

EZ2[®] Connect MDx User Manual

For use with software version 1.3 or later



IVD

For in vitro diagnostic use



REF

9003230



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1. Introduction

Thank you for choosing the EZ2 Connect MDx. We are confident it will become an integral part of your laboratory.

This user manual describes the EZ2 Connect MDx.

Before using the EZ2 Connect MDx, it is essential that you read this user manual carefully and pay attention to the safety information. The instructions and safety information in the user manual must be followed to ensure safe operation of the instrument and to maintain the instrument in a safe condition.

1.1. About this user manual

This user manual provides information about the EZ2 Connect MDx in the following sections:

- Introduction — contains the intended use and requirements for users
- Safety Information — includes important information on any hazards related to the EZ2 Connect MDx and how to properly use the instrument
- General Description — an overview of the features of the EZ2 Connect MDx
- Installation Procedures — instructions on how to set up the instrument before its first use
- Operating Procedures — includes instructions related to protocol runs
- Maintenance Procedures — contains information about cleaning and maintenance
- Troubleshooting — instructions on what to do in case of any problems with the EZ2 Connect MDx
- Glossary — an alphabetical list of terms or words used in this user manual with explanations
- Technical Specifications — Technical data
- Appendices — additional information about the EZ2 Connect MDx

The appendices contain the following information:

- Appendix A – Legal requirements for the EZ2 Connect MDx
 - Declaration of Conformity
 - Waste Electrical and Electronic Equipment (WEEE)
 - California Proposition 65 Warning
 - Liability Clause
 - License information
- Appendix B – EZ2 Connect MDx Parts and Components/Consumables — Ordering information of the accessories available for the EZ2
- Document Revision History — the changes made to the user manual

1.2. General information

1.2.1. Technical assistance

At QIAGEN®, we pride ourselves on the quality and availability of our technical support. Our Technical Support Departments are staffed by experienced scientists with extensive practical and theoretical expertise in molecular biology and the use of QIAGEN products. If you have any questions or experience any difficulties regarding the EZ2 Connect MDx or QIAGEN products in general, do not hesitate to contact us.

QIAGEN customers are a major source of information regarding advanced or specialized uses of our products. This information is helpful to other scientists and to the researchers at QIAGEN. We therefore encourage you to contact us if you have any suggestions about product performance or new applications and techniques.

For technical assistance and more information, please see our Technical Support Center at support.qiagen.com or call one of the QIAGEN Technical Service Departments or local distributors.

When contacting QIAGEN Technical Support about errors, please have the following information ready:

- EZ2 Connect MDx serial number and software version
- Error code (if applicable)
- Description of instrument status after error (worktable, consumables, etc.) and photos if possible
- Timepoint when the error occurred for the first time
- Frequency of error occurrence (i.e., intermittent or persistent error)
- EZ2 Support Package (see Section 8.1.1 Creating a support package)

1.2.2. Policy statement

It is the policy of QIAGEN to improve products as new techniques and components become available. QIAGEN reserves the right to change specifications at any time. In an effort to produce useful and appropriate documentation, we appreciate your comments on this user manual. Please contact QIAGEN Technical Support.

1.3. Intended use of the EZ2 Connect MDx

The EZ2 Connect MDx system is designed to perform automated isolation and purification of nucleic acids in molecular diagnostic and/or molecular biology applications. It is intended to be used only in combination with QIAGEN kits indicated for use with the EZ2 Connect MDx instrument.

The system is intended for use by professional users, such as technicians and physicians trained in molecular biological techniques and the operation of the EZ2 Connect MDx system.

1.3.1. Limitations of use

It is not intended to use the EZ2 Connect MDx with labware or chemicals that are not supplied with the corresponding kits or specified in the kit handbooks.

The load check is designed to support the operator in ensuring that the worktable is correctly set up as detailed on the graphical user interface (GUI). It is not intended as a replacement for operator diligence in confirming that consumables/reagents/samples are correctly placed on the worktable. For more details about the limitations of the load check, please check the Load check limitations section under Section 5.7.1 Load check.

1.3.2. Research mode

Users can start a protocol in either the IVD mode (validated IVD applications only) or the Research mode (for non-clinical laboratory research applications). * IVD protocols can be used only in IVD mode. This user manual focuses on operating the EZ2 Connect MDx in the IVD mode of the software. Refer to Section 7 Research Mode of this user manual and to the *EZ2 Connect and EZ2 Connect Fx User Manual* (www.qiagen.com) for details on using life science kits on EZ2 instruments.

1.4. Requirements for EZ2 Connect MDx users

The table below covers the general level of competence and training necessary for transportation, installation, use, maintenance, and servicing of the EZ2 Connect MDx.

Task	Personnel	Training and experience
Delivery	No special requirements	No special requirements
Installation	Laboratory technicians or equivalent	Appropriately trained and experienced personnel familiar with the use of computers and automation in general
Routine use (running protocols)	Laboratory technicians or equivalent	Professional users, such as technicians or physicians, trained in molecular biology techniques
Routine maintenance	Laboratory technicians or equivalent	Professional users, such as technicians or physicians, trained in molecular biology techniques
Servicing and annual maintenance	QIAGEN Field Service Specialists or service technicians of an authorized agent	Specialists trained, certified, and authorized by QIAGEN

1.5. Materials required

All instrument parts and components that are required for usage are delivered with the instrument. In case that a part needs to be replaced, refer to Appendix B (Ordering information).

Note: Only use parts and components supplied by QIAGEN.

* Products intended for non-clinical laboratory research include products intended for use in discovering and developing medical knowledge related to human disease and conditions and products for molecular research, genotyping, forensic and human identity testing, food and animal feed safety and quality testing, cancer research, microbiological research, and animal pathogen research. They are not intended to produce results for clinical use and are not themselves the object of the research. These applications do not have medical purpose and thus they are not considered medical devices.

1.6. Materials required but not provided

One of the following QIAGEN DSP kits is required to perform automated isolation and purification of nucleic acids on the EZ2 Connect MDx using the IVD mode of the software:

- EZ1® DSP DNA Blood Kit (cat. no. 62124)
- EZ1 DSP Virus Kit (cat. no. 62724)

Note: Only use kits manufactured by QIAGEN.

Note: The required sample types and instructions for sample collection, handling, and storage are specified within the kit handbooks.

Additionally, the Research mode of the software supports the usage of EZ1&2™ or EZ2 kits for Life Science applications. Kits that are specific for the forensic version of the EZ2 (EZ2 Connect Fx) cannot be used with the EZ2 Connect MDx (e.g., the EZ1&2 DNA Investigator Kit).

2. Safety Information

Before using the EZ2 Connect MDx, it is essential that you read this user manual carefully and pay attention to the safety information. The instructions and safety information in the user manual must be followed to ensure safe operation of the instrument and to maintain the instrument in a safe condition.

Possible hazards that could harm the user or result in damage to the instrument are clearly stated at the appropriate places throughout this user manual.

Always use the EZ2 Connect MDx as specified in this user manual. If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

The following types of safety information appear in this user manual.

WARNING



The term **WARNING** is used to inform you about situations that could result in **personal injury** to you or other persons.

Details about these circumstances are given in a box like this one.

CAUTION



The term **CAUTION** is used to inform you about situations that could result in **damage to an instrument** or other equipment.

Details about these circumstances are given in a box like this one.

The guidance provided in this manual is intended to supplement, not supersede, the normal safety requirements prevailing in the user's country.

Please be aware that you may be required to consult your local regulations for reporting serious incidents that have occurred in relation to the device to the manufacturer and/or its authorized representative and the regulatory authority in which the user and/or the patient is established.

Read carefully the *EZ2 Connect MDx Privacy and Security Guide* for a safe and secure installation, configuration, operation, and maintenance and for compliance with your data protection regulations.

The guide helps you to fulfill your privacy and security responsibilities. QIAGEN informs in this document about the technical implementation of the EZ2 Connect MDx and its limitations. Furthermore, it provides details for potential additional mitigation measures that can be taken in the case that our technical measures cannot fully mitigate potential issues without your support.

Visit the EZ2 Connect MDx product page at www.qiagen.com/EZ2ConnectMDx to obtain the *EZ2 Connect MDx Security and Privacy Guide*.

2.1. Proper use

**WARNING/
CAUTION**



Risk of personal injury and material damage

Improper use of the EZ2 Connect MDx may cause personal injuries or damage to the instrument. The EZ2 Connect MDx must only be operated and maintained by qualified personnel who have been appropriately trained. Servicing of the EZ2 Connect MDx must only be performed by a QIAGEN Field Service Specialist.

WARNING



Risk of personal injury and material damage

The EZ2 Connect MDx is too heavy to be lifted by one person. To avoid personal injury or damage to the instrument, do not lift the instrument alone. Use the handle attached to the box to lift the EZ2 Connect MDx. After the EZ2 Connect MDx has been unpacked, two people must lift the instrument. Lift the instrument by placing your hands underneath the bottom of the instrument.

WARNING



Risk of personal injury and material damage

Do not attempt to move the EZ2 Connect MDx during operation.

Perform the maintenance as described in Section 6 Maintenance Procedures. QIAGEN charges for repairs that are required due to incorrect maintenance.

In case of emergency, power off the EZ2 Connect MDx at the power switch located in front of the instrument and unplug the power cord from the power outlet.

CAUTION



Damage to the instrument

Avoid spilling water or chemicals onto the EZ2 Connect MDx. Instrument damage caused by water or chemical spillage will void your warranty.

WARNING



Risk of fire or explosion

When using ethanol or ethanol-based liquids on the EZ2 Connect MDx, handle such liquids carefully and in accordance with the required safety regulations. If liquid has been spilled, wipe it off and leave the EZ2 Connect MDx hood open to allow flammable vapors to disperse.

WARNING



Risk of explosion

The EZ2 Connect MDx is intended for use with reagents and substances supplied with QIAGEN kits as outlined in respective instructions for use. Use of other reagents and substances may lead to fire or explosion.

If hazardous material is spilled on or inside the EZ2 Connect MDx, the user is responsible for carrying out appropriate decontamination.

Note: Do not place items on top of the EZ2 Connect MDx.

Note: In case of emergency, power off the EZ2 Connect MDx and unplug the power cord from the power outlet.

CAUTION



Risk of personal injury and material damage

Ensure that the EZ2 Connect MDx is switched off and the main plug is removed from the power outlet before you manually move the mechanical components of the instrument.

CAUTION**Damage to the instrument**

Do not lean against the instrument or touchscreen.

2.2. Electrical safety

Note: If instrument operation is interrupted in any way (e.g., due to interruption of the power supply or a mechanical error), switch off the EZ2 Connect MDx instrument first, then disconnect the electrical cord from the power supply before attempting troubleshooting or service activity.

WARNING**Electrical hazard**

Any interruption of the protective conductor (earth/ground lead) inside or outside the instrument or disconnection of the protective conductor terminal is likely to make the instrument dangerous.

Intentional interruption is prohibited.

Lethal voltages inside the instrument

When the instrument is connected to line power, terminals may be live and opening covers or removing parts is likely to expose live parts.

WARNING**Damage to electronics**

Before powering on the instrument, make sure that the correct supply voltage is used.

Use of incorrect supply voltage may damage the electronics.

To check the recommended supply voltage, refer to the specifications indicated in the type plate of the instrument.

WARNING**Risk of electric shock**

Do not open any panels on the EZ2 Connect MDx.

Risk of personal injury and material damage

Only perform maintenance that is specifically described in this user manual. Any other maintenance or repair may only be carried out by an authorized QIAGEN Field Service Specialist.

To ensure satisfactory and safe operation of the EZ2 Connect MDx, follow the advice below:

- The line power cord must be connected to a line power outlet that has a protective conductor (earth/ground).
- Place the instrument in a location so that the power cord is accessible and can be readily connected/disconnected.
- Use only the power cord delivered by QIAGEN.
- Do not adjust or replace internal parts of the instrument.
- Do not operate the instrument with any covers or parts removed.
- If liquid has spilled inside the instrument, switch off the instrument, and if the spill has not been completely contained in the bottom tray, disconnect it from the power outlet and contact QIAGEN Technical Support for advice before attempting any troubleshooting.

If the instrument becomes electrically unsafe, prevent other personnel from operating it and contact QIAGEN Technical Support.

The instrument may be electrically unsafe when:

- The EZ2 Connect MDx or the line power cord appears to be damaged.
- The EZ2 Connect MDx has been stored under unfavorable conditions for a prolonged period.
- The EZ2 Connect MDx has been subjected to severe transport stresses.
- Liquids have come into direct contact with electrical components of the EZ2 Connect MDx.
- The power cord has been exchanged with a non-official power cord.

WARNING

Electrical hazard



Do not touch the EZ2 Connect MDx with wet hands.

WARNING

Electrical hazard



Never install a fuse different from that specified in the user manual.

2.3. Operating environment

Parameters such as temperature range and humidity range are described in the Section 10 Technical Specifications.

WARNING

Explosive atmosphere



The EZ2 Connect MDx is not designed for use in an explosive atmosphere.

WARNING

Risk of overheating



To ensure proper ventilation, maintain a minimum clearance of 10 cm at the sides and rear of the EZ2 Connect MDx.

Slits and openings that ensure the ventilation of the instrument must not be covered.

WARNING

Risk of explosion



The EZ2 Connect MDx is intended for use with reagents and substances supplied with QIAGEN kits as outlined in respective instructions for use. Use of other reagents and substances may lead to fire or explosion.

CAUTION

Damage to the instrument



Direct sunlight may bleach parts of the instrument and cause damage to plastic parts. The EZ2 Connect MDx must be located out of direct sunlight.

CAUTION

Damage to the instrument



Do not use the EZ2 Connect MDx in the vicinity of sources of strong electromagnetic radiation (e.g., unshielded, deliberately operated high-frequency sources or mobile radio devices), because these can interfere with the proper operation.

2.4. Biological safety

Specimens and reagents containing materials from humans should be treated as potentially infectious. Use safe laboratory procedures as outlined in publications such as Biosafety in Microbiological and Biomedical Laboratories, HHS (www.cdc.gov/labs/bmbl).

Samples may contain infectious agents. You should be aware of the health hazard presented by such agents and should use, store, and dispose of such samples according to the required safety regulations.

WARNING



Samples containing infectious agents

Some samples used with EZ2 Connect MDx may contain infectious agents. Handle such samples with the greatest of care and in accordance with the required safety regulations.

Always wear safety glasses, two pairs of gloves, and a lab coat.

The responsible body (e.g., a laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe and that the instrument operators are suitably trained and not exposed to hazardous levels of infectious agents as defined in the applicable Safety Data Sheets (SDSs) or the OSHA, * ACGIH,[†] or COSHH[‡] documents.

Venting for fumes and disposal of waste must be in accordance with all national, state, and local health and safety regulations and laws.

* OSHA — Occupational Safety and Health Organization (United States of America)

[†] ACGIH — American Conference of Government Industrial Hygienists (United States of America)

[‡] COSHH — Control of Substances Hazardous to Health (United Kingdom)

2.5. Chemicals

WARNING



Hazardous chemicals

Some chemicals used with EZ2 Connect MDx may be hazardous or may become hazardous after completion of purification.

Always wear safety glasses, two pairs of gloves, and a lab coat.

The responsible body (e.g., a laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe and that the instrument operators are not exposed to hazardous levels of chemicals as defined in the applicable Safety Data Sheets (SDSs) or the OSHA, * ACGIH,[†] or COSHH[‡] documents.

Venting for fumes and disposal of waste must be in accordance with all national, state, and local health and safety regulations and laws.

* OSHA — Occupational Safety and Health Organization (United States of America)

[†] ACGIH — American Conference of Government Industrial Hygienists (United States of America)

[‡] COSHH — Control of Substances Hazardous to Health (United Kingdom)

Toxic fumes

If working with volatile solvents or toxic substances, you must provide an efficient laboratory ventilation system to remove vapors that may be produced.

WARNING



Toxic fumes

Do not use bleach to clean or disinfect the EZ2 Connect MDx or the used labware. Bleach in contact with salts from the buffers can produce toxic fumes.

2.6. Waste disposal

Used consumables, such as reagent cartridges and disposable filter-tips, may contain hazardous chemicals or infectious agents from the purification process. Such waste must be collected and disposed of properly, according to local safety regulations.

For information about how to dispose of the EZ2 Connect MDx, see Appendix A: Waste Electrical and Electronic Equipment (WEEE).

WARNING

Hazardous chemicals and infectious agents



Waste may contain toxic or infectious material and must be disposed of properly. Refer to your local safety regulations for proper disposal procedures.

2.7. Mechanical hazards

The hood of the EZ2 Connect MDx must remain closed during operation of the instrument. Only open the hood when instructed to do so by the instructions for use or when prompted by the GUI.

The worktable of the EZ2 Connect MDx moves during operation of the instrument. While loading the worktable, always stand clear of the instrument. Do not lean on the worktable when the robotic arm of the instrument is moving to reach the loading position with its lid open. Wait until the robotic arm completes its movements before you start to load or unload.

WARNING

Moving parts



To avoid contact with moving parts during the operation of the EZ2 Connect MDx, the instrument must be operated with the hood closed.

The hood is locked during operation for safety reasons and a sensor detects the hood position. If the hood sensor or lock is not functioning correctly, contact QIAGEN Technical Support.

WARNING

Moving parts



Avoid contact with moving parts during operation of the EZ2 Connect MDx. Under no circumstances should hands be placed under the pipetting unit during movement. Do not attempt to remove any plasticware from the worktable while the instrument is operating.

2.8. Heat hazard

The EZ2 Connect MDx worktable contains a heating system.

WARNING

Hot surface



The heating system can reach temperatures of up to 95°C (203°F). Avoid touching it when it is hot, in particular, shortly after a run has been carried out.

2.9. Radiation safety

The EZ2 Connect MDx instrument has a UV LED lamp. The wavelength of the UV light produced by the UV LED lamp is 275 to 285 nm. This wavelength corresponds to ultraviolet light Type C, which can be used to support decontamination procedures. A mechanical lock ensures that the hood is closed for operation of the UV LED. If the hood sensor or lock is not functioning correctly, contact QIAGEN Technical Support.

WARNING

Risk of personal injury



Avoid looking directly into UV light. Do not expose your skin to UV light.

The EZ2 Connect MDx has a 2D handheld barcode scanner to allow kit barcode and sample barcode scanning.

WARNING

Risk of personal injury



Class 2 Laser: Do not stare into the light beam when using a handheld barcode scanner.

2.10. Maintenance safety

Perform the maintenance as described in Section 6 Maintenance Procedures. QIAGEN charges for repairs that are required due to incorrect maintenance.

Operate the EZ2 Connect MDx only as described in Section 5 Operating Procedures. QIAGEN charges for repairs that are required due to incorrect operation.

WARNING/ CAUTION



Risk of personal injury and material damage

Only perform maintenance that is specifically described in this user manual.

WARNING/ CAUTION



Risk of personal injury and material damage

Improper use of the EZ2 Connect MDx may cause personal injuries or damage to the instrument.

The EZ2 Connect MDx must only be operated by suitably qualified personnel.

Servicing of the EZ2 Connect MDx must only be performed by QIAGEN Field Service Specialists.

WARNING



Risk of fire

When cleaning the EZ2 Connect MDx with alcohol-based disinfectant, leave the instrument door open to allow flammable vapors to disperse.

Only clean the EZ2 Connect MDx with alcohol-based disinfectant when worktable components have cooled down.

CAUTION



Damage to the instrument

Do not use bleach, solvents, or reagents containing acids, alkalis, or abrasives to clean the EZ2 Connect MDx. Do not wash any instrument parts in a dishwasher.

CAUTION**Damage to the instrument**

Do not use spray bottles containing alcohol or disinfectant to clean surfaces of the EZ2 Connect MDx. Spray bottles should be used only to clean items that have been removed from the worktable and if permitted by local laboratory operating practices.

CAUTION**Damage to the instrument**

After wiping the worktable with paper towels, make sure that no residual pieces of paper towel remain. Pieces of paper towel remaining on the worktable could lead to a worktable collision.

**WARNING/
CAUTION****Risk of personal injury and material damage**

Do not open any panels on EZ2 Connect MDx.

Only perform maintenance that is specifically described in this user manual.

2.11. Symbols on the EZ2 Connect MDx

The following symbols appear on the EZ2 Connect MDx instrument.

Symbol	Location	Description
	Heating system — inside instrument	Heat hazard — The temperature of the heating system can reach up to 95°C (203°F).
	Near the tip rack	Biohazard — The tip rack may be contaminated with biohazardous material and must be handled with gloves.
	On the back of the instrument	UV radiation hazard — Avoid looking directly into UV light. Do not expose your skin to UV light.
	On handheld barcode scanner	Class 2 Laser: Do not stare into the light beam when using a handheld barcode scanner.
	Robotic arm — inside instrument	Crush hazard — The nozzle unit may crush your fingers or hand.
	Type plate on the back of the instrument	CE mark for Europe
	Type plate on the back of the instrument	CSA listing mark for Canada and the USA
	Type plate on the back of the instrument	RCM (former C-Tick) for Australia and New Zealand
	Type plate on the back of the instrument	RoHS mark for China (the restriction of the use of certain hazardous substances in electrical and electronic equipment)

Symbol	Location	Description
	Type plate on the back of the instrument	Waste Electrical and Electronic Equipment (WEEE) mark for Europe
	Type plate on the back of the instrument	Legal manufacturer
	Type plate on the back of the instrument	Unique Device Identifier (UDI) as a 2D barcode in Data Matrix format
	Type plate on the back of the instrument	Global Trade Item Number
	Type plate on the back of the instrument	Serial number
	Type plate on the back of the instrument	Catalog number
	Type plate on the back of the instrument.	In vitro diagnostic medical device
	Type plate on the back of the instrument	Consult instructions for use.
	Type plate on the back of the instrument	See warnings and precautions.
	Type plate on the back of the instrument	Date of manufacture

3. General Description

The EZ2 Connect MDx system is designed to perform automated isolation and purification of nucleic acids in molecular diagnostic (using the IVD mode of the software) and/or molecular biology applications (using the Research mode of the software).

3.1. EZ2 Connect MDx principle

The EZ2 Connect MDx performs fully automated nucleic acid purification from up to 24 samples per single run in molecular diagnostic and molecular biology applications using magnetic particle technology. The EZ2 Connect MDx is designed to automate EZ1 DSP kits available from QIAGEN (in the IVD mode of the software), processing of life science kits is also supported (in the Research mode of the software). Refer to Section 7 Research Mode for details.

To start operation, the user must first log in to the software in IVD mode using the touchscreen, followed by scanning a kit barcode. After selection of a certain kit-specific script, labware, reagents, and samples are loaded onto the EZ2 Connect MDx worktable. The user then closes the instrument hood and starts the protocol, which provides all necessary commands for sample lysis and purification. A fully automated load check at the beginning of the procedure helps to ensure correct loading of the worktable.

Offering an augmented user interface, users stay connected to their instrument through the built-in screen and also remotely with a computer or a mobile device (e.g., a tablet) and the QIASphere App using the associated QIASphere Connectivity Package (see Section 5.4.9 Configuring network and QIASphere Base connections), enabling quick response times and the ability to monitor runs while being away from the instrument.

The aspiration and dispensation of samples and reagents and the separation of magnetic particles are performed by the 24-channel pipettor head and magnet module. If required by the protocol, the temperature of the liquids is controlled by the heating system.

The EZ2 Connect MDx incorporates the following features:

- An internal camera, which is used for load checks and reagent cartridge barcode reading
- An external barcode reader, which is used for reading sample IDs and kit barcodes
- Extended user management
- Extended user interface
- Additional reporting functions
- Connectivity (Wi-Fi, LAN, QIASphere, and LIMS)

3.2. External features of the EZ2 Connect MDx



Figure 1. The front of EZ2 Connect MDx.

- | | | | |
|----------|-------------|----------|---------------------|
| A | Touchscreen | C | Power button |
| B | Hood | D | General Description |

Note: Two additional USB ports are located on the rear of the touchscreen (not shown).

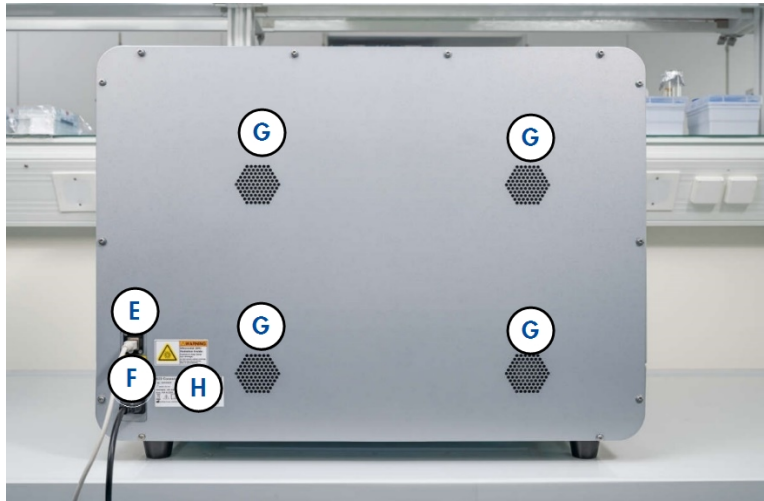


Figure 2. The back of EZ2 Connect.

- | | | | |
|----------|--|----------|-----------------------|
| E | RJ-45 ethernet port | G | General Description |
| F | Power cord socket — including instrument main fuse | H | Instrument type plate |

3.2.1. Touchscreen

The EZ2 Connect MDx has a 10.1 inch color touchscreen display with a resolution of 1280 × 800 pixels. The GUI is displayed on the touchscreen, allowing the user to operate the instrument, set up and start runs, perform maintenance procedures, monitor the instrument status, change settings, and download reports.



Figure 3. EZ2 Connect MDx touchscreen display with GUI.

3.2.2. Hood

The EZ2 Connect MDx hood protects the interior of the instrument from external contamination during protocol runs. Additionally, the hood protects operators from moving parts during protocol runs and UV irradiation during decontamination procedures.

The hood must be closed to enable a protocol run to start. The hood is locked at the beginning of a run and remains locked throughout the duration of the run. This protects users from moving parts on the worktable. The hood can be manually opened to gain access to the worktable when no protocol is running. During operation of the EZ2 Connect MDx, the hood must remain closed and should only be opened when you are instructed to do so by the user manual or instructions on the GUI.

WARNING

Moving parts



To avoid contact with moving parts during the operation of the EZ2 Connect MDx, the instrument must be operated with the hood closed.

The hood is locked during operation for safety reasons and a sensor detects the hood position. If the hood sensor or lock is not functioning correctly, contact QIAGEN Technical Support.



Figure 4. EZ2 Connect MDx with the hood closed.

3.2.3. Power button

The power button is located on the bottom right corner of the front of the EZ2 Connect MDx. To turn on the EZ2 Connect MDx, press the button. After pressing the button, the power button lights up, the startup screen appears on the touchscreen, and the instrument initializes.

To save energy, the EZ2 Connect MDx can be turned off when not in use. To turn off the EZ2 Connect MDx, press the power button.



Figure 5. Location of the power button.

3.2.4. USB ports

The EZ2 Connect MDx has three USB ports. One is located next to the power button, on the front of the instrument. The other two are located on the back of the touchscreen display.

The USB ports allow you to connect a USB drive to the EZ2 Connect MDx. A USB drive that is connected to the instrument can be used to, for example, transfer report files. For more information on saving reports, refer to the instructions provided in Section 5.9 Saving a run report.

In addition, you can use the USB drive to upload protocols, or update the software, if you have the relevant files on your USB drive. For more information on uploading protocols, refer to Section 5.4.6 Installing new protocols. For more information on software updates, refer to Section 5.4.8 Updating software.

The handheld barcode scanner is connected to the EZ2 Connect MDx using any one of the three available USB ports.

The Wi-Fi adapter, if used, is connected to the EZ2 Connect MDx using any one of the three available USB ports. Those on the rear of the touchscreen might be most convenient.

Important: Use only the USB stick provided by QIAGEN. Do not connect other USB stick devices to USB ports.

Important: Do not remove the USB drive or interrupt power while downloading or transferring data or software to or from the instrument.

Important: USB devices other than those listed above should not be connected to any of the USB ports on the EZ2 Connect MDx.

3.2.5. RJ-45 ethernet port

The RJ-45 ethernet port is located on the back of the instrument (highlighted white in image below). The port is used to connect the EZ2 Connect MDx to a local area network.



Figure 6. Location of RJ-45 port (highlighted by white frame).

3.2.6. Power cord socket

The power cord socket is located on the back of the EZ2 Connect MDx (highlighted white in image below) and is used for connecting the instrument to a power outlet via the supplied power cord.



Figure 7. Location of power cord socket (highlighted by white frame).

On some instruments, there might be a sign with 230 V on the power cord socket (Figure 8). This power socket can still work with different input voltages. There is no action needed if the input voltage differs from the voltage written on the type plate, if the voltage is inside of the allowed operating voltage range (100–240 V).



Figure 8. Alternative variant of the power socket with 230 V sign.

WARNING



Electrical hazard

Any interruption of the protective conductor (earth/ground lead) inside or outside the instrument or disconnection of the protective conductor terminal is likely to make the instrument dangerous.

Intentional interruption is prohibited.

Lethal voltages inside the instrument

When the instrument is connected to line power, terminals may be live and opening covers or removing parts is likely to expose live parts.

WARNING**Damage to electronics**

Before powering on the instrument, make sure that the correct supply voltage is used.

Use of incorrect supply voltage may damage the electronics.

To check the recommended supply voltage, refer to the specifications indicated in the type plate of the instrument.

WARNING**Risk of electric shock**

Do not open any panels on the EZ2 Connect MDx.

Risk of personal injury and material damage

Only perform maintenance that is specifically described in this user manual. Any other maintenance or repair may only be carried out by an authorized QIAGEN Field Service Specialist.

3.2.7. Ventilation openings

EZ2 Connect MDx ventilation openings allow the internal components of the instrument to be cooled.

WARNING**Risk of overheating**

To ensure proper ventilation, maintain a minimum clearance of 10 cm at the sides and rear of the EZ2 Connect MDx.

Slits and openings that ensure the ventilation of the instrument must not be covered.

3.2.8. Barcode scanner

The barcode scanner delivered with the instrument can be connected to the EZ2 Connect MDx using any one of the three USB ports. The scanner is used for reading the barcode on the kit Q-Card (supplied with sample preparation kits) and sample barcodes. For more information on how to use the barcode scanner, refer to Section 5.5.1 Using the barcode scanner.

WARNING**Risk of personal injury**

Class 2 Laser: Do not stare into the light beam when using a handheld barcode scanner.

3.3. Internal features of the EZ2 Connect MDx

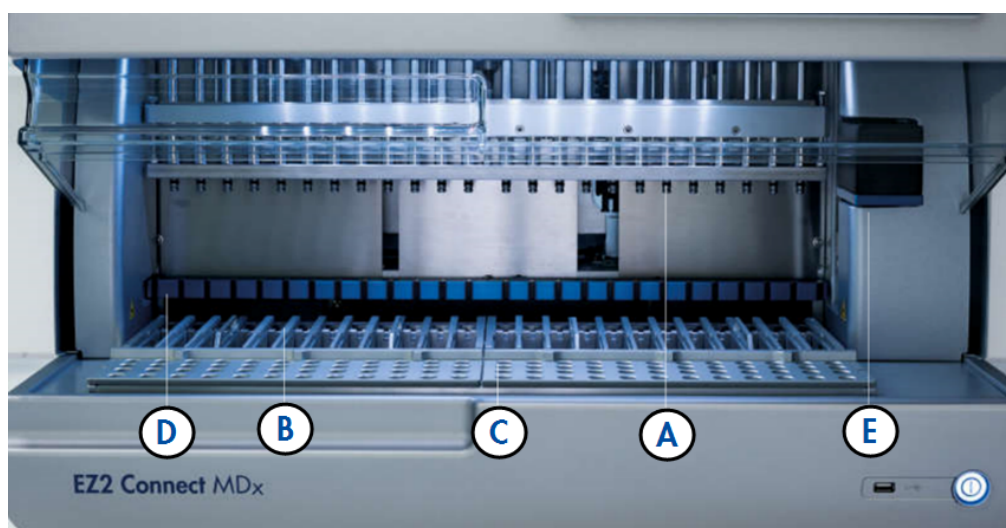


Figure 9. Interior of the EZ2 Connect MDx.

- A Pipettor head
- B Cartridge rack
- C Tip rack
- D Magnet module
- E Camera

Internal features not marked in the picture:

- Heating system
- UV LED lamp
- Internal light

3.3.1. Pipettor head

The pipettor head is mounted above the worktable and moves in the Z direction (meaning up and down) to reach the sample and reagent tubes on the worktable. The worktable itself moves in the Y direction (meaning front to back) so that the pipettor head is above the appropriate position in the cartridge or tip rack during each action that is performed by the instrument.

The pipettor head contains 24 high-precision syringe pumps that are connected to tip adapters that can be attached to filter-tips. The syringe pumps operate simultaneously and can aspirate or dispense small volumes of liquid through the attached filter-tips.

Another component of the pipettor head is the piercing unit that is located behind the tip adapters. The piercing unit is a row of 24 metal spikes that puncture the foil sealing the reagent cartridges. During operation, the piercing unit opens all wells of the reagent cartridges in a dedicated order. The pipettor head then automatically picks up filter-tips from the tip rack and performs aspiration and dispensation operations at different locations on the worktable before ejecting the tips back into the tip holder held on the tip rack at the end of the run.



Figure 10. EZ2 Connect MDx pipettor head.

WARNING

Moving parts



To avoid contact with moving parts during the operation of the EZ2 Connect MDx, the instrument must be operated with the hood closed.

The hood is locked during operation for safety reasons and a sensor detects the hood position. If the hood sensor or lock is not functioning correctly, contact QIAGEN Technical Support.

WARNING

Moving parts



Avoid contact with moving parts during operation of the EZ2 Connect MDx. Under no circumstances should hands be placed under the pipetting unit during movement. Do not attempt to remove any plasticware from the worktable while the instrument is operating.

3.3.2. Worktable

CAUTION

Damage to the instrument



Do not use bleach, solvents, or reagents containing acids, alkalis, or abrasives to clean the EZ2 Connect MDx. Do not wash any instrument parts in a dishwasher.

The EZ2 Connect MDx worktable contains two movable rack types (the cartridge rack and the tip rack) that hold all the labware required for a protocol run, and the heating system, which controls the temperature of liquids during a run.

Cartridge rack



Figure 11. Cartridge rack with some cartridges inserted.



Figure 12. Removable cartridge rack inside the instrument.

There are two position-dedicated cartridge racks: the left cartridge rack is used for cartridges in positions 1 to 12 and the right cartridge rack is used for cartridges in positions 13 to 24. The left and right cartridge racks together hold up to 24 reagent cartridges.

For more information on how to load the EZ2 Cartridge Rack, refer to Section 5.6.1 Loading the cartridge rack(s).

Sealed reagent cartridges (supplied with the EZ1 DSP and EZ1&2 kits) are prefilled and contain the reagents needed for a protocol run. Each cartridge consists of 10 sealed reagent wells and 2 empty heating positions. One heating position is a well, and the other is a slot that can hold a tube.

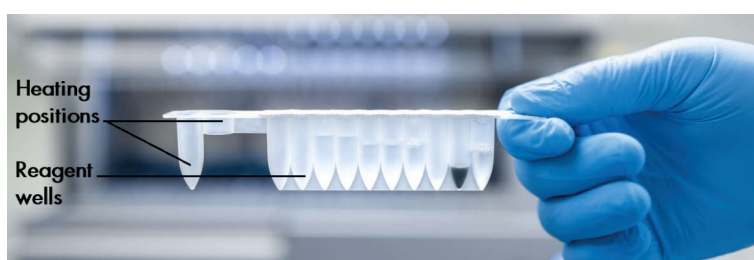


Figure 13. An EZ1/2 cartridge.

Tip rack



Figure 14. Tip rack with four inserted tip holders/filter tips.



Figure 15. Tip racks inside the instrument.

There are two position-dedicated tip racks: the left tip rack is used for labware in positions 1 to 12 and the right tip rack is used for labware in positions 13 to 24.

The tip racks are located at the front of the worktable. Each consists of 4 rows and 12 positions:

- Row A — which is the row that is closest to the cartridge rack, holds up to 24 sample tubes.

Important: Only use QIAGEN recommended tubes (see the respective EZ1 DSP or EZ1&2 kit handbooks for more information).

- Row B — may contain a tube with manually filled components, such as carrier RNA or ethanol (see the respective EZ1 DSP or EZ1&2 kit handbooks for more information).
- Row C — usually holds up to 24 tip holders with filter tips, which are provided with the EZ1 DSP or EZ1&2 kits (see respective EZ1 DSP or EZ1&2 kit handbook for more information).



Figure 16. Tip holders and filter tips.

- Row D — holds empty elution tubes, this is also the row closest to the front of the instrument, holds up to 24 elution tubes. The tubes recommended by QIAGEN are provided with EZ1 DSP or EZ1&2 kits.

Important: Only use QIAGEN-recommended tubes for elution.

For information on how to load the tip rack, refer to Section 5.6.2 Loading the tip rack.

3.3.3. Heating system

The heating system is located under the rear part of the cartridge rack. If necessary, the protocol heats the wells in positions 11 and 12 of the cartridge (depending on the used protocols).



Figure 17. Heatable positions in the cartridge rack (highlighted by white frame).

WARNING



Hot surface

The heating system can reach temperatures of up to 95°C (203°F). Avoid touching it when it is hot, in particular, shortly after a run has been carried out.

3.3.4. Bottom tray

The two bottom trays are located underneath the tip and cartridge racks. Their role is to prevent contamination of the EZ2 Connect MDx that could be caused by liquids that are unintentionally spilled. The bottom trays can be removed and cleaned as described in Section 6.3 Daily maintenance.



Figure 18. The EZ2 Connect MDx bottom tray.

3.3.5. Magnet module

The EZ2 Connect MDx magnet module consists of magnets that are used to capture magnetic particles that are present in the liquid aspirated into the filter-tips.



Figure 19. The EZ2 Connect MDx magnet module.

3.3.6. Camera

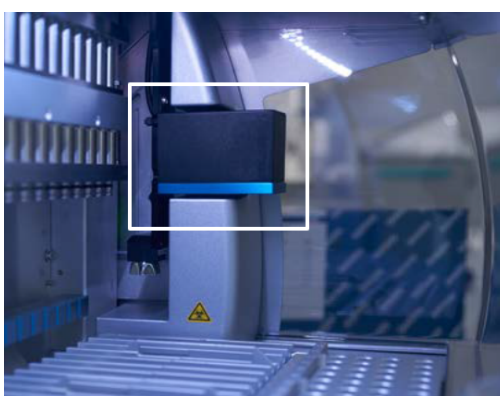


Figure 20. Camera module (highlighted by white frame).

The EZ2 Connect MDx has a built-in camera that is used for load checks, which includes reading barcodes from cartridges.

