



MeMedKey[®]

Instructions for Use

Please read this document carefully before using MeMed Key[®]



CAUTION!

This device is restricted to sale by or on the order of a physician or licensed practitioner.



MeMed Key®

FG130001



Conformité Européenne (CE Mark)



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In vitro diagnostic medical device



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According to European Directive 2012/19/EU (WEEE), the device must not be disposed of in the municipal waste system.

NOTICE TO RECIPIENTS ABOUT LICENSES

By opening this package or using this kit in any manner, you are consenting and agreeing to be bound by terms and conditions mentioned herein. You also agree that these terms and conditions constitute a legally valid and binding contract that is enforceable against you. If you do not agree to all the terms and conditions set forth below, you must promptly return the kit for a full refund prior to using it in any manner. Components of this kit are covered, in whole or in part, or manufactured by processes covered by one or more patents and foreign counterparts thereof. Do not reverse engineer, decompile, disassemble or modify the kit.

TRADEMARK INFORMATION

MeMed Key® is a registered trademark of MeMed Diagnostics Ltd. ("MeMed Diagnostics")

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1. Introduction

MeMed Key® analyzer is a multi-assay analyzer for in vitro testing, designed to analyze supported proprietary test cartridges that contain all materials required to conduct the test, as well as a safe waste compartment.

1.1. About this Manual

This document provides instructions for installation, operation, troubleshooting, maintenance, and disposal of your MeMed Key® analyzer.

This document uses various types of messages. An explanation of each type, in the appropriate format, is given below.



NOTE: Provides information, emphasizing or supplementing the main text. The information does not relate directly to issues that might cause injury to patients or users, or damage to the Analyzer.



IMPORTANT! Provides important information, emphasizing or supplementing the main text. The information does not relate directly to issues that might cause injury to patients or users, or damage to the Analyzer.



CAUTION! Relates to issues that might cause damage to the Analyzer, if the caution is not followed.



WARNING! Relates to issues that might cause injury to patients or users, or serious damage to the Analyzer, if the warning is not followed.

1.2. What is in the Box

1.2.1. Box Contents

The MeMed Key® shipping box contains:

- MeMed Key® analyzer
- Quick Guide
- Accessories box:
 - Power supply
 - Power cable
 - Ethernet cable



CAUTION! If the box is damaged or package content is found incomplete, report missing items or shipping damage to your MeMed representative. Failure to report package damaged within 5 business days of arrival will void the warranty.

1.2.2. Supported Test Types

The MeMed Key® analyzer supports a variety of tests. For instructions regarding analyzing patient samples or controls, refer to the respective IFUs of test cartridges, calibrators, and controls.



WARNING! Failure to observe the guidelines and instructions provided in this document could result in faulty functioning of MeMed Key® or injury to the user.

2. Safety Information

2.1. Intended Purpose / Indications for Use

The MeMed Key® analyzer is an automated laboratory instrument intended to be used for quantitative in-vitro determination of analytes and/or semi-quantitative interpretation of test results in a clinical specimen, using dedicated test cartridges. For information regarding intended purpose/indications for use of a specific test cartridge, refer to the corresponding test cartridge IFU.

2.2. Test Principle

The method for quantitative determination of TRAIL, IP-10 and CRP proteins is a sandwich chemiluminescence immunoassay. All reagents and disposables are contained within the cartridge and the events that occur within the analyzer are transparent to the user.

For each analyte, the analyzer combines specific antibody-coated magnetic particles, assay buffer, enzyme-linked specific antibodies and the patient specimen to create analyte-specific immune complexes (either via one-step or two-step incubation periods). Subsequently, the analyzer applies a magnetic field to separate the immune complexes from unbound materials and to allow washing of non-specific binding events. Then the analyzer adds chemiluminescence substrate to the reaction, which emits light in a manner correlated to the amount of target analyte present in the specimen. The photo detection device in the analyzer detects the photons that are emitted during the reaction.

2.3. Labels and Symbols

Symbol	Description	Symbol	Description
	High voltage hazard	Rx ONLY	Prescription use only
	Caution		Manufacturer
	Warning		Manufacture date
	Biohazard	EC REP	Authorized representative in EU
	Fragile, handle with care	UK REP	Authorized representative in UK
	Keep dry		This side up
	Refer to IFU		Stacking limit
	Humidity limits		Temperature limits
REF	Part number	IVD	In-vitro diagnostic device

Symbol	Description	Symbol	Description
	Serial number		In-doors use only
	Electrical and electronic equipment marked with this symbol are covered by the European Directive 2012/19/EU (WEEE). The symbol denotes that the equipment must not be disposed of in the municipal waste system.		Customer service email address
			Customer service telephone number

2.4. Warnings and Precautions

Read the following warning and precaution messages carefully before attempting to use MeMed Key®.

	Do not place any part of the body inside the test cartridge port. Doing so may result in injury.
	There are hazardous voltages inside the power supply. Opening the power supply could result in electrocution and will void the warranty.
	Do not attempt to use the analyzer if any visible damage is observed (broken screen or covers, loose covers, etc.)
	Use protective equipment and act according to good laboratory practices when handling cartridges, cleaning spills, dispensing samples, and disposing of used test cartridges. Dispose of used cartridges as biohazard waste. Failure to safely handle and dispose of test cartridges may result in contamination or undesired exposure.
	Use protective equipment and act according to applicable laws, regulations, and good laboratory practices when handling biological samples. Failure to safely handle and dispose of biological samples may result in contamination or undesired exposure.
	Use only the power supply and power cord supplied with the MeMed Key®. Using an alternative power supply might damage the analyzer.
	Avoid placing magnets and massive metal objects in the analyzer proximity. Doing so will cause the analyzer to malfunction.
	The analyzer is not user-serviceable. Do not open the covers or insert any objects other than MeMed test cartridge into the analyzer. Doing so will void the warranty.
	There are no user-serviceable parts inside the power supply. Opening the power supply will void the warranty.

	Keep the power supply clear of any fluids. Exposure to fluids may cause short circuit and damage the analyzer.
	Do not cover any part of the test cartridge label. Doing so will result in test failure.
	Portable and mobile RF communications equipment might affect the operation of medical electrical equipment. The MeMed Key® analyzer could exhibit interference from other electrical/electronic equipment, even if that equipment complies with CISPR/FCC Emissions requirements. In the case of interference with the performance of the device, the following measures could be applied: ▪ Re-orient the equipment ▪ Move the system away from interfering equipment or vice versa ▪ Use a different power outlet ▪ Limit contact with rear of instrument when in operation
	Any serious incident that has occurred in relation to the MeMed Key® analyzer and its ancillaries shall be reported to the manufacturer and local competent authorities.

2.5. Conformity and Compliance

MeMed Key® complies with the following standards and regulations:

Number	Title
IVDR 2017/746	EU In Vitro Diagnostic Regulation
21 CFR Part 809	In vitro diagnostic products for human use
IEC/EN 61010-1: 2010	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements
IEC/EN 61010-2-010:2014	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
IEC 61010-2-101:2015	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
IEC 61326-1:2012 EN 61326-1:2013	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements

IEC 61326-2-6:2012 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
47 CFR Telecommunications, Chapter I FCC Part 15 Subpart C	Radio Frequency Devices – Intentional Radiators

2.6. Wireless Communication

The MeMed Key® analyzer generates an in-vitro diagnostic test results and presents the result on the analyzer's display. In the case of interference with the performance of the device, manifested as loss of wireless communications, information is retained on the MeMed Key® analyzer and may be retrieved when wireless connection is restored.

The MeMed Key® analyzer supports Wi-Fi as per IEEE 802.11 b/g/n. (see [Table 9: Wireless Communication Characteristics](#))

The Wi-Fi module supports the following security protocol: WEP, WPA, WPA2 and WPA2-Enterprise security. The expected nominal operating range/distance for 2.4 GHz Wi-Fi is 20-25 m for the intended use environments.

The analyzer software allows the user to select the wireless network and enter the network password. The software does not allow connection to an unsecured network.



NOTE: Analyzer operation is independent of connectivity to wireless devices. Therefore, Quality of Service (QoS) is left to the discretion of the installer. The default network settings are expected to be sufficient.

3. Overview

3.1. Analyzer

The MeMed Key® analyzer is an automated liquid-handling device comprising hardware and software, that conducts chemiluminescence-based analyte measurements and their computational integration.

3.2. Test Cartridge

The MeMed test cartridges are single-use, multi-well containers that receive the patient's sample, contain all the reagents and disposables necessary to conduct immunoassays and are the reservoirs for the waste.

3.3. Basic Operation

The MeMed Key® analyzer has the following user interfaces:

- **Front Panel**
 - Touch screen
 - Cartridge port
 - Bar/QR Code Scanner
- **Rear Panel**
 - Power switch
 - Two USB connection ports
 - Power supply connection port
 - Ethernet connection port



Figure 1: MeMed Key® Analyzer

Text messages that appear on the screen will guide you through the testing procedures. For details, refer to [Graphical User Interface](#) chapter.

The cartridge port is designed to receive the test cartridge in one orientation only, which is marked on the cartridge label. As a test cartridge is inserted into the analyzer, the test cartridge information is read from the QR for identification and verification before starting the test.

**IMPORTANT!**

When scanning test or calibration cartridges, samples, or vials, hold them exactly as shown on the screen.

A typical workflow includes the following steps:

1. The user turns on the MeMed Key® analyzer (or wakes it up if in standby mode).
2. The user logs in.
3. The user identifies the patient.
4. The user selects the test cartridge matching the desired test type and verifies the selection.
5. The user dispenses the patient's sample into the designated cartridge well.
6. The user scans and inserts test cartridge into the analyzer.
7. The analyzer auto-reads the test cartridge barcode and checks the cartridge expiration date and that the cartridge lot has a valid calibration.
8. The analyzer indicates that sample processing is initiated and when the user should expect the test result.
9. After completing the test, the analyzer indicates that the test workflow has been completed successfully or failed.
Following successful completion of a test, the results are displayed on the screen and/or transferred to one or more external systems or devices (e.g. printer, LIS, etc.)
10. The user removes the cartridge and disposes of it according to the safe laboratory practices.

3.4. Calibration

MeMed Key® analyzer must be calibrated periodically according to the specific test requirements and when introducing a new test cartridge lot.

The Calibrators are reagents placed in the same well of the test cartridge as the patient sample.

The calibration process simulates a test by running a number of calibrators (for example, high, medium, and low concentrations) on separate disposable cartridges. The exact number of calibrators depends on the specific test and lot the analyzer is being calibrated for. The calibrators are reagents that contain known amount of target analytes, representing various values of the analyte ranges that impact the test results, to optimize the clinical accuracy of the analyzer.

For further information, refer to [Calibrating the Analyzer](#) chapter.

3.5. External Control

External controls serve to verify proper functioning of the analyzer and respective test cartridge lot.

The external control (EC) process involves running controls simulating various test results on separate disposable cartridges.

External controls are available for users who choose to perform additional control processes.

For further information, refer to [External Control](#) chapter.

4. Graphical User Interface

4.1. About User Interface

All user interactions with the MeMed Key® analyzer software are performed using the analyzer's touch screen. The graphical user interface displays all analyzer screens, messages, and controls, operated by tapping or swiping the relevant control. After the analyzer is powered on and login is successfully completed, the Home screen is displayed. The Home screen elements are detailed below.



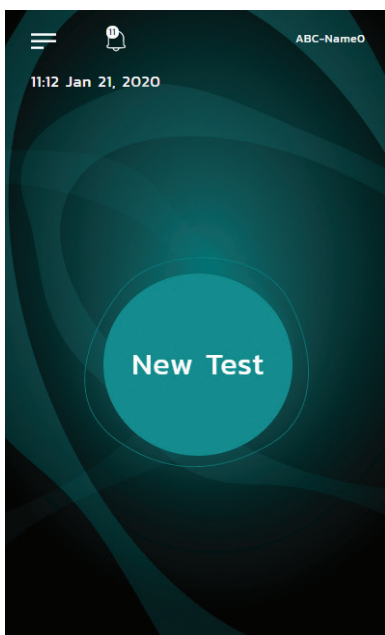
IMPORTANT!

Screen images used in this document are for illustration only, and some of them may vary depending on specific test types.



NOTE: The first time the Analyzer is powered on, the Setup Wizard screen will guide you through the initial installation process (see [Initial Setup Wizard](#) section for details).

4.2. Home Screen

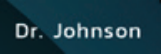


The home screen consists of a status bar in the upper area and a main content area. The status bar provides access to the analyzer menu and notifications and displays the analyzer status while the main screen area displays changing content according to the currently operated screen.

4.2.1. Status Bar Components

The status bar is displayed at the top of any GUI screen and contains the following components:

Icon	Element	Operations
	Menu	Tap to open the main menu
	Notifications status button	The icon displays the number of minimized notifications (see Notifications section for details). Tap the icon to open the analyzer notifications list.

Icon	Element	Operations
	USB storage device connected	Displayed while a USB storage device is connected to the analyzer
	User identification	Username of currently logged-in user
	WiFi Status indicator	Wifi not connected
	WiFi Status indicator	WiFi connecting (animated icon)
	WiFi Status indicator	Wifi connected

4.2.2. Date and Time

Date and time are always displayed at the top of home screen main area.

To change the date and time, navigate to **Menu > Settings > Time and Date**.

4.2.3. New Test Button

To initiate a new test, tap the **New Test** button in the Home screen (see [Running a Test](#) chapter for detailed description of the test flow and operation).

4.3. Main Menu

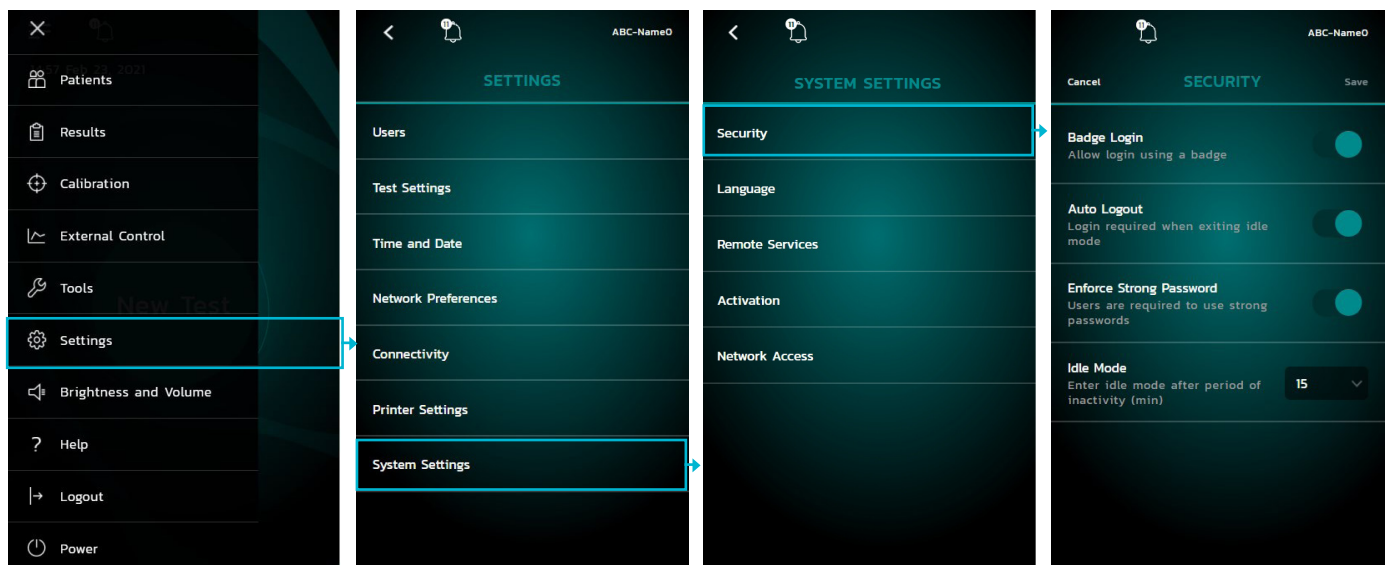
Table 1: Main Menu Items

Menu	Operation
 Patients	Tap to display the list of patients stored in the analyzer memory.
 Results	Tap to open the saved test results.
 Calibration	Tap to run calibration, view calibration results or calibration status.
 External Control	Tap to run external control, view previous external control results.
 Tools	Tap to access tools for software updates, analyzer self-test, data management, or anonymization
 Settings	Tap to access the settings menu (users, tests, time and date, network, connectivity, security, language, and remote services)

Menu	Operation
 Brightness and Volume	Tap to set brightness and volume
 Help	Tap to open help content
 Logout	Tap to log out
 Power	Tap to restart or shut down the analyzer

4.3.1. Menu Navigation

The menus are hierarchical, allowing you to move between menu levels using the menu navigation controls as described below:



Main Menu

- Tap **X** to close menu window
- Tap the desired menu item to open the relevant screen

Secondary Menu

- Tap **<** to close menu screen
- Tap the desired menu item to open the relevant screen
- Swipe to scroll up and down the list

Submenu

Select the specific settings you want to edit

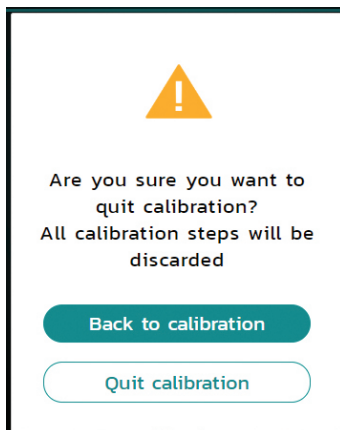
Settings Editing Screen

- Tap any data field to open keyboard
- Tap **Save** to save changes and close the screen
- Tap **Cancel** to discard changes and close screen

4.4. Notifications

The analyzer provides notifications regarding various states which require your attention or response.

4.4.1. Pop-up Notifications



Pop-up notifications are displayed on top of the current screen, in response to operator actions, as part of the current process. During the display of a pop-up notification the underlying screen is disabled, until the user has responded.

4.4.2. System Notifications

System notifications are generated and displayed in response to system events of varying severity levels. The severity level is represented by the following color-codes:

	Type	Description
	Error Messages	A major malfunction has occurred, and the analyzer's functionality is impacted
	Alerts and Warnings	User response is required to maintain analyzer functionality
	Informative notice or Success message	Reminder of actions to be taken or information of analyzer status or feedback on successful process completion

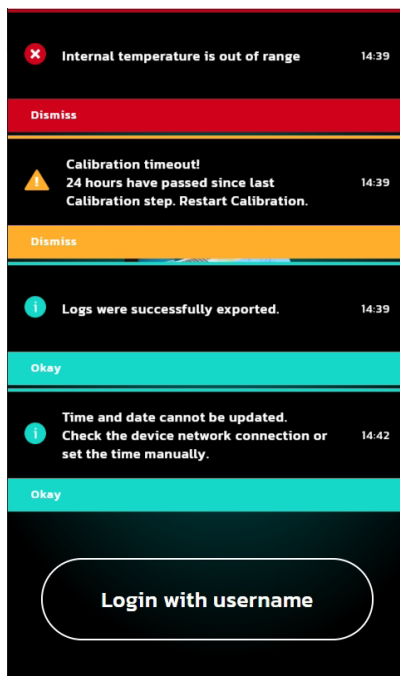
A newly generated notification is displayed as a push message in the screen upper area.

System notification elements are explained in [Table 2: System Notifications](#).

Table 2: System Notifications

Element	Description
Notification type icon and color	Type and severity level
Notification text	Textual content for the specific notification
Time stamp	Exact time the notification was created in the analyzer
Response controls	The notification appears on the current screen covering it, and must be acted upon, dismissed, or minimized to access the screen's functionality, using the following controls:

Element	Description
Later	The notification is minimized and added to the minimized notifications list (notification counter status icon in the status bar is updated accordingly).
Dismiss	The notification is deleted from the list.
Act	The specific action changes according to the notification content. Tapping the specific action name will open the relevant screen (such as Calibration) and minimize all open notifications.

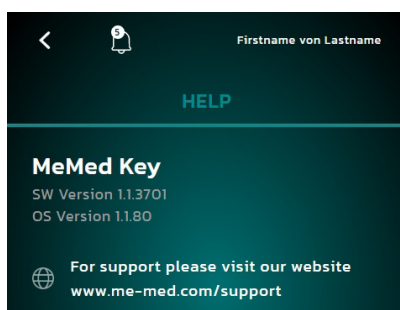


If new notifications are generated before the previous notification was dismissed or responded to, they will be added to the notifications stacked list. Higher severity notifications are displayed above the lower severity ones

The list may be scrolled up and down or minimized (closed) by tapping on the empty area at the bottom of the screen.

To access the minimized notifications at any time, tap **Notifications Status** in the analyzer's status bar. The icon also displays the number of minimized notifications.

4.5. Help Screen



To access the Help screen, tap **Menu > Help**.

For additional support regarding the analyzer operation, contact MeMed support (IL/EMEA: support@me-med.com; USA: help@me-med.com).

5. Getting Started

5.1. Preparing the Site

Prior to installing and connecting your MeMed Key® analyzer, ensure that the designated surface is level, close to power outlet, immune to vibrations, not exposed to direct sunlight and is far away from any magnets. The analyzer footprint is W=25 cm; D=34 cm (13.4"); H=25 cm (10"); allow at least 20 cm (8") behind and at least 20 cm (8") above the analyzer for connection, proper cooling, and operation. Refer to chapter [18. Technical Specifications](#), for more information regarding the environmental conditions.

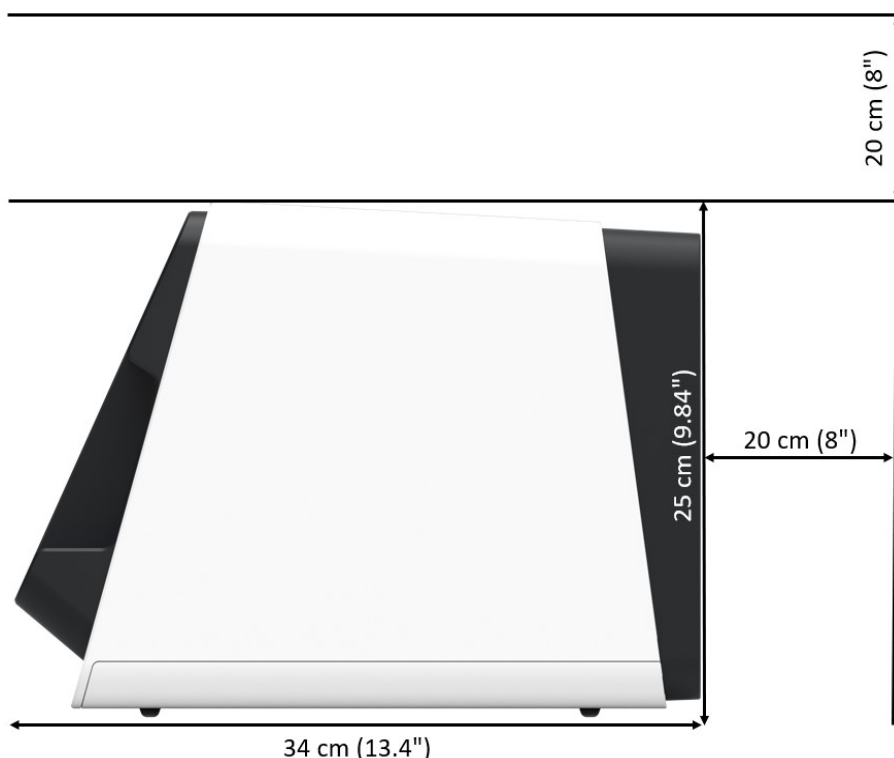


Figure 2: MeMed Key® Analyzer Dimensions

5.2. Opening the Box

Refer to section [What is in the Box](#)

5.3. Installing your Analyzer



CAUTION! If the Analyzer has been stored at a temperature outside the operating temperature range (see [Table 5: Environmental Conditions – Operating](#)), allow sufficient time for the analyzer to equilibrate to room temperature before use.

