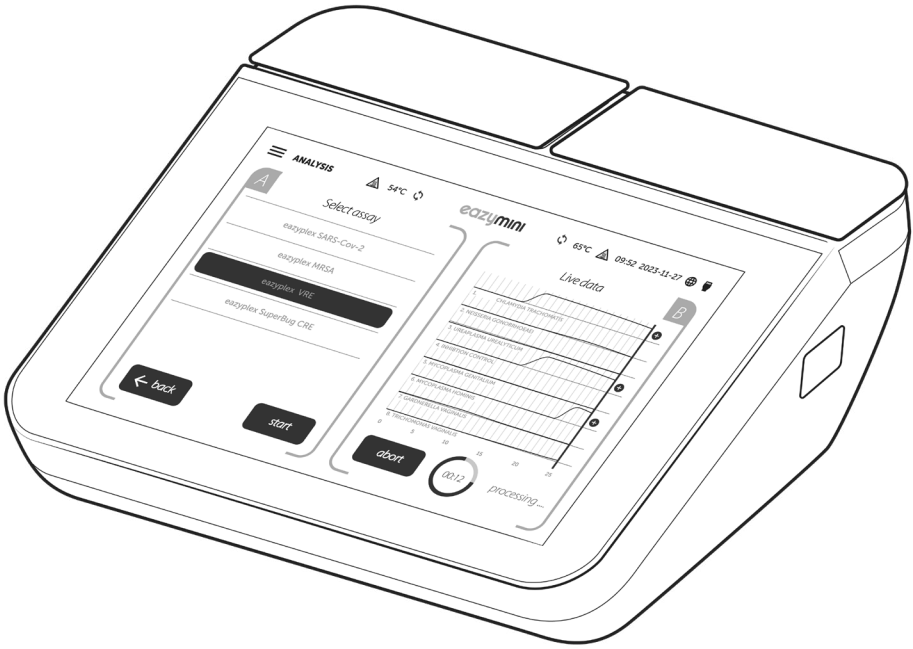
INSTRUCTIONS FOR USE

eazymini

real-time NAAT analyser
7510



NAAT Nucleic Acid Amplification Technique

DELTA FAB

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WARNINGS & SAFE USE

The following warnings are intended to help you minimize risks.

Improper use of the device that is not specified by the manufacturer may result in injury to the user or damage to the device.

Always make sure that the surface on which you place the device is level, clean, stable, and will not cause the device to fall. Make sure the surface can support the weight of the device and is large enough.
If the device is dropped, it may be damaged.

The device must never be lifted by the lids.
Always grasp the sides of the device with both hands when lifting.

Do not expose the device to direct sunlight. Make sure that the air supply to the vents at the back and bottom of the unit is not obstructed.

The device is electrically operated. Please make sure you connect the device to the correct voltage before plugging in the device. If you are unsure, consult a qualified technician. The device has a label on the bottom. Please check there if necessary.

Never try to open the device housing or penetrate the interior of the device (e.g. into the cavities of the optical unit) with objects!
The device does not contain any self-serviceable parts and must be sent in for repair. Opening also voids the warranty claim.

The device is protected against splashing water in the best possible way, but does not have an IP protection class certificate. In the event that liquids are poured over the device, it may be damaged or an electrical short circuit may be triggered.

In the event of a malfunction, please disconnect the device from the power supply immediately. Do not touch the device or any leaking liquids while the device is still connected to the power supply. Always follow local health and safety guidelines.

When switching off, please note:

The device is disconnected from the power supply by disconnecting the power cord from the socket.

The heating blocks, lids and test strips are hot during use. Allow these parts to cool before touching them.

The safe removal of liquids from the device depends on the chemicals used. This requires information about the fluids used in the system and compliance with local safety and health regulations. If you are unsure, contact the person in charge at the laboratory.

Serious Incidents:
Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

In addition to the information provided in these instructions for use, known significant remaining risks: none

1. INTRODUCTION

1.1 Intended purpose

The product is intended to perform isothermal amplification of nucleic acid sequences with real-time fluorescence detection. It is intended for in vitro diagnostic use in combination with special IVD test sets and is intended for professional use only.

1.2 Safety instructions: Intended use

Please read these instructions for use and all notices carefully and completely before using the eazyMini device.

The present device has been developed under the highest safety standards. In order to avoid any risks to the device, the user or persons in the vicinity of the device, please read the following chapters before unpacking and operating the device. The information in these instructions for use supplements the valid safety regulations in the user‘s country and does not replace them. If you have any questions about the correct use, please contact your distributor.

2. GETTING STARTED

Please read these instructions carefully, in particular **chapter 2.6 Maintenance of the system** and **chapter 7. TROUBLESHOOTING**.

2.1 Workplace preparation

Place the device on a clean and flat surface (laboratory bench). Make sure that the device and its surroundings are free of obstructions at all times. In the event of an emergency or under unusual operating conditions, the site should provide enough space at all times to allow for easy disconnection of the device from the power supply.

A scanner is integrated on the side of the device to scan Data Matrix, QR and barcodes. Therefore, leave enough space to the right of the instrument to be able to scan sample IDs, test barcodes and test profile QR codes.

Make sure that the air supply on the back of the device and the exhaust fan on the bottom of the device are always clear. Blocked ventilation of the device can impair its function and reduce performance.

Electrical outlets should be close to the device to prevent accidents caused by cables lying around.

The device should not be placed near sinks or wet areas. The eazyMini is an electrical device and care should be taken not to operate it when there is a risk of water damage.

The eazyMini is a highly sensitive and precise optical instrument. Results can be affected by vibration if the device is placed too close to a vibrating machine (e.g. centrifuge).

The device must not be moved under any circumstances while tests are being performed.

2.2 Unpacking

Open the package carefully without damaging it. In the case of service or repair work, this is required as transport packaging (see also **chapter 8. SERVICE & REPAIR**).

Lift the eazyMini out of the box only by the front and back of the device.
Never lift the device by the lids.

Check that the following things are included:

- Device eazyMini
- Instructions for use
- Power cord
- Touch pen

Check the device carefully to make sure it hasn‘t been damaged in shipment.