Load checks are done before a protocol run starts. The camera checks if labware has been loaded in the correct positions. The results of the load check are shown on the screen. For more information on the load check, refer to the Section 5.7.1 Load check.

The camera also reads the cartridge 2D barcodes. Information that is collected from the 2D barcodes is included in run reports.

3.3.7. UV LED lamp

The EZ2 Connect MDx is equipped with a UV LED light to support decontamination. During the maintenance decontamination procedure, the UV LED moves over the worktable.

Note: The hood must be closed before starting a maintenance procedure and is automatically locked during the procedure.

WARNING

Risk of personal injury



Do not expose your skin to UV light from the UV LED lamp.

WARNING

Moving parts



To avoid contact with moving parts during the operation of the EZ2 Connect MDx, the instrument must be operated with the hood closed.

The hood is locked during operation for safety reasons and a sensor detects the hood position. If the hood sensor or lock is not functioning correctly, contact QIAGEN Technical Support.

3.3.8. Internal light

The EZ2 Connect MDx has a built-in LED light. The internal light illuminates the worktable and indicates the current status of the run. There are two modes of the LED light:

- Blinking light – indicates that operator activity is required (e.g., when an error occurs).
- Constant light – the default setting, used in all other situations.

4. Installation Procedures

This section provides instructions on installation environment requirements as well as unpacking, installing, and packing the EZ2 Connect MDx.

4.1. Site requirements

The EZ2 Connect MDx must be located out of direct sunlight, away from heat sources, and away from sources of vibration and electrical interference. Refer to Section 10 Technical Specifications for the operating conditions (temperature and humidity). The site of installation should be free of excessive drafts, excessive moisture, and excessive dust, and should not be subject to large temperature fluctuations.

Use a level workbench that is large and strong enough to accommodate the EZ2 Connect MDx. To ensure proper ventilation, maintain a minimum clearance of 10 cm at the sides and rear of the EZ2 Connect MDx. Refer to Section 10 Technical Specifications for the weight and dimensions of the EZ2 Connect MDx. Ensure that the workbench is dry, clean, and vibration-proof, and has additional space for accessories.

The EZ2 Connect MDx must be placed within approximately 1.5 m of a properly grounded (earthed) AC power outlet. The power line to the instrument should be voltage regulated and surge protected. Ensure that the EZ2 Connect MDx is positioned so that it is easy to access the power connector at the back of the instrument and the power switch on the front at all times, and that it is easy to turn the instrument off and disconnect it.

Note: It is recommended to plug the instrument directly into its own power outlet and to not share the power outlet with another lab equipment.

WARNING



Explosive atmosphere

The EZ2 Connect MDx is not designed for use in an explosive atmosphere.

WARNING



Risk of overheating

To ensure proper ventilation, maintain a minimum clearance of 10 cm at the sides and rear of the EZ2 Connect MDx.

Slits and openings that ensure the ventilation of the instrument must not be covered.

WARNING



Risk of personal injury and material damage

The EZ2 Connect MDx is too heavy to be lifted by one person. To avoid personal injury or damage to the instrument, do not lift the instrument alone. Use the handle attached to the box to lift the EZ2 Connect MDx. After the EZ2 Connect MDx has been unpacked, two people must lift the instrument. Lift the instrument by placing your hands underneath the bottom of the instrument.

CAUTION



Damage to the instrument

Direct sunlight may bleach parts of the instrument and cause damage to plastic parts. The EZ2 Connect MDx must be located out of direct sunlight.

CAUTION**Damage to the instrument**

Do not use the EZ2 Connect MDx in the vicinity of sources of strong electromagnetic radiation (e.g., unshielded, deliberately operated high-frequency sources or mobile radio devices), because these can interfere with the proper operation.

4.2. Power requirements

The EZ2 Connect MDx operates at 100–240 V AC $\pm$ 10%, 50/60 Hz, 1000 VA.

Make sure the voltage rating of the EZ2 Connect MDx is compatible with the AC voltage available at the installation site.

WARNING**Damage to electronics**

Before powering on the instrument, make sure that the correct supply voltage is used.

Use of incorrect supply voltage may damage the electronics.

To check the recommended supply voltage, refer to the specifications indicated in the type plate of the instrument.

WARNING**Electrical hazard**

Any interruption of the protective conductor (earth/ground lead) inside or outside the instrument or disconnection of the protective conductor terminal is likely to make the instrument dangerous.

Intentional interruption is prohibited.

Lethal voltages inside the instrument

When the instrument is connected to line power, terminals may be live and opening covers or removing parts is likely to expose live parts.

4.3. Grounding requirements

To protect operating personnel, the National Electrical Manufacturers' Association (NEMA) recommends the EZ2 Connect MDx should be correctly grounded (earthed). The instrument is equipped with a 3-conductor AC power cord that, when connected to an appropriate AC power outlet, grounds (earths) the instrument. To preserve this protection feature, do not operate the instrument from an AC power outlet that has no ground (earth) connection.

WARNING**Electrical hazard**

Any interruption of the protective conductor (earth/ground lead) inside or outside the instrument or disconnection of the protective conductor terminal is likely to make the instrument dangerous.

Intentional interruption is prohibited.

Lethal voltages inside the instrument

When the instrument is connected to line power, terminals may be live and opening covers or removing parts is likely to expose live parts.

4.4. Unpacking the EZ2 Connect MDx

WARNING



Risk of personal injury and material damage

The EZ2 Connect MDx is too heavy to be lifted by one person. To avoid personal injury or damage to the instrument, do not lift the instrument alone. Use the handle attached to the box to lift the EZ2 Connect MDx. After the EZ2 Connect MDx has been unpacked, two people must lift the instrument. Lift the instrument by placing your hands underneath the bottom of the instrument.

The following items are delivered:

- EZ2 Connect MDx instrument
- Quick-start guide and safety instructions
- Left and right cartridge racks
- Left and right sample/tip racks
- Power cord set
- USB drive
- Silicone grease
- Handheld barcode scanner
- Connectivity package (supplied separately)

To unpack the EZ2 Connect MDx

1. Before unpacking the EZ2 Connect MDx, move the package to the site of installation and check that the arrows on the package point upward. In addition, check whether the package is damaged. In case of damage, contact QIAGEN Technical Support.
2. Open the top of the transportation box and remove the top layer (PE foam).
3. Remove the accessories box together with the PE foam at its perimeter.



Figure 21. Accessories box.

4. Remove the outer carton box by holding it at the cut-out area and lifting the outer carton box.
5. Remove the two pieces of protective foam from the unit.

6. Move the unit to the workbench or trolley from the packaging. When lifting the EZ2 Connect MDx, slide your fingers under the side of the instrument and keep your back straight.

Important: Two persons are required to lift the EZ2 Connect MDx.

Important: Do not hold the touchscreen display while unpacking or lifting the EZ2 Connect MDx. This might damage the instrument.

7. Remove the foam strip that is placed in the gap between the hood and the front top cover.
8. Remove the pieces of tape that secure the hood to the base panels.
9. Remove the protective film that covers the hood.
10. Open the hood and remove the transport lock from the pipetting head by pulling the transport lock from the bottom.



Figure 22. Transport lock.

11. Remove the silica gel package from the unit.
12. Remove the transport lock for Y-axis (front to back) by pushing the bottom of the transport lock toward the rear direction and pulling the transport foam out from the rear. There are two transport locks for the Y-axis.
13. Check if the packing list document is included after unpacking the EZ2 Connect MDx.
14. Read the packing list to check if all items have been received. If anything is missing, contact QIAGEN Technical Support.
15. Check that the EZ2 Connect MDx is not damaged and that there are no loose parts. If anything is damaged, contact QIAGEN Technical Support. Make sure that the EZ2 Connect MDx has equilibrated to ambient temperature before powering on.
16. Retain the package in case you need to transport the EZ2 Connect MDx in the future. Refer to the Section 4.6 Packaging and transportation of the EZ2 Connect MDx for more details. Using the original package minimizes the possibility of damage during transportation of the EZ2 Connect MDx.

4.5. Installing the EZ2 Connect MDx

This section describes important actions that must be performed before operating the EZ2 Connect MDx. These actions include:

- Removal of the EZ2 Connect MDx accessories and shipping material
- Installation of the AC power cord
- Installation of external barcode scanner
- Installation of the Wi-Fi adapter (if supplied with connectivity package)
- Initial configuration
- Camera exposure calibration
- If an installation qualification/operational qualification (IQ/OQ) is required in your laboratory setup, this service can be ordered together with the instrument. For details, please contact QIAGEN Technical Support.

Note: To ensure that your EZ2 Connect MDx has the latest software and protocol versions installed, visit the EZ2 Connect MDx product page (www.qiagen.com/EZ2ConnectMDx).

4.5.1. Removal of the EZ2 Connect MDx accessories and shipping materials

1. Remove the power cord, barcode scanner, and the quick-start guide from accessories box on top of the EZ2 Connect MDx.
2. Remove the USB stick, cartridge racks, and tip racks.
3. Ensure all shipping foams, transport locks, and other packing material have been removed as described in the Section 4.4 Unpacking the EZ2 Connect MDx.

4.5.2. Installation of the AC power cord

1. Remove the power cord from the foam packing material on top of the EZ2 Connect MDx.

Note: Only use the power cord that is supplied with the EZ2 Connect MDx.

2. Ensure that the power button is set to off. When on, the power button is slightly pushed into the slot, when off, it is flush with the surface.



Figure 23. Location of the power button.

3. Check that the voltage rating on the type plate at the back of the EZ2 Connect MDx matches the voltage available at the installation site.

Note: The EZ2 Connect MDx AC inlet is set up to accept all input voltages within the range 100–240 V AC and does not need to be configured manually – see Section 3.2.6 Power cord socket.

4. Plug the power cord into the instrument power cord socket.
5. Plug the power cord into a grounded power outlet.
6. Do not switch on the power to the instrument at this point. Power must be off for the subsequent installation of the USB devices described in the following steps.

WARNING

Damage to electronics



Before powering on the instrument, make sure that the correct supply voltage is used.

Use of incorrect supply voltage may damage the electronics.

To check the recommended supply voltage, refer to the specifications indicated in the type plate of the instrument.

WARNING

Electrical hazard



Any interruption of the protective conductor (earth/ground lead) inside or outside the instrument or disconnection of the protective conductor terminal is likely to make the instrument dangerous.

Intentional interruption is prohibited.

Lethal voltages inside the instrument

When the instrument is connected to line power, terminals may be live and opening covers or removing parts is likely to expose live parts.

4.5.3. Installation of external barcode scanner (optional)

1. Remove the barcode scanner from the box.
2. Before powering on the instrument, connect the barcode scanner to any one of the three USB ports located on the front of the instrument or on the rear of the touchscreen.

WARNING

Risk of personal injury



Class 2 Laser: Do not stare into the light beam when using a handheld barcode scanner.

4.5.4. Installation of Wi-Fi adapter (optional)

Note: Wi-Fi adapter is supplied with the connectivity package in certain regions. If supplied, the following steps should be performed to correctly install the Wi-Fi adapter.

1. Remove the Wi-Fi adapter from the packaging.
2. Before turning on the instrument, plug the Wi-Fi adapter into one of the three USB ports located on the front of the instrument or on the rear of the touchscreen.

Note: It may be more convenient to use the USB ports on the rear of the touchscreen.

4.5.5. Initial configuration of the EZ2 Connect MDx

Note: Make sure that the EZ2 Connect MDx has equilibrated to ambient temperature before powering on.

1. To power on the EZ2 Connect MDx instrument, first ensure the hood is closed. Press the power button. The power button lights up, the startup screen appears on the touchscreen, a sound plays, and the instrument initializes.

The screenshot shows the login interface of the EZ2 Connect MDx instrument. At the top left is the QIAGEN logo. At the top right is a circular icon with a question mark and the word 'Help' below it. The main heading reads 'Welcome to EZ2' followed by 'Log in to continue'. Below the heading are two text input fields: 'User ID:' and 'Password:'. Under the password field are two radio buttons labeled 'Research Mode' and 'IVD Mode'. A grey 'Log in' button is positioned below the radio buttons. At the bottom left of the screen, a timestamp '8/11/2023 13:16' is displayed.

Figure 24. The login screen.

Tap the **Help** icon in the header on the login screen to open the Help Center window. The Help Center allows the user to change the password in case all users with the Admin role are locked or the current password has been forgotten.

Note: It is recommended to create a second user with the Admin role to allow unlocking the other Admin account if needed.

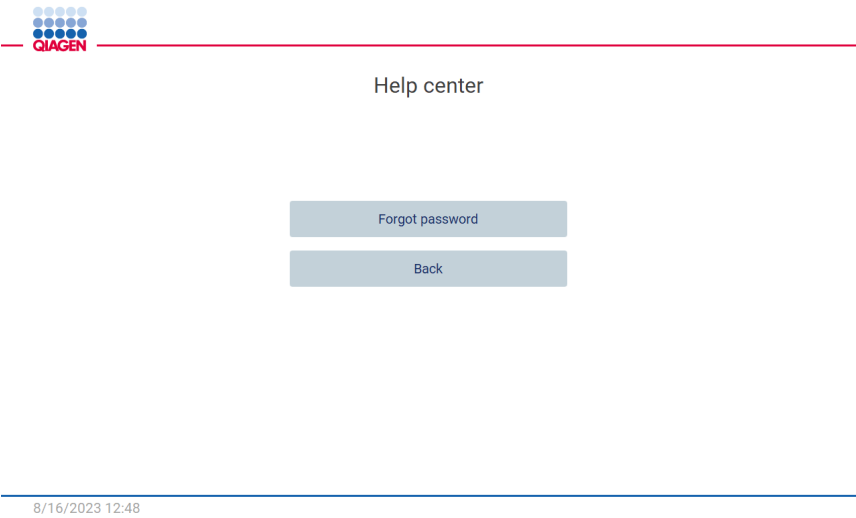


Figure 25. Help Center window.

- 2. To log in for the first time, enter “Admin” in both User ID and Password fields, then press **Log in**. The Set a new password screen appears.

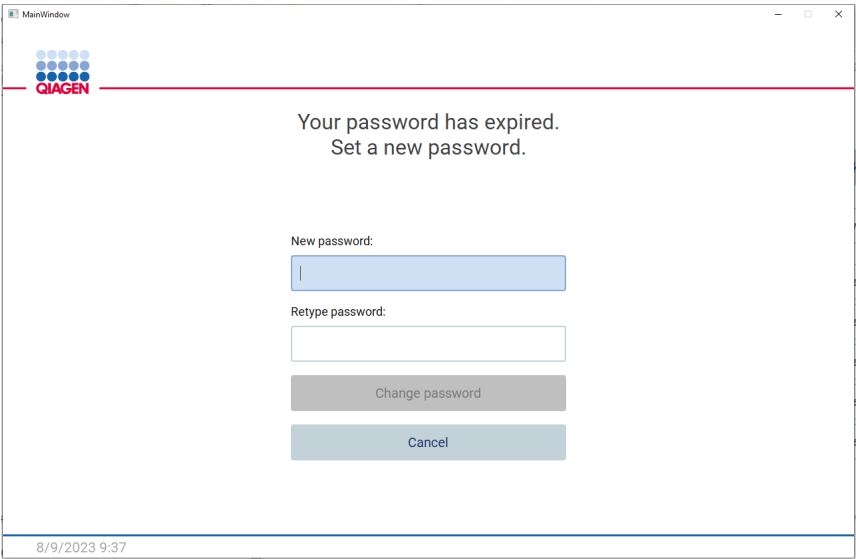


Figure 26. Set a new password screen after first log in.

Note: Only administrators can change instrument settings.

Note: The system requires a password change for all newly created accounts. The EZ2 Connect MDx default password policy requires a strong password of 8–40 characters that includes upper- and lowercase letters, a number, and a special character.

- From the **Configuration** menu under the **System** tab, you can modify the Device Name, Date, and Time fields. Information on the software version, serial number, and firmware version is also available. For further details, see Section 5.4.1 Setting basic system data.

The screenshot shows the 'System configuration' tab selected under the 'Configuration' menu. The interface includes a top navigation bar with icons for Setup, Maintenance, Configuration (active), Data, Network, Notifications, and Session. Below this is a sub-menu bar with tabs for System configuration, Language, Instrument settings, Protocols, User management, User security, LAN, Wi-Fi, QIASphere, and LIMS. The main content area is divided into two panels. The left panel contains fields for Instrument name (unnamed), Date (8/14/2023), Date format (M/d/yyyy), Time (8:42), 24-hour time format (checked), and Time zone (UTC). The right panel displays instrument information: Instrument variant (EZ2 Connect MDx), Software version (1.2.0), Serial number (Z0920007M), and Firmware version ([noFWversion]). It also includes buttons for 'Check for updates' and 'Manage updates', along with a note about inserting a USB stick for updates. At the bottom of the right panel, there is a section for Remote service access (SSH) which is currently disabled, with buttons to 'Enable' or 'Generate new key'. At the bottom of the screen, a status bar shows the date and time (8/14/2023 8:42), the mode (Mode: IVD), and the user (Admin Admin).

Figure 27. The System configuration tab.

- You may adjust settings of the EZ2 Connect MDx according to your preferences through the **Instrument settings** tab under the **Configuration** menu. For further details, see the Section 5.4.2 Changing instrument settings.

The screenshot shows the 'Instrument settings' tab selected under the 'Configuration' menu. The interface is similar to the previous one, with the same top navigation bar and sub-menu bar. The main content area displays settings for Audio volume, Display brightness, and Internal light brightness, each with a slider control. Below these is a dropdown menu for 'Screen locks after' set to '5 minutes'. At the bottom of the settings panel are 'Cancel' and 'Accept' buttons. The status bar at the bottom of the screen shows the date and time (8/14/2023 8:42), the mode (Mode: IVD), and the user (Admin Admin).

Figure 28. Details on the Instrument setting tab.

4.5.6. Performing camera exposure calibration

Note: Only administrators can perform the camera exposure calibration.

WARNING

Moving parts



To avoid contact with moving parts during the operation of the EZ2 Connect MDx, the instrument must be operated with the hood closed.

The hood is locked during operation for safety reasons and a sensor detects the hood position. If the hood sensor or lock is not functioning correctly, contact QIAGEN Technical Support.

1. Before first use at the final installation site, perform the camera exposure calibration.
2. From the **Maintenance** menu under the **Camera LED** tab, follow the instructions on the user interface.
3. Make sure to use the tip racks from the same instrument in the same order (the racks are designed to be installed in only one orientation) as later on in the run. Only the standard tip rack (cat. no. 9027009) shall be used for exposure calibration.

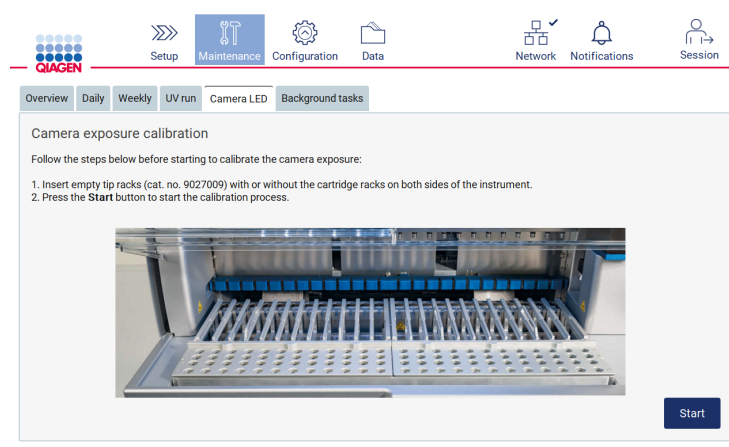


Figure 29. Camera exposure calibration screen.

4. During the calibration routine, the following message is displayed:

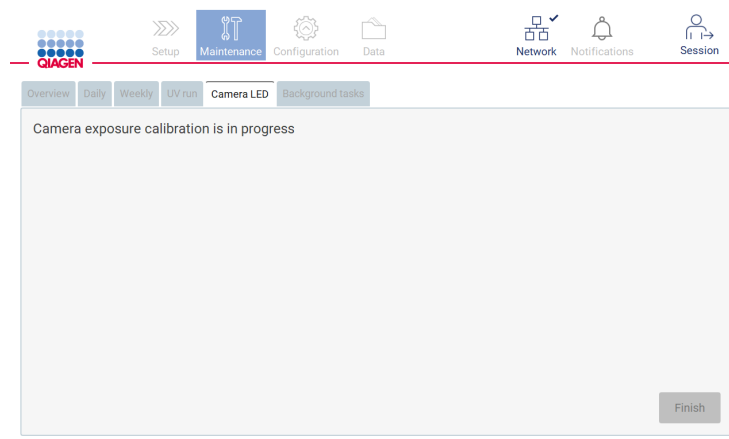


Figure 30. Camera exposure calibration is in progress message.

Note: For support or technical advice regarding this, please contact QIAGEN Technical Service Department, or see our Technical Support Center (support.qiagen.com).

4.6. Packaging and transportation of the EZ2 Connect MDx

WARNING



Risk of personal injury and material damage

The EZ2 Connect MDx is too heavy to be lifted by one person. To avoid personal injury or damage to the instrument, do not lift the instrument alone. Use the handle attached to the box to lift the EZ2 Connect MDx. After the EZ2 Connect MDx has been unpacked, two people must lift the instrument. Lift the instrument by placing your hands underneath the bottom of the instrument.

Before transporting the EZ2 Connect MDx, the instrument must first be decontaminated. Refer to Sections 6.1.1 Disinfecting the EZ2 Connect MDx and 6.1.2 Removing contamination for more details. Then prepare the instrument as follows.

1. Prepare the packing materials.
2. Install the transport locks (two) for the Y axis.
3. Install the transport lock for the P axis.
4. Close the instrument hood and install the foam strip in the gap between the hood and the front top cover.
5. Move the instrument to the transportation box base.

Important: Two persons are required to lift the EZ2 Connect MDx.

Important: Do not hold the touchscreen display while unpacking or lifting the EZ2 Connect MDx; this might damage the instrument.

6. Install the outer carton box.
7. Package the accessories into the accessories box, then place it on top of the transportation box, with the PE foam around its perimeter.
8. Add the top layer PE foam.
9. Seal the outside edges of the carton with tape.

Note: Using the original package minimizes potential damage during transportation of the EZ2 Connect MDx.

5. Operating Procedures

This section describes how to operate the EZ2 Connect MDx instrument.

Before proceeding, familiarize yourself with the features of the instrument as described in Sections 3.2 External features of the EZ2 Connect MDx and 3.3 Internal features of the EZ2 Connect MDx.

The EZ2 Connect MDx is intended to be used only in combination with QIAGEN kits indicated for use with the instrument for the applications described in the kit handbooks.

The hood of the EZ2 Connect MDx must remain closed, and it locks automatically during instrument operation. Open the hood only when instructed to do so by the instructions for use or the GUI.

The worktable of the EZ2 Connect MDx moves during the instrument operation. Never open the hood while the instrument is operating.

WARNING

Moving parts



To avoid contact with moving parts during the operation of the EZ2 Connect MDx, the instrument must be operated with the hood closed.

The hood is locked during operation for safety reasons and a sensor detects the hood position. If the hood sensor or lock is not functioning correctly, contact QIAGEN Technical Support.

WARNING

Moving parts



Avoid contact with moving parts during operation of the EZ2 Connect MDx. Under no circumstances should hands be placed under the pipetting unit during movement. Do not attempt to remove any plasticware from the worktable while the instrument is operating.

WARNING

Risk of personal injury and material damage



Do not attempt to move the EZ2 Connect MDx during operation.

WARNING/ CAUTION

Risk of personal injury and material damage



Improper use of the EZ2 Connect MDx may cause personal injuries or damage to the instrument. The EZ2 Connect MDx must only be operated and maintained by qualified personnel who have been appropriately trained. Servicing of the EZ2 Connect MDx must only be performed by a QIAGEN Field Service Specialist.

CAUTION

Damage to the instrument



Avoid spilling water or chemicals onto the EZ2 Connect MDx. Instrument damage caused by water or chemical spillage will void your warranty.

WARNING

Risk of fire or explosion



When using ethanol or ethanol-based liquids on the EZ2 Connect MDx, handle such liquids carefully and in accordance with the required safety regulations. If liquid has been spilled, wipe it off and leave the EZ2 Connect MDx hood open to allow flammable vapors to disperse.

WARNING**Risk of explosion**

The EZ2 Connect MDx is intended for use with reagents and substances supplied with QIAGEN kits as outlined in respective instructions for use. Use of other reagents and substances may lead to fire or explosion.

CAUTION**Risk of personal injury and material damage**

Ensure that the EZ2 Connect MDx is switched off and the main plug is removed from the power outlet before you manually move the mechanical components of the instrument.

CAUTION**Damage to the instrument**

Do not lean against the instrument or touchscreen.

WARNING**Samples containing infectious agents**

Some samples used with EZ2 Connect MDx may contain infectious agents. Handle such samples with the greatest of care and in accordance with the required safety regulations.

Always wear safety glasses, two pairs of gloves, and a lab coat.

The responsible body (e.g., a laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe and that the instrument operators are suitably trained and not exposed to hazardous levels of infectious agents as defined in the applicable Safety Data Sheets (SDSs) or the OSHA,* ACGIH,[†] or COSHH[‡] documents.

Venting for fumes and disposal of waste must be in accordance with all national, state, and local health and safety regulations and laws.

* OSHA — Occupational Safety and Health Organization (United States of America)

[†] ACGIH — American Conference of Government Industrial Hygienists (United States of America)

[‡] COSHH — Control of Substances Hazardous to Health (United Kingdom)

WARNING**Hazardous chemicals and infectious agents**

Waste may contain toxic or infectious material and must be disposed of properly. Refer to your local safety regulations for proper disposal procedures.

WARNING**Hot surface**

The heating system can reach temperatures of up to 95°C (203°F). Avoid touching it when it is hot, in particular, shortly after a run has been carried out.

WARNING**Risk of personal injury**

Avoid looking directly into UV light. Do not expose your skin to UV light.

WARNING**Risk of personal injury**

Class 2 Laser: Do not stare into the light beam when using a handheld barcode scanner.

5.1. General information

The EZ2 Connect MDx is operated via a touchscreen display that guides you step-by-step through the correct loading of the worktable and selection of the protocol. The following actions can be done using the user interface:

- Guided run setups
- Checking the status of the run and the instrument
- Guided maintenance procedures
- Generating, saving, and downloading run reports, support files, sample list templates, and audit trails
- Changing instrument settings to customize your EZ2 Connect MDx

Note: The instrument's touchscreen does not support swiping and multi-gestures.

Each screen of the user interface consists of three elements: the toolbar, the main content, and the footer.

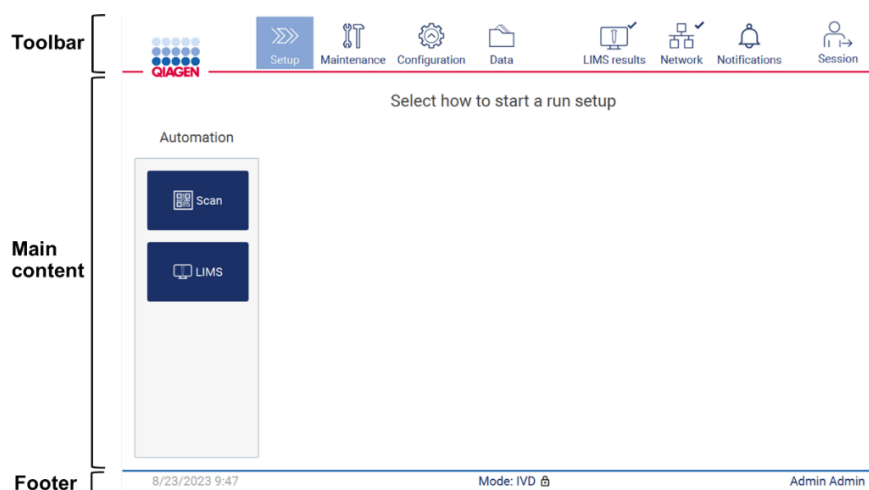


Figure 31. Home screen.

Toolbar

The toolbar is used to access the main sections of the EZ2 Connect MDx software, check the connection status of the LAN/Wi-Fi and notifications, and log out of the application. The toolbar contains the same buttons throughout the whole application; however, some buttons are disabled during protocol setup, protocol runs, and maintenance procedures.

The following elements enable the user to work and interact with the user interface:

Table 1. Description of elements in the user interface

Element	Description
 Setup	Tap this button to go to the Home screen, where you can start the setup process of a protocol run.
 Maintenance	Tap this button to go to the Maintenance section, where you can configure data exchange, and access maintenance procedures.
 Configuration	Tap this button to go to the Configuration section, where you can change settings, manage users, configure network and QlAsphere Base connections, and change your password.
 Data	Tap this button to access Run reports, Support packages, and Audit trail.
 LIMS results	Tap this button to display the LIMS sending results status.
 Network	Tap this button to see the current status of the network connection(s) (LAN and Wi-Fi).
 Notifications	Tap this button to see a new warning, errors, or important info notifications.
 Session	Tap this button to lock the screen or log out from the current session.

Main content

The part of the screen where the main content of each view is displayed.

Footer

The footer shows the current date and time and the name of the user that is currently logged in.

5.1.1. Entering text and numbers

An on-screen keyboard is used for entering text in editable fields of the EZ2 Connect MDx software. To access the keyboard, tap the field that you want to edit. The keyboard appears.

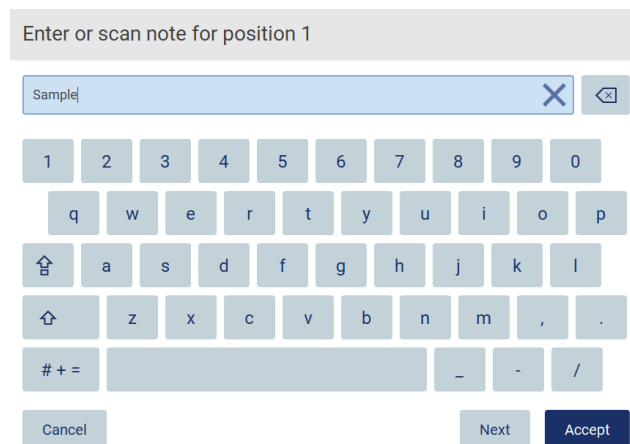


Figure 32. The on-screen keyboard.

The default layout of the keyboard is lowercase QWERTY, with numbers from 1 to 0, commonly used special characters, a space bar, a **Shift** key, a **Caps Lock** key, and the **Special Characters** **#+=** key. To enter a character, tap the relevant letter, number, or special character on the keyboard. To enter one uppercase letter, tap **Shift** . To enter multiple consecutive uppercase letters, tap **Caps Lock** . Tap **Caps Lock** again to turn off the uppercase input mode. To see special characters, tap **Special Characters** **#+=**. To go back to the alphabetic characters, tap **A B C** .

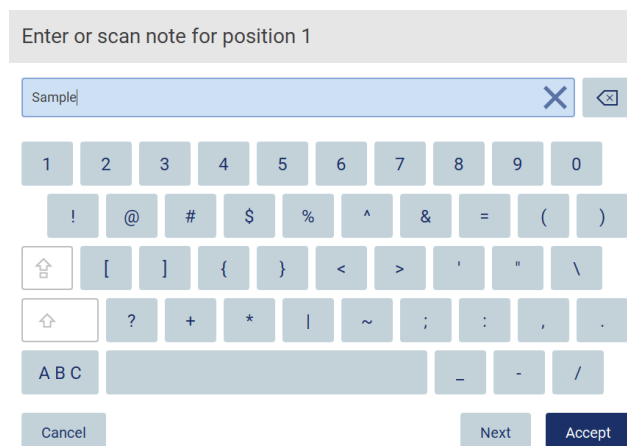


Figure 33. The on-screen keyboard in special character mode.

To remove one character to the left of the cursor, tap **Backspace** . To delete all characters from the field, tap **Clear All** .

Some fields have requirements or restrictions that need to be followed. If the entered text does not match the requirements of the field, an error message appears, and the input is not accepted.

To proceed, modify the text to meet the requirements.

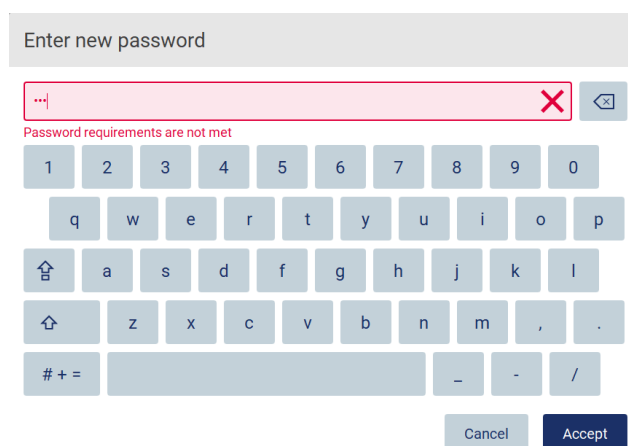
The image shows a mobile interface for entering a new password. At the top, there is a header "Enter new password". Below it is a text input field containing three dots, indicating a masked password. To the right of the input field is a red 'X' icon and a clear button (an 'X' inside a square). Below the input field, a red error message states "Password requirements are not met". Below the error message is an on-screen keyboard with four rows of keys: the first row contains digits 1-0; the second row contains letters q-p; the third row contains letters a-l; and the fourth row contains letters z-m, a comma/semicolon key, and a period/apostrophe key. At the bottom right of the keyboard area are two buttons: "Cancel" and "Accept".

Figure 34. Example of text field validation.

If certain characters are not allowed in a field, they are deactivated on the keyboard and cannot be entered in the field.

5.2. Powering on the EZ2 Connect MDx

1. Close the hood of the instrument.
2. Press the power button. If sounds are enabled on the instrument, a sound is played as the instrument is switched on. The startup screen appears, and the instrument is initialized. After the initialization is done, the Log in screen appears.

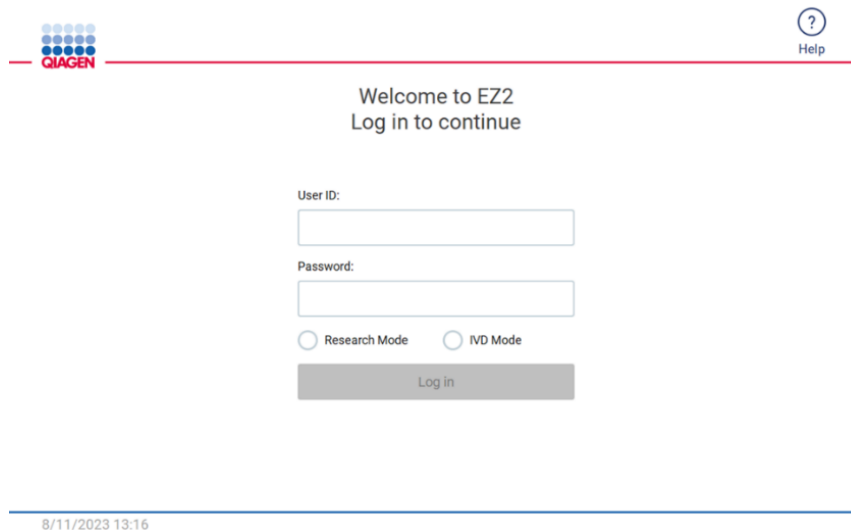
The image shows the login screen of the EZ2 Connect MDx instrument. At the top left is the QIAGEN logo. At the top right is a "Help" button with a question mark icon. The main heading in the center is "Welcome to EZ2" followed by "Log in to continue". Below this are two text input fields: "User ID:" and "Password:". Under the "Password:" field are two radio buttons labeled "Research Mode" and "IVD Mode". Below the radio buttons is a "Log in" button. At the bottom left of the screen, there is a timestamp "8/11/2023 13:16".

Figure 35. Log in screen.

3. Tap the User ID field and enter your user ID using the on-screen keyboard. For more information on using the on-screen keyboard, refer to Section 5.1.1 Entering text and numbers.

Note: If this is the first time the EZ2 Connect MDx is switched on, enter the default user ID, which is "Admin".

4. Tap the Password field and enter your password using the on-screen keyboard.

Note: If this is the first time the EZ2 Connect MDx is switched on, enter the default password, which is "Admin".

Note: After logging in, the system checks the available disk space. A warning message appears if insufficient disk space is available for five protocol runs. See Section 5.13, Data menu > Run reports, for details on how to download and delete run reports to free up disk space.

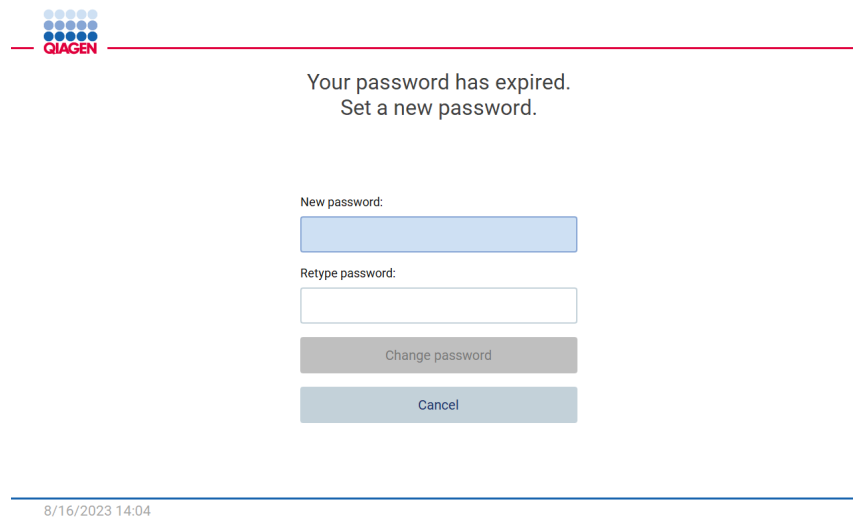
The screenshot shows a mobile application interface. At the top left is the QIAGEN logo, consisting of a grid of blue dots above the word 'QIAGEN' in red. A red horizontal line spans the width of the screen. Below this line, the text 'Your password has expired. Set a new password.' is centered. Underneath, there are two input fields: the first is labeled 'New password:' and the second is labeled 'Retype password:'. Below these fields are two buttons: a grey 'Change password' button and a blue 'Cancel' button. At the bottom of the screen, a blue horizontal line is followed by the timestamp '8/16/2023 14:04'.

Figure 36. Set a new password screen after first log in.

Note: After the first login using the default Admin account, the password must be changed according to the password policy described in Section 5.4.5 Managing user security and as per the instructions in Section 5.4.4 Changing password.

5. Please select the IVD or Research mode to launch. For details of the software modes, please refer to Section 3.1 EZ2 Connect MDx principle.
6. Tap **Log in**. If the credentials you entered are correct, the Home screen appears. If the credentials you entered are incorrect, an error message is shown.

Note: If the number of failed login attempts exceeds the limit set by your administrator (three by default), your account is locked. To activate your account, contact your administrator. If you are the only user with an Administrator role and your account is locked, contact QIAGEN Technical Support.