1. Remove packing materials.
2. Place the analyzer on the prepared surface (see [Figure 2: MeMed Key® Analyzer Dimensions](#)).
3. Verify that the analyzer stands firmly on the surface and it is level.

5.4. Connecting Power Supply

- 1 Remove the power supply and power cable from the accessories box.
2. Connect the power supply to the power port (see [Figure 3: Connection Ports on Rear Panel.](#))
3. Connect the power cable to the power supply.



WARNING! Use only the power supply and power cable supplied with the MeMed Key®. Using an alternative power supply might damage the Analyzer.

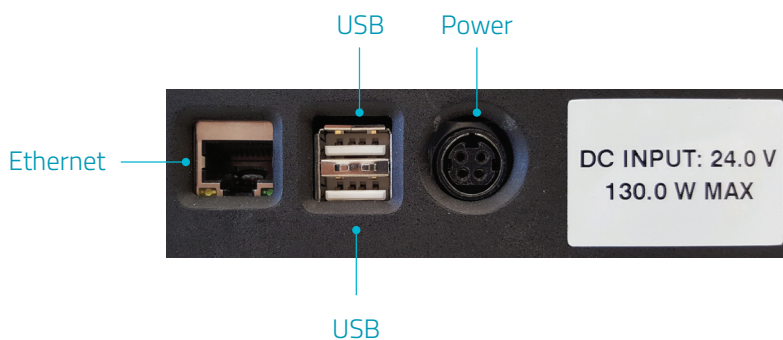


Figure 3: Connection Ports on Rear Panel

5.5. Connecting to LAN

If you choose to connect to Local Area Network, use the provided Ethernet cable to connect the Ethernet port to the LAN outlet.

5.6. Connecting Printer

The MeMed Key® analyzer supports USB and network printers. For current list of recommended printer models, contact your MeMed representative.

To connect a local printer, use one of the two USB ports.

To connect a network printer, follow the instructions in section [12.6](#).

5.7. Powering on



Make sure the analyzer's power cable is connected to the power outlet. Power up the analyzer by pressing the ON button located on the analyzer's back panel.



The analyzer's status light will illuminate and after a few seconds the **Startup** screen will be displayed.

After a few more seconds, an automatic self-test will be initiated. During the test a progress indication will be displayed on the analyzer's screen. Allow some time for the analyzer to complete the test.

After the self-test is successfully completed, the first screen of the Initial Setup Wizard will be displayed.

5.8. Initial Setup Wizard

The first time a new MeMed Key® analyzer is powered up, the Setup Wizard will guide you through the initial setup process required for analyzer operation.

The initial setup may be performed manually as described below, or through the data restoration feature. See [Setup Wizard Screen Components and Navigation](#) section for more details.

It is recommended to complete the setup process in a continuous manner. However, if the analyzer is powered off during the setup, the process will restart the next time the analyzer is powered on, enabling you to complete the setup.

Below is a summary of the sequence of actions performed during initial setup:

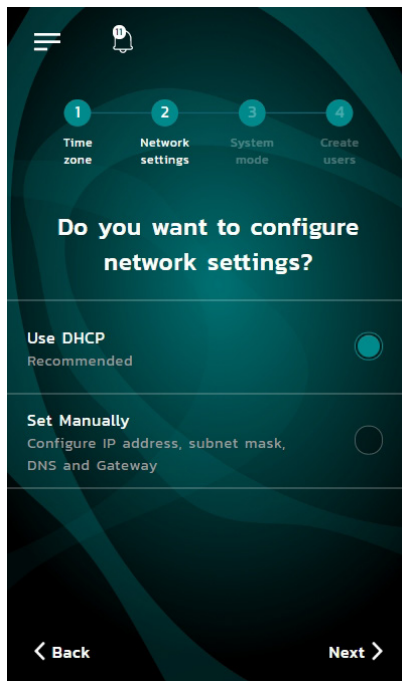
#	Screen name	What to do
1	Select language	Select the language for analyzer operation
2	Enter initial login code	Upon purchasing the analyzer, an initial login code will be provided by your MeMed representative for authentication purposes. If you can't locate the code, please contact MeMed support.
3	Welcome screen	Select whether to continue the setup manually or Restore Data from USB Storage Device (see section Restoring Data from USB Storage Device).
4	Select Time Zone	Select your local time zone
5	Connect to Network	Connecting the analyzer to a LAN or WiFi network allows the analyzer to connect to lab information system and to remote services. To connect the analyzer to a LAN network make sure the Ethernet cable is connected to the analyzer. If you decide to skip this step during setup, the network connection may be configured later through the Network Preferences menu. To connect the analyzer to external data management systems (LIS), the network configuration must be completed first.
6	Connect to Remote Services	Enable or disable automatic checking for system updates and sending anonymized failure logs to MeMed.
7	Configure Network Settings	Define network setting using DHCP ¹ (default) or manually.
8	Select Operation Mode	During initial setup, you will select the analyzer operation mode: ▪ Connected to LIS ▪ Standalone mode: Patient Identification by patient name or ID (managing via patient list) ▪ Standalone mode: Sample Identification by sample barcode
9	Create Admin User	Enter the authentication data for a user with administration privileges. Additional users with different roles may be added later through the Settings menu.



IMPORTANT! The Analyzer must be calibrated at least once in order to run tests. Prior to this, the Analyzer **Login** screen appears in a pre-calibrated state and no test may be initiated.

¹ A Dynamic Host Configuration Protocol (DHCP) Server is a network server that automatically provides and assigns IP addresses, default gateways, and other network parameters to client devices.

5.8.1. Setup Wizard Screen Components and Navigation



The top area displays the 4-step progress bar and indicates the current step throughout the setup process.

The center area displays the instructions and content of the current step

To move from one screen to the next, use the buttons on the bottom of the screen:

- Tap **Next** to continue to the next screen. In mandatory steps, the **Next** button becomes enabled only after all mandatory fields are filled.
- Tap **Back** to return to the previous screen
- In optional steps, tap **Skip** to go to next screen without completing the current step.

5.8.2. About Operation Modes

The MeMed Key® analyzer can be set up to operate in any of the following operation modes:

- [Connected to LIS](#)
- [Standalone Mode: Patient](#)
- [Standalone Mode: Sample](#)

The selected operation mode determines which identification methods will be available during test setup, as described below.

To change the operation mode, refer to the [Connectivity Menu](#).

5.8.2.1. Connected to LIS

In this mode the analyzer is connected to a Laboratory Information System. The relevant connectivity protocol is entered during Initial Setup or completed later using the [Connectivity Menu](#).

Sample identification for test purposes is performed by scanning the sample barcode or manually entering the sample ID.



CAUTION! Connection to LIS with unprotected protocol may expose the system to cybersecurity threats. It is recommended to connect to LIS via a secure protocol.

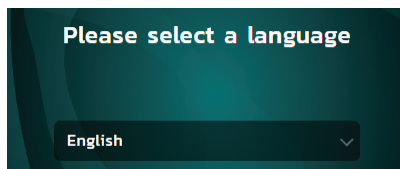
5.8.2.2. Standalone Mode: Patient

In this mode, patients' data are stored and managed locally in the analyzer memory. The patient identification for test purposes is performed by selecting patients from the locally managed patients' list (see also [Managing Patients](#)) or manually typing the patient ID.

5.8.2.3. Standalone Mode: Sample

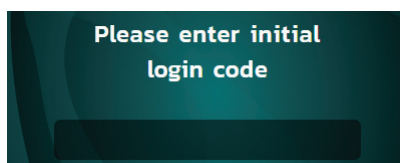
In this mode, the test results are stored locally in the analyzer memory. Test samples are identified through barcode scanning or manually typing the sample ID.

5.8.3. Setup Wizard Screens



Select Language

Tap the drop-down list and select your language from the menu



Enter Initial Login Code

Tap to open the virtual keyboard. **Enter** the code provided by MeMed and tap Enter on the keyboard to continue. Alternatively, tap outside the username field to close the keyboard.

If the code is not recognized by the analyzer, an error message will be displayed.

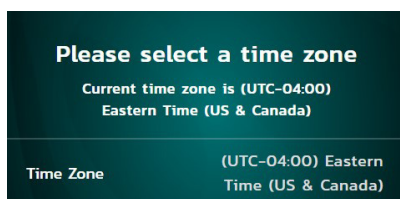
If the login attempt has failed, contact MeMed support for further assistance.



Welcome Screen

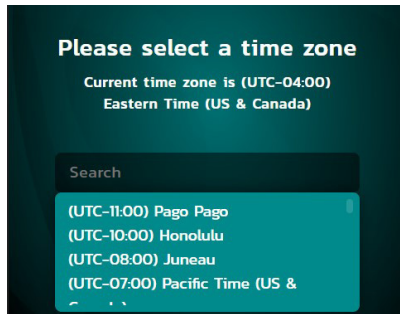
The welcome screen allows you to either start the 4-step manual setup process, or restore the backed up data (see [Restoring Data from USB Storage Device](#) section).

Tap **Restore** to restore data from a backup, otherwise—tap **Next** to continue the manual setup.



Select Time Zone

1. Tap the Time Zone.



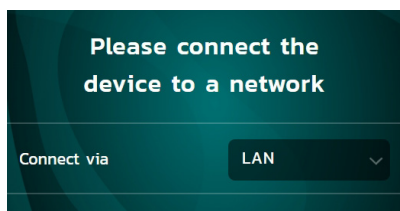
2. Scroll or start typing to select your time zone from the drop-down list.

Connect to Local Network



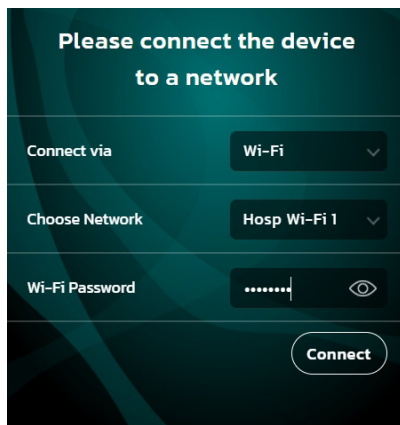
NOTE: Local network connections are to be set up by IT Admin. Technical details would be required in order to allow connectivity (IP address, etc.).

For **LAN connection**, connect the Ethernet cable to the analyzer and tap **Next**.



Connect Via LAN

1. From the **Connect via** drop-down list, select **LAN**.
2. Tap **Next**.

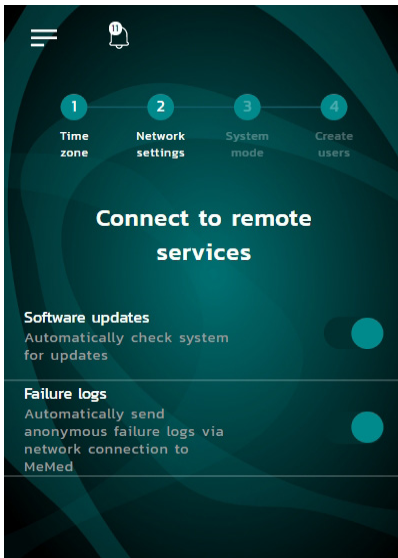


Connect Via WiFi

1. From the **Connect via** drop-down list, select **WiFi**.
 2. Tap the **Choose Network** drop-down list to view available Wi-Fi networks and select a network from the list.
 3. Tap the **WiFi Password** field to enter the network password using the virtual keyboard.
 4. Tap **Connect** to complete connection.
- After the connection is successfully completed, the **Next** button at the bottom of the screen will become active.

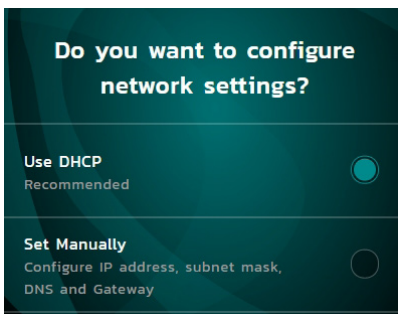


CAUTION! Connection to unsecured networks may expose the system to cybersecurity threats. It is recommended to connect to a secure network.



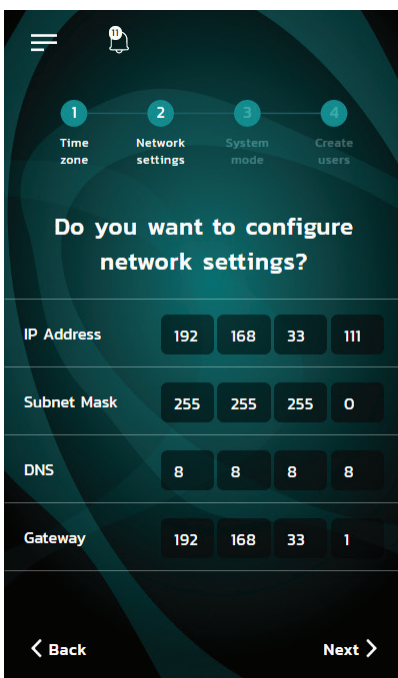
Connect to Remote Services

Use this screen to enable or disable the remote services. When enabled, the analyzer will automatically check for system updates and send anonymized failure logs to MeMed.



Select the preferred network management protocol: Use DHCP or Set Manually. DHCP is selected by default.

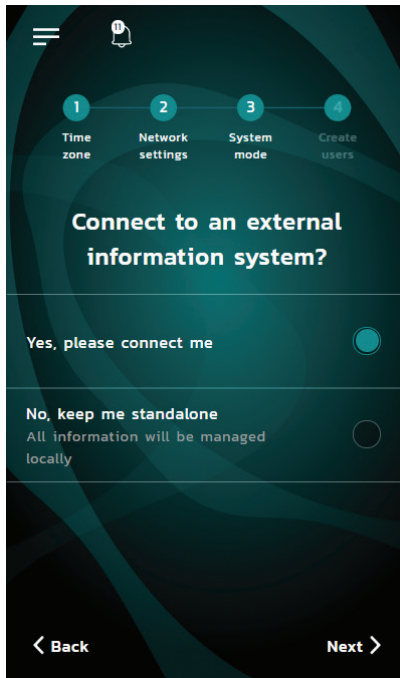
If manual setup is selected, in the next screen the network connectivity settings may be entered.



Manual LAN Setup

This screen is displayed if you selected **Set Manually** in the previous screen.

Tap a field to enter the value using virtual keyboard. Tap **Enter** on the keyboard to go to the **next** field. Tap Next at the bottom of the screen to complete the connection. After your connection is successfully completed, the next screen will be displayed automatically.



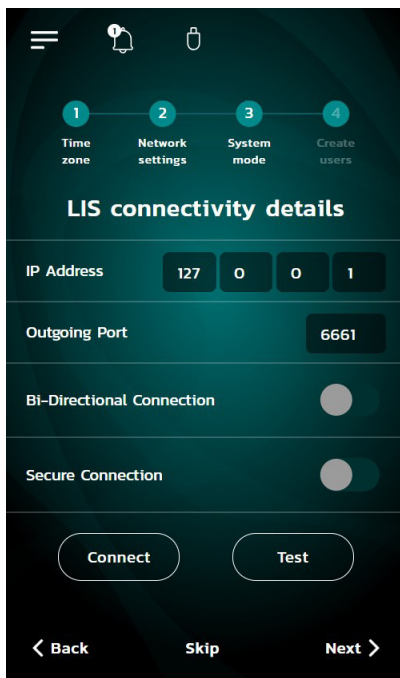
Select Operation Mode

This screen is used for selection between standalone or network modes.
By default, Connected mode is selected.

Tap **Yes, please connect me** to confirm Connected mode of operation.
Tap **No, keep me standalone** to disconnect.



NOTE: To connect the Analyzer to external data management systems, the network setup must be completed first.



LIS Setup

This screen is displayed if Lab Information System (LIS) was selected in the previous screen.

Tap a field to enter the values using virtual keyboard.
Tap **Enter** on the keyboard to go to the next field.

Tap **Bi-Directional Connection** to enable sending data to and receiving it from LIS.
When this option is off, only sending data to LIS is enabled.



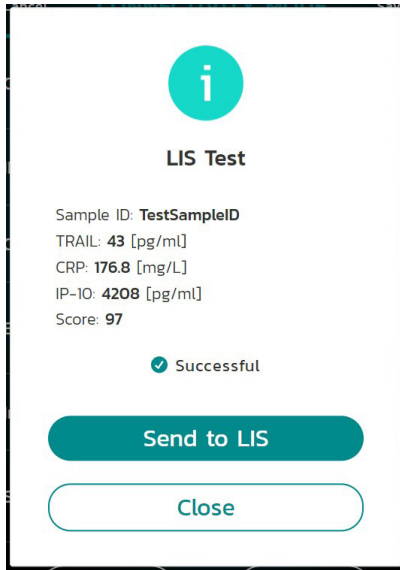
NOTE: The same IP address must be added to the [Network Access](#) list.

Tap **Secure Connection**² to enable or disable secure connection.
Tap **Connect** to connect to LIS.

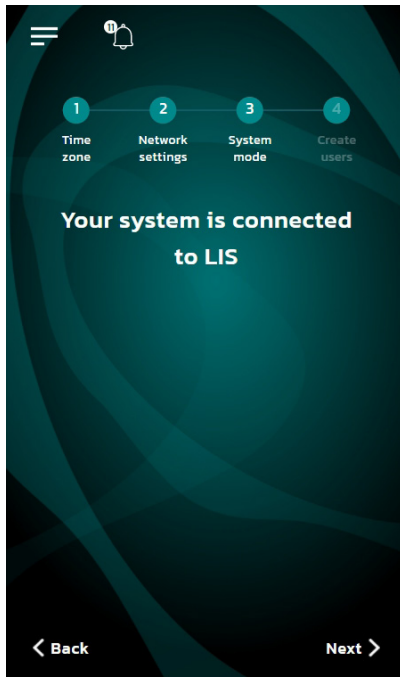
LIS Connectivity Test

Optionally, after successful connection, tap **Test** to send a test message containing pre-defined test results through the LIS connection.
These settings can also be managed through [Connectivity Menu](#).

² A secure connection is encrypted by one or more security protocols to ensure the security of data flowing between two or more nodes.

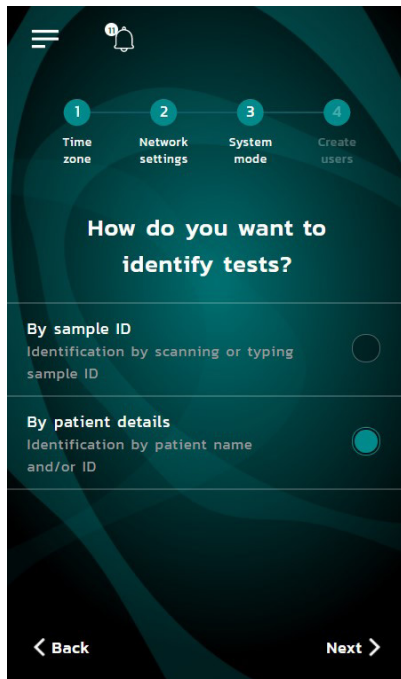


Tap **Send to LIS** and wait for the **Successful** checkmark to appear.
Tap **Close**.



Operation Mode Confirmation

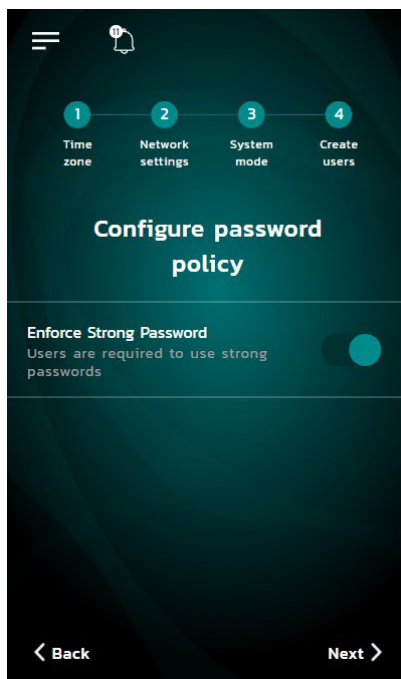
This screen is displayed following operation mode selection and setup.
Confirm your selection by tapping **Next**.



Select Test Identification Method

This screen is displayed if **Standalone** mode was selected in **Select Operation Mode** screen.

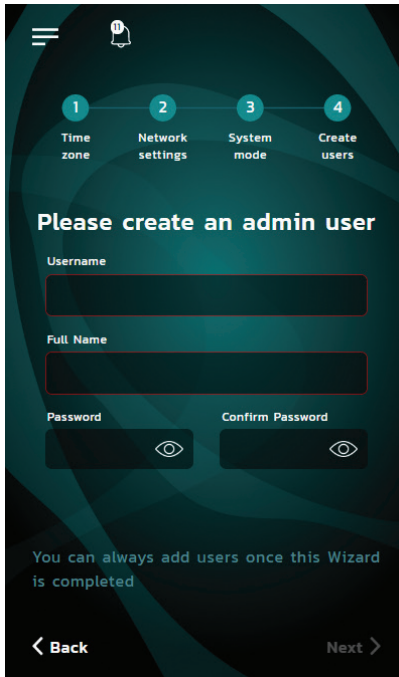
Tap to select the test sample identification method.



Configure Password Policy

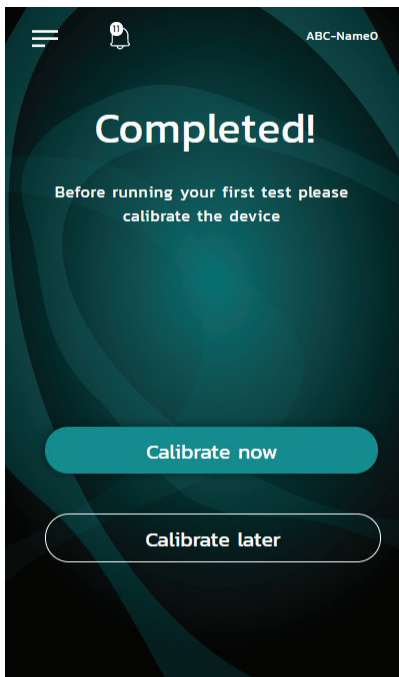
Use this screen to enable or disable the enforcing of strong password. When enabled, the analyzer interface will enforce password length and complexity requirements: a valid password will be required to be 8 characters or longer and contain at least 3 of the following character types:

- Lowercase characters (a-z)
- Uppercase characters (A-Z)
- Numeric characters (0-9)
- Special characters (!#\$%)



Create Admin User

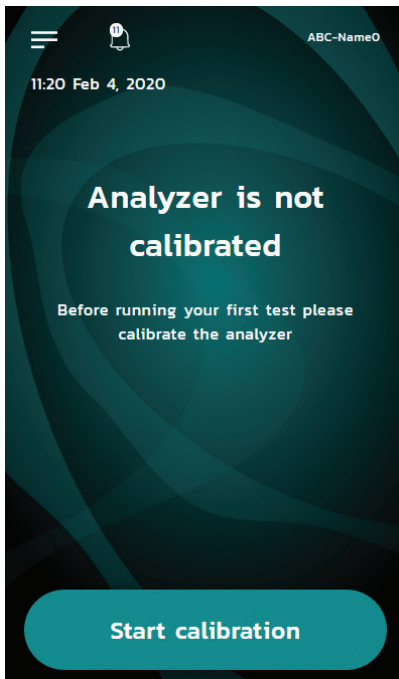
Tap a field to open the virtual keyboard and enter username, full name and password for the new admin user.



Setup Completed Screen

Tap **Calibrate now** to start the first calibration process (required to run tests).

Tap **Calibrate Later** to go to the home screen in pre-calibrated state.



