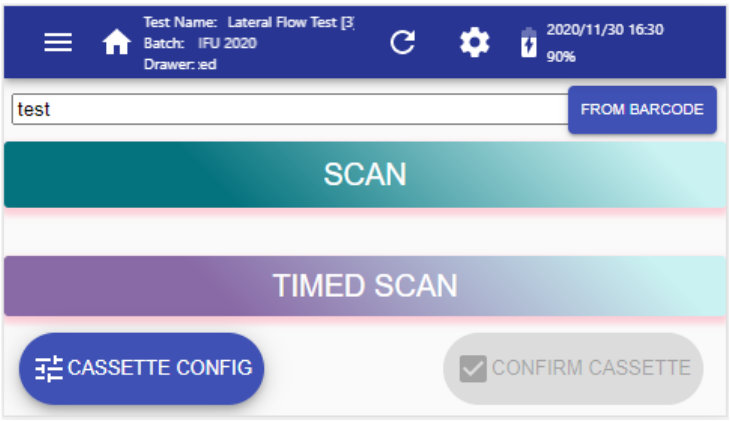
5- Insert the cassette into the corresponding drawer. Ensure that the code in the drawer bottom (see yellow circle) matches with the drawer code displayed along with the cassette settings at the Top Bar. Ensure that the cassette and the drawer surfaces are leveled; then press the drawer inside the LFR.

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

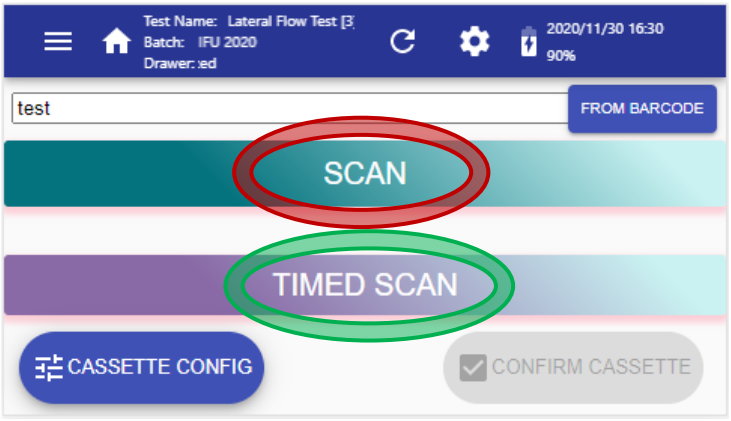
A warning is shown on the screen when the drawer is not properly closed (see next image). Place the drawer properly inside the LFR.



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 LFR. Depending on the LFR'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- Results of the scan are displayed when the process ends. Drag up and down on the touchscreen and press the different tabs to see all data. See section 5.5.3 for more information about result screens and functionalities of its buttons.

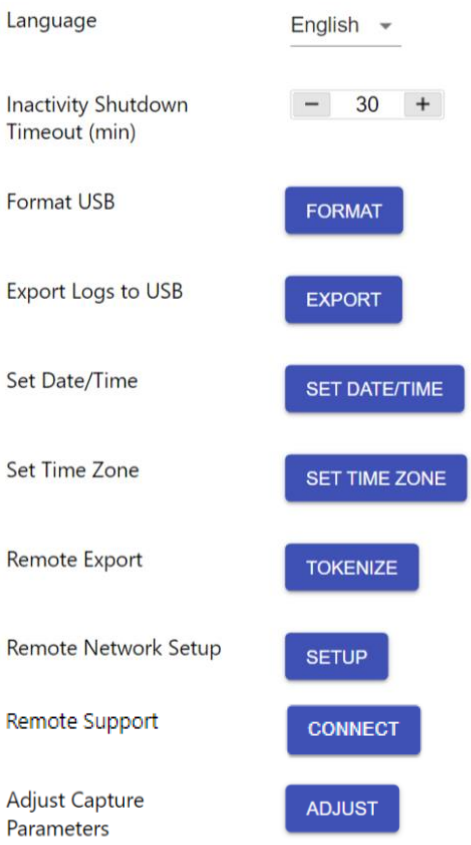
To process another cassette, press the ‘NEW SCAN’ button on the bottom-right corner.

WARNING	The reader will provide reliable results as long as the tests are running according to Verséa Ophthalmics, LLC 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 installed in the LFR.
- Inactivity Shutdown Timeout (min): Time in minutes since the last interaction with the LFR, 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 properly a slim USB memory stick, and then be able to use it to export CSV and PDF results, write logs, and update the LFR software.
- Export Logs to USB: Press this button to write internal data to a slim USB memory stick plugged into the USB host port. Important for the Technical Service as an aid for diagnosing.
- Set Date/Time: Define the current date and time. This parameter has configurable access.

NOTE: The LFR is not ready to work with dates before the manufacturing date.

- Set Time Zone: Define the current time zone.

ATTENTION: After changing 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 the available SFTP setup, including network domain: Ethernet, WLAN, and airplane mode. The LFR'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.

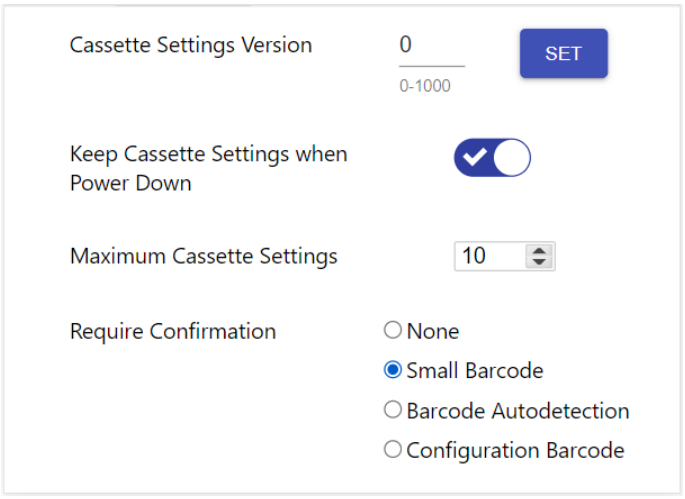
ATTENTION: To use the 'TOKENIZE' and 'SETUP' buttons, an Internet connection is needed.