Note: It is recommended to create at least one more account with the Administrator role in addition to the default Admin account. If one administrator is locked out due to incorrect credentials, the other administrator can unlock the account (see Section 5.4.3 Managing users).

5.3. Shutting down the EZ2 Connect MDx

1. Ensure that the system is not operating.
2. Press the power button.

5.4. Configuring the EZ2 Connect MDx

Administrators of the EZ2 Connect MDx can adjust instrument settings, manage users, upload protocols, update software, and configure network connectivity.

Note: Users whose role is defined as Operator do not have access to settings and configuration features of the software.

5.4.1. Setting basic system data

To set the instrument name, date, time, and date format, follow the steps below:

Note: Only administrators can change system settings.

1. Tap the **Configuration** icon on the toolbar.



Figure 37. Configuration button on the toolbar.

2. Tap the **System configuration**.

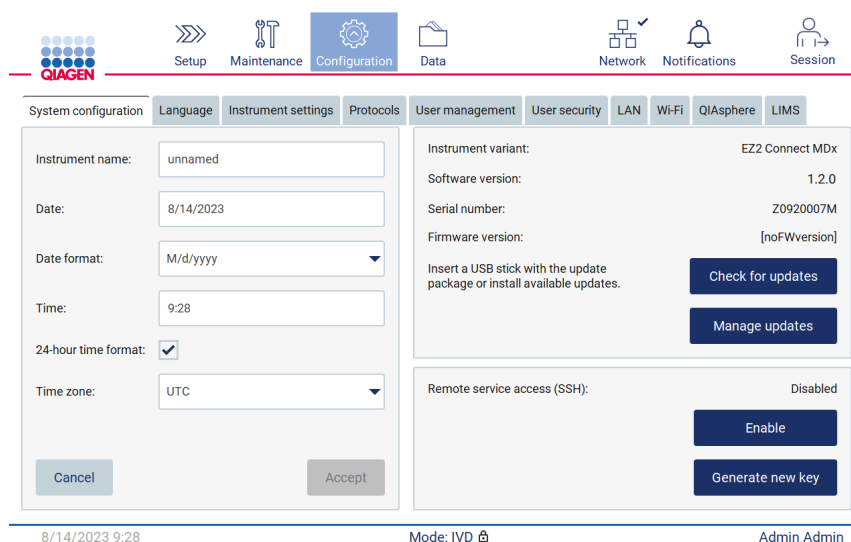


Figure 38. The System configuration tab.

3. To set the device name, tap the Instrument name field and enter a name using the on-screen keyboard. To save the name, tap **Accept**.

Note: The device name cannot be longer than 24 characters. The name cannot contain special characters or spaces.

- To set the date, tap the Date field and select the date using the date picker. To change the month, the year, or both, use the left and right arrows on either side of the month and year label. To select a specific date, tap the day on the calendar. To confirm your selection, tap **Accept**.

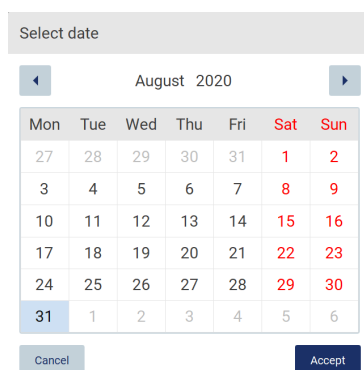


Figure 39. Select date dialog box.

- To set the date format, tap the Date format drop-down list and select one of the listed formats.
- To set the time, tap the Time field and enter the time using the on-screen keyboard.
- To use the 24 hour time format, select the "24-hour time format" checkbox. To use the 12 hour format, clear the "24-hour time format" checkbox.
- To save the settings, tap **Accept**.

5.4.2. Changing instrument settings

You can adjust the settings of the EZ2 Connect MDx according to your preferences.

Note: Only administrators can change Instrument settings.

To modify Instrument settings, follow the steps below:

- Tap the **Configuration** icon on the toolbar.



Figure 40. Configuration button on the toolbar.

2. Tap **Instrument settings**.

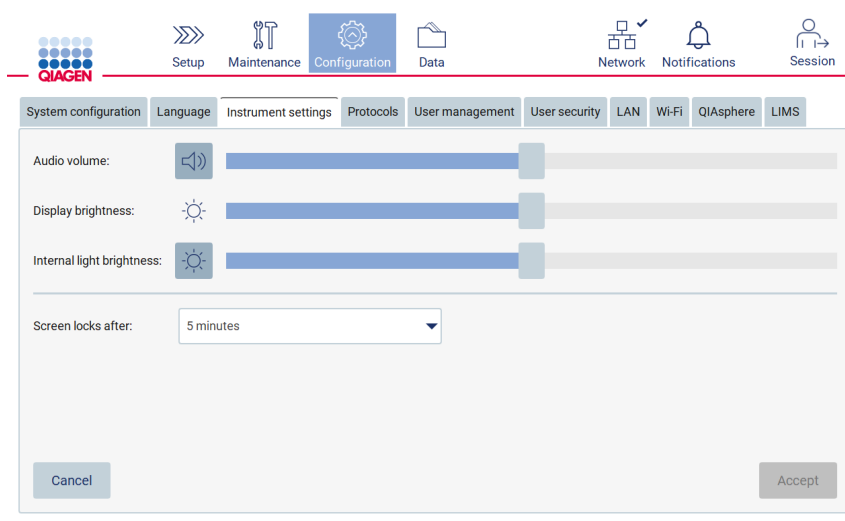


Figure 41. The Instrument settings tab.

3. To adjust the volume of the audio, use the **Audio volume** slider. A sound is played each time you change the volume. To mute the device, tap **Audio** or move the slider to the far-left position.
4. To adjust the brightness of the touchscreen, use the **Display brightness** slider. By moving the slider to far left, the minimal brightness will be set.
5. To adjust the brightness of the internal light, use the **Internal light brightness** slider. To turn the internal light off, tap **Internal light brightness** or move the slider to the far-left position.
6. To adjust the time until the lock screen appears, tap on the drop-down menu next to "Screen locks after". It is possible to set the time between 1 and 30 minutes or to disable the lock screen. The lock screen appears after 5 minutes with default settings.

Note: It is recommended to leave the lock screen function activated in order to avoid unauthorized access to the system.

7. Tap **Accept** to save the modified settings, or tap **Cancel** to restore previously saved settings.

5.4.3. Managing users

The EZ2 Connect MDx user management allows you to create and edit user accounts with two different roles: Administrator and Operator. When you use the EZ2 Connect MDx for the first time, a default user (Admin) is pre-installed and configured.

Note: User management is only available to users with the Administrator role.

Adding a new user

Note: Only administrators can add new users.

1. Tap the **Configuration** icon on the toolbar.



Figure 42. Configuration button on the toolbar.

2. Tap the **User management** tab. Existing users are shown in the table.

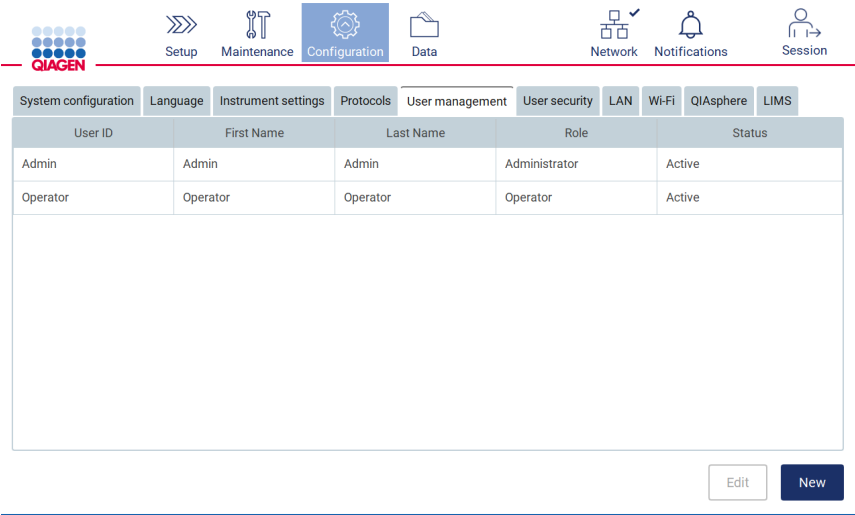


Figure 43. The User management tab.

3. To add a new user, tap **New**. The Create new account dialog box is shown.

Create new account

Anonymous ID:
-

User ID:

First name:

Last name:

User role:
Administrator

User status:
Active

Password status: Not set

Cancel

Set password

Accept

Figure 44. Create new account dialog box.

4. Tap the respective boxes to enter the User ID, First name, and Last name using the on-screen keyboard. The Anonymous ID is generated automatically and is used to identify users in reports and audit trails.

Note: Only administrators can view the full details of a user account. As a result, only administrators can identify users based on their anonymous IDs.

5. Select the User role and User status from their respective drop-down lists.
6. Tap **Set password**. The Set user password dialog box appears. Enter the password in the New password field and again in the Retype password field. The password must meet the criteria displayed in the dialog box. To look up the password policy, refer to Section 5.4.5 Managing user security.

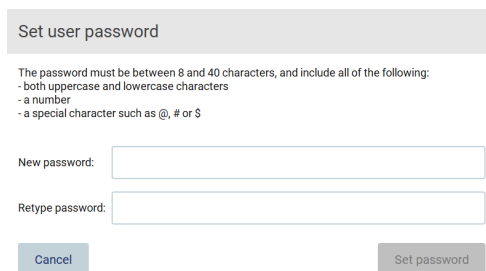
The image shows a 'Set user password' dialog box. At the top, it says 'Set user password'. Below that, it states: 'The password must be between 8 and 40 characters, and include all of the following: - both uppercase and lowercase characters - a number - a special character such as @, # or \$'. There are two input fields: 'New password:' and 'Retype password:'. At the bottom, there are two buttons: 'Cancel' and 'Set password'.

Figure 45. Set user password dialog box.

7. Tap **Set password**. If the passwords match, the password status is set to active.

Note: Users must change their password after upon first login. Tap **Accept**. The user is added.

Note: It is recommended to create at least one more account with the Administrator role in addition to the default Admin account. If one administrator is locked out due to incorrect credentials, the other administrator can unlock the account.

Editing an existing user account

Note: Only administrators can edit user accounts.

1. Tap the **Configuration** icon on the toolbar and tap the **User management** tab. Existing users are shown in the table.



Figure 46. Configuration button on the toolbar.

2. Tap the **User management** tab. Existing users are shown in the table.

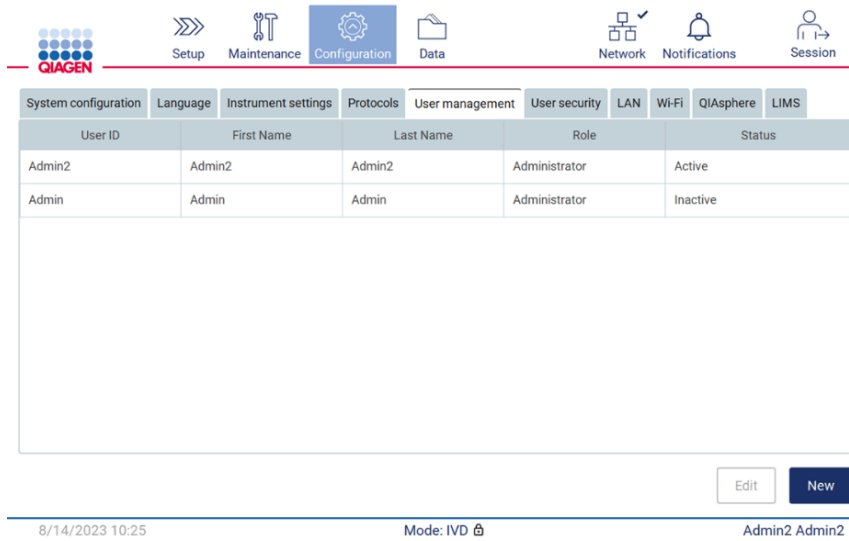


Figure 47. The User management tab.

3. Tap the table row that corresponds to the user whose profile you want to edit. The Edit user account dialog box appears.

Edit user account

Anonymous ID:

dc213c87

User ID:

Operator

First name:

Operator

Last name:

Operator

User role:

Operator

User status:

Active

Password status:

Active

Cancel

Change password

Accept

Figure 48. Edit user account dialog box.

4. To edit the First name or Last name, tap the respective boxes and modify the contents using the on-screen keyboard.

5. To change the **User role** or **User status**, tap the respective drop-down lists and select an option.

6. To change the password of the user, tap **Change password**. The Change user password dialog box appears.

Note: This can be done if a user forgets his password.

Change user password

The password must be between 8 and 40 characters, and include all of the following:

- both uppercase and lowercase characters
- a number
- a special character such as @, # or \$

New password:

Retype password:

Cancel

Change password

Figure 49. Change user password screen.

- Enter the password in the New password field and again in the Retype password field. The password must meet the criteria displayed in the dialog. To look up the password policy, refer to Section 5.4.3 Managing user security.
- Tap **Change password**.
- To save the changes made to the user account, tap **Accept**.

Note: For cybersecurity reasons, an Operator must change the password provided by the Administrator upon first login.

Deactivating/activating a user

Note: Only administrators can delete user accounts. If a user account is automatically inactivated due to multiple incorrect login attempts, it can be reactivated either by a secondary administrator and the procedure below or by using the Help center (see Section 4.5.5 Initial configuration of the EZ2 Connect MDx).

- Tap the **Configuration** icon on the toolbar.



Figure 50. Configuration button on the toolbar.

- Tap the **User management** tab. Existing users are shown in the table.

User ID	First Name	Last Name	Role	Status
Admin2	Admin2	Admin2	Administrator	Active
Admin	Admin	Admin	Administrator	Inactive

8/14/2023 10:25 Mode: IVD Admin2 Admin2

Figure 51. The User management tab.

- Tap the table row that corresponds to the user that you want to deactivate or reactivate.
- Tap **Edit**.
- Tap the User status drop-down list and select the desired status (**Active** or **Inactive**).
- Tap **Accept**.

5.4.4. Changing password

All active users can change their own passwords. Additionally, administrators can change the passwords of other users. For more information on how to change passwords of other users, refer to the Editing an existing user account section under Section 5.4.3 Managing users.

Note: For cybersecurity reasons, an Operator must change the password provided by the Administrator upon first login.

Note: The new passwords must be different from the three previous passwords.

To change your own password, follow the procedure below.

1. Tap the **Configuration** icon on the toolbar.

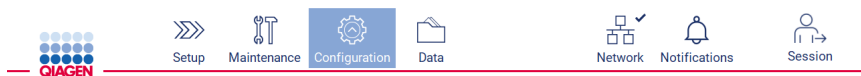


Figure 52. The Configuration button on the toolbar.

2. Tap **Edit**.

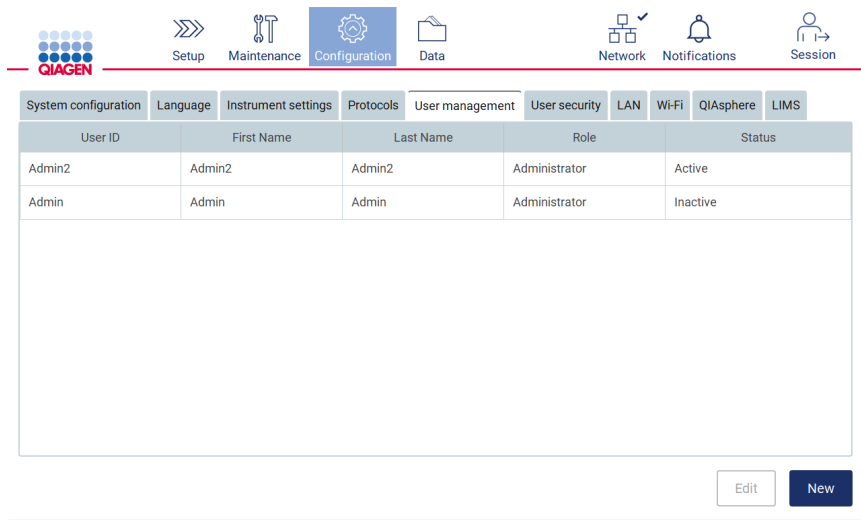


Figure 53. User management tab (visible only for Administrator roles).

3. Tap **Change password**.

Edit user account

Anonymous ID:

732d230c

User ID:

Operator

First name:

Operator

Last name:

Operator

User role:

Operator

User status:

Active

Password status: Active

Cancel

Change password

Accept

Figure 54. Change password screen.

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4. Tap the Current password field and enter your current password using the on-screen keyboard.
5. Tap **Accept**.
6. Enter the password in the New password field and again in the Retype password field. The password must meet the criteria displayed on the screen.
7. Tap **Change password**.

Note: For Operator roles, the configuration screen looks different.

Figure 55. Configuration screen for Operator role.

8. If you are logged in with an Operator role, you can change your password directly in the Configuration screen.
9. If the current Admin password is unknown, the password can be changed via the Help Center (see Section 4.5.5 Initial configuration of the EZ2 Connect MDx).

5.4.5. Managing user security

Only administrators can change the settings for password expiration, policies, and limit incorrect login attempts.

To modify settings related to user security, follow the steps below:

1. Tap the **Configuration** icon on the toolbar.



Figure 56. The Configuration button on the toolbar.

2. Tap the **User security** tab.

The screenshot displays the QIAGEN EZ2 Connect MDx user interface. At the top, there is a navigation bar with icons for Setup, Maintenance, Configuration (highlighted), and Data. Below this is a secondary navigation bar with tabs for System configuration, Language, Instrument settings, Protocols, User management, and User security (highlighted). The User security tab is active, showing a form for configuring password policies. The form includes a 'User role' dropdown menu set to 'Administrator', a 'Password policy' dropdown menu set to 'Strong policy', an 'Enable password expiration' checkbox, a 'Password expires every' field set to '90' days, and an 'Account locks after' field set to '3' incorrect login attempts. A 'Cancel' button is at the bottom left, and an 'Accept' button is at the bottom right. A 'Password policies' section on the right provides details for three policy types: 'No policy' (password up to 40 characters, can be empty), 'Standard policy' (password must be between 8 and 40 characters), and 'Strong policy' (password must be between 8 and 40 characters and include uppercase, lowercase, numbers, and special characters).

Figure 57. User security tab.

3. To look up the password policy, select the user role whose policy you want to see from the User role drop-down list.
4. The password policies can be changed for each user role. It is recommended to leave the password policies at “strong” to avoid cybersecurity risks.

Note: Changing the password policies may lead to non-compliance with national or international laws, standards, or regulations, and could seriously compromise the product’s cybersecurity. If the policies are changed, the user is accepting full responsibility for these risks. The administrator ID and the action will be recorded in the audit trail for traceability.

5. To enable password expiration, select the “Enable password expiration” checkbox.
6. To specify the number of days after which user passwords expire, enter a value in the Days field within the acceptable range of 1 to 360.
7. To specify the number of incorrect login attempts after which a user account is locked, enter a value in the Incorrect login attempts field within the acceptable range of 1 to 50. It is recommended to set at least two incorrect attempts. Otherwise, one typographical error will lock your account. Only administrators can unlock locked accounts.
8. Tap **Accept** to save all changes, or tap **Cancel** to restore previously saved settings.

5.4.6. Installing new protocols

Note: Only administrators can install new protocol packages.

Note: The Protocols tab is only available to users with Administrator role.

The protocols are integrated into the EZ2 Connect MDx software. However, QIAGEN can provide protocol packages independently of the software to update existing protocols or provide new protocols. If an updated protocol version is available, it can be found on the EZ2 Connect MDx product page (www.qiagen.com/EZ2ConnectMDx). It is recommended to check regularly for the latest version of the protocol package. Protocols can be installed using a USB stick or the QIAsphere. QIAsphere automatically checks for the latest version and notifies the user if a new package is available. During installation from the USB stick, the EZ2 Connect MDx informs the user whether the latest version is already installed or whether the package contains newer versions or even new protocols. The system also shows the currently installed protocol versions and the new protocol versions.

Installing protocols using a USB stick

Note: To ensure your EZ2 Connect MDx has the latest protocol versions installed, please visit the EZ2 Connect MDx product page (www.qiagen.com/EZ2ConnectMDx). You can find the protocol versions in step 2 of 7 of the setup wizard.

Note: Installing a new protocol package overwrites all existing protocols. Make sure that all previously installed protocols are available on a USB stick for rollback if required.

Important: Use only EZ2 Connect MDx–related files downloaded from www.qiagen.com or provided by QIAGEN Technical Support.

Note: Checksum confirmation is required to secure software integrity after the web download is successfully completed and before subsequent handling of the software. For detailed information on confirmation of software integrity during download and file transfer, please check the “QIAGEN software integrity verification process” description document, which is provided on the QIAGEN webpage.

Important: Use only the USB stick provided by QIAGEN. Do not connect other USB stick devices to the USB ports.

Important: Do not remove the USB drive while downloading or transferring data or software to or from the instrument.

1. Plug in a USB stick with a protocol package.
2. Tap **Configuration** on the toolbar.



Figure 58. Configuration button on the toolbar.

3. Tap **Protocols**.

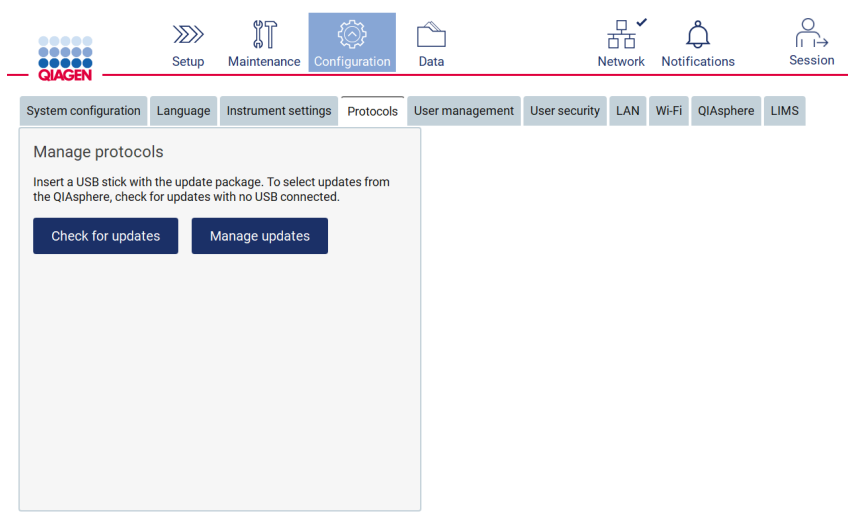


Figure 59. Protocols tab.

4. Tap **Check for updates**.

5. If protocol upload packages are detected on the USB stick, a pop-up window appears.

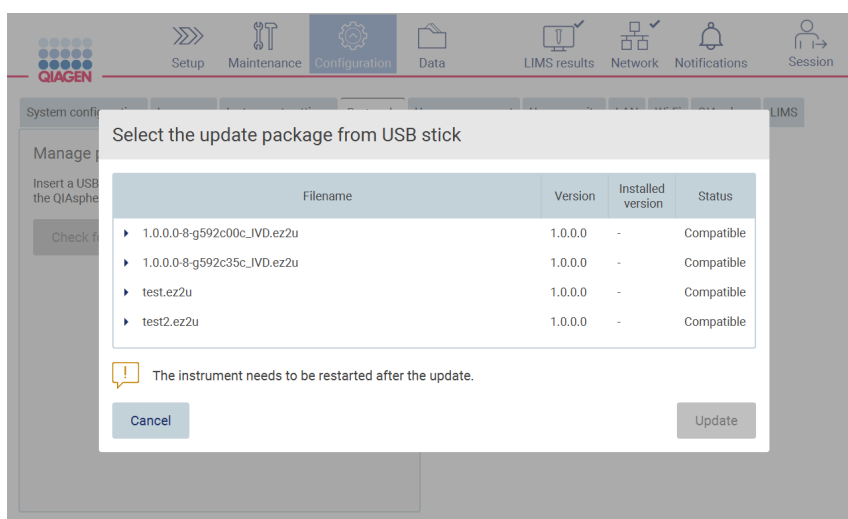


Figure 60. Update package pop-up window.

6. Start the installation by choosing the desired protocol package and tap **Update**.

7. After the installation is finished, a message box appears. Restart the device to make the new protocols available.

Note: Not all protocols are installable on all instrument variants. Those protocols are marked as not available on this instrument type if they are included in the protocol update package. The package can still be installed, just the marked protocols will not be installed.

Installing protocols via QIASphere

1. Ensure that the QIASphere connection is established (see Section 5.4.9 Configuring network and QIASphere Base connections).
2. If an update is available, QIASphere automatically informs the user about an available update.

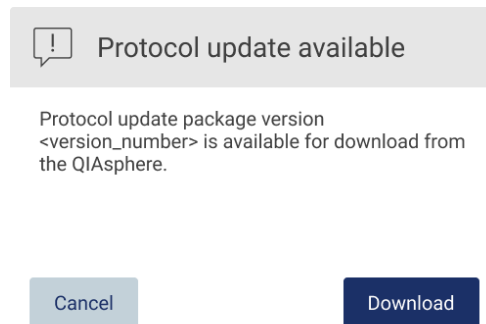


Figure 61. Protocol update available pop-up window.

3. Tap **Download**. The download process starts.

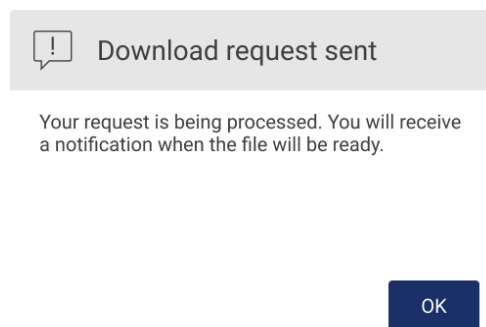


Figure 62. Download request notification pop-up window.

4. Tap **OK**. A notification is sent when the download is finished.
5. Tap **Configuration** on the toolbar.
6. Tap **Check for updates**.
7. If protocol upload packages were downloaded, a pop-up window appears.

8. Start the installation by choosing the desired protocol package and tapping **Update**.

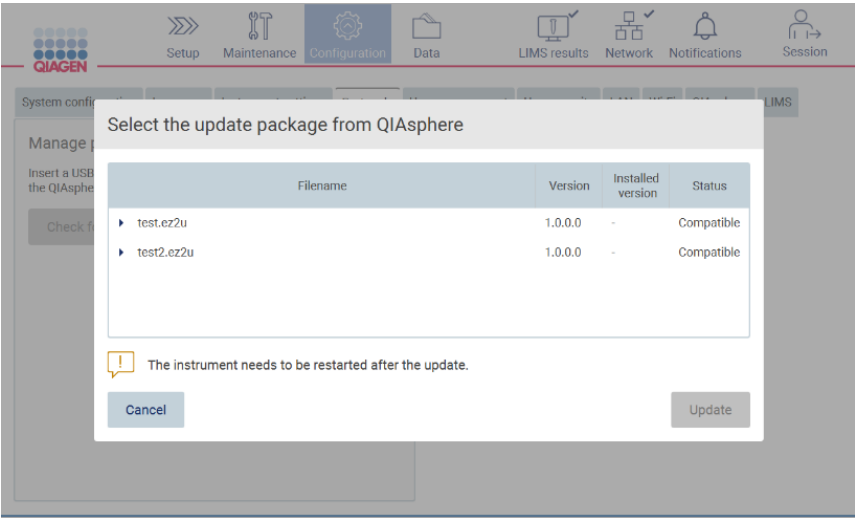


Figure 63. QIAsphere pop-up window for protocol updates.

9. After installation is finished, a message box appears. Restart the device to make the new protocols available.

Note: Downloaded protocol packages (via QIAsphere) can be deleted by tapping the **Manage updates** button (under **Protocols** tab) and selecting the protocol package to delete. Subsequently, tap **Delete**.

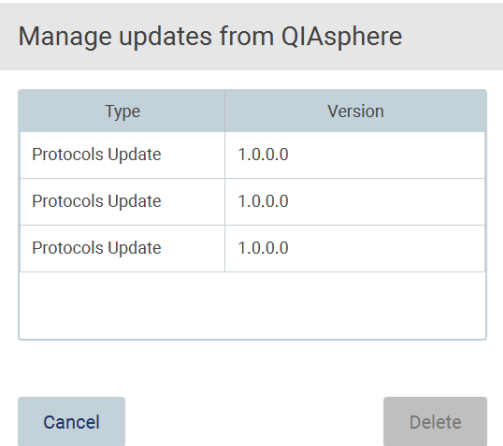


Figure 64. Manage updates from QIAsphere dialog box.

5.4.7. Installing language packages and changing languages

Note: Only administrators can change language and install new language packages.

Note: The **Language** tab is only available to users with the Administrator role.

Note: The text for protocol loading and descriptions screens may not be translated and remain in English version. It might be that, in the Research Mode, the text of the protocol loading and description screens is not translated and stays in English.

Important: Use only EZ2 Connect MDx–related files downloaded from www.qiagen.com or provided by QIAGEN Technical Support.

Note: Checksum confirmation is required to secure software integrity after the web download is successfully completed and before subsequent handling of the software. For detailed information on confirmation of software integrity during download and file transfer, please check the “QIAGEN software integrity verification process” description document, which is provided on the QIAGEN webpage.

Important: Use only the USB stick provided by QIAGEN. Do not connect other USB stick devices to the USB ports.

Important: Do not remove the USB drive while downloading or transferring data or software to or from the instrument.

1. The language packs are integrated into the EZ2 Connect MDx software. However, QIAGEN may also provide language packs independently of the software to update current or provide new languages. If there is an updated version of the language pack available, it can be found on the EZ2 Connect MDx product page (www.qiagen.com/EZ2ConnectMDx). Plug in a USB stick with a language package.
2. Tap **Configuration** on the toolbar.



Figure 65. Configuration button on the toolbar.

3. Tap **Language**.
4. You have the choice of either uploading a new language package to make a new language available or changing the language settings.

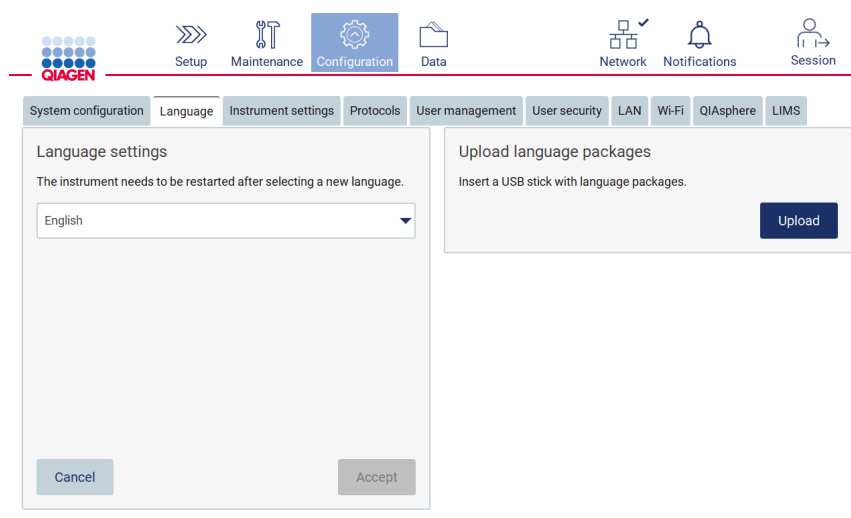


Figure 66. Language tab.

5. Tap **Upload** in the Upload language packages window.

6. If language upload packages are detected on the USB stick, a pop-up window appears.

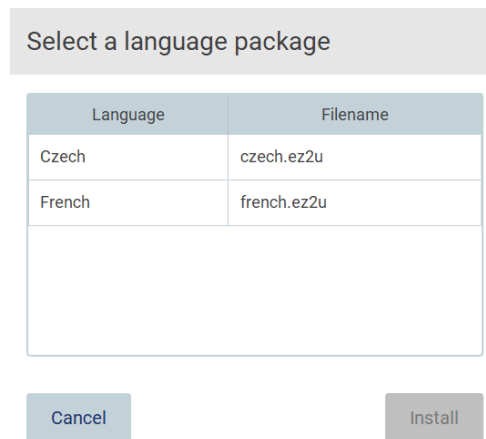


Figure 67. Language package pop-up window.

7. Select the desired language package and tap **Install**. Only one language package can be uploaded at a time.
8. From the Language screen, tap the **Language settings** drop-down list.
9. Select the required language.
10. Tap **Accept**.

Note: Restart the EZ2 Connect MDx to apply the selected language.

5.4.8. Updating software

Note: Only administrators can update the software.

Note: System configuration is only available to users with the Administrator role.

Note: To ensure your EZ2 Connect MDx has the latest software versions installed, visit the EZ2 Connect MDx product page (www.qiagen.com/EZ2ConnectMDx). The currently installed software version can be found in the **Configuration** menu, under the **System configuration** tab.

Important: Use only the USB stick provided by QIAGEN. Do not connect other USB stick devices to the USB ports.

Important: Use only EZ2 Connect MDx–related files downloaded from www.qiagen.com or provided by QIAGEN Technical Support.

Note: Checksum confirmation is required to secure software integrity after the web download is successfully completed and before subsequent handling of the software. For detailed information on confirmation of software integrity during download and file transfer, please check the “QIAGEN software integrity verification process” description document, which is provided on the QIAGEN webpage.

Important: Do not remove the USB drive while downloading or transferring data or software to or from the instrument.

The latest version of the software is available on the EZ2 Connect MDx product page (www.qiagen.com/EZ2ConnectMDx). Check the webpage regularly to ensure that the latest version is used. Software updates can be installed using a USB stick or via QIASphere. QIASphere automatically checks for the latest version and notifies the user if a new version is available. The currently installed software version can be seen in the **Configuration** tab.

Installing the newest software version using a USB stick

- 1. Plug in a USB stick with the newest software version.
- 2. Tap the **Configuration** icon on the toolbar.



Figure 68. Configuration button on the toolbar.

- 3. Tap the **System configuration** tab.

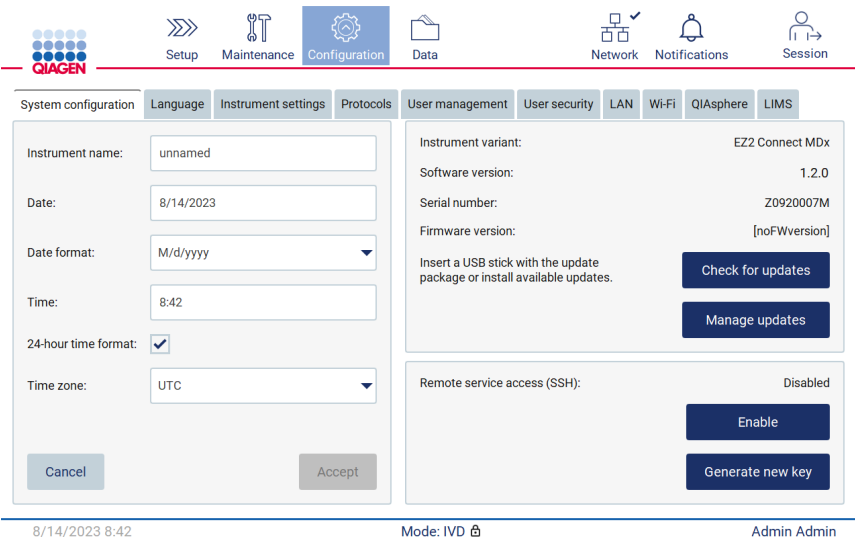


Figure 69. The System configuration tab.

- 4. Tap **Check for updates** to check the attached USB drive.
- 5. If a software update package has been detected on the USB stick, a pop-up window appears.

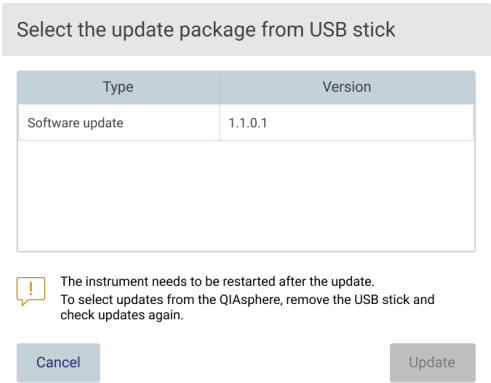


Figure 70. Update package pop-up window.

6. Start the installation by choosing the desired software package and tap **Update**.
7. After the installation is finished, restart the device.

Installing software updates via QIAsphere

1. Ensure that the QIAsphere connection is established (see Section 5.4.9 Configuring network and QIAsphere Base connections).
2. If an update is available, QIAsphere automatically informs the user about an available update.

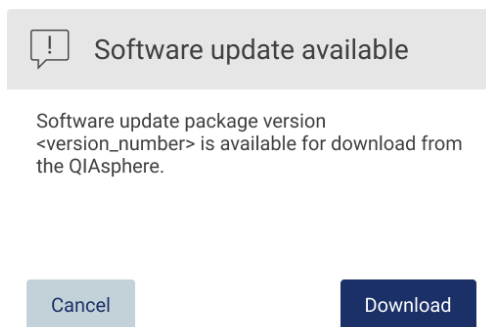


Figure 71. Software update pop-up window.

3. Tap **Download**. The download process starts.

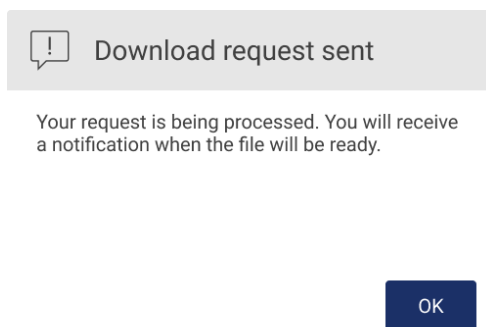


Figure 72. Download request notification pop-up window.

4. Tap **OK**. A notification is sent when the download is finished.

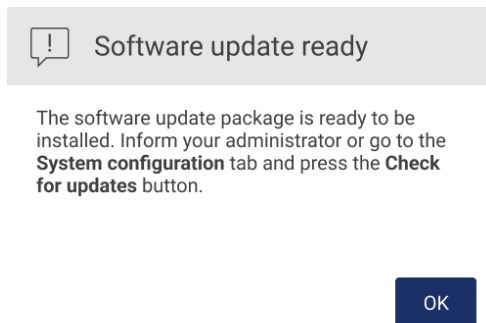


Figure 73. Software update notification pop-up window.

5. Tap the **System configuration** tab.

6. Tap **Check for updates**.
7. If a software update package has been downloaded, a pop-up window appears.

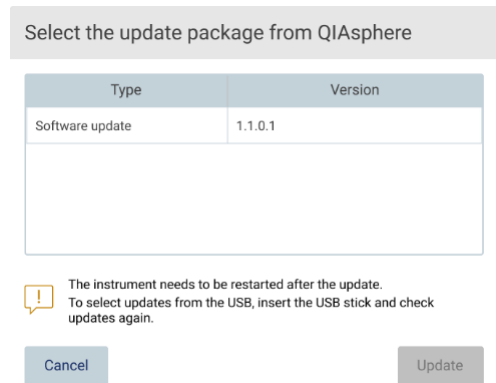


Figure 74. Update selection pop-up window.