If damage has occurred or parts are missing, contact your distributor.

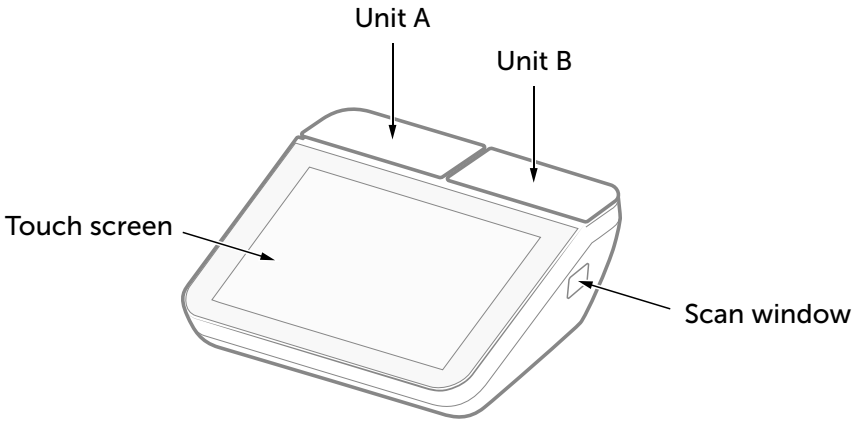
2.3 Additional equipment and materials required

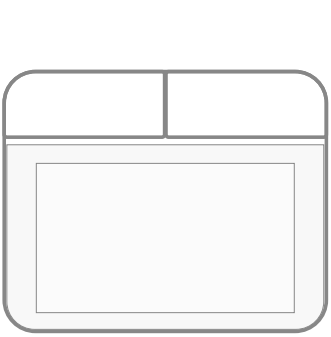
1. Test kits (e.g. eazyplex® kits; AmplexDiagnostics GmbH)

2. General laboratory equipment:

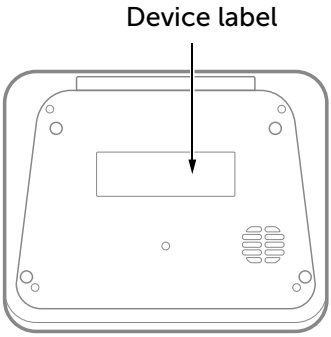
- DYMO® LabelWriter™ 550 printer with appropriate labels (36 mm × 89 mm)
- Pipetting blocks (e.g. AmplexDiagnostics GmbH)
- USB stick (FAT32 format)

2.4 Overview

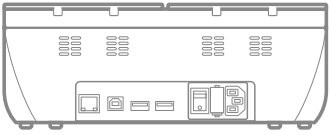




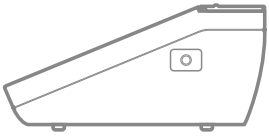
Top of the device



Bottom of the device



Back of the device



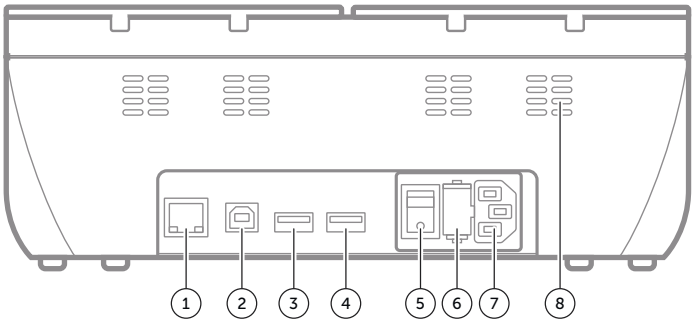
Side view

2.5 Connections

Plug one end of the power cord into the designated power plug on the back of the device and then the other end into the socket.

On the back of the device is the **power ON/OFF switch**. When the device is switched on, the system starts to boot up.

Back of the device:



1. Ethernet
2. USB interface (**USB Type B**)
3. USB interface (**USB Type A**)
4. USB interface (**USB Type A**)
5. Power switch ON/OFF
6. Fuse holder
7. Mains connection, power connection (power plug)
8. Ventilation slots

Only use the power cord provided by the manufacturer.
To reorder, please contact your distributor.

2.6 Maintenance of the system

Cleaning:
For daily or weekly disinfection of device surfaces, touch screens and cables, use Meliseptol® Wipes sensitive from B. Braun Medical AG or something comparable.

The use of wipes minimizes the risk of liquid ingress into the optical system.

It is absolutely necessary to prevent moisture from entering the optical system. **For this reason, it is not permitted to pipette into the test strips when they are in the device. All pipetting steps must be carried out outside the device.** If liquid has entered the optical system, contact your distributor to arrange service and repair of the device.

Operation
The test strips are shaped so that they only fit into the block in one direction. The pins located on the heating block fit into the corresponding rear eyelets of the test strips.

Open and close the lids gently. The lids are locked with a push-to-open mechanism. The lids can be opened and closed by gently pressing down on the front edge. Make sure nothing is in the way when you close the lids. **Under no circumstances should you open or close the lids by force.**

General laboratory equipment
The device requires special test strips that optimize optical and thermal efficiency. Using other non-recommended test strips or other consumables will damage the device and void warranty claims.

Any unauthorized modification of the device, as well as damage caused by improper handling, will void the warranty.

If possible, keep the lids closed when not in use to minimize the risk of contamination of the analysis units.

3. OPERATION

The device is operated via a touch screen to display or enter data.

Gently touch the screen and tap the appropriate buttons if needed. The touch screen can also be operated with protective gloves or with a corresponding touch pen that is supplied with the device.

