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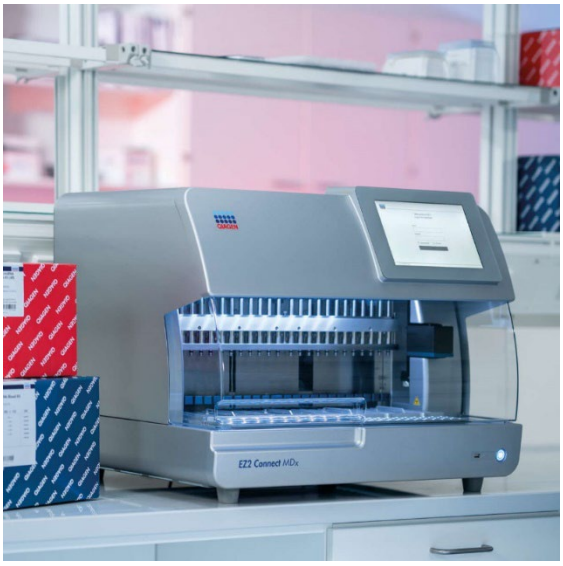
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March 2024

# EZ2® Connect MDx User Manual

For use with software version 1.2 or higher

The EZ2 Connect MDx is intended for in vitro diagnostic use.




IVD

CE

REF

9003230

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Sample to Insight

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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 (hereafter also referred to as EZ2) in the following sections:

- Introduction — contains the intended use and requirements for users
- General information — contains information regarding the intended use and requirements of the EZ2
- Safety Information — includes important information on any hazards related to the EZ2 and how to properly use the instrument
- General Description — an overview of the features of the EZ2
- 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
- Glossary — an alphabetical list of terms or words used in this user manual with explanations
- Technical Specification - Technical data

The appendices contain the following information:

- Appendix A – Legal requirements for the EZ2 Connect MDx
- Appendix B – EZ2 Connect MDx Parts and Components/Consumables — an overview 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 Services 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 as well as 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 Services about errors, please have the following information ready:

- EZ2 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)

### 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.

To produce useful and appropriate documentation, we appreciate your comments on this user manual. Please contact QIAGEN Technical Services.

## 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. The EZ2 Connect MDx is intended to be used only in combination with QIAGEN kits indicated for use with the EZ2 Connect MDx instrument for the applications described in the kit handbooks. The EZ2 Connect MDx system is intended for use by professional operators, such as technicians and physicians trained in molecular biological techniques and the operation of the EZ2 Connect MDx system.

## 1.4 Research mode

It is noted that customers shall have the option to start a protocol either in the IVD mode of the software (validated IVD applications only) or in the Research Mode used for non-clinical laboratory research applications.* The usage of IVD protocols is only possible and strictly restricted to the IVD mode of the software. 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 user manual of the EZ2 Connect (**www.qiagen.com**) for details on using life science kits on EZ2 instruments.

## 1.5 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 |

* 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 products do not have medical purpose and thus they are not considered medical devices.

## 1.6 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.

## 1.7 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).

## 1.8 Glossary

For a glossary of terms used in this user manual, refer to the Glossary section (page 163) of this user manual.

## 1.9 Parts and components

For information about EZ2 parts and components, refer to the Appendix B – EZ2 Connect MDx Parts and Components/Consumables section (page 170) of this user manual.

# 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 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 others.<br>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.<br>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 (only applicable for CE-marked devices with an authorized representative established in the EU) and the regulatory authority in which the user and/or the patient is established.

## 2.1 Proper use

| | |
|---|---|
| **WARNING/ CAUTION**  | **Risk of personal injury and material damage**<br>Improper use of the EZ2 may cause personal injuries or damage to the instrument. The EZ2 must only be operated by qualified personnel who have been appropriately trained. Servicing of the EZ2 must only be performed by a QIAGEN Field Service Specialist. |

| | |
|---|---|
| **WARNING**  | **Risk of personal injury**<br>The EZ2 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. After the EZ2 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**<br>Do not attempt to move the EZ2 during operation. |

Perform the maintenance as described in the Maintenance Procedures section (see page 136). QIAGEN charges for repairs that are required due to incorrect maintenance.