8. Start the installation by choosing the desired software package and tapping **Update**.
9. As instructed by the user interface, restart the device one or several times during the update process.

5.4.9. Configuring network and QIASphere Base connections

Configuring a LAN connection

Note: The **LAN** tab is only available to users with Administrator role.

1. Tap the **Configuration** icon on the toolbar.



Figure 75. Configuration button on the toolbar.

2. Tap the **LAN** tab.

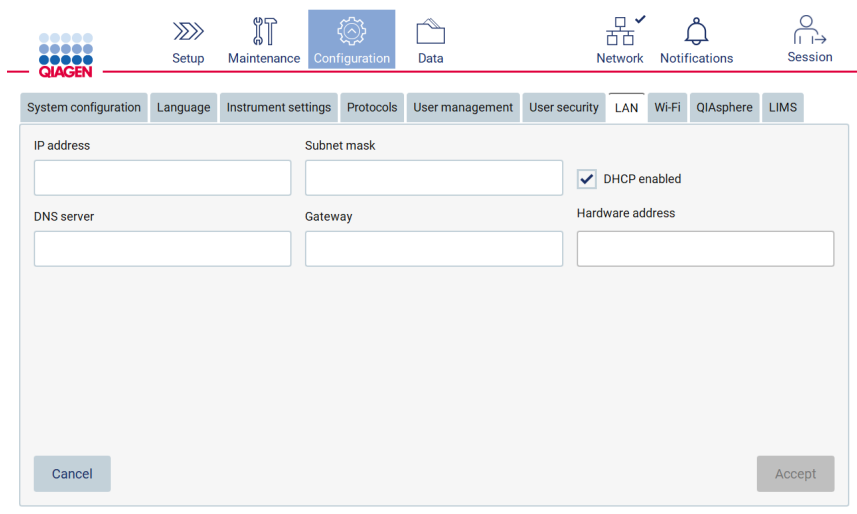


Figure 76. The LAN tab.

3. Enter the appropriate network setting as provided by your IT department.
4. Tap **Accept**.

Note: Configure the network settings so that EZ2 Connect MDx is not visible outside your organization's network.

Note: Hardware address = MAC address

The screenshot shows the EZ2 Connect MDx Configuration screen. The top toolbar includes icons for Setup, Maintenance, Configuration (highlighted), Data, Network, Notifications, and Session. Below the toolbar is a horizontal menu with tabs: System configuration, Language, Instrument settings, Protocols, User management, User security, LAN (selected), Wi-Fi, QIAsphere, and LIMS. The LAN tab displays the following settings:

IP address 10.10.10.139	Subnet mask 255.255.255.0	☐ DHCP enabled
DNS server 8.8.8.8	Gateway 10.10.10.1	Hardware address 2C:54:91:88:C9:E3

At the bottom of the screen are two buttons: "Cancel" and "Accept".

Figure 77. Configured LAN tab.

Configuring a Wi-Fi connection

Note: Only administrators can configure Wi-Fi settings.

Note: Make sure that the Wi-Fi USB device is plugged in before starting the instrument.

The EZ2 Connect MDx can be connected to a Wi-Fi network using a Wi-Fi adapter inserted into one of the USB ports. The Wi-Fi adapter supports the 802.11b, 802.11g, and 802.11n Wi-Fi standards, as well as WEP, WPA-PSK, and WPA2-PSK encryption.

The SSID of the network must be visible. It is not possible to connect to a network with a hidden SSID.

To configure the Wi-Fi connection, follow the steps below:

1. Tap the **Configuration** icon on the toolbar.



Figure 78. Configuration button on the toolbar.

2. Tap the **Wi-Fi** tab.

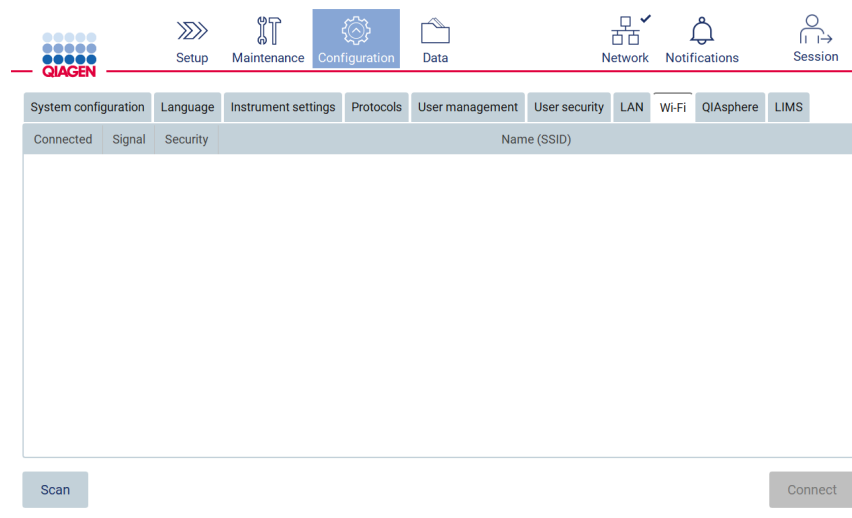


Figure 79. The Wi-Fi tab.

3. To search for available networks, tap **Scan**. The signal strength, encryption type, and name of each network are shown.

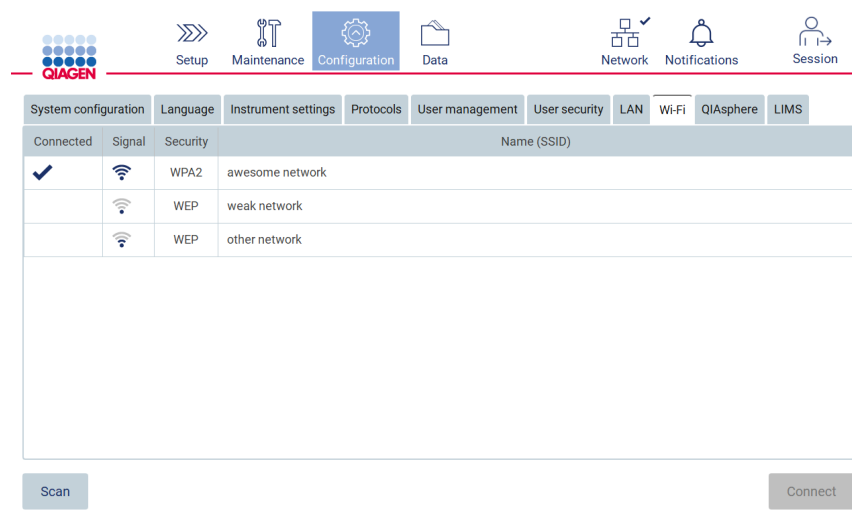


Figure 80. List of available Wi-Fi networks.

4. To select a network, tap the row that corresponds to the network you want to select.
5. To connect to the selected network, tap **Connect**.
6. Enter the network password using the on-screen keyboard and tap **Connect**. The instrument connects to the network, and the connection status is updated on the screen.

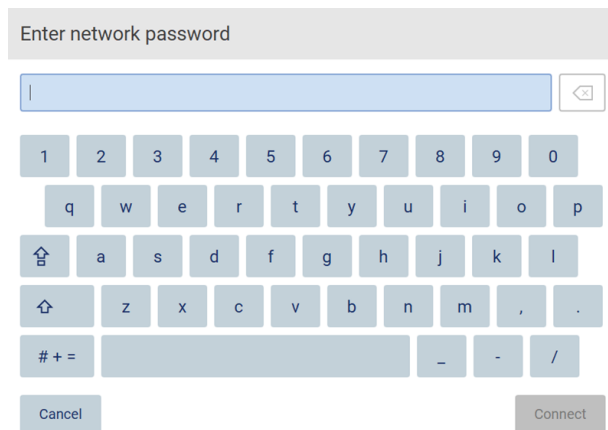


Figure 81. On-screen keyboard.

Note: If you failed to connect to the network after several attempts despite entering the correct password, restart the instrument.

Note: In case of errors, refer to Section 8 Troubleshooting for more information.

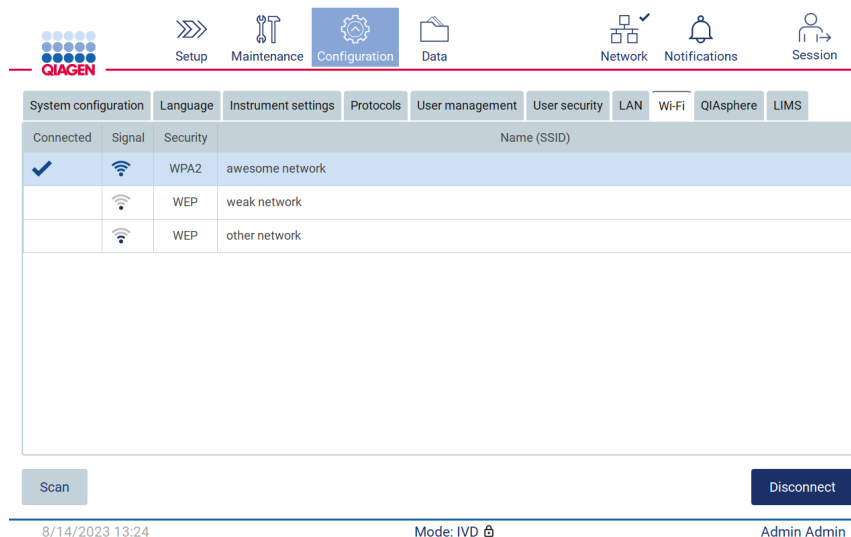


Figure 82. Successful connection to a Wi-Fi network.

- To disconnect from a network, tap the row that represents the network that the instrument is connected to. Then, tap **Disconnect**.

Note: Configure the department network in a way that makes the EZ2 Connect MDx not visible outside the network of your organization.

Configuring QIASphere Base connection

For information on how to configure QIASphere Base for connection to the QIASphere App, refer to the *QIASphere User Manual*.

For more details on the QIASphere Base network configuration and how to connect the EZ2 Connect MDx, refer to the *QIASphere User Manual* that is available at www.qiagen.com/qiasphere

Only users assigned the Administrator role can change the network configuration. It is recommended to consult your network administrator when configuring the network. For communication with QIASphere Base, the outbound TCP port 443 (https) is used; ping is supported.

1. Tap the **Configuration** icon on the toolbar.



Figure 83. Configuration button on the toolbar.

2. Tap the **QIASphere** tab.

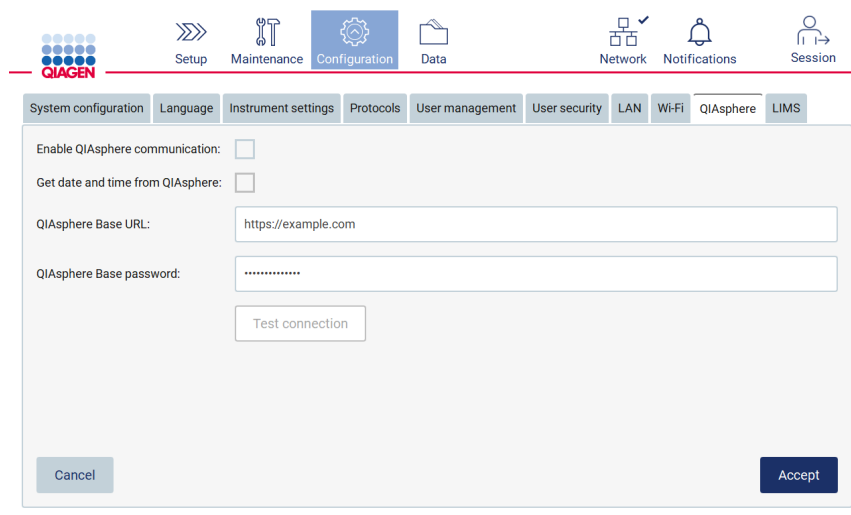


Figure 84. The QIASphere tab.

3. Enter the QIASphere Base URL.
4. Enter the QIASphere Base password.
5. Tick the “Enable QIASphere communication” checkbox.
6. **Optional:** To synchronize the date and time with QIASphere, tick the “Get date and time from QIASphere” checkbox.
Note: Time synchronization is performed only if the EZ2 Connect MDx is connected to QIASphere.
7. Tap **Accept**.
8. Tap **Test connection**.

Note: If you have any trouble regarding the QIASphere, please refer to *QIASphere User Manual* or contact QIAGEN Technical Support.

Configuring LIMS connection

Note: Only administrators can configure the LIMS connection.

Note: System configuration is only available to users with Administrator role.

Note: QIAGEN offers a dedicated service to establish the communication between the EZ2 Connect MDx and your LIMS system. To request this service, contact your QIAGEN Sales Representative to request a quotation.

Important: Use only the USB stick provided by QIAGEN. Do not connect other USB stick devices to USB ports.

Important: Do not remove the USB drive while downloading or transferring data or software to or from the instrument.

The EZ2 Connect MDx can be connected to a LIMS system. Configure the connection in the Configuration menu under the LIMS tab and by completing the following steps:

- Upload the LIMS Connector certificate
- Generate new instrument certificate
- Enter the LIMS Connector URL
- Register the instrument in the LIMS Connector

QIAGEN LIMS Connector is a connectivity component that enables the data transfer between the EZ2 Connect MDx and Laboratory Information Systems (LIS), Laboratory Information Management Systems (LIMS), Laboratory Automation System (LAS), Workflow Management Systems, or Middleware Systems.

Important: The installation of QIAGEN LIMS Connector must be performed by a QIAGEN representative. A person who is familiar with your laboratory and computer equipment should be present during the installation of the QIAGEN LIMS Connector.

In some rare cases, it may be necessary to reupload the QIAGEN LIMS Connector certificate. This certificate is generated locally by the QIAGEN Service Team during the LIMS Connector setup and is saved on a USB drive; it cannot be provided remotely. For support with a QIAGEN LIMS Connector certificate, contact your local Technical Service team.

1. Plug in a USB stick with the QIAGEN LIMS Connector certificate.
2. Tap **Configuration** on the toolbar.



Figure 85. Configuration button on the toolbar.

3. Tap the **LIMS** tab.

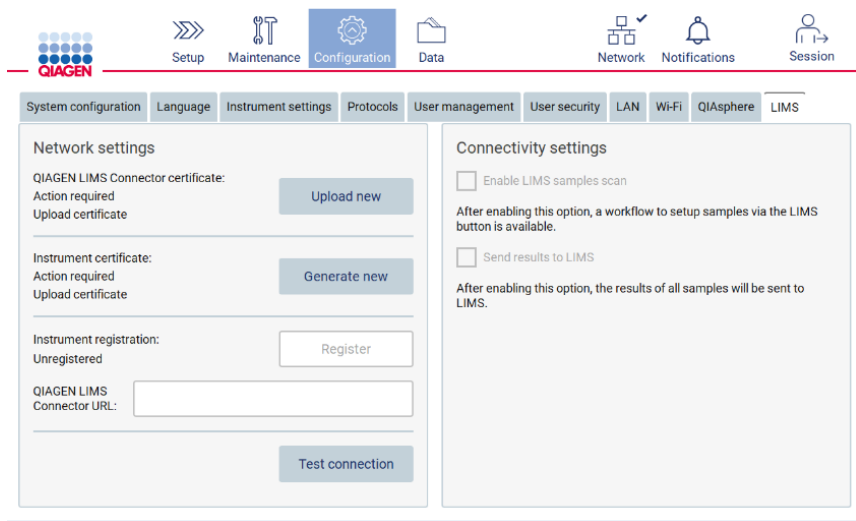


Figure 86. LIMS configuration tab.

4. Tap **Upload new**.

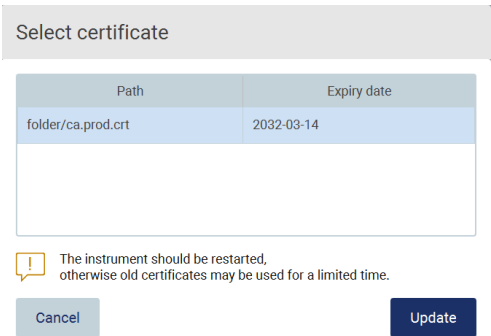


Figure 87. Select certificate screen.

5. Select the certificate and tap **Update**.

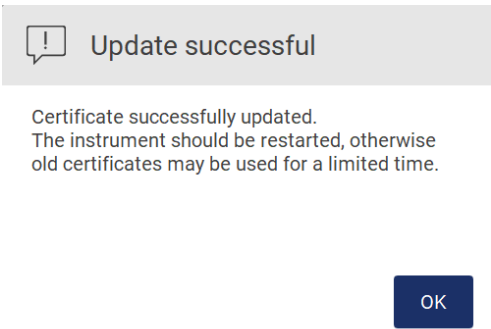


Figure 88. Successful certificate update.

6. Tap **OK** and restart the EZ2 Connect MDx.

- From the **LIMS configuration** tab, tap **Generate new**. The certificate is stored on attached USB stick.

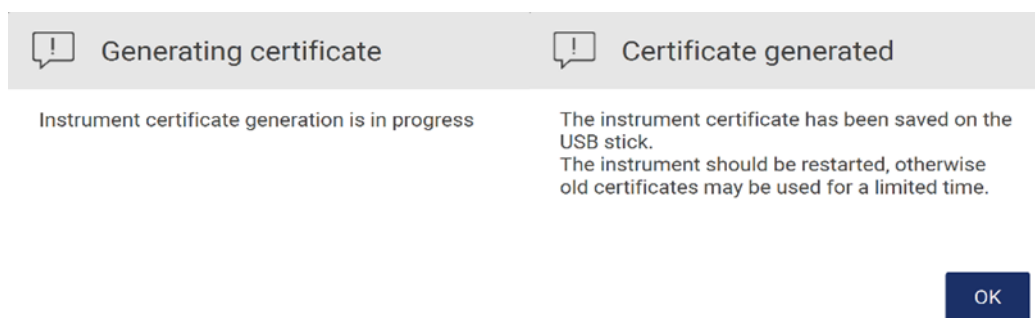


Figure 89. Generation of Instrument certificate.

- Tap **OK**.
- Install the generated certificate from the USB stick on the QIAGEN LIMS Connector.
- Tap the QIAGEN LIMS Connector URL box to enter the URL using the on-screen keyboard.



Figure 90. Enter QIAGEN LIMS Connector URL.

- Tap **Accept**.

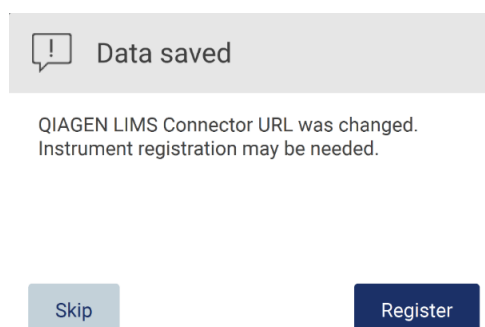


Figure 91. URL accepted.

- Tap **Register** to register the instrument and select a configuration.

If the instrument is already registered and only the LIMS Connector address is changed, enter a new URL and tap **Skip**.

13. To select a new configuration, you can also tap **Register** on the **LIMS configuration** tab.

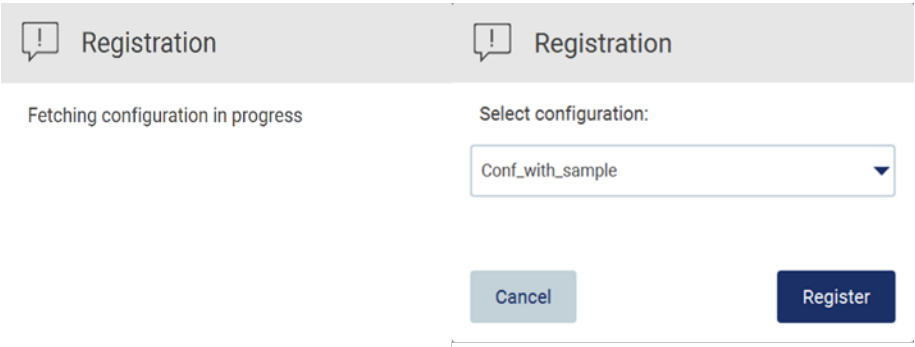


Figure 92. LIMS registration.

14. Select configuration from the drop-down list and tap **Register**.

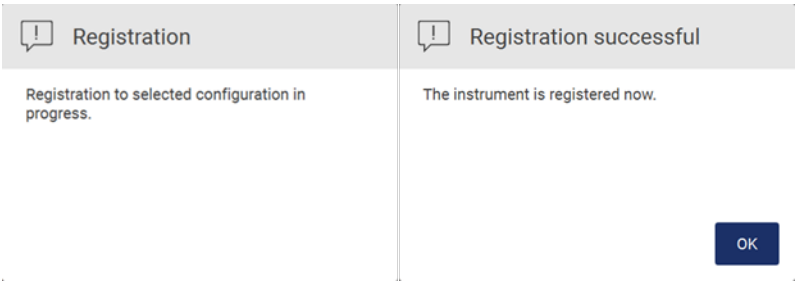


Figure 93. LIMS registration successful.

15. Tap **OK**, then tap **Test connection**.

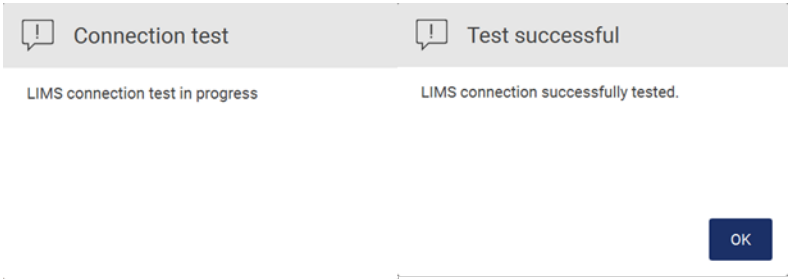


Figure 94. LIMS connection test.

16. If the “Enable LIMS sample scan” checkbox is active, the **LIMS** button is available on the Setup screen.

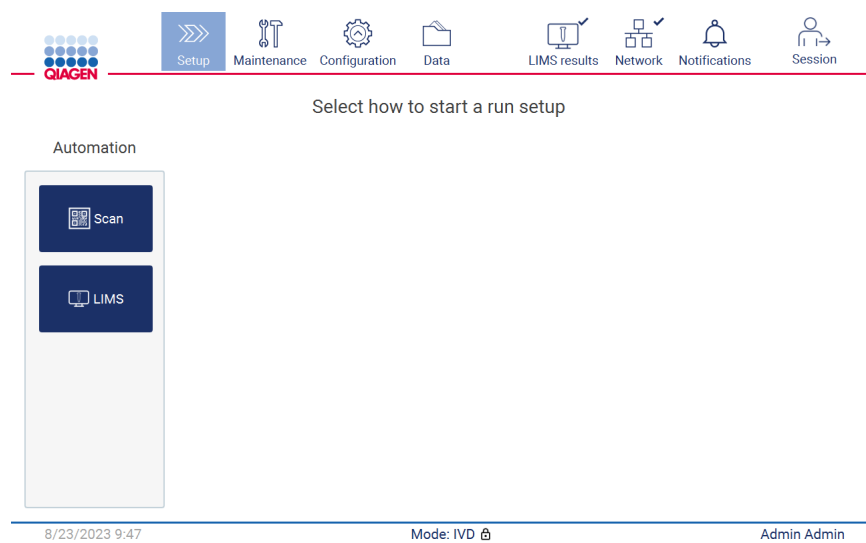


Figure 95. LIMS button available on the Setup screen.

Note: If the user checks the “Send results to LIMS” checkbox, the LIMS results status is displayed and the results for each sample is sent to LIMS after the run. This setting does not change after the instrument restart.

Note: If the user disables the “Send results to LIMS” checkbox, the following warning is displayed.

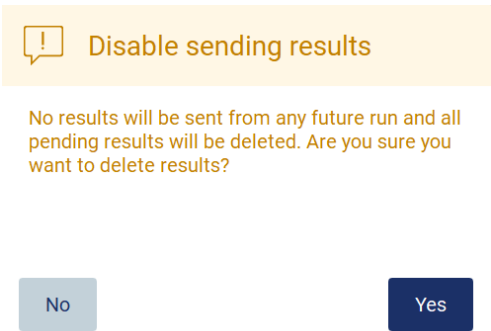


Figure 96. Disable sending results warning.

The LIMS results status is shown by an icon in the upper right corner of the screen. This icon has three states:

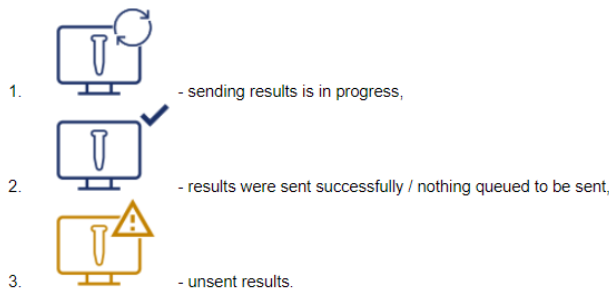


Figure 97. LIMS icon status.

17. Tapping the icon opens the Results sending status screen. The information in the table on the Results sending status screen depends on the status of the results currently being sent.

- Status icon:



The results sending status table is empty when all results have been successfully sent and no results are queued to be sent. The user sees the LIMS results status icon with a checkmark.

The screenshot shows the LIMS results status page. The top navigation bar includes icons for Setup, Maintenance, Configuration, Data, LIMS results (highlighted with a checkmark), Network, Notifications, and Session. Below the navigation bar, the title "Results sending status" is displayed. The main content area contains a table with the following columns: Status, Sample ID, Run ID, End time, and Last sending attempt. The table is empty, and a message states: "There are no results to send. Results sending status will be visible when you perform a protocol run." At the bottom of the page, there is a footer with the text "To send unsent results, select them and press Send." and two buttons: "Select all" and "Send".

Figure 98. Results sending status Empty.

- Status icon:



If the user selects unsent results and taps **Send** button, the selected unsent samples are sent to the configured LIMS. If the sending results is in progress, the Results sending status table informs the user about sending and pending results. Results with the Sending status are currently being sent to the LIMS system. Results with Pending status are queued and waiting to be sent. The user also sees the LIMS results status icon with the cached symbol.

The screenshot shows the LIMS results status page with results in progress. The top navigation bar is the same as in Figure 98. The title "Results sending status" is displayed. The main content area contains a table with the following columns: Status, Sample ID, Run ID, End time, and Last sending attempt. The table has three rows of data:

Status	Sample ID	Run ID	End time	Last sending attempt
Sending	2023-06-22_11-11_01	2023-06-22_11-10-10-306_Z090007F	23/6/2023 11:10	23/6/2023 11:10
Pending	2023-06-22_11-11_02	2023-06-22_11-10-10-306_Z090007F	23/6/2023 11:10	-
Pending	2023-06-22_11-11_03	2023-06-22_11-10-10-306_Z090007F	23/6/2023 11:10	-

At the bottom of the page, there is a footer with the text "To send unsent results, select them and press Send." and two buttons: "Select all" and "Send". The bottom status bar shows the date and time "23/6/2023 10:06" and the user name "Admin Admin".

Figure 99. Results sending status In Progress.

- Status icon:



If the results cannot be sent, sending status table informs the user about the unsent status and occurred error. The Unsent status is displayed with an error ID and detailed description. The user also sees the LIMS results status icon with the warning symbol. Unsent results are not resent automatically after the failure. The user can select unsent results and tap the **Send** button to re-send results to a configured LIMS. Unsent results are sent automatically only after the instrument restart.

Status	Sample ID	Run ID	End time	Last s
Unsent (ID: 015012, Description: The sample result was rejected.)	2023-06-22_11-11_03	2023-06-22_11-10-10-306_Z090007F	23/6/2023 11:10	23/6/20
Unsent (ID: 015012, Description: The sample result was rejected.)	2023-06-22_11-11_04	2023-06-22_11-10-10-306_Z090007F	23/6/2023 11:10	23/6/20
Unsent (ID: 015012, Description: The sample result was rejected.)	2023-06-22_11-11_05	2023-06-22_11-10-10-306_Z090007F	23/6/2023 11:10	23/6/20
Unsent (ID: 015012, Description: The sample result was rejected.)	2023-06-22_11-11_06	2023-06-22_11-10-10-306_Z090007F	23/6/2023 11:10	23/6/20
Unsent (ID: 015012, Description: The sample result was rejected.)	2023-06-22_11-11_07	2023-06-22_11-10-10-306_Z090007F	23/6/2023 11:10	23/6/20
Pending	2023-06-22_11-11_08	2023-06-22_11-10-10-306_Z090007F	23/6/2023 11:10	-

To send unsent results, select them and press **Send**.

Select all **Send**

23/6/2023 10:06 Admin Admin

Figure 100. Results sending status error.

5.5. Setting up a protocol run

To setup a protocol run, press the Setup tab on the Home screen.

All available QIAGEN protocols are pre-installed on the EZ2 Connect MDx upon delivery. You can download all available QIAGEN protocols from the QIAGEN website (www.qiagen.com). For MDx applications, choose the IVD mode when logging in the EZ2 Connect MDx.

Note: The EZ2 Connect MDx does not support protocols obtained from sources other than QIAGEN.

Note: The protocol run setup can be aborted at any time by pressing the **Abort** button (see Section 5.7 Starting the protocol run and monitoring its progress).

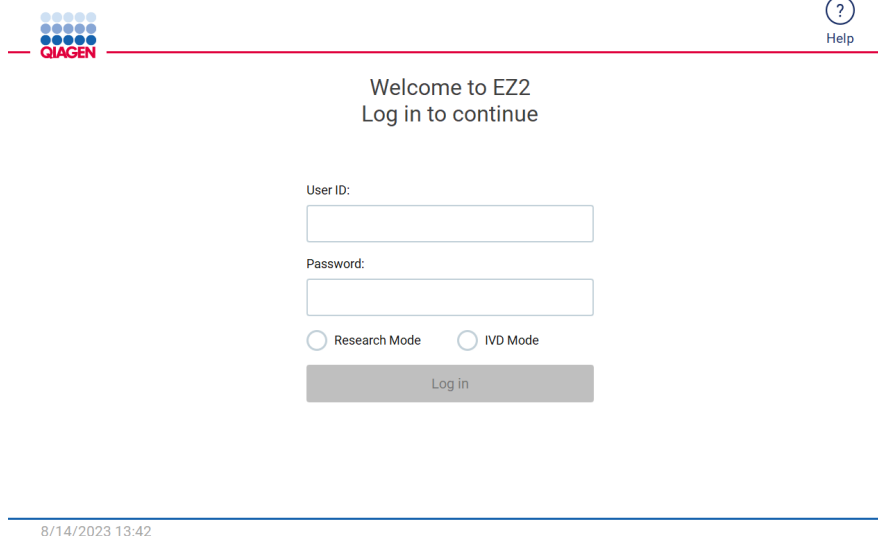


Figure 101. The log in screen.

The EZ2 Connect MDx software guides the user through the protocol run setup process. The steps of the protocol wizard vary depending on the selected protocol and may differ from the figures in this section. Some descriptions on the touchscreen may only be visible using a scrollbar. Ensure that all instructions are read completely.

To start the process, tap either the **SCAN** or the **LIMS** button on the **Set Up** tab. The **LIMS** button is only available if LIMS was configured before.

Important: Before starting a protocol run, read the relevant QIAGEN kit handbook and follow the instructions (e.g., sample handling, and preparation) provided in the handbook.

After login in, the Setup screen appears (Figure 103).

5.5.1. Using the barcode scanner

The EZ2 Connect MDx has a 2D handheld barcode scanner that can be used to scan the following barcodes during Protocol setup:

- Kit Q-Cards
- Sample barcodes

Details of readable barcode types can be found in Section 10.5 Barcode reader specifications and in the manual supplied with the barcode scanner.

Direct the handheld scanner at the required Q-Card/Barcode or sample barcode to scan the information into the instrument when prompted by the user interface.

Note: Barcode information may also be entered manually.

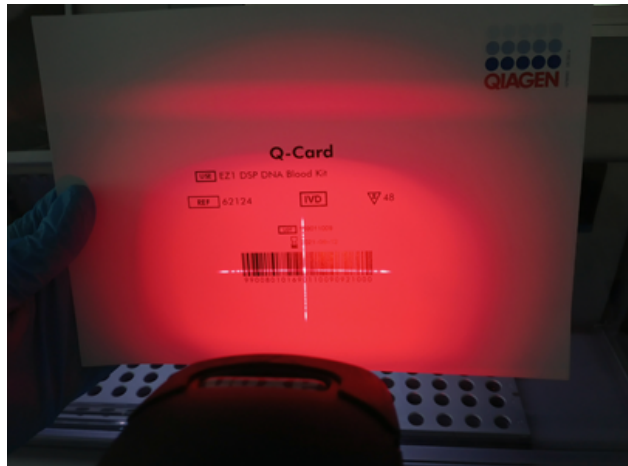


Figure 102. Scanning the information into the instrument.

WARNING

Risk of personal injury



Class 2 Laser: Do not stare into the light beam when using a handheld barcode scanner.

5.5.2. Scanning Q-Card barcode

- To begin set up of a protocol run, start at the **Setup** tab then tap the scan button in the Applications pane.

Note: The application checks in the background if there is enough disk space. A warning appears if the disk space is lower than required for five runs. Previous run reports should be downloaded and deleted to free up disk space. Check Section 5.13.1 Run reports about how to delete run reports if this message appears.

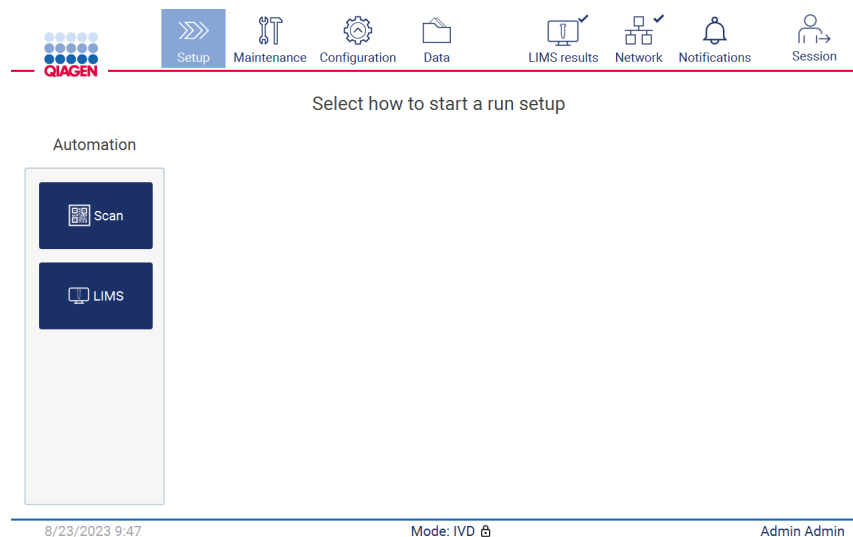
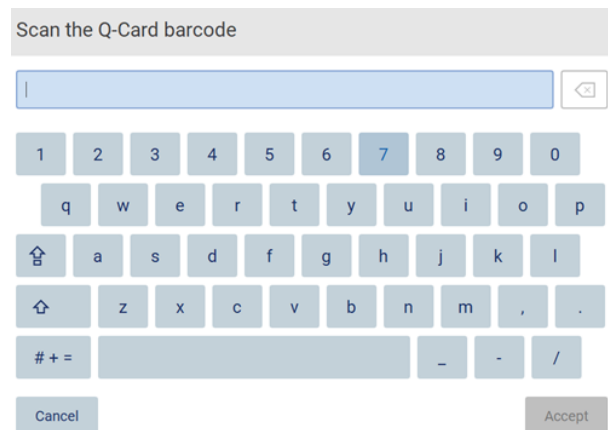


Figure 103. Setup screen.

2. Tap into the field showing up in the next screen and scan the 1D Barcode on the Q-Card provided with the kit.



Scan the Q-Card barcode

A text input field with a blue border and a back arrow icon on the right.

A numeric keypad with digits 1-0 and a QWERTY keyboard layout.

Buttons: Cancel, Accept

Figure 104. Scan the Q-Card barcode screen.

Important: If scanning of the Q-Card fails, the barcode number can be entered manually via the user interface.



Q-Card

USE EZ1 DSP Virus Kit

REF 62724 IVD Σ 48

LOT 1234567

2020-12-31

990090100012345671220000

Figure 105. Q-Card sample.

3. By scanning the 1D Barcode on the Q-Card provided with the kit, the application type is selected and information on protocol options is given. See Section 5.12 LIMS workflow.

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Select protocol Step 2 of 7

DSP DNA Blood

Application: DNA
Kit: EZ1 DSP DNA Blood Kit
Protocol: DSP DNA Blood

Protocol description:
This protocol is designed for automated isolation and purification of DNA from human samples. The protocol is intended for in vitro diagnostic use.

NOTE: If you have used the instrument in Research Mode before, ensure that you have performed the daily maintenance and a UV run after switching software modes.

Protocol version: 7.0.0.1
Sample volume: 200 or 350 µl
Materials: Human whole blood

Cancel Back Next

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Figure 106. Select protocol screen.

4. Tap **Next** to continue. Tap **Back** or **Cancel** to return to the Setup screen.

5.5.3. Defining parameters

To set values for protocol parameters, tap the box next to each parameter in the Define parameters pane and select from the drop-down lists.

Note: Available protocol parameter options, such as sample volume, depend on the selected protocol.

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Define parameters Step 3 of 7

Parameter name	Value
Pure ethanol wash	No
Sample volume	200 µl
Elution volume	50 µl

50 µl
100 µl
200 µl

Application: DNA
Kit: EZ1 DSP DNA Blood Kit
Protocol: DSP DNA Blood

Pretreatment:
Ensure that all samples have been left at room temperature for a sufficient period of time to equilibrate before transfer to sample tubes (ST). For handling and pretreatment of samples and reagents, please refer to the EZ1® DSP DNA Blood Kit Handbook.

Cancel Back Next

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Figure 107. Define parameters step with open drop-down list.

Additional protocol information is also displayed on the screen, for example, references to the relevant kit handbook for sample storage, handling, and pretreatment (if required). Ensure that all instructions are read completely using the scroll buttons (if applicable).

Note: The description on the GUI is for guidance only. Read the respective information in the kit handbook.

- To proceed to the “Select sample positions” step, tap **Next**.
- To return to the previous screen, tap **Back**.
- To cancel the protocol, tap **Cancel**.

5.5.4. Selecting sample positions

To select the positions of your samples, tap the relevant rows on the worktable diagram or tap the corresponding row numbers underneath the diagram. The selected positions are highlighted. To select or deselect all positions, tap the **Select all** toggle.