- Adjust capture parameters: To readjust the camera parameters insert the adjustment drawer (Cat.900013732), connect the reader to the power supply if the battery level is below 70%, and press 'SETUP' 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. 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 Development Software. Below are some examples of different combinations:

Value of the Cassette Settings Version in **Verséa™ Ophthalmics T-POC LFR**:	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.

- 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 10 and the minimum is 1.

- Require Confirmation: Four options are available: ‘None’, ‘Small Barcode’, ‘Barcode Autodetection’, and ‘Configuration Barcode’. 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.

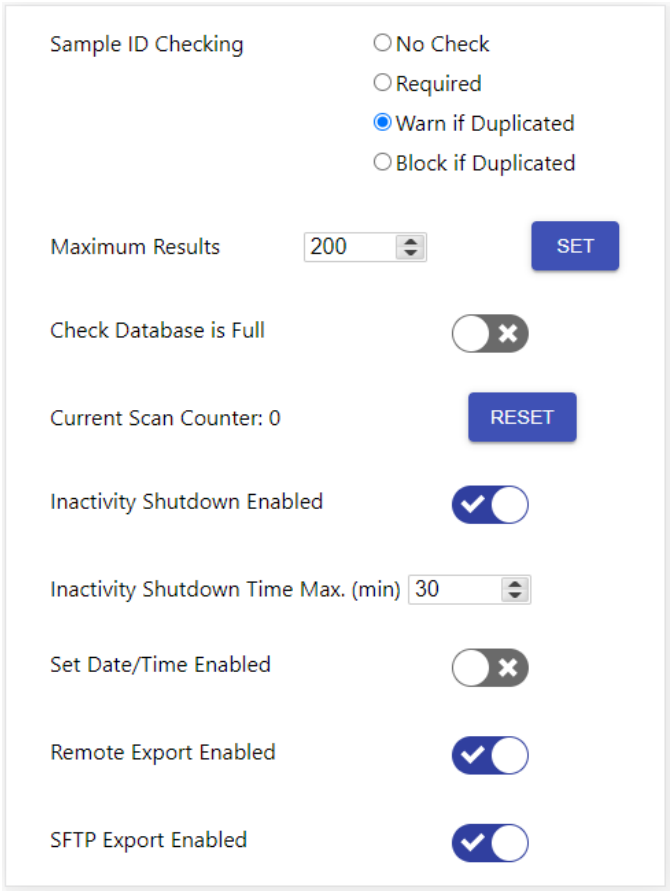
  Barcode Autodetection → After launching a scan (with ‘SCAN’ or ‘TIMED SCAN’ buttons), the device tries to find the Cassette Settings that match with one of the Cassette Settings list, reading the barcode embedded on the cassette. Using this option you can also use the Small-Data Matrix to confirm the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

  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.

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

5.4.3. PREFERENCES (ADMINISTRATOR ONLY)

Only user “admin” can access this screen. Some parameters are displayed and can be edited:



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

  No Check → There are no restrictions or warnings.

  Required → A value is mandatory.

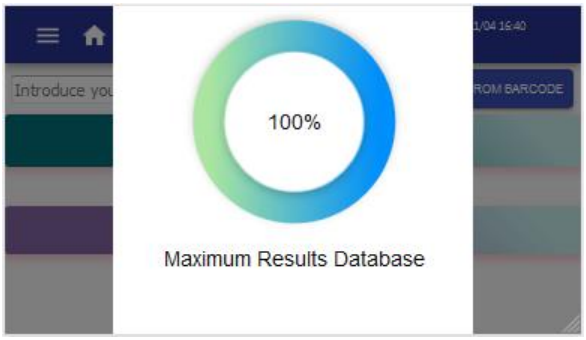
  Warn if Duplicate → A value is mandatory, and a warning is displayed if the current value is in the LFR’s stored results.

  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.

ATTENTION: To avoid losing older results, before decreasing the Max Results Database, an Export Results procedure must be performed (see section 5.5.3).

- 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 you decide not 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).
- 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. As well as SFTP Export the 'CONFIGURE' button is accessible (see section 5.4.1) and the Scan Results list displays an SFTP state for each scan and a RETRY SFTP button when required (see section 5.5.3).

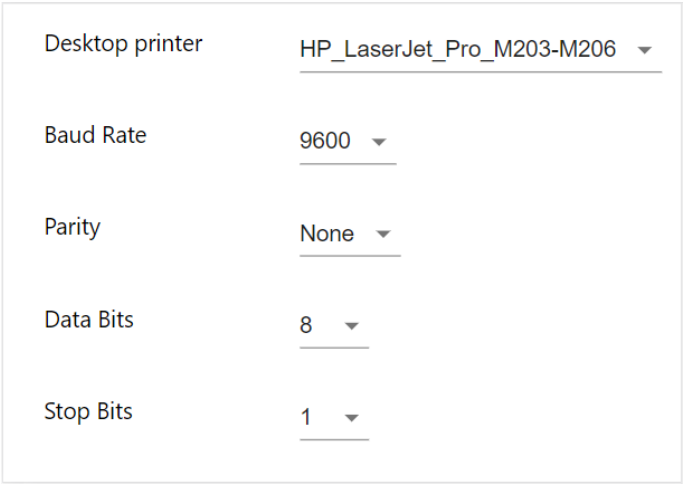
NOTE: Contact Verséa Ophthalmics, LLC to request technical specifications of Remote Export or SFTP Export functionalities:

Phone: +1 800-397-0670

Email: ophthalmics@versea.com

5.4.4. PRINTER (ADMINISTRATOR OR MANAGER ONLY)

Only users with the role of Administrator or 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: 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 LFR USB host port (see section 3.1).

