Instructions for Use (IFU)

Lateral Flow Reader

myilab research

App Version 1.7.0

Device for Lateral Flow Assay (LFA) Measurements

REF MYILABR 1

IFU / REF MYILABR 1 / REV A / 2025-07-01

Note: Significant changes are indicated by dotted lines in the margin.
A change history can be found at the end of the manual.

Measuring Device not for diagnostic purposes!

Milenia Biotec GmbH
Versailler Str. 1
35394 Gießen
Germany
Tel.: +49 641 94 8883-0
Fax: +49 641 94 8883-80
E-mail: info@milenia-biotec.de
Web: www.milenia-biotec.com

Table of Contents

1 Explanation of Symbols

Symbol	Explanation	Symbol	Explanation
	Manufacturer		Direct current
	Date of manufacture		Research Use Only
	Collection and recycling of electronic devices by manufacturer		Unique Device Identifier
	Catalogue number		Consult Instructions for Use
	Serial number		

2 General Warnings and Precautions

- Please read this instructions for use (IFU) carefully before using **myilab research**, hereinafter also referred to as the **device**.
- The device should be placed on a table or other stable flat surface.
- In an emergency, it must be possible to cut off the power supply immediately.
- Protect the device from high humidity and contact with liquids.
- Do not use damaged devices.
- Do not expose the device to excessive heat.
- Do not expose the device to strong electromagnetic radiation.
- The function of the device may be impaired if it is used in an other way than described in this IFU.
- Any use of the device other than the intended use is not recommended.
- Do not dismantle the device.
- Serious occurrences must be reported to the manufacturer.

3 Storage and Handling

3.1 Where to use myilab research

The myilab research should be placed on a table or other stable flat, vibration-free surface. It must be protected from extreme temperature fluctuations and strong electromagnetic fields.

3.2 Power/Battery operation

The myilab research is connected to the power supply using the included power supply unit. The batteries integrated in the device are automatically charged when the power supply unit is connected. Only use the supplied, associated power supply unit.

Important Notice!

Myilab research may not be used in battery mode!

It always has to be connected to an external power supply!
The connection to the power supply is indicated by the display of the Status LED, it lights green with short interruption every 3 seconds.

The integrated rechargeable batteries only serve as a buffer, e.g. in the event of a voltage drop or to reposition the device while it is switched on.

3.3 Interferences

The myilab research is a highly sensitive and precise optical measuring device. Normal scattered light has no negative impact on the measurement.
Incoming light of extremely high intensities onto the device may significantly distort the measurement and therefore cause false or invalid results.

3.4 Cleaning

The housing of the device must be cleaned regularly with a damp cloth. In the case of stubborn dirt, it is also possible to clean the housing using a cloth dipped in 70% (v/v) ethanol or similar disinfectants.

Note! Do not use any corrosive chemicals, e.g., Acetone.

3.5 Contamination

If infectious material gets into the drawer or onto the housing of the device, it must be decontaminated.
Decontamination of the device is always necessary when returning it to the manufacturer (for more information, please see chapter 15.2 Returning the Device).

3.6 Damage

Do not use myilab research if it is damaged. Check the housing and the display for damage before using the device.

3.7 myilab research App

Warning!

The myilab research app runs on an Apple iOS operating system and can be deleted by the user. If the app is accidentally deleted, the device is no longer functional and the measured data is lost. The data cannot be restored. Therefore, we recommend exporting the data at regular intervals.

3.8 Settings

See chapter 12.

4 Materials Supplied and Storage

REF MYILABR 1

Component	REF	Content	Storage
myilab research	MYILAB R	1	+5 to 35 °C
Power supply	8014471	1	+5 to 35 °C
Quickstart Guide	Kurz/MYILAB R/A	1	
Technical Data	Technical Data MYILAB R	1	
myilab adapter	MRADAP 1	1	+5 to 35 °C
Adapter plug	(depending on country)	1	+5 to 35 °C

5 Accessories

Component	REF	Content	Storage
QC Chip	MRQC 1	1	+15 to 35 °C **Pleas note!** Always store QC Chip in the pouch, protected from light.
myilab adapter	MRADAP 1	1	+5 to 35 °C

6 Material Required, but not supplied

Completed Lateral Flow Test of the following Milenia Biotec GmbH products:

HybriDetect	REF	MGHD 1*
HybriDetect 2T	REF	MGHD2 1*
HybriDetect Cassette	REF	MGHC 1

* **myilab Adapter required (REF: MRADAP 1)**

7 Intended Use

The myilab research is an optoelectronic device. It is intended to enable the user to carry out a desktop computer independent, objective measurement of specific Lateral Flow Assays from Milenia Biotec GmbH. In this process, a photo-optical measurement of the Lateral Flow Assays is performed.

8 Device Installation

8.1 Environmental Conditions

The myilab research can be used under following conditions:

Temperature range	+15 °C to +35 °C
Relative humidity	Up to 70%, non-condensing
Air pressure	300 - 1060 hPa
Maximum altitude	2000 m

- The location of the device should be on a desk or stable surface with enough surrounding space in order to insert the test units easily or unplug the device in case of emergency.
- The device must be located on a vibration-free surface.
- Protect from extreme temperatures.
- Do not expose the device to direct sunlight during operation.
- Protect from moisture and keep it away from liquids.

8.2 Action upon Delivery

After unpacking myilab research, please check the following:

- Delivery completeness (see chapter 4 Materials supplied and Storage).
- Damages during transportation (touchscreen and housing).

8.3 Put myilab research into Operation

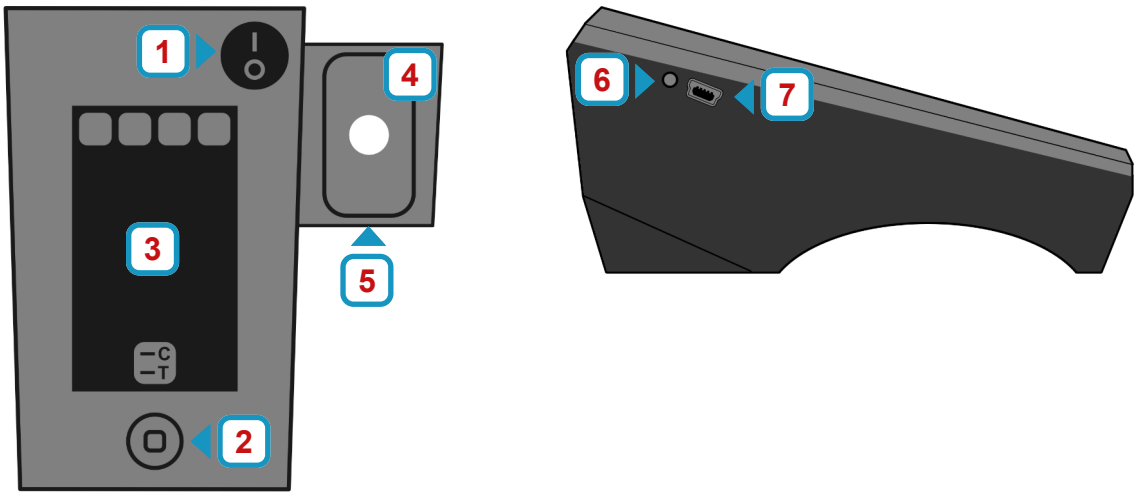
- Connect the external power supply to the mini USB port on the upper left side of the device (see chapter 9 Device Overview, no 7). Use the associated power supply unit for connection.
- Remove the transport lock from the light switch.