Home screen in pre-calibrated state

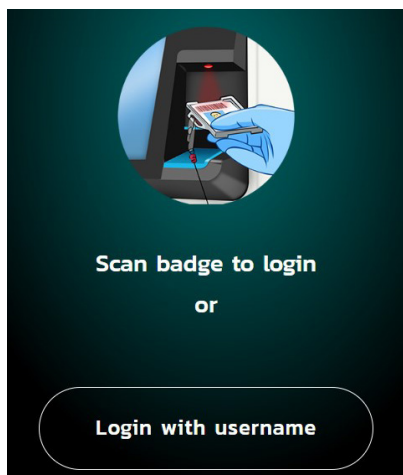
After completing the Initial Setup process, you may choose to initiate the first calibration process or to calibrate the analyzer later. If the latter option is selected, the home screen will be displayed in the pre-calibrated state until the first calibration is successfully completed.

6. Logging In and Out

If this is the first time the analyzer is used, make sure you have read the [Getting Started](#) chapter.

After powering on, the analyzer will perform a self-test as described in [Initial Setup Wizard](#) section. When the test is complete, the analyzer will display the Login screen. The Login screen is also displayed after user-initiated or automatic log out (see [Logging Out and Shutting Down](#) section for more details).

6.1. Logging In

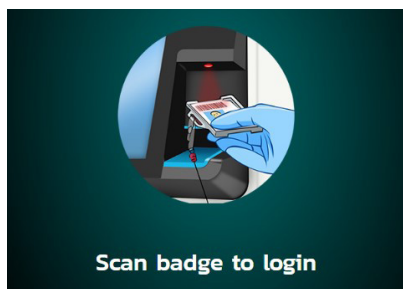


You can log in by:

- Scanning your employee badge – this option is available only if Badge Scan was enabled in the analyzer settings (see section [Security Settings](#), for details) and a badge was assigned to the user.
- Entering your username and password.

If both methods are available, the Login screen will enable you to select the desired identification method.

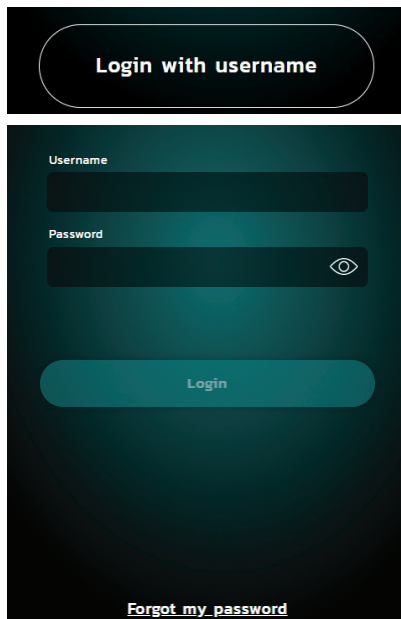
To adjust the login settings, navigate to **Menu > Settings > System Settings > Security**.



6.1.1. Badge Scan Login

Scan your badge using the analyzer's built-in scanner.

Upon scanning the badge, you will be logged in and the Home screen will be displayed.



6.1.2. Username Login

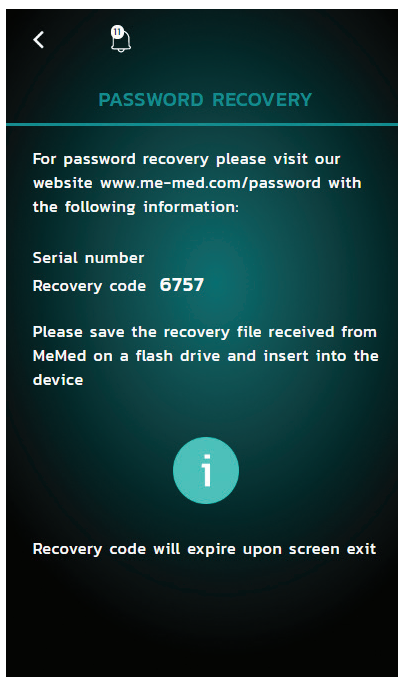
1. In the login screen, tap **Login with username**. The Username Login screen will be displayed.
2. Tap the **Username** field to open the virtual keyboard. Enter your username using the keyboard or select the relevant username from the list.
3. Tap **Enter** on the keyboard to move to the next field or tap outside the **Username** field to close the keyboard.
4. Tap the **Password** field to open the virtual keyboard and enter your password. To display the password, tap  **Show password** on the right of the password field. If you have forgotten your identification credentials, refer to your lab manager or IT administrator.
5. Tap **Login** to log into the analyzer. Upon logging in, the Home screen will be displayed.



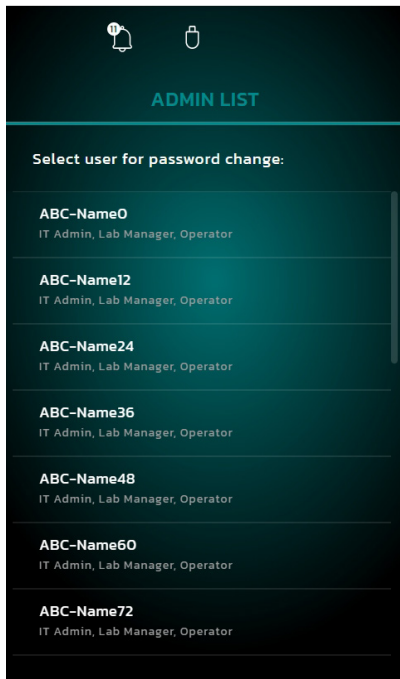
NOTE: If you cannot log in or have forgotten your username or password, refer to your IT administrator or Lab manager to unlock the identification credentials.

6.1.3. Password Recovery Process

If you cannot log in, contact your IT Admin to initiate a password recovery process as detailed below. To recover your password:



1. Tap **Forgot my password** at the bottom of the Login screen to open the password recovery screen. The password recovery screen will display the analyzer serial number and a system-generated recovery code. The recovery code will expire after 48 hours if not used or upon leaving the recovery screen. A new code will be generated with each access to the screen.
2. Contact MeMed at the web address that appears on the screen to receive the recovery file to your email. Open your email and save the recovery file sent by MeMed to a USB storage device.
3. Connect the USB storage device containing the recovery file into the analyzer's USB port. The recovery process will automatically start. Do not remove the USB storage device until the process is completed.



4. If the recovery file contained an expired recovery code, you will be notified accordingly. In this case, remove the USB storage device and start the recovery process again. Perform the recovery process in one session to ensure that the code does not expire.
5. After the access recovery process is completed, the screen will display the list of admin users stored in the analyzer. Tap on a username to open the **Password Change** screen for the selected username.
6. In the **Password Change** screen, tap the Password field to open the virtual keyboard and insert a new password (at least 6 characters).
7. Re-enter the new password and tap **Save** to complete the password change. Once the password has been changed the Users screen is displayed. It is recommended to verify that all the admin users' passwords are known and up to date.

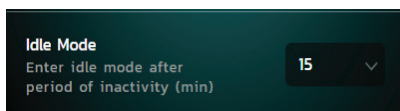
6.2. Idle Mode



The analyzer enters the Idle mode to protect patients' privacy and prevent random screen taps from interrupting or accidentally starting operations. During idle mode the idle screen is displayed and the user is logged out. Tapping anywhere on the screen will close the idle screen and display the **Login** screen.

6.2.1. Setting up Idle Mode

By default, the Idle Screen will be displayed after 15 minutes of inactivity. To change the idle screen activation time:



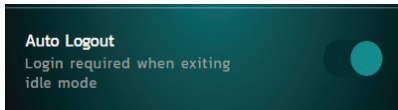
1. Tap **Menu** to open the main menu.
2. In the main menu, tap **Settings > System Settings > Security**.
3. In the Security screen tap the **Idle Mode** drop-down and select the desired inactivity time.
4. Tap **Save** in the screen navigation bar to save your changes.



NOTE: Idle mode is disabled during a test run, calibration or external control, self-test, or software updates.

6.2.2. Auto Logout in Idle Mode

For additional protection, you may also setup the analyzer to automatically log out whenever the idle mode is activated. If the auto logout feature is enabled, tapping anywhere on the idle screen will display the Login screen and you will have to re-enter your user credentials to continue using the analyzer.



To set up the auto logout feature:

1. Tap **Menu** to open the main menu.
2. In the main menu, tap **Settings > System Settings > Security**.
3. By default, the auto logout feature is enabled. Select the desired state of the **Auto Logout** toggle button to enable or disable the auto logout feature.

6.3. Logging Out and Shutting Down

6.3.1. Manual Logout

To manually log out of the analyzer, perform the following steps:

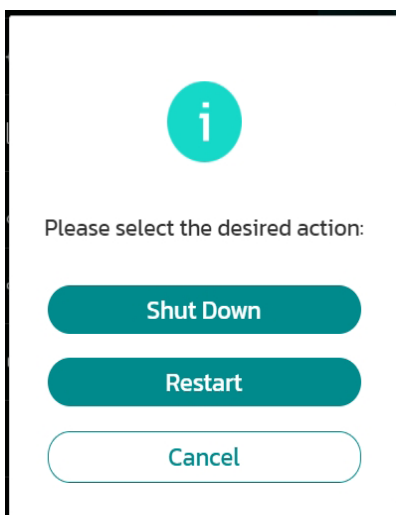
1. Tap **Menu** to open the main menu.
2. Select **Logout** from the menu:
3. The current user will be logged out and the **Login** screen will be displayed.

6.3.2. Shutting Down the Analyzer



NOTE: Shutting down the Analyzer is possible at any time except during a test run, calibration or external control, self-test, or software updates.

Verify that the cartridge has been removed from the Analyzer (shutting down will not be possible until the cartridge is removed).



To shut down the analyzer:

1. Tap **Menu** to open the main menu.
2. Select **Power** to display the shutdown confirmation dialog.
3. Tap **Shut Down** to start the shutdown sequence, or **Restart** to restart the analyzer, or **Cancel** to abort the shutdown process.

The screen will display a shutdown progress indication until the shutdown is completed.



WARNING! Do not unplug the power cable before the Analyzer is shut down. This might result in permanent damage to the Analyzer's components.

7. Calibrating the Analyzer

The calibration process simulates a test by running a number of calibrators (for example, high, medium, and low concentrations) on separate disposable cartridges. The exact number of calibrators depends on the specific test and lot the analyzer is being calibrated for. The calibrators are reagents that contain known amount of target analytes, representing various values of the analyte ranges that impact the test results, to optimize the clinical accuracy of the analyzer.

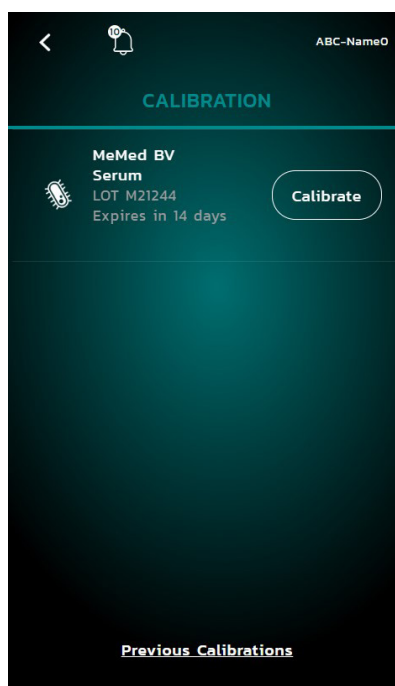
The MeMed Key® analyzer must be calibrated as often as required for each specific test and before starting using each new test cartridge lot.



IMPORTANT! The Calibration process is performed individually for each test type and each sample type.

7.1. View Calibration Status

To view the analyzer calibration status for available tests, tap **Menu** and select **Calibration**.



The **CALIBRATION** screen displays a list of available tests and sample types. For each test type and sample type, the following information is available:

Lot information. The lot information is displayed only for calibrated tests and sample types. If there are more than one lot of same test and sample type with valid calibration, a **Multiple Lots** indication is displayed.

Tap **Multiple Lots** to view the calibrated lots information for the selected test and sample type.

Calibration status. For calibrated tests and sample types, the calibration expiration date is displayed. The analyzer will provide a reminder prior to the calibration expiration, according to the time set in the **Test Settings**. A graphical indication of uncalibrated tests will also be displayed in the relevant test screen (see [Running a Test](#) chapter for more details).

7.2. Running a Calibration



IMPORTANT! The Analyzer must be calibrated at least once in order to run tests. Prior to this, the Analyzer **Login** screen appears in a pre-calibrated state and no test may be initiated.

7.2.1. Initiating Calibration Process

The calibration process may be initiated by tapping **Calibrate** in the **Calibration** screen or a system notification. The calibration process may be initiated at any time when the analyzer is not running a test, another calibration, or an external control.

Prior to starting the calibration process make sure to have:

1. Cartridges appropriate for the test and sample type that belong to the selected lot.
2. Calibration fluid vials appropriate for test and sample type and belonging to the same lot.

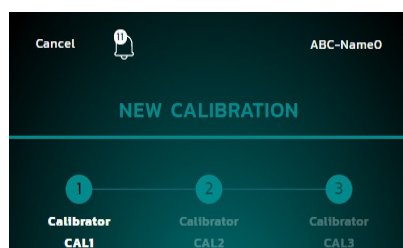


IMPORTANT! Before running a calibration, refer to the appropriate test cartridge and calibrator Instructions for Use for details and safety-related aspects.

Aborting the process before all stages are completed removes data for the last attempted stage. Repeat the last stage if necessary.

It is recommended to complete all calibration stages in one session to avoid timeouts

7.2.2. Calibration Stages



The calibration process for all test types consists of three stages. Each stage must be successfully completed in order to continue to the next stage.

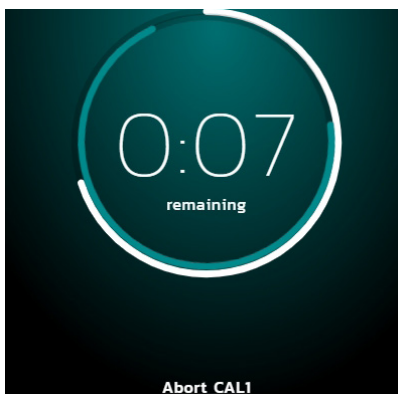
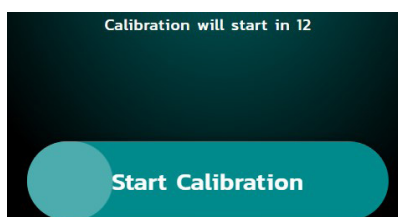
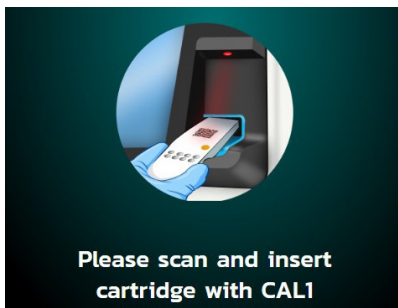
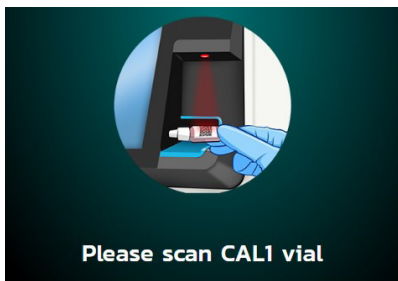
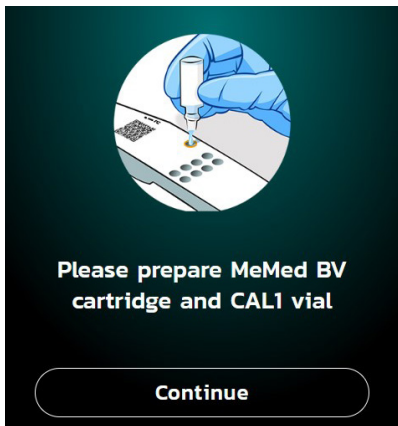
The current stage is indicated throughout the calibration process in the upper progress bar.

[Table 3: Calibration Stages](#) below outlines a three-stage calibration process presented on the analyzer screens.

Table 3: Calibration Stages

	Stage 1	Stage 2	Stage 3
1	Scan CAL1 vial	Scan CAL2 vial	Scan CAL3 vial
2	Fill cartridge with CAL1 calibrator fluid, scan and insert cartridge	Fill cartridge with CAL2 calibrator fluid, scan and insert cartridge	Fill cartridge with CAL3 calibrator fluid, scan and insert cartridge
3	Start calibration	Start calibration	Start calibration
4	Acknowledge stage 1 completion	Acknowledge stage 2 completion	Acknowledge calibration completion

7.2.3. Calibration Workflow



Initiate calibration

1. Tap **Menu > Calibration** to open the **CALIBRATION** screen.
2. Locate the desired test and sample type and tap **Calibrate**.
3. Follow the Calibrator Instructions for Use to prepare test cartridge and CAL1 calibrator vial.
4. Tap **Continue** on the **New Calibration** screen to start the first stage.

5. Identify Calibration vial #1.

To identify the vial, place it under the barcode scanner focused beam as illustrated.

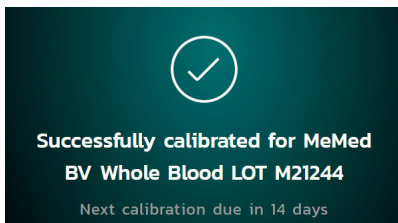
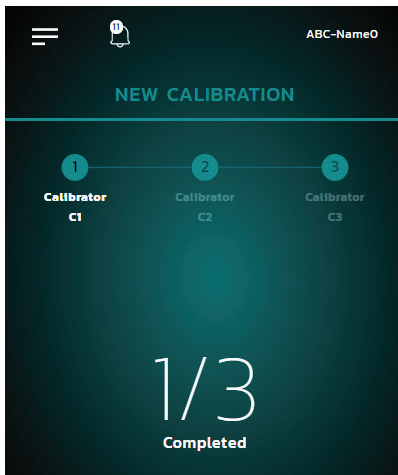
6. Dispense Calibration fluid and insert test cartridge.

Dispense the prescribed volume of Vial#1 Calibration fluid into the sample well of the cartridge, as instructed in the Calibrator IFU, scan and insert the test cartridge as illustrated.

7. Start calibration.

Verify the process details and tap **Start Calibration** or wait 15 seconds for the first calibration stage to start automatically.

At this time, a progress indication is displayed.



Once stage 1 is completed, the stage completion screen will be displayed.

1. Tap **Remove Cartridge** to remove the used test cartridge and proceed to stage 2.
2. Remove the test cartridge and dispose of it according to your lab practices.
3. Follow on-screen instructions to repeat the process for further stages using the next cartridge(s) and Calibration fluid vials.

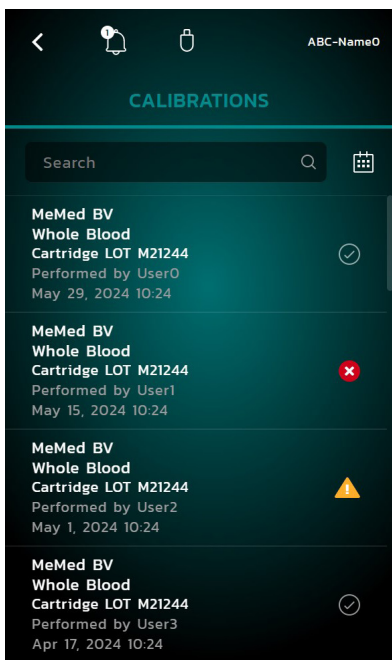
After the last stage is completed the completion message for the entire process will be displayed.

Remove the last test cartridge and tap **Finish** to return to the **Home** screen.



WARNING! Use safe laboratory practices when handling biological samples and reagents. Failure to safely dispose of samples or reagents may result in contamination or injury.

7.3. Viewing Calibration History



You can view calibration history data in the calibration history screen.

Tap **Menu > Calibration > Previous Calibrations** to access the **CALIBRATION HISTORY** screen.

The **CALIBRATION HISTORY** screen displays a chronological list of previously performed calibration processes. For each test type and sample type the following information is available:

- Test and sample type
- Lot data
- Calibration date and time
- User who performed the calibration
- Calibration result (pass/fail/aborted)

You can search for calibration results according to:

- Test types via the filter control (provided there are two or more test types)
- Specific dates via a calendar control.

To set the dates:

1. Tap the Calendar icon  next to the **Search** field.
2. Select the desired dates.
3. Tap **Confirm** to view the calibration results for the selected period.



Successfully calibrated for MeMed
BV Whole Blood LOT M21244

To view a specific calibration result, tap a row from the **CALIBRATION HISTORY** list. The calibration result details screen will open.

8. Running a Test

The MeMed Key® analyzer enables you to perform tests on patient samples using designated single-use MeMed Test Cartridges that contain all necessary reagents and disposables for measuring the concentration of specific analytes in the sample. The barcode on the test cartridge label contains information necessary for the test identification by the analyzer, including:

- Test type
- Sample type
- Cartridge expiration date
- Lot data



CAUTION! Do not attach any stickers to the cartridge. Doing so will result in test failure.

By scanning the test cartridge label, the analyzer verifies the data and initiates the appropriate sequence for the specific test type before the test cartridge is inserted.



NOTE: Before running a test, ensure the selected test cartridge matches the desired test and sample type, and refer to the cartridge IFU for the cartridge and sample preparation procedures.

8.1. Test Overview

The test process for all test types consists of the stages listed below. Each stage must be successfully completed in order to continue to the next stage.



IMPORTANT! Before running a test, verify the calibration status ([View Calibration Status](#)). The Analyzer must be calibrated at least once in order to run tests. Prior to this, the Analyzer is in pre-calibrated state and no test may be initiated.

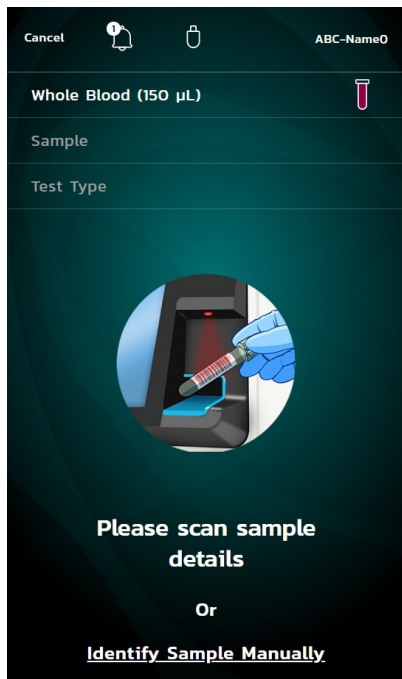
1. Prepare test cartridge.
Make sure the selected test cartridge matches the desired test type.
2. Initiate new test.
3. Identify patient or sample.
4. Dispense patient sample into the test cartridge's designated well as specified in the test cartridge Instructions for Use.
5. Scan and insert test cartridge with sample.
6. Verify details and start test.
7. View test results.

Depending on the Operation Mode, skip to the appropriate workflow section:

- [Running a Test when Connected to LIS](#)
- [Running a Test in Standalone Mode: Patient](#)
- [Running a Test in Standalone Mode: Sample](#)

8.2. Running a Test when Connected to LIS

The test identification area populates with the scanned or manually entered data.

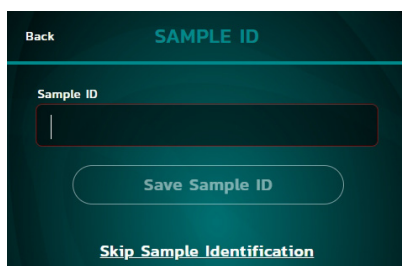


On the **Home** screen, tap **New Test**. The **Test Details** screen is displayed

1. Place the sample identification label facing upward under the barcode scanner as illustrated and wait for the scanning beeper to sound.