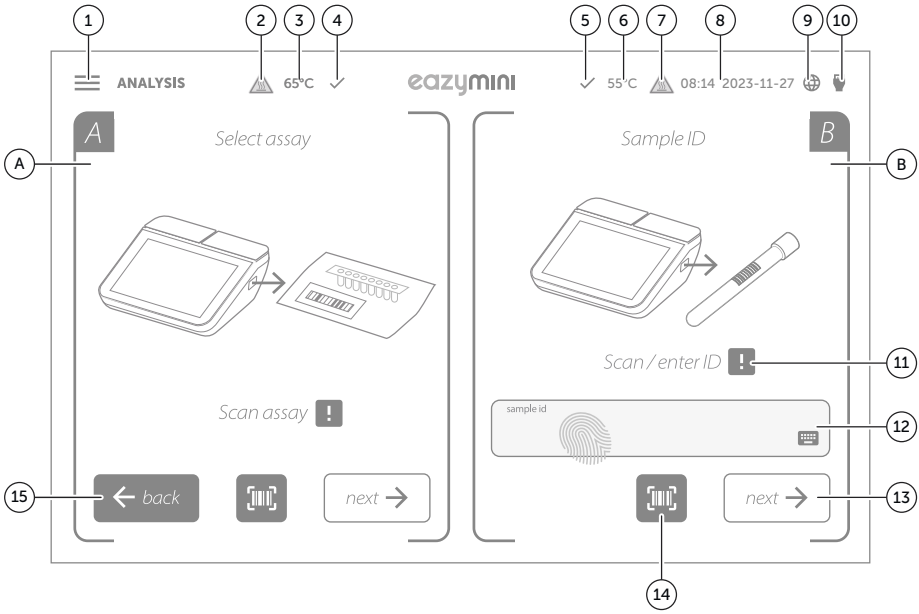
NEVER use sharp or pointed objects or writing implements to operate the touch screen. This will cause damage to the touch screen.

3.1 User Interface

The graphical user interface of the tactile screen is divided into several areas. The menu and various output displays are located in the upper area. The lower area with input and control panels is divided in the middle into two sections A and B. These are each assigned to the heating/analysis unit (Unit A and Unit B) above the display.

Since the two heating/analysis units work independently of each other, they are also operated independently of each other via the corresponding section.

For a better overview, individual work instructions in these instructions for use are given as examples using section A. The instructions therefore apply equally to section B; the operation is identical.

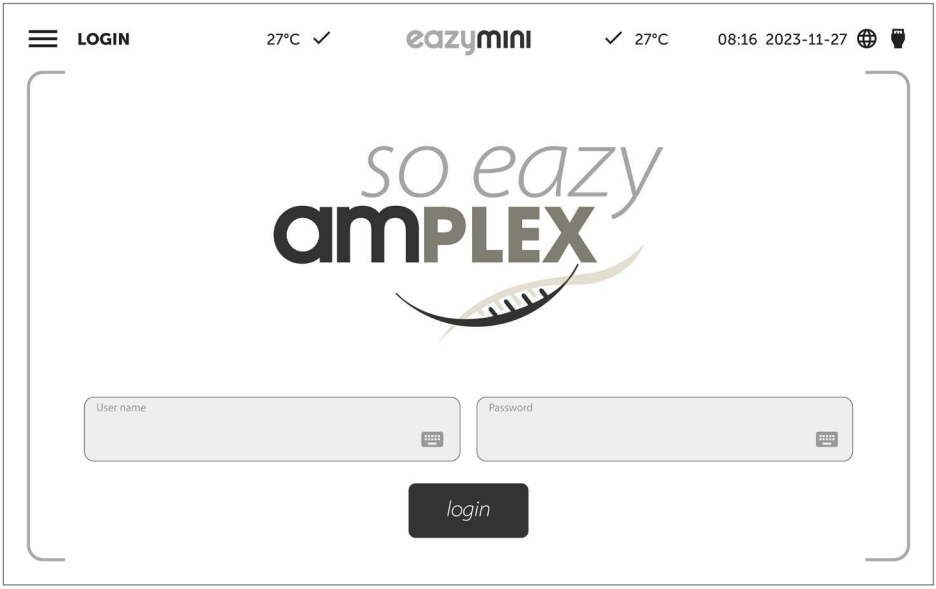


1. Main menu
2. Warning field for “Hot Surface Warning“ – lid and heating block A
3. Temperature display in °C – heating block A
4. Display field for status messages Section A:
   “Calibration process”, “Process run”, “Operational” ✓, “Warning”
5. Display field for status messages Section B:
   “Calibration process”, “Process run”, “Operational” ✓, “Warning”
6. Temperature display in °C – heating block B
7. Warning field for “Hot Surface Warning“ – lid and heating block B
8. Time and date display(hh:mm, YYYY-MM-DD)
9. Ethernet connection indicator
10. USB connection indicator
11. Prompt to the user
12. Input field; *On-screen keyboard opens upon touch*
13. Control element: inactive button -next-
14. Control element: active button -scan-
15. Control element: active button -back-

3.2 Home screen

When you switch on the device, the system boots up.
The start screen is initially shown on the display.

Once the system is fully booted and ready for operation, the login input mask appears.



Enter the login details (see **chapter 3.7 User management**).

The device has already been calibrated before delivery. In some cases, the device will prompt you to recalibrate after logging in.
For more information, see **chapter 3.4 Calibration**.

The two analysis units can be calibrated after you have logged in successfully. Before calibrating the device (see **chapter 3.4 Calibration**) make sure that there are no test strips in the heating blocks and that the lids are closed.

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3.3 Date and time

The menu item **-SETTINGS-** takes you to the time setting **-DATE & TIME-**.