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

| | |
|---|---|
| **CAUTION**  | **Damage to the instrument**<br>Avoid spilling water or chemicals onto the EZ2. Instrument damage caused by water or chemical spillage will void your warranty. |

| | |
|---|---|
| **WARNING**  | **Risk of fire or explosion**<br>When using ethanol or ethanol-based liquids on the EZ2, handle such liquids carefully and in accordance with the required safety regulations. If liquid has been spilled, wipe it off and leave the EZ2 hood open to allow flammable vapors to disperse. |

| | |
|---|---|
| **WARNING**  | **Risk of explosion**<br>The EZ2 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, the user is responsible for carrying out appropriate decontamination.

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

| | |
|---|---|
| **CAUTION**  | **Damage to the instrument**<br>Ensure that the EZ2 is switched off (power OFF) and main plug removed from power outlet before you manually move the mechanical components of the instrument. |

| | |
|---|---|
| **CAUTION**  | **Damage to the instrument**<br>Do not lean against the instrument or touchscreen. |

## 2.2 Electrical safety

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

| | |
|---|---|
| **WARNING**  | **Electrical hazard**<br>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.<br>Intentional interruption is prohibited.<br>**Lethal voltages inside the instrument**<br>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**<br>Before powering ON the instrument, make sure that the correct supply voltage is used.<br>Use of incorrect supply voltage may damage the electronics.<br>To check the recommended supply voltage, refer to the specifications indicated in the type plate of the instrument. |

| | |
|---|---|
| **WARNING**  | **Risk of electric shock**<br>Do not open any panels on the EZ2.<br>**Risk of personal injury and material damage**<br>Only perform maintenance that is specifically described in this user manual. Any other maintenance or repair may only be carried out by authorized field service. |

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

- The line power cord must be connected to a line power outlet that has a protective conductor (earth/ground).
- Place 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 Services for advice before attempting any troubleshooting.

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

The instrument may be electrically unsafe when:

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

| | |
|---|---|
| **WARNING**  | **Electric hazard**<br>Do not touch the EZ2 with wet hands. |

| | |
|---|---|
| **WARNING**  | **Electric hazard**<br>Never install a fuse different from that specified in the user manual. |

## 2.3 Operating conditions

Parameters such as temperature range and humidity range are described in the Technical Specification section (see page 164).

| | |
|---|---|
| WARNING  | **Explosive atmosphere**<br>The EZ2 is not designed for use in an explosive atmosphere. |

| | |
|---|---|
| WARNING  | **Risk of overheating**<br>To ensure proper ventilation, maintain a minimum clearance of 10 cm at the sides and rear of the EZ2.<br>Slits and openings that ensure the ventilation of the instrument must not be covered. |

| | |
|---|---|
| WARNING  | **Risk of explosion**<br>The EZ2 is intended for use with reagents and substances supplied with QIAGEN kits. Use of other reagents and substances may lead to fire or explosion. |

| | |
|---|---|
| CAUTION  | **Damage to the instrument**<br>Direct sunlight may bleach parts of the instrument, cause damage to plastic parts. The EZ2 must be located out of direct sunlight. |

| | |
|---|---|
| CAUTION  | **Damage to the instrument**<br>Do not use the EZ2 in the vicinity of sources of strong electromagnetic radiation (for example, unshielded, deliberately operated high-frequency sources or mobile radio devices), because these can interfere with the proper operation. |