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

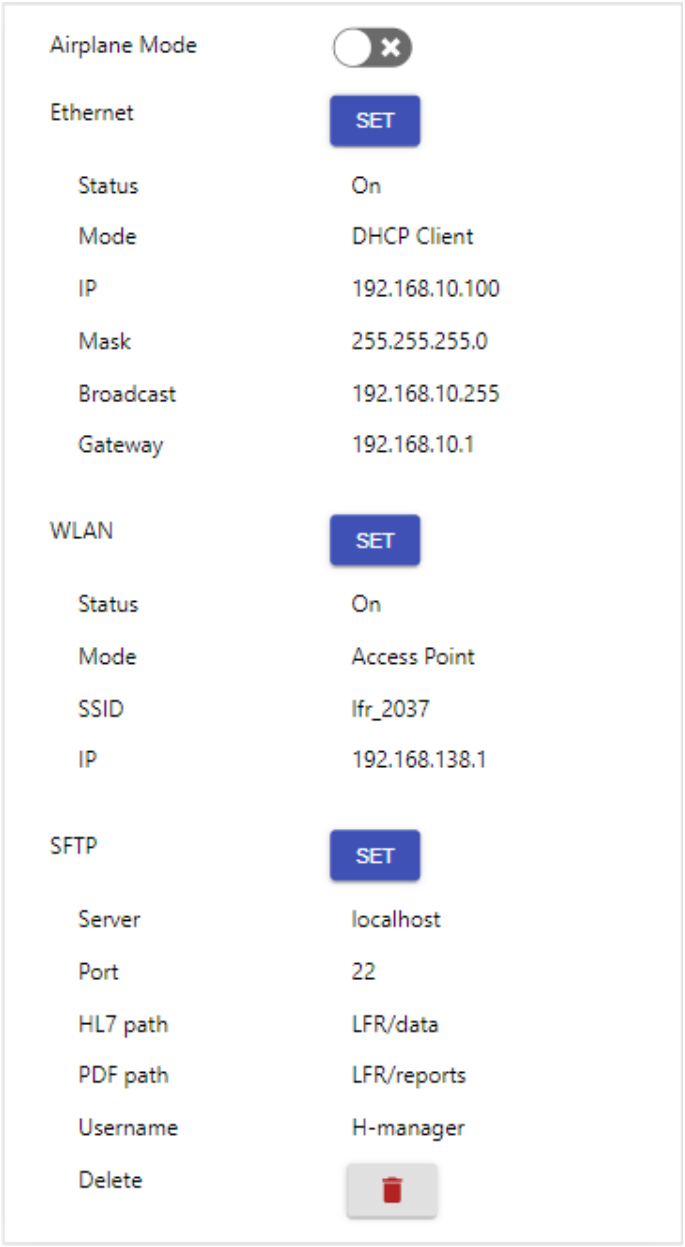
The ticket printer MUST support ESC/P control language, and there are two options:

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

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

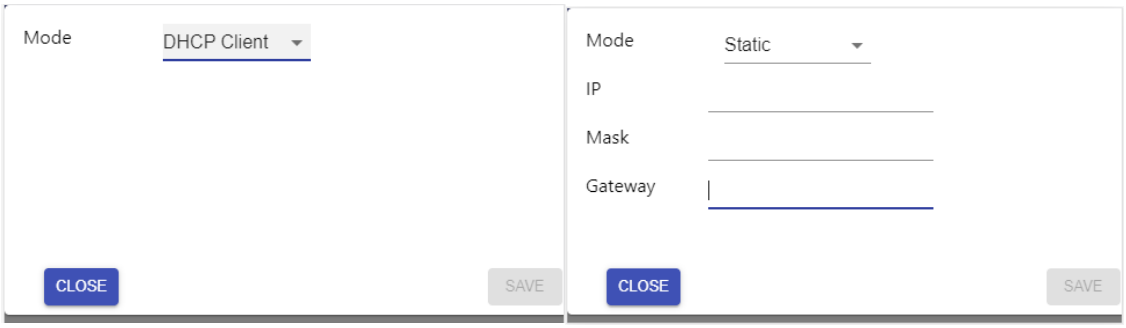
5.4.5. NETWORK (ADMINISTRATOR OR MANAGER ONLY)

Only users with the Administrator or Manager roles can edit the parameters of this screen. Users with the Operator role can only set the Airplane Mode. Network communications parameters are displayed:

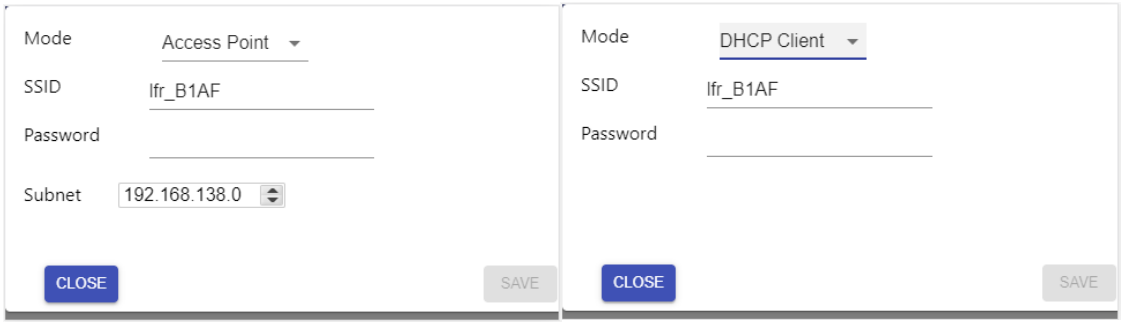


- Airplane Mode: If ON, Wi-Fi connections are disabled, and an airplane icon is shown on the Top Bar.