The entry is made in the number field according to the following conventions:

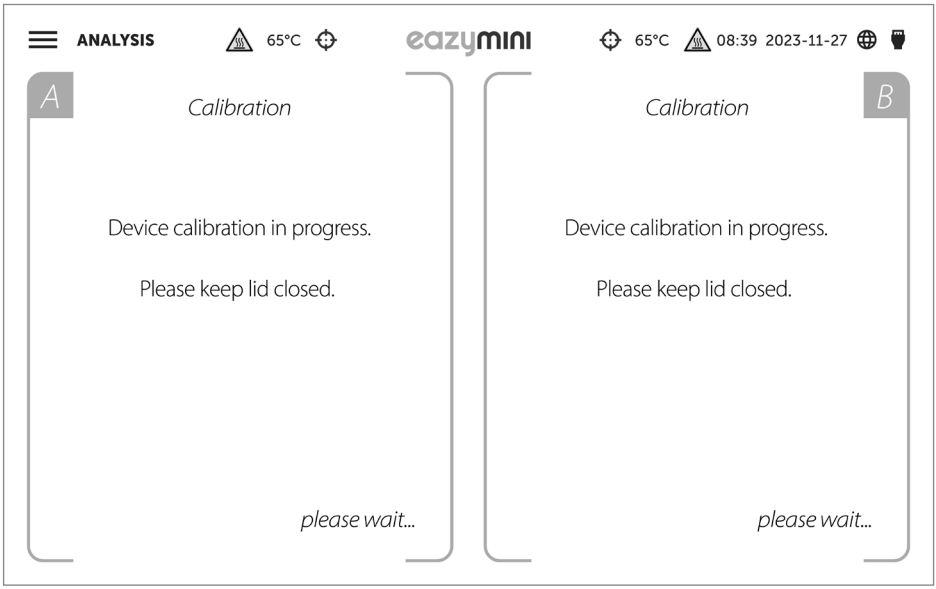
for the date: YYYY-MM-TT Example: 2023-11-27
for the time: hh:mm Example: 07:45

If the time display is not visible, deviates from the last set values or you are taken directly to the time setting after each login, see **chapter 7.3.1 System time is not stored permanently**.

3.4 Calibration

The device is calibrated when delivered.
Calibration can still be requested by the device after login. This usually only happens after several test runs.

Follow the device instructions. First remove any remaining test strips from the device before proceeding.



Keep both lids closed during the process and avoid vibrations of the device.

The calibration process takes a few minutes. After successful calibration, you can carry out test runs again.

Calibration can also be initiated manually. The menu item **-SETTINGS-** takes you to the calibration **-CALIBRATION-**. The last calibration times for Unit A and Unit B are also displayed here.

If an error occurs, proceed according to **chapter 7.2.3 Error message after calibration process**.

3.5 Software-Support

The firmware version of your device can be found via menu item **-SETTINGS-** under **-DEVICE INFO-**. Your distributor will inform you whether your version is up to date. If a newer version is available, an update can be carried out using a USB stick. To do this, please contact your distributor.

3.6 Laboratory / Hospital Information System (LIS/HIS)

The device can be connected to a laboratory or hospital information system over Ethernet.

A licence needs to be purchased for a fee and the software must be set up by your system administrator.

The HL7 communication with different systems requires additional administrative work.

If you would like to use the LIS/HIS feature, please contact your distributor first. After obtaining a license, your system administrator can configure the device.

The input masks for LIS/HIS and the network connection can be found under menu item **-SETTINGS>LIS/HIS-** or **-SETTINGS>ETHERNET-**.

Tap the scan icon under **-LIS/HIS-** and scan the QR code provided for initial activation of the device-specific licence.

For further information and HL7 specifications, please contact your distributor.

3.7 User management

Only people with the **supervisor** property have full user rights. Among other things, you can create or delete other users.
For standard **users**, access rights are restricted. They cannot delete either user or archive data.

In the delivery state, two users (supervisor and labuser) are created. First, log in using the login input mask as follows:

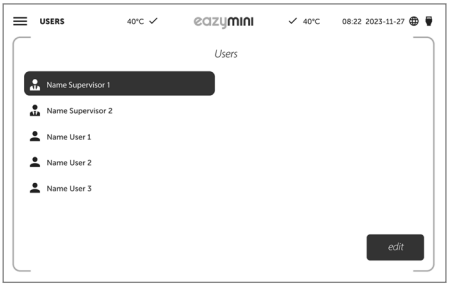
user name: supervisor password: supervisor

Under the menu item **-USERS-** you can create new users or edit or delete existing user data. The deletion of users occurs independently of the test runs saved in the **-ARCHIVE-**; These are not lost in the process.

First change the supervisor‘s password and write it down in a safe place. If you lose your **supervisor** password, please contact your distributor.

The character length for user and password is at least 6 characters.

You can create multiple users with the **supervisor** property. These have the same user rights.



4. TEST RUN

It is absolutely necessary to prevent moisture from entering the optical system. For this reason, it is not permitted to pipette into the test strips when they are in the device. **All pipetting steps must be carried out outside the device**. In the event that liquids have leaked into the optical system, contact your distributor to arrange service and repair of the device (see **chapter 8. SERVICE & REPAIR**).

4.1 Log In

Authentication is required before a test can be started (see also **chapter 3.7 User management**).

4.2 Run tests

After logging in or using the menu item **-ANALYSIS-** you will reach the user interface for test runs A and B.

4.2.1 Profiles

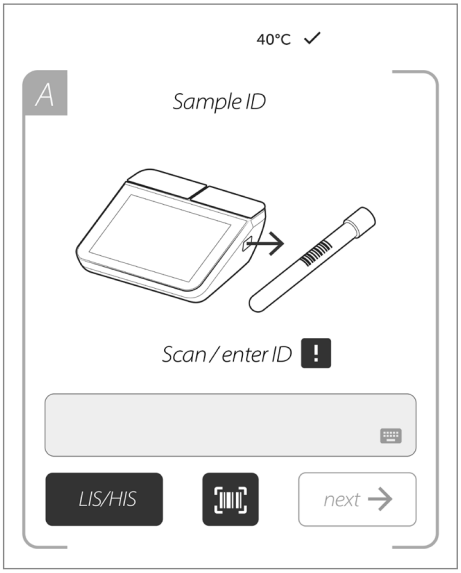
To carry out the analysis, profiles for the respective test kits stored on the device are required. A number of profiles are already stored in the delivery state of the device.

If you have information that this test kit is explicitly a NEW test, or if you are unsure about this, please read this chapter carefully.