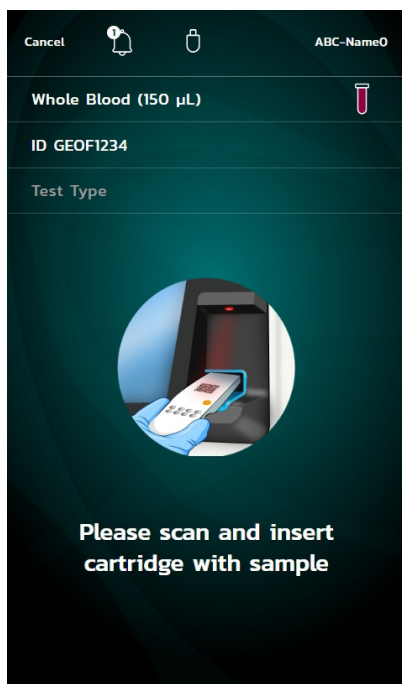
The Sample data field will be updated according to the data entered.

If sample identification data is not available on the label, tap **Identify Sample Manually**.



2. Manually enter sample ID and tap **Save Sample ID** or tap **Skip Sample Identification**

to continue to the test cartridge insertion stage. In such case, a random ID will be assigned to the test automatically. The generated ID cannot be updated at a later time. This random ID will be sent to LIS; write down the assigned ID for further test identification.



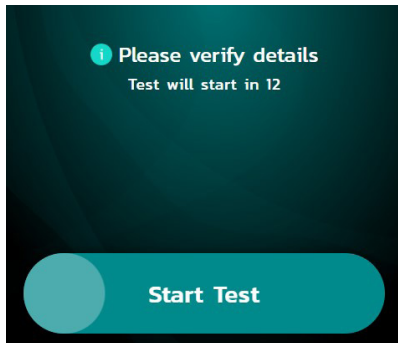
3. Place the test cartridge with the patient sample so that the label is facing upward until the scanning beeper is heard. Refer to the test cartridge IFU for instructions on how to load the sample.
4. Verify that the test cartridge orientation is correct and insert it into the test cartridge port. The **Test Type** field will be updated accordingly. The test details screen is displayed.



NOTE: If the test cartridge is ejected or the test details screen is not displayed, refer to the [Troubleshooting](#) chapter.



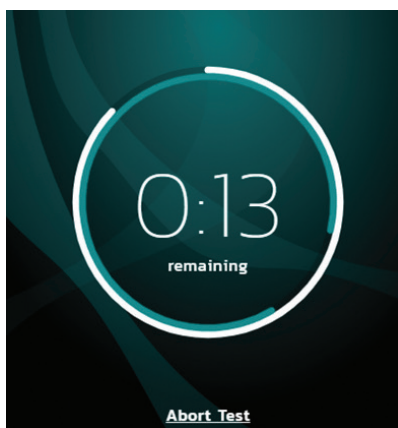
IMPORTANT! A scanned test cartridge cannot be reused. If the test is aborted or canceled after scanning the test cartridge, dispose of the test cartridge according to laboratory safety procedures.



5. Verify that the **Sample ID**, **Test Type** and **Sample Type** are correct.
6. Tap **Start Test** or wait 15 seconds for the test to start automatically.

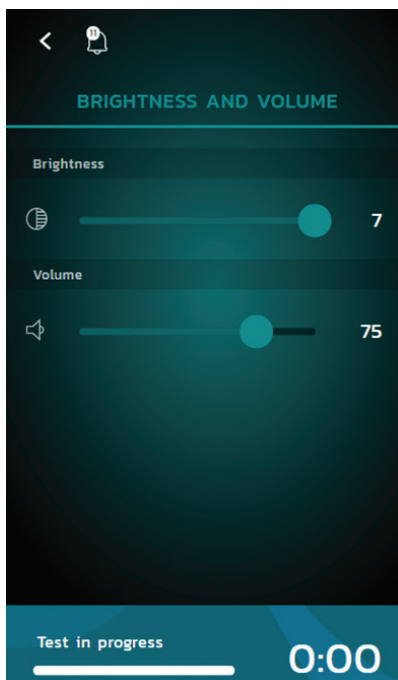


NOTE: If the Analyzer identifies a test as not ordered by the LIS system, an **Unordered in LIS** indication will be displayed. You may cancel the test or proceed with the test.

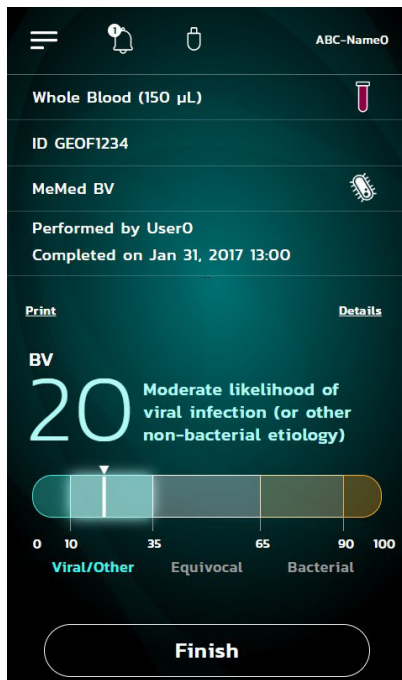


During the test process:

- Tap **Abort Test** to cancel the test.
- A progress indication is displayed.
- Menu access is limited to Results history, volume and brightness adjustment and Help screen.
- Upon accessing one of these functionalities through the menu, the test screen is minimized at the bottom of the screen. To open the screen again, tap the minimized panel.



IMPORTANT! Aborting an active test will result in test cartridge expiration and all test data will be discarded.



After the test is completed, the test results are displayed and test cartridge is ejected. Remove the test cartridge.

- Tap **Details** to view test result details.
- Tap **Finish** to close test results and return to the **Home** screen. The test results are automatically stored in your analyzer. You may review the results at a later time in the **Results History** screen.
- If a printer is configured, a **Print** control will be displayed. Tap **Print** to print the test report, when necessary.



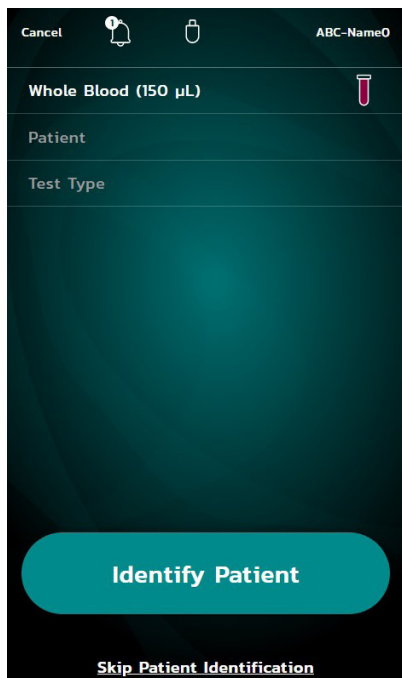
NOTE: For detailed information on the specific test type results and interpretation, refer to the relevant test cartridge Instructions for Use.



WARNING! Use safe laboratory practices when handling biological samples and reagents. Failure to safely dispose of samples or reagents may result in contamination or injury.

8.3. Running a Test in Standalone Mode: Patient

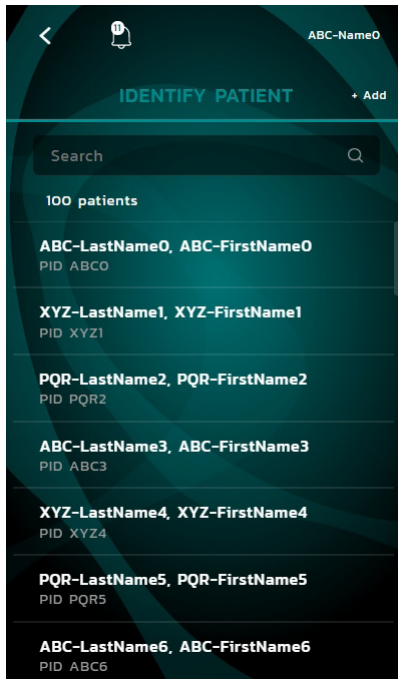
The patient identification details are populated with the scanned or manually entered data.



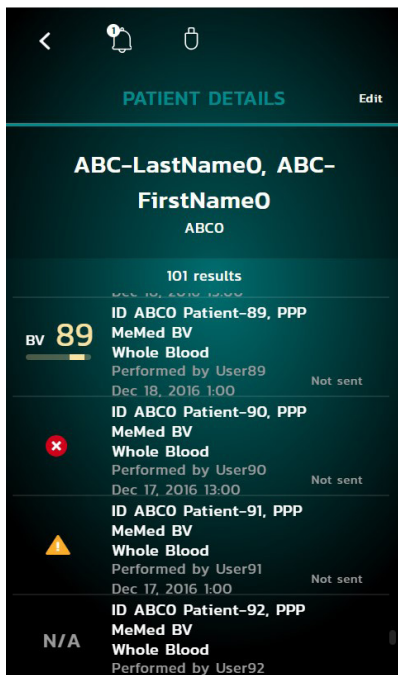
1. On the **Home** screen, tap **New Test**. The **Test Details** screen is displayed.

You can **Skip patient identification** to continue to the next stage without completing the current one.

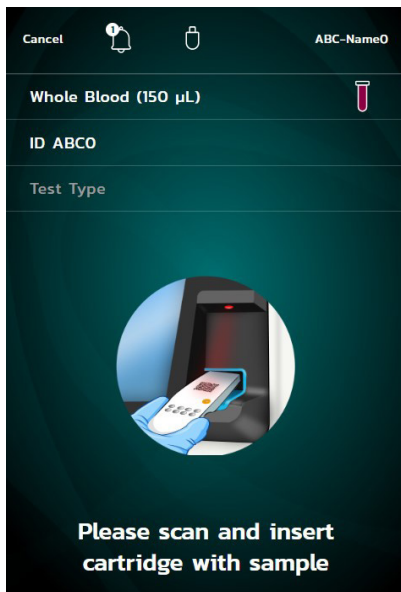
2. Tap **Identify Patient** to open the **Identify Patient** screen.



3. Locate and tap a patient to open the patient details screen or tap **Add** to create a new patient.



4. In the patient details screen tap **Select**. The patient data field will be updated accordingly.
5. Place the test cartridge with the patient sample so that the label is facing upwards until the scanning beeper is heard. Refer to the cartridge IFU for instructions on how to load the sample.
6. Verify that the test cartridge orientation is correct and insert it into the cartridge port.



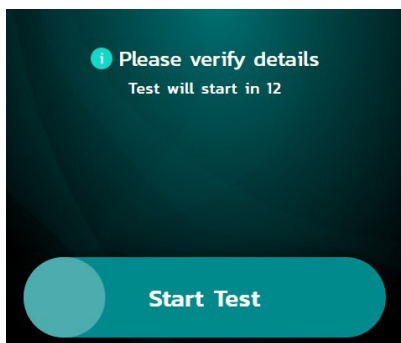
The **Test Type** field will be updated accordingly. The test details screen is displayed.



NOTE: If the test cartridge is ejected or the test details screen is not displayed, refer to the [Troubleshooting](#) chapter.

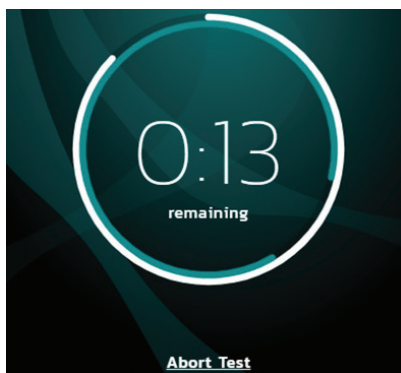


IMPORTANT! A scanned test cartridge cannot be reused. If the test is aborted or canceled after scanning the test cartridge, dispose of the test cartridge according to laboratory safety procedures.



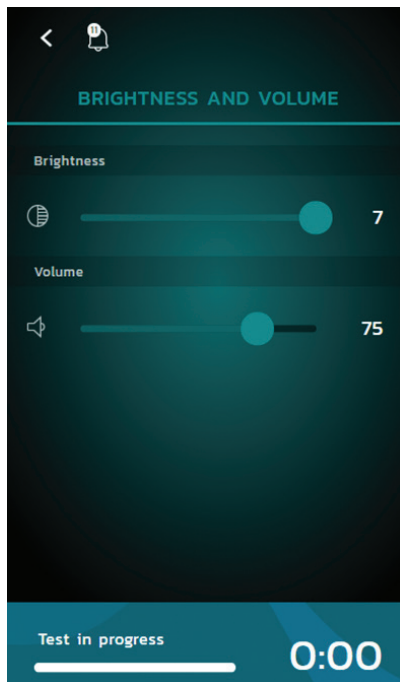
Verify Details and Start Test

1. Verify that the **Patient ID**, **Test Type** and **Sample Type** are correct.
2. Tap **Start Test** or wait 15 seconds for the test to start automatically.



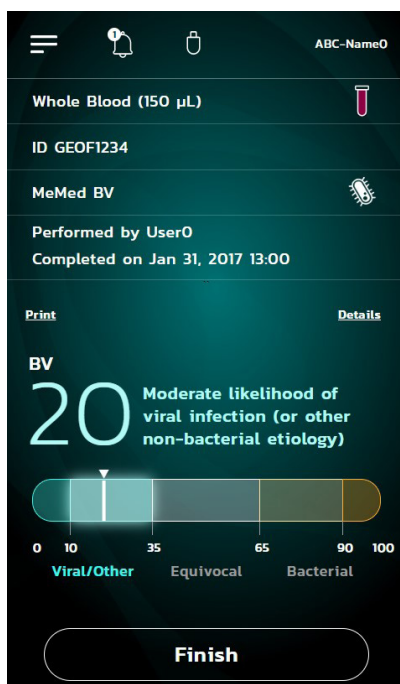
During the test process:

- A progress indication is displayed.
- Menu access is limited to Results history, volume and brightness adjustment and Help screen.
- Upon accessing one of these functionalities through the menu, the test screen is minimized at the bottom of the screen. To open the screen again tap the minimized panel.
- Tap **Abort Test** to cancel the test.



IMPORTANT! Aborting an active test will result in test cartridge expiration and all test data will be discarded.

After the test is completed, the test results are displayed and test cartridge is ejected. Remove the test cartridge.



- Tap **Details** to view test result details.
- Tap **Finish** to close test results and return to the **Home** screen. The test results are automatically stored in your analyzer. You may review the results at a later time in the **Results History** screen.
- If a printer is configured, a **Print** control will be displayed. Tap **Print** to print the test report, when necessary.

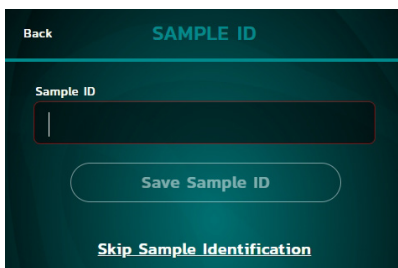
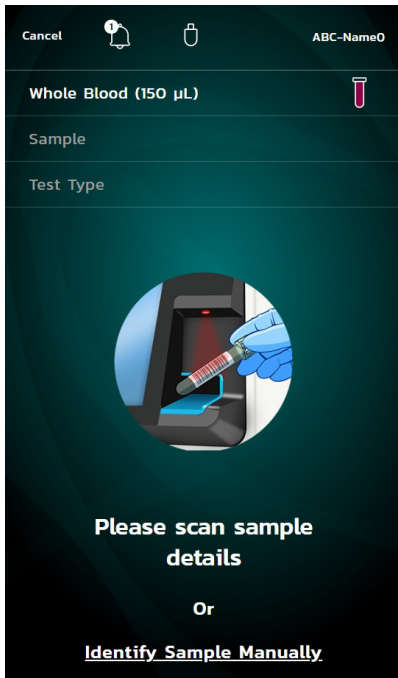


NOTE: For detailed information on the specific test type results and interpretation, refer to the relevant test cartridge Instructions for Use.



WARNING! Use safe laboratory practices when handling biological samples and reagents. Failure to safely dispose of samples or reagents may result in contamination or injury.

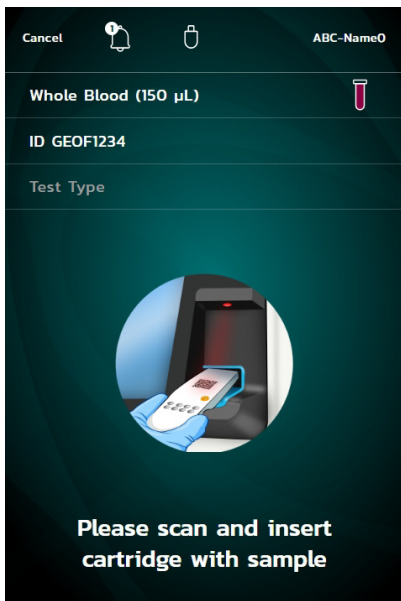
8.4. Running a Test in Standalone Mode: Sample



On the **Home** screen, tap **New Test**. The Identify Sample screen is displayed.

Identify Sample

1. To identify the sample, place sample identification label facing upward under the barcode scanner as illustrated and wait for the scanning beeper to sound. If sample data is not available on the label, tap **Identify Sample Manually**.
2. Manually enter the sample ID and tap Save Sample ID or tap **Skip Sample Identification** to continue to the test cartridge insertion stage.
3. Place the test cartridge with the patient sample so that the label is facing upward until the scanning beeper is heard. Refer to the cartridge IFU for instructions on how to load the sample.



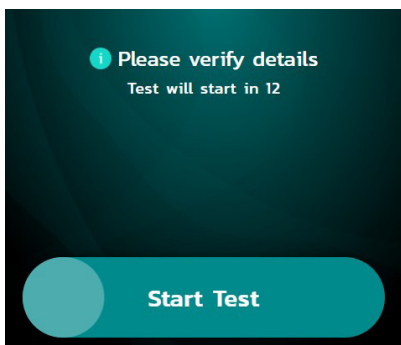
4. Verify that the test cartridge orientation is correct and insert it into the cartridge port. The **Test Type** field will be updated accordingly. The test details screen is displayed.



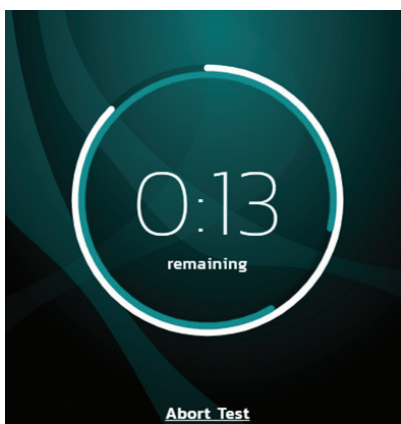
NOTE: If the test cartridge is ejected or the test details screen is not displayed, refer to the [Troubleshooting](#) chapter.



IMPORTANT! A scanned test cartridge cannot be reused. If the test is aborted or canceled after scanning the test cartridge, dispose of the test cartridge according to laboratory safety procedures.

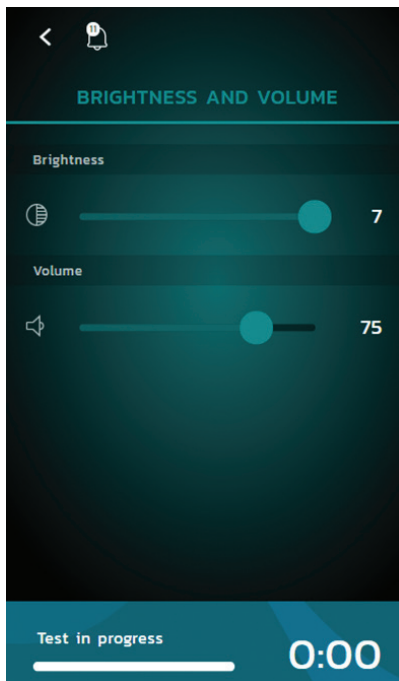


5. Verify that the **Sample ID**, **Test Type** and **Sample Type** are correct.
6. Tap **Start Test** or wait 15 seconds for the test to start automatically.



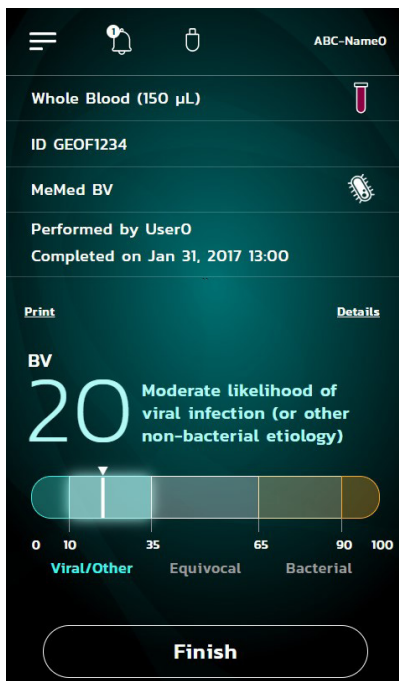
During the test process:

- A progress indication is displayed.
- Menu access is limited to Results history, volume and brightness adjustment and Help screen.
- Upon accessing one of these functionalities through the menu, the test screen is minimized at the bottom of the screen. To open the screen again tap the minimized panel.
- Tap **Abort Test** to cancel the test.



IMPORTANT! Aborting an active test will result in test cartridge expiration and all test data will be discarded.

After the test is completed, the test results are displayed and test cartridge is ejected. Remove the test cartridge.



- Tap **Details** to view test result details.³
- Tap **Finish** to close test results and return to the **Home** screen. The test results are automatically stored in your analyzer. You may review the results at a later time in the Results History screen.
- If a printer is configured, a **Print** control will be displayed. Tap **Print** to print the test report, when necessary.



NOTE: For detailed information on the specific test type results and interpretation, refer to the relevant test cartridge Instructions for Use.



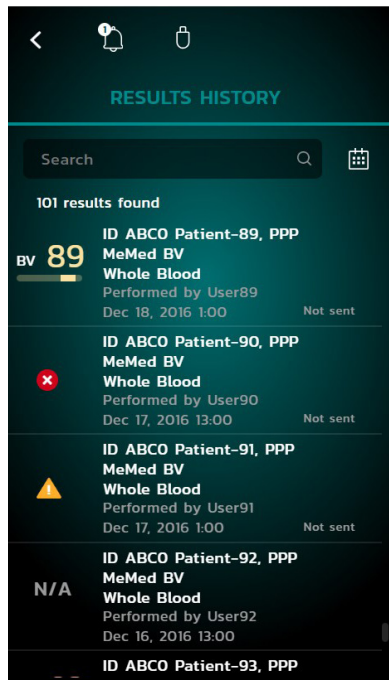
WARNING! Use safe laboratory practices when handling biological samples and reagents. Failure to safely dispose of samples or reagents may result in contamination or injury.

³ Where available

9. Reviewing Results History

You can review previous test results at any time in the Results history screen.

9.1. Access Results History



To access the **RESULTS HISTORY** screen, tap **Menu > Results**.

The results history screen displays a chronological list of previously completed tests, with the newest test on top. For each test the following information is available:

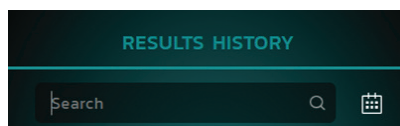
- **Test results are displayed with a corresponding icon:**
 - Score** - for successfully completed tests
 - for failed tests
 - N/A** - for aborted tests
 - for tests with invalid results
- **LIS status indication, displayed when Connectivity mode is set to LIS:**
 - **No indication:** valid test result was sent successfully
 - **Not sent:** A valid test result not sent to LIS due to connectivity issues. The test result will be sent, and the indication will be automatically removed after the connectivity issues are resolved.
- **General information:** Displays the test type, sample type, test identification data (Patient name & ID / Sample ID), test date and time, and the user who performed the test.