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



- WLAN: Displays the current Wi-Fi network’s configuration. Press 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 LFR to a Wi-Fi network if the proper SSID and password are set.

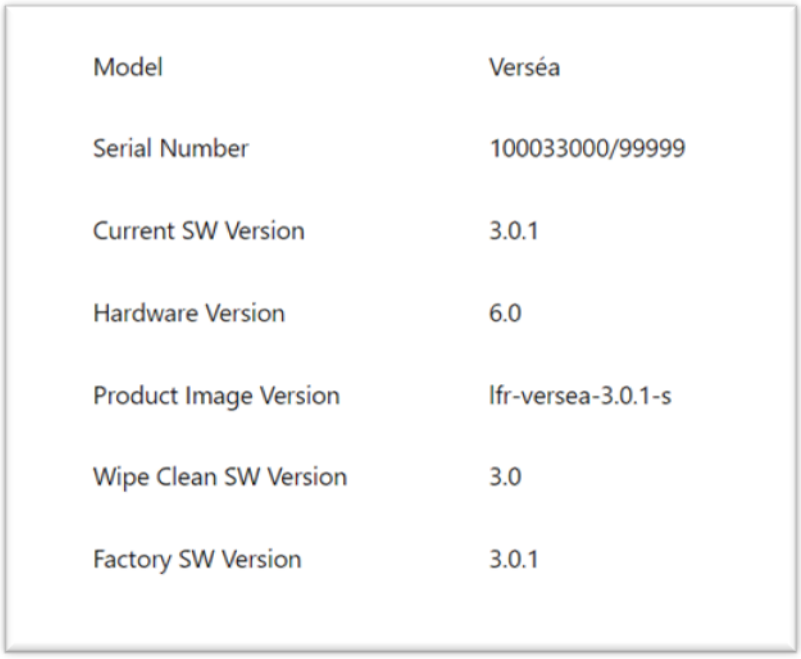


NOTE: WLAN Password field must contain between 8 and 63 characters (IEEE 802.11i-2004 compliant).

- 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).

5.4.6. VERSIONS

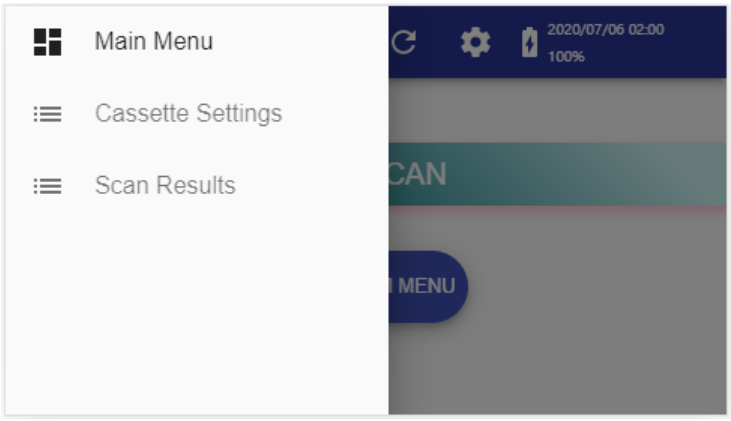
Displays a list of information related to the LFR and its software.



- Model: It is related to 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 LFR (see bottom label).
- Current SW Version: Software version of the LFR.
- Hardware Version: Hardware version of the LFR.
- 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 dropdown menu is displayed with the following options:

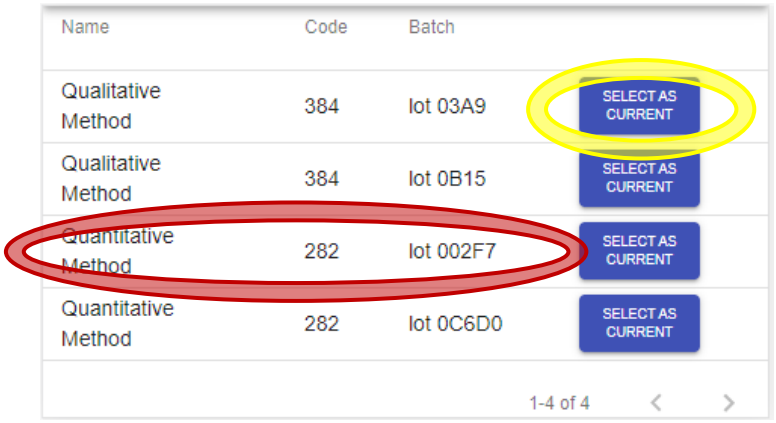


5.5.1. MAIN MENU

Returns to the Home screen.

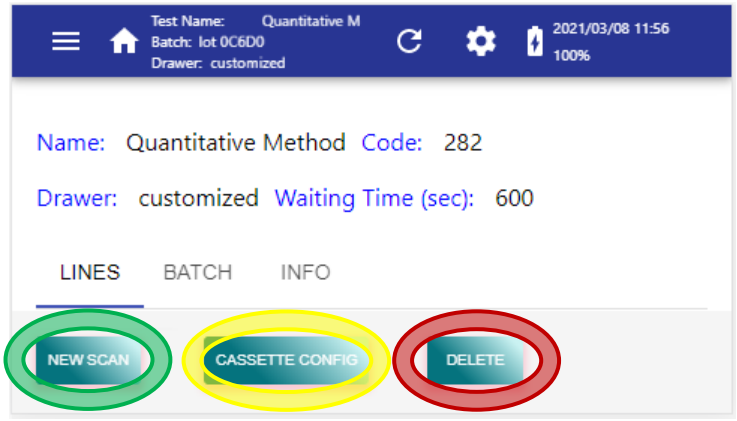
5.5.2. CASSETTE SETTINGS

The available Cassette Settings list is displayed. After pressing one 'SELECT AS CURRENT' button (see yellow circle) the corresponding Cassette Settings 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 LFR stores may be set between 1 and 10 (see section 5.4.2 for more explanations).