## 2.4 Biological safety

Samples 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 (**https://www.cdc.gov/labs/pdf/CDC-BiosafetymicrobiologicalBiomedicalLaboratories-2009-P.pdf**). 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**<br>Samples used with the EZ2 may contain infectious agents. Handle such samples with the greatest of care and in accordance with the required safety regulations.<br>Always wear safety glasses, gloves, and a lab coat.<br>The responsible body (for example, 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 Material Safety Data Sheets (MSDSs) or the OSHA1,* ACGIH,† or COSHH‡ documents.<br>Venting for fumes and disposal of wastes 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**<br>Some chemicals used with the EZ2 may be hazardous or may become hazardous after completion of a purification.<br>Always wear safety glasses, gloves, and a lab coat.<br>The responsible body (for example, 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 toxic substances (chemical or biological) as defined in the applicable Material Safety Data Sheets (MSDSs) or the OSHA,* ACGIH,† or COSHH‡ documents.<br>Venting for fumes and disposal of wastes must be in accordance with all national, state, and local health and safety regulations and laws. |

* OSHA: Occupational Safety and Health Administration (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

| | |
|---|---|
| WARNING  | **Toxic fumes**<br>Do not use bleach to clean or disinfect the EZ2. Bleach in contact with salts from the buffers can produce toxic fumes. |

| | |
|---|---|
| WARNING  | **Toxic fumes**<br>Do not use bleach to disinfect used labware. Bleach in contact with salts from the buffers can produce toxic fumes. |

Note: If you work with volatile solvents, toxic substances, etc., you must provide an efficient laboratory ventilation system to remove vapors that may be produced.

## 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).

| | |
|---|---|
| CAUTION  | **Hazardous chemicals and infectious agents**<br>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 moves during operation of the instrument. While loading the worktable, always stand clear of the instrument. Do not lean on the worktable when the pipetting unit of the instrument is moving to reach loading position with its lid open. Wait until the pipetting unit completes its movements before you start to load or unload.

| | |
|---|---|
| **WARNING**  | **Moving parts**<br>To avoid contact with moving parts during the operation of the EZ2, the instrument must be operated with the hood closed.<br>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 Services. |

| | |
|---|---|
| **WARNING**  | **Moving parts**<br>Avoid contact with moving parts during operation of the EZ2. 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**<br>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

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 Services.

| | |
|---|---|
| **WARNING**  | **UV radiation**<br>Avoid looking directly into UV light. Do not expose your skin to UV light. |

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

| | |
|---|---|
| **WARNING**  | **Risk of personal injury**<br>Hazard Level 2 laser light: Do not stare into the light beam when using handheld barcode scanner. |

## 2.10 Maintenance safety

| | |
|---|---|
| **WARNING/ CAUTION**  | **Risk of personal injury and material damage**<br>Only perform maintenance that is specifically described in this user manual. |

Perform the maintenance as described in the Maintenance Procedures section (see page 136). QIAGEN charges for repairs that are required due to incorrect maintenance.

| | |
|---|---|
| **WARNING/ CAUTION**  | **Risk of personal injury and material damage**<br>Improper use of the EZ2 may cause personal injuries or damage to the instrument.<br>The EZ2 must only be operated by suitably qualified personnel.<br>Servicing of the EZ2 must only be performed by QIAGEN Field Service Specialists. |

Operate the EZ2 only as described in the Operating Procedures section (see page 50). QIAGEN charges for repairs that are required due to incorrect operation.

| | |
|---|---|
| **WARNING**  | **Risk of fire**<br>When cleaning the EZ2 with alcohol-based disinfectant, leave the instrument door open to allow flammable vapors to disperse.<br>Only clean the EZ2 with alcohol-based disinfectant when worktable components have cooled down. |

| | |
|---|---|
| **CAUTION**  | **Damage to the instrument**<br>Do not use bleach, solvents, or reagents containing acids, alkalis, or abrasives to clean the EZ2. |

| | |
|---|---|
| **CAUTION**  | **Damage to the instrument**<br>Do not use spray bottles containing alcohol or disinfectant to clean surfaces of the EZ2. 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**<br>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 electric shock**<br>Do not open any panels on the EZ2.<br>Only perform maintenance as described in this user manual. |