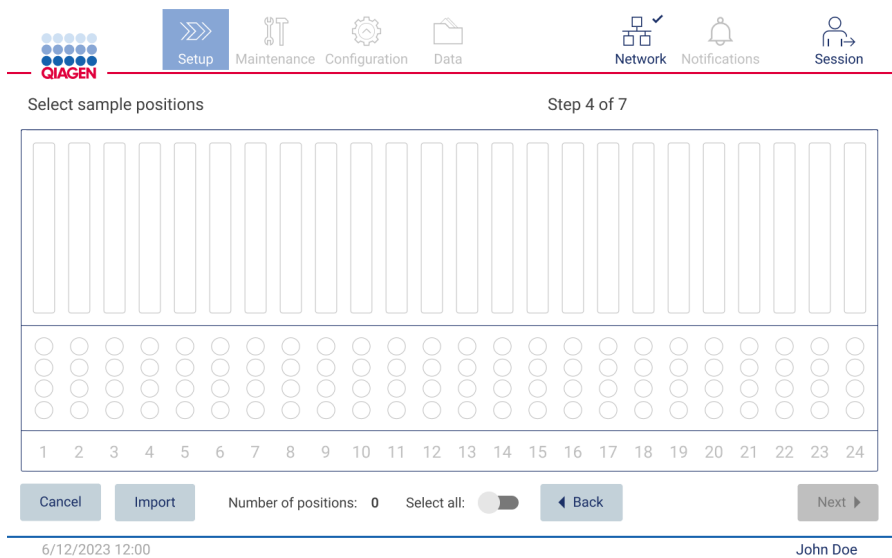


Figure 108. Select sample positions screen.

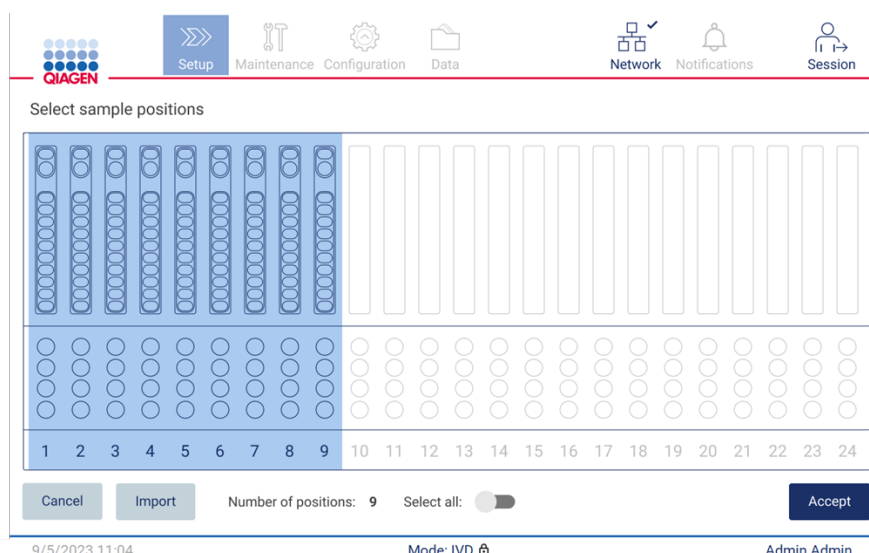


Figure 109. “Select sample positions” step.

After at least one sample position is selected, the **Next** button is enabled. To proceed to the “Enter sample IDs” step, tap **Next**.

5.5.5. Import sample list

Alternative option: Instead of manually defining the sample positions via the touchscreen, a pre-filled sample list file can be uploaded to the EZ2 Connect MDx. The sample list can assign the sample positions, sample IDs, and optional sample notes, and can be filled-in using an external PC and the sample list template, which can be downloaded from the EZ2 Connect MDx. Instructions to download a sample list template can be found in Section 5.13.4 Sample list template. When using a pre-filled sample list, insert a USB stick with the sample list and tap **Import** on the Select sample position screen.

Note: The EZ2 Connect MDx detects and displays all **.xlsx** files on the USB stick. To avoid confusion, keep only one **.xlsx** file with a meaningful name on the USB stick for sample list upload.

- To return to the previous screen, tap **Back**.
- To cancel the protocol, tap **Cancel**.
- To import sample list in **.xlsx** format from the USB stick tap **Import**.

Note: After importing the sample list, verify on the touchscreen if all information is correct.

Select sample list

Path

source/sample_list1.xlsx
source/sample_list2.xlsx

Cancel

Import

Figure 110. Select sample list dialog box.

5.5.6. Entering sample IDs

Tap **Generate missing sample IDs** to automatically generate IDs in the format of YYYY-MM-DD_hh-mm_XX, where the first 16 characters represent the current date and time, and the XX is the sample number.

Note: Sample IDs can also be entered manually using the on-screen keyboard, the handheld barcode scanner, or a sample list. Ensure that each entered sample ID corresponds to the sample in the respective position.

Note: Sample list upload is described in Section 5.5.4 Selecting sample positions. Sample list template download is described in Section 5.13.4 Sample list template.

Note: When using the handheld barcode scanner to input the sample IDs, ensure that the barcode is of appropriate type and quality to be read by the scanner.

Note: All sample IDs or notes can be entered or edited without manually selecting the next sample cell from the table. When a sample ID is edited and a barcode is scanned, the input is saved and the keyboard appears for the next sample ID.

Note: The number of characters that can be entered for sample IDs, elution IDs, or notes is limited to 80.

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Enter sample IDs

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Position	Sample ID <>	Elution ID <>	Note <>
	Verify ID	Verify ID	
1	2025-02-24_13-02_01		
3	2025-02-24_13-02_03		
5			
7			
9			

Cancel

Generate missing sample IDs

Back

Next

Application: RNA

Kit: RNA Tissue Mini Kit

Protocol: RNA Universal Tissue without DNase digestion

Sample volume: 200 µl

Rack type: TipRack

Estimated run time: 23 min 0 sec

Number of samples: 5

Pretreatment: Pretreat the samples following the instructions in the kit handbook.

Sample ID must be entered and be unique.

Figure 111. “Enter sample IDs” step (two IDs autogenerated).

Modifying a sample ID

To modify a sample ID, tap it and use the on-screen keyboard to change the text.

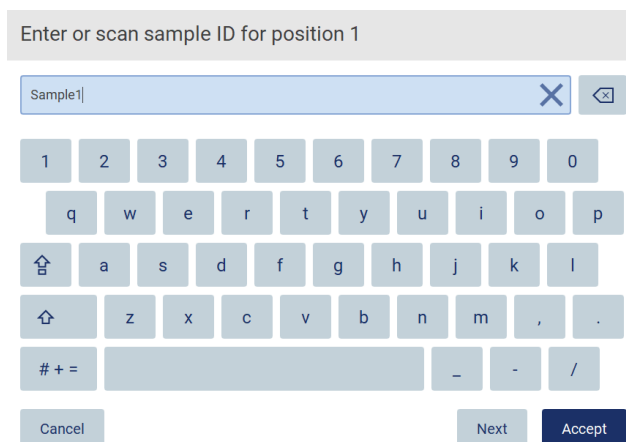


Figure 112. Changing the sample ID.

There is an 80-character limit for the Sample ID field. Tap **Accept** to save the changes, or tap **Cancel** to go back to the Enter sample IDs screen.

Note: Samples IDs must be unique. The **Next** button is not active until unique sample IDs have been entered for all samples.

Adding a note or elution ID to a sample

Optionally, add a note or elution ID to each sample. Tap the Note or Elution ID (optional) field next to the relevant sample ID, then use the on-screen keyboard to enter the note or elution ID.

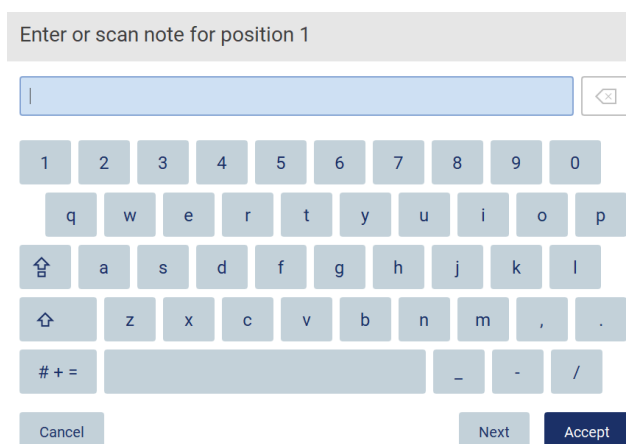


Figure 113. Adding a note to a sample.

There is an 80-character limit for the Note (optional) field. Tap **Accept** to save the changes, or tap **Cancel** to go back to the Enter sample IDs screen.

- To proceed to the “Load the cartridge rack” step, tap **Next**.
- To return to the previous screen, tap **Back**.
- To cancel the protocol, tap **Cancel**.

Verifying IDs

After entering or uploading the sample and elution IDs, the IDs can be verified if a barcode or QR code is available for the corresponding IDs (optional). To verify the correct IDs, tap **Verify ID**. Then scan the barcode or QR code at the indicated position. If the barcode matches, the software automatically proceeds to the next position.

5.6. Setting up the worktable

This section describes how to set up the EZ2 Connect MDx worktable. This includes removing the empty tip racks and cartridge racks from the instrument; preparing them with respective cartridge(s), consumables, and samples; and reloading them onto the instrument.

1. Remove one or both sections of the tip rack from the worktable, depending on which positions you chose in the “Select sample positions” step of the protocol run setup. To remove a tip rack section, grab both sides of the section and gently pull up.
2. Remove one or both sections (left or right) of the cartridge rack from the worktable, depending on which positions you chose in the “Select sample positions” step of the protocol run setup. To remove the cartridge rack sections, grab their handles and gently pull the rack up.

Note: First remove the tip racks, then the cartridge racks.

5.6.1. Loading the cartridge rack(s)

To load the cartridge rack(s), follow the steps below (also displayed on the GUI). To highlight the well on the diagram and the corresponding row in the table of the GUI, tap the well or the table row.

Important: Read the following instructions (as well displayed on the GUI) carefully before loading the rack:

1. Follow the instructions of the respective kit handbook on how to treat the reagent cartridges before loading onto the cartridge rack (e.g., pre-warming).

Note: Remember to prepare the same number of reagent cartridges as the number of positions you chose in the “Select sample positions” step of the protocol run setup.

2. Invert each cartridge four times to ensure the magnetic beads are resuspended.
3. Tap each reagent cartridge until the reagents are deposited at the bottom of the wells. No droplets should remain on the walls and ceiling of the cartridge.
4. If required for the script, add the extra tube(s) into the empty “heater” position of the cartridge(s).
5. Slide the reagent cartridges, with the orientation depicted in the user interface, into the cartridge rack in the direction of the arrow that is engraved on each cartridge rack section, until you feel resistance. The cartridge should click into place.
6. Once all the reagent cartridges are loaded, place each cartridge rack section onto the worktable. The rim of the reagent cartridge plastic flag (where the 2D barcode label is placed) must sit below the tip rack, but the label itself should not be covered.

Note: Ensure the cartridge racks are placed in the correct position.

Note: Place the cartridges in the positions chosen during sample loading, numbers are engraved onto the rack. Numbering reads 1 to 24 from left to right.

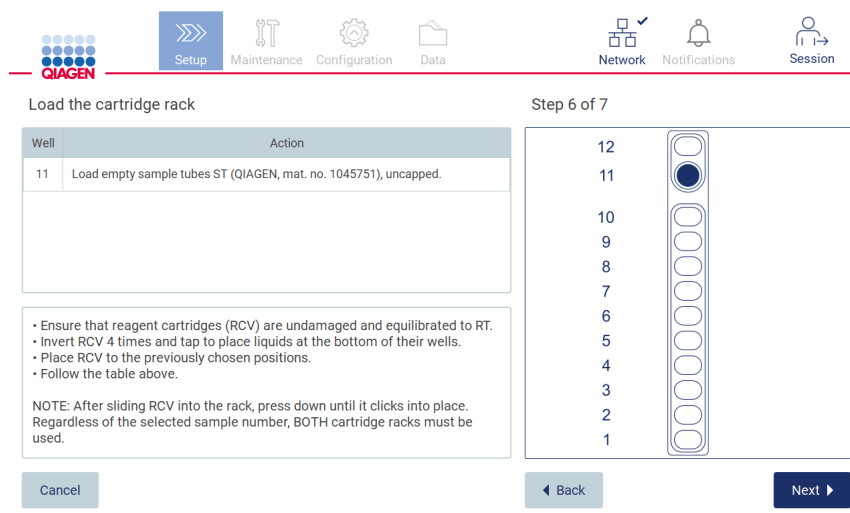


Figure 114. "Load the cartridge rack" step.

- To proceed to the "Load the tip rack" step, tap **Next**. To return to the previous screen, tap **Back**.
- To cancel the protocol, tap **Cancel**.
- To proceed to the "Load the tip rack" step, tap **Next**.

5.6.2. Loading the tip rack

To load the tip rack(s), follow the steps below (also displayed on the GUI). To highlight a position on the tip rack diagram and the corresponding row in the table, tap the position or the table row.

Important: Read the instructions carefully before loading the rack, and make sure to follow all directions including those in the respective kit handbook. To load the tip rack, follow the steps below:

- Load the labware according to the instructions on the user interface.

Note: Follow any protocol-specific directions shown on the screen in the "Load the tip rack" step of the run setup process. Additional actions may be required. The instructions can also be found in the kit handbooks.

Note: Remove any caps from the labware and store safely. Do not to mix up lids between different samples.
- Once all the labware is loaded, place the tip rack sections onto the worktable.
- Always place the tip racks after loading the cartridge racks. The rim of the reagent cartridge plastic flag (where the 2D barcode label is placed) must sit below the tip rack, but the label should not be covered.

Important: Ensure that the tubes are inserted as far as possible into the rack; push them all the way down into the respective position. Do not use thick tube labels, because the tube may get stuck at an elevated position, which may interfere with subsequent pipetting steps.

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Load the holder

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Row	Labware	Content
A	2.0 ml sample tube (ST), uncapped	Sample
B	2.0 ml screw-cap tube (Sarstedt, cat. no. 72.693.), uncapped	1800 µl of 80% EtOH
C	Tip holder (DTH)	1000µl tip (DFT)
D	1.5 ml elution tube (ET), uncapped	Empty

- Place the labware to the previously chosen positions.
- Ensure that samples have been equilibrated to room temperature.
- Ensure that the sample volume equals the volume previously defined.
- Ensure that the tubes are inserted as far as possible into the rack.

NOTE: Regardless of the selected sample number, BOTH labware holders must be used.

Cancel

◀ Back

Next ▶

8/16/2023 10:22

Mode: IVD

Admin Admin

Figure 115. “Load the tip rack” step.

Note: In some applications, not all positions of the tip rack are to be used. This is indicated by the lack of this position on the left-hand side and a white circle on the right-hand side.

Important: Both tip racks should be inserted even if just one is used.

To proceed to the start of the protocol, tap **Next**. Before the run starts, an overview of the selections made during the run setup process is displayed.

Run setup selection overview

Application: DNA
Kit: EZ1 DSP DNA Blood Kit
Protocol: DSP DNA Blood
Sample volume: 200 µl
Elution volume: 50 µl
Pure ethanol wash: Yes
Rack type: TipRack
Estimated run time: 23 min 40 sec
Number of samples: 3

Do you want to start the protocol run?

Return

Start

Figure 116. Run set up overview.

To return to the previous screen, tap **Return**.

To start the protocol run, tap **Start**.

5.7. Starting the protocol run and monitoring its progress

After successfully completing all the steps of the protocol run setup, the run can be started. During the protocol run, the progress can be monitored. The current step, an estimated run time, and the elapsed run time are displayed on the screen.

To start the run and view its progress, follow the steps below:

1. Tap **Next** in the “Load the tip rack” step. The Run setup selection overview dialog box is displayed.

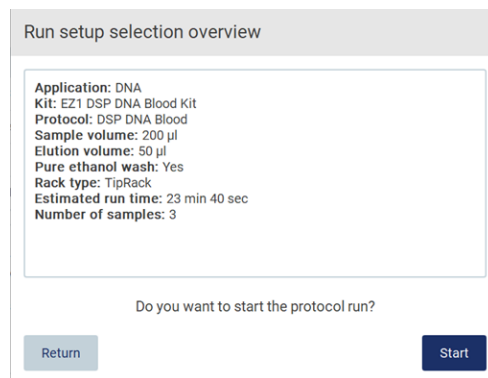


Figure 117. Run setup selection overview dialog box.

2. If all the information in the overview is correct, tap **Start** to immediately proceed with the protocol run. To make modifications to any of the selections, tap **Return** to go back to the run setup.

Note: The Estimated run time does not include the time to complete the load check, which is approximately 6 minutes.

3. If the hood of the instrument is open, close it and the run starts.

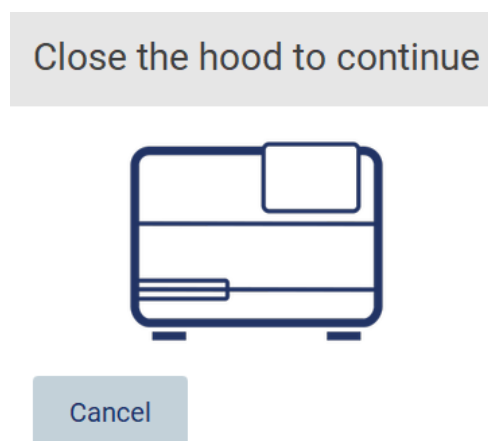


Figure 118. Close the hood dialog box.

4. The load check is performed. For more information about the load check, refer to Section 5.7.1 Load check. The run starts after the check is successfully completed. To stop the load check, tap **Abort**.

Important: Wait until the load check has successfully completed before leaving the instrument unattended. Upon a failure of the load check (e.g., due to operator errors during worktable setup), the run does not start and operator action is required. Leaving the instrument unattended for an extended period may affect the stability of samples and reagents.

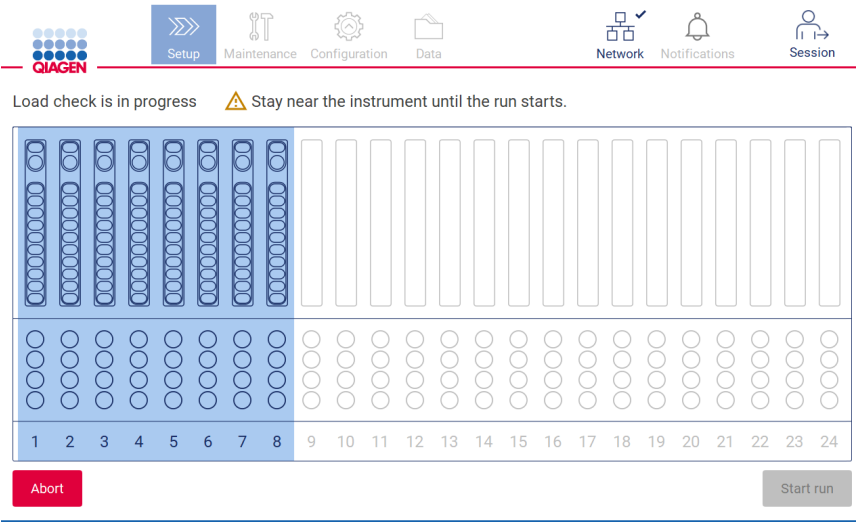


Figure 119. Load check in progress screen.

5. After successful completion of the Load Check progress of the run and the elapsed run time are displayed on the Protocol run in progress screen.

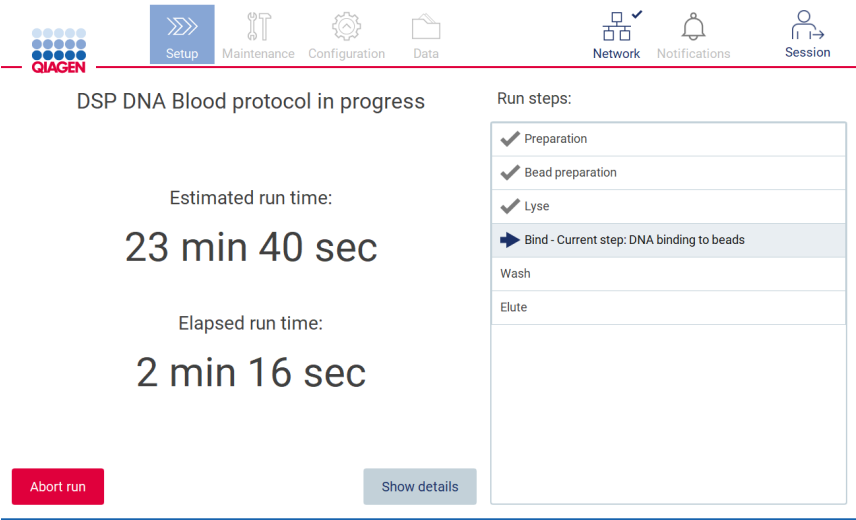


Figure 120. Run progress screen.

6. Tap the **Show details** button to display the protocol parameters during the run.

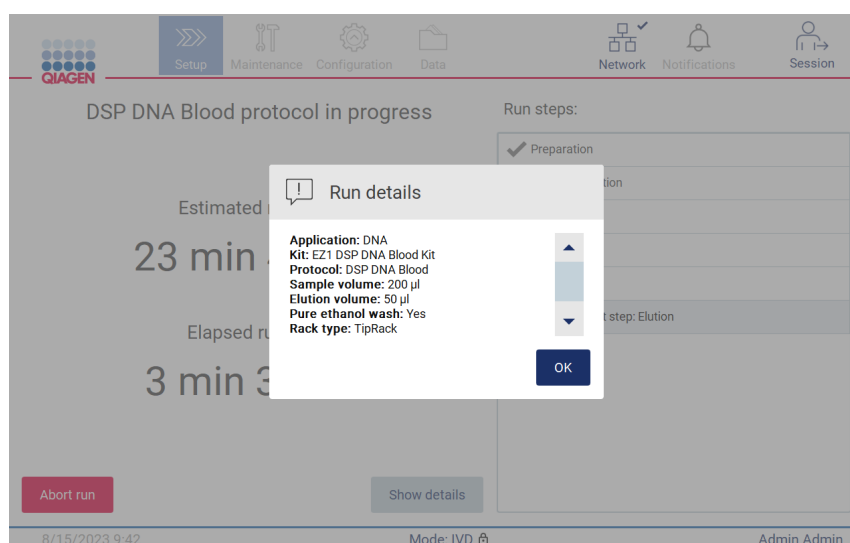


Figure 121. Run details dialog window.

5.7.1. Load check

The EZ2 Connect MDx comes with a built-in camera, which is designed as an aid to ensure that the operator has loaded all of the cartridges and labware into the correct positions on the worktable. However, the contents of the labware (e.g., liquid levels) in the tip rack are not checked, so the operators must make sure that they have carefully followed the instructions related to the protocol being run.

Note: Follow the instructions on the user interface as well as those given in the respective kit handbook.

Note (research mode only): To ensure a successful load-check process when using flip-cap racks, ensure that each tube's cap is properly seated in the corresponding square-shaped slot of the rack.

The load check is mandatory and automatically starts after tapping **Start** in the Run setup selection overview dialog window. For more information on starting a run, refer to Section 5.7 Starting the protocol run and monitoring its progress.

After the load check starts, the camera moves above the worktable and checks all positions on the cartridge rack and the tip rack. The Load check is in progress screen is displayed. The positions selected in the Select sample positions screen are highlighted.

Important: Operator should confirm completion of load check prior to leaving the EZ2 Connect MDx unattended as in the event of failed load check operator intervention may be required. Leaving the instrument unattended for an extended period may affect the stability of samples and reagents.

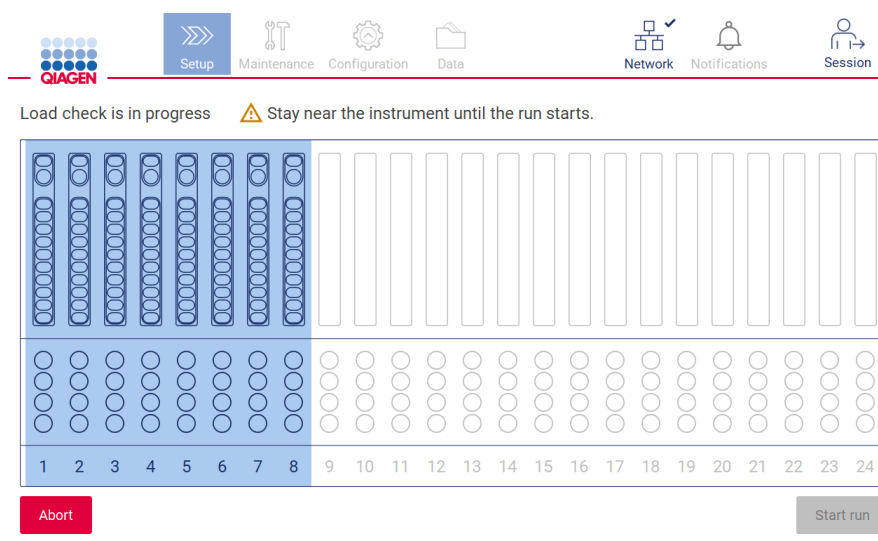


Figure 122. Load check is in progress screen.

Load check limitations

Important: The load check is designed to support the operator in ensuring that the worktable is correctly set up as detailed on the GUI. It is not intended as a replacement for operator diligence in confirming that consumables/reagents/samples are correctly placed on the worktable.

It should be noted that the load check will not detect the following:

- Liquid presence in tubes
- Distinguish between 1.5 and 2.0 mL tubes
- Distinguish between a tip holder (with tip) and a capped tube
- Distinguish between a tip holder (without tip) and tube

Successful load check

If all of the labware is loaded correctly, the load check ends successfully and the run starts automatically.

Failed load check

If the camera discovers one or more errors during the load check procedure, the Load check failed screen is shown. Incorrect labware placements are marked in red. To get more information about a particular load check error, tap one of the red positions. A dialog window with details about the error appears.

Note: All consumable positions should be visually checked to confirm correct placement in accordance with the instructions detailed in the Loading the worktable GUI wizard. Do not rerun a failed load check without first completing this visual inspection. Also, stability of samples and reagents may be impaired due to extended time on the instrument during repeated running of the load check.

To return to the loading instructions and start the load check procedure again, tap **Back**. The Load the tip rack screen is displayed. If the instructions from the previous screen are required, press **Back** again. Once correct loading of the worktable is confirmed, tap **Next** in the Load the tip rack screen. The Run setup selection overview screen is displayed where a **Skip load check** button is available (see “Skip load check option” section under Section 5.7.1 Load check). If the loading must be corrected, repeat the load check.

Note: Only use EZ1 DSP kits within their expiration date. If an expired kit is used, the EZ2 Connect MDx software displays a warning message. The run/sample is not valid anymore if you use a kit with an expired shelf life, and accordingly, the run results cannot be used for diagnostic use. This is marked as invalid sample in the run report.

Note: In case of repeated load check failure, after correct worktable setup has been confirmed, recalibrate the camera (refer to Section 6.6 Camera calibration). Contact QIAGEN Technical Support for additional support. During this time samples should be removed from the worktable and held at appropriate storage conditions.

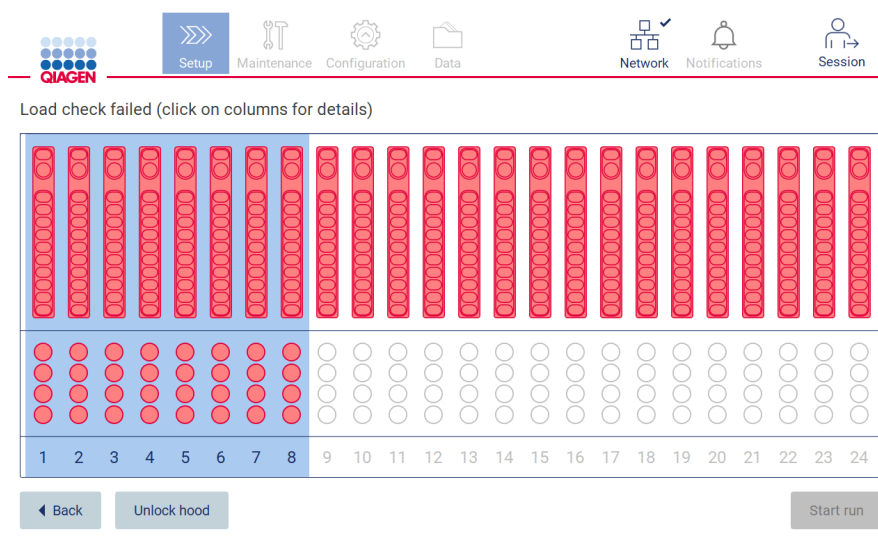


Figure 123. Load check failed screen.

Detailed loading faults can be shown in a pop-up window by tapping the affected column.

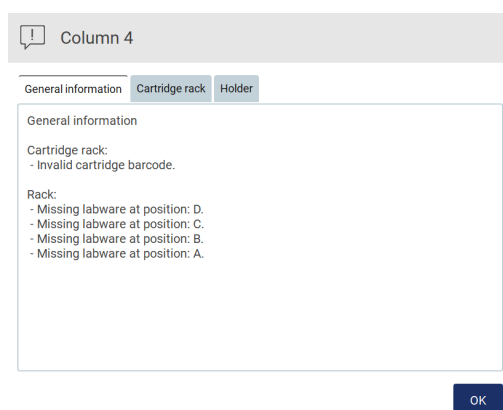


Figure 124. Pop-up window with faults to be corrected.

Tap **Unlock hood** button to correct the loading. The load check for the run is mandatory and the skipping of the load check is not possible, if the hood was unlocked.

To go back to the Load check failed screen, tap **No**. To start unlocking, tap **Yes**.

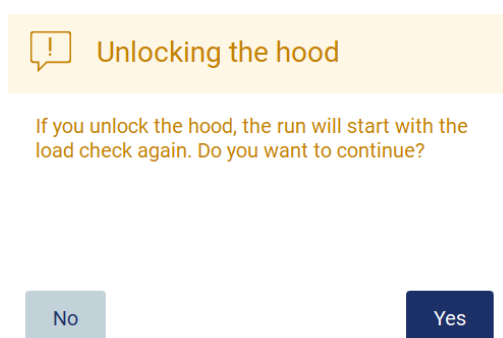


Figure 125. Warning after unlocking the hood.

The following pop-up window appears after confirming that the hood has been unlocked.

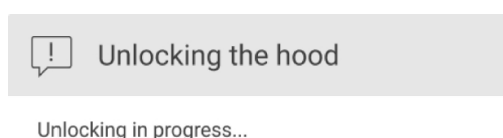


Figure 126. Unlocking in progress pop-up window.

The following pop-up window appears after the hood is unlocked.

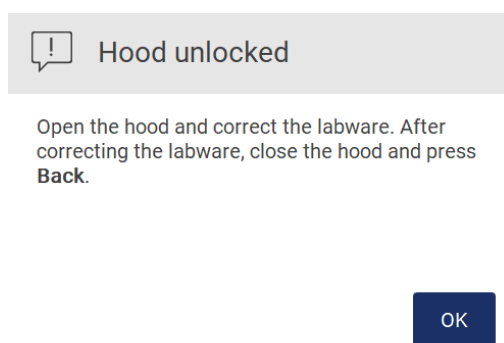


Figure 127. Hood unlocked pop-up window.

Tap **OK**, then the following warning message appears on the Load check failed screen.

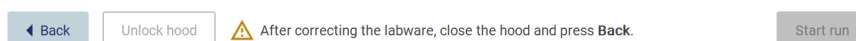


Figure 128. Warning on the Load check failed screen.

Skip load check option

The first load check is mandatory and cannot be skipped in the Run setup selection overview dialog box. If the first load check fails, the operator can skip the load check and proceed with protocol start by first tapping the back button to return to the Load the holder screen. When using this option, the operator is responsible for visually verifying correct placement of all consumables in all worktable positions in accordance with the instructions detailed in the loading the worktable GUI wizard, without opening the hood.

Note: If the hood is unlocked, the load check must be repeated.

It is recommended to perform this check while the Load check failed screen (Figure 123) is still displayed. If **Back** is tapped, information about the failed positions is no longer displayed. Once correct loading is confirmed, tap **Next** to proceed to the Run setup selection overview screen where the **Skip load check** button is available.

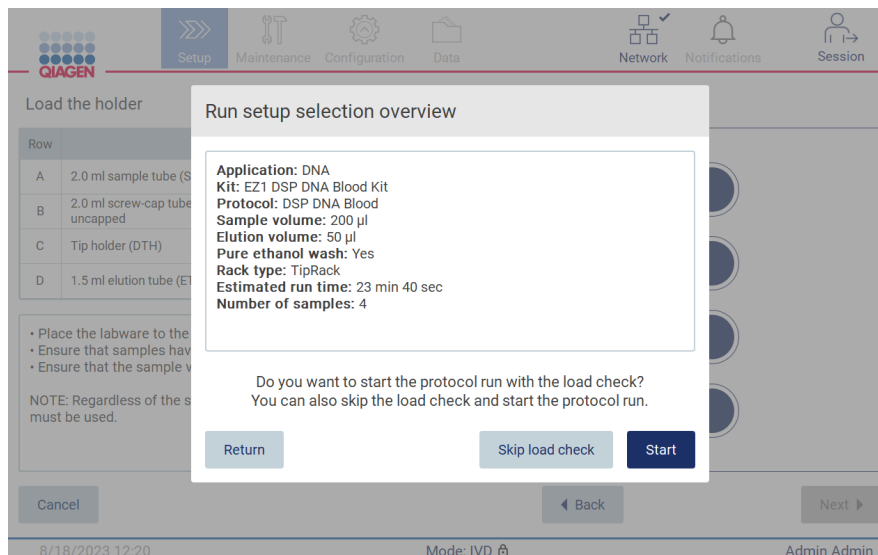


Figure 129. Skip load check option.

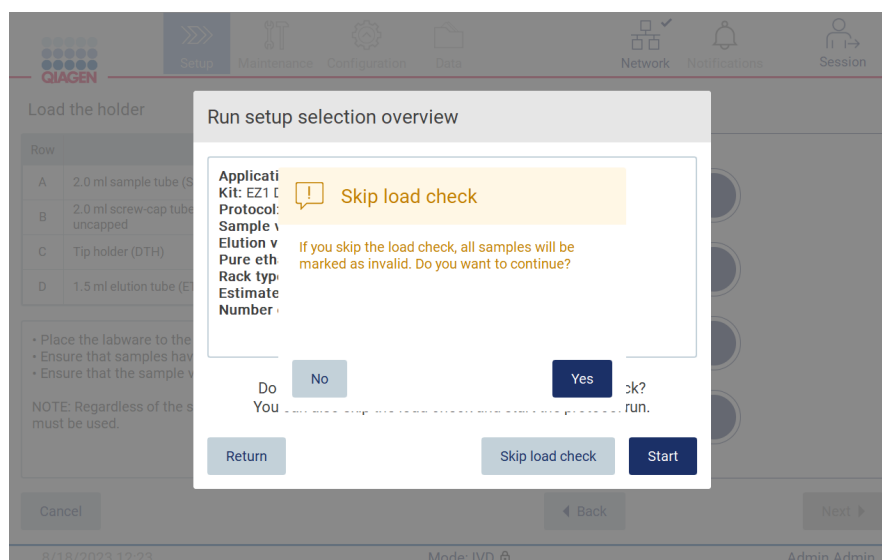


Figure 130. Confirm skip load check screen.

If the operator uses the Skip load check option following a previously failed load check, this is recorded in the run report and all samples are flagged as invalid.

If positions are loaded incorrectly, tap **Unlock hood** button to correct the loading.

Note: If the operator unlocks the hood because of correcting actions or returns to the Select sample positions screen or Scan sample ID screen (LIMS workflow), the load check becomes mandatory again.

5.8. End of the protocol run

When the protocol has successfully finished, the Protocol run completed screen is shown. Information about required cleanup/maintenance steps is also displayed.

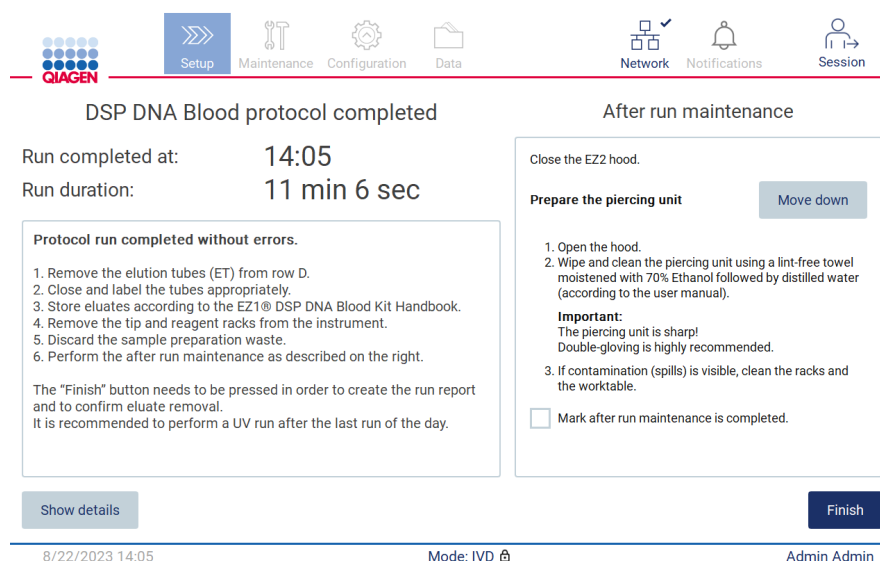


Figure 131. Protocol run completed screen.

Note: Once the **Finish** button is pressed, cooling after run starts.

At the end of a protocol run, remove the labware by following these steps:

1. Remove left, right, or both parts of the tip rack from the worktable. To remove a tip rack, grab both sides of the rack, and gently pull up.
2. Cap and remove eluate tubes from the rack and store accordingly.

Note: Remove the elution tube containing the eluate, close, label, and store it appropriately before removing the used labware from the tip rack. When handling the open elution tubes, take care not to carryover the eluate from one tube to another.

Important: Make sure to timely remove eluates from the instrument after the run has finished and store as indicated in the corresponding kit handbook. The eluates are exposed to ambient temperature in the EZ2 Connect MDx and extended time before removal may cause nucleic acid degradation.

3. Remove the labware from the tip rack and dispose according to local safety regulations.

WARNING

Hazardous chemicals and infectious agents



Waste may contain toxic or infectious material and must be disposed of properly. Refer to your local safety regulations for proper disposal procedures.

4. In case of visible spillage, disinfect the tip rack and remove any spilled liquids or potential contamination that is present on the cartridge rack sections. For more information on disinfecting and removing contamination, refer to Sections 6.1 Cleaning agents, 6.1.1 Disinfecting the EZ2 Connect MDx, and 6.1.2 Removing contamination.
5. Remove one or both sections (left or right) of the cartridge rack from the worktable. To remove the cartridge rack sections, grab their handles and gently pull the rack up.
6. Slide out the reagent cartridges and dispose of them properly, according to local safety regulations.