Note:
Before using myilab research for the first time or after long storage, fully charge the device.

The **myilab research app** is pre-installed. The user does not have to do any further steps for installation.

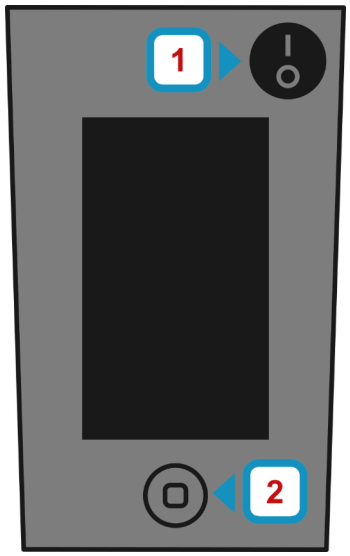
9 Device Overview

Top View **Side View**



Number	Description
1	Switch for analysis chamber lighting system (on/off)
2	Home button for analysis computer
3	Touch display for operating the myilab research app
4	Pull-out drawer
5	Recess for Test Unit
6	Status LED
7	Mini USB port, for connecting the external power supply to the myilab research

10 Turning on the Device



1. Set the switch 1 to the on position „I“ to switch on the lighting system.

   Note: Always set the light switch to “0” when the device is not in use.

1. Press the Home button 2 twice in order to activate the touchscreen and unlock the device.

Important Notice!
When using the myilab research, **it must always be connected to an external power supply** via the mini-USB port on the left-hand side of the device.
Only use the power supply unit supplied with the device.

If the touchscreen stays black after pressing the home button, the ups battery (uninterruptable power supply) is probably empty and the device is not connected to a power supply.
Connect it to a power supply via the mini USB port. It may take up to 1 hour for the device to turn on.

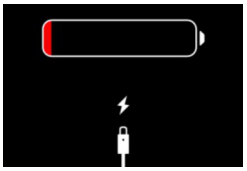


Figure 1

If the touch display is showing a red battery symbol **(see figure 1)**, the battery of the analysis computer does not have enough power for use.
Keep the device connected to the power supply. The device switches on automatically if the battery of the analysis computer has reached a minimum state of charge.

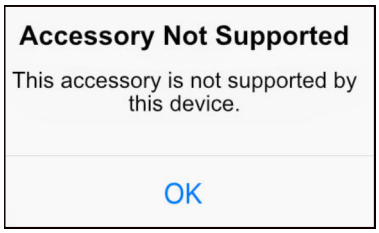


Figure 2

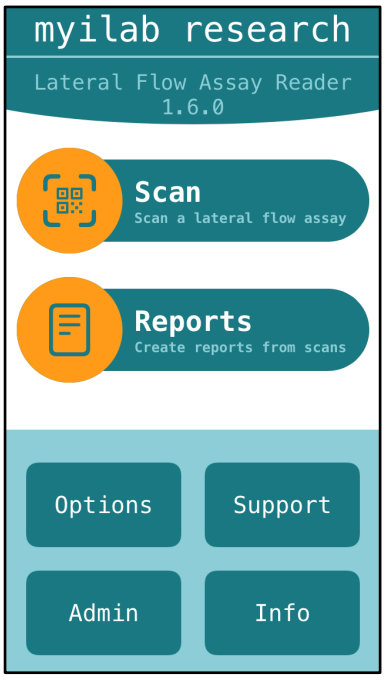
Note:
During use the message shown in figure 2 may appear on the display.
Close the message, touching the OK button.
Disconnect the mini USB cable and reconnect to the device.

11 App

11.1 Turning on the App

1. Check the state of charge indicator 1 of the myilab research. The lightning symbol combined with a green battery symbol indicates correct grid operation.
2. Touch the button 2 to launch the myilab research app.

11.2 Main Screen



After the myilab research app has been launched, you will be taken to the main screen. From here, you can call up the functions **Scan** and **Reports**.

The menu items **Options**, **Admin**, **Support** and **Info** can be found in the lower region of the touch display.

Details on the individual functions and menu items will be explained in the following chapters.

11.3 Scan - Scan a Lateral Flow Assay

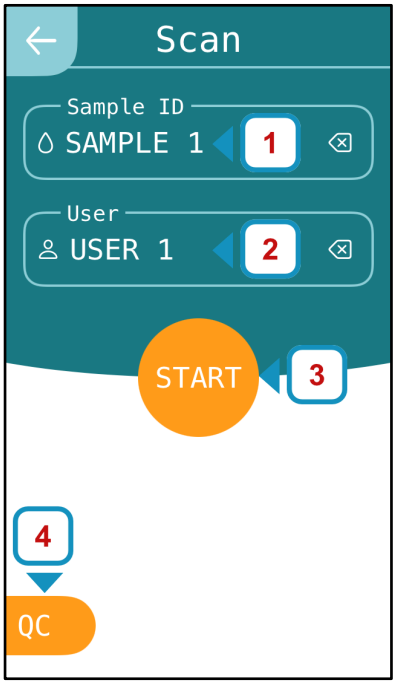
11.3.1 Prior to the Scan Process

- The lateral flow assay (LFA) must be carried out according to the instructions for use (IFU) of the respective test kit.
  The incubation time should always be the same, e.g. 5 min, in order to be able to compare results!
- **Please note!**
  Before measuring the dipsticks of the assays HybriDetect (MGHD 1) and HybriDetect 2T (MGHD2 1), the adapter must be inserted and the corresponding program selected (see chapter 11.7.6 Options - Dipstick (Measuring with Adapter))
- Please ensure that the lighting system of the device is switched on before starting the scan (see chapter 9 Device Overview, no 1).

11.3.2 Start Scan Process

Press **Scan** on the Main Menu to open the Scan Screen.