## 2.11 Symbols on the EZ2 Connect MDx instrument

The following symbols appear on the EZ2 Connect MDx instruments.

| Symbol | Location | Description |
|---|---|---|
|  | Heating system — inside instrument | Heat hazard — the temperature of the heating system can reach up to 95°C. |
|  | 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 | Hazard Level 2 laser light: Do not stare into the light beam when using 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 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). |
|  | Type plate on the back of the instrument | WEEE mark for Europe. |
|  | Type plate on the back of the instrument | Legal manufacturer. |

| Symbol | Location | Description |
|---|---|---|
|  | 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 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 (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 bar code reading
- An external bar code reader, which is used for reading sample IDs and kit bar codes
- Extended user management
- Extended User Interface
- Additional reporting functions
- Connectivity (Wi-Fi, LAN, QIAsphere, LIMS)

## 3.2 External features of the EZ2 Connect MDx




**Figure 1. The front of the EZ2.**

1 Touchscreen
2 Hood
3 Power button
4 USB port

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




**Figure 2. The back of the EZ2.**

5 RJ-45 Ethernet port
6 Power cord socket — including instrument main fuse
7 Ventilation openings
8 Instrument type plate

### 3.2.1 Touchscreen

The EZ2 Connect MDx has a 10.1-inch color touchscreen display with a resolution of 1280 x 800 pixels. The Graphical User Interface (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 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, 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 graphical user interface.

| WARNING | **Moving parts**<br>To avoid contact with moving parts during the operation of the EZ2, the instrument must be operated with the hood closed.<br>If the hood sensor or lock is not functioning properly, contact QIAGEN Technical Services. |
|---|---|




**Figure 4. The EZ2 Connect MDx with the hood closed.**

### 3.2.3 Power button

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

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




**Figure 5. Location of the power button.**

### 3.2.4 USB ports

The EZ2 Connect MDx has 3 USB ports. One is located next to the power button, on the front of the instrument. Two are located on the back of the touchscreen display.

The USB ports allow you to connect a USB drive to the EZ2. 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 the "Saving a run report" section (see page 115).

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 the Installing new protocols section (Section 5.3.6). For more information on software updates, refer to the Updating software section (see page 75).

The handheld barcode scanner is connected to the EZ2 using any one of the 3 available USB ports.

The Wi-Fi adapter, if used, is connected to the EZ2 using any one of the 3 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.

### 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 sign, 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**<br>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.<br>**Lethal voltages inside the instrument**<br>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**<br>Before turning the instrument on, make sure that the correct supply voltage is used.<br>Use of incorrect supply voltage may damage the electronics.<br>To check the recommended supply voltage, refer to the specifications indicated on the type plate of the instrument. |

| | |
|---|---|
| WARNING  | **Risk of electric shock**<br>Do not open any panels on the EZ2.<br>**Risk of personal injury and material damage**<br>Only perform maintenance that is specifically described in this user manual. |

### 3.2.7 Ventilation openings

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

| | |
|---|---|
| **CAUTION**  | **Risk of overheating**<br>To ensure proper ventilation, maintain a minimum clearance of 10 cm at the sides and rear of the EZ2.<br>Slits and openings that ensure the ventilation of the instrument must not be covered. |

### 3.2.8 Barcode scanner

The bar code scanner delivered with the instrument can be connected to the EZ2 using any one of the 3 USB ports. The scanner is used for reading the barcode on the kit Q-Card (supplied with sample preparation kits) and sample bar codes. For more information on how to use the bar code scanner, refer to the "LIMS Workflow" section (see page 118).

| | |
|---|---|
| **WARNING**  | **Risk of personal injury**<br>Hazard Level 2 laser light: Do not stare into the light beam when using handheld barcode scanner. |