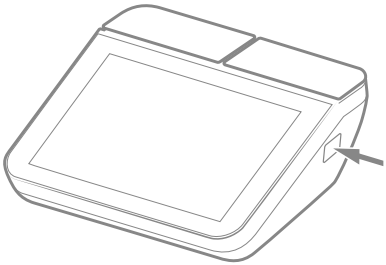
Under 4.2.3 you will be asked to scan the barcode of the test kit. If no matching profile is stored for the current test, the message
No matching profile found ⚠ *Add a profile by scanning profile code* ❗ appears.

Tap the scan icon and scan the QR code of the new test profile. The profile is now stored and will be listed. Users can now run tests with test kits for this profile.
QR codes for new profiles can be obtained from the manufacturer of your test kits.

4.2.2 Sample ID



Enter the sample ID either using the display keyboard (opens when you touch the input field) or via barcode scan.
To do this, tap the scan icon and hold the code of the patient sample in front of the scanner on the right side of the device.



Check that the displayed sample ID (entered manually or scanned) matches the original. A change is no longer possible after the test run has started.

Confirm your entry by tapping the **–next–** button or correct it using the input field or a new scan process.

Once the LIS/HIS connection is activated, you can use the **-LIS/HIS-** button to select requests sent from your system to the device. The sample ID is taken from these after selecting the request.

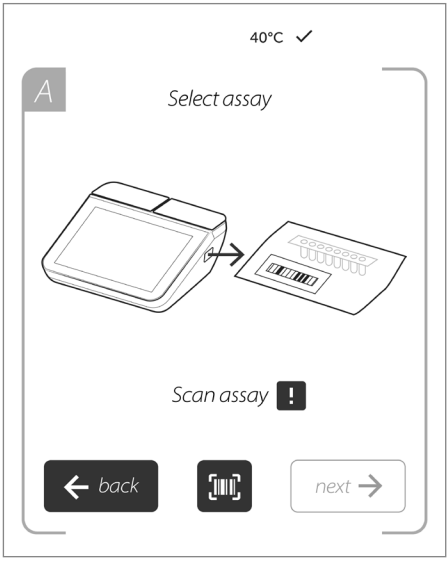
4.2.3 Start test

The test requires a correctly carried out pipetting process with the test kits intended for this device. To avoid damage to the device, only use these test kits.

Carry out the sample preparation. To do this, follow the instructions of the manufacturer‘s respective test kit.

It is absolutely necessary to prevent moisture from entering the optical system. For this reason, it is not permitted to pipette into the test strips when they are in the device. **All pipetting steps must be carried out outside the device**. In the event that liquids have leaked into the optical system, contact your distributor to arrange service and repair of the device (see **chapter 8. SERVICE & REPAIR**).

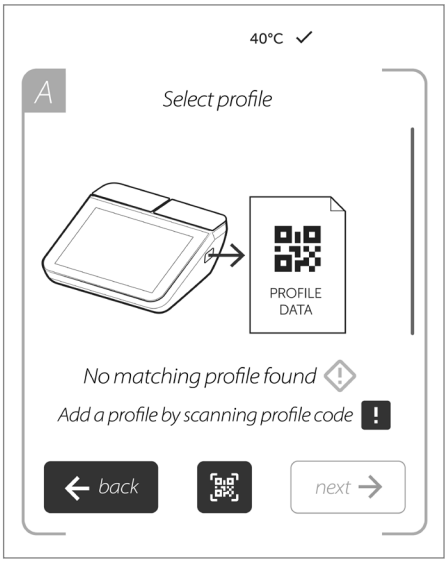
If pipetting has been carried out according to the instructions, you can proceed as follows:



Tap the scan icon and scan the barcode on the test kit packaging.

Confirm your scan via **–next–** or correct the scan by scanning again. You can use the **–back–** button to return to entering the sample ID.

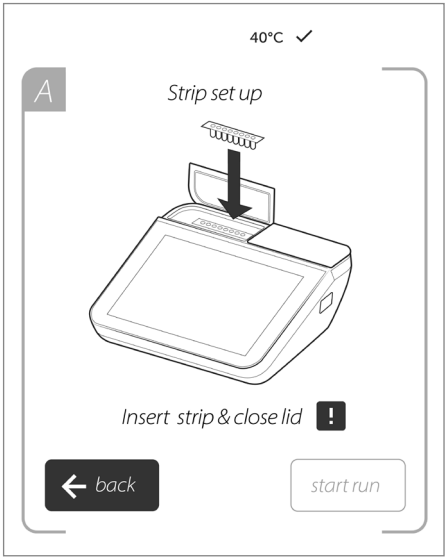
If there are several test profiles to choose from, tap to select the profile required from the list now being displayed and confirm with **–next–**.



If the profile is stored, open the lid of the relevant side using Push-to-Open as requested.

If there is no suitable profile stored for this test, the message *No matching profile found* appears.

In this case, first scan the code of the associated profile as described in chapter **chapter 4.2.1 Profiles**.



Check that there are no air bubbles at the bottom of each vial of the test strip. These can disrupt the analysis process.
Read the instructions for use provided by the test kit manufacturer carefully.

Before inserting, pay attention to any contamination or damage to the cavities in the heating/analysis unit and the test strip.

Be sure to pay attention to the direction of insertion! The two pins on the heating block must fit exactly into the rear eyelets of the test strip.

Close the lid gently. If it does not close easily, check the insertion direction before proceeding.

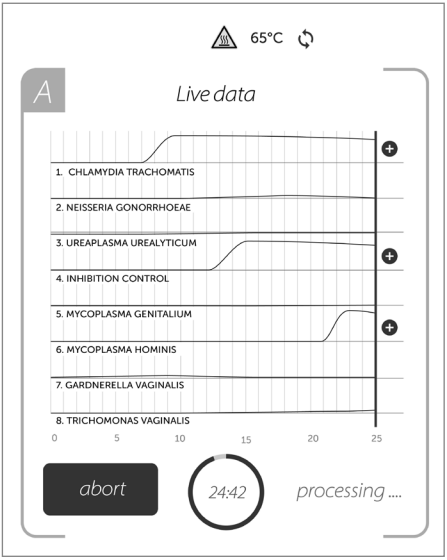
Check the details on the display again. Then start the run with **–start run–**.

Do not use open, broken, or otherwise damaged test strips to carry out test runs.