- The scanning process should be started exactly after the **test specific incubation time** has elapsed. **The incubation time should always be the same, e.g. 5 min.**
- The device identifies the test unit/adapter using the QR code on it.



Note:
The Keyboard appears automatically when a text box is tapped.

1. Optional: Enter the **Sample ID** into the corresponding field 1.
2. Optional: Enter **User** into the corresponding field 2.
3. Open the drawer and insert the **test unit** or **adapter** to be scanned.

   Test unit: The QR code has to be in the upper region of the drawer, facing the user.

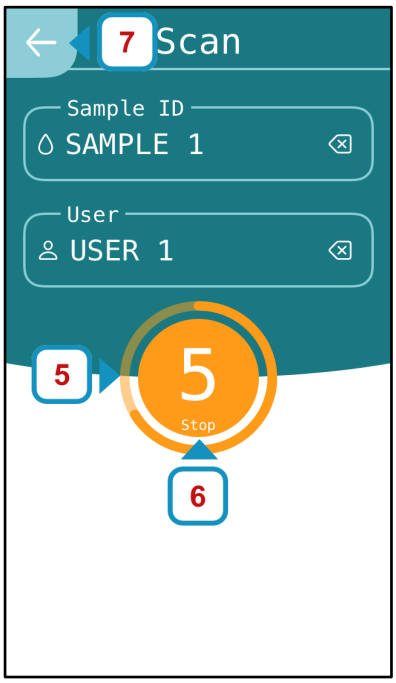
   

   Adapter: The QR code has to be in the lower region of the drawer, facing the user.

   Close the drawer.
4. Touch **START** 3 to begin scanning process.

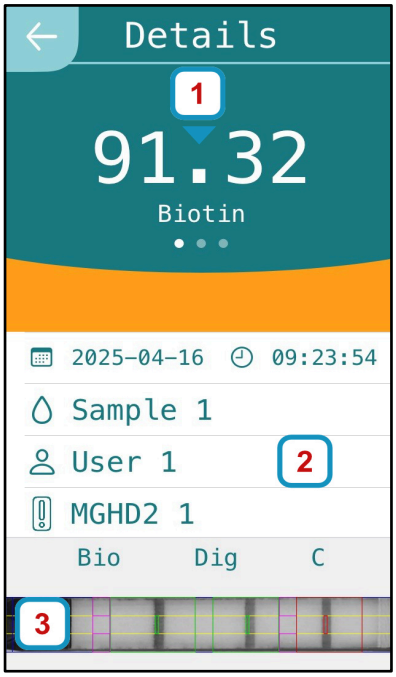
4 QC information is displayed in this field, if QC is enabled. See chapter 11.7.5 Options - Enable/Disable Quality Control (QC) for further information.



5. The measurement takes 15 seconds. The status is displayed by a countdown and a process bar 5.
6. To stop the scanning, press **STOP** 6 or **BACK** 7 (arrow in the upper left corner, leads to Main Menu).
7. Once the analysis has ended, you will be taken automatically to the result screen.

11.4 Result Display

The detailed view of the results appears automatically after the scan process or can be called up via Reports (see chapter 11.5 Report History point 7).



1 Area in which the result is displayed.
By swiping to the left you can see the result for every single line.

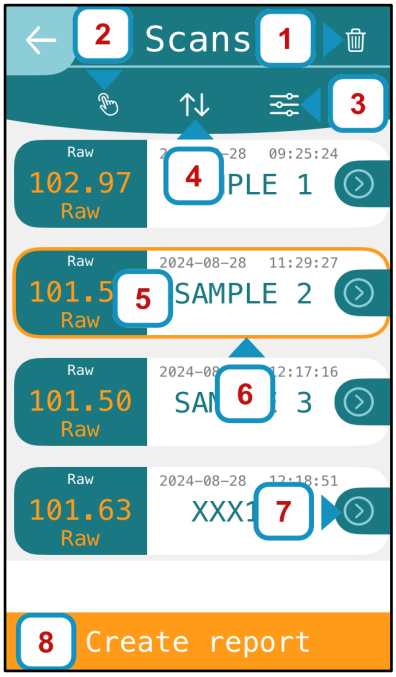
2 Area of the assay data display:
Date/Time, Sample ID, User ID, Assay.

3 Image of the scanned test strip.
Tapping on it displays a full screen image of the strip.

Note:
Results are automatically saved and can be accessed and exported at a later time using the **Reports** function on the main menu.

11.5 Report History

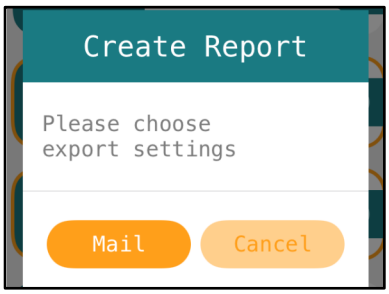
Press **Reports** on the Main Menu to open the Report Screen.



1. Button to delete selected scans.
   Deletion must be additionally confirmed by the user.
2. Button to select / deselect all scans.
3. Button to call filter settings.
4. Button to set sorting criteria.
5. Area of the scan result data display.
   Tapping the area selects the scan.
6. Orange marking indicates a selected scan.
7. Button to show result details (see chapter 11.4 Result Display).
8. Button to create a report.
   All selected scan results are summarised and exported in a CSV file.

11.5.1 Report History - Create and Export Report

Press **Reports** on the Main Menu to open the Report Screen.



After **Create Report** 8 has been selected, a CSV file is generated.

- Press **Mail** to send the file to one or more e-mail addresses.
- Press **Cancel** to cancel exporting the CSV file and return to the previous screen

Note:

- See chapter 12.6 Mail to set up the email account. **This step must be completed once before reports can be sent via e-mail.**
- See chapter 11.7.7 Options - Mail Recipients to enter standard e-mail addresses.
- See chapter 11.7.8 Options - CSV Options to customise the fields of the CSV file.

11.6 Quality Control

The measurement of quality controls can be enabled or disabled in the myilab research app (see chapter 11.7.5 Options - Enable/Disable Quality Control (QC)).

Note: The QC Chip (REF MRQC 1) must be ordered separately to perform QC.

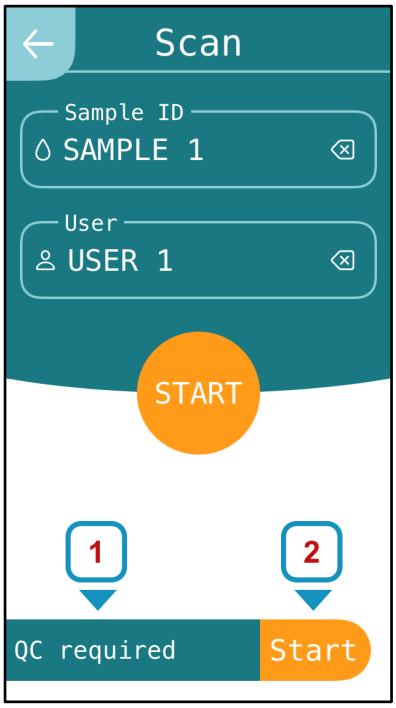
11.6.1 Quality Control Enabled

QC Status Valid

Press **Scan** on the Main Menu to open the Scan Screen.