After selecting one row the following screen is reached:



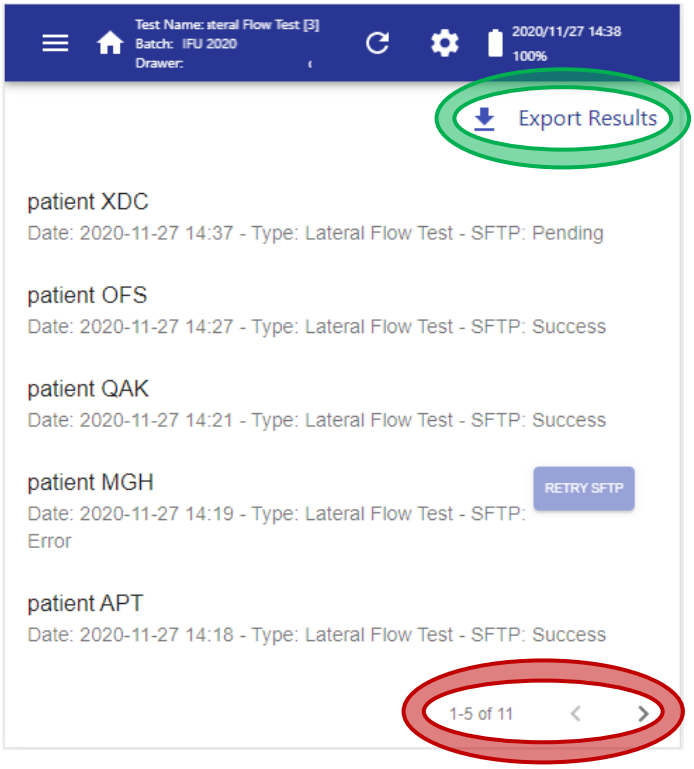
Press ‘NEW SCAN’ (see green circle) to start a new Cassette Processing. Press ‘CASSETTE CONFIG’ (see yellow circle) to load a Cassette Settings through a barcode reader. Press ‘DELETE’ (see red circle) to delete this Cassette Settings from the available list.

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

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

5.5.3. SCAN RESULTS

Access the list of stored scan results. The list is ordered with the most recent scan on top and a maximum of 5 results are shown on each page. Drag up and down on the touchscreen to displace the list of the results and press on each one to explore the result. Swipe left to return to the list results. 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: By default, a maximum of 200 or 800 results are kept (depending on your model). If you do not want to lose your old results before archiving this amount, you must 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 Settings 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 and (for users with the role of Administrator or Manager) delete the scan result.

Available tabs:

- STRIP (tab’s name depends on Cassette Settings): 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 Settings 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 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. (Administrator role only).