IMPORTANT! For detailed information on the specific test type results and interpretation, refer to the relevant test cartridge Instructions for Use.

9.2. Locating a Test Result

You can locate specific test results by searching for a patient name or ID, a sample ID or test type, and/ or by time filtering the tests history as described below.



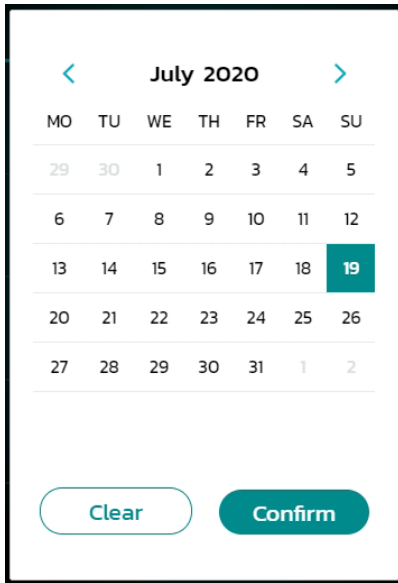
To locate specific test results:

Tap the **Search** field and type in one of the following:

- Patient name
- Patient ID
- Sample ID
- Test type

The analyzer will automatically display the relevant test results.

Tap a result to open the test result screen or tap the control to cancel the search.



To filter test results according to specific dates:

1. Tap the calendar control  to open the calendar.
2. Select the desired date or start and end dates for the desired time range and tap **Confirm** to view the test results for the selected time range.

The applied date filter is indicated by the highlighted calendar control .

To clear the filter, open the calendar and tap **Clear**.

10. Managing Patients



NOTE: Information provided in this chapter refers to standalone: patient mode only.

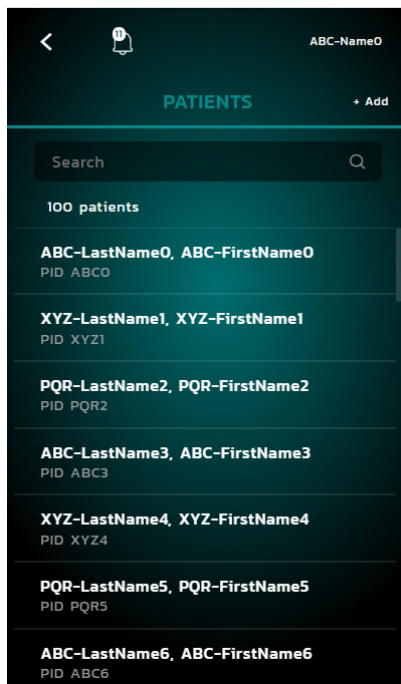
If your MeMed Key® analyzer was set up in Standalone Mode: Patient, all tests will be identified using locally stored patient details (name or patient ID). In this case:

- At the beginning of every test you will identify the patient for whom the test is performed by selecting from a list stored in the analyzer itself, or by adding a new patient to the list
- You can manage the local patients list by adding, editing, and deleting patients as described below
- For each patient listed in your analyzer, you can access tests previously performed on the same analyzer and view specific test results at any time



NOTE: For more details about operation modes, see [About Operation Modes](#) section.

10.1. Locate Patient

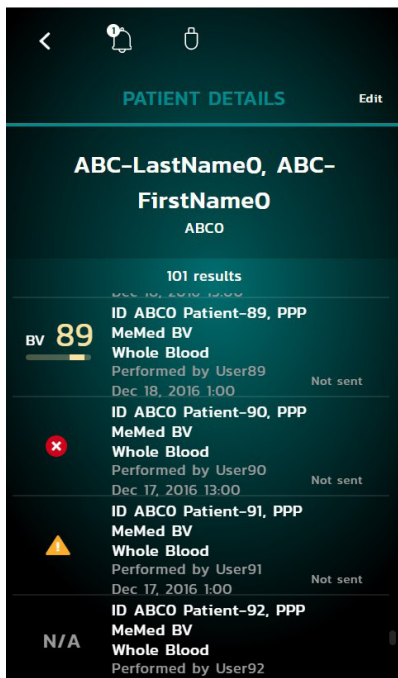


In the **Patients** screen you can manage the list of patients stored locally in the analyzer, by adding, editing, or deleting patients as described below. To access the patient list, tap **Menu** and select **Patients** from the menu.

The **Patients** screen displays the list of locally stored patients in alphabetic order. For each patient, the patient name and ID number (when available) are displayed.

- To locate a patient, scroll the list to locate the desired patient or tap the **Search** field and type in patient's name or ID.
- After the desired patient is located, tap the patient to open the **Patient Details** screen.

10.2. View Patient Test Results History



The **Patient Details** screen displays:

- Patient details – including patient first name, last name, and patient ID (PID), if available.
- Patient test results history – the list of all tests performed for the selected patient, in chronological order (newest test on top).

For each test result the following information is available:

- Test type
- Sample type
- User who performed the test
- Test date and time

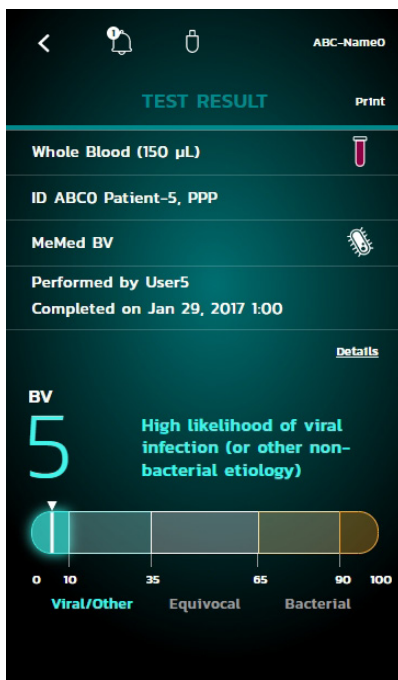
Test results are displayed with a corresponding icon:

Score - for successfully completed tests

- for failed tests

N/A - for aborted tests

- for tests with invalid results



Tap a test result to open the **Test Result Details** screen.

10.3. Add a New Patient

1. From the **Home** screen, tap **Menu > Patients** to open the **Patients** screen.
2. Tap **Add** in the upper right corner to open the New Patient screen.
3. In the **New Patient** screen:
 - Enter patient first name
 - Enter patient surname
 - Enter patient ID if available
4. Tap **Save** to save the new patient and return to the patients list.

10.4. Edit or Delete Existing Patient



CAUTION! Deleting a patient record cannot be undone. All test history associated with the deleted patient will be permanently removed from the Analyzer.

1. From the **Home** screen, tap **Menu > Patients** to open the **Patients** screen.
2. Scroll the list to locate the desired patient on the list, or tap the **Search** field and type in the patient's name or ID.
3. After locating the patient on the list, tap patient to open the **Patient Details** screen.
4. Tap **Edit** in the upper right corner to open the editing patient screen.
5. Modify the patient's details and tap **Save** or tap **Delete** to remove the patient record.

11. External Control

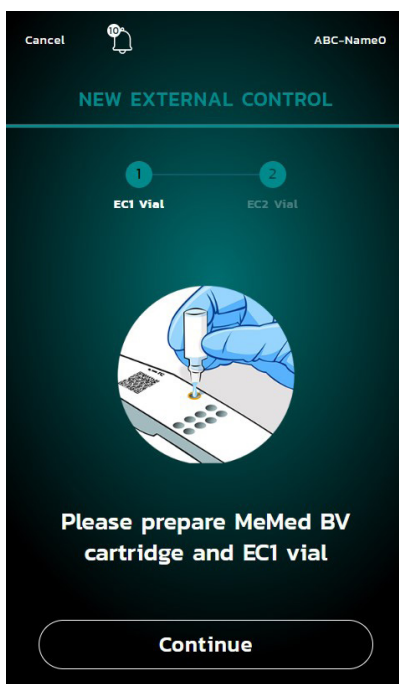
External controls serve to verify proper functioning of the analyzer. The External Control (EC) process involves running controls simulating various test results on separate disposable cartridges.

External controls are available for users who choose to perform additional control processes.



IMPORTANT! The EC process is performed individually for each test type and each sample type.

11.1. Initiating EC Process



The EC process may be initiated by tapping **Menu > External Control**, at any time, except during an active test run or calibration run.

The **EXTERNAL CONTROL** screen displays a list of available tests and sample types (for the detailed description, see [View Calibration Status](#) section). In case the analyzer is not calibrated for the selected test and sample type, you will be notified to calibrate prior to proceeding with the external control process.



NOTE: The Analyzer may be calibrated for multiple test cartridge lots compatible with the same specific test and sample type. You may perform external control for any of these calibrated LOTs. Tap **Multiple lots** to see the calibrated lots' details.

Prior to starting the external control process make sure to have:

1. Cartridges from the same lot, appropriate for the test and sample type.
2. EC vials appropriate for test and sample type belonging to the same lot.

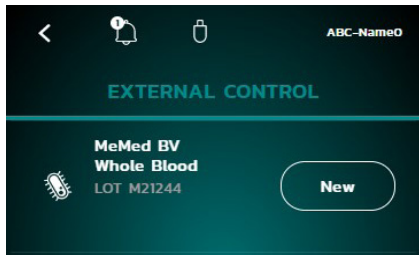


NOTE: The Analyzer must be calibrated for the test cartridge lot to be used in the EC – check calibration status in the **Calibration** screen.



IMPORTANT! Before running an external control process, refer to the appropriate test cartridge and external control Instructions for Use for details and safety-related aspects.

11.2. External Control Stages



The EC process for all test types consist of two stages. Each stage must be successfully completed in order to continue to the next stage.



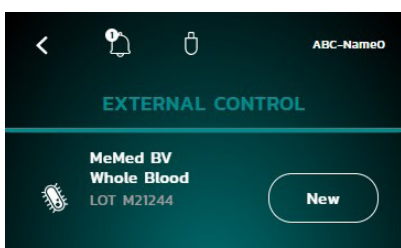
NOTE: Aborting the process before all stages are completed removes data for the last attempted stage. Repeat the last stage if necessary.

[Table 4: EC Stages](#) below outlines the EC process, following the stages presented on the analyzer screens.

Table 4: EC Stages

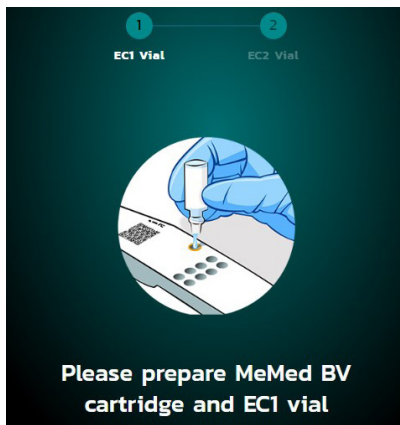
	Stage 1	Stage 2
1	Scan EC1 vial	Scan EC2 vial
2	Fill test cartridge with EC1 calibrator fluid, scan and insert test cartridge	Fill test cartridge with EC2 calibrator fluid, scan and insert test cartridge
3	Start External Control	Start External Control
4	Acknowledge stage 1 completion	Acknowledge External Control completion

11.3. External Control Workflow



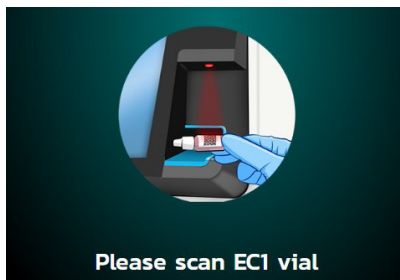
Initiate External Control

1. Tap **Menu > External Control** to open the **EXTERNAL CONTROL** screen.
2. Locate the desired test and sample type and tap **New**.



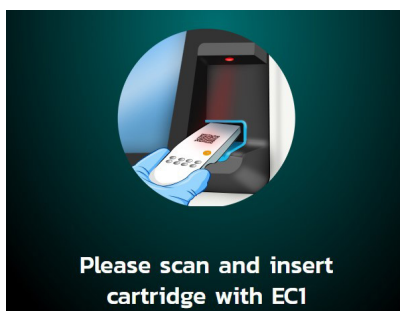
3. Prepare the test cartridge and EC1 vial. Refer to the test cartridge and EC IFUs for details.

4. Tap **Continue** on the **EXTERNAL CONTROL** screen to start the first stage.



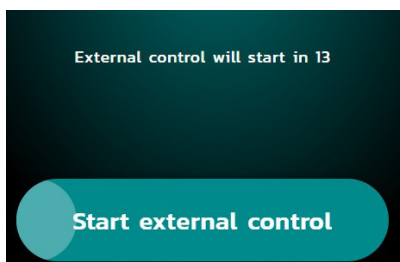
5. Identify External Control vial #1.

To identify the vial place it under the barcode scanner focused beam as illustrated.



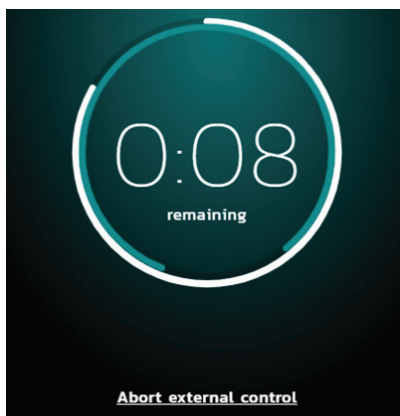
6. Dispense EC fluid and insert test cartridge.

Fill a test cartridge with the appropriate volume of EC Vial#1 fluid as instructed in the External Control IFU, scan and insert the test cartridge as illustrated.

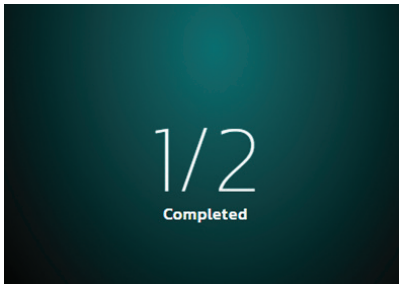


7. Start External Control.

Verify the process details and tap **Start External Control** to start the first stage.

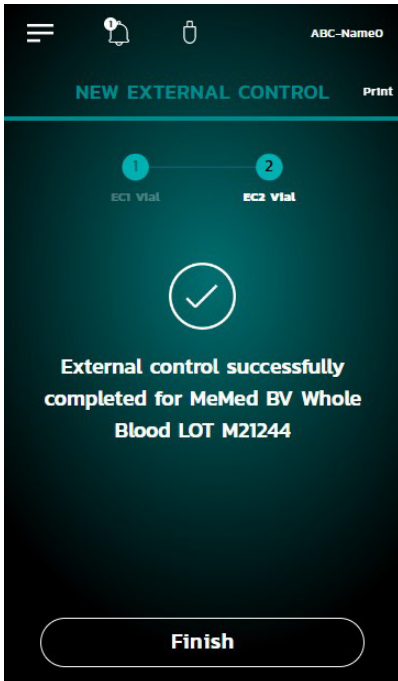


During the EC process, a progress indication is displayed.



Once stage 1 is completed, the stage completion screen will be displayed.

1. Tap **Remove Cartridge** to remove the used test cartridge and proceed to stage 2.
2. Remove the test cartridge and dispose of it according to your lab practices.
3. Repeat the process for stage 2 using the second test cartridge and the second EC fluid.



After the second stage is completed, the completion message for the entire process will be displayed.

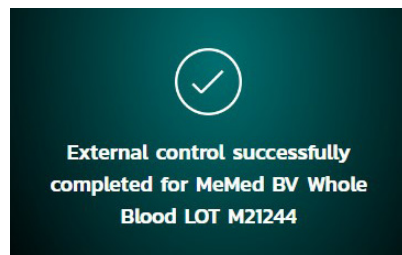
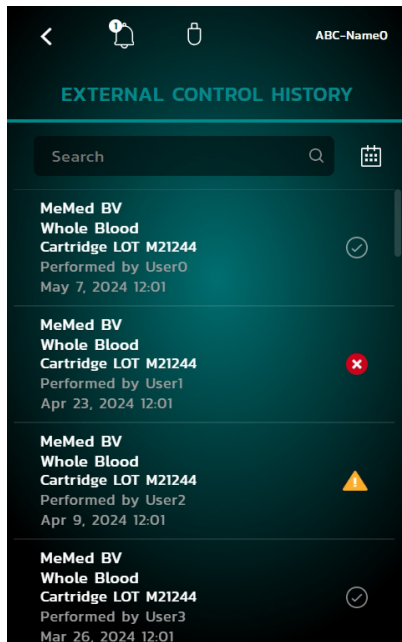
Remove the last test cartridge and tap **Finish** to return to the **Home** screen.

If a printer is configured, a **Print** control will be displayed. Tap **Print** to print the External Control result, when necessary.



WARNING! Use safe laboratory practices when handling biological samples and reagents. Failure to safely dispose of samples or reagents may result in contamination or injury.

11.4. Viewing External Control History



You can view External Control history data in the **EXTERNAL CONTROL HISTORY** screen.

Tap **Menu > External Control > Previous Results** to access the **EXTERNAL CONTROL HISTORY** screen.

The **EC HISTORY** screen displays the list of previously completed EC processes.

For each test type and sample type the following information is available:

- Test and sample type
- Lot data
- User who performed the EC
- EC date and time
- EC result (pass/fail/aborted)

The EC results may be filtered according to:

- Test types via the filter control (provided there are two or more test types).
- Specific dates via a calendar control

To set the dates:

1. Tap the **Calendar** icon  next to the **Search** field.
2. Select the desired dates.
3. Tap **Confirm** to view the EC results for the selected period.

To view a specific result, tap a row from **EC HISTORY** list. The EC result details screen will open.

12. Settings

You can view and edit the MeMed Key® analyzer configuration through the **Settings** screens. Tap **Menu** and select **Settings** from the main menu to access the settings screens.



NOTE: Access to various settings editing screens depends on your user roles as assigned in the **New User** screen.

12.1. User Settings

In the **Users** screen you can create new users and view or edit existing users. The MeMed Key® analyzer supports three types of users:

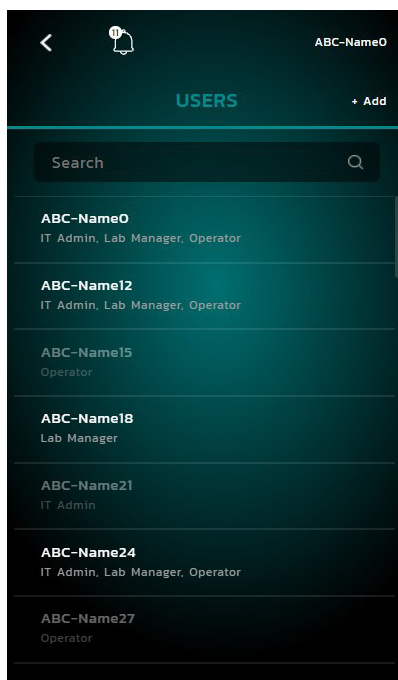
- Lab Manager
- IT Admin
- Operator

User roles define the access privileges as listed in the table below:

User Role	Menu	Used to...
Operator, Lab Manager, and IT Admin	Patients	Manage patients
	Results	View and print test result
	Calibration	Run calibration
	External Control	Run external control
	Tools	Run self-test Export failure report Export calibration and EC reports Device backup Run performance verification
	Settings	Change own password
Lab Manager, and IT Admin	Tools	Anonymize device
	Settings	Manage users Set time and date Set network preferences Set printing preferences
Lab Manager only	Tools	Export clinical data
	Settings	Manage test settings

User Role	Menu	Used to...
IT Admin only	Tools	Export audit trail Manage software updates
	Settings	Manage connectivity Manage system settings

12.1.1. Create a New User



To create a new user:

1. Tap **Menu > Settings > Users** to open the **Users** screen.
2. Tap **+Add** in the right upper corner to open the **NEW USER** screen.

3. In the **New User** screen, fill the new user's data:
 - Enter **Username**. This username will be used for logging in and will appear in the drop-down list on the login screen.
 - Enter user's first and last name (letters only).
 - **Role** – check one or more roles on the list
 - Enter and confirm password.
 - For systems in which badge-based login is enabled (see [Security Settings](#) section), tap **Assign Badge** and scan the badge using the barcode reader.
4. Tap **Save** to save the new user data.

12.1.2. Edit an Existing User

To edit an existing user:

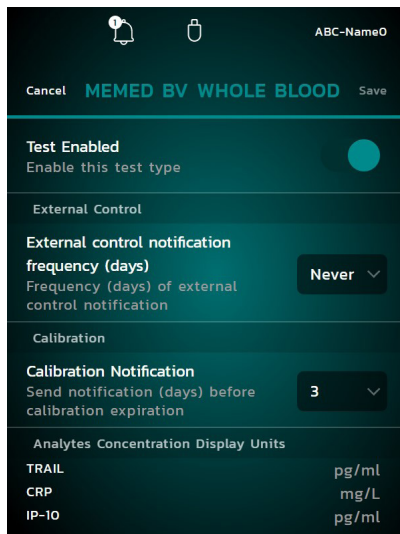
1. Tap **Menu > Settings > Users** to open the **Users** screen.
2. Scroll the list to locate the desired user on the users list or tap the **Search** field and type the user's full name or username in the **Search** window. Tap the desired user to open the **EDIT USER** screen.
3. Edit user's data:

- Tap the **Full Name** field to edit the users first or last name
- Check or uncheck functions check-boxes to edit **Role**
- Tap **Change Password** to enter a new password
- To reassign badge, tap **Reassign Badge** and scan the new badge
- Change the user **State (Active/ Inactive)**. Inactive users' access to the analyzer is blocked.
- Scroll down and tap **Delete User** to remove the user record.
- Tap **Save** to save changes and return to **Users** list.

12.2. Test Settings

In the **TEST SETTINGS** screen, you can individually set External Control and Calibration related settings for each test type supported by the MeMed Key® analyzer.

1. Tap **Menu > Settings > Test Settings** to open the **Test Settings** screen.
2. Tap a test to open the desired test type screen settings.



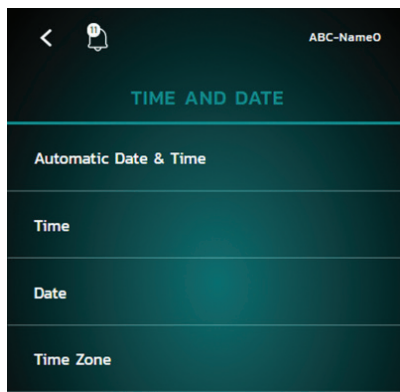
Test settings per test type

- To enable the selected test type, switch on the **Test Enabled** control of the relevant test.
- **External control notification interval (days):** select a desired period of time to receive periodic reminders to perform External control.
- **Calibration Notification:** select a desired period of time to receive reminders prior to calibration expiration.
- **Analytes Concentration Display Units:** view the units in which analytes concentrations are displayed

Tap **Save** to save changes.

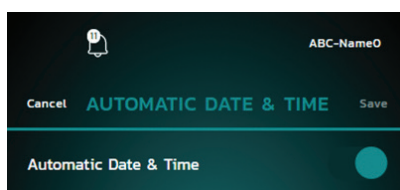
12.3. Time and Date Settings

In the **TIME AND DATE** settings screens you can set and manage the times preferences for the analyzer.



TIME AND DATE menu

1. Tap **Menu > Settings > Time and Date** to open the main **TIME AND DATE** menu and view the current time, date and time zone settings.
2. Tap the desired setting to open the relevant screen.

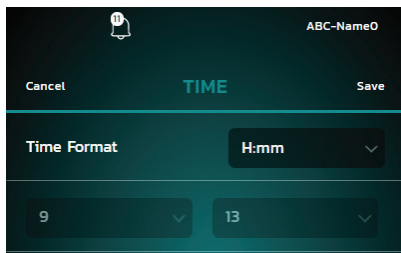


IMPORTANT! This option is only available when the Analyzer is connected to Internet.