QC field shows no message 1.

Selecting the **QC** button opens the QC bar with detailed information on the status of the QC:



QC Status Overdue

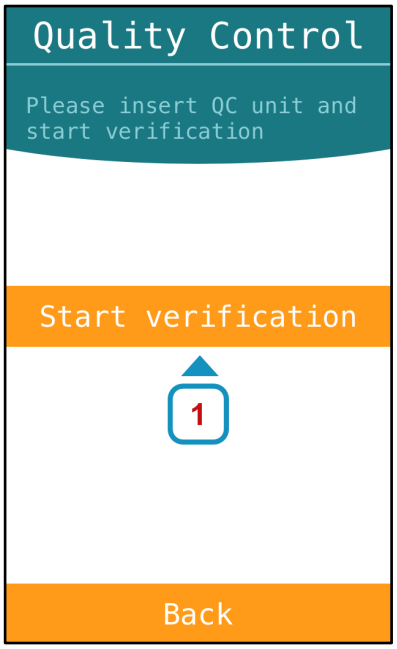
Press **Scan** on the Main Menu to open the Scan Screen.

The Message **QC required** appears in the QC field 1.

Press **Start** to open the Quality Control Screen 2.

Note:
Sample measurements are no longer possible until a QC has been started.

11.6.2 Start Quality Control

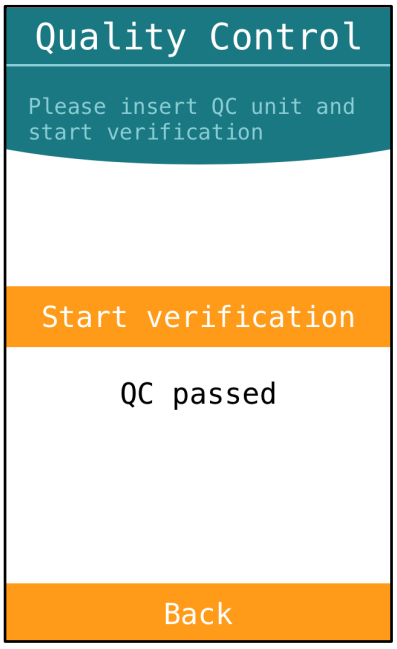


1. Open the Quality Control Screen via QC button and press **Start** (see chapter 11.6.1 Quality Control Enabled).
2. Open the drawer and place the QC unit in it.

   The QR code has to be in the upper region of the drawer, facing the user.

   Close the drawer.

3. Touch **Start verification** 1 to begin scanning process.



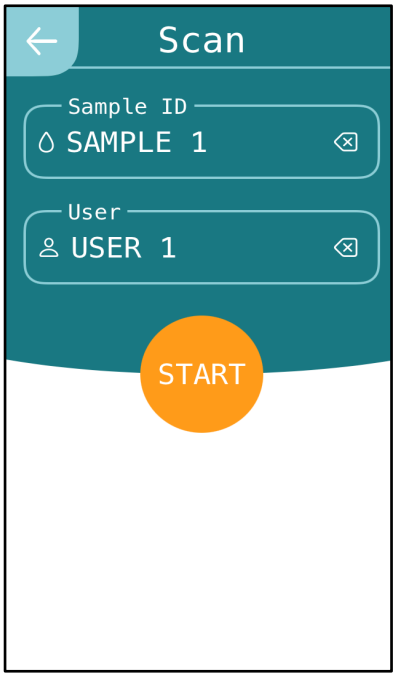
Quality Control Results

After successful quality control, the device is ready for sample measurements.

If the control failed, please complete the following steps:

1. Check the QC cassette for contamination. Minor impurities such as lint can lead to a negative QC.
2. Measure the QC cassette again
3. If the control fails again, please contact Milenia Biotec Support via e-mail: **support@milenia-biotec.de**

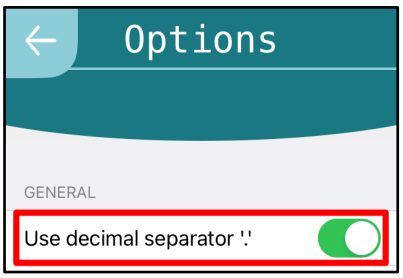
11.6.3 Quality Control Disabled



No QC field visible.

11.7 Options

11.7.1 Options - Use Decimal Separator '.'



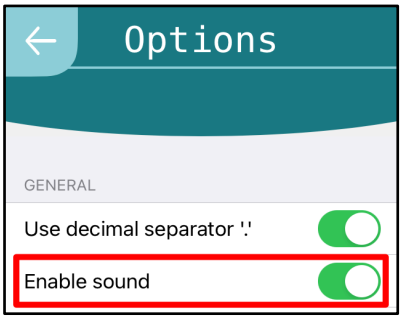
Use decimal separator is **activated** by default.

If '**Use decimal separator**' is **activated**, the point is used as the decimal separator (e.g. used by default in Excel versions in the USA, UK, Australia).

If '**Use decimal separator**' is **not activated**, the comma is used as the decimal separator (e.g. used by default in Excel versions in Germany).

11.7.2 Options - Enable/Disable Sound

Press **Options** on the Main Menu to open the Options Screen.

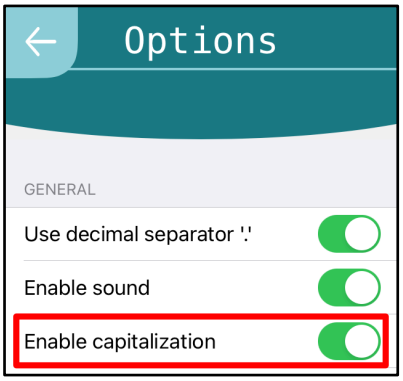


Select **Enable sound** to activate acoustic signals during the measurement process.

Note:
If there is still no sound, please check whether the volume has been manually set to "0" in the settings.

11.7.3 Options - Enable/Disable Capitalization

Press **Options** on the Main Menu to open the Options Screen.