Always keep the lid closed during a run. Otherwise, there is a risk that the test will become invalid.
Avoid vibrations of the device.

Another test run can be started in the other heating/analysis unit.

The duration of the test run varies depending on the test profile.



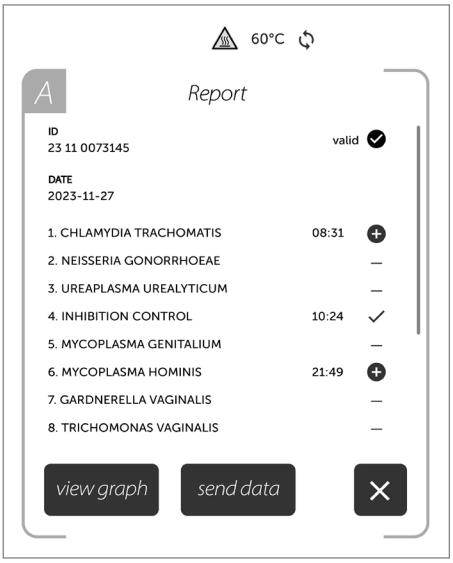
During the test run, the icon ⊕ may appear on some analysis curves before the others follow.

Whether the test is valid or invalid is displayed on the following screen.

Valid test runs are marked with the *valid* ✓ symbol.

Invalid test runs are marked with the *invalid* ⊗ symbol.

The symbol *Warning: Error message* ⚠ is displayed in the event of errors.



Positively rated curves are marked with the ⊕ icon behind the listed test parameters.

The symbol *Warning: Error message* ⚠ next to “expired”, “lid” and “too much sample material” provides information about the test kit’s expiration date being exceeded, lid openings during the test run or too much cell material in the vials.

For information on effects on test results and their evaluation, please refer to the test kit manufacturer‘s instructions for use.

For additional information, see **chapter 7. TROUBLESHOOTING**.

4.3 End test

The test can be terminated prematurely at any time. To do this, press the **–abort–** button and confirm the desired termination.

Opening the lid of the unit in question for a longer period of time during the test run will also result in termination.

Attention: Every time a test is aborted, it becomes invalid.

After each aborted or completed test run, remove the test strips from the device after the corresponding heating block has cooled down sufficiently and dispose of them in accordance with the manufacturer‘s instructions and legal regulations.

If the device will not be used for a long period of time, switch it off.

5. RESULTS

If an analysis result is invalid or raises questions, please read **chapter 7. TROUBLESHOOTING** or refer to the relevant instructions for use of the test carried out. If in doubt, contact your distributor.

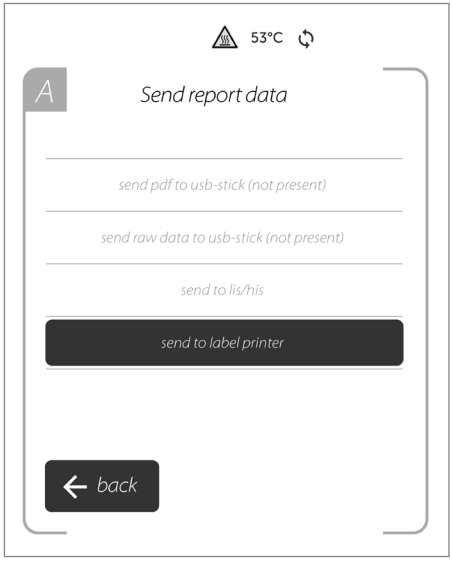
All test runs are stored in the device. These can be accessed via **-ARCHIVE-** in the menu.

Using **–send data–** you will be taken to the selection of the available storage media (since connected to the device) or the printer.

5.1 Printing

The eazyMini only supports label printing via the printer DYMO® LabelWriter-550 with the appropriate label size (36 mm × 89 mm).

Select **–send to label printer–** to print the test result on a label.



5.2 Creating a PDF file

If a suitable USB stick is plugged into the back of the device, the individual tests can be saved there as a PDF document via **–send pdf to usb-stick–**.

5.3 File Export

The data can also be saved as a RAW file.
Select **–send raw data to usb-stick–** to write the file to the stick.

5.4 LIS/HIS data transfer

After setup and licensing, the LIS/HIS is also available. Select **–send to lis/his–** to send the data to your system over Ethernet.

5.5 Archive

All test runs are stored in the system and can be accessed at any time via **-ARCHIVE-** in the menu.

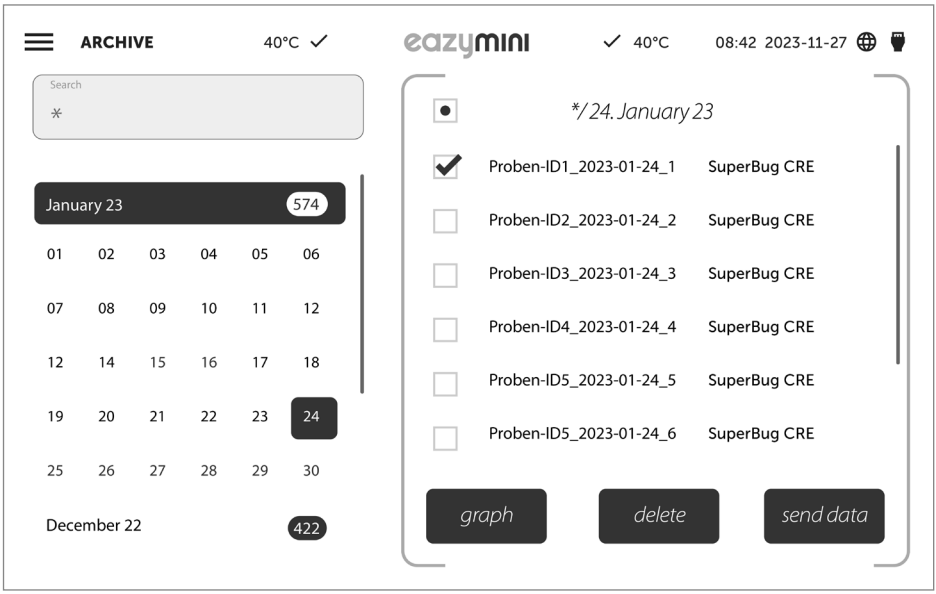
The results can be narrowed down using the search field at the top left. For example, all test runs can be filtered by ID and displayed in the list field on the right. In addition, test runs for individual days can also be called up by selecting them in the calendar.