## 3.3 Internal features of the EZ2

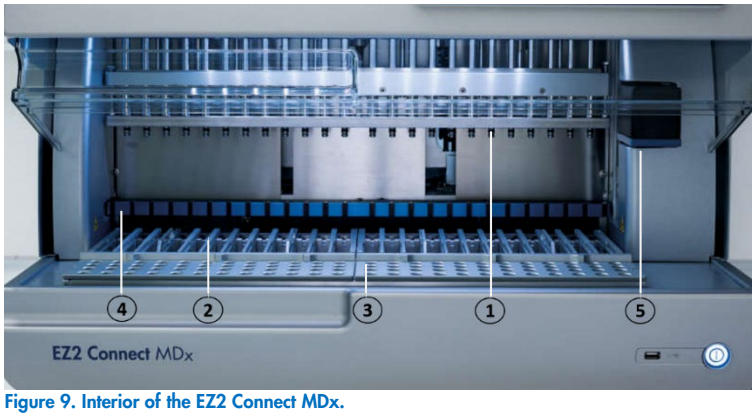



**Figure 9. Interior of the EZ2 Connect MDx.**

1 Pipettor head
2 Cartridge rack
3 Tip rack
4 Magnet module
5 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 which 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 pipettor head.**

| | |
|---|---|
| **WARNING**  | **Moving parts**<br>To avoid contact with moving parts during the operation of the EZ2, the instrument must be operated with the hood closed.<br>If the hood sensor or lock is not functioning correctly, contact QIAGEN Technical Services. |

| | |
|---|---|
| **WARNING**  | **Moving parts**<br>Avoid contact with moving parts during operation of the EZ2. Under no circumstances should hands be placed under the pipetting arm during movement. Do not attempt to remove any plasticware from the worktable while the instrument is operating. |

### 3.3.2 Worktable

The EZ2 Connect MDx worktable contains 2 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.**

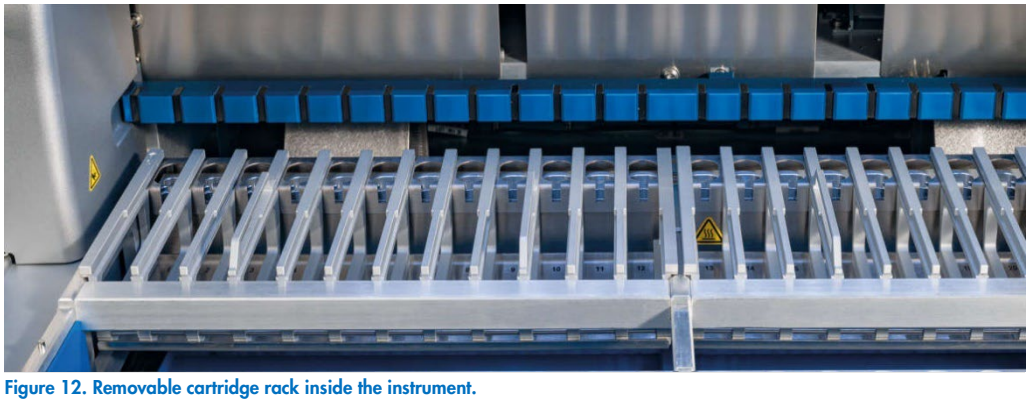


**Figure 12. Removable cartridge rack inside the instrument.**

There are two position dedicated cartridge racks: the left cartridge rack is used for cartridges in positions 1 to 12, 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 the Loading the cartridge rack section (see page 101).

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.