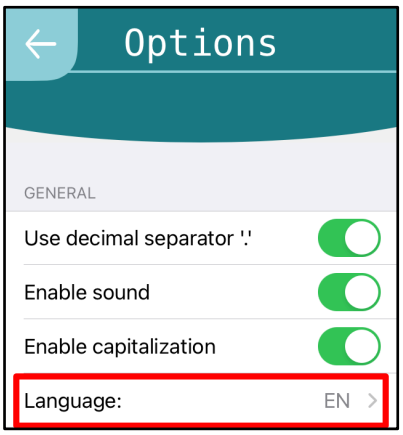


Capitalization is **deactivated** by default.
It can be activated via **Enable capitalization**.

This function activates the automatic capitalization of the input fields **Sample ID** and **User** on the scan screen.

11.7.4 Options - Choose Language

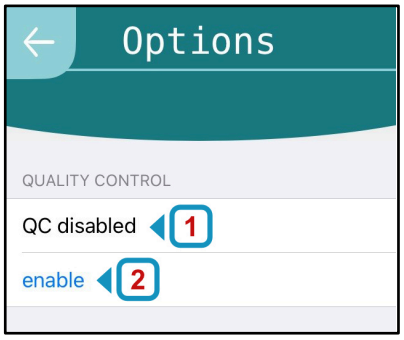
Press **Options** on the Main Menu to open the Options Screen.



Select preferred language from the drop-down menu.

11.7.5 Options - Enable/Disable Quality Control (QC)

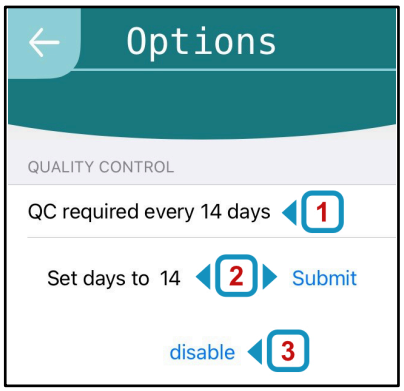
Press **Options** on the Main Menu to open the Options Screen.



1 Status display, whether Quality Control (QC) is enabled or disabled.

2 Enable/Disable QC via this button.

If **enable** is selected, the QC interval can be set (see next figure **Setting the QC Interval).**



Setting the QC interval

1 This field shows whether the QC is enabled and after how many days a QC is requested.

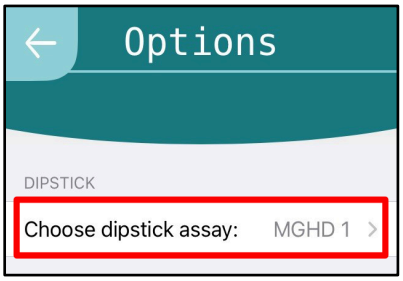
2 Set the number of days after which a new QC is to be requested and select **Submit**.

3 Select **disable** to disable QC measurements.

Note:
QC measurements are possible at any time, but at the latest after the entered QC interval.

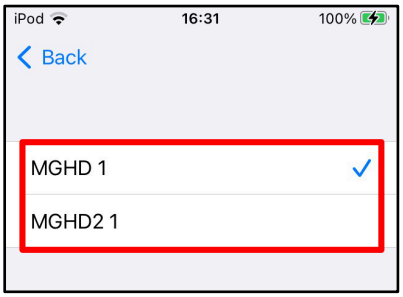
11.7.6 Options - Dipstick (Measuring with Adapter)

Press **Options** on the Main Menu to open the Options Screen.



The **Dipstick** option allows for the measurement of dipsticks in the myilab adapter.

Select **Choose dipstick assay**.

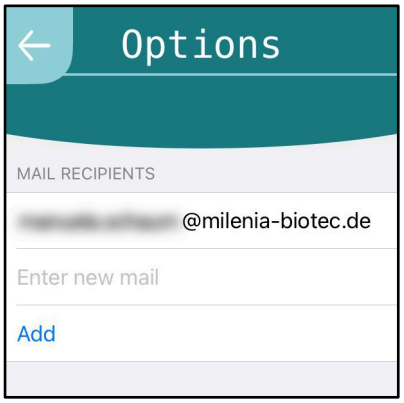


To measure **HybriDetect** (REF: MGHD 1) select the program **MGHD 1**.

To measure **HybriDetect 2T** (REF: MGHD2 1) select the program **MGHD2 1**.

11.7.7 Options - Mail Recipients

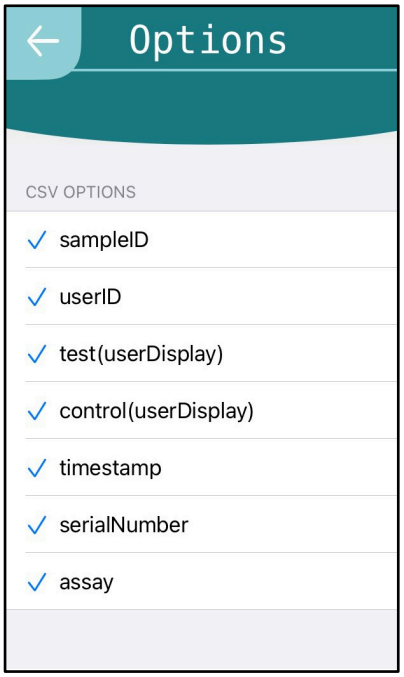
Press **Options** on the Main Menu to open the Options Screen.



Data exports are only sent by e-mail.
The e-mail address(es) to which the data export is sent can be entered in advance under **Mail Recipients**.

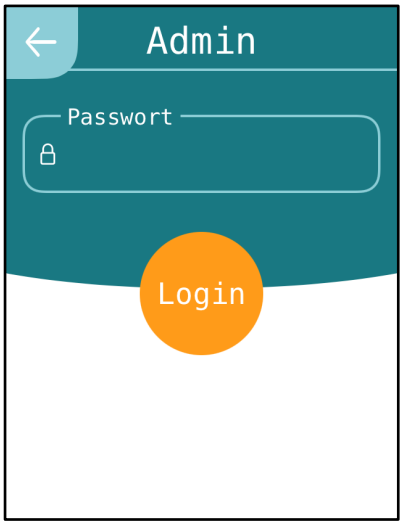
11.7.8 Options - CSV Options

Press **Options** on the Main Menu to open the Options Screen.



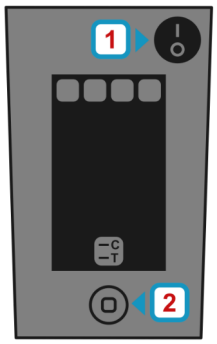
The data export fields can be customised under **CSV Options**.
The order of activating the single csv options determines the order of the resulting csv.

11.8 Manufacturer Administration



Area for internal settings made by the manufacturer.
This area is password protected and not accessible for users.