To set the Automatic time and date, tap **AUTOMATIC DATE AND TIME** in the

TIME AND DATE menu. Then toggle the Automatic Time and Date switch ON to disable manual editing of the analyzer time and date.

Tap **Save** to save changes.



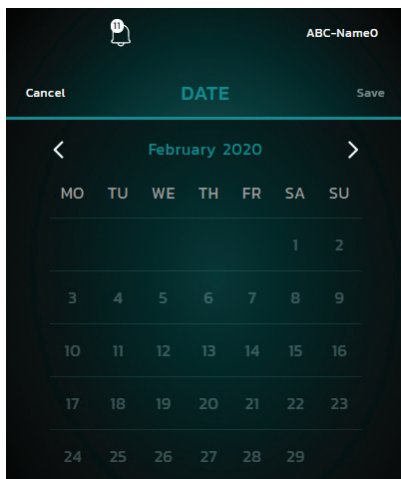
TIME

You can manually set the time using the time picker in one of two formats – AM/PM or 24 hours.

The time format editing is disabled when **Automatic Date and Time** is ON.

To set the time manually:

1. Tap **Time** in the **TIME AND DATE** menu.
2. Tap the format, hours, minutes, and AM/PM fields to set the time.
3. Tap **Save** to save changes.



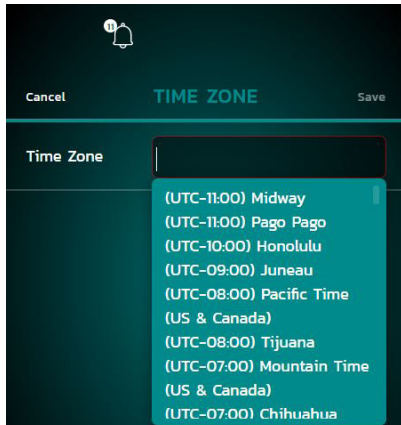
DATE

You can manually set the date using the calendar.

The date selection is disabled when **Automatic Date and Time** is ON.

To set the time manually:

1. Tap **Date** in the **TIME AND DATE** menu.
2. Tap the current date.
3. Tap **Save** to save changes.



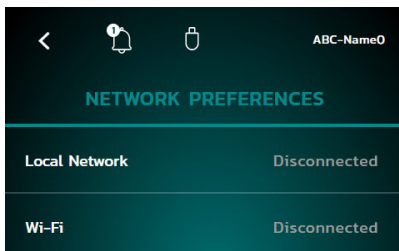
TIME ZONE

To set the time zone, tap **Time Zone** in the **TIME AND DATE** menu, then scroll or start typing to select your time zone from the drop-down list.

Once the time zone is changed, tap **Save**. The analyzer time will be updated accordingly.

12.4. Network Preferences

In the "Network preferences" settings" screens you can configure the analyzer's connection to a network of your choice.



NETWORK PREFERENCES menu

Tap **Menu > Settings > Network Preferences** to open the **NETWORK PREFERENCES** menu. On the right side the current network settings status is displayed. Tap the desired option to open to the relevant configuration screen.



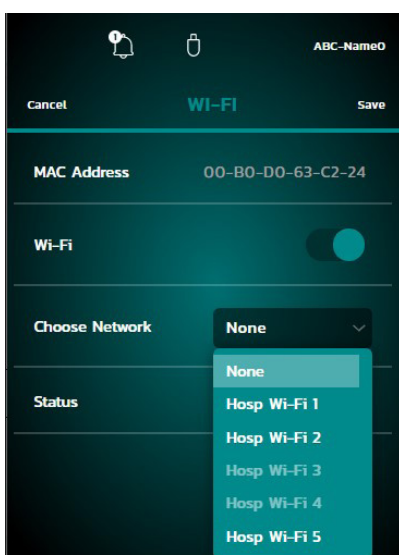
NOTE: The analyzer's MAC address may be required to connect the analyzer to the network. It can be found in both Local Network and Wi-Fi Settings screens.



LOCAL NETWORK SETTINGS

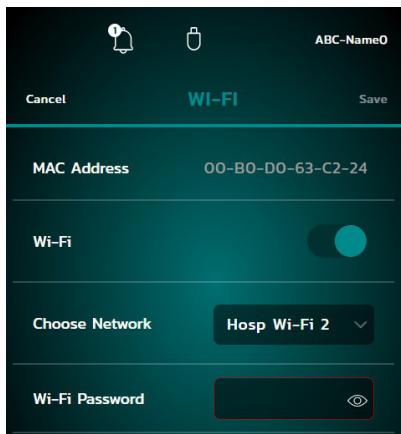
DHCP is set to ON by default. To manually configure the network connection:

1. Set the **DHCP** toggle to OFF.
2. Tap the fields and use the virtual keyboard to enter the IP address, Subnet Mask, DNS and Gateway data.
3. Tap **Save** to save changes and return to the previous screen. The **NETWORK PREFERENCES** screen will be updated accordingly.



WiFi Connection

1. From the **NETWORK PREFERENCES** screen, tap **WiFi**.
2. Enable the WiFi connection.
3. Tap the **Choose Network** drop-down list to view available Wi-Fi networks and select a network from the list.

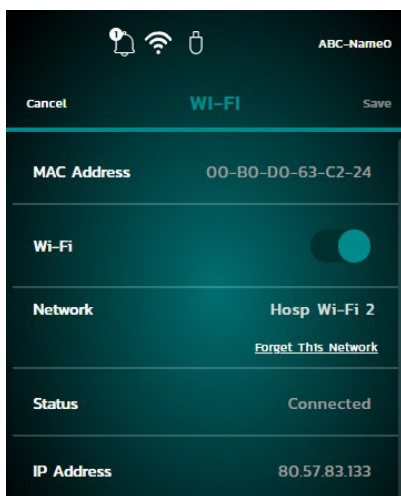


4. Tap the **WiFi Password** field to enter the network password using the virtual keyboard.
5. Tap **Enter** to complete connection.



NOTE: MeMed Analyzer software does not support:

1. Wi-Fi networks that require username.
2. CAPTCHA Verification..



After the connection is established, the following will be displayed under the network name:

- IP address
- **Forget This Network** button
- Status will be changed to **Connected**



NOTE: The purpose of the Forget This Network button is to allow re-entering the Wi-Fi network password.



CAUTION! Connection to unsecured networks may expose the system to cybersecurity threats. It is recommended to connect to a secure network.

12.5. Connectivity

12.5.1. Operation Modes

During the Initial Setup, the analyzer's operation mode is selected (see [About Operation Modes](#) section for details).



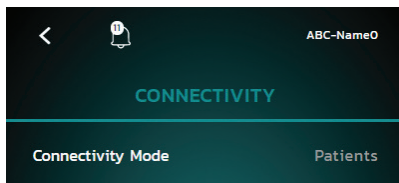
NOTE: Prior to connecting the Analyzer to an external data management system, connect to a network (see [Network Preferences](#) section).

The operation mode can be changed at any time via the settings menu as described below.



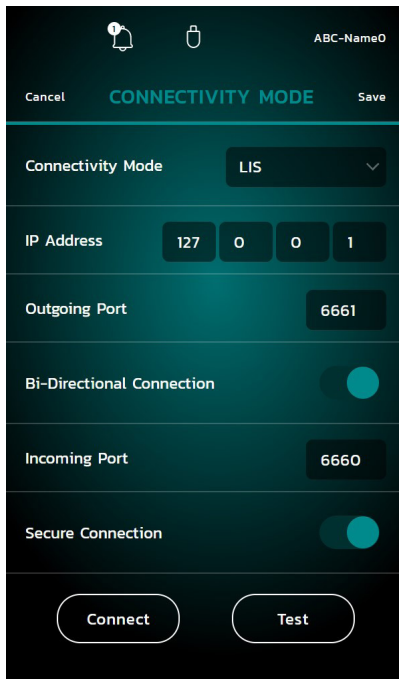
IMPORTANT! If the operation mode is changed via the settings screen, all test results and patient data stored on the Analyzer up to that point will be deleted.

12.5.2. Connectivity Menu



CONNECTIVITY Menu

1. Tap **Menu > Settings > Connectivity** to open the **CONNECTIVITY** menu. The current connectivity mode is indicated on the right (LIS / Patients / Samples).
2. Tap **Connectivity Mode** to view and change the connectivity mode.



CONNECTIVITY MODE

The **CONNECTIVITY MODE** screen displays the current connectivity mode. Tap the **Connectivity Mode** drop-down list and select the desired connectivity mode:

PATIENT - for more information, refer to [Standalone Mode: Patient](#)

SAMPLE - for more information, refer to [Standalone Mode: Sample](#)

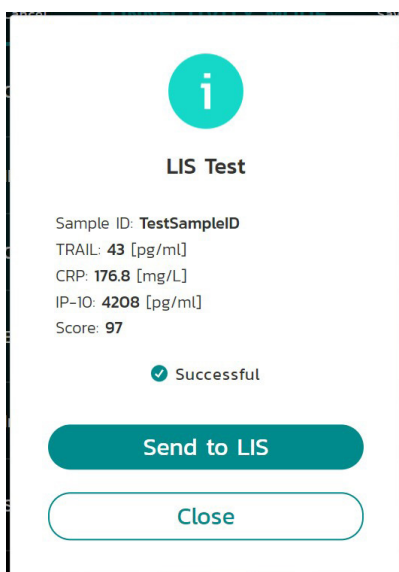
LIS
If LIS is selected, enter the relevant connectivity details:

- LIS IP address
- Tap **Bi-Directional Connection** to enable sending data to and receiving it from LIS. When this option is off, only sending data to LIS is enabled.
- Tap **Secure Connection**⁴ to enable or disable secure connection.



NOTE: The same IP address must be added to the [Network Access](#) list.

Tap **Connect** to connect to LIS.



LIS Connectivity Test

Optionally, after successful connection, tap **Test** to send a test message containing pre-defined test results through the LIS connection. The **LIS Test** pop-up message will appear.

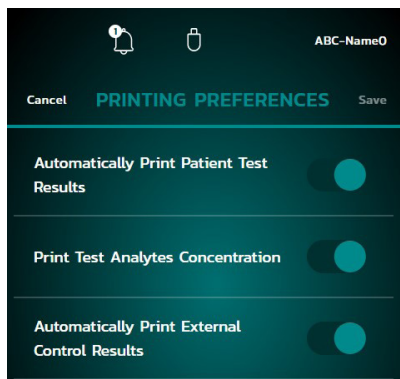
Tap **Send to LIS** and wait for the **Successful** checkmark to appear.

Tap **Close** to return to The **CONNECTIVITY MODE** screen.

Tap **Save** to connect and return to the **CONNECTIVITY** menu. The connection status will be updated accordingly.

4 A secure connection is encrypted by one or more security protocols to ensure the security of data flowing between two or more nodes.

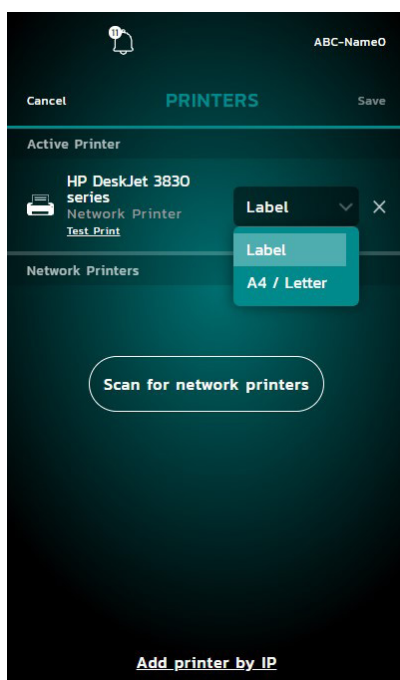
12.6. Printer Settings



Printing Preferences

Tap **Printing Preferences** to select the preferred setting for:

- Automatic printing of test results
- Printing of test analytes concentrations
- Automatic printing of EC results



Managing Printers

- Tap **Printers** to add, set up, or remove printers.
- To select the Active Printer type (Label or A4/Letter), tap the drop-down list next to the printer name

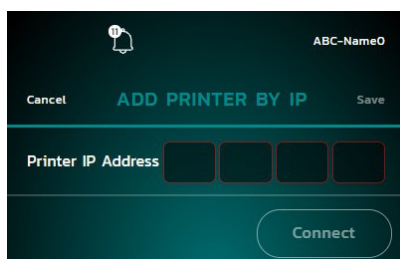


NOTE: It is recommended to print a test page when a new printer is connected to the analyzer.

- To print a test page, tap **Test Print**

The options below are only available when no local printer is connected:

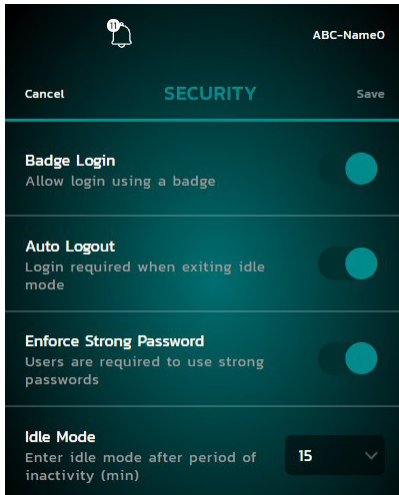
- To find network printers, tap **Scan for network printers**.



- To add a printer by IP address, tap **Add printer by IP**. Then fill in the IP address and tap **Connect**.

12.7. System Settings

12.7.1. Security Settings

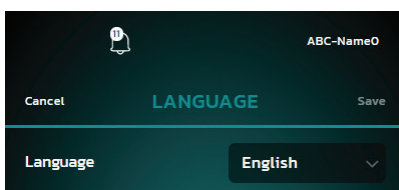


Tap **Menu > Settings > System Settings > Security** to access the SECURITY options screen.

- Toggle the **Badge Login** switch to enable or disable login using a badge scan.
- Toggle the **Auto Logout** switch ON to automatically log out whenever the idle mode is activated (see also [Idle Mode](#) section).
- Toggle the **Enforce Strong Password** switch to enable or disable enforcing password length and complexity requirements.
- Tap the **Idle Mode** inactivity time drop-down list to select the desired time interval between the last touch on the screen and analyzer entering the **Idle Mode**.

Tap **Save** to keep the changes or **Cancel** to discard.

12.7.2. Languages Settings

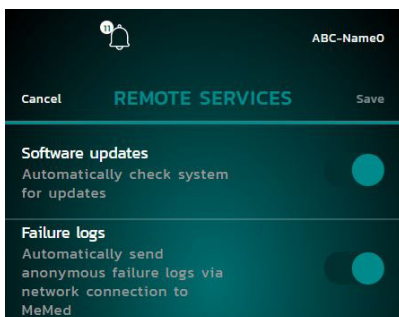


Tap **Menu > Settings > System Settings > Language** to access the LANGUAGE selection screen.

Tap the drop-down list to select the interface and input language.

Tap **Save** to keep the changes or **Cancel** to discard.

12.7.3. Remote Services



Tap **Menu > Settings > System Settings > Remote Services** to access the REMOTE SERVICES screen.

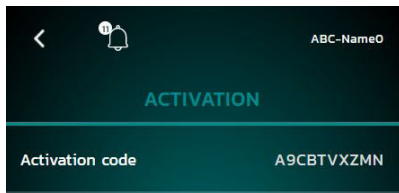
- Toggle the **Software Updates** switch to enable or disable automatic checking for updates.
- Toggle the **Failure Logs** switch to enable or disable automatic sending of anonymized failure logs to MeMed.

NOTE: to allow transfer of the logs please make sure to:

1. Open port 443 for outgoing HTTPS traffic.
2. Whitelist the following addresses in the network settings:
 - a. <https://www.googleapis.com/>
 - b. <https://storage.googleapis.com/>

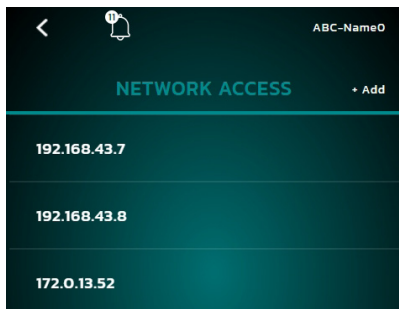


12.7.4. Activation

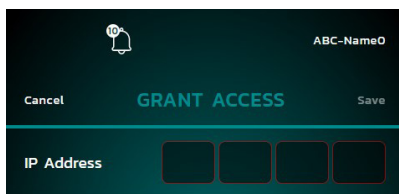


Tap **Menu > Settings > System Settings > Activation** to access the ACTIVATION screen. This screen displays the currently used activation code. Tap the Activation code line to enter a new one.

12.7.5. Network Access

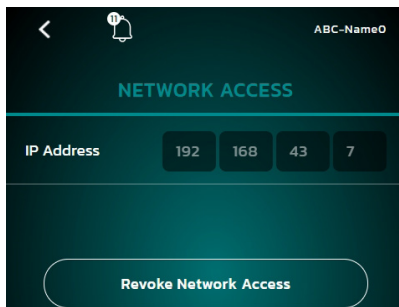


Tap **Menu > Settings > System Settings > Network Access** to allow access to the analyzer via network. The list of IP addresses allowed access is displayed.



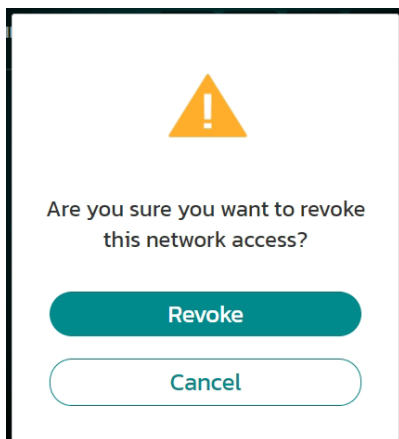
To add a new address:

1. Tap **+Add**.
2. In the GRANT NETWORK ACCESS screen, type in the IP address.
3. Tap **Save**.



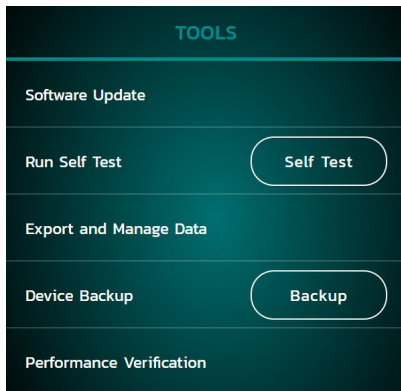
To revoke access:

1. Tap the address line and select **Revoke Network Access**.



2. In the confirmation dialog, tap **Revoke**.

13. Tools



The Tools menu provides access to:

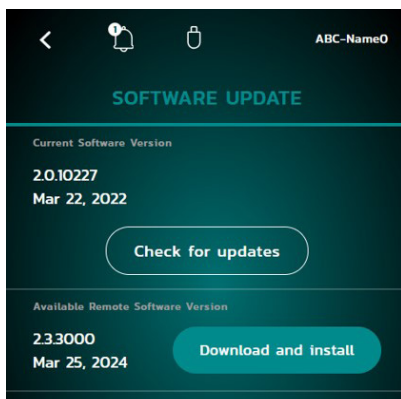
- Installing software updates
- Running self-test
- Data export and management
- Backup
- Performance Verification⁵

To access the **TOOLS** menu, tap **Menu > Tools**.



NOTE: Access to various tools is subject to User Settings. [User Settings](#)

13.1. Software Updates



To view the current software version, open the Tools menu and select **Software Update**.

The **Software Update** screen displays the current software version information as well as available updates. Software updates released by MeMed Diagnostics can be either available on the remote MeMed server or on the SW Update USB storage device as described below.

To install a software update from a USB storage device:

1. Connect the USB storage device containing the software update to your MeMed Key® analyzer's USB port.
2. In the **Software Update** screen, the USB software version will appear below the current software version.
3. Tap **Install** to begin the update process.

To install a software update from a remote server:

1. Tap **Check for updates**. If an updated software version is available it will appear below the current software version.
2. Tap **Download and Install** to begin the update process.

The software update process may take up to 40 minutes. The analyzer will not be accessible for any operations during this time. Do not shut down the analyzer during this time. After the update is over, the analyzer will automatically restart and display the software update results.

The following information is preserved during software updates:

- Test, EC, and calibration results
- User accounts
- Locally stored patients
- System settings
- Audit trail

⁵ Availability of this mode depends on the sample type configuration.



NOTE: If the **Install** button is disabled, check the USB storage device connection. If both remote and USB SW update are available, the newest version installation will be enabled.



NOTE: Software updates can be installed by users with IT Admin access rights when the Analyzer is in Ready or Degraded mode.

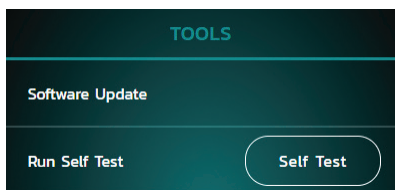


NOTE: The duration of the software download from the remote server may be affected by the network connection quality.

13.2. Self-Test

The MeMed Key® analyzer software includes a self-test routine that is run every time the analyzer is powered on or reset to factory settings.

If the self-test has not been run for over one week, the system triggers the periodic self-test and provides indication that the self-test is running.



To initiate a self-test, tap **Menu > Tools > Run Self-test**.

During the self-test a progress indication will be displayed. Do not shut down the analyzer during this time.

Once the self-test is completed, the **Home** screen will be displayed. If the self-test has failed, the analyzer will enter Degraded Mode.

13.3. Export and Manage Data

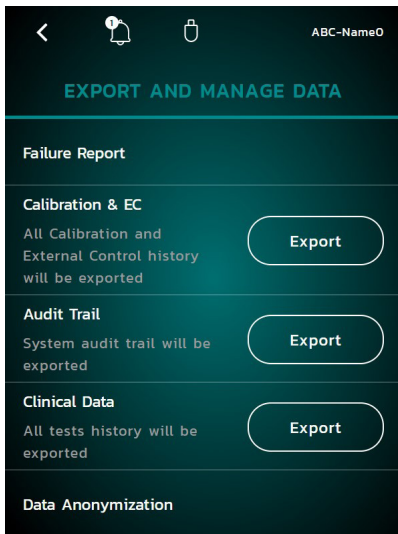
13.3.1. Export Data to a USB Storage Device

You may export data from your MeMed Key® analyzer to a USB storage device by accessing the Data export functionality in the Tools menu. The following data types can be exported:

User Type	Available Reports
Operator	Calibration and external control, failure report
Lab Manager	Calibration and external control, failure report, clinical data,
IT Admin	Audit trail export, calibration and external control, failure report, clinical data,



NOTE: Data Anonymization function is available for Lab Manager and IT Admin only.



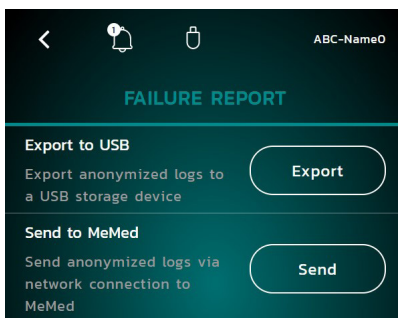
To initiate a data export process:

1. Connect a USB storage device to your MeMed Key® analyzer's USB port.
2. Navigate to **Menu > Tools > Export and Manage Data**.
3. Tap **Export** for the desired data type to begin the exporting process.

During data exporting process, a progress indication will be displayed. Do not shut down the analyzer or remove the USB storage device during this time. After the data is exported, the analyzer will display a completion notification. Tap **OK** to acknowledge and remove the USB storage device as indicated.