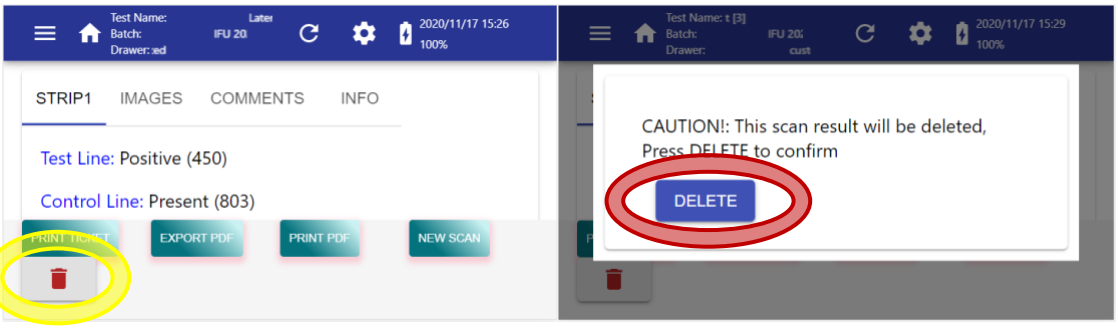
```
2020-11-16  16:51:23 (CET)
ID: test
Lateral Flow Test (3)
Lot: IFU 2020
Expiration: 2022-02-22
Reader: 100033000/99999
Comment:

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

- 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 LFR's USB host port and press the 'EXPORT PDF' button.

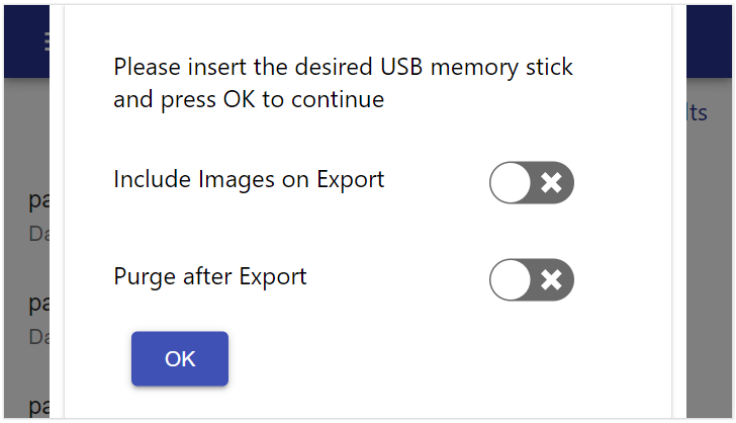
NOTE: PDF report filename contains a maximum of the 228 first characters from Patient/sample ID followed by a timestamp. Special characters are removed from the file name, spaces replaced by dashes, and uppercases replaced by lowercases.

- PRINT PDF: If a desktop printer is connected and properly configured, press the 'PRINT PDF' button to print the scan result report. See section 5.4.4 to connect and configure a desktop printer (Administrator role only).
- NEW SCAN: To start a new Cassette Processing.
- DELETE: 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. Only available for users with the role of Administrator or Manager.



B- EXPORT RESULTS BUTTON

After pressing the 'Export Results' button from the Scan Results screen a pop-up dialog is displayed to select export options. Before pressing the '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 LFR'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 scan 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 with 1 Control line and 2 Test lines, the result is 6 rows in the .CSV.
- In the case of a strip where the Control line is not found, no rows corresponding to Test lines are present (because they cannot be evaluated if the Control line is missing).

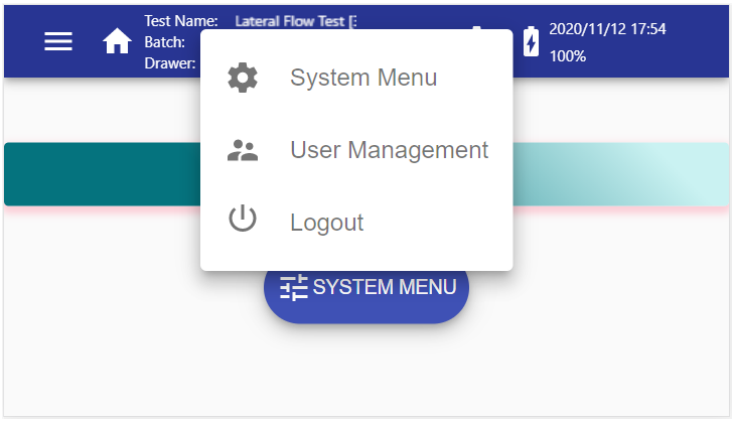
Parameters included in the results (for each processed line):

- **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 scan.
- **comments**: Comments added after the scan.
- **cassette type**: Name of Cassette Settings.
- **cassette code**: Code of Cassette 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 processed line.
- **quantification**: Quantification result of processed line (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 parameters.
- **applied thresholds**: Cassette Settings parameter.
- **fiducials**: Processing parameter.

5.6. Tools Menu

Pressing the gear symbol on the centre-right of the Top Bar a dropdown menu is displayed, with the following options:



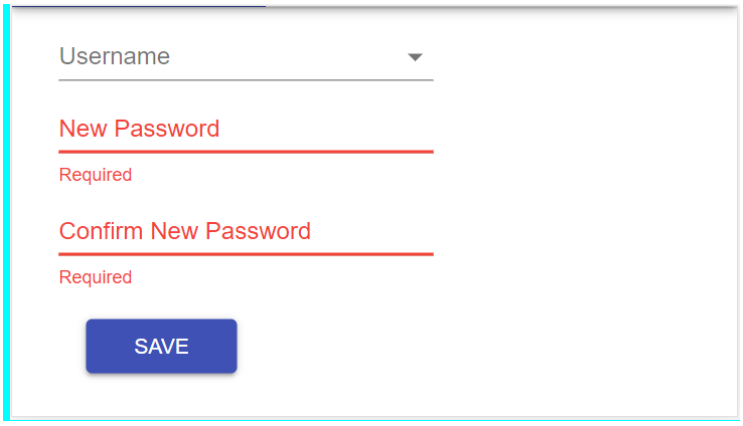
5.6.1. SYSTEM MENU

Explained in section 5.4.1.

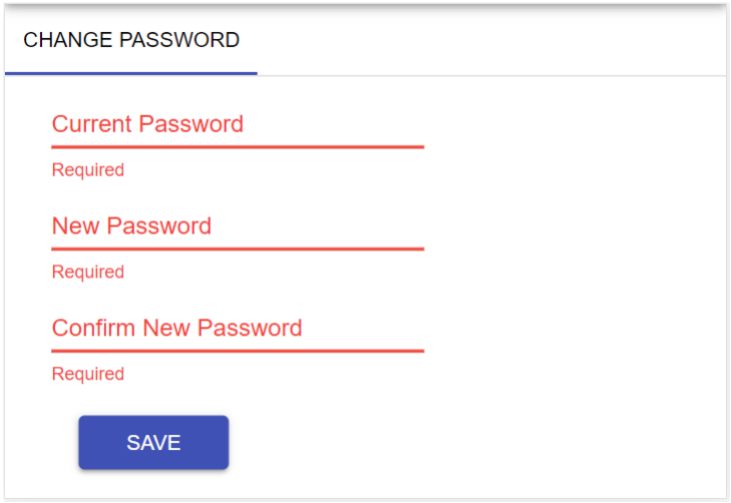
5.6.2. USER MANAGEMENT – CHANGE PASSWORD

This screen allows password change.

As Administrator or Manager, a 'Username' must be selected, and a new password must be typed in both the 'New Password' and 'Confirm New Password' fields.



As 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.

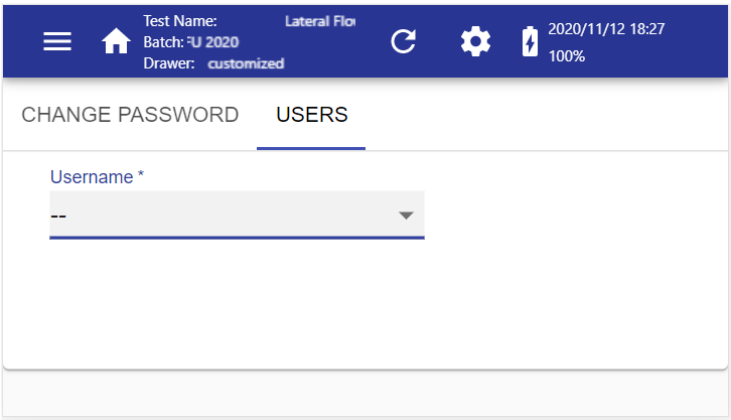


After editing all fields, press the 'SAVE' button:

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

5.6.3. USER MANAGEMENT - USERS (ADMINISTRATOR OR MANAGER ONLY)

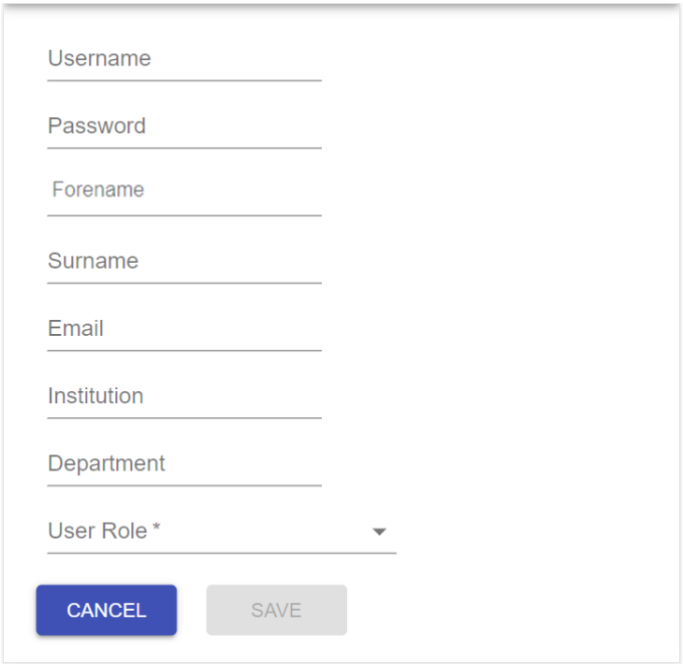
Press the 'USERS' tab to create, edit and delete user accounts. This screen is only accessible for users with the role of Administrator or Manager.



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

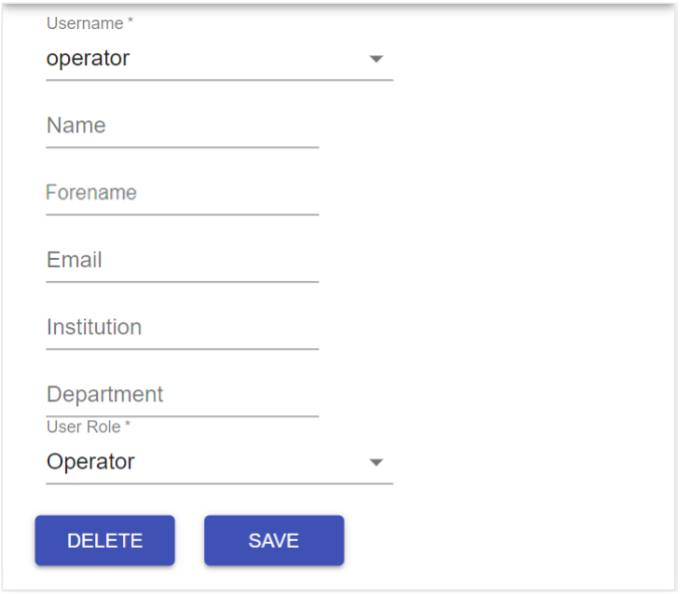
To create a new user, select the first item of the ‘Username’ list, ‘*Create new* user’, and fill in the fields available. Only the ‘Username’, ‘Password’, and ‘User Role’ fields are mandatory.



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.

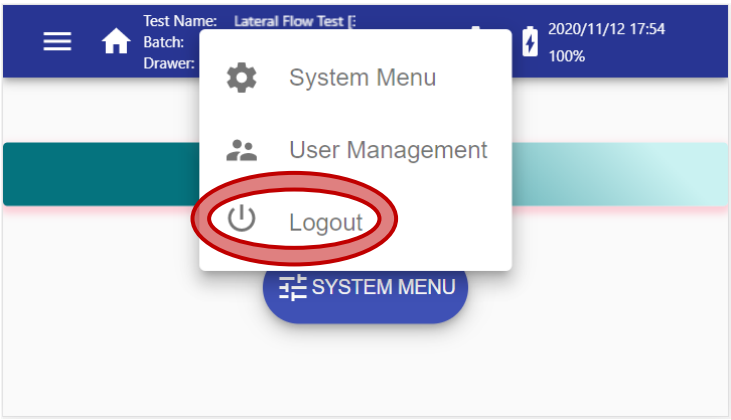


Press each field to edit its value using a virtual keyboard. To save changes press the ‘SAVE’ button and then the ‘CONFIRM’ button from the pop-up dialog.

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

5.6.4. LOGOUT