11.9 Shutdown Options



11.9.1 Stand-by

- Turn off the Light switch 1 to position „0“.

Note: Always set the light switch to “0” when the device is not in use.

- Press the Home Button 2.

The device will turn in stand by mode after 5 minutes (preset) automatically (see chapter 12.5 Display Brightness and Auto-Lock Time).

11.9.2 Switch off

Myilab research is never switched off.

Only stand-by mode is used by setting the light switch to pos. "0" (see chapter 11.9.1 Stand-by).

Exception:
The only exception in which the myilab research is switched off is, when it is returned to Milenia Biotec GmbH. Please observe the procedure in chapter 15.2 Returning the device.

11.9.3 Temporarily taking device out of operation

Option 1: Device will remain connected to the power supply.

No further actions are necessary, device will remain in stand-by mode.
The device can be put back into operation directly.

Option 2: Device will be disconnected from the power supply.

Important Notice!
Device must be charged once every half year for several hours, even without working with it!
The device can be put back into operation when a base charge is established and the display turns on (could take up to 1 hour).

12 Settings

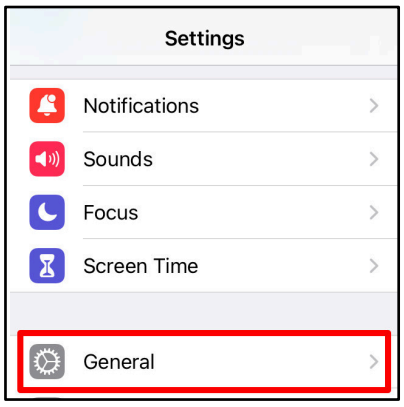
The following parameters can be configured under **Settings:**

- Language
- Date and Time
- Wi-Fi
- Passcode
- Display Brightness and Auto-Lock Time
- Mail

Press **Settings** 2 on the Home Screen of the Operating System (OS) to open the Settings Screen.

Note:
To return to the Home Screen from the myilab research App, press the Home Button 1 once.

12.1 Select Language



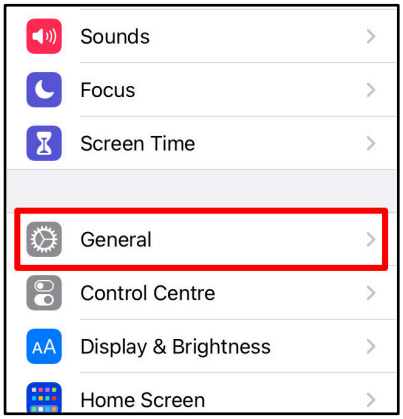
Note:
If the time and date are not set to match the time zone, internet access will not work and the data cannot be exported via e-mail.

Scroll down to the menu item **General** and tap on it.

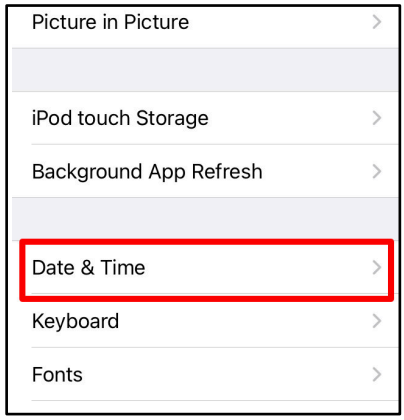
Scroll down to the menu item **Language & Region** and tap on it.

1. Tap on **Language** and select preferred language.
2. Confirm the changes.

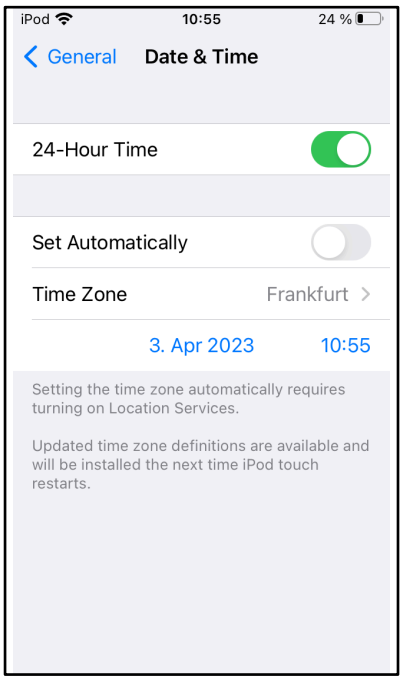
12.2 Date and Time



Scroll down to the menu item **General** and tap on it.

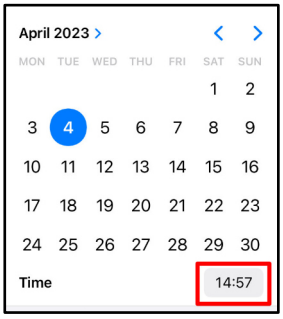


Scroll down to the menu item **Date & Time** and tap on it.



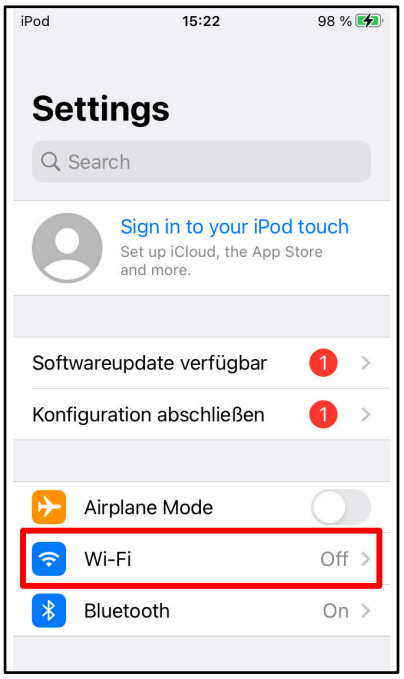
1. Select the preferred **Time Format** (24-Hour Time).
2. Choose the **Time Zone.**

   Note:
   It is recommended to set the Time Zone manually and not automatically, if no permanent WLAN/Internet connection is to be used.
3. Change the **Date** by tapping on it and scroll down to change the **Time** (see figure below).



12.3 Wi-Fi

Wi-Fi connection is required to export reports.



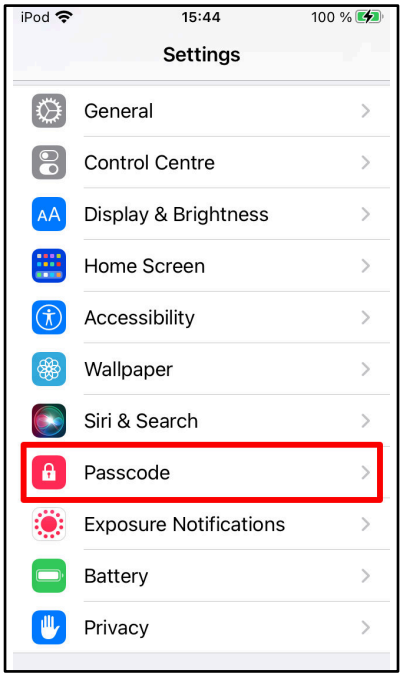
Tap on menu item **Wi-Fi** to get to the Wi-Fi Settings.