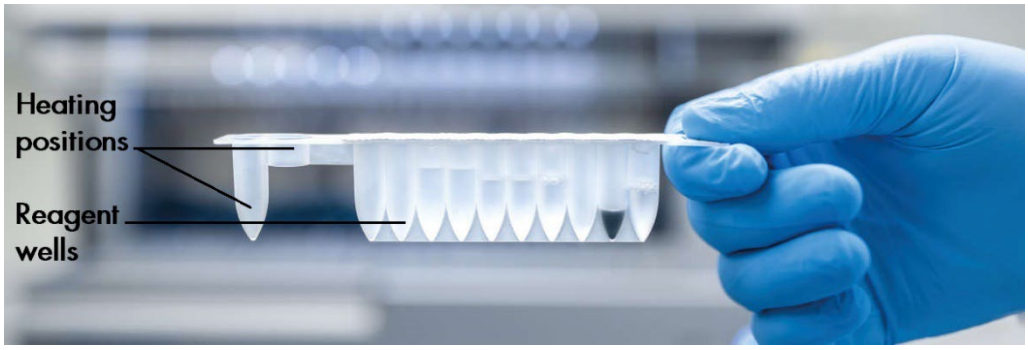



Figure 13. An EZ1/2 cartridge.

## Tip rack

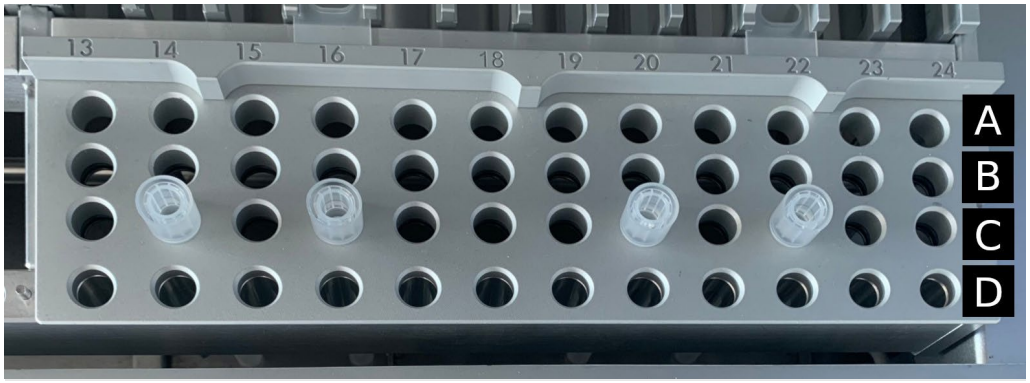



Figure 14. Tip rack with four inserted tip holders/filter tips.



Figure 15. Tip racks inside the instrument.

There are 2 position dedicated tip racks: the left tip rack is used for labware in positions 1 to 12, 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 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 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 the Loading the tip rack section (see page 102).

## Heating system

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



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

| | |
|---|---|
| WARNING  | **Hot surface**<br>The heating system can reach temperatures of up to 95°C (203°F). Avoid touching it when it is hot. |

### 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 the Daily maintenance section (see page 143).




**Figure 18. The EZ2 bottom tray.**

## 3.3.3 Magnet module

The EZ2 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 magnet module.**

### 3.3.4 Camera

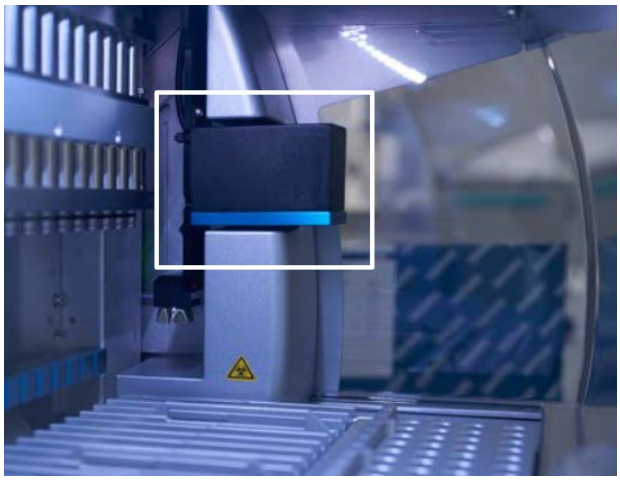


**Figure 20. Camera module (highlighted by white frame).**

The EZ2 Connect MDx has a built-in camera that is used for load checks, which includes reading bar codes 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 Load check section (see page 107).