Select this option (see red circle) to disable the current user’s session and shift to Login Screen.



See section 5.1 for an explanation of the login process.

5.7. Software Update

Verséa Ophthalmics will contact a user in the event a software update is required.

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

5.8. Browser Generic Operations

Here are some tips to browse the Verséa™ Ophthalmics T-POC LFR:

- Return to the previous screen by 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 … z			A … Z			
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 LFR 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 Verséa Ophthalmics for repair at ophthalmics@versea.com
The LFR switches spontaneously off (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
The LFR switches off spontaneously (a message has been displayed for a while before switching off)	Main cord unplugged and battery getting too low	Plug the main 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 Verséa Ophthalmics for repair at ophthalmics@versea.com

Symptom	Probable cause	Recommended action
The LFR cannot perform as expected	Old version of software	Upgrade the software
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 Ethernet is not detected	The Ethernet is not connected	Correctly connect the Ethernet device
The Ethernet is not detected	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 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 dirt/debris on the barcode reader window	Clean it with an antistatic cloth or a brush
The LFR 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 LFR cannot access the USB memory stick	The USB is not properly formatted	Format the USB memory stick using the option in the System options
The LFR cannot access the USB memory stick	Damage to USB socket or its internal connection port	Contact Verséa Ophthalmics for repair at ophthalmics@versea.com
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	Remove the obstacle
It is not possible to perform a scan and the following message is displayed “Please fit drawer and cassette properly”	There is no cassette inserted	Place the cassette properly
It is not possible to perform a scan and the following message is displayed “Please fit drawer and cassette properly”	The drawer is damaged	Replace the drawer
It is not possible to perform a scan and the following message is displayed “Please fit drawer and cassette properly”	The internal drawer sensor is damaged	Contact the Technical Service for details
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

Symptom	Probable cause	Recommended action
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 Verséa Ophthalmics
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 the start-up
The LFR cannot reset to defaults	Damage in the software	Contact Verséa Ophthalmics for repair at ophthalmics@versea.com
The LFR restarts itself	Electrostatic discharge on the touchscreen	Wait until reboot process ends
The LFR does not respond	Electrostatic discharge on the touchscreen	Press and hold the power button for 10 seconds to force shutdown. Then press the power button again to restart the LFR.

If you contact Verséa Ophthalmics for other malfunctions beyond those described above, we 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 Verséa Ophthalmics.

7. MAINTENANCE

7.1. Cleaning Procedure

To clean the Verséa™ Ophthalmics T-POC LFR device, use a slightly moistened cloth or an antistatic cloth with 70% ethanol dilution or 10% bleach dilution.

CAUTION 	**Damage to the device** Do not sprinkle inside the device 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. Product Life

The Verséa™ Ophthalmics T-POC LFR can run for 5 years from the manufacturing date indicated in the Verséa™ Ophthalmics T-POC LFR label.