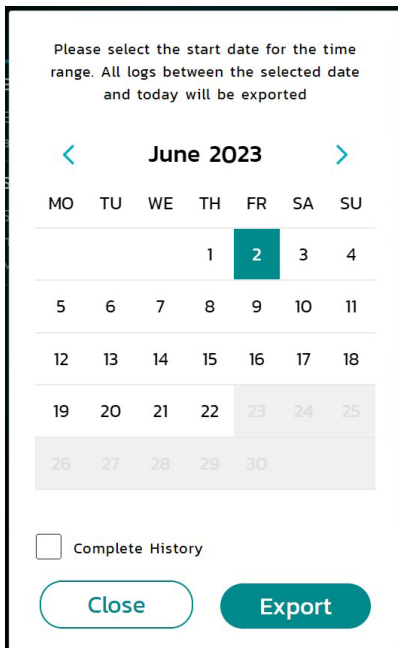


NOTE: If the **Export** button is disabled, check the USB storage device connection.



Under Failure Report, you can:

- Export failure reports to a USB storage device
- Send anonymized failure logs to MeMed directly from the analyzer using remote service.



To set the date range when exporting data to a USB storage device:

1. Tap **Export**. The Date Picker window will be displayed.
2. Select the start date for the time range (from the selected date to today) or tick the **Complete History** checkbox for all logs.
3. Tap **Export** to export the logs.

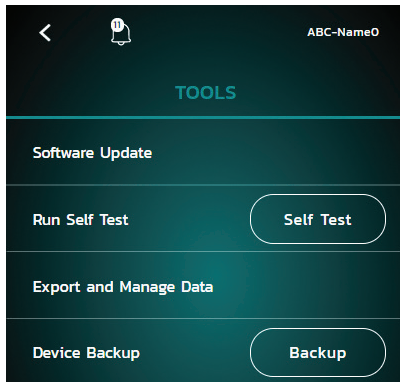
13.3.2. Backup the Analyzer

You can perform a data backup in preparation for restoring the data on another device or as a routine backup. The following data is included in the backup process:

- Patients list (in Standalone Mode only)
- Test results history
- Settings, including Users



NOTE: Calibration and external control data are not included in the Analyzer backup.



To initiate a backup process:

1. Connect a USB storage device to the MeMed Key® analyzer's USB port.
2. Navigate to **Menu > Tools**.
3. Tap **Backup** to begin the analyzer backup process.

During the backup, a progress indication will be displayed. Do not shut down the analyzer or remove the USB storage device during this time.

After the data is backed up, the analyzer will display a completion notification. Tap **OK** to acknowledge and remove the USB storage device as indicated.

13.3.3. Restoring Data from USB Storage Device

The Data Restore feature allows you to reuse settings from an existing device to complete the installation of a new analyzer, as part of the Initial Setup Wizard. The following data is included in the Backup & Restore process:

- Patients list (Standalone Mode only)
- Test results history
- Settings
- Users' details



NOTE: Calibration and external control data are not included in the data restore. After the data restoration is completed, the Analyzer must be calibrated before the first test.

The data restore process consists of the following steps:

1. Locate the USB storage device with the data backup.
2. Connect the USB storage device containing the backup file to your new MeMed Key® analyzer's USB port.

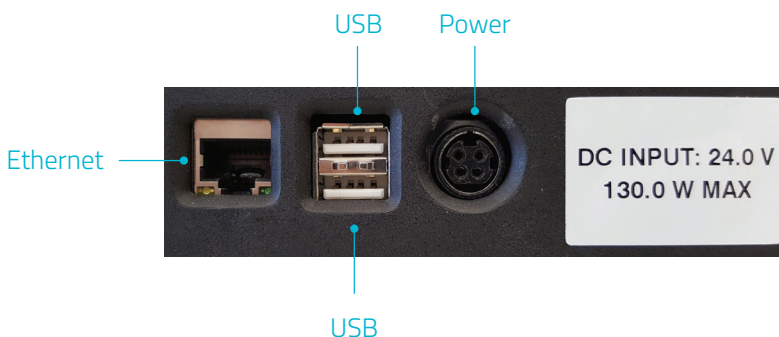


Figure 4: Connection Ports on Rear Panel

3. Power up the analyzer and perform the first steps of the Initial Setup Wizard, until the **Welcome** screen is displayed.
4. Tap **Restore** on the **Welcome** screen (if the **Restore** button is disabled, check the USB storage device connection).
5. Wait until the data reading process is completed and the analyzer is restarted.



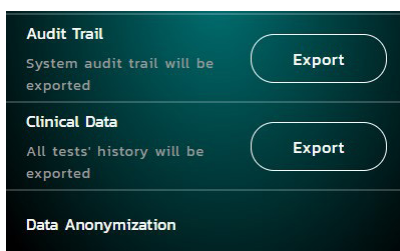
IMPORTANT! The Analyzer must be calibrated at least once in order to run tests. Prior to this, the Analyzer Login screen appears in a pre-calibrated state and no test may be initiated.

13.4. Data Anonymization

Data anonymization is the process of removing all patient-identifying information stored in the analyzer's memory.



CAUTION! All patient-identifying information will be removed, including the patient list and patients' identification in the test results history. The patients' identification details will be replaced with randomly generated identifiers.

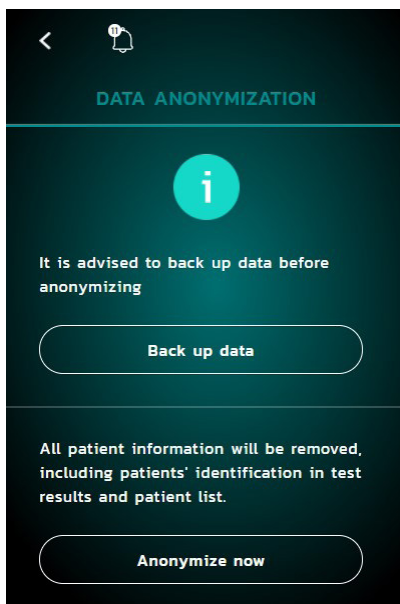


To initiate anonymization process:

1. Navigate to **Menu > Tools > Export and Manage Data**.
2. Tap **Data Anonymization** to open the analyzer anonymization screen.

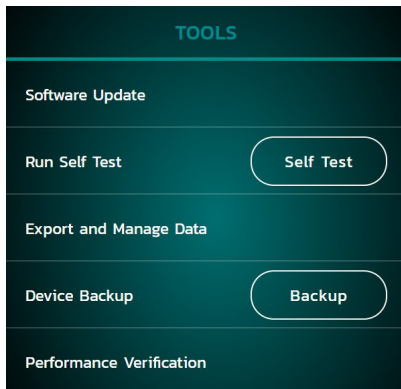


IMPORTANT! It is recommended to back up the Analyzer data before anonymizing your data!



3. During anonymization process, a progress indication will be displayed. Do not shut down the analyzer during this time. After data anonymization completion, the home screen is displayed.

13.5. Performance Verification

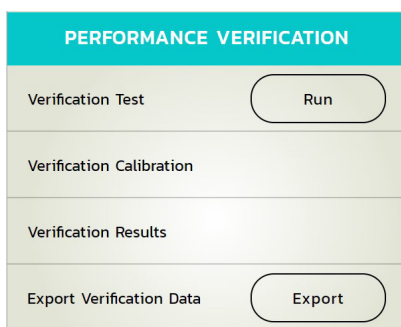


NOTE: Availability of this mode depends on the sample type configuration.

In the Tools menu, tap Performance Verification to run the Performance Verification sequence.



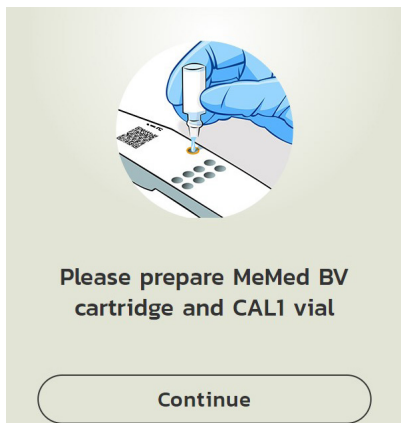
CAUTION! This mode is not intended for patient testing.



From this menu you can:

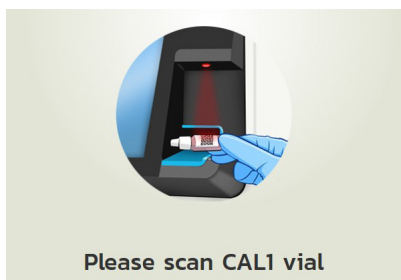
- Run Performance Verification
- Calibrate the analyzer for Performance Verification
- View Performance Verification results
- Export Performance Verification data

13.5.1. Calibrating the Analyzer for Performance Verification



Initiate calibration

1. From the Performance Verification menu, select **VERIFICATION CALIBRATION**.
2. Locate the desired test and sample type and tap **Calibrate**.
3. Follow the Calibrator Instructions for Use to prepare test cartridge and CAL1 calibrator vial.
4. Tap **Continue** on the **New Calibration** screen to start the first stage.



5. Identify Calibration vial #1.

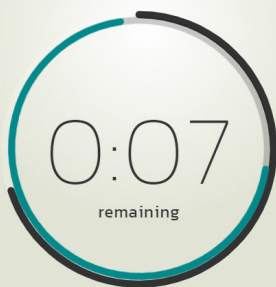
To identify the vial, place it under the barcode scanner focused beam as illustrated.



Please scan and insert
cartridge with CAL1

Calibration will start in 11

Start Calibration



6. Dispense Calibration fluid and insert test cartridge.

Dispense the prescribed volume of Vial #1 Calibration fluid into the sample well of the cartridge, as instructed in the Calibrator IFU, scan and insert the test cartridge as illustrated.

7. Start calibration.

Verify the process details and tap **Start Calibration** or wait 15 seconds for the first calibration stage to start automatically.

At this time, a progress indication is displayed.

Once stage 1 is completed, the stage completion screen will be displayed.

1. Tap **Remove Cartridge** to remove the used test cartridge and proceed to stage 2.
2. Remove the test cartridge and dispose of it according to your lab practices.
3. Follow on-screen instructions to repeat the process for further stages using the next cartridge(s) and Calibration fluid vials.

ABC-NameO

NEW VERIFICATION CALIBRATION

1 Calibrator CAL1
2 Calibrator CAL2
3 Calibrator CAL3

1/3
Completed

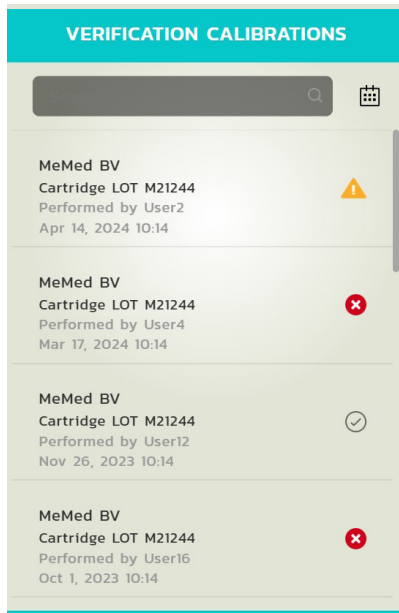


Successfully calibrated for BV
Verification LOT M21244

After the last stage is completed the completion message for the entire process will be displayed.

Remove the last test cartridge and tap **Finish** to return to the **PERFORMANCE VERIFICATION** menu.

13.5.2. Viewing Performance Verification Calibration History



You can view Performance Verification data in the **VERIFICATION CALIBRATIONS** screen.

The **VERIFICATION CALIBRATIONS** screen displays a chronological list of previously completed calibrations. The following information is available:

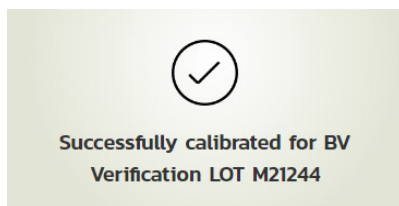
- Lot data
- Calibration date and time
- User who performed calibration
- Calibration result (pass/fail/aborted)

You can search for calibration results according to:

- Test types via the filter control (provided there are two or more test types)
- Specific dates via a calendar control.

To set the dates:

1. Tap the Calendar icon  next to the **Search** field.
2. Select the desired dates.
3. Tap **Confirm** to view the calibration results for the selected period.



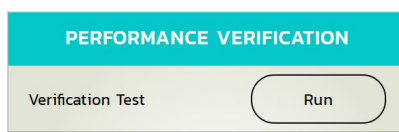
To view a specific calibration result, tap a row from the **VERIFICATION CALIBRATIONS** list. The calibration result details screen will open.



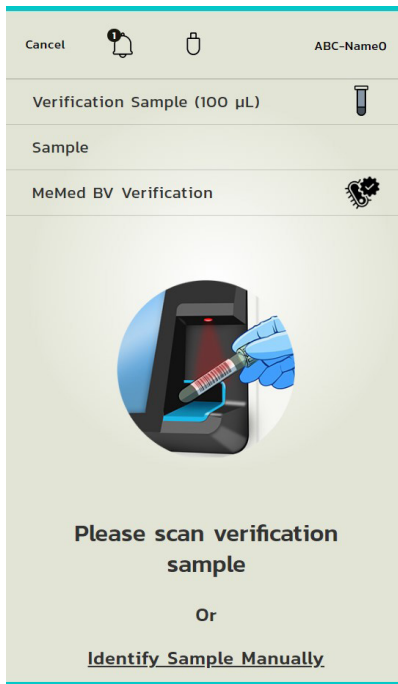
NOTE: Calibration results obtained in this mode are valid only for Performance Verification and cannot be accessed through regular calibration menus.

Calibration results obtained through regular calibration process are valid only for clinical tests and cannot be accessed in this mode.

13.5.3. Running Performance Verification



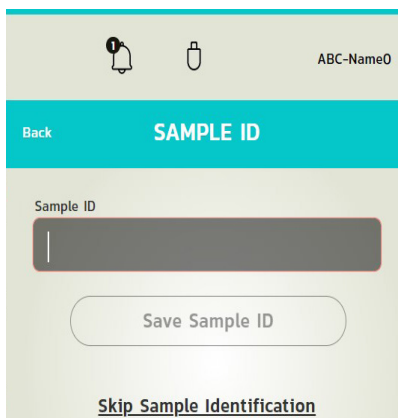
1. Tap **Run** in the Verification Test line. The **Test Details** screen is displayed.



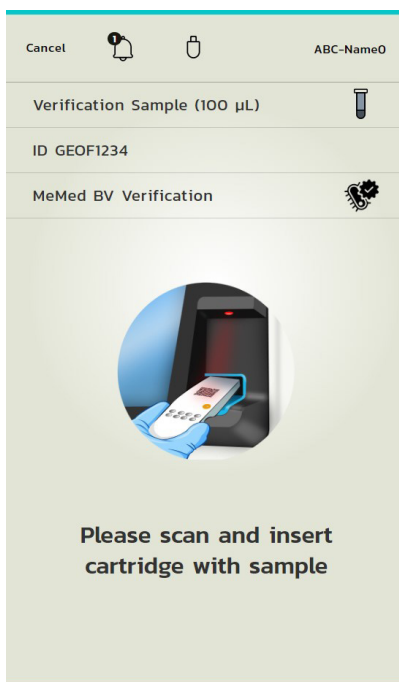
2. Place the sample identification label facing upward under the barcode scanner as illustrated and wait for the scanning beeper to sound.

The Sample data field will be updated according to the data entered.

If sample identification data is not available on the label, tap **Identify Sample Manually**.



3. Manually enter sample ID and tap **Save Sample ID** or tap **Skip Sample Identification** to continue to the test cartridge insertion stage. In such case, a random ID will be assigned to the test automatically. The generated ID cannot be updated at a later time. Write down the assigned ID for further test identification.



4. Place the test cartridge with the verification sample so that the label is facing upward until the scanning beeper is heard.
5. Verify that the test cartridge orientation is correct and insert it into the test cartridge port.

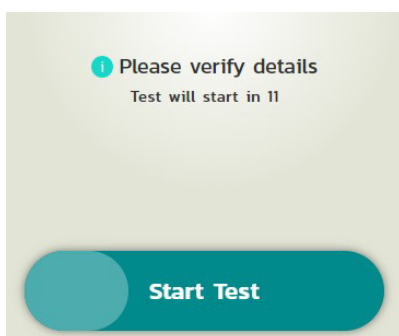
The **Test Type** field will be updated accordingly. The test details screen is displayed.



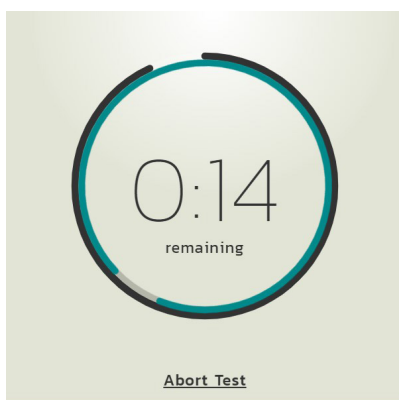
NOTE: If the test cartridge is ejected or the test details screen is not displayed, refer to the [Troubleshooting](#) chapter.



IMPORTANT! A scanned test cartridge cannot be reused. If the test is aborted or canceled after scanning the test cartridge, dispose of the test cartridge according to laboratory safety procedures.

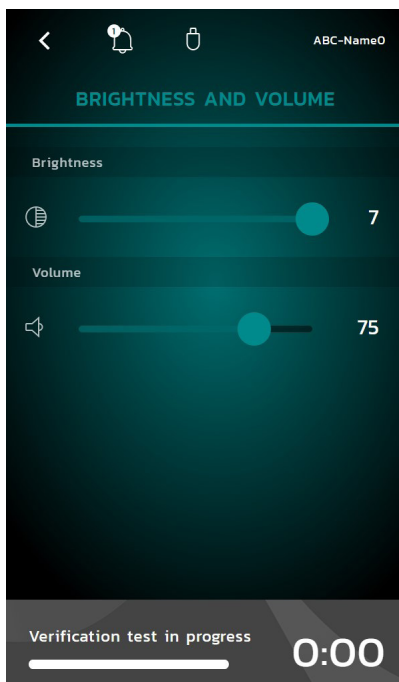


6. Verify that the **Sample**, **Test Type** and **Sample Type** are correct.
7. Tap **Start Test** or wait 15 seconds for the test to start automatically.

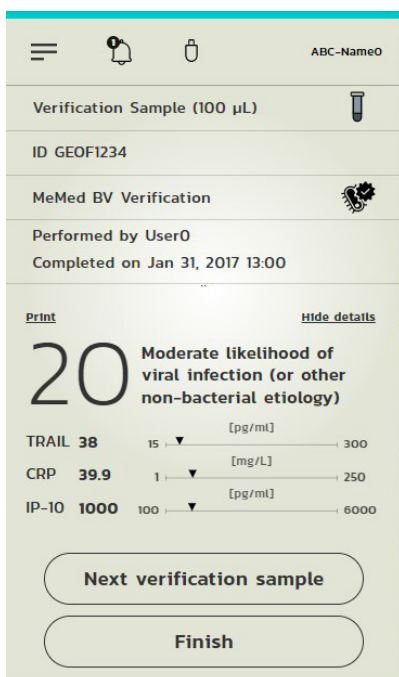


During the test process:

- Tap **Abort Test** to cancel the test.
- A progress indication is displayed.
- Menu access is limited to Results history, volume and brightness adjustment and Help screen.
- Upon accessing one of these functionalities through the menu, the test screen is minimized at the bottom of the screen. To open the screen again, tap the minimized panel.



IMPORTANT! Aborting an active test will result in test cartridge expiration and all test data will be discarded.



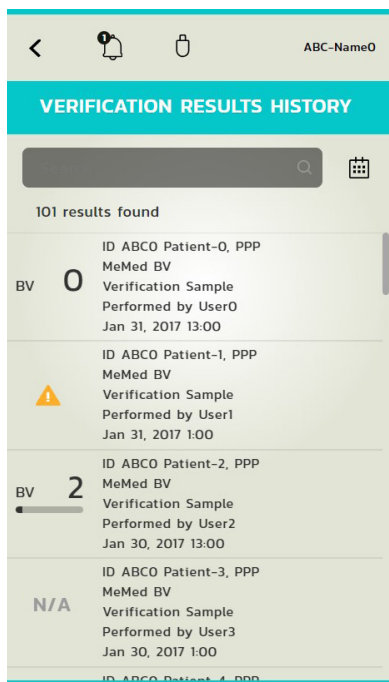
After the test is completed, the detailed test results are displayed and test cartridge is ejected. Remove the test cartridge.

- Tap **Hide Details** to view the test score only.
- Tap **Next Verification Sample** to run another Performance Verification test.
- Tap **Print** to print the Performance Verification test results.
- Tap **Finish** to close test results and return to the Performance Verification menu. The test results are automatically stored in your analyzer. You may review the results at a later time, as described in [Viewing Verification Results History](#).



WARNING! Use safe laboratory practices when handling samples and reagents. Failure to safely dispose of samples or reagents may result in contamination or injury.

13.5.4. Viewing Verification Results History



To access the **VERIFICATION RESULTS HISTORY** screen, tap **Verification Results** in the PERFORMANCE VERIFICATION menu.

The **VERIFICATION RESULTS HISTORY** screen displays a chronological list of previously completed tests, with the newest test on top. For each test the following information is available:

- **Test results are displayed with a corresponding icon:**

Score - for successfully completed tests

- for failed tests

N/A - for aborted tests

- for tests with invalid results

For each test result, the Sample ID and the test date and time are indicated.



NOTE: Test results obtained in this mode are valid only for Performance Verification and cannot be accessed through regular Results menus.

Clinical test results cannot be accessed in this mode.



IMPORTANT! For detailed information on the specific test type results and interpretation, refer to the relevant test cartridge Instructions for Use.

13.5.5. Locating a Performance Verification Result

You can locate specific test results by searching for a patient name or ID, a sample ID or test type, and/ or by time filtering the tests history as described below.



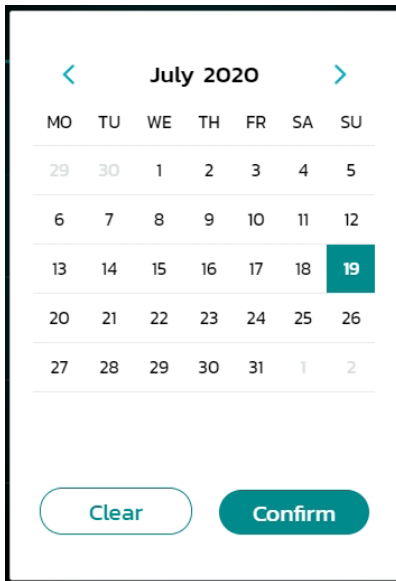
To locate specific test results:

Tap the **Search** field and type in one of the following:

- Sample ID
- Test type

The analyzer will automatically display the relevant test results.

Tap a result to open the test result screen or tap the control to cancel the search.



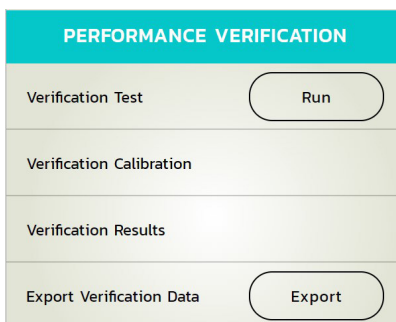
To filter test results according to specific dates:

1. Tap the calendar control  to open the calendar.
2. Select the desired date or start and end dates for the desired time range and tap **Confirm** to view the test results for the selected time range.

The applied date filter is indicated by the highlighted calendar control .

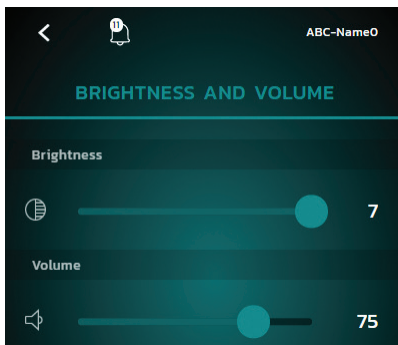
To clear the filter, open the calendar and tap **Clear**.