By selecting the boxes in the list field, you can select individual or multiple test runs. After selecting a test run individually, the **–graph–** button takes you to its graphical representation.

In the case of multiple selections, the selected test runs can be stored on external storage media via **–send data–** as described above.

People with the **supervisor** property can also delete entire data sets here.

Caution: Deleted data cannot be restored!



6. MAINTENANCE

The device has no parts that require regular maintenance. Nevertheless, as with all electronic devices that contain optical components, dirt can accumulate on the surfaces after a certain period of time. General wear and tear can reduce performance.

We therefore recommend that you organize a service after a term of **2 years** or after **4000** test runs at the latest (see also **chapter 8. SERVICE & REPAIR**).

6.1 Cleaning and decontamination

For daily or weekly disinfection of the device surfaces, the touch screen and the cable, use Meliseptol® wipes sensitive from B. Braun Medical AG or something comparable.

The use of wipes minimizes the risk of liquid ingress into the optical system.

Contamination caused by potentially infectious material should be wiped off immediately with Meliseptol® wipes or similar.

Do not disassemble the device for cleaning.
Do not immerse the device in water or cleaning products.
Do not clean the device with soap or other solvents.

Keep the lids closed if possible to minimize the risk of contamination of the analytical units. If necessary, clean the cavities with commercially available cleaning swabs that are suitable for optics. Never use liquid cleaning agents! This will cause permanent damage to the optics.

6.2 Functional test

A functional test can be carried out using special test kits (e.g. eazyCheck from AmplexDiagnostics GmbH) in accordance with the manufacturer‘s instructions for use.

7. TROUBLESHOOTING

7.1 Starting problems

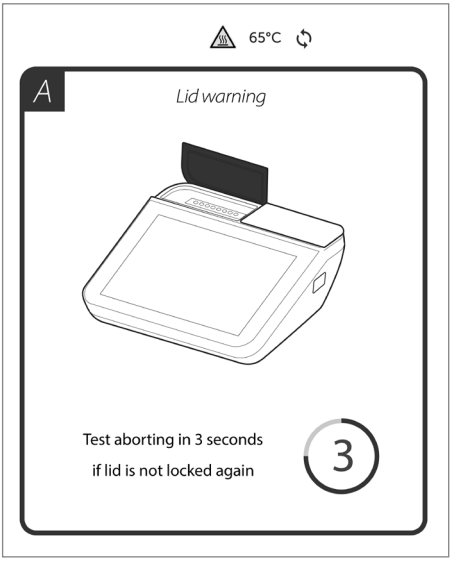
If the device does not start after switching on, please switch off the power switch on the back and switch it on again after 15 seconds.

If this measure is not successful, please contact your distributor.

7.2 Error messages

7.2.1 Lid warning

If a lid is opened during a test run (which should always be avoided!) or if a lid is opened shortly after the end of the run when the heating block is still hot, the message “Lid warning” is displayed.



If the lid is not closed again within 3 seconds during the test run, this will result in the test being aborted.

If the lid does not close easily, either the direction of insertion of the test strip was not observed or there is a defect.

If there is a defect, please contact your distributor.

For further tests, use the other analysis unit.

Caution! Please do not touch the heating block while it is still hot to avoid skin burns!

When the lid is opened during a test run, the incidence of light has a decisive influence on the signal measurement. This can lead to a false positive result.

7.2.2 Warnings on the report

In addition to the “lid” warning described when the lid is opened during the test run, further warnings can be issued on the report. If the expiration date of the test kit used has been exceeded, the message “expired” appears; if there is too much cell material, the message “too much sample material” appears.

Example image of a report with an invalid test and all possible error messages

The following error messages can be displayed:

- Exceeding the expiry date of the test kit (⚠ **expired**)
- Lid opening during analysis (⚠ **lid**)
- Too much cell material (⚠ **too much sample material**)

For information on effects on test results, their evaluation and measures to be taken, please refer to the test kit manufacturer‘s instructions for use.

7.2.3 Error message after calibration process

If an error occurred during the calibration process, visually inspect the heating/ analysis unit for contamination.

If necessary, clean the cavities with commercially available cleaning swabs that are suitable for optics. Never use liquid cleaning agents! This will cause permanent damage to the optics.

Repeat the calibration process. The further process is described in **chapter 3.4 Calibration**. If an error message is displayed again, please contact your distributor.

7.2.4 General error message - internal device error

An error has occurred. Please turn the device off. Wait 15 seconds before turning it back on and try the desired operation again. If this error message appears again, please contact your distributor.

7.2.5 Invalid test results

If a test run produces an **invalid** result, no result will be displayed. Please refer to the test kit manufacturer‘s instructions for further action.

7.2.6 Full Memory

If the device reports that the memory limit has been reached, back up your test runs to an external storage device as described in **chapter 5.2 Creating a PDF file, chapter 5.3 File Export** and **chapter 5.4 LIS/HIS data transfer**. Clear storage to continue.

7.3 Other problems

7.3.1 System time is not stored permanently

If you reach the **-DATE & TIME-** menu every time you restart the system and log in, the system battery must be replaced. Contact your distributor to arrange for the device to be serviced.

Enter the current date and time in the fields provided and save the data before continuing. The exact process is described in **chapter 3.3 Date and time**.

7.3.2 Network issues

First, check that the LIS/HIS license has been activated. Activation is described in **chapter 3.6 Laboratory / Hospital Information System (LIS/HIS)**. It is not possible to connect to your laboratory or hospital information system via the network without purchasing a licence. If the licence has been activated, contact your network administrator.

8. SERVICE & REPAIR

If you would like a service or repair, please contact your distributor. They will register the service with the manufacturer and inform you about the further process.

Before shipping the device, you will receive a “decontamination certificate” from your distributor. Please follow the instructions described there and enclose the completed document with the device.

To avoid damage during transport, the original packaging must be used for shipping. The device can only be shipped after approval by the distributor

Any unauthorized modification of the device or damage caused by improper handling will void the warranty.

9. DISASSEMBLY & DISPOSAL

The device and its electronic components must be disposed of as electrical or electronic waste in accordance with applicable regulations.

The device contains electronic components. In order to avoid health hazards and potential environmental damage, the electrical device must not be disposed of with household waste.

Follow local recycling regulations for electronic devices. In this way you support sustainable material use (Directive 2012/19/EU) and contribute to environmental protection.

Please observe the legal requirements when disposing of old devices. You have the option of returning the device to the manufacturer. There is no obligation for handing back.

If the functionality allows it, delete all stored data from your device before passing it on to a third party. This includes all stored test runs as well as all created user profiles.

If you would like to return the old device, follow the instructions for contacting your distributor and shipping in **chapter 8. SERVICE & REPAIR**. The return to the manufacturer is free of charge.

Before shipping the device, you will receive a “decontamination certificate” from your distributor. Please follow the instructions described there and enclose the completed document with the device.

The device or parts are reused, recycled or disposed of by the manufacturer in accordance with legal regulations.

The operator is responsible for the proper disposal of biological samples.

10. TECHNICAL DATA

Designation	Value	Unit
Model	eazyMini	
Catalogue number	7510	
Number of analysis units	2	Piece
Cavities per analysis unit	8	Piece
Sample volume	15 - 150	µl
Dimensions	271 × 220 × 106	mm
Weight	2.7	kg
Display: capacitive touchscreen	1280 × 720	Pixel
	266 × 169	mm
Maximum installation height	2000	m above sea level
Operating temperature	10 - 40	°C
Temperature constancy	± 0.1	°C
Operating humidity	10 - 80	% RH
Storage temperature	10 - 40	°C
Storage humidity	10 - 80	% RH
Supply voltage	100 - 240	VAC
Power frequency	50 - 60	Hz
Electrical power	200	W
Average sound emission	42.1	dB(A)

11. SYMBOLS

11.1 Explanations of symbols and indications

The following terms and symbols are used in these instructions for use to indicate hazards and information:

This symbol indicates a possible or imminent threat to the life and health of persons. Failure to follow these instructions can or will result in serious adverse health effects, including life-threatening injuries.

This symbol indicates a possible or imminent threat to the life and health of persons caused by electrical voltage. Failure to follow these instructions can or will result in serious adverse health effects, including life-threatening injuries.

This symbol indicates the risk of injury from hot surfaces. Failure to follow these instructions may result in minor injuries.

This symbol indicates a possible or imminent biohazard. Failure to follow these instructions can or will result in serious adverse health effects, including life-threatening infections.

This symbol indicates a potentially dangerous situation. Failure to follow these instructions may result in minor injuries or damage to property or the environment.

This symbol indicates important facts. Failure to do so may lead to incorrect or undesirable results.

Symbol for separate disposal of old electrical and electronic equipment in accordance with Directive 2012/19/EU.

11.2 Graphical User Interface

 Main Menu

 Menu **-LOG OUT-**

 Menu **-USERS-**

 Menu **-ANALYSIS-**

 Menu **-ARCHIVE-**

 Menu **-SETTINGS-**

 Menu **-DATE & TIME-**

 Menu **-CALIBRATION-**

 Menu **-LIS/HIS-**

 Menu **-ETHERNET-**

 Menu **-DEVICE INFO-**

 USB connection

 Ethernet connection

 Labuser (standard)

 Supervisor

 On-screen keyboard

 Scan button barcode

 Scan button QR code

 Calibration process

 Operation in progress

 Operational / valid

 invalid

 Positive assessment of the curve

 Command prompt

 Warning: Error message

 Warning: Hot surface

11.3 Symbols on the device

The following symbols and signs are marked on the device:

Attention, consult accompanying documents
The symbol indicates the need to consult the instructions for use for important safety information, such as warnings and precautions, that cannot be found on the device itself.

Observe the instructions for use
The symbol indicates the need to consult the instructions for use.

Symbol for separate collection of waste electrical and electronic equipment according to Directive 2012/19/EU.

CE mark

This symbol indicates the risk of injury from hot surfaces. Failure to observe these instructions may result in minor injuries.

Catalogue number/order number

Serial number

In vitro diagnostic medical device

Manufacturer

Date of Manufacture

12. WARRANTY

2-year limited warranty

The eazyMini device is only intended for use as described in **chapter 1.1 Intended purpose**. Strictly following the instructions in this instruction for use is essential for proper operation. The same applies to products used in combination with the eazyMini and their instructions for use.

Failure to follow the instructions may lead to incorrect or faulty results. In addition, there is a risk of damage to the device.

Limited Warranty

The manufacturer warrants to the original purchaser of the device that the device will be free from material defects for two years from the date of purchase. This warranty does not guarantee uninterrupted operation of the device. The manufacturer‘s sole liability, and the purchaser‘s sole remedy under this warranty, is that during the warranty period, the manufacturer will repair or replace, free of charge, any component of the equipment that has material defects, at its sole discretion. The manufacturer does not provide any further guarantees.

The device does not contain any user-serviceable parts. This warranty will be void if any part of the device is tampered with, the device is misused, or used other than in accordance with these instructions for use. This warranty does not apply to components that have been damaged by incorrect storage in conditions outside the recommended range, by an unforeseen event or by alteration, misuse, tampering or improper use.

The manufacturer‘s entire liability in connection with the device is limited to the purchase price of the device. The manufacturer is not liable for incidental, indirect, special or consequential damages related to the device. There are no claims for damages or claims from third parties.

The buyer is obliged to notify the manufacturer of the warranty claim in writing and within the corresponding warranty period. Please contact your distributor before returning defective devices (see also **chapter 8. SERVICE & REPAIR**).

13. NOTES

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REF 7510 CE IVD