It is the responsibility of the final user and not Verséa Ophthalmics, LLC to use the device beyond this date.

If the Verséa™ Ophthalmics T-POC LFR is used as a POC (“point of care") device that needs to be recharged more than once per week, it could have an impact on the capacity of the battery with a lower useful life.

APPENDIX A: ORDERING CODES

a. Spare Parts

Product	Contents	Cat. #
Customized Drawer	1 unit	900014095
External power supply (US)	1 unit	900020089
Power cord (US / JP)	1 unit	900020078

b. Optional Accessories

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

APPENDIX B: TECHNICAL DATA

Verséa Ophthalmics, LLC reserves the right to change specifications at any time.

a. Specifications

Process time	from 15 seconds
Camera sensor	8 Mpixel
Touch screen	4.3''
Operating system	Linux

b. 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	LFR can export to an external SFTP server

c. 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.)
Place of operation	For indoor use only

Pollution level	2

d. Transportation conditions

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

e. Storage conditions

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

f. Dimensions and Weight

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

APPENDIX C: WARRANTY

The Verséa Ophthalmics T-POC LFR unit has a 12-month warranty period.

The warranty is void when misuse of the equipment can be proven. 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 warranty coverage.

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

As part of this warranty, all shipping costs related to technical service are the responsibility of the customer.

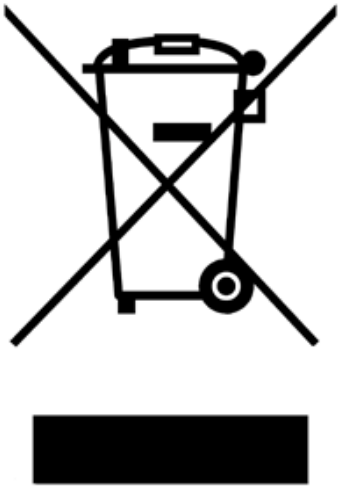
APPENDIX D: WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT (WEEE)

This appendix 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.

Please contact Versea Ophthalmics for more information, if required.



APPENDIX E: FCC STATEMENT

FCC Declaration of Conformity

Responsible party:

IUL, S.A.
C/ Ciutat d'Asunción 4
08030 Barcelona
Spain

This device:

- Contains TX FCC ID:2ABCB-RPI4B
- Contains IC: 20953-RPI4B
- Complies with Part 15 of FCC Rules, Operation is Subject to the following two conditions:

  (1) This device may not cause harmful interference, and

  (2) This device must accept any interference received including interference that causes undesired operation.

Any changes or modifications to the equipment not expressly approved by the party responsible for compliance could void the user's authority to operate the device.

APPENDIX F: ROHS STATEMENT

The following information has been made available to comply with The Restriction of Hazardous Substances Directive, (RoHS2 & RoHS3), short for Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

APPENDIX G: APPLIED STANDARDS

The Verséa™ Ophthalmics T-POC Lateral Flow Reader is in conformity with the following standards:

- ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes
- CFR21 PART 820 Quality System Regulation
- EN 61010-1:2010 Safety requirements for electrical equipment for measurement, control and laboratory use -- Part 1: General requirements
- EN 61010-2-101:2017 Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
- EN 60601-1:2006+AC:2010+A1:2013 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
- EN 61326-2-6:2013 Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 2-6: Particular requirements — In vitro diagnostic (IVD) medical equipment (IEC 61326-2-6:2012)
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- ISO 14971:2019 Medical devices – Application of risk management to medical devices
- IEC 62304:2006 & IEC 62304:2006/A1:2015 Medical device software – Software life-cycle processes
- ISO 15223-1:2021 Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements