

iPeak® reader 4,3"

Instructions for Use

Software Version 3.x



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INDICATION OF THE INTRODUCED MODIFICATIONS

If it's the first time that you use iPeak® reader 4,3", please read the entire document carefully.

If it's not the first time that you use iPeak® reader 4,3" and you use it before, in the table below you can read the indication of the introduced modifications.

Revision	Description of change
10	Update section 2.8 Symbols on the iPeak® reader 4,3" Device
	Update section 5.4.2 Cassette (Administrator only)
	Update section 5.4.3 Preferences (Administrator only)
	Update section 5.5.2 Cassette Settings
	Update section 5.5.3 Scan Results
	Update section 6 Troubleshooting

0. GLOSSARY

LFR - Lateral Flow Reader, it is a device such as iPeak® reader 4,3" 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 behaviour and functionalities of the LFR. Most of them are only available by the Administrator user.

IUL's partner - It is the institution, company, or other legal entity responsible to provide the LFR together with the cassettes to the health organization. Moreover, the IUL's partner defines the necessary LFR's configuration for the intended use environment using the LFR's Administrator user mode to update the LFR's configuration when it is necessary.

Health Organization - It is an institution, company, or other legal entity responsible to operate 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 iPeak® reader 4,3". We are confident that this instrument will become an integral part of your laboratory.

Before using the iPeak® reader 4,3", 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 occurred in relation to the device, it shall be reported to IUL 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 of the iPeak® reader 4,3"

The iPeak® reader 4,3" 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 IUL' partners.

The iPeak® reader 4,3" is intended to be used only in combination with lateral flow (LF) tests indicated for use with the iPeak® reader 4,3", and only for applications that are described in the respective handbooks of our reader associates.

1.2. Target Population

The iPeak® reader 4,3" 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 Regulation (EU) 2017/746, iPeak® reader 4,3" is classified as CLASS A thus only an EU Declaration of Conformity and CE Marking are required.

According to US Food and Drugs Administration (FDA) requirements, iPeak® reader 4,3" 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 iPeak® reader 4,3" 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 iPeak® reader 4,3”
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 IUL's partner.

The iPeak® Development Software for personal computer enables IUL's partner to define and assess the settings required to process each cassette supported by the LFR.

1.6. Contraindications

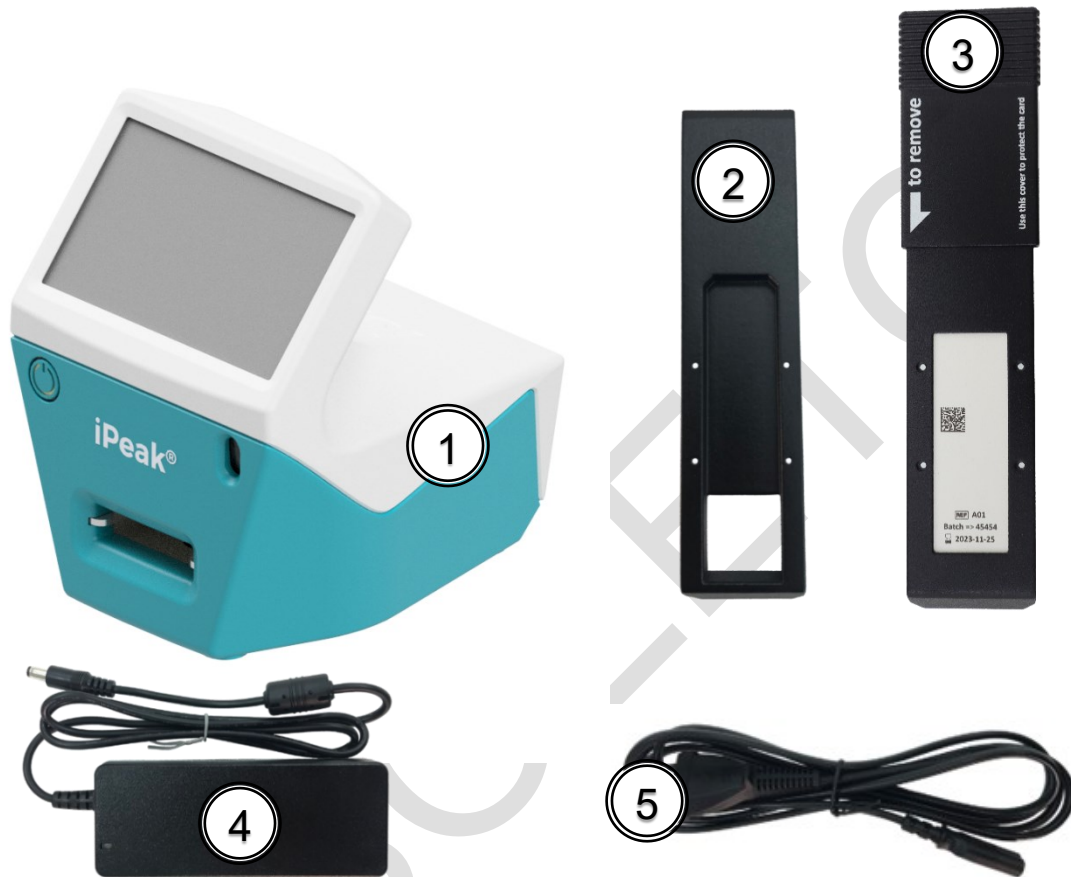
Not applicable.

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1.7. General Information

1.7.1. Scope of Delivery

The delivery includes the following items:



1. iPeak® reader 4,3" main unit (Cat.100033000).
2. Drawer (Customized for each IUL's Partner Cat. 9000xxxxx).
3. Adjustment drawer (Cat.900013732)
4. External power supply unit (Cat. 900020088 or 900020089).
5. Power cord (Cat. 900020077, Cat. 900020079, Cat. 900020080, Cat. 900020081, Cat. 900020082 or Cat. 90004873).

See Ordering Codes for more information.

1.7.2. Technical Assistance

At IUL SA 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 IUL SA products. If you have any questions or experience any difficulties regarding the iPeak® reader 4,3" or IUL SA products in general, do not hesitate to contact us.

Phone: +34932740232

Email: iul@iul-inst.com

IUL SA 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 IUL SA. We, therefore, encourage you to contact us if you have any suggestions about product performance or new application and techniques.

For technical assistance, contact the IUL SA Technical Service Department or local distributors.

Email: support@iul-inst.com

1.7.3. Policy Statement

It is the policy of IUL SA to improve products as new techniques and components become available. IUL SA 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 IUL SA Technical Service with any feedback.

1.7.4. Requirements for iPeak® reader 4,3" Users

Table 1 covers the general level of competence for the use and servicing of the iPeak® reader 4,3".

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 IUL SA.

2. SAFETY INFORMATION

Before using the iPeak® reader 4,3", it is essential that you read this 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.

The following types of safety information appear throughout the iPeak® reader 4,3" 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.
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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 iPeak® reader 4,3" instrument may cause personal injury or damage to the instrument. The instrument must only be operated by qualified personnel.
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CAUTION 	Damage to the instrument Avoid spilling water or chemicals onto the iPeak® reader 4,3" instrument. Damage caused by water or chemical spillage will void your warranty.
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In case of emergency, switch off the iPeak® reader 4,3" with the power button and unplug the power cord from the power outlet.

2.2. Electrical Safety

If the operation of the iPeak® reader 4,3" 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 IUL SA Technical Service after such an incident.

WARNING 	Rechargeable Batteries The iPeak® reader 4,3" 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 IUL SA. • After a storage period of 6 months, it is necessary to charge the batteries to obtain maximum performance.
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WARNING 	Electrical hazard Any interruption of the protective conductor (earth/ground lead) inside or outside the instrument or disconnection of the protective conductor terminal is likely to make the instrument unsafe. This must be checked after service or maintenance. Intentional interruption is prohibited. Lethal voltages inside the instrument This WARNING is applicable to routine users as well as to technical service users. • Risk of electrical shock and energy hazard. All failures should be examined by a qualified technician. Please do not remove the case of the AC adaptor by yourself! • Adaptors should be placed on a reliable surface. A drop or fall could cause damage. • Please do not place the AC adaptor in places with high moisture or near the water. • Please do not place the AC adaptor in places with high ambient temperature or near a fire source. About the maximum ambient temperature, please refer to "Appendix B: Technical Data". • Disconnect the AC adaptor from the AC power before cleaning. Do not use any liquid or aerosol cleaner. Only use a damp cloth to wipe it. • In case of replacement or a losing 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 to IUL SA.
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To ensure satisfactory and safe operation of the iPeak® reader 4,3":

- 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 "Ordering Codes" must be used. In case of replacement, this must be ordered from IUL SA.
- The instrument must not be operated with the cover removed.
- If you suspect any instrument damage, contact IUL SA Technical Service.

If the iPeak® reader 4,3" becomes electrically unsafe, prevent other personnel from operating it, and contact IUL SA 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 unfavourable conditions for a prolonged period.
- A different external power supply is used other than the one provided by IUL SA's partner.

WARNING 	Risk of electric shock In case of replacement or loss of the external power supply or the power cord, these must be replaced <u>only</u> with the external power supply or power cords listed on the "Ordering Codes" and provided by IUL SA's partner.
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2.3. Environment

Operating conditions

WARNING 	Explosive atmosphere The iPeak® reader 4,3" is not designed for use in an explosive atmosphere.
CAUTION 	Direct sunlight Do not expose the iPeak® reader 4,3" to direct sunlight or other powerful lights during operation.
CAUTION 	High humidity or liquids Protect the iPeak® reader 4,3" from high humidity and contact with liquids.
CAUTION 	Strong electromagnetic radiation Do not expose the iPeak® reader 4,3" to strong electromagnetic radiation.
CAUTION 	Strong ultrasonic radiation Do not expose the iPeak® reader 4,3" 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 iPeak® reader 4,3" may contain infectious agents. Handle such samples in accordance with the required safety regulations. Always read how to proceed in the cassette'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 <i>Biosafety in Microbiological and Biomedical Laboratories</i>, HHS: https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF See: Section III—Principles of Biosafety Laboratory Practices and 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.

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 <i>Biosafety in Microbiological and Biomedical Laboratories</i>, HHS: https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF See: Section III—Principles of Biosafety Safety Equipment (Primary Barriers and Personal Protective Equipment) Safety equipment includes BSCs, enclosed containers, and other engineering controls designed to remove or minimize exposures to hazardous biological materials.
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2.5. Chemicals

WARNING 	Hazardous chemicals Some chemicals used with the iPeak® reader 4,3" 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.
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2.6. Maintenance Safety

CAUTION 	Damage to the instrument Do not use spray bottles containing alcohol or disinfectant to clean the surface of the iPeak® reader 4,3" instrument. Do not use products containing alcohol or other corrosive solvents to clean the iPeak® reader 4,3" 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. 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 iPeak® reader 4,3” Device

Symbol	Location	Description
	Type plate on the bottom of the instrument and the external box label	CE Mark, Declaration of Conformity, see “EU Declaration of Conformity”.
	Type plate on the bottom of the instrument and the external box label ¹	UKCA Mark, Declaration of Conformity, see “UK Declaration of Conformity”
	Type plate on the bottom of the instrument and the external box label ²	Caution: Federal law restricts this device to sale by or on the order of a physician.
	Type plate on the bottom of the instrument and the external box label ²	Caution: Federal law restricts this device to sale by or on the order of a physician.
	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.

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

² The symbol will be included only for shipments to the United States of America and Canada

Symbol	Location	Description
	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".
	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).

Symbol	Location	Description
	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 “Appendix F: FCC Statement”.

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 IUL’s partner. The LFR’s partner is the legal entity that defines the setup for a specific intended environment of use, including the 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 sections 5.6.1).

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

NOTE: Contact your iPeak® reader 4,3” ‘s partner to request technical specifications of Remote Export and Audit Trail functionalities.

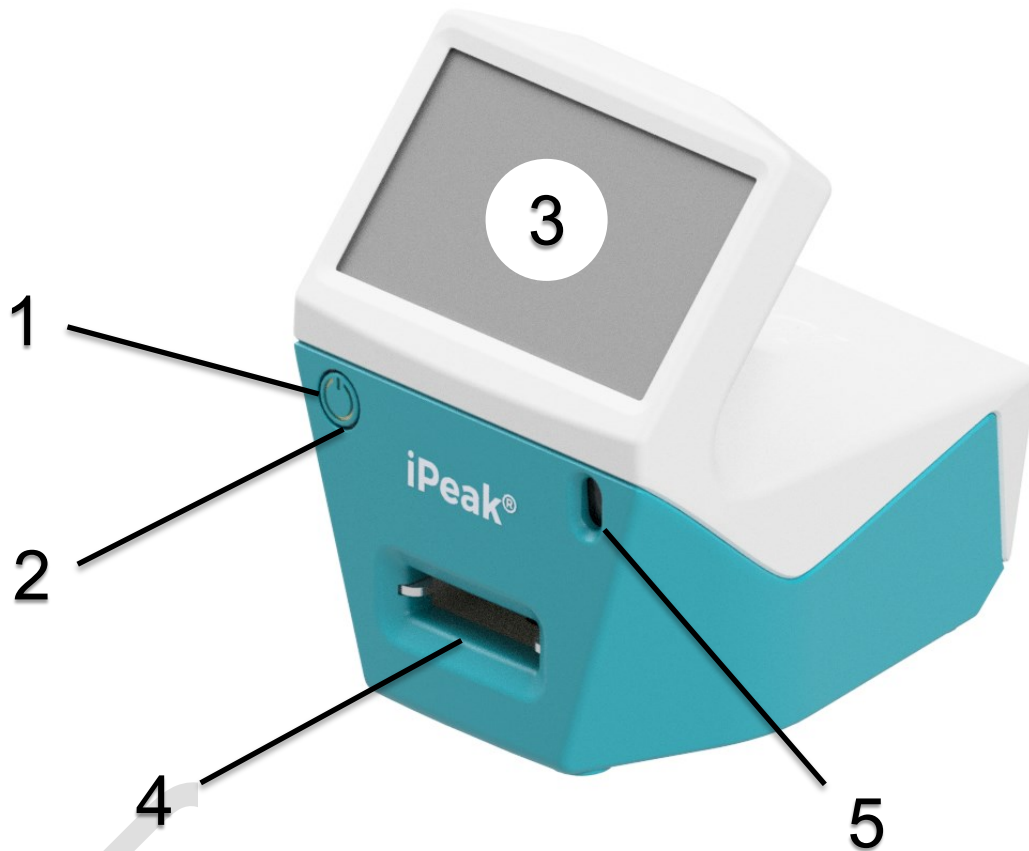
Phone: +34932740232

Email: iul@iul-inst.com

3. GENERAL DESCRIPTION

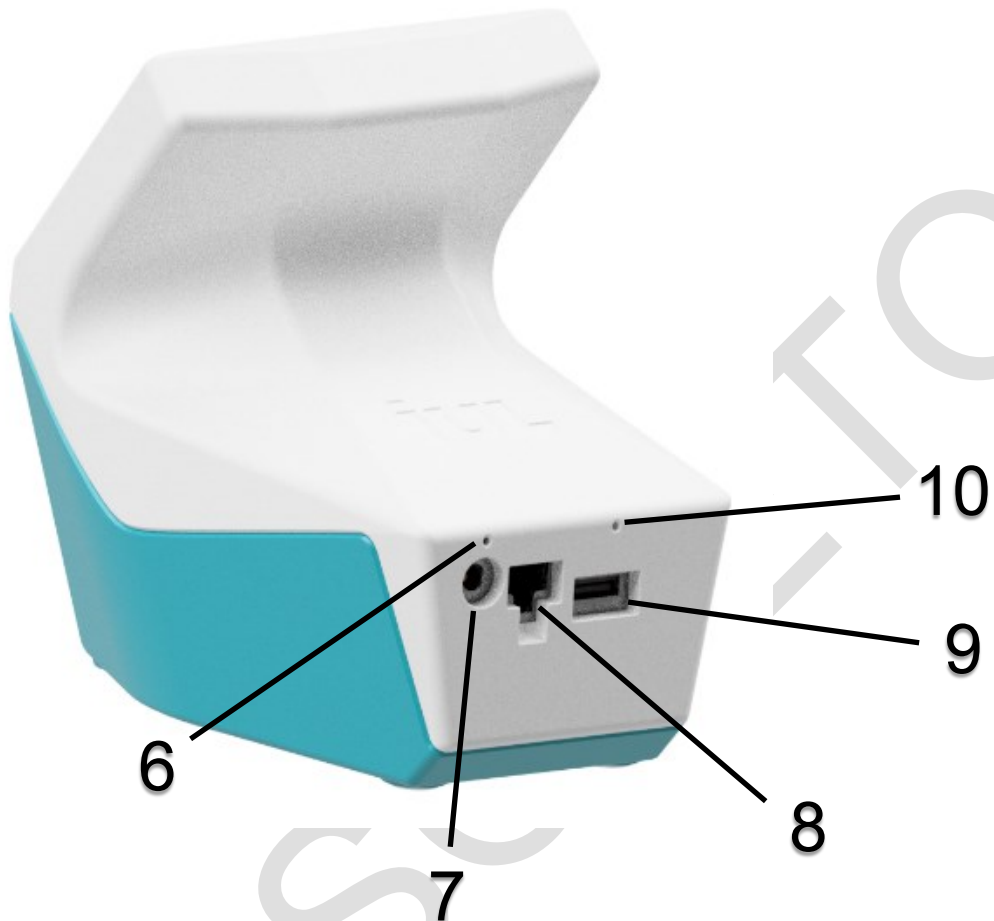
3.1. Device Overview

FRONT VIEW:



- 1. Power button.
- 2. Power ON indicator (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 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 mains, 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 <u>only</u> with one of the power cords listed on the “Ordering Codes” delivered by IUL SA.
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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 <u>only</u> with one of the power cords listed on the “Ordering Codes” delivered by IUL SA.
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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.
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4. INSTALLATION

4.1. Unpack the Device



The packaging of the iPeak® reader 4,3" 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 iPeak® reader 4,3" device on a stable surface, far away from powerful lights and near an earthed/grounded electrical outlet.

It is recommended to connect the iPeak® reader 4,3" 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 iPeak® reader 4,3" device.

When the iPeak® reader 4,3" is not in use for a long period of time, we recommend disconnecting the power cable.

4.4. Cassette Requirements

Before using the iPeak® reader 4,3" device 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 a 6 months 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 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”**.

CAUTION



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

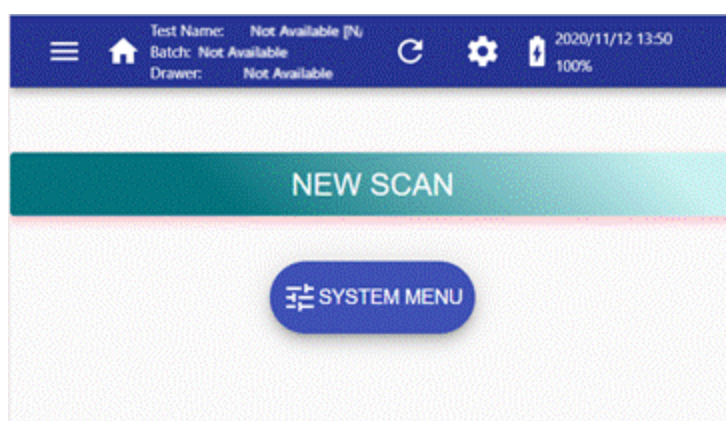
See section 5.6.2 for explanations on how to change passwords. Retain the new password in a secure location.

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.

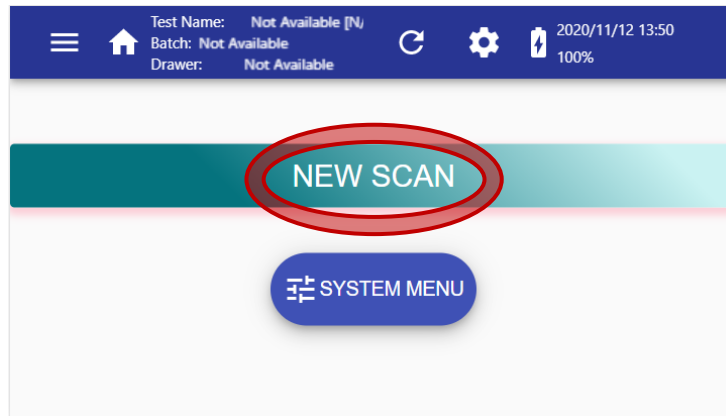


Remote export icon. Depends on configuration. Only visible when a valid token is checked.

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).

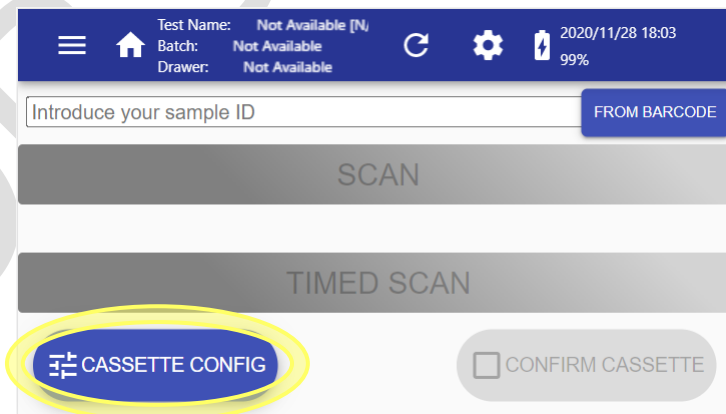


- 2- Omit this step if the Cassette Settings on the Top Bar is the Cassette Settings to use in the next scan. This step may be required in certain configurations.

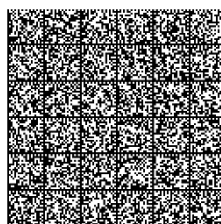
To set the proper Cassette Settings that will be used in the next scan, there are the following options:

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 approximately 5 cm of distance. 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.

WARNING 	If the barcode hasn't been read correctly, the former setting 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.

Name	Code	Batch	
Qualitative Method	384	lot 03A9	<button>SELECT AS CURRENT</button>
Qualitative Method	384	lot 0B15	<button>SELECT AS CURRENT</button>
Quantitative Method	282	lot 002F7	<button>SELECT AS CURRENT</button>
Quantitative Method	282	lot 0C6D0	<button>SELECT AS CURRENT</button>

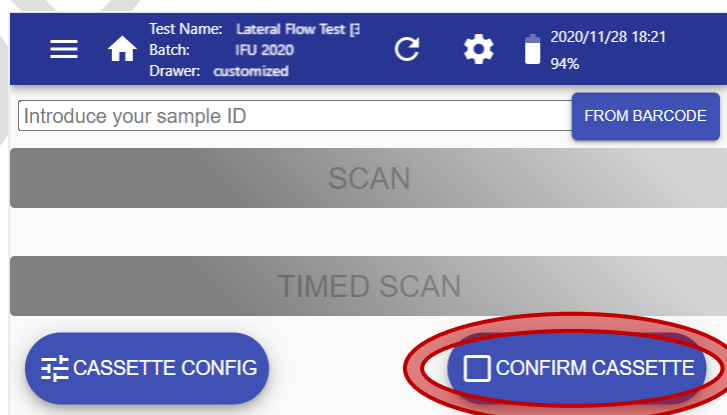
1-4 of 4 < >

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

B.2 ‘Barcode Autodetection’ launches directly the scan if the option ‘Barcode Autodetection’ is selected by the IUL’s partner.

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.



The screenshot shows the LFR interface. At the top, there is a header bar with the following information: Test Name: Lateral Flow Test [E], Batch: IFU 2020, Drawer: customized, a refresh icon, a settings icon, a battery icon showing 94%, and the date/time 2020/11/28 18:21. Below the header, there is a text input field labeled 'Introduce your sample ID' and a button labeled 'FROM BARCODE'. Below the input field, there are two large buttons: 'SCAN' and 'TIMED SCAN'. At the bottom, there are two buttons: 'CASSETTE CONFIG' and 'CONFIRM CASSETTE'. The 'CONFIRM CASSETTE' button is circled in red.

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

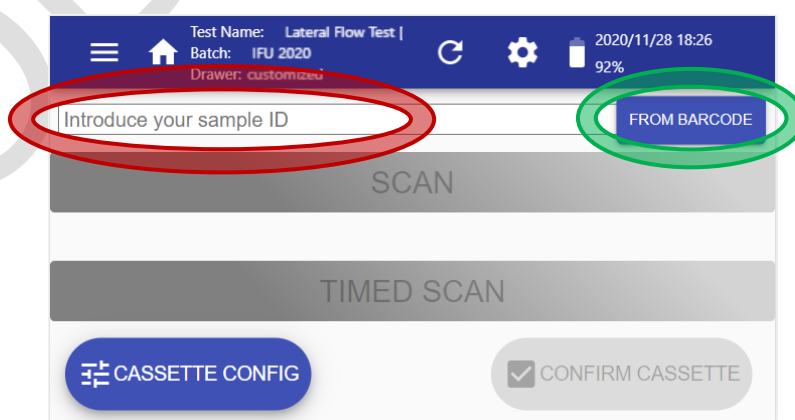
Press the 'ACTIVATE BARCODE READ' button (see yellow circle). The barcode reader starts its reading process using a light. This light disappears when a barcode has been read or after 10 seconds of trying.



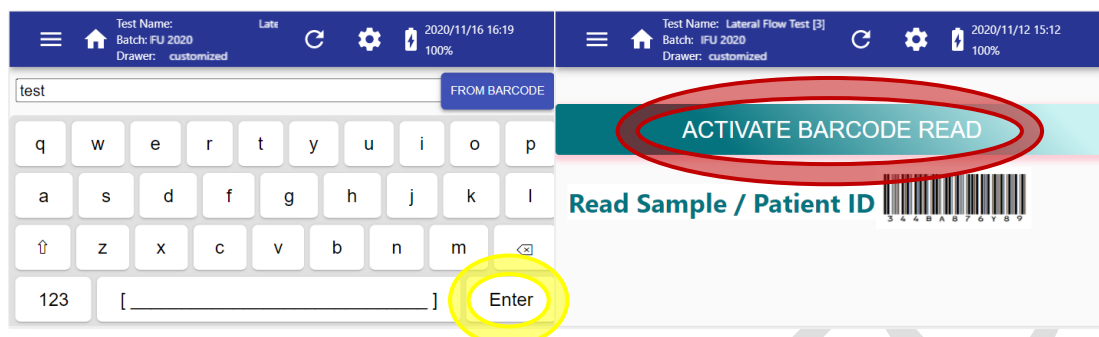
If the Small-Data Matrix does not correspond to the Cassette Settings currently loaded in the LFR, an error message is displayed. In such a case, use a cassette of the proper type, or load another Cassette Settings corresponding to the current cassette.

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.



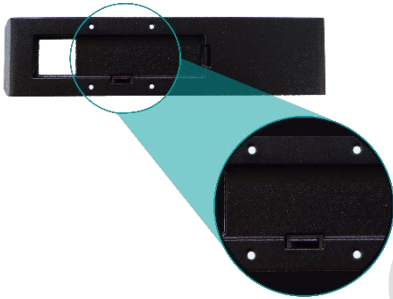
NOTE: Depending on the LFR's configuration, if the reference you enter is already in the LFR's stored results, a message is displayed, and scan buttons could be disabled.

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

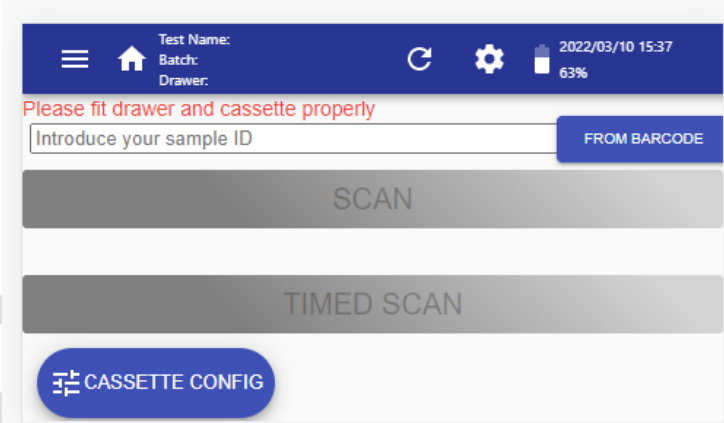
Sample/patient ID using barcode reader: Special characters are allowed and the maximum length is 1024. See section 5.5.3 to know how IDs are displayed in different scenarios.

- 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 levelled; then press the drawer inside the LFR.

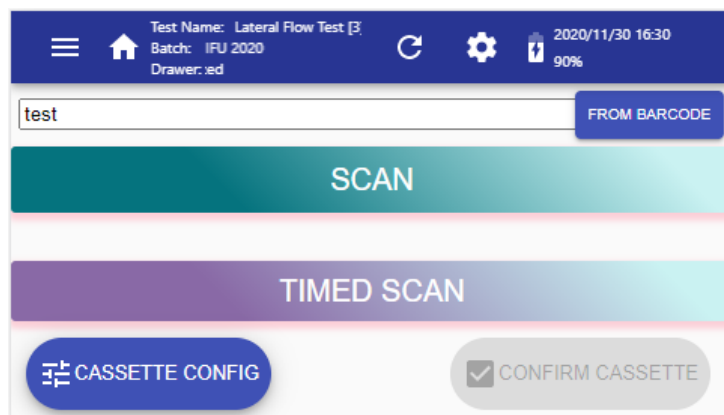


WARNING 	Before launching a scan: - Ensure that the four (4) white dots (fiducials) on top of the drawer are present, undamaged, clean (see section 7.1), and round (e.g., in its original factory condition).  - Ensure that strips embedded in the cassette are free of impurities such as fiber or dust. Failing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

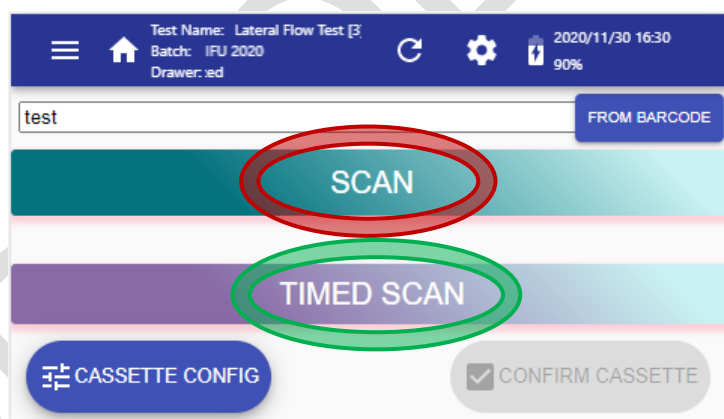
A warning is shown when the drawer is not properly closed (see next image).
Place the drawer properly inside the LFR.



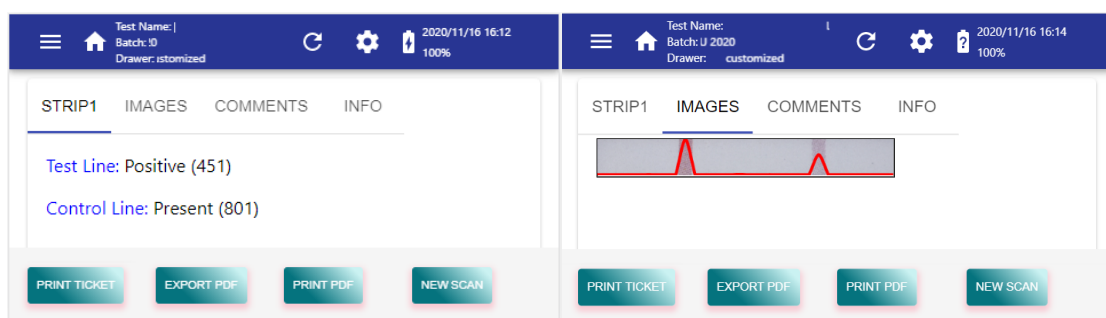
The scan buttons ('SCAN' and 'TIMED SCAN') remain in grey until a valid Cassette Settings is loaded, an ID is set (if required), and a drawer is placed inside the LFR. Depending on the LFR's configuration a cassette's confirmation barcode could be also required. When all conditions are reached the scan 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- The 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 the data. See section 5.5.3 for more information about result screens and the functionalities of its buttons.



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

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

5.4. System Menu

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

5.4.1. System

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

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.

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 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.

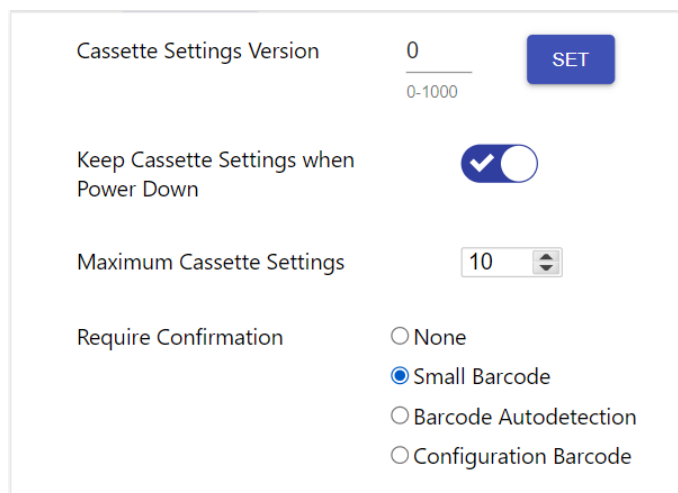
WARNING 	To use the 'TOKENIZE' and 'SETUP' buttons Internet connection is needed.
---	---

- **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 '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 iPeak® reader 4,3 :	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 20 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.

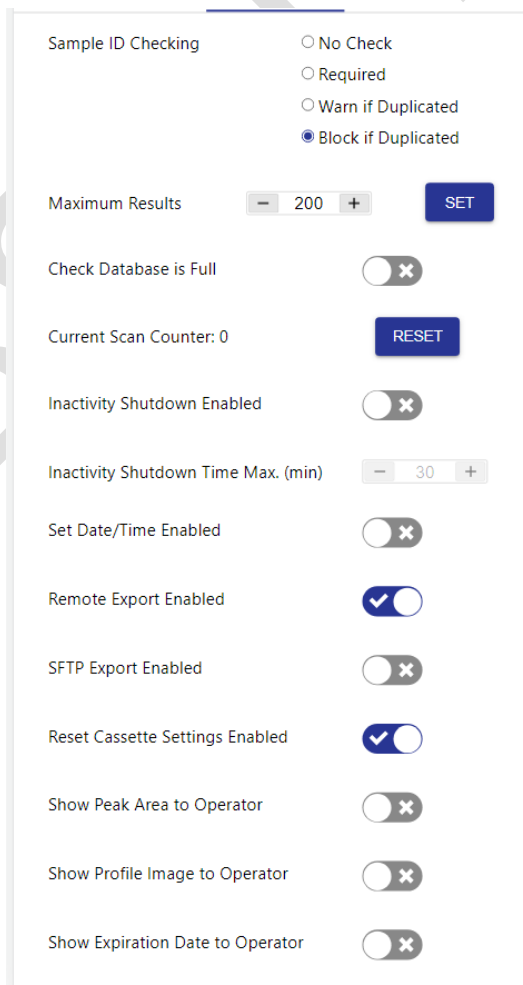
Barcode Autodetection → After launching a scan (with 'SCAN' or 'TIMED SCAN' buttons), the device tries to find the Cassette Settings that match with one of the Cassette Settings list, reading the barcode embedded on the cassette. Using this option you can also use the Small-Data Matrix to confirm the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

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

- ☐ No Check
- ☐ Required
- ☐ Warn if Duplicated
- ☒ Block if Duplicated

Maximum Results: SET

Check Database is Full: ☐ X

Current Scan Counter: 0 RESET

Inactivity Shutdown Enabled: ☐ X

Inactivity Shutdown Time Max. (min): +

Set Date/Time Enabled: ☐ X

Remote Export Enabled: ☒

SFTP Export Enabled: ☐ X

Reset Cassette Settings Enabled: ☒

Show Peak Area to Operator: ☐ X

Show Profile Image to Operator: ☐ X

Show Expiration Date to Operator: ☐ X

- 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.

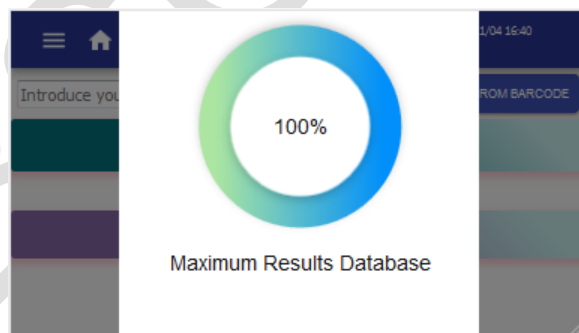
Warn if Duplicate → A value is mandatory, and a warning is displayed if the current value is in the LFR's stored results.

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.

WARNING 	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 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).
- 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 5.5.3).
- Reset Cassette Settings Enabled: If ON, users with the Operator role can restore the Cassette Settings to their factory defaults. 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 IUL SA to request technical specifications of Remote Export or SFTP Export functionalities: Phone: +34932740232; Email: iul@iul-inst.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	HP_LaserJet_Pro_M203-M206 ▼
Baud Rate	9600 ▼
Parity	None ▼
Data Bits	8 ▼
Stop Bits	1 ▼

- Desktop printer: To select a desktop printer model.
- Baud rate: Default value is “9600”.
- Parity: Default value is “None”.
- Data bits: Default value is “8”.
- Stop bits: Default value is “1”.

Both the 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.

5.4.5. Network (Administrator or Manager only)

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

Airplane Mode	☒
Ethernet	<button>SET</button>
Status	On
MAC	b8:27:eb:77:ee:9f
Mode	Static
IP	192.168.0.156
Mask	255.255.255.0
Broadcast	192.168.0.255
Gateway	192.168.0.1
WLAN	<button>SET</button>
Status	On
MAC	b8:27:eb:22:bb:ca
Mode	Access Point
SSID	lfr_xxxx
IP	192.168.138.1
SFTP	<button>SET</button>
Server	localhost
Port	22
HL7 path	LFR/data
PDF path	LFR/reports
Username	H-manager
Delete	<button></button>

- 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 the 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).

Mode <u>DHCP Client</u> ▼ CLOSE SAVE	Mode <u>Static</u> ▼ IP _____ Mask _____ Gateway _____ CLOSE SAVE
--	--

- **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 net if the proper SSID and password are set.

Mode <u>Access Point</u> ▼ SSID <u>lfr_B1AF</u> Password _____ Subnet <u>192.168.138.0</u> ▼ CLOSE SAVE	Mode <u>DHCP Client</u> ▼ SSID <u>lfr_B1AF</u> Password _____ CLOSE SAVE
--	--

NOTES: 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. It could be set remotely and loaded with an Internet connection (see section 5.4.1).

5.4.6. Versions

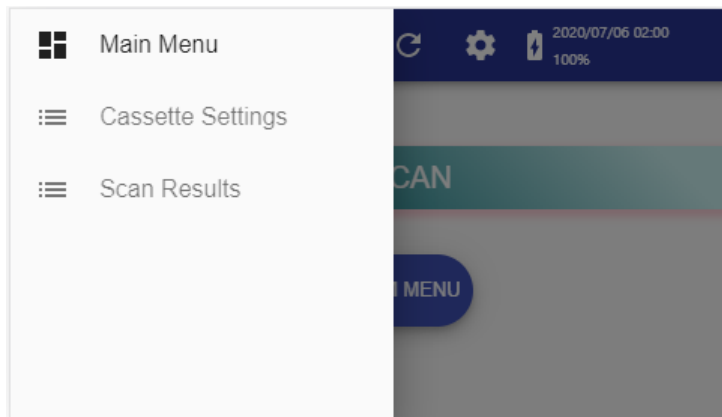
Displays a list of information related to the LFR and its software.

Model	ipeak® 4.3
Serial Number	100033000/99999
Current SW Version	3.0
Hardware Version	6.0
Product Image Version	Lfr-ipeak-4.3-3.0-s
Wipe Clean SW Version	3.0
Factory SW Version	3.0

- **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 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 drop-side menu is displayed with the following options:

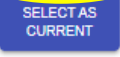
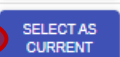
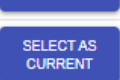


5.5.1. Main Menu

Returns to the Home screen.

5.5.2. Cassette Settings

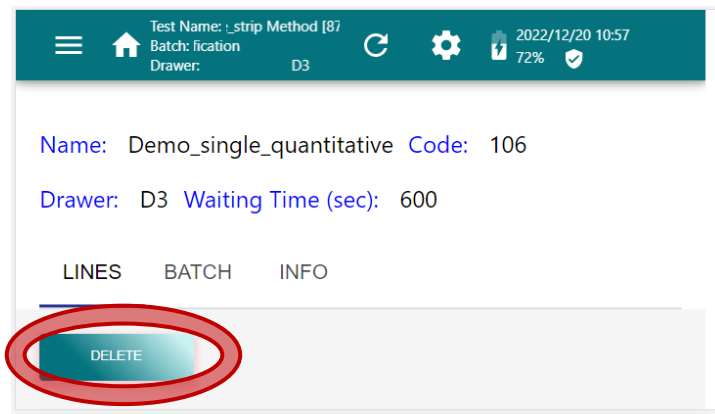
The available Cassette Settings list is displayed. After pressing one 'SELECT AS CURRENT' button (see yellow circle) the corresponding Cassette Settings will be displayed on the Top Bar and it will be ready to use. Press on a row (see red circle) to access each Cassette Settings screen.

Name	Code	Batch	
Qualitative Method	384	lot 03A9	
Qualitative Method	384	lot 0B15	
Quantitative Method	282	lot 002F7	
Quantitative Method	282	lot 0C6D0	

1-4 of 4 < >

NOTE: The maximum number of Cassette Settings that LFR stores could be set between 1 and 20 (see section 5.4.2 for more explanations).

After selecting one row the following screen is reached:



Test Name: _strip Method [87]
Batch: fication
Drawer: D3

Name: Demo_single_quantitative Code: 106
Drawer: D3 Waiting Time (sec): 600

LINES BATCH INFO

DELETE

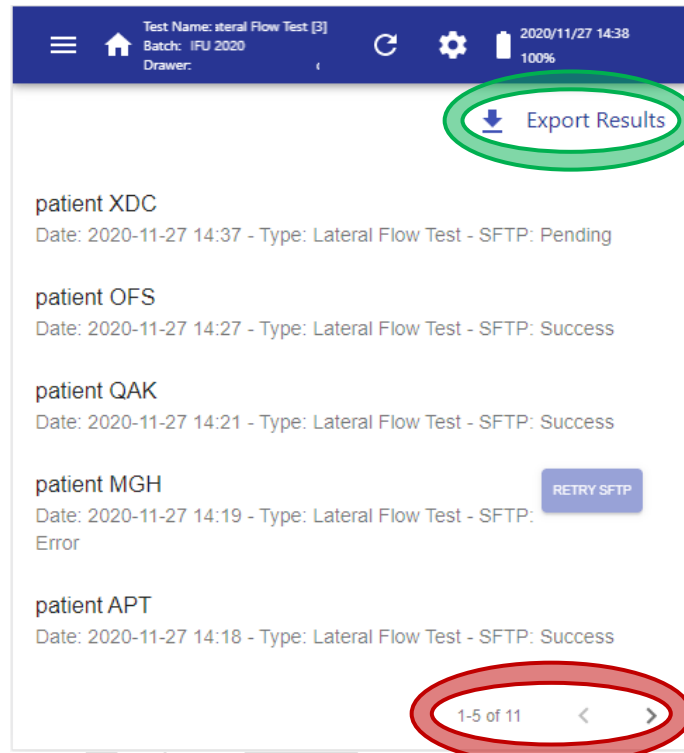
Press 'DELETE' (see red circle) to delete this Cassette Settings from the available list.

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.



WARNING 	By default, a maximum of 200 results are kept. 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.

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 0 to connect and configure a ticket printer (Administrator and Manager roles only).

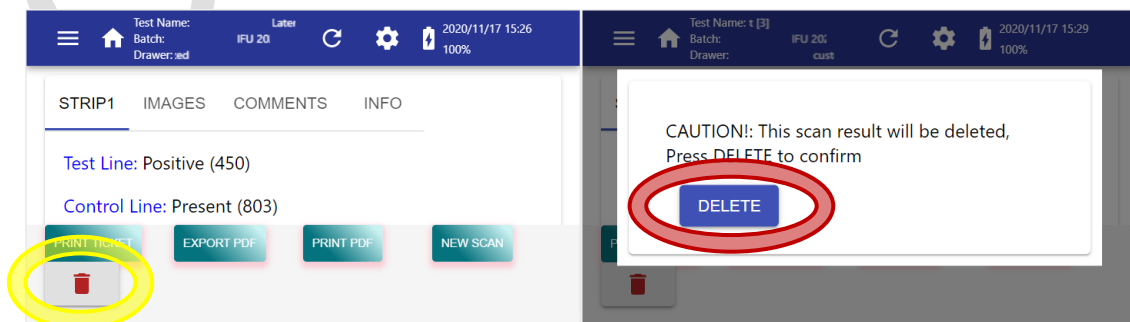
```
2020-11-16 16:51:23 (CET)
ID: test
Lateral Flow Test (3)
Lot: IFU 2020
Expiration: 2022-02-22 01:00:00 (CET)
Reader: 100033000/99999
Username: Operator
Comment:

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

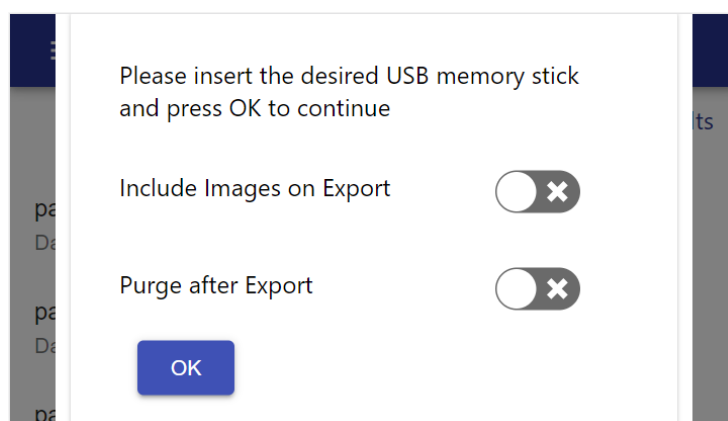
NOTE: PDF report filename contains a maximum of 228 first characters from Patient/sample ID followed by a timestamp. Special characters are removed from the file name, spaces are replaced by dashes, and uppercases are replaced by lowercases.

- **PRINT PDF:** If a desktop printer is connected and properly configured, press the 'PRINT PDF' button to print the scan result report. See section 0 to connect and configure a desktop printer (Administrator or Manager 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 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 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).

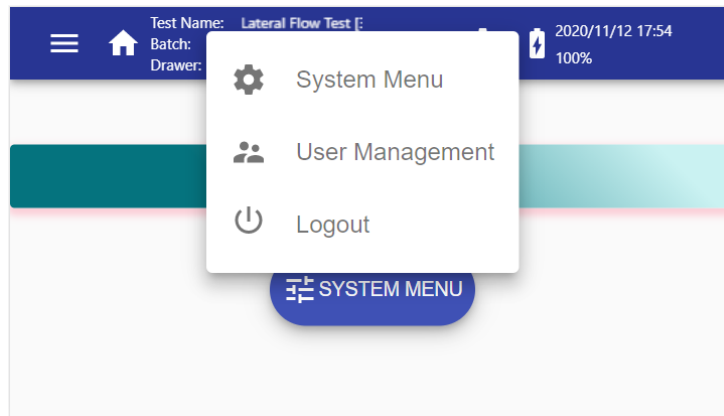
Parameters included in the results (for each processed line):

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 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:



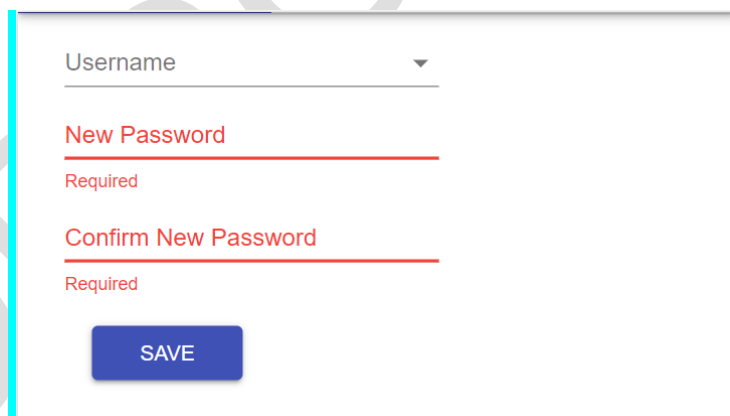
5.6.1. System Menu

Explained in section 5.4.1.

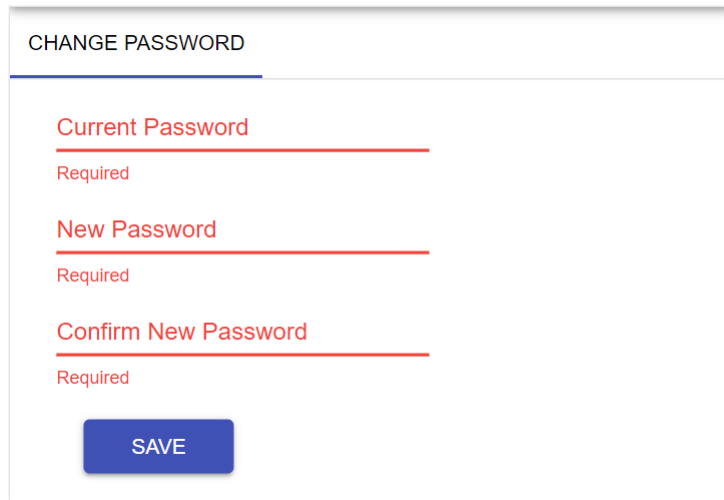
5.6.2. User Management – Change Password

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.

A screenshot of a 'Change Password' form. It features a 'Username' dropdown menu at the top. Below it are two text input fields: 'New Password' and 'Confirm New Password'. Each field has a red underline and the word 'Required' in red text below it. At the bottom of the form is a blue 'SAVE' button.

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.

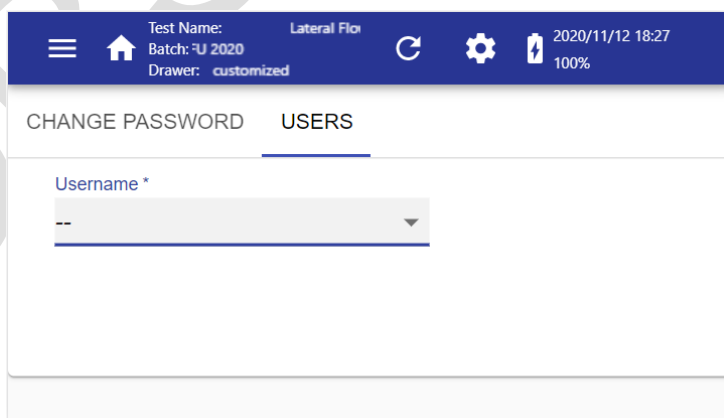


After editing all fields, press the 'SAVE' button:

- 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)

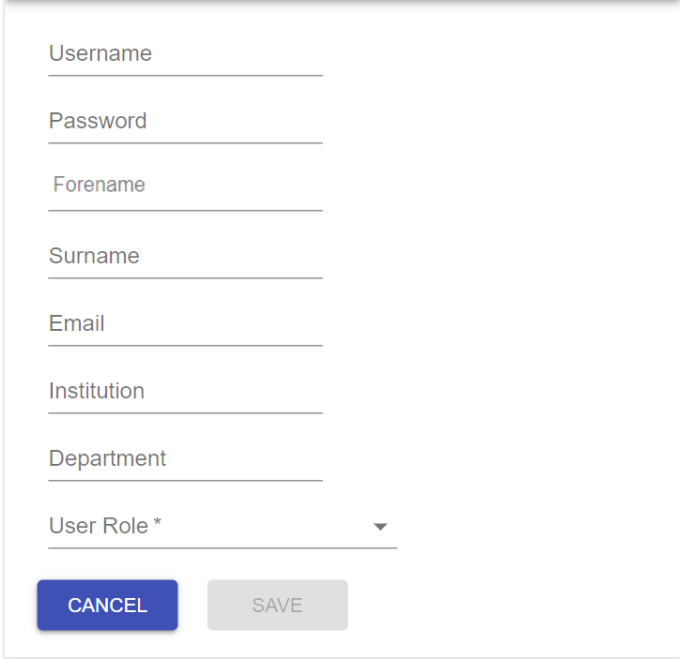
Press the 'USERS' tab to create, edit, and delete user accounts. This screen is only accessible to users with the role of Administrator or Manager.



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.

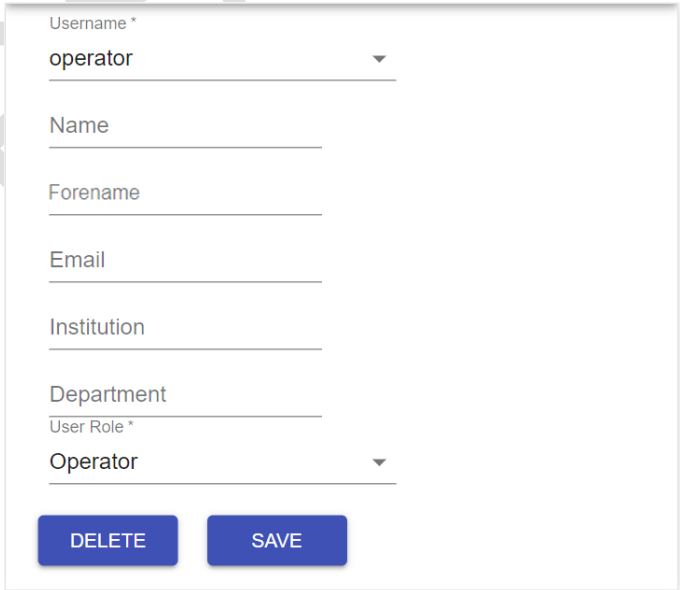


A form for creating a new user. It contains the following fields: Username, Password, Forename, Surname, Email, Institution, Department, and User Role * (a dropdown menu). At the bottom, there are two buttons: CANCEL (blue) and SAVE (grey).

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

B- EDIT or DELETE AVAILABLE USER

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



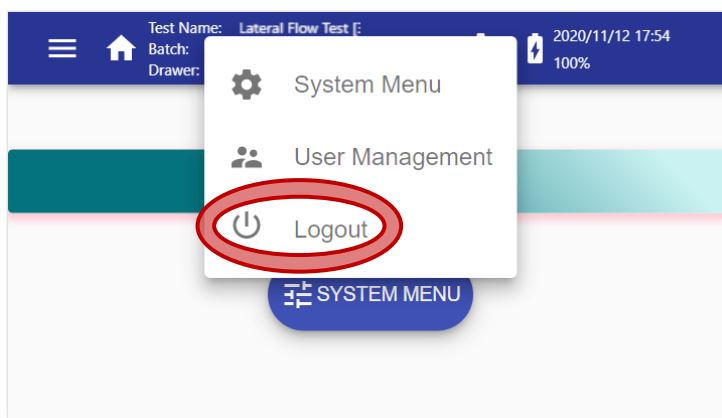
A form for editing or deleting an existing user. It contains the following fields: Username * (a dropdown menu with 'operator' selected), Name, Forename, Email, Institution, Department, User Role * (a dropdown menu with 'Operator' selected), and Operator (a dropdown menu). At the bottom, there are two buttons: DELETE (blue) and SAVE (blue).

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 the Login Screen.



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 LFR to the mains supply.
CAUTION 	Do not update a LFR with software version 3.x using an update package 2.x or 1.x.

To update the Software, follow these steps (under IUL's partner supervision if you do not have an Administrator role):

- 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 from IUL SA website 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 IUL's partner 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 LFR 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 device may seem unresponsive. Do not power off the device until the procedure is completed.
---	---

5.8. Browser Generic Operations

Here are some tips to browse the iPeak® reader 4,3” :

- 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 ... 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 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 LFR 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
	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
	No drawer has been inserted in the LFR	Place the cassette in the drawer correctly and insert completely the drawer into the slot.
	The drawer is damaged	Replace the drawer
When launching scan, the device shows a message: "cassette not present"	The operator forgot to place the cassette in the drawer	Place the cassette in the drawer
When launching scan, the device shows a message: "image normalization failed"	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 dots 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	Inoculate the cassette correctly. 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 'SETUP' 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