Note: If the additional tube in the heater position was used in the reagent cartridge, these tubes must be wasted according to local safety regulations.

WARNING**Hazardous chemicals and infectious agents**

Waste may contain toxic or infectious material and must be disposed of properly. Refer to your local safety regulations for proper disposal procedures.

7. In case of visible spillage, disinfect the cartridge rack and remove any spilled liquid or potential contamination that is present on the cartridge rack sections. For more information on disinfecting and removing contamination, refer to Sections 6.1 Cleaning agents, 6.1.1 Disinfecting the EZ2 Connect MDx, and 6.1.2 Removing contamination.
8. Place the cartridge rack sections back in the instrument, followed by the tip rack.

Clean the piercing unit, see Section 6.2 After run maintenance. When after run maintenance is completed, tap the checkbox to transfer the maintenance status into the run report. Tap **Finish** to end the run, to create the report file and to go back to the Home screen. After a run is finished, a run report is generated. For more information on how to save and download a run report, refer to Section 5.9 Saving a run report.

Note: Once the **Finish** button is pressed the automatic cooling after run will start (see Section 5.16 Cooling after run). This procedure will move the worktable to the back of the instrument. The process can be aborted if not required.

Note: After the last run of the day, the daily maintenance needs to be conducted (see Section 6.3 Daily maintenance).

5.9. Saving a run report

After a run finishes successfully, fails, or is aborted, a run report is generated in two formats: PDF and XML.

To automatically save a run report, tap **Finish** in the Protocol run completed, Protocol run failed, or Protocol run aborted screen.

For more information on what the run report contains, refer to Section 5.9.1 Run report contents.

5.9.1. Run report contents

An EZ2 run report is created by the software application after a run is completed, is aborted, or fails, after the user taps the Finish button on the screen displayed at the end of the run.

Each run report is saved in two formats: PDF and XML. Both formats include the same information, that is:

- The user ID that was logged in when the run was started
- The serial number of the instrument
- The duration of the run
- The time and date when the run was started and when it ended
- Protocol information:
 - Name
 - Version
 - Application
 - Parameters selected
 - Number of samples
- The kit name, material number, lot number, and expiration date
- The lot number(s) of the cartridges
- The title of the run report file, which includes the date when the run ended and the serial number of the instrument
- The status of the run, which indicates if the run was completed successfully, if it failed, or if it was aborted
- Errors (if occurred)
- The status of the cleanup procedure that is required after a run ends
- Information about the samples: their positions, names and any notes that were added by the user
- Information on sample flags
- Maintenance information (due, executed, etc.)
- Validity status of samples

5.10. Canceling the protocol run setup

The protocol run setup process can be canceled at any time. If the run setup is canceled, the progress is not saved and the worktable does not move. If labware has been loaded onto the worktable, remove it.

To cancel the setup, tap **Cancel**. In the Cancel run setup dialog box, tap **Yes** to confirm the cancellation or tap **No** to go back to the run setup.

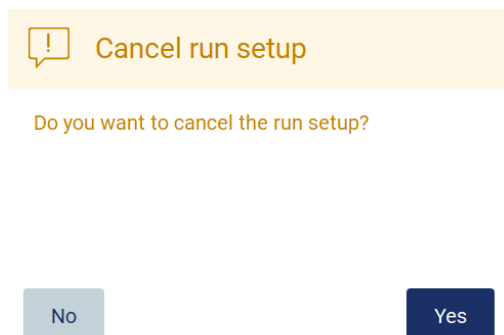


Figure 132. The Cancel run setup dialog box.

5.11. Aborting a protocol run

A protocol run can be stopped at any time. To stop the run, follow the steps below:

1. In the Protocol run in progress screen, tap **Abort run**. A confirmation dialog box appears.
2. Tap **Yes** to stop the run, or tap **No** to go back to the Protocol run in progress screen.

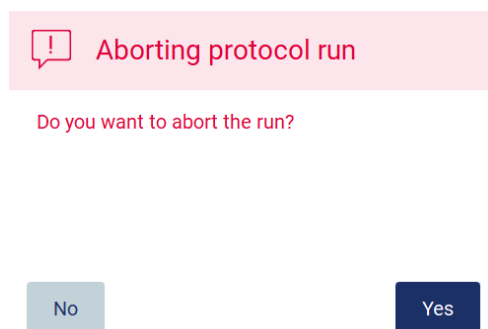


Figure 133. Aborting protocol run dialog box.

- When the run is aborted, the instrument finishes the current movement and then attempts to dispense the contents of the pipettes into the first available empty tubes and to release tips into empty tip holders. Then the worktable returns to its initial position. These actions place the consumables/worktable in suitable positions to support a safe clean-up procedure. After this is done, a message is displayed and the **Proceed to the summary** button is activated. Tap **Proceed to the summary**.

Note: If **Abort** is tapped during a pause or when the instrument is reaching a specific temperature, the run is stopped immediately.

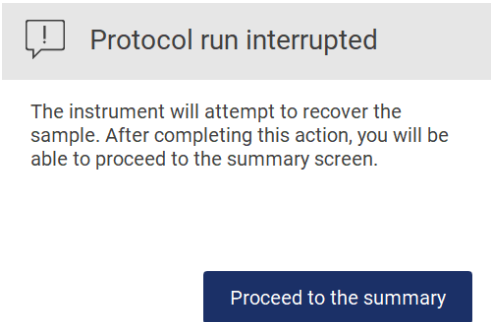


Figure 134. Protocol run interrupted dialog box.

- Tap **Finish** to end the run and go back to the Home screen. A run report is generated. For more information on how to save a run report, refer to Section 5.9 Saving a run report.

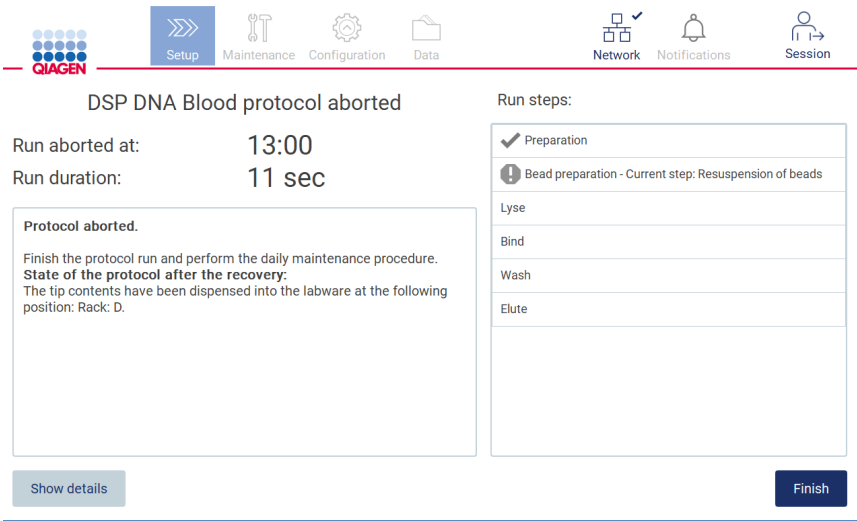


Figure 135. Protocol run aborted screen.

- Also, for aborted protocol runs, the after run maintenance needs to be performed. Follow the instructions regarding the cleaning of the piercing unit from Section 6.3 Daily maintenance.

5.12. LIMS workflow

Important: Before using the LIMS features of the EZ2 Connect MDx for the first time, contact a QIAGEN representative. The EZ2 Connect MDx must be integrated with an existing LIMS by setting up and configuring external service called LIMS Connector; this setup can be performed with assistance from QIAGEN Service Team. To begin setup of a protocol run using the LIMS interface, start on the **Setup** tab, then tap the **LIMS** button.

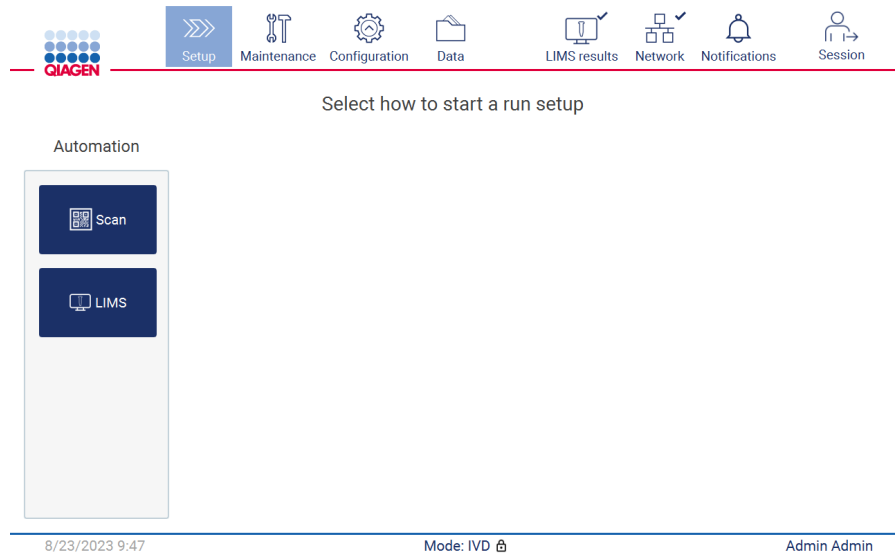


Figure 136. Setup screen.

1. Scan sample ID screen is displayed. Use preselected position and scan sample ID, or select a new position and scan sample ID.



Figure 137. Scan sample ID screen.

2. Tap **Scan sample ID** to scan either using the handheld barcode scanner or using the on-screen keyboard.

Enter or scan ID for sample at position 1

1	2	3	4	5	6	7	8	9	0	
	q	w	e	r	t	y	u	i	o	p
⌂	a	s	d	f	g	h	j	k	l	
↶	z	x	c	v	b	n	m	,	.	
# + =						-	-	/		

Figure 138. Scan or enter sample ID.

3. After scanning the first sample the Check parameters and load the holder screen is displayed.

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Check parameters and load the holder

Parameter name	Value
Pure ethanol wash	Yes
Sample volume	200 µl
Elution volume	200 µl

Row	Labware	Content
A	2.0 ml sample tube (ST), uncapped	Sample
B	2.0 ml screw-cap tube (Sarstedt, cat. no. 72.693.), un...	1800 µl of 80% EtOH
C	Tip holder (DTH)	1000µl tip (DFT)
D	1.5 ml elution tube (ET), uncapped	Empty

A

B

C

D

Application: DNA
Kit: EZ1 DSP DNA Blood Kit
Protocol: DSP DNA Blood
Sample volume: 200 µl
Elution volume: 200 µl
Pure ethanol wash: Yes
Rack type: TipRack
Estimated run time: 23 min 0 sec
Number of samples: 1

Pretreatment:
 Ensure that all samples have been left at room temperature for a sufficient period of time to equilibrate before transfer to sample tubes (ST). For handling and pretreatment of samples and reagents, please refer to the EZ1® DSP DNA Blood Kit Handbook.

Figure 139. Check parameters and load holder screen.

4. Check the preselected parameters and select the parameters in empty fields. Tap **Scan next sample ID**, or tap **End scanning** if you want to run just one sample.

Scan sample ID

RCB_01																									
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24		

Cancel Number of positions: 1 Scan sample ID End scanning

Figure 140. "Scan additional samples or proceed to next" step.

5. **Important:** Information entered in the note field is not transmitted/transferred to LIMS. After **End scanning** is tapped, the Review collected samples screen appears. On this screen, the setup can be reviewed and notes can be added (optional). Also, samples that have not been found in LIMS can be processed.

Note: If the Sample ID fields contain scanned sample IDs found in LIMS, these fields are not editable.

Review collected samples

Position	Sample ID	Elution ID	Note
	Verify ID	Verify ID	
1	RCB_01		
2	RCB_02		
3	RCB_03		
4	Sample_04		

Application: DNA
 Kit: EZ1 DSP DNA Blood Kit
 Protocol: DSP DNA Blood
 Sample volume: 200 µl
 Elution volume: 200 µl
 Pure ethanol wash: Yes
 Rack type: TipRack
 Estimated run time: 23 min 0 sec
 Number of samples: 4

Pretreatment:
 Ensure that all samples have been left at room temperature for a sufficient period of time to equilibrate before transfer to sample tubes (ST).
 For handling nad pretreatment of samples and reagents, please refer to the EZ1 DSP

The sample ID was not found in LIMS.

Cancel Back Next

Figure 141. Review collected samples.

6. Tap **Next** to proceed to scan Q-card information. Tap **Scan Q-Card**. Use the handheld barcode scanner to scan the barcode of the Q-Card or enter via the on-screen keyboard. Tap **Next** when complete.

Lot Number	Expiration Date
------------	-----------------

Figure 142. Scan Q-card.

The “Load the cartridge rack” steps feature (Section 5.6.1 Loading the cartridge rack(s)) instructions on how to load the cartridge rack. To highlight the well on the diagram and the corresponding row in the table, tap the well or the table row.

Important: Read the instructions carefully before loading the rack, and make sure to follow all directions including those in the respective kit handbook.

Well	Action
------	--------

• Ensure that reagent cartridges (RCB) are undamaged and equilibrated to RT.
• Ensure that no precipitates are present in the lysis buffer in well 1.
• Invert RCB 4 times and tap to place liquids at the bottom of their wells.
• Place RCB to the previously chosen positions.

NOTE: After sliding RCB into the rack, press down until it clicks into place. Regardless of the selected sample number, BOTH cartridge racks must be used.

Figure 143. Load the cartridge rack.

7. Tap **Next** to proceed to next step.

The “Load the holder” step features instructions on how to load the tip rack. To highlight a position on the tip rack diagram and the corresponding row in the table, tap the position or the table row.

Important: Read the instructions carefully before loading the rack, and make sure to follow all directions including those in the respective kit handbook.




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Load the holder

Parameter name	Value
Pure ethanol wash	Yes
Sample volume	200 µl
Elution volume	200 µl

Row	Labware	Content
A	2.0 ml sample tube (ST), uncapped	Sample
B	2.0 ml screw-cap tube (Sarstedt, cat. no. 72.693.), un...	1800 µl of 80% EtOH
C	Tip holder (DTH)	1000µl tip (DFT)
D	1.5 ml elution tube (ET), uncapped	Empty

Application: DNA
Kit: EZ1 DSP DNA Blood Kit
Protocol: DSP DNA Blood
Sample volume: 200 µl
Elution volume: 200 µl
Pure ethanol wash: Yes
Rack type: TipRack
Estimated run time: 23 min 0 sec
Number of samples: 4

Pretreatment:
 Ensure that all samples have been left at room temperature for a sufficient period of time to equilibrate before transfer to sample tubes (ST).
 For handling and pretreatment of samples and reagents, please refer to the EZ1® DSP DNA Blood Kit Handbook.

Cancel

◀ Back

Next ▶

Figure 144. Load the holder.

8. Tap **Next** to proceed to the run overview screen.












Load the holder

Parameter name	
Pure ethanol wash	Yes
Sample volume	200 µl
Elution volume	200 µl

Row	Labware
A	2.0 ml sample tube (S) uncapped
B	2.0 ml screw-cap tube (Sarstedt, cat. no. 72.000.000)
C	Tip holder (DTH)
D	1.5 ml elution tube (E) uncapped

Run setup selection overview

Application: DNA

Kit: EZ1 DSP DNA Blood Kit

Protocol: DSP DNA Blood

Sample volume: 200 µl

Elution volume: 200 µl

Pure ethanol wash: Yes

Rack type: TipRack

Estimated run time: 23 min 0 sec

Number of samples: 4

Do you want to start the protocol run?

Return

Start

Cancel

Back

Next

Figure 145. Run setup overview.

9. Tap **Start** to begin the selected protocol run.

Note: The first scanned sample ID must be known for the LIMS. The next scanned sample IDs can be unknown for the LIMS, and can be used with the preselected protocol and parameters. In this case, this dialog box appears:

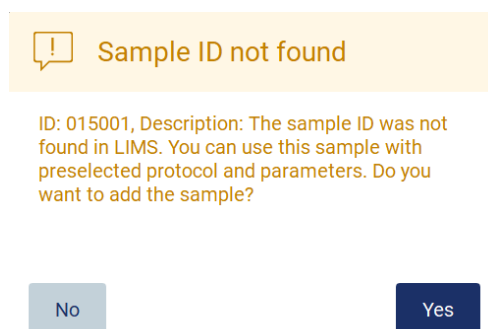


Figure 146. LIMS Sample ID not found dialog box.

10. To process the unknown sample along with the sample IDs found in LIMS, tap **Yes**. Previously scanned ID is displayed.

Note: The audit trail and support package will also contain LIMS results sending and LIMS Connector information.

11. The system checks available disk space when the protocol run is started. If the available space is lower than that required for five runs, a warning message is displayed.

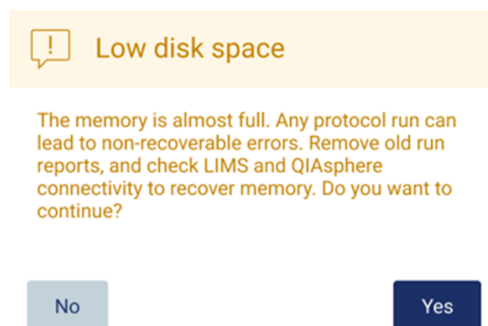


Figure 147. Pop-up window with low disk space after attempting to start a run.

Previous run reports should be downloaded and deleted to free up disk space.

5.13. Data menu

Important: Use only the USB stick provided by QIAGEN. Do not connect other USB stick devices to USB ports.

Important: Do not remove the USB drive while downloading or transferring data or software to or from the instrument.

The following functions can be completed through the Data menu:

- Download and/or delete run files
- Create and download support package
- Download audit trail
- Download sample list template

Tap **Data** on the toolbar to access the Data screen.

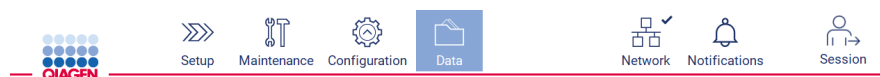


Figure 148. Data button on the toolbar.

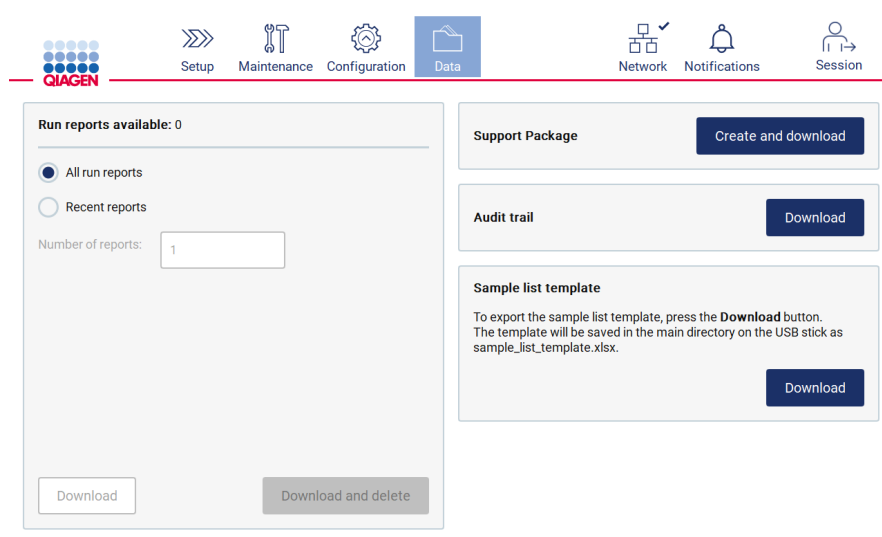


Figure 149. Data screen.

5.13.1. Run reports

If there is currently no run report on the instrument, the **Download** and the **Download and delete** buttons are disabled.

If run reports are available, tap either one of the available options below:

- All run reports
- Recent reports, for this option you should also specify the number of reports

Tap either **Download** or **Download and delete**.

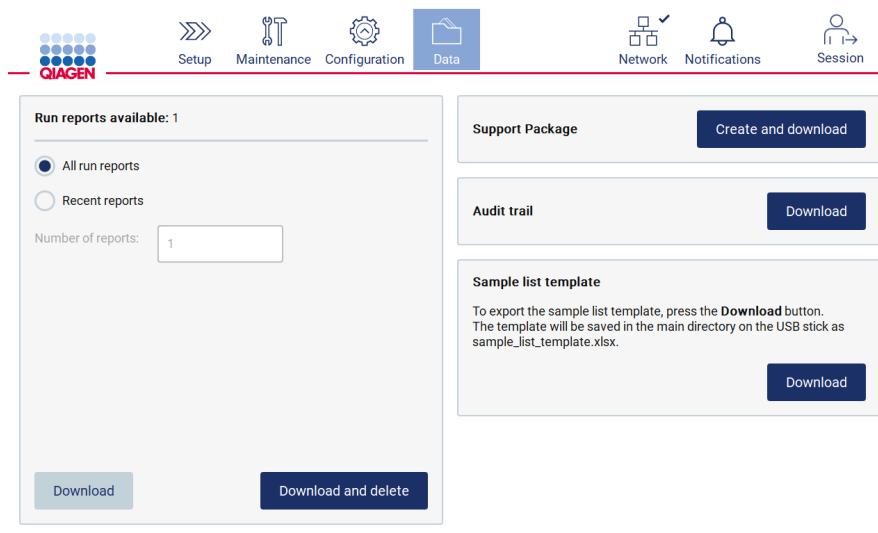


Figure 150. Data tab.

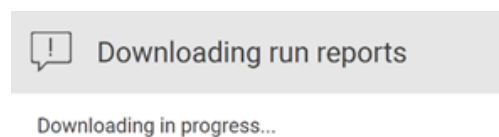


Figure 151. Download reports in progress.

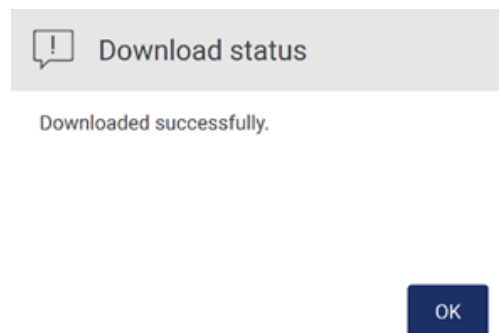


Figure 152. Report download successful.

If **Download and delete** is selected, the following screen is displayed prior to start of the delete process.

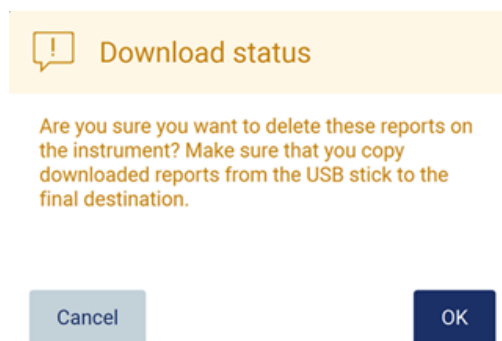


Figure 153. Confirm delete run reports.

Tap **OK** to confirm deletion, or **Cancel** to go back. Downloaded files should be copied from the USB stick to a final destination of the user's choosing.

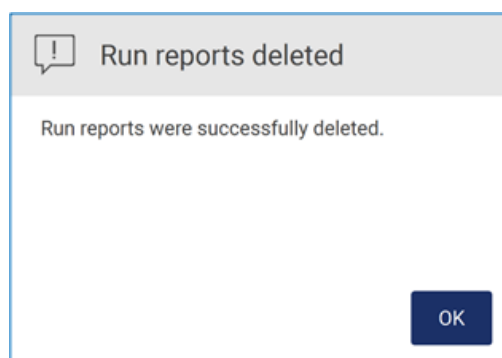


Figure 154. Run reports deleted confirmation.

Tap **OK** to complete process.

If no USB drive is inserted, the following screen is displayed:

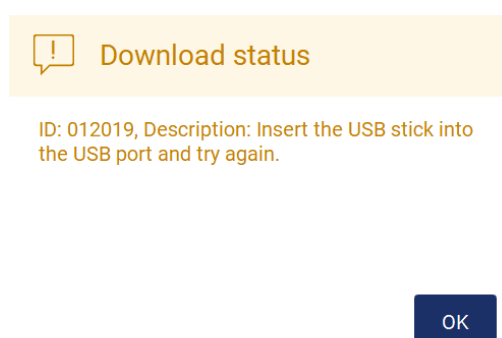


Figure 155. USB drive not inserted.

Insert a USB drive and attempt the process again.

5.13.2. Support package

Detailed instruction can be found in Section 8.1.1 Creating a support package.

5.13.3. Audit trail

Note: Download of the Audit trail file(s) is only available to Admin users.

Tap the **Download** button, in the Audit trail section of the Data screen. The following screen is displayed:

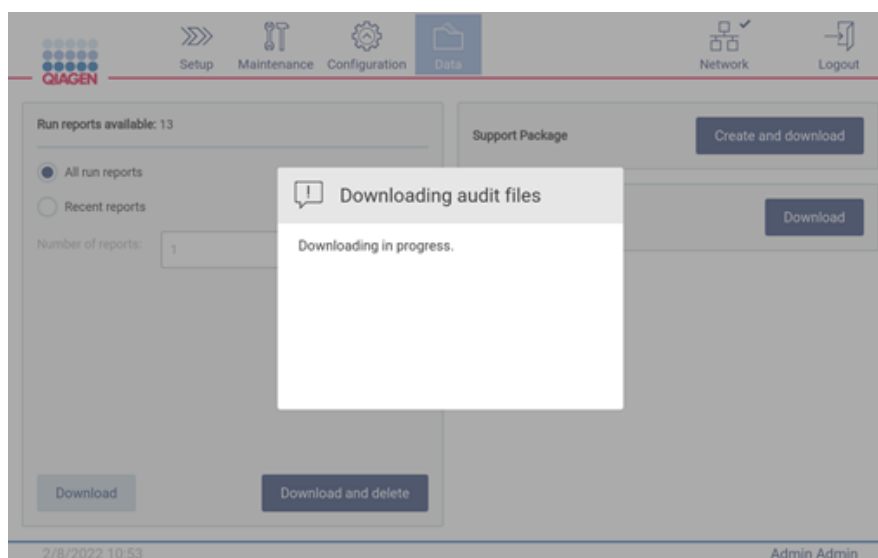


Figure 156. Download audit trail in progress.

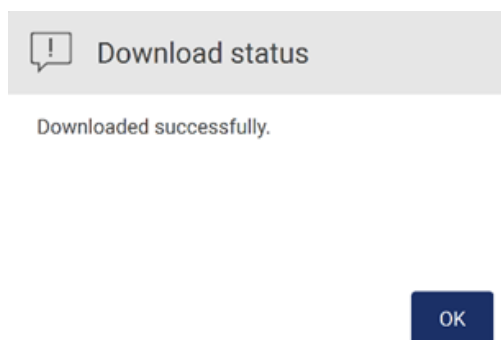


Figure 157. Audit trail download successful.

If no USB drive is inserted the following is displayed:

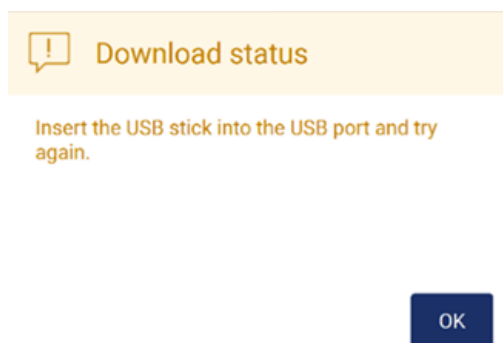


Figure 158. USB drive not inserted.

Insert a USB drive and attempt the process again.

5.13.4. Sample list template

The sample list template is an **.xlsx** file that can be used to predefine sample positions, sample IDs, and optional sample notes. It can be filled in on an external PC by using a spreadsheet calculation software and uploaded to the EZ2 Connect MDx during protocol run setup.

Note: Download of a sample list template is only available to Admin users.

1. To download the sample list template tap the **Download** button in the sample list template section of the data screen.

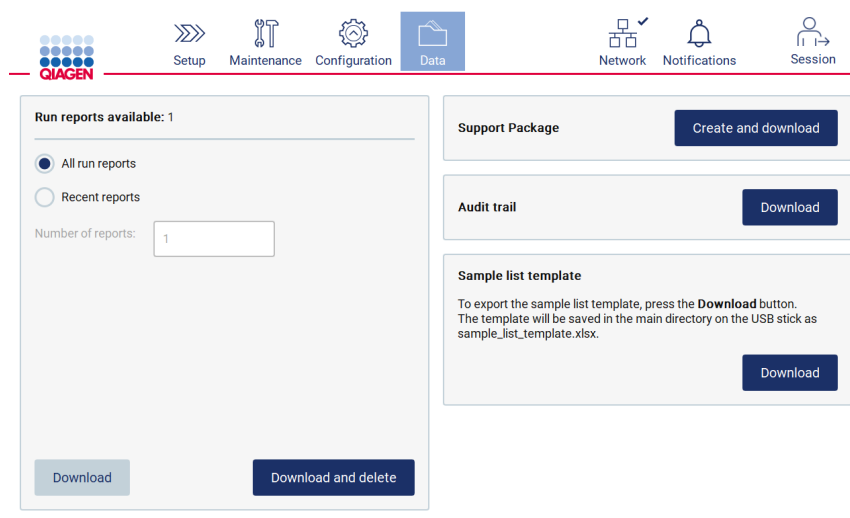


Figure 159. Data screen.

- Wait until the download is completed and confirm by tapping **OK** on the pop-up window.

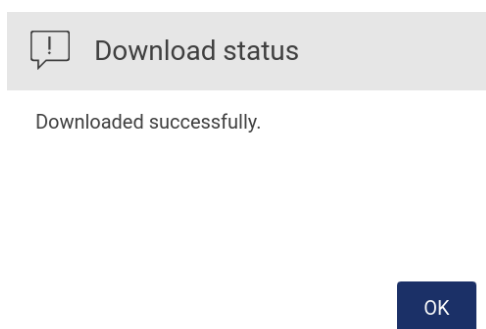


Figure 160. Download successful pop-up window.

- Use an external PC with a spreadsheet calculation software to open and edit the template.
- Fill out the sample IDs of the used sample positions in the table. It is possible to leave positions empty. It is optional to add sample notes.

Position ▾	Sample ID ▾	Note ▾
1	Example ID 1	Example Note (Optional)
2	Example ID 2	
3	Example ID 3	
4		
5		
6		

Figure 161. Sample list template.

5.14. Session handling

Tap the **Session** button to open the Session handling window (Figure 162). The Session handling dialog offers two options: **Lock screen** and **Logout** (Figure 163).

Lock screen allows the screen to be locked while the current session remains active, to prevent unauthorized access to the instrument. To unlock the screen, enter the valid user ID and password. It is possible for another user to take over the session if the screen is locked. To take over the session, the **Use different account** button needs to be tapped. After entering the user ID and password, the session gets handed over to the user with the corresponding log in data. The handover is logged in the audit trail.

Logout allows to end the current session. To log out of the software, tap the **Logout** button.

To switch the instrument off, press the power button.

Important: Do not switch the instrument off when a protocol run, maintenance procedure, or file transfer is in progress. This could result in damage to the instrument and samples and/or data may be lost.

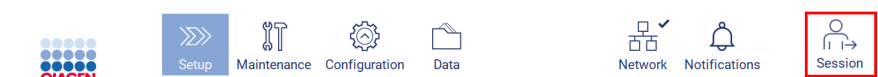


Figure 162. Location of the Session button.

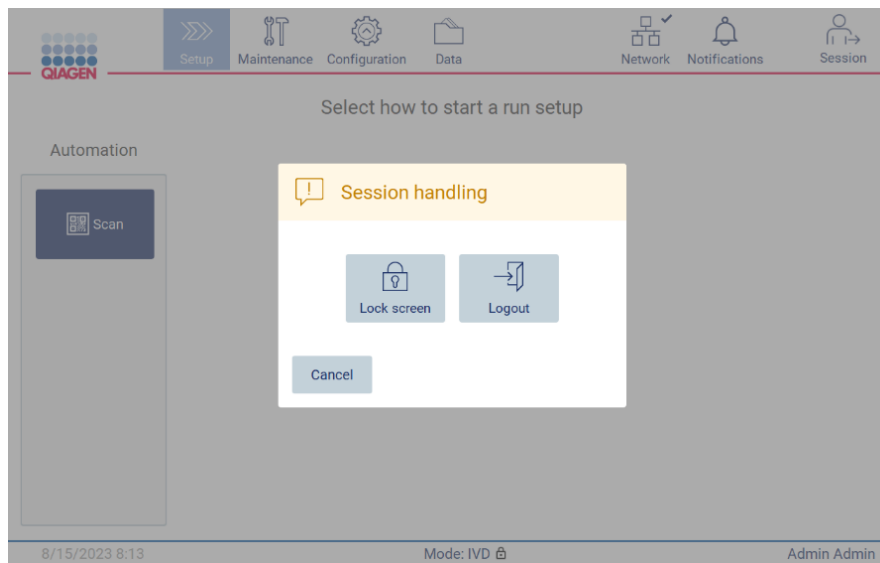


Figure 163. Session handling dialog window.

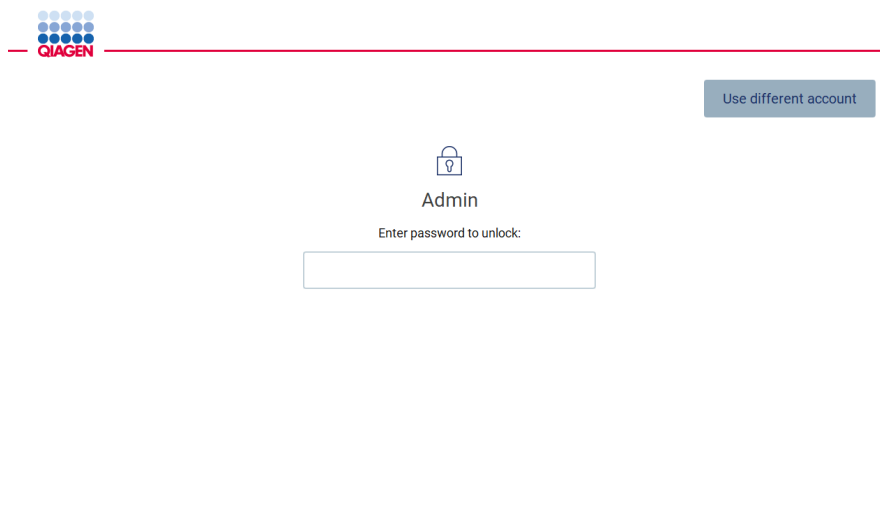


Figure 164. Lock screen.

5.15. Notifications and banners

The **Notifications** icon changes the status, if new warning, errors, and important info notification appears in the system. The **Notifications** icon has two states:

-  — There are no new notifications.
-  — There is at least one new notification.

Tap the **Notifications** icon to check the notifications. The notification list is divided into three sections: errors (red), warnings (yellow), information, and notifications (gray) in the particular section are sorted by date.

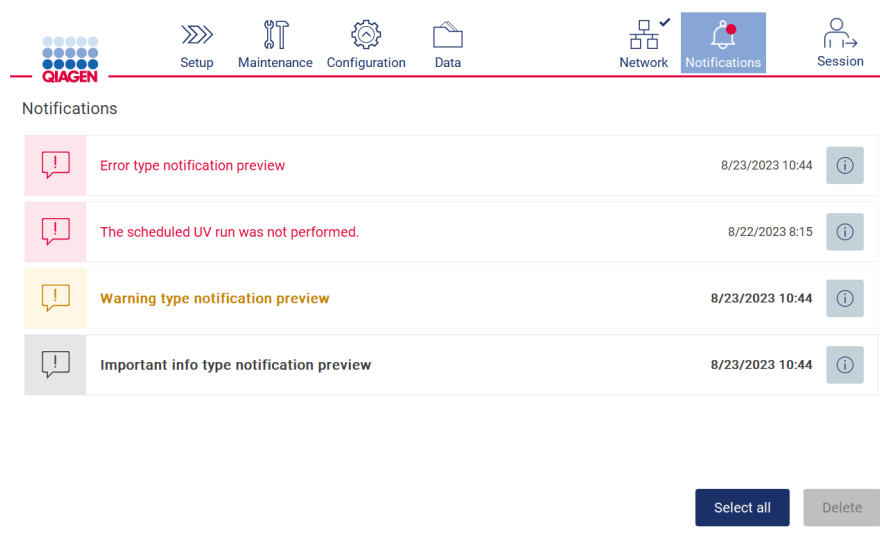


Figure 165. Notification center.

To see detailed description of the info listed in the notification center tap the info icon ().

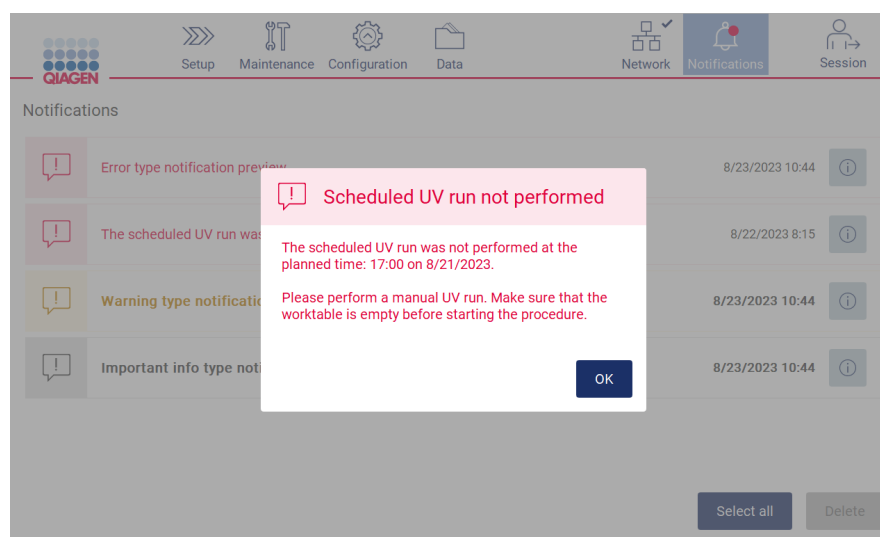


Figure 166. Detailed information in notifications.

Notification banners may also appear in every environment except the run setup workflow (if the setup is started and the run is performing). The newest three notifications are visible on the screen. The latest is always displayed on the top. If multiple notification banners pop out on the screen, only the latest three will be displayed. The screen is blocked until all notifications are closed. To see the rest of the notifications tap the **Notifications** icon on top.