13.5.6. Exporting Performance Verification Data



To export the performance verification data, connect a USB storage device to the analyzer and tap **Export** in the **Export Verification Data** line of the **PERFORMANCE VERIFICATION** menu.

14. Brightness and Volume



To change the display settings of the analyzer screen:

1. Tap **Menu** to open the main menu.
2. Select **Brightness and Volume**.
3. In the **Brightness and Volume** screen, drag the control slider to change the brightness and volume levels as needed.



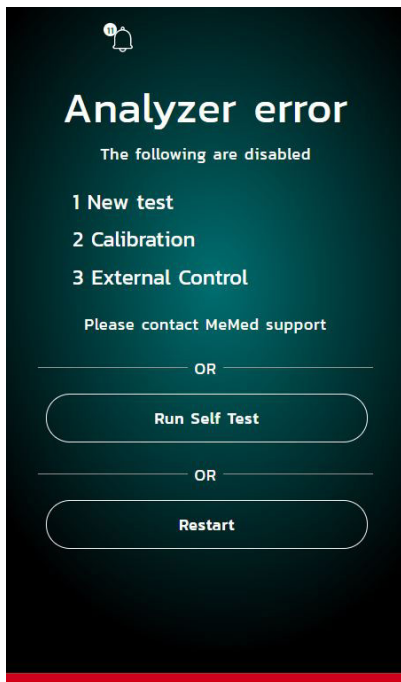
IMPORTANT! Moving the Volume control all the way to the left results in muting the Analyzer.

15. Troubleshooting

15.1. Error Modes

To protect the system's integrity and test results accuracy, some system errors may cause the analyzer to enter Degraded or Fatal mode.

15.1.1. Degraded Mode



In degraded mode, the following functionalities are not available:

- Running tests
- Running Calibration
- Running External control

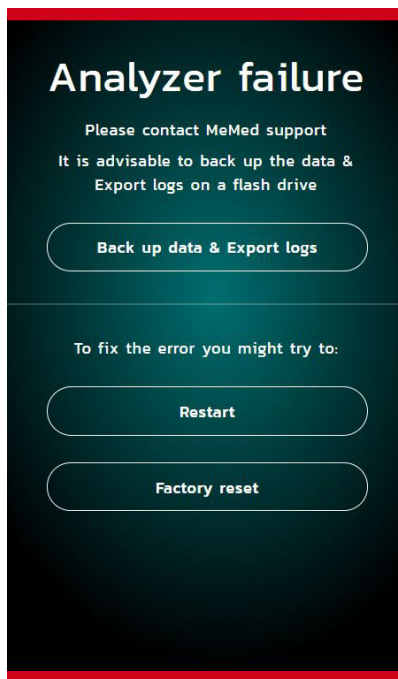
All other functionalities may be accessed as usual via the main menu. A visual indication of the degraded mode is provided in all system screens.

The **Home** screen in degraded mode displays a **Restart** control. Tap **Restart** to restart the analyzer.



NOTE: If the degraded mode persists after rebooting the Analyzer, contact MeMed support (IL/EMEA: support@me-med.com; USA: help@me-med.com).

15.1.2. Fatal Mode



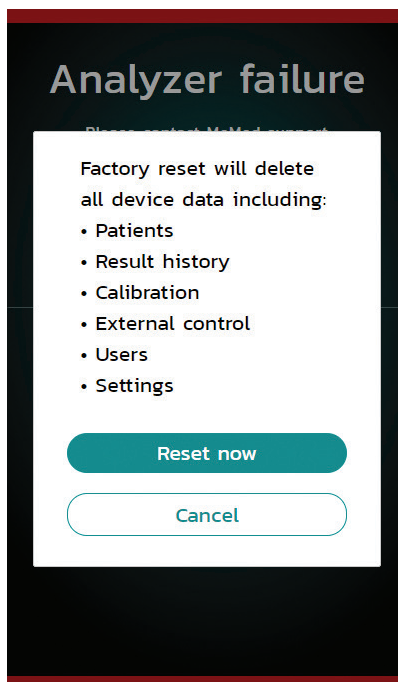
In Fatal mode none of the analyzer functionalities are available.

- Tap **Back up data and Export Logs** to initiate the backup process.
- Tap **Restart** to restart the analyzer
- Tap **Factory reset** to restore factory settings.

15.1.2.1. Restoring Factory Settings



CAUTION! If you restore factory settings, all data is permanently erased. It is strongly recommended to back up the Analyzer data before starting the factory reset process.



The factory reset functionality is only available in fatal mode. To reset the analyzer to factory settings:

1. In the **Analyzer Failure** screen, tap **Factory reset** to initiate the process.
2. Tap **Reset now** in the confirmation pop-up to begin the factory reset process.

During the factory reset process a progress indication will be displayed. Do not shut down the analyzer during this time.

After the process is successfully completed the analyzer will restart and the Initial Setup Wizard will be launched.

15.2. Error Messages and Common Notifications

15.2.1. Login and Initial Setup

Description	Course of action
The system failed to initialize the barcode scanner	If the malfunction occurred during login, try logging in using your password. If the malfunction occurred during active test run, calibration, or external control, the process cannot be completed. Restart the analyzer and reinitiate the process.
The scanned user badge is invalid	Verify that the scanner light is on. Retry scanning the badge or login using your username and password.
Incorrect username or password	Tap the eye icon to show the password characters, verify your identification details and retry login. If login fails a second time, contact your IT Admin or Lab Manager to receive your username and password or scan your badge if applicable.
Disabled user account	The user account has been disabled due to multiple login attempts. Contact IT Admin or Lab Manager.
Incorrect activation code	The analyzer could not verify the initial login code. Retype the code making sure the correct characters are inserted. If the activation fails a second time, contact your local MeMed representative or MeMed support (IL/EMEA: support@me-med.com; USA: help@me-med.com).
Badge is already in use	The scanned badge is already assigned to another user. Please scan a different badge.
Username already exists	Username is already assigned to another user. Use a different username.
Could not find the recovery file in the connected USB storage device	No recovery file was found in the connected USB storage device. Connect the storage device with your recovery file and restart the password recovery process.
Connected USB storage device is not recognized as a recovery device	The analyzer could not identify the USB storage device. Disconnect and reconnect the storage device to a different USB port and try again. If the problem persists, try saving the recovery file on a different USB storage device and try again.

15.2.2. Running a test

Description	Course of action
The scanned barcode is invalid	The scanned barcode does not belong to a MeMed cartridge. Scan a MeMed cartridge to start the test. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).
Cartridge lot expired	The scanned cartridge belongs to an expired lot. Initiate the test using a valid cartridge lot. Check the expiry date on the cartridge label prior to cartridge preparation. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).
Cartridge previously used	The scanned cartridge is no longer valid due to prior use. Prepare a new cartridge. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).
The scanned cartridge was not recognized	The scanned cartridge region code does not match the system region code. Contact MeMed support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).
Pipetting error	Ensure the sample contains no aggregates of any type or clots. Verify sample volume, pipettor calibration, and absence of bubbles. Handle and store cartridges with care. Retry using a different cartridge. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).
Insufficient sample volume	Confirm correct sample volume. Ensure use of calibrated pipettor. Retry using a different cartridge. Refer to the test cartridge IFU for sample volume instructions. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).
Clogged tip error	Ensure the sample contains no aggregates of any type or clots. Retry using a different cartridge. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).
Blocked tip error	Ensure the sample contains no aggregates of any type or clots. Retry using a different cartridge. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).
Internal control out of range	Prevent contamination: wear clean gloves, avoid touching the cartridge top, and ensure there are no spills during sample introduction. Retry using a different cartridge. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).
Analyte measurement error	Retry using a different cartridge. If the error persists: - With the same sample: the sample is not suitable for testing - With a different sample: contact MeMed for further support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).

15.2.3. Calibration

Description	Course of action
The scanned barcode is invalid	The scanned barcode does not belong to a MeMed calibrator vial. Locate the appropriate MeMed calibrator vial and repeat your attempt. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).
Calibration for lot XXX has expired	Calibration for specified lot has expired. Initiate a new calibration for this lot or perform calibration later via the Calibration menu. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).
Timeout between calibration steps	24 hours have passed since the previous calibration stage was completed. Process will be aborted. Reinitiate the calibration making sure the process is completed within 24 hours. It is recommended to complete all calibration stages in one session to avoid timeouts. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).
Calibration vial expired	The scanned calibrator vial has expired. Initiate a new calibration using valid calibrator vials from the same lot. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).
Different calibration vials lot	The scanned calibrator vial lot number is different from the vials used in previous steps. Restart the calibration and verify that all 3 calibrator vials are from the same lot. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).
Cartridge lot mismatch	The scanned cartridge lot number is different from the cartridge used in previous steps. Restart the calibration and verify that all 3 cartridges belong to the same lot. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).
Incorrect calibration vial number	The scanned calibrator vial number does not match the expected vial order. Verify that the calibrator vial number matches the current calibration step to continue. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).
Cartridge expired	The scanned cartridge belongs to an expired lot. Replace the cartridge lot with a valid one and reinitiate calibration. Check the expiry date on the cartridge package label prior to scanning the cartridge. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).
Incorrect calibration vial type	The scanned calibrator vial doesn't match the selected test or sample type. Verify that the test or sample type specified on the calibrator vial label matches the required test or sample type for current calibration and reinitiate the process. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).

Description	Course of action
Insufficient sample volume	Ensure sufficient number of calibrator drops. Retry using a different cartridge. Refer to the Calibrator IFU for sample volume instructions. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).
Pipetting error	Ensure sufficient number of calibrator drops. Verify absence of bubbles. Handle and store cartridges with care. Retry using a different cartridge. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).
Internal control out of range	Prevent contamination: wear clean gloves, avoid touching the cartridge top, and ensure there are no spills during sample introduction. Retry using a different cartridge. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).
Invalid calibration sequence	Repeat the calibration process. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).
Analyte measurement error	Retry using a different cartridge. If the error persists, contact MeMed for further support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).

15.2.4. External Control

Description	Course of action
External control vial is expired	The scanned EC vial has expired. Initiate a new EC process using valid EC vials. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).
Incorrect external control vial type scanned	The scanned EC vial doesn't match the selected test or sample type. Verify that the test or sample type specified on the EC vial label matches the required test or sample type for current EC process, and reinitiate the process. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).
The scanned barcode is invalid	The scanned barcode does not belong to a MeMed EC vial. Use valid MeMed vials. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).
Timeout between external control stages	24 hours have passed since the previous EC stage was completed. Process will be aborted. Reinitiate the EC process and complete both stages within 24 hours. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).

Description	Course of action
External control vial lot mismatch	The scanned EC vial lot number is different from the vial used in the previous step. Restart the EC process and verify that both vials belong to the same lot. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com; USA: help@me-med.com).
Cartridge lot mismatch	The scanned cartridge lot number is different from the cartridge used in the previous step. Restart the process and verify that both cartridges belong to the same lot. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com; USA: help@me-med.com).
Incorrect external control vial scanned	The scanned EC vial number does not match the expected vial order. Verify that the EC number matches the current EC step and continue the process. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com; USA: help@me-med.com).
External control cartridge lot expired	The scanned cartridge belongs to an expired lot. Use a cartridge from a valid lot. Check the expiry date on the cartridge label prior to scanning the cartridge. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com; USA: help@me-med.com).
Insufficient sample volume	Ensure sufficient number of EC drops. Retry using a different cartridge. Refer to the External Control IFU for sample volume instructions. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com; USA: help@me-med.com).
Pipetting error	Ensure sufficient number of EC drops. Verify absence of bubbles. Handle and store cartridges with care. Retry using a different cartridge. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com; USA: help@me-med.com).
Internal control out of range	Prevent contamination: wear clean gloves, avoid touching the cartridge top, and ensure there are no spills during sample introduction. Retry using a different cartridge. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com; USA: help@me-med.com).
Invalid external control sequence	Repeat the external control process. If the problem persists, contact MeMed for further support (IL/EMEA: support@me-med.com; USA: help@me-med.com).
Analyte measurement error	Retry using a different cartridge. If the error persists, contact MeMed for further support (IL/EMEA: support@me-med.com; USA: help@me-med.com).

15.2.5. General notifications

Description	Course of action
Please disconnect the USB printer from the analyzer before proceeding with the software upgrade	Pops after tapping Install/Download and Install , if a USB printer is connected to the analyzer. Disconnect the USB printer and tap Install/Download and Install again.
Failed to install new software version	Software update was not completed. Repeat the process or continue working with current software version.
Software was reverted to previous version	Software update was not completed. Continue working with current software version.
Unable to connect to remote file server for upgrade	Software update was not completed. Check the analyzer's network connection via the Network settings menu. If still unable to connect, continue working with current software version and contact MeMed support (IL/EMEA: support@me-med.com ; USA: help@me-med.com).
Badge is already in use	The scanned badge is already assigned to another user. Please scan a different badge.
Username already exists	Username is already assigned to another user. Use a different username.
Unable to export failure report to USB	Data export was unsuccessful. Ensure the USB storage device has enough available memory. If the error persists, try using a different USB storage device.
Unable to export Audit Logs	Data export was unsuccessful. Ensure the USB storage device has enough available memory. If the error persists, try using a different USB storage device.

15.3. Password Recovery

If a user cannot log in, a password recovery process may be initiated by the IT administrator or Lab manager. For more details, see [Password Recovery Process](#) section.

15.4. Check Before Requesting Repair

Before requesting support or making a service call, make sure you have checked the analyzer connections and followed the instructions provided in [Error Messages and Common Notifications](#) section.

15.5. Service Information

For servicing and user support, please contact a MeMed representative at:

IL/EMEA: support@me-med.com

+972 (4) 8500302

USA: help@me-med.com

1-888-2034550 (US Toll-free)

16. Maintenance

No user maintenance of the MeMed Key® analyzer is required other than external cleaning of the device. For proper functioning of the analyzer, power off or restart the device once a month.

16.1. Cleaning

Cleaning of the MeMed Key® analyzer should be performed whenever necessary. Most spills and stains can be removed with damp cloth or a mild detergent. The approved cleaning materials are:

- Purified water (PW)
- Bleach solution, 10%
- Isopropyl Alcohol, 70%
- Ethanol Alcohol, 70%



CAUTION!

- The Analyzer must be powered off and unplugged before cleaning.
 - Do not use any cleaning liquid or equipment other than those listed above.
 - Do not immerse the Analyzer in water or other liquids.
 - Do not use spraying devices.
- Failure to follow the above precautions could result in damage to the Analyzer.

To clean the analyzer:

1. Power off the analyzer.
2. Unplug the power supply after the shutdown procedure is completed.
3. Clean the outside of the analyzer and the touch display with a clean, lint-free and non-abrasive damp cloth (use water or mild detergent).

16.2. Disposal of the Analyzer

According to European Directive 2012/19/EU (WEEE), the analyzer must not be disposed of in the municipal waste system.

16.3. Software Update

For details and instructions regarding available software updates, refer to [Software Updates](#) section.

17. Terms and Conditions

17.1. General

Use of the MeMed Key® analyzer is subject to the MeMed Terms and Conditions of Sale, provided by MeMed at the time of purchase of the MeMed Key® analyzer or upon delivery of the MeMed Key® analyzer ("Terms and Conditions"). Please review the Terms and Conditions carefully before using the MeMed Key® analyzer.

The procedures described in this User Manual for this MeMed Key® analyzer must be observed in order to ensure proper analyzer performance and to avoid hazards.

MeMed Diagnostics cannot provide or verify MeMed Key® analyzer performance characteristics if the MeMed Key® analyzer is not installed, used and/or maintained in accordance with MeMed Diagnostics' procedures or if accessories not meeting the specifications provided by MeMed Diagnostics are not used.

This MeMed Key® analyzer is for professional In-Vitro Diagnostic Use Only.

MeMed Diagnostics is not engaged in rendering medical advice or services. The results from the MeMed Key® analyzer are not intended in any manner to substitute any professional medical advice or treatment from a trained healthcare professional. MeMed Diagnostics is not responsible for any clinical decisions that are made with respect to the results from the MeMed analyzer.

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The MeMed Key® software and manual were developed solely for use with the MeMed Key® and for in vitro diagnostic applications in line with the intended use as per each test, all as specified in the operating instructions in the Manual.

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18. Technical Specifications

Table 5: Environmental Conditions – Operating

Condition	US	EU
Altitude	Up to 6562 ft	Up to 2000 m
Temperature	59 to 86°F	15 to 30°C
Relative Humidity	20-80% (non-condensing)	

Table 6: Environmental Conditions – Shipping and Storage

Condition	US	EU
Temperature	-20 to 140°F	-29 to 60°C
Relative Humidity	20-80% (non-condensing)	

Table 7: Power Consumption

	US	EU
Current	~1.0 A	~0.5 A
Voltage	100-240 VAC	
Frequency	50/60 Hz	
Max Power Consumption	120 W	
Power Supply Output Voltage	24 VDC	

Table 8: Dimensions

	Metric	Imperial
Height	250 mm	9.84"
Width	250 mm	9.84"
Depth	340 mm	13.4"
Weight	7.5 kg (TBC)	17 lb.

Table 9: Wireless Communication Characteristics

Type	Operating Frequency and Power
Cellular RF Transmit/Receive	800 MHz, 0.25W (+24 dBm) (WCDMA) 800/850 MHz, 2W (+33 dBm) (GSM) 900 MHz, 0.5W (+27 dBm) (EGSM) 1800 MHz, 0.4W (+26 dBm) (DCS) 1900 MHz, 0.4W (+26 dBm) (PCS) 1900 MHz, 0.25W (+24 dBm) (WCDMA) 2100 MHz, 0.25W (+24 dBm) (WCDMA)
IEEE 802.11 b/g/n	2412 – 2472 MHz, 0.215 W

Table 10: Pollution Degree of the intended environment

Pollution Degree (IEC 61010-1:2010)	Level 2
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Table 11: Guidance and manufacturer's declaration – Electromagnetic Emissions

The MeMed Key® analyzer is suitable for use in the electromagnetic environment specified below. The customer or the user of the MeMed Key® analyzer should assure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic Environment Guidance
RF Emissions (Radiated & conducted) CISPR 11 CISPR 32 CFR 47, Part 15 Subpart B	Meets Limits specified in the standards: Group1, Class A Class A Class A	The MeMed Key® analyzer is an unintentional radiator and RF emissions from the device are a byproduct of its internal functions. Therefore, the RF emissions from the device are not likely to cause interference in adjacent electronic equipment.
Radiated RF Spurious Emissions from On-board Wireless Devices CFR 47, FCC 15.247 CFR 47, FCC Part 22&24 EN 301 511 EN 301 908-1 EN 300 328	Meets Limits specified in the standards	The RF spurious emissions from the on-board wireless devices (Cellular and Wi-Fi) in MeMed Key Analyzer are below the limits specified in the standards and therefore are not likely to cause interference to adjacent electronic equipment.
Harmonic Emissions IEC 61000-3-2 (EN 61000-3-2)	Meets Limits specified in the standard: Class A equipment	The MeMed Key® analyzer harmonic emissions are within the limitations specified for harmonic currents injected into the public supply system.
Voltage Fluctuations and Flicker Emissions IEC 61000-3-3 (EN 61000-3-3)	Meets Limits specified in the standard	The MeMed Key® analyzer voltage fluctuations and flicker emission are within the limitations specified for voltages fluctuations and flicker of devices connected to the public low-voltage system.

Table 12: Guidance and manufacturer's declaration - Electromagnetic Immunity

The MeMed Key® analyzer is suitable for use in the electromagnetic environment specified below. The customer or the user of the MeMed Key® analyzer should assure that it is used in such an environment.

Immunity Test	Test Level	Electromagnetic Compliance
Electrostatic Discharge (ESD) IEC (EN) 61000-4-2	±4 kV contact discharge ±8 kV air discharge	The MeMed Key® analyzer complies with the test levels specified in IEC (EN) 61326-2-6 and EN 301 489-1.
Electrostatic Discharge (ESD) IEC 60601-1-2:2014 Ed 4.0	±8 kV contact discharge ±15 kV air discharge	Deviation: When ESD (IEC 60601 levels) is applied to the cover rear top screws and around the Power Supply Unit (PSU) connector, the system might shutdown or require a manual restart to recover. Hence, the analyzer might not be able to generate an in-vitro diagnostic test result.
Radiated Electromagnetic Fields IEC (EN) 61000-4-3	3V/m 80 MHz – 2.7 GHz AM 80% 1kHz	The MeMed Key® analyzer complies with the test levels specified in IEC (EN) 61326-2-6 and EN 301 489-1.
Radiated Electromagnetic Fields IEC (EN) 61000-4-3	3V/m 2.7 GHz – 6 GHz AM 80% 1kHz	The MeMed Key® analyzer complies with the test levels specified in EN 301 489-1.
Radiated Electromagnetic Fields IEC 60601-1-2:2014 Ed 4.0	28V/m 790 MHz – 1100 MHz 1600 MHz – 2090 MHz 2350 MHz – 2650 MHz 5 GHz – 6 GHz AM 80% 1kHz	The MeMed Key® analyzer complies with the test levels specified in IEC (EN) 60601.
Radiated Electromagnetic Fields IEC 60601-1-2:2014 Ed 4.0	28V/m 300 MHz – 790 MHz AM 80% 1kHz	Deviation: When the MeMed Key Analyzer is exposed to Radiated Electromagnetic Fields (IEC 60601 levels), the system might shutdown or might not be able to generate an in-vitro diagnostic test result.
Electrical Fast Transients IEC (EN) 61000-4-4	AC Power Port ±1 kV 5 kHz Signal Input/Output Ports ±0.5 kV 5 kHz	The MeMed Key® analyzer complies with the test levels specified in IEC (EN) 61326-2-6 and EN 301 489-1.

Immunity Test	Test Level	Electromagnetic Compliance
Electrical Fast Transients IEC 60601-1-2:2014 Ed 4.0	AC Power Port ±2 kV 100 kHz Signal Input/Output Ports ±1 kV 100 kHz	The MeMed Key® analyzer complies with the test levels specified in IEC (EN) 60601.
Surge Immunity IEC (EN) 61000-4-5	AC Power Port ±2 kV	The MeMed Key® analyzer complies with the test levels specified in IEC (EN) 61326-2-6 and EN 301 489-1.
Conducted RF Disturbances IEC (EN) 61000-4-6	AC Power Lines 3Vrms 0.15 – 80 MHz AM 80% 1kHz Signal Input/Output Ports 3Vrms 0.15 – 80 MHz AM 80% 1kHz	The MeMed Key® analyzer complies with the test levels specified in IEC (EN) 61326-2-6 and EN 301 489-1.
Conducted RF Disturbances IEC 60601-1-2:2014 Ed 4.0	AC Power Lines 6Vrms 0.15 – 80 MHz AM 80% 1kHz Signal Input/Output Ports 6Vrms 0.15 – 80 MHz AM 80% 1kHz	The MeMed Key® analyzer complies with the test levels specified in IEC (EN) 60601.
Rated Power Frequency Magnetic Fields IEC (EN) 61000-4-8	3A/m 50 and 60 Hz	The MeMed Key® analyzer complies with the test levels specified in IEC (EN) 61326-2-6.
Rated Power Frequency Magnetic Fields IEC 60601-1-2:2014 Ed 4.0	30 A/m 50 and 60 Hz	The MeMed Key® analyzer complies with the test levels specified in IEC (EN) 60601.
Voltage Dips and Interruptions IEC (EN) 61000-4-11	AC Power Lines 0% 0.5 cycles 0% 1 cycle 40% 5/6 cycles 70% 25/30 cycles 0% 250/300 cycles	The MeMed Key Analyzer complies with the test levels specified in IEC (EN) 61326-2-6 and EN 301 489-1.



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