The unit cannot turn ON the Power ON indicator (white LEDs)	Damage in the Power ON indicator (white LEDs)	Contact the Technical Service for repair

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

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7. MAINTENANCE

7.1. Cleaning Procedure

To clean the iPeak® reader 4,3" 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.
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To clean the drawer 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.
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7.2. Product Life

The iPeak® reader 4,3" can run for 5 years from the manufacturing date indicated in the iPeak® reader 4,3" label.

It is the responsibility of the final user and not IUL SA to use the device beyond this date.

If the iPeak® reader 4,3" is used as a POC ("point of care") 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

Spare Parts

Product	Contents	Cat. #
<i>Customized Drawer</i>	1 unit	9000xxxxx
iPeak® self-adjusting light drawer	1 unit	900013732
External power supply	1 unit	900020088
External power supply (US)	1 unit	900020089
Power cord Schuko	1 unit	900020077
Power cord (US / JP)	1 unit	900020080
Power cord (UK)	1 unit	900020079
Power cord (AR)	1 unit	900020081
Power cord (CN / AU)	1 unit	900020082
Power cord (IN / ZA)	1 unit	90004873

Optional Accessories

Product	Contents	Cat. #
Ticket printer (serial interface, 40 columns)	1 unit	90004875
iPeak 4,3" UQC	1 unit	900012106

APPENDIX B: TECHNICAL DATA

IUL SA 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
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	LFR can export to an external SFTP server

Operating Conditions

Power range	12V +/-5% (it is supplied with an external power supply unit that can be used in 100V-240V)
Frequency range	D.C. (it is supplied with an external power supply unit that can be used in 50Hz-60Hz)
Maximum power	40 W
Overvoltage category	II
Air temperature	15 ~ 30 °C

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

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

Transportation conditions

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

Storage conditions

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

Dimensions and Weight

Dimensions (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 iPeak® reader 4,3" 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 the selected technical service are the responsibility of the Buyer.

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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.



APPENDIX E: EU DECLARATION OF CONFORMITY

Manufacturer:

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

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



Declares that the product Name:

iPeak® reader 4,3" Lateral Flow Reader

Catalog Number:

REF: 900033000 ¹

Basic UDI-DI:

8437022431LFR8L

Intended purpose:

iPeak® reader 4,3" 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 IUL's partners.

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 the Regulation (EU) [2017/746](#) of the European Parliament and of the council of 5 April 2017 on in vitro diagnostic medical devices.

Barcelona, November the 28th 2022



A blue ink signature of Vicenç Font, written in a cursive style.

Vicenç Font
(IVD Technical Manager)

A blue ink signature of David Guerrero, written in a cursive style.

David Guerrero
(Quality Manager)

¹ Generic reference, current version of this EU Declaration of conformity available in IUL internal document 50008290.

APPENDIX F: FCC STATEMENT

FCC Declaration of Conformity

Responsible party:

IUL SA
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 G: UK DECLARATION OF CONFORMITY

Manufacturer:

IUL, SA - Carrer de la 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

Declares the following product:

iPeak® reader 4,3" Lateral Flow Reader (REF: 900033000¹)

Intended Purpose:

The iPeak® reader 4,3" 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 by IUL's partners

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:

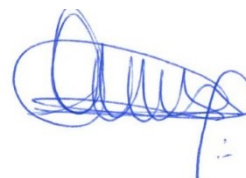
- EN ISO 13485:2016 & EN ISO 13485:2016/AC:2018 - Medical devices - Quality management systems - Requirements for regulatory purposes
- EN 61010-2-101:2002 - Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (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)

¹ Generic reference, current version of this UK Declaration of conformity available in IUL internal document 50008514.

APPENDIX H: 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.



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APPENDIX I: APPLIED STANDARDS

The iPeak® reader 4,3" 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.

Notes

OBSOLETE

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