Please contact your system administrator for the Wi-Fi access data and internal regulations.

12.4 Passcode

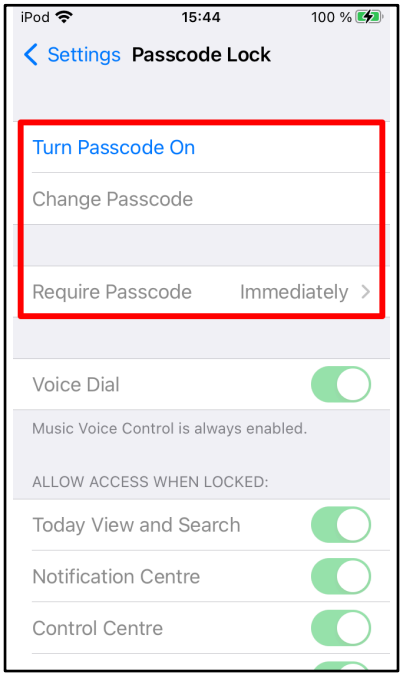
Access control for the OS and myilab research app.

Warning!
In case of password loss, the password cannot be reset. The device must be replaced. Data stored on the device cannot be restored when it is replaced.



Scroll down and tap on menu item **Passcode** to open the settings.

Note:
If a passcode is set, it must be entered to unlock the display.

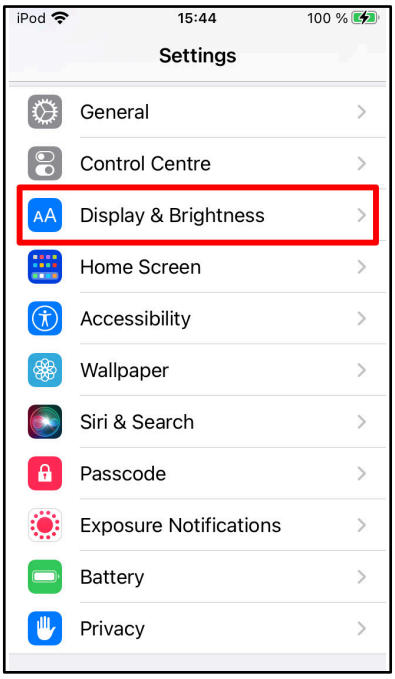


The following actions can be set:

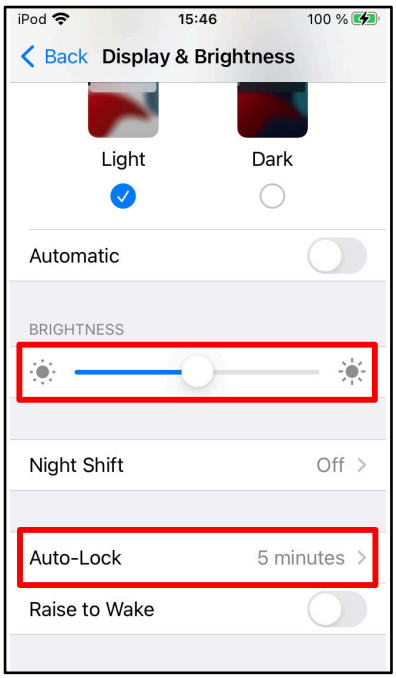
- Turn on/off Passcode
- Change Passcode
- Required Passcode*

* Recommended setting: **Immediately**
Passcode is requested immediately after display is turned on.

12.5 Display Brightness & Auto-Lock Time



Scroll down and tap on menu item **Display & Brightness** to open the settings.



The following actions can be set:

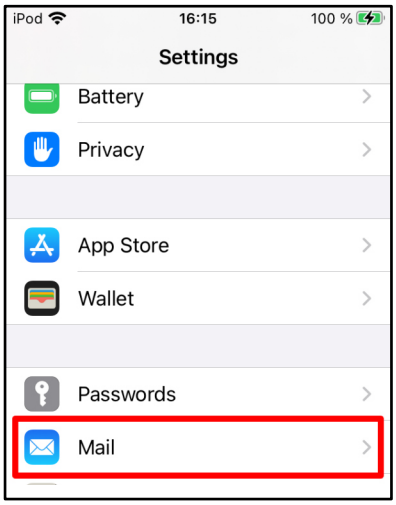
- Brightness
- Auto-Lock*

* The display switches off and the analysis computer is locked after the set Auto-Lock time.

If a passcode has been assigned, it must be entered after reactivation of the display.

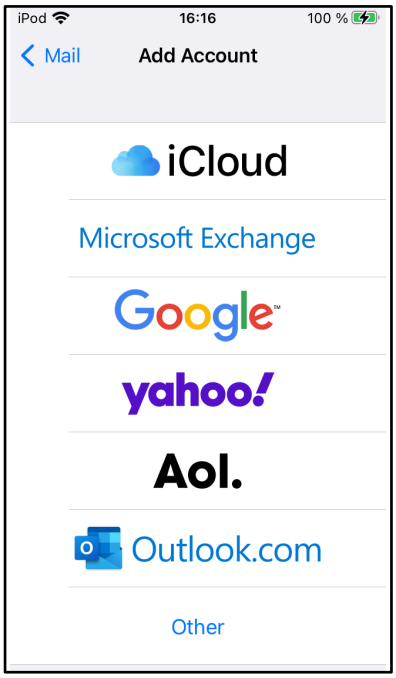
12.6 Mail

Must be configured to send reports via e-mail.



Scroll down and tap on menu item **Mail** to open the settings.

Tap on **Add Account**.

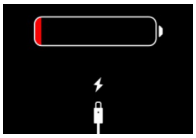


Please contact your system administrator for the mail account settings and internal regulations.

13 Specifications

Specification	**myilab research**
Power Supply	5 V ⎓ 2 A
Power Supply Unit	**Input:** 100–240 V AC, 50/60 Hz, 0.40 A **Output:** 5.0 V ⎓ 2.0 A, 10.0 W
Mobile power supply	Uninterruptible power supply, provides an automatic backup power supply for a load if the input power source or the mains power supply fails.
Temperature range	**Operation:** +15 °C to +35 °C **Storage:** +5 °C to +35 °C **Transport:** + 5 °C to +45 °C
Relative humidity	Up to 70%, non-condensing
Permissible elevation above sea level	2000 m above NN, without pressure equalisation
Installation	Operate the device on an even surface without vibrations
System Test	Runs automatically with every measurement
Dimensions (LxWxH)	185 mm x 112 mm x 101 mm
Weight	620 g
EMV and Safety standards: • IEC 61010-1 • EN IEC 61326-1	 Safety requirements for electrical equipment Electrical equipment for measurement, control and laboratory use - EMC

14 Troubleshooting

Problem	Possible cause	Recommendation
Package is damaged.	Improper handling during transport.	Contact Support **Phone: +49 641 948883-0** **E-mail: support@milenia-biotec.de**
Status LED flashes red/green alternately after being switched on.	The device is not connected to the power grid.	Connect the device to the power grid via the mini USB port.
The touch display does not switch on (black screen).	Analysis computer battery is empty.	Connect the device to the power grid via the mini USB port in order to charge the computer battery. If the device has not been used for a few days, it may take up to 1 hour for the analysis computer to turn on.
The touch display shows a red battery symbol, even though the device is connected to the power supply. 	The computer battery is running too low.	Keep the device connected to the power supply. The device switches on automatically if the computer battery has reached a certain minimum state of charge (can take up to 20 minutes).

If you have any questions about error messages, please contact our support department at the e-mail address: **support@milenia-biotec.de**

15 Maintenance, Return and Disposal

15.1 Cleaning the Housing and Drawer

The housing must be cleaned regularly with a damp cloth. In the case of stubborn dirt, it is also possible to clean the housing using a cloth dipped in 70% ethanol.

Note! Do not use any corrosive chemicals, e.g. Acetone.

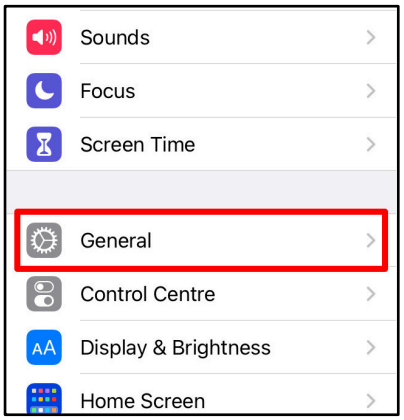
15.2 Returning the Device

In the event of a defect, the device may have to be sent back to Milenia Biotec GmbH.
Please contact the Support Team before returning the device!

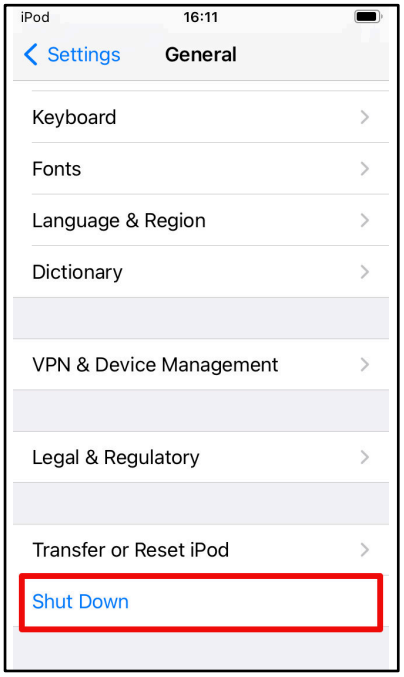
15.2.1 Switching off the Device

Press **Settings** 2 on the Home Screen of the Operating System (OS) to open the Settings Screen.

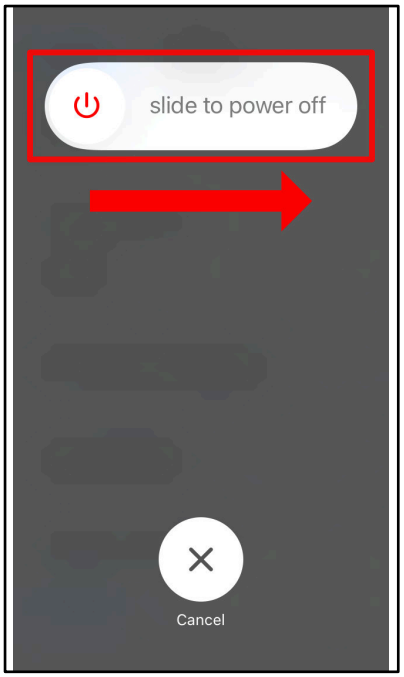
Note:
To return to the Home Screen from the Analysis App, press the Home Button 1 once.



Scroll down to the menu item **General** and tap on it.



Scroll down to the menu item **Shut Down** and tap on it.



Slide to the right to shut down.

15.2.2 Decontamination of the Device

The device may have come into contact with contaminated material during use,
decontaminate the device before sending it back to Milenia Biotec GmbH.

Decontamination is done by thoroughly cleaning the housing and the drawer using a cloth dipped in 70% ethanol.

Note! Do not use any corrosive chemicals, e.g. acetone.

15.2.3 Decontamination Certificate

After decontamination, a proof of disinfection must be filled out and sent to Milenia Biotec GmbH by e-mail or fax before returning the device.

The proof of disinfection is sent to you upon request by our support team.

Important Notice!
Returned devices are only accepted by the manufacturer once this proof of disinfection has been provided.
Otherwise, your delivery will be sent back unopened.

Milenia Biotec GmbH
Support Team
Versailler Straße 1
35394 Gießen
GERMANY

E-mail: support@milenia-biotec.de
Telephone: +49 641 94 8883-0
Fax: +49 641 94 8883-80

15.3 Disposal

The disposal of waste must be done according to local regulations.

Do not dispose with regular waste in accordance with 2012/19/EU of the EUROPEAN Parliament and the council about electrical and electronics old devices.

15.3.1 Disposal of the Device

Note! Device contains lithium ion battery.

Devices can be returned to the manufacturer for disposal.

15.3.2 Disposal of the Test Units

The test unit, except the myilab adapter, is only intended for one-time use.
The test units must not be disposed of with household waste!
The package inserts of the HybriDetect tests contain further information about this.

16 Contact

Milenia Biotec GmbH
Versailler Str. 1
35394 Gießen
Germany

www.milenia-biotec.com

info@milenia-biotec.de

support@milenia-biotec.de

+49 641 948883-0

Or write to us using our contact form.

17 Change History

Date	Revision	Cause of Revision
2025-07-01	A	Creation of the myilab research instructions for use (IFU)

Milenia Biotec GmbH • Versailler Str. 1 • 35394 Gießen, Germany
Tel.: +49 641 948883-0 • Fax: +49 641 948883-80
E-mail: info@milenia-biotec.de • Web: www.milenia-biotec.com