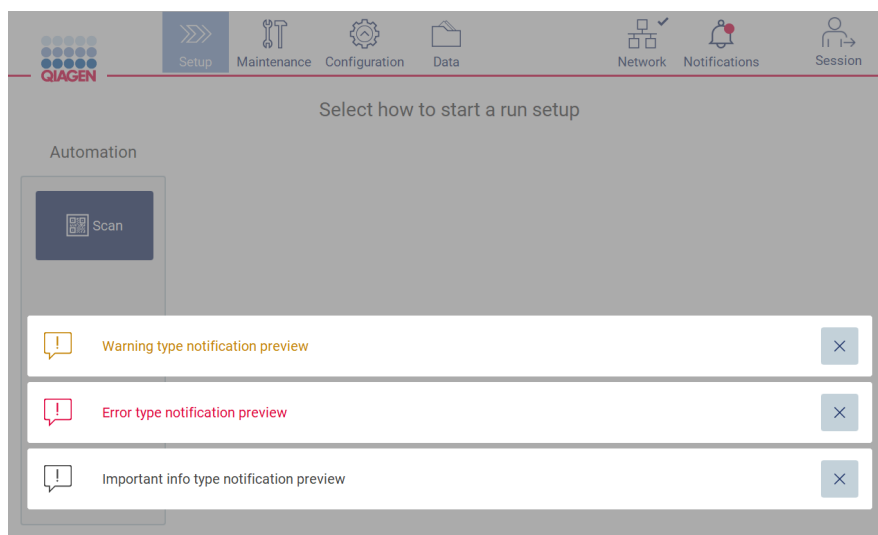


Figure 167. Notification banners on the startup page.

The banners appear on the bottom of the screen when the user starts a background task (e.g., cooling after the run or scheduled UV run). When the banners are displayed, the rest of the screen becomes inactive until all banners have been closed by tapping **X**.

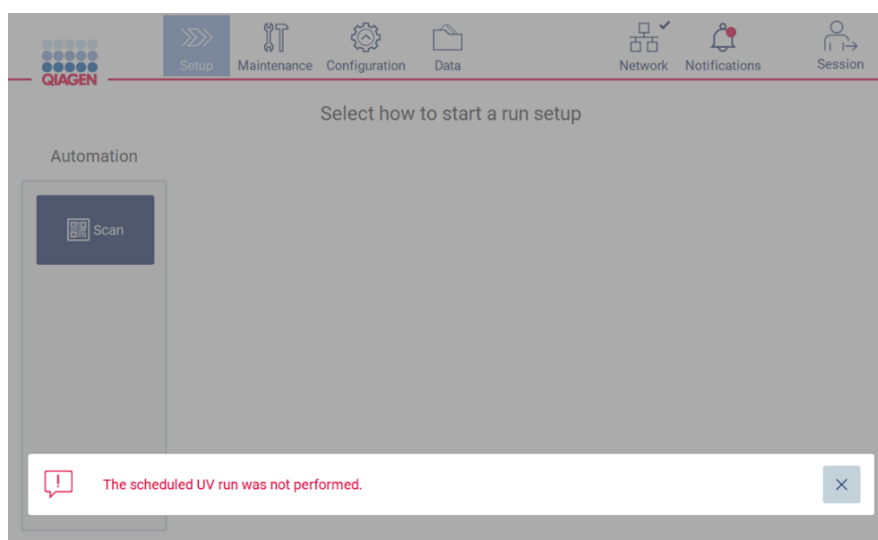


Figure 168. Background task banner.

The background task banner also appears by tapping on the status icon in the footer (UV or snowflake). The icon appears only when a background task is running.

8/23/2023 14:14	Mode: IVD 	Admin Admin 
8/23/2023 14:26	Mode: IVD 	Admin Admin 

Figure 169. Status icons indicating a specific background task.

5.16. Cooling after run

The software supports cooling of the heating system to 35°C after a finished protocol run, for applications that require a cold instrument at the start of a protocol run (see respective kit handbook).

The cooling starts if:

- The **Finish** button on the Protocol run completed/aborted/failed screen is activated.
- The heating system temperature is above 35°C.
- The hood is closed.

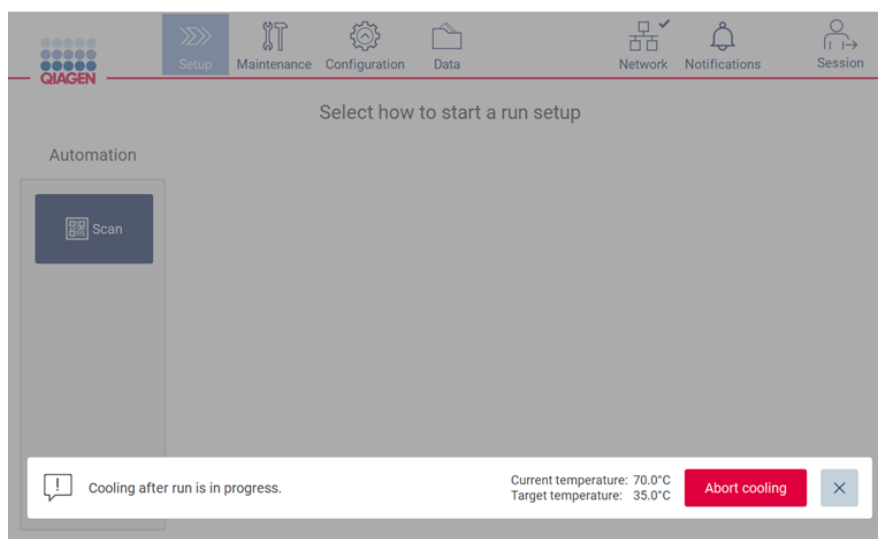


Figure 170. Cooling after run is in progress banner.

Note: Cooling stops when the heater reaches 35°C.

The cooling status can be checked in the **Background Tasks** tab in the **Maintenance** environment. The cooling process is indicated by a banner and a snowflake symbol in the lower-right corner. The snowflake can be tapped for further information when the banner is closed.

Cooling of the heating block is performed by the fan, and the time for the instrument to cool down depends on the used protocol, ambient temperature, and distance of fan to the wall. Depending on these parameters, it may take up to 90 minutes for the heating block to reach a temperature below 35°C. Ensure that the worktable is empty before tapping the **Finish** button and proceeding with the cooling. After **Finish** button is tapped, the instrument hood is locked during cooling.

Cooling can be canceled when a timeout occurs or manually by tapping **Abort cooling**. The next run can be initiated. However, this may lead to the prolonged run time (the instrument initiates the run only after the heater is passively cooled), a heater timeout error (the required temperature of the heating block is not reached within a specified time) and/or risk of sample damage. For protocols that require a cooled heating block, this information is provided in the loading instructions.

Canceling cooling does not affect any maintenance procedures after the run. After the pop-up window “Abort cooling after run” has been closed, there are two methods to abort the cooling procedure. First is to tap on the snowflake symbol in the lower-right corner of the display – this reopens the pop-up window. Second is to open the **Background task** tab in the **Maintenance** section and abort the **Cooling after run** task. If necessary, cooling can be started manually after it has been aborted.

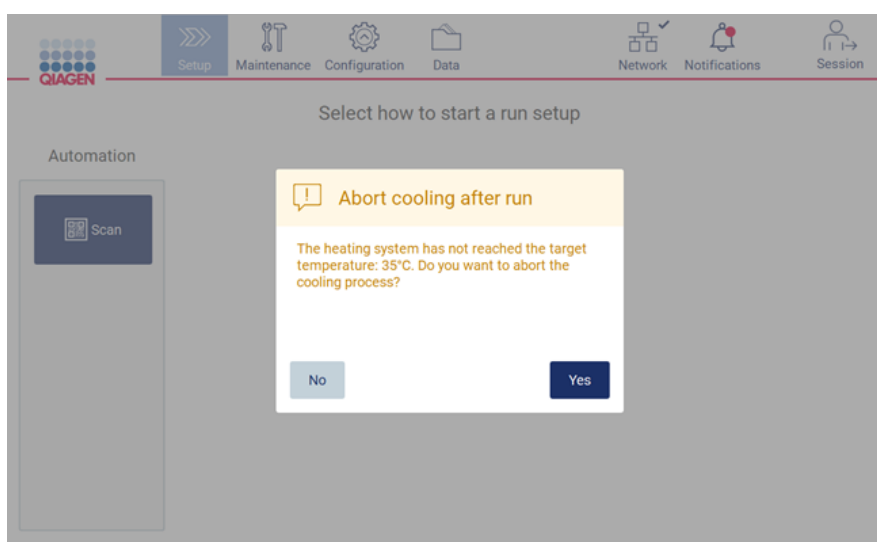


Figure 171. Pop-up window with aborted cooling after run.

6. Maintenance Procedures

**WARNING/
CAUTION**



Risk of personal injury and material damage

Only perform maintenance that is specifically described in this user manual.

To ensure reliable operation of the EZ2 Connect MDx, maintenance procedures must be performed. The procedures are shown in the table below. Each maintenance procedure must be carried out by appropriate personnel, as specified below.

Table 2. Maintenance schedule

Type of task(s)	Frequency	Personnel
After run maintenance	After each run.	Laboratory technicians or equivalent
Daily maintenance	At the end of each day, if at least one run was performed that day. Note: Perform this procedure after you are done with the after run maintenance.	Laboratory technicians or equivalent
Weekly maintenance	Once a week. Note: Perform this procedure after you are done with the daily maintenance.	Laboratory technicians or equivalent
Annual maintenance and servicing	Annually or semiannually, depending on your requirements (for more information contact QIAGEN Technical Support).	QIAGEN authorized Service Specialists only

Optionally, a UV decontamination procedure may be performed as required to support pathogen and nucleic acid decontamination. See Section 6.5 UV decontamination for further details.

An overview of the status of the maintenance tasks can be found under the **Maintenance** tab. The **Overview** tab displays a table with the tasks listed when they were last performed and when they should be performed again. Additionally, the table has a column with an icon that warns of overdue maintenance.

Maintenance task			
		Last	Due
!	Daily maintenance	8/16/2023	0 hours
	Weekly maintenance	8/16/2023	5 days
	UV run	8/16/2023	9 hours
	Camera LED maintenance	-	-

Figure 172. Maintenance overview.

The **Background tasks** tab presents a table with the running or inactive background activities (e.g., cooling after run or scheduled UV run). The background task is indicated by a banner and by a sign in the lower right corner. In case of a running active cooling process, a snowflake is shown (Figure 173). A scheduled UV run is indicated by a UV sign.

Task	Status	Start time
Cooling after run	Running	8/25/2023 12:54
Scheduled UV run	Not running	-

Abort

Figure 173. Background tasks tab.

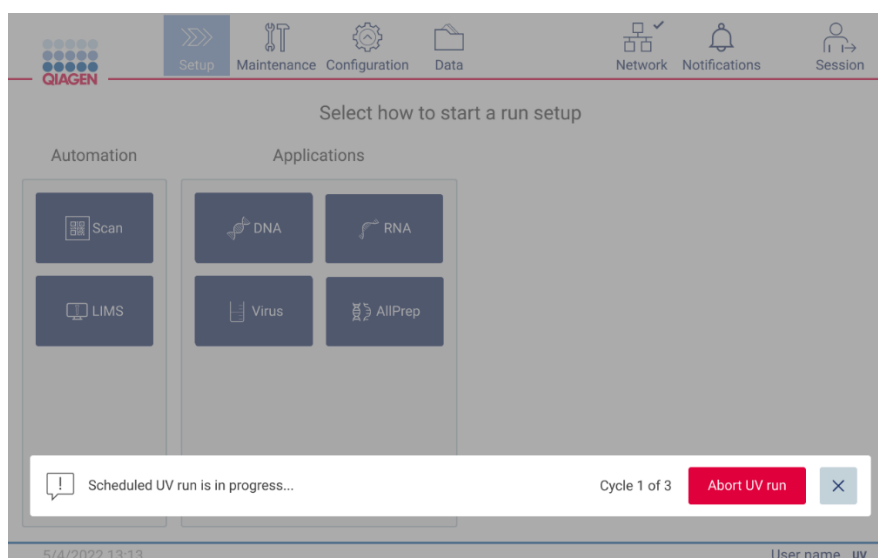


Figure 174. Scheduled UV run is running.

6.1. Cleaning agents

The surfaces and removable parts of the EZ2 Connect MDx must be cleaned and disinfected with compatible detergents and disinfectants. Follow the instructions provided by the manufacturer of such materials to safely clean the instrument.

Note: If you want to use different disinfectants than the recommended ones, make sure that they have the same composition.

If you are unsure about the suitability of the detergents or disinfectants to be used with the EZ2 Connect MDx, do not use them.

General cleaning of the EZ2 Connect MDx, with the exception of the hood, can be done using mild detergents/disinfectant, such as the Mikrozid® AF (www.schuelke.com), or 70% ethanol. The hood should only be cleaned with lint-free tissue moistened with water.

WARNING



Toxic fumes

Do not use bleach to clean or disinfect the EZ2 Connect MDx or the used labware. Bleach in contact with salts from the buffers can produce toxic fumes.

CAUTION



Damage to the instrument

Do not use spray bottles containing alcohol or disinfectant to clean surfaces of the EZ2 Connect MDx. Spray bottles should be used only to clean items that have been removed from the worktable and if permitted by local laboratory operating practices.

CAUTION



Risk of fire

Do not allow cleaning fluid or decontamination agents to come into contact with the electrical parts of the EZ2 Connect MDx.

WARNING**Risk of electric shock**

Do not open any panels on the EZ2 Connect MDx.

Risk of personal injury and material damage

Only perform maintenance that is specifically described in this user manual. Any other maintenance or repair may only be carried out by an authorized QIAGEN Field Service Specialist.

WARNING**Risk of fire or explosion**

When using ethanol or ethanol-based liquids on the EZ2 Connect MDx, handle such liquids carefully and in accordance with the required safety regulations. If liquid has been spilled, wipe it off and leave the EZ2 Connect MDx hood open to allow flammable vapors to disperse.

6.1.1. Disinfecting the EZ2 Connect MDx

Ethanol-based disinfectants can be used for disinfecting surfaces such as the worktable. An example of ethanol-based disinfectant are the Mikroqid Liquid (Mikroqid Liquid consists of 25 g ethanol and 35 g 1-propanol per 100 g) or Mikroqid AF wipes. These are available from Schülke & Mayr GmbH, see cat. no. 109203 or 109160. For countries where Mikroqid Liquid is not available, 70% ethanol can be used.

Disinfectants based on quaternary ammonium salt can be used for racks, worktable, and the magnet. Example of such disinfectant is the Lysetol® AF/Gigasept® Instru AF (Schülke & Mayr GmbH). These disinfectants consist of around 15 g cocospropylene–diamine–guanidine diacetate, 35 g phenylpropanol, and 2.5 g benzalkonium chloride per 100 g, with anticorrosion components, fragrance, and 15–30% nonionic surfactants.

Note: If you want to use different disinfectants than the recommended ones, make sure that they have the same composition.

Important: Always follow the manufacturer's instructions when preparing disinfectants.

Note: The hood and touchscreen should only be cleaned with lint-free tissue moistened with water.

CAUTION**Damage to the instrument**

Do not use spray bottles containing alcohol or disinfectant to clean surfaces of the EZ2 Connect MDx. Spray bottles should be used only to clean items that have been removed from the worktable and if permitted by local laboratory operating practices.

6.1.2. Removing contamination

The EZ2 Connect MDx could be contaminated during operation. To remove the contamination, use appropriate decontamination solutions.

In case of RNase contamination, the RNaseZap® RNase Decontamination Solution (Ambion, Inc., cat. no AM9780) can be used for cleaning surfaces and submerging worktable items. RNaseZap can also be used to perform decontamination by spraying worktable items, if they have been removed from the instrument.

In case of nucleic acid contamination, DNA/RNA-ExitusPlus™ (AppliChem, cat. no. A7089,0100) can be used for cleaning surfaces and submerging worktable items. DNA/RNA-ExitusPlus can also be used to perform decontamination by spraying worktable items, if they have been removed from the instrument. Cleaning with DNA/RNA-ExitusPlus can leave a residue on surfaces so for this reason, after cleaning the items with DNA/RNA-ExitusPlus, it is required to clean the items with a wet cloth several times, or rinse them with running water, until the DNA/RNA-ExitusPlus is completely removed.

Note: Always carefully follow the manufacturer's instructions when using decontamination solutions.

6.2. After run maintenance

After run maintenance is required after each run of the EZ2 Connect MDx.

The EZ2 Connect MDx must only be operated by qualified personnel who have been appropriately trained.

Servicing of the EZ2 Connect MDx must only be performed by QIAGEN Field Service Specialists.

WARNING

Moving parts



To avoid contact with moving parts during the operation of the EZ2 Connect MDx, the instrument must be operated with the hood closed.

The hood is locked during operation for safety reasons and a sensor detects the hood position. If the hood sensor or lock is not functioning correctly, contact QIAGEN Technical Support.

WARNING

Moving parts



Avoid contact with moving parts during operation of the EZ2 Connect MDx. Under no circumstances should hands be placed under the pipetting unit during movement. Do not attempt to remove any plasticware from the worktable while the instrument is operating.

WARNING/ CAUTION



Risk of personal injury and material damage

Improper use of the EZ2 Connect MDx may cause personal injuries or damage to the instrument. The EZ2 Connect MDx must only be operated and maintained by qualified personnel who have been appropriately trained. Servicing of the EZ2 Connect MDx must only be performed by a QIAGEN Field Service Specialist.

WARNING**Samples containing infectious agents**

Some samples used with EZ2 Connect MDx may contain infectious agents. Handle such samples with the greatest of care and in accordance with the required safety regulations.

Always wear safety glasses, two pairs of gloves, and a lab coat.

The responsible body (e.g., a laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe and that the instrument operators are suitably trained and not exposed to hazardous levels of infectious agents as defined in the applicable Safety Data Sheets (SDSs) or the OSHA,* ACGIH,[†] or COSHH[‡] documents.

Venting for fumes and disposal of waste must be in accordance with all national, state, and local health and safety regulations and laws.

* OSHA — Occupational Safety and Health Organization (United States of America)

[†] ACGIH — American Conference of Government Industrial Hygienists (United States of America)

[‡] COSHH — Control of Substances Hazardous to Health (United Kingdom)

WARNING**Hazardous chemicals**

Some chemicals used with EZ2 Connect MDx may be hazardous or may become hazardous after completion of purification.

Always wear safety glasses, two pairs of gloves, and a lab coat.

The responsible body (e.g., a laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe and that the instrument operators are not exposed to hazardous levels of chemicals as defined in the applicable Safety Data Sheets (SDSs) or the OSHA,* ACGIH,[†] or COSHH[‡] documents.

Venting for fumes and disposal of waste must be in accordance with all national, state, and local health and safety regulations and laws.

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[‡] COSHH — Control of Substances Hazardous to Health (United Kingdom)

Materials used on the EZ2 Connect MDx, such as human blood, serum, or plasma, are potentially infectious. Thus, the EZ2 Connect MDx should be decontaminated after use (for more details, see Sections 6.1.1 Disinfecting the EZ2 Connect MDx and 6.1.2 Removing contamination).

After running a protocol, perform after run maintenance as described below. The after run maintenance must be performed to avoid inhibitor carryover to the next run.

Note: Make sure that the eluates have been retrieved, closed, labelled, stored according to the respective kit handbook before performing after run maintenance.

Note: Perform the after run maintenance (as displayed on the GUI) before tapping the **Finish** button. Once pressed, cooling of the instruments starts.

1. Remove all sample preparation waste and discard it according to your local safety regulations.
2. If position 11 of the reagent cartridge has been equipped with a tube, this can either be removed before removing the reagent cartridge, but it is also possible to lift the cartridge rack with the tube inside.

3. Close the hood.

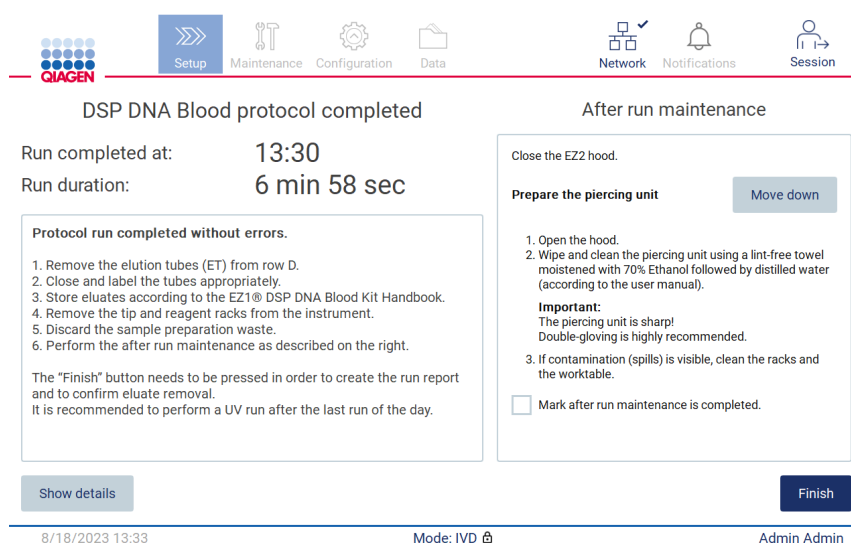


Figure 175. Protocol run completed screen.

4. Put on gloves; two pairs are recommended as the piercing unit is sharp.
5. To prepare the piercing unit, tap **Move down**. The instrument lowers the piercing unit of the pipettor head.
6. Open the hood.
7. Carefully wipe the piercing unit using a lint-free tissue moistened with 70% ethanol. Enclose each individual piercing spike with the tissue, apply firm pressure and twist several times. Repeat for all piercing spikes.

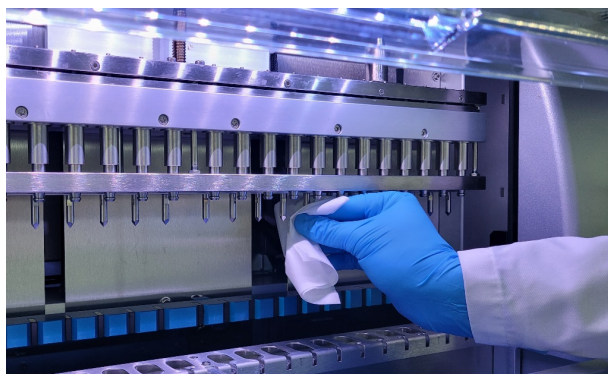


Figure 176. Cleaning the EZ2 Connect MDx piercing unit.

8. Carefully wipe the piercing unit with a lint-free tissue moistened with distilled water. Enclose individual piercing spike with the tissue, apply firm pressure and twist several times. Repeat for all piercing spikes.
9. Close the hood.
10. To document the cleaning procedure in the run report, confirm that the maintenance has been completed by activating the checkbox on the touchscreen.
11. On the touchscreen, tap **Finish**. The “cooling-after-run” procedure starts and the piercing unit returns to its home position.
12. Open the hood.
13. If contamination is visible on the worktable, clean it with 70% ethanol, and then with distilled water.

6.3. Daily maintenance

Daily maintenance is required after the last run of each day.

WARNING



Moving parts

To avoid contact with moving parts during the operation of the EZ2 Connect MDx, the instrument must be operated with the hood closed.

The hood is locked during operation for safety reasons and a sensor detects the hood position. If the hood sensor or lock is not functioning correctly, contact QIAGEN Technical Support.

WARNING



Moving parts

Avoid contact with moving parts during operation of the EZ2 Connect MDx. Under no circumstances should hands be placed under the pipetting unit during movement. Do not attempt to remove any plasticware from the worktable while the instrument is operating.

WARNING/ CAUTION



Risk of personal injury and material damage

Improper use of the EZ2 Connect MDx may cause personal injuries or damage to the instrument. The EZ2 Connect MDx must only be operated and maintained by qualified personnel who have been appropriately trained. Servicing of the EZ2 Connect MDx must only be performed by a QIAGEN Field Service Specialist.

WARNING



Samples containing infectious agents

Some samples used with EZ2 Connect MDx may contain infectious agents. Handle such samples with the greatest of care and in accordance with the required safety regulations.

Always wear safety glasses, two pairs of gloves, and a lab coat.

The responsible body (e.g., a laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe and that the instrument operators are suitably trained and not exposed to hazardous levels of infectious agents as defined in the applicable Safety Data Sheets (SDSs) or the OSHA,* ACGIH,[†] or COSHH[‡] documents.

Venting for fumes and disposal of waste must be in accordance with all national, state, and local health and safety regulations and laws.

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[‡] COSHH — Control of Substances Hazardous to Health (United Kingdom)

WARNING



Hazardous chemicals

Some chemicals used with EZ2 Connect MDx may be hazardous or may become hazardous after completion of purification.

Always wear safety glasses, two pairs of gloves, and a lab coat.

The responsible body (e.g., a laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe and that the instrument operators are not exposed to hazardous levels of chemicals as defined in the applicable Safety Data Sheets (SDSs) or the OSHA,* ACGIH,[†] or COSHH[‡] documents.

Venting for fumes and disposal of waste must be in accordance with all national, state, and local health and safety regulations and laws.

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[‡] COSHH — Control of Substances Hazardous to Health (United Kingdom)

1. On the touchscreen, tap **Maintenance**.
2. Tap **Daily**. The date of the last finished procedure is shown on the screen.

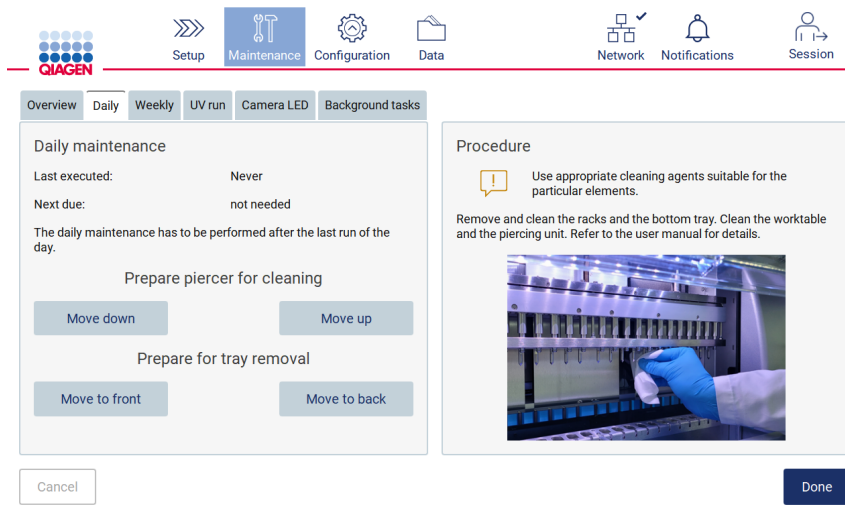


Figure 177. Daily maintenance screen.

3. Put on gloves.
4. Clean the piercing unit (if this is not yet done during after run maintenance).
 - a. To prepare the piercing unit for cleaning, tap **Move down**.
 - b. Open the hood.
 - c. Clean the piercing unit as recommended in Section 6.2 After run maintenance.
5. Clean the worktable with 70% ethanol or Mikrozid AF, and then with distilled water (if this is not yet done during after run maintenance).
6. Close the hood.
7. To return the piercing unit to home position, tap **Move up**.
8. To allow bottom tray removal, tap **Move to back**.

Note: Right bottom tray must be removed first.
9. Clean the bottom tray with 70% ethanol, and then with distilled water.

Note: After removal of the bottom tray for cleaning purposes, ensure it is correctly reinstalled. The left bottom tray must be inserted first.

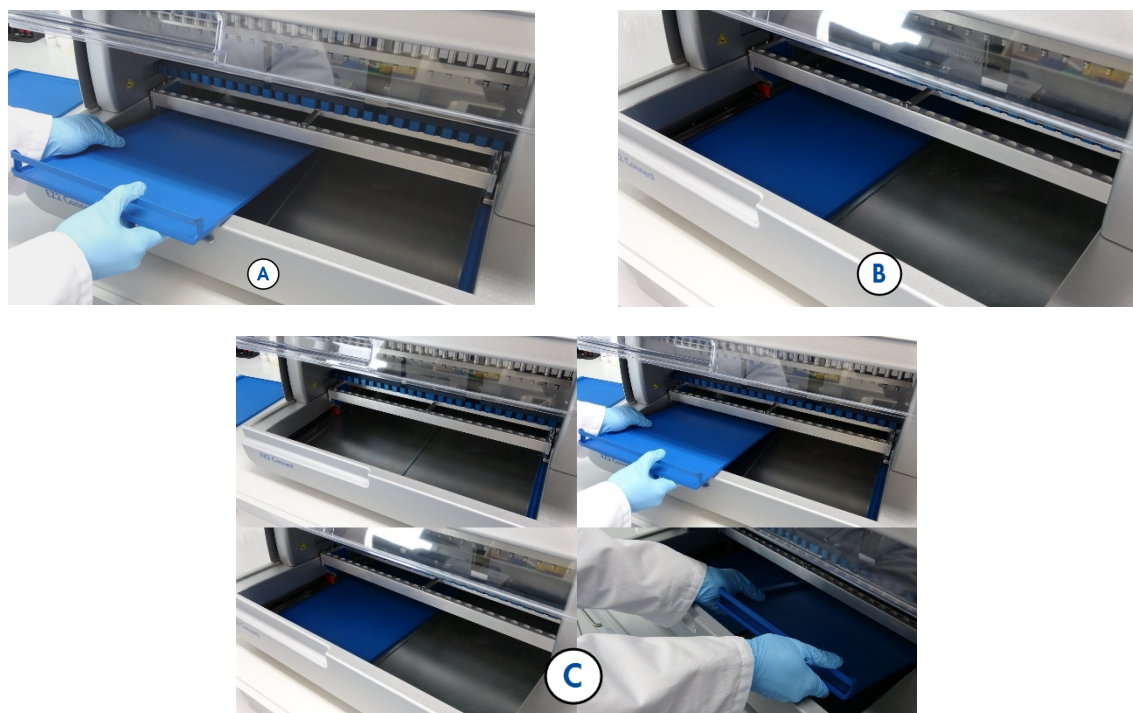


Figure 178. Bottom tray. (A) Installing left side of the bottom tray, (B) left side of the bottom tray installed, and (C) Correct installation of the bottom trays.

10. Wipe the cartridge and tip racks with 70% ethanol or Mikrozid AF, and then with distilled water.
11. Wipe the surface of the instrument using a lint-free tissue moistened with 70% ethanol.
12. Tap **Move to front**. Racks can now be inserted into the instrument again.

Note: The hood and touchscreen should only be cleaned with lint-free tissue moistened with water.

6.4. Weekly maintenance

WARNING/ CAUTION



Risk of personal injury and material damage

Improper use of the EZ2 Connect MDx may cause personal injuries or damage to the instrument. The EZ2 Connect MDx must only be operated and maintained by qualified personnel who have been appropriately trained. Servicing of the EZ2 Connect MDx must only be performed by a QIAGEN Field Service Specialist.

WARNING**Samples containing infectious agents**

Some samples used with EZ2 Connect MDx may contain infectious agents. Handle such samples with the greatest of care and in accordance with the required safety regulations.

Always wear safety glasses, two pairs of gloves, and a lab coat.

The responsible body (e.g., a laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe and that the instrument operators are suitably trained and not exposed to hazardous levels of infectious agents as defined in the applicable Safety Data Sheets (SDSs) or the OSHA,* ACGIH,[†] or COSHH[‡] documents.

Venting for fumes and disposal of waste must be in accordance with all national, state, and local health and safety regulations and laws.

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WARNING**Hazardous chemicals**

Some chemicals used with EZ2 Connect MDx may be hazardous or may become hazardous after completion of purification.

Always wear safety glasses, two pairs of gloves, and a lab coat.

The responsible body (e.g., a laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe and that the instrument operators are not exposed to hazardous levels of chemicals as defined in the applicable Safety Data Sheets (SDSs) or the OSHA,* ACGIH,[†] or COSHH[‡] documents.

Venting for fumes and disposal of waste must be in accordance with all national, state, and local health and safety regulations and laws.

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Important: Before starting the weekly maintenance procedure, complete Section 6.3 Daily maintenance.

To maintain good contact between tip adapters and filter-tips, and to prevent liquid leaking from the tips, a light application of grease should be applied to the D-rings (on tip adapter) of the tip adapters every week.



Figure 179. Tip adapter with a highlighted D-Ring.

1. On the touchscreen, tap **Maintenance**.
2. Tap **Weekly maintenance**. The date the weekly maintenance procedure was last completed and the next due date are shown on the screen.



Figure 180. Weekly maintenance screen.

3. Put on gloves.
4. Clean the D-rings (on tip adapter) with a lint-free tissue to remove any previously applied grease.
5. Apply a small amount of silicon grease (see Appendix B – EZ2 Connect MDx Parts and Components/Consumables, Ordering information) onto the inner wall of the large end of a fresh filter-tip by using the fine end of a second fresh tip.



Figure 181. Preparation of filter tips for grease application.

6. Place the previously prepared filter-tip with grease applied to the inner wall at the wide end onto each tip adapter subsequently, and rotate the filter-tip on the tip adapters to distribute the silicon grease evenly. The same tip can be used for the distribution of grease on all D-rings. Apply new grease into the filter tip after every four tip adapters according to the previous step.
7. Make sure that the D-rings are only moistened with grease and that there are no visible grease residues. Residues should be removed with lint-free cloth and greasing restarted.
8. Make sure that there is no grease present on parts other than the D-rings, especially on the bar on top and the opening of the pipettors (see Figure 182).

Note: Excess or insufficient grease can affect the performance of the EZ2 Connect MDx.

Note: The opening in the nub of the pipettor should be checked after greasing to ensure no grease is present within the opening.

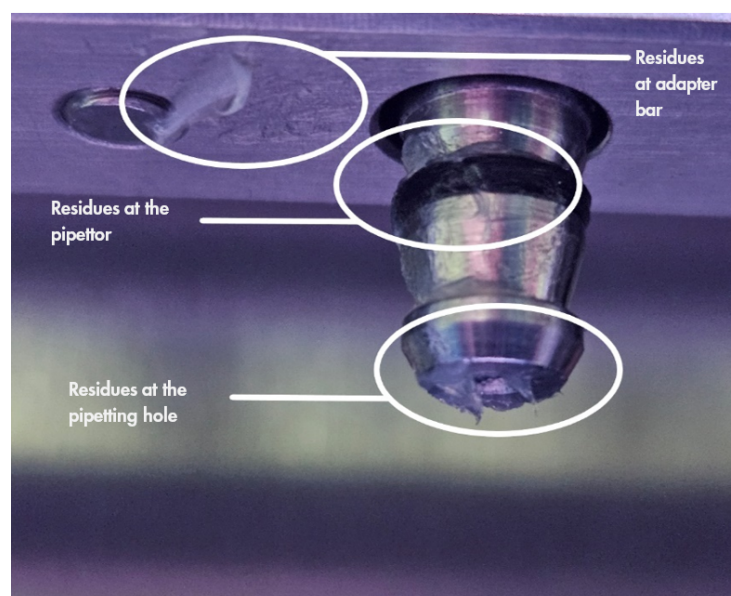


Figure 182. Example of an overgreased tip adapter. All marked spots should be checked and all visible grease residues should be removed.

6.5. UV decontamination

WARNING/ CAUTION



Risk of personal injury and material damage

Improper use of the EZ2 Connect MDx may cause personal injuries or damage to the instrument. The EZ2 Connect MDx must only be operated and maintained by qualified personnel who have been appropriately trained. Servicing of the EZ2 Connect MDx must only be performed by a QIAGEN Field Service Specialist.

WARNING



Samples containing infectious agents

Some samples used with EZ2 Connect MDx may contain infectious agents. Handle such samples with the greatest of care and in accordance with the required safety regulations.

Always wear safety glasses, two pairs of gloves, and a lab coat.

The responsible body (e.g., a laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe and that the instrument operators are suitably trained and not exposed to hazardous levels of infectious agents as defined in the applicable Safety Data Sheets (SDSs) or the OSHA,* ACGIH,[†] or COSHH[‡] documents.

Venting for fumes and disposal of waste must be in accordance with all national, state, and local health and safety regulations and laws.

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WARNING**Hazardous chemicals**

Some chemicals used with EZ2 Connect MDx may be hazardous or may become hazardous after completion of purification.

Always wear safety glasses, two pairs of gloves, and a lab coat.

The responsible body (e.g., a laboratory manager) must take the necessary precautions to ensure that the surrounding workplace is safe and that the instrument operators are not exposed to hazardous levels of chemicals as defined in the applicable Safety Data Sheets (SDSs) or the OSHA,* ACGIH,[†] or COSHH[‡] documents.

Venting for fumes and disposal of waste must be in accordance with all national, state, and local health and safety regulations and laws.

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[‡] COSHH — Control of Substances Hazardous to Health (United Kingdom)

WARNING**Risk of personal injury**

Avoid looking directly into UV light. Do not expose your skin to UV light.

Important: Before starting the UV decontamination, complete the Daily maintenance (Section 6.3) and ensure that the labware is removed from the instrument. The racks are not affected by the UV light and must be inserted before the UV run.

Note: The bottom trays should be inserted before the UV run is started.

Note: For a proper decontamination of the system, QIAGEN recommends to additionally wipe the surfaces with disinfectants. The procedure is described in Section 6.1.1 Disinfecting the EZ2 Connect MDx.

The UV run can be set manually (for all users) or in scheduled mode (only for administrator and service users).

Figure 183. UV run maintenance tab with manual UV run settings (for Operator and Advanced users).

Setup

Maintenance

Configuration

Data

Network

Notifications

Session

Overview

Daily

Weekly

UV run

Camera LED

Background tasks

Scheduled UV run settings

☒ Scheduled UV run
 Start time: 17:00

☒ Monday
 ☐ Tuesday
 ☐ Wednesday
 ☐ Thursday

☒ Friday
 ☐ Saturday
 ☐ Sunday

Close hood notification: 15 minutes before

Cycles: 1
 -
 +

Duration: 8 sec

Cancel

Accept

UV run status

Last executed: 8/16/2023 10:50 (Manual UV run)
 Never (Scheduled UV run)

1 cycle(s) runs every: Monday, Friday, 17:00

Close hood notification: 15 minutes before UV run

Manual UV run

Cycles: 1
 -
 +

Duration: 8 sec

Make sure that the worktable is empty before starting the procedure.

Start

Figure 184. UV run maintenance tab with scheduled UV run turned on (for Administrator and Service users).

Setup

Maintenance

Configuration

Data

Network

Notifications

Session

Overview

Daily

Weekly

UV run

Camera LED

Background tasks

Scheduled UV run settings

☐ Scheduled UV run
 Start time: 0:00

☒ Monday
 ☒ Tuesday
 ☒ Wednesday
 ☒ Thursday

☒ Friday
 ☒ Saturday
 ☒ Sunday

Close hood notification: Never

Cycles: 1
 -
 +

Duration: 8 sec

Cancel

Accept

UV run status

Last executed: 8/16/2023 10:33 (Manual UV run)
 Never (Scheduled UV run)

1 cycle(s) runs every: Never

Close hood notification: Never

Manual UV run

Cycles: 1
 -
 +

Duration: 8 sec

Make sure that the worktable is empty before starting the procedure.

Start

Figure 185. UV run maintenance tab with scheduled UV run turned off (for Administrator and Service users).