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

### 3.3.5 UV LED lamp

The EZ2 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**  | **UV radiation**<br>Do not expose your skin to UV light from the UV LED lamp. |

| | |
|---|---|
| **WARNING**  | **Moving parts**<br>To avoid contact with moving parts during the operation of the EZ2, the instrument must be operated with the hood closed.<br>If the hood sensor or lock is not functioning correctly, contact QIAGEN Technical Services. |

### 3.3.6 Internal light

The EZ2 Connect MDx has a built-in LED light. The internal light illuminates the worktable and informs about the current status of the run. There are 2 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 Installation environment

### 4.1.1 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 the Technical Specifications section (see page 164) 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 enough and strong enough to accommodate the EZ2. Refer to the Technical Specifications section (see page 164) for the weight and dimensions of the EZ2. Ensure that the workbench is dry, clean, and vibration-proof, and has additional space for accessories.

The EZ2 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 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**<br>The EZ2 is not designed for use in an explosive atmosphere. |

| | |
|---|---|
| **CAUTION**  | **Risk of overheating**<br>To ensure proper ventilation, maintain a minimum clearance of 10 cm at the sides and rear of the EZ2.<br>Slits and openings that ensure the ventilation of the instrument must not be covered. |

| | |
|---|---|
| **WARNING**  | **Risk of personal injury and material damage**<br>The EZ2 is too heavy to be lifted by one person. To avoid personal injury or damage to the instrument, do not lift the instrument alone. |

| | |
|---|---|
| CAUTION  | **Damage to the instrument**<br>Direct sunlight may bleach parts of the instrument, may cause damage to plastic parts, and may interfere with the load check.<br>The EZ2 must be located out of direct sunlight. |

| | |
|---|---|
| CAUTION  | **Damage to the instrument**<br>Do not use the EZ2 in the vicinity of sources of strong electromagnetic radiation (for example, unshielded, deliberately operated high-frequency sources or mobile radio devices), because these can interfere with the proper operation. |

### 4.1.2 Power requirements

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

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

| | |
|---|---|
| WARNING  | **Damage to electronics**<br>Before turning the instrument on, make sure that the correct supply voltage is used.<br>Use of incorrect supply voltage may damage the electronics.<br>To check the recommended supply voltage, refer to the specifications indicated on the type plate of the instrument. |

| | |
|---|---|
| WARNING  | **Electrical hazards**<br>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.<br>Intentional interruption is prohibited.<br>**Lethal voltages inside the instrument**<br>When the instrument is connected to line power, terminals may be live and opening covers or removing parts is likely to expose live parts. |

### 4.1.3 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 hazards**<br>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.<br>Intentional interruption is prohibited.<br>**Lethal voltages inside the instrument**<br>When the instrument is connected to line power, terminals may be live and opening covers or removing parts is likely to expose live parts. |

## 4.2 Unpacking the EZ2 Connect MDx

| | |
|---|---|
| **WARNING**  | **Risk of personal injury**<br>The EZ2 is too heavy to be lifted by one person. To avoid personal injury or damage to the instrument, do not lift the instrument alone. |

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
- Hand-held bar code 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 Service.
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 at the cut-out area and lifting up the outer carton box.
5. Remove the 2 pieces of protective foam from the unit.
6. Move the unit to the workbench or trolley from the packaging. When lifting the EZ2, slide your fingers under the side of the instrument and keep your back straight.

   **Important**: Two persons are required to lift the EZ2.

   **Important**: Do not hold the touchscreen display while unpacking or lifting the EZ2. This might damage the instrument.
7. Remove the foam strip which 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 bottom.