6.5.1. Manual UV run

1. Close the hood.
2. On the touchscreen, tap **Maintenance**.

The screenshot shows the 'Maintenance' tab selected in the top navigation bar. Below the navigation bar, there are tabs for 'Overview', 'Daily', 'Weekly', 'UV run', 'Camera LED', and 'Background tasks'. The 'UV run' tab is active. The screen is divided into two main sections. The left section, titled 'Scheduled UV run settings', contains a warning: 'Only the administrator can change the scheduled UV run settings.' Below this, there are checkboxes for 'Scheduled UV run', 'Monday', 'Tuesday', 'Wednesday', 'Thursday', 'Friday', 'Saturday', and 'Sunday'. A 'Start time' field is set to '0:00'. There is a 'Close hood notification' dropdown menu set to 'Never'. Below that, there are 'Cycles' and 'Duration' fields. The 'Cycles' field is set to '1' and the 'Duration' field is set to '8 sec'. There are 'Cancel' and 'Accept' buttons at the bottom of this section. The right section, titled 'UV run status', shows 'Last executed: 8/16/2023 10:33 (Manual UV run)' and 'Never (Scheduled UV run)'. It also shows '1 cycle(s) runs every: Never' and 'Close hood notification: Never'. Below this, there is a 'Manual UV run' section with a 'Cycles' field set to '1' and a 'Duration' field set to '8 sec'. There is a 'Start' button at the bottom right of this section. A warning message says 'Make sure that the worktable is empty before starting the procedure.'

Figure 186. Manual UV run section in the UV run tab (user without administrator rights view).

3. Tap **UV run**. The date when the procedure was last completed is shown on the screen.
4. Select the number of decontamination cycles. The required decontamination time depends on the biological material processed on the device. One cycle takes around 34 minutes.
5. To begin the procedure, tap **Start**.

The screenshot shows the 'UV run is in progress' screen. The top navigation bar is the same as in Figure 186. The 'UV run' tab is active. The screen displays 'UV run is in progress' at the top. Below this, it shows 'Cycle 2 of 3'. A progress bar is shown, with a blue segment indicating the progress. Below the progress bar, it says '14 sec to complete'. At the bottom left, there is a red 'Abort' button. At the bottom right, there is a grey 'Finish' button.

Figure 187. UV run is in progress screen.

6. If there is a need to abort the UV cycle prior to completion, tap the **Abort** button.

Important: The UV cycle does not stop immediately upon selecting **Abort**; the system needs to complete the currently running step of the cycle, this can take up to 2 minutes.

7. A message (see the Figure 188 below) is displayed after execution of the UV run. Tap **Finish** to complete the UV run.

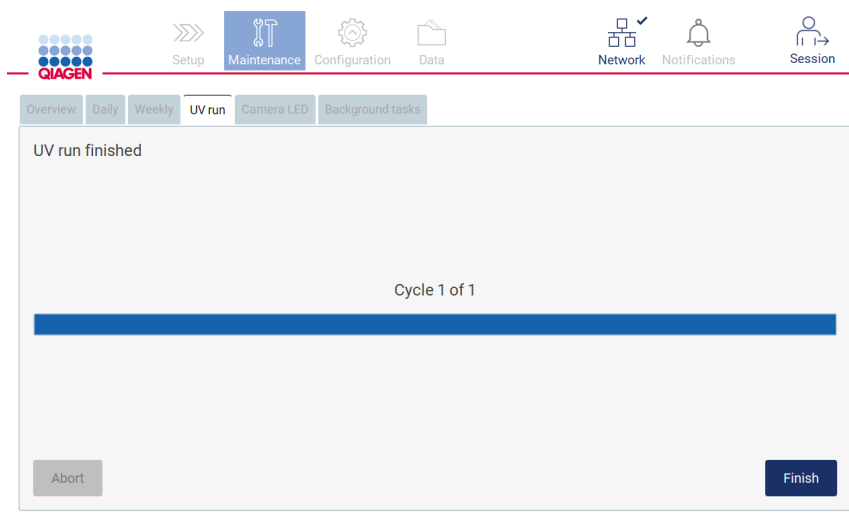


Figure 188. UV run finished screen.

6.5.2. Scheduled UV run

The **UV run** tab allows the administrator and service user to set a scheduled UV run on the instrument.

1. On the touchscreen, tap **Maintenance**.
2. Tap **UV run**. The date of the last procedure is shown on the screen.
3. Enable the “Scheduled UV run” checkbox.
 - Set Start time.
 - Set weekdays by selecting corresponding checkboxes.
 - Set time for the Close hood notification.
 - Set number of cycles.

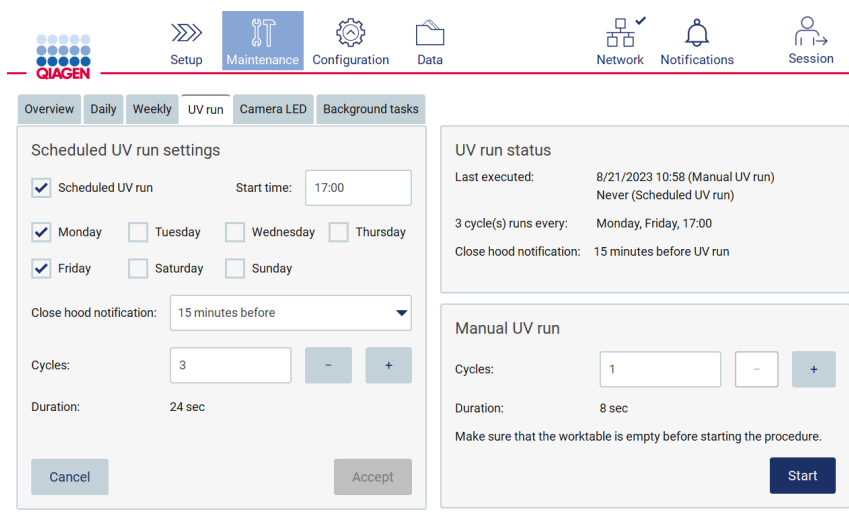


Figure 189. Scheduled UV run settings.

The Close hood notification informs all users when the scheduled UV run starts and reminds them to remove labware, close the hood, and not turn off the instrument. This notification can be turned off by selecting the **Never** option.

Note: When the instrument is turned off, a protocol run is performed, or the hood is open, the scheduled UV run is not performed. A notification is displayed indicating that the UV run was not performed.

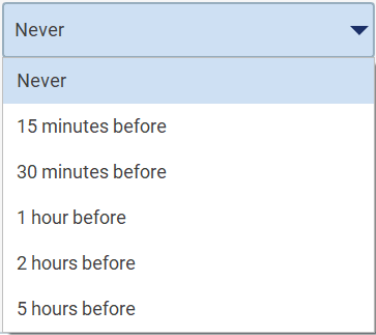


Figure 190. Timeout selection for Close hood notification.

If the Close hood notification is turned on, it appears before the scheduled UV run:

- At the defined time.
- When the protocol run is finished, aborted, or failed.
- By going back to the home screen from the protocol setup.

The user can go to the **Notification** tab and check details by tapping the **More info** button.

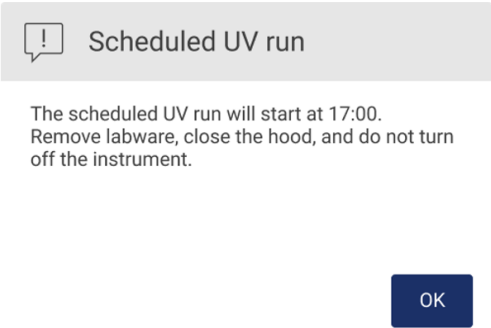


Figure 191. Close the hood notification.

When the UV run starts the scheduled UV run banner appears at the bottom of the screen. Additionally, a UV sign appears in the lower-right corner during the UV run. This sign can be tapped for more information.

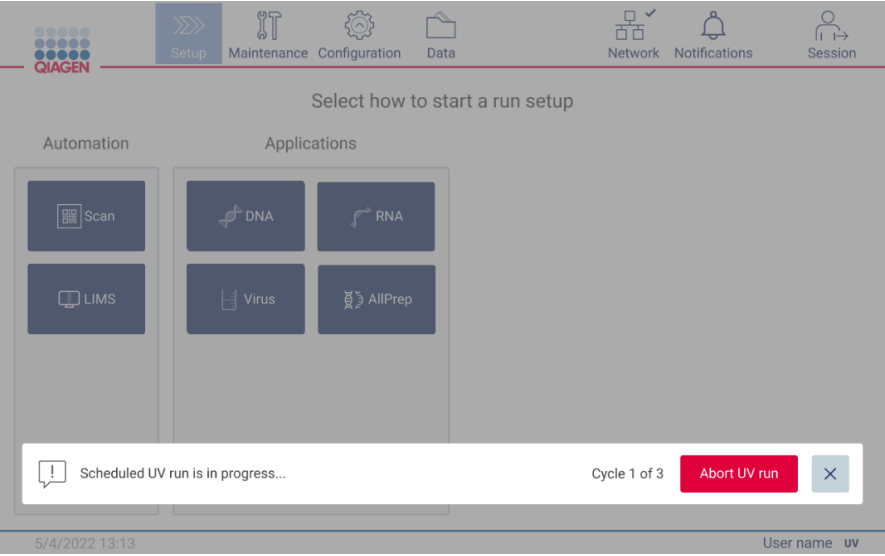


Figure 192. Scheduled UV run is in progress banner.

6.6. Camera calibration

The EZ2 Connect MDx provides an internal camera which performs an inventory scan prior to run execution.

Note: The camera calibration should be performed as part of installation procedure, after moving the instrument, as well as in case of load check issues.

1. On the touchscreen, tap **Maintenance**.
2. Tap **Camera LED**.

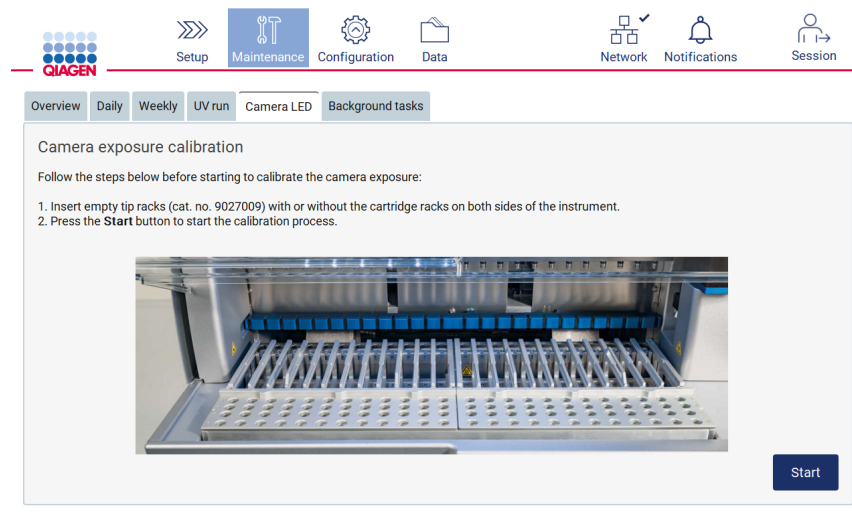


Figure 193. Camera exposure calibration screen.

3. Insert empty tip racks (cat. no. 9027009) without the cartridge racks on both sides of the instrument.
4. Close the hood.
5. To begin the procedure, tap **Start**. The camera unit commences to move across the deck and take a series of exposure images.
6. Press **Finish** after the calibration is completed.

6.7. Servicing

Contact your local QIAGEN Technical Support or your local distributor for more information about flexible Service Support Agreements from QIAGEN.

Note: Before service of the EZ2 Connect MDx can be performed, the instrument must first be decontaminated. Refer to Sections 6.1.1 Disinfecting the EZ2 Connect MDx and 6.1.2 Removing contamination.

WARNING/ CAUTION



Risk of personal injury and material damage

Improper use of the EZ2 Connect MDx may cause personal injuries or damage to the instrument. The EZ2 Connect MDx must only be operated and maintained by qualified personnel who have been appropriately trained. Servicing of the EZ2 Connect MDx must only be performed by a QIAGEN Field Service Specialist.

7. Research Mode

The EZ2 Connect MDx offers two modes at instrument startup: the IVD mode (for validated IVD applications only) and the Research mode (for molecular biology applications [MBA] only). This section provides brief instructions on the use of the Research mode.

For detailed instructions on how to operate the EZ2 Connect MDx using the Research mode (with MBA protocols or any customized protocols), refer to the user manual of the EZ2 Connect (available on the EZ2 Connect product webpage under the **Resources** section).

- To start the EZ2 Connect MDx in Research mode, select **Research Mode** at the log-in screen.
- If this is the first time use of the EZ2 Connect MDx, use “Admin” as user ID and password. Tap Log in to launch the software.

QIAGEN

Help

Welcome to EZ2
Log in to continue

User ID:
Admin

Password:
.....

☒ Research Mode ☐ IVD Mode

Log in

8/18/2023 13:12

Figure 194. The login screen.

- A password change screen opens to request a password change after first login.
- Change your password according to the screen instructions.
- The Setup screen opens to display available applications.
- To start an application either:
 - Tap **Scan** in the Applications pane. By scanning the 1D barcode on the Q-Card provided with the kit, the application type is selected and protocol options are displayed. Depending on the scanned Q-Card barcode, the software automatically displays the protocol options for the corresponding kits. See Section 5.12 LIMS workflow; or
 - Tap an application in the Applications pane. The software automatically proceeds to the protocol selection screen.

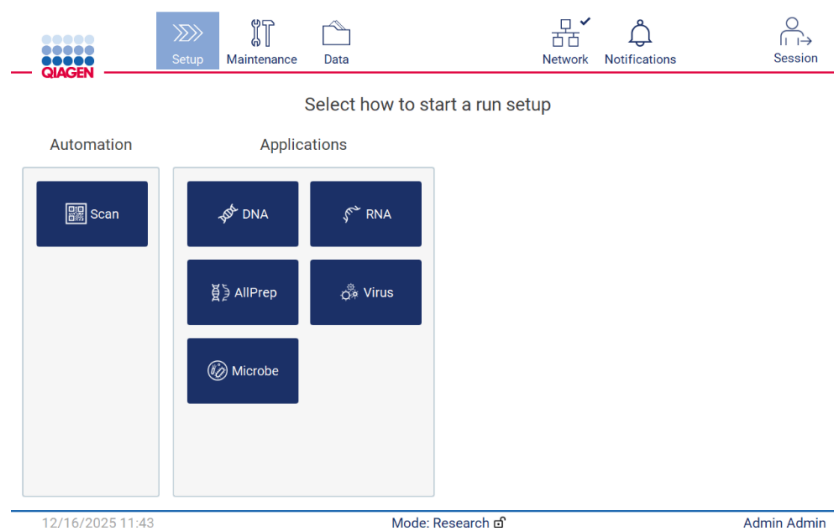


Figure 195. Select an application screen.

- Select a protocol and follow the instructions given on the user interface to progress through the steps required to set up the protocol. See the subsections in the Section 5.5 Setting up a protocol run for further details.

Note: Using the EZ2 Connect MDx in Research mode gives the option to skip the initial load check. When skipping the load check, the instrument does not check the worktable setup but immediately start the protocol run. For the best safety level, QIAGEN recommends to always perform the load check.

Note: Some protocols in the Research mode could contain checkboxes that allow to deactivate the load check for certain rows.

Note: When switching the EZ2 Connect MDx back to IVD mode, it is important to thoroughly clean and decontaminate the instrument. The following maintenance must be completed:

- Section 6.3 Daily maintenance (if not already completed)
- Section 6.5 UV decontamination

8. Troubleshooting

This section contains information about what to do if an error occurs when using the EZ2 Connect MDx. Contact QIAGEN Technical Support at support.qiagen.com

8.1. Contacting QIAGEN Technical Support

Whenever encountering an EZ2 Connect MDx error, note the steps leading up to the error and any information in any dialog boxes. This information helps the QIAGEN Technical Support solve the problem. Have the following information at hand:

Note: Most of the information listed below can be found in the run report.

- Protocol name and version
- Software version
- Serial number of the instrument (found on the type plate at the rear of the instrument, in the **Configuration** tab in the software, or in each run report)
- Sample input material, sample volume, and sample pre-treatment
- Elution volume
- Detailed description of the error situation
- Support package (Section 8.1.1 Creating a support package)
- Kit name and lot number
- Photos of the error conditions (if appropriate)

This information helps you and your QIAGEN Technical Support Specialist resolve the issue efficiently.

Note: Information about the latest software and protocol versions is available in EZ2 Connect MDx product page (www.qiagen.com/EZ2ConnectMDx). In some cases, updates may be available for addressing specific problems.

8.1.1. Creating a support package

The EZ2 Connect MDx can create a support package containing information about the device and the device status. This information will help QIAGEN Technical Support troubleshoot the issue.

1. Log into the EZ2 Connect MDx, if not already logged in.
2. Insert a USB stick into an available USB port.
3. Tap **Data** on the toolbar.

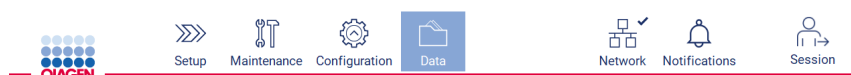


Figure 196. Data button on the toolbar.

4. Tap **Create and download** in the Support Package section.

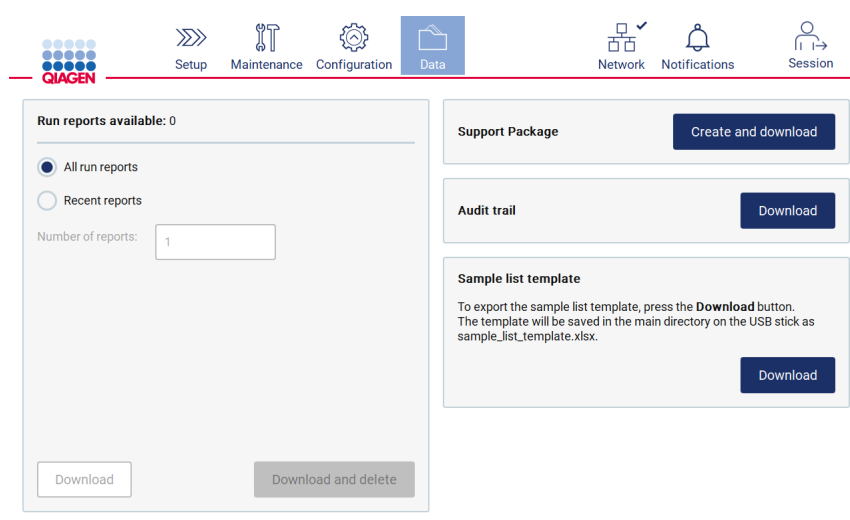


Figure 197. Data tab.

5. The support package is saved on the USB stick. The Download successful screen is displayed. Tap **OK** to close.

Note: The support package contains information about the most recent runs and may include sensitive information (e.g., sample IDs).

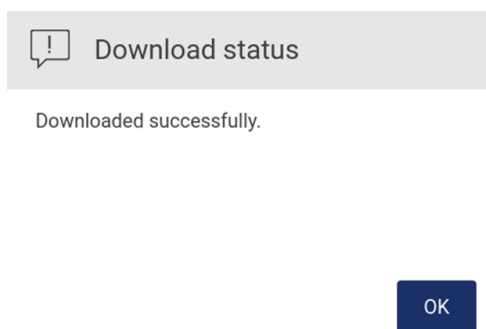


Figure 198. Download successful status.

6. If creation of the support package is not possible, the screen below is displayed. Attempt to create the support package again.

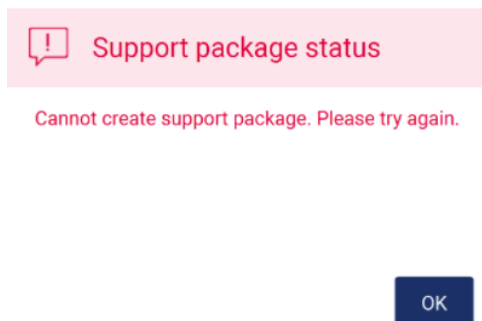


Figure 199. Support package creation failure status.

Note: The support package contains information about the last performed runs and hence can contain sensitive information.

8.2. Operation

Comments and suggestions

Hardware and software errors

Load check failed	Perform camera exposure calibration according to Section 4.5.6. Both standard tip racks (not large-volume or flip-cap racks) must be loaded for the camera exposure calibration. During protocols, both left and right tip rack must be inserted and must be of the same type rack. Racks have to be the same type. Check that there is no contamination (e.g., drops) on the labware. Note: To ensure a successful load-check process when using flip-cap racks, make sure that each tube's cap is properly seated in the corresponding square-shaped slot of the rack. The load check fails if tubes are used without caps. Note: Avoid strong environmental light changes and direct sunlight. Replace any failing consumable with new consumables. Perform load check again. Load check might fail because of solid samples (e.g., swabs). Any use of custom labware or labels (especially at the upper part of the tubes) can lead to load check issues.
Restricted mode	In case the instrument enters restricted mode, the functionality is limited and protocol runs cannot be started. It is still possible to download a support package for troubleshooting. One possible root cause is that the hood is not properly closed. Ensure that the hood is fully closed by pressing it down gently, then restart the device.
Filter inside the tips is dirty or wet	A dirty or wet filter can be caused by: • Incorrect sample volume: Ensure the used sample volume is according to the protocol instructions • Incorrect sample pretreatment: Pretreat samples according to the kit handbook • Sample condition (e.g., clotted, thick, or viscous): According to the kit handbook • Incorrect tubes: Use only the tubes provided with the kit or specified in the kit handbook or loading screen. If the liquid passed through the filter, please reach out to QIAGEN Technical Support.
Hood lock error	Check if the hood is firmly closed. Confirm by pressing down the hood gently.
Heater Fuse error	Install the latest software update. If software update is not possible, ensure that the hood is closed during startup and restart the device. If error still persists contact QIAGEN Technical Support.
Pipetting tips sticking to pipettor	Use lab tissue to wipe the D-rings and ensure weekly maintenance has been performed correctly. No visible grease residues should remain after the weekly maintenance. Remove grease residues with a lint-free tissue. Check and clean all positions shown in Figure 182.
Pipette tip was crushed	Pipetting tip may stick to pipettor (see "Pipetting tips sticking to pipettor"). Ensure that correct and compatible tubes were used. Use only tubes from the appropriate kit or specified by the kit handbook shall be used. Check the worktable set up and tip rack type.
Imprecise pipetting	If imprecise pipetting occurs over several runs (elution volume): Ensure that weekly maintenance has been performed. Check that the tips are firmly seated on the pipettor adapter. Ensure that correct sample volume is used.
Leaking pipette tips	Ensure that weekly maintenance has been performed. Install the latest protocol update package.
Pipette tips not picked up by pipettor	Ensure that the tip rack is not damaged and is correctly positioned on the worktable. Check that there are no grease residues at the pipette adapter.
Cross-contamination	Ensure that maintenance has been performed. Clean the piercing unit and worktable with 70% ethanol. Start UV decontamination. Make sure samples and cartridge rack were handled properly.
Error and warning messages	
Software or protocol update fails	Restart the device and attempt the update again. Use only the QIAGEN USB stick. Ensure that the USB stick remains connected during the entire update procedure.
USB device not detected	Wait a few seconds after plugging the USB stick. Unplug and plug in the USB stick again. Restart the device. Try using a different USB port or supported USB stick. Check the USB stick on a PC to ensure it is functional. Make sure you use the QIAGEN USB stick. If the error persists, contact QIAGEN Technical Support.
LAN Connection problem	Check if the ethernet cable is connected correctly. Check the LAN settings (Section 5.4.9).
No W-LAN connection	Check the Wi-Fi setting (Section 5.4.9). W-LAN adapter should be connected before you start the device. Reboot the device.

Comments and suggestions

Freeze during run	Reboot the device. Perform after run maintenance and start a new protocol run. Report such incidences to QIAGEN Technical Service and provide the support package (Section 8.1.1).
Surface damaged	Ensure that only the cleaning agents as described in Section 6.1 were used.
Display does not turn on	Do not touch the display with excessive force or use corrosive chemicals to clean the display surface. Contact QIAGEN Technical Support for repair.
Low disk space	Download and delete old run reports.
No maintenance or config tab visible	Probably the research mode is used. Currently these tabs are just visible in the IVD mode.
QIAsphere connection not working	Check the network connection. Install the latest software version.
User account locked	Use an Admin account to unlock the account by using the User Management menu. If there is no unlocked Admin account, tap on the question mark icon in the upper right corner of the login screen and follow the instructions on the display.

9. Glossary

Term	Definition
Barcode reader	A handheld device that enables scanning of barcodes and conversion of them into data that is transmitted to the EZ2 Connect MDx.
Bottom Tray	A metal tray that is located under the worktable. It collects any drops of liquid that may spill.
Cartridge rack	A metal rack that accommodates reagent cartridges on the worktable.
Connector panel	The panel on the rear of the EZ2 Connect MDx. It contains the power switch, the socket for the power cord, and the fuse box.
D-ring	A ring that is fitted at the bottom of a tip adapter. It is required for good contact between the tip adapter and a filter-tip.
Elution tube	A polypropylene, screw-capped 1.5 mL tube for collecting purified nucleic acids. The recommended elution tubes are screw capped, made of polypropylene, supplied by Sarstedt (cat. no. 72.692) and provided in EZ2 kits.
Error code	A number that represents an error of the EZ2 Connect MDx.
EZ2 kits	Kits supplied by QIAGEN containing reagents, reagent cartridges and plasticware for use with EZ2 Connect instruments.
Filter-tip	Labware that is picked up by a tip adapter during operation of the EZ2 Connect MDx. Liquid is aspirated into and dispensed from a filter-tip. A filter-tip is also the location where separation of magnetic particles occurs. A filter in the upper part of the tip prevents contamination between the tip and the tip adapter.
Heating system	A component of the EZ2 Connect MDx that accommodates the heating positions of the reagent cartridges and heats samples.
Hood	The main door at the front of the EZ2 Connect MDx. When open, it provides complete access to the worktable.
Pipettor head	The component of the EZ2 Connect MDx that aspirates and dispenses liquid, and pierces cartridges via the piercing unit. The pipettor head moves up and down above the worktable and contains 24 syringe pumps, each of which is connected to a tip adapter.
Protocol	A set of instructions for the EZ2 Connect MDx that allows the instrument to automate a nucleic acid purification procedure.
Reagent cartridge	An item of labware that contains 10 wells and 2 heating positions. One heating position is a well, the other is a slot that can hold a tube. A reagent cartridge is prefilled with reagents and included in EZ2 kits.
Report file	A file generated by the EZ2 Connect MDx that contains system and run parameters.
Sample tube	A polypropylene, screw-capped 2 mL tube for holding a sample containing nucleic acids to be purified. Sample tubes are 2 mL in volume, screw capped, made of polypropylene, supplied by Sarstedt (cat. no. 72.693), and provided in EZ2 kits.
Tip adapter	One of 24 metal probes installed on the pipettor head. During operation of the EZ2 Connect MDx, the tip adapters pick up filter-tips from the worktable.
Tip holder	A polypropylene tube that holds a single filter-tip. Tip holders are loaded onto the tip rack.
Tip rack	A metal rack that accommodates tip holders containing filter-tips on the worktable. The tip rack also accommodates sample tubes and elution tubes.
UV LED lamp	A light source of ultraviolet light for decontamination.
Worktable	The surface of the EZ2 Connect MDx that contains racks. The worktable is where samples, reagent cartridges and disposable labware are loaded. The worktable moves backward and forward to position samples and reagents under the pipettor head.

10. Technical Specifications

QIAGEN reserves the right to change specifications at any time.

10.1. Operating conditions

Description	Requirement
Power	100–240 V AC, 50/60 Hz, 1000 VA Mains supply voltage fluctuations are not to exceed 10% of nominal supply voltages.
Fuse	AC Inlet: T4A H 250 V Heater block (temperature fuse): 10 A, 250 V, 117 C
Overvoltage category	II
Air temperature	18–30°C (64–86°F)
Relative humidity	10–75% RH
Altitude	Up to 2000 m (6500 ft)
Place of operation	For indoor use only
Pollution level	2
Environmental class	3K21 (IEC 60721-3-3) 3M11 (IEC 60721-3-3)
Average noise level (over 8 hours)	Max. 70 dBA
IP Code (IEC 60529)	IP20

10.2. Transport conditions

Description	Requirement
Air temperature	–25°C to 60°C (–13°F to 140°F) in manufacturer's package Note: If the EZ2 Connect MDx is transported in temperatures below 0°C (32°F), it is recommended to wait 24 hours before switching on the instrument to allow it to reach the temperature conditions of the installation environment.
Relative humidity	5–85% RH
Environmental class	2K11 (IEC 60721-3-2) 2M4 (IEC 60721-3-2)

10.3. Storage conditions

Description	Requirement
Air temperature	5–40°C (41–104°F) in manufacturer's package
Relative humidity	5–85% RH
Environmental class	2K11 (IEC 60721-3-2) 2M4 (IEC 60721-3-2)

10.4. Mechanical data and hardware features

Description	Requirement
Dimensions	Width: 720 mm (28.35 in) Height: 575 mm (22.6 in) Depth: 560 mm (22 in)
Weight	70 kg (154.32 lb)
Instrument features	Automated nucleic acid isolation using magnetic particles Desktop instrument Protocols stored on instrument Processes up to 24 samples in one run Aspirates and dispenses up to 24 samples or reagents simultaneously using a 24-channel pipettor head Separates magnetic particles using patented technology Controlled through a touchscreen Temperature control through a heating system
Data tracking	Bar code reader and on-screen keyboard enable data tracking of samples and consumables. System and run parameters are stored in a report file.
Pipettor head	Contains 24 high-precision syringe pumps, each containing a tip adapter that attaches to filter-tips. Syringe pumps are air-filled. Liquids containing salts, alcohol, solvents and/or magnetic particles can be aspirated and dispensed. Air gaps can be aspirated to prevent aspirated liquid from dripping. Filter-tips are picked up from the tip rack and ejected back into the tip rack. The pipettor head moves in the Z direction (up and down) above the worktable.
Heating system	Accommodates the heating positions of reagent cartridges and has a temperature range of between ambient temperature and 95°C (203°F). Heating block accuracy is $\pm 2^{\circ}\text{C}$. *
Filter tips	Attach to the tip adapters of the pipettor head to allow liquid aspiration and dispensation. Capacity of 10–1000 μL . The EZ2 Connect MDx accommodates up to 48 tip holders in 2 rows, each containing a filter-tip, in the tip rack on the worktable.
Labware	Reagents are loaded onto the worktable in reagent cartridges. These cartridges are already prefilled by QIAGEN. Up to 24 reagent cartridges can be placed in the cartridge rack. Samples are loaded onto the worktable in 2 mL sample tubes. Steps that require heating occur on the heating system, which accommodates the heating positions of the reagent cartridges. Purified nucleic acids are collected in 1.5 mL elution tubes.
UV LED lamp	UV LED wavelength: 275–285 nm
Capacity	Up to 24 samples per run
Display	10.1 inch color touchscreen. Display with resolution 1280 × 800 pixels.
Camera	Monochrome camera. The USB interface provide power and communication. Sensor resolution is 0.34 MP. Width: 24 mm (0.94 in) Height: 34 mm (1.34 in) Depth: 39 mm (1.54 in)
Network	Wi-Fi: Designed for usage with Wi-Fi adapter provided by QIAGEN. The Wi-Fi adapter supports the 802.11b, 802.11g, and 802.11n Wi-Fi standards, and WEP, WPA-PSK, and WPA2-PSK encryption. Supports LAN If network functionality is used: the administrator must ensure that the instrument is not visible to the outside of the network

* Measured at temperature test position.

10.5. Barcode reader specifications

Note: The following specifications are referring to the supported Barcode Reader (cat. no. 9027101) for the EZ2 Connect system.

Decoding Capability: 1D / LINEAR CODES: Autodiscriminates all standard 1D codes including GS1 DataBar™ linear codes.

2D CODES: Aztec Code; China Han Xin Code; Data Matrix; MaxiCode; Micro QR Code; QR Code

STACKED CODES: EAN/JAN Composites; GS1 DataBar Composites; GS1 DataBar Expanded Stacked; GS1 DataBar Stacked; GS1 DataBar Stacked Omnidirectional; MacroPDF; MicroPDF417; PDF417; UPC A/E Composites

Reading range

TYPICAL DEPTH OF FIELD Minimum distance determined by symbol length and scan angle. Printing resolution, contrast, and ambient light dependent.

GD4500 Standard Range (SR)

Code 39: 5 mils: 7.0 to 38.0 cm / 2.7 to 14.9 in

Code 39: 10 mils: 2.2 to 58.0 cm / 0.8 to 22.8 in

Data Matrix: 10 mils: 5.5 to 27.0 cm / 2.2 to 10.6 in

Data Matrix: 15 mils: 2.8 to 41.0 cm / 1.1 to 16.1 in

EAN-13: 13 mils: 1.0 to 71.0 cm / 0.4 to 27.9 in

PDF417: 10 mils: 2.5 to 41.0 cm / 1.0 to 16.1 in

QR Code: 10 mils: 5.5 to 24.0 cm / 2.2 to 9.5 in

GD4500 High Density (HD)

Code 39: 3 mils: 5.0 to 15.0 cm / 2.0 to 5.9 in

Code 39: 5 mils: 0.5 to 25.0 cm / 0.2 to 9.8 in

Data Matrix: 5 mils: 5.5 to 9.0 cm / 2.2 to 3.5 in

EAN-13: 13 mils: 1.0 to 40.0 cm / 0.4 to 15.7 in

Data Matrix: 10 mils: 2.0 to 27.0 cm / 0.8 to 10.6 in

EAN-13: 7.5 mils: 2.0 to 23.5 cm / 0.8 to 9.3 in

PDF417: 4 mils: 3.0 to 12.0 cm / 1.2 to 4.7 in

PDF417: 10 mils: 0.5 to 31.0 cm / 0.2 to 12.2 in

QR Code: 10 mils: 2.0 to 25.0 cm / 0.8 to 9.8 in

Note: Further information can be found in the Barcode reader manual.

Appendix A

Declaration of Conformity

Name and address of the legal manufacturer

QIAGEN GmbH
QIAGEN Strasse 1
40724 Hilden
Germany

An up-to-date declaration of conformity can be requested from QIAGEN Technical Services.

Waste Electrical and Electronic Equipment (WEEE)

This section provides information about disposal of waste electrical and electronic equipment by users.

The crossed-out wheeled bin symbol (see below) indicates that this product must not be disposed of with other waste; it must be taken to an approved treatment facility or to a designated collection point for recycling, according to local laws and regulations.

The separate collection and recycling of waste electronic equipment at the time of disposal helps to conserve natural resources and ensures that the product is recycled in a manner that protects human health and the environment.



Recycling can be provided by QIAGEN upon request at additional cost. In the European Union, in accordance with the specific WEEE recycling requirements and where a replacement product is being supplied by QIAGEN, free recycling of its WEEE-marked electronic equipment is provided.

To recycle electronic equipment, contact your local QIAGEN sales office for the required return form. Once the form is submitted, you will be contacted by QIAGEN either to request follow-up information for scheduling collection of the electronic waste or to provide you with an individual quote.

California Proposition 65 Warning

This product contains chemicals known to the State of California to cause cancer, birth defect or other reproductive harm.

FCC Declaration (US) and Compliance with ICES (Canada)

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

For Canada, this is a Class A digital apparatus compliant with Canadian ICES-003 "Information Technology Equipment (including Digital Apparatus)" standard.

Liability Clause

QIAGEN shall be released from all obligations under its warranty in the event repairs or modifications are made by persons other than its own personnel, except in cases where the Company has given its written consent to perform such repairs or modifications.

All materials replaced under this warranty will be warranted only for the duration of the original warranty period, and in no case beyond the original expiration date of original warranty unless authorized in writing by an officer of the Company. Read-out devices, interfacing devices, and associated software will be warranted only for the period offered by the original manufacturer of these products. Representations and warranties made by any person, including representatives of QIAGEN, which are inconsistent or in conflict with the conditions in this warranty shall not be binding upon the Company unless produced in writing and approved by an officer of QIAGEN.

The EZ2 Connect MDx is equipped with an Ethernet port and a Wi-Fi USB device. QIAGEN has implemented industry-standard measures to ensure the cybersecurity of this medical device. However, the device may be exposed to risks if connected to external systems or media that are compromised. QIAGEN shall not be liable for any malware, virus infections, or other cybersecurity incidents resulting from the use of infected USB storage devices, compromised endpoints, or insecure network environments. Users are responsible for ensuring that any external systems or media connected to the device are adequately protected and free from malicious software. QIAGEN provides guidance on secure integration practices in the Instructions for Use and recommends adherence to recognized cybersecurity standards to minimize risk.

License information

The EZ2 Connect MDx software package contains open source software. License texts are available on the EZ2 Connect MDx product pages (www.qiagen.com).

Appendix B – EZ2 Connect MDx Parts and Components/Consumables

Ordering information

Product	Contents	Cat. no.
EZ2 Connect MDx	Instrument and 1-year warranty on parts and labor	9003230
Accessories		
EZ2 Connect Tip Rack	Tip Rack for EZ2 Connect, for use with screw-cap tubes	9027009
EZ2 Connect Cartridge Rack	Cartridge rack for EZ2 Connect, for use with prefilled kit cartridges	9027012
USB Flash Drive	USB flash drive provided by QIAGEN, for use with EZ2 USB ports	9026881
Barcode Reader	Barcode scanner to allow kit barcode and sample barcode scanning	9027101
Silicone Grease	Silicone Grease to maintain good contact between tip adapters and filter tips and to prevent leakage from the tips.	9027102
Consumables		
Filter-tips and holder, EZ1 (50)	50 Disposable Filter-Tips, 50 Disposable Tip Holders; additional tips and holders for use with EZ1 Kits	994900

For up-to-date licensing information and product-specific disclaimers, see the respective QIAGEN kit handbook or user manual. QIAGEN kit handbooks and user manuals are available at www.qiagen.com or can be requested from QIAGEN Technical Support or your local distributor.

Document Revision History

Date	Changes
R1, 04/2022	Initial release
R2, 03/2024	Update according to new SW 1.2 functionalities: Cooling after run, UV run scheduler, patch management via QlAsphere, screen lock, time synchronization with QlAsphere, time zone support, notification center. Improved description of the weekly maintenance procedure. Improved structure.
R3, 04/2026	Update according to new SW 1.3 functionalities. Updated cooling after run description. Safety information update to not wash instrument parts in the dishwasher. Updated intended use, managing user security, entering sample IDs, tray figures, liability clause, and changes to warning symbols and laser descriptions.

Trademarks: QIAGEN®, Sample to Insight®, QIAsphere®, EZ1&2™, EZ1®, EZ2® (QIAGEN Group); DNA-ExitusPlus™ (AppliChem); Gigasept®, MikroZid®, Lysetol® (Schülke & Mayr GmbH); RNaseZap® (Ambion, Inc.). Registered names, trademarks, etc. used in this document, even when not specifically marked as such, are not to be considered unprotected by law.

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