**Figure 22. Transport lock.**

11. Remove silica gel 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 pull the transport foam out from the rear. There are a total of two transport locks for Y-axis.
13. Check if the packing list document is included after unpacking the EZ2.
14. Read the packing list to check all items have been received.. If anything is missing, contact QIAGEN Technical Services.
15. Check that the EZ2 is not damaged and that there are no loose parts. If anything is damaged, contact QIAGEN Technical Services. Make sure that the EZ2 has equilibrated to ambient temperature before powering on.
16. Retain the package in case you need to transport the EZ2 in the future. Refer to the Packaging and transportation of the EZ2 section (page 49) for more details. Using the original package minimizes the possibility of damage during transportation of the EZ2.

## 4.3 Installing the EZ2 Connect MDx

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

- Removal of the EZ2 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 Services.

**Note**: To ensure that your EZ2 Connect MDx has the latest Software and Protocol versions installed, please visit the EZ2 Connect MDx webpage at **www.qiagen.com/products/ez2-connect-mdx/**.

### 4.3.1 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.
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 Unpacking the EZ2 section (see page 40).

### 4.3.2 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.
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 matches the voltage available at the installation site.

   **Note**: The EZ2 AC inlet is set up to accept all input voltages with-in the range 100-240 VAC 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 power to the instrument at this point. Power needs to be OFF for subsequent installation of USB devices described in the following steps.

| WARNING | **Damage to electronics**<br>Before powering ON the instrument, make sure that the correct supply voltage is used.<br>Use of incorrect supply voltage may damage the electronics.<br>To check the recommended supply voltage, refer to the specifications indicated on the type plate of the instrument. |
|---|---|

| | |
|---|---|
| **WARNING**  | **Electrical hazard**<br>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.<br><br>**Lethal voltages inside the instrument**<br>When the instrument is connected to line power, terminals may be live and opening covers or removing parts is likely to expose live parts. |

### 4.3.3 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 3 USB ports located either on the front of the instrument or on the rear of the touchscreen.

| | |
|---|---|
| **WARNING**  | **Risk of personal injury**<br>Hazard Level 2 laser light: Do not stare into the light beam when using handheld barcode scanner. |

### 4.3.4 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 3 USB ports located on either 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.

### 4.3.5 Initial configuration of the EZ2

**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. After you press the power button, the power button lights up, the startup screen appears on the touchscreen, a sound plays, and the instrument initializes.

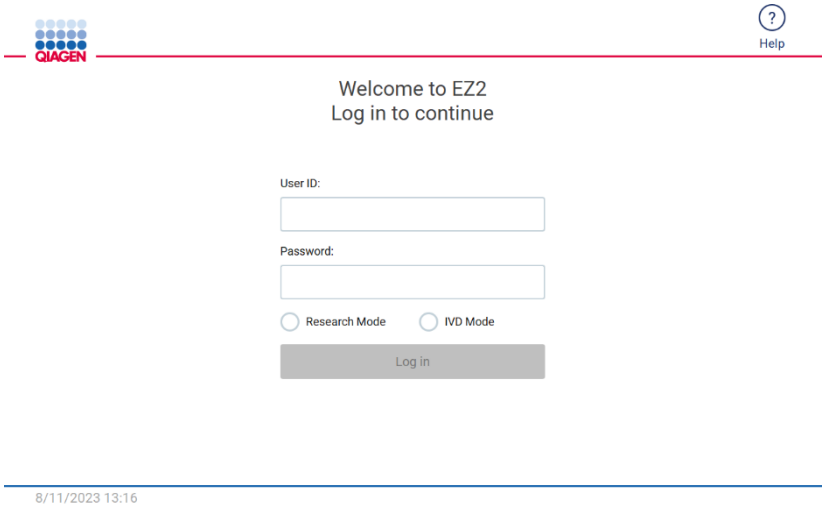



**Figure 24. The login screen.**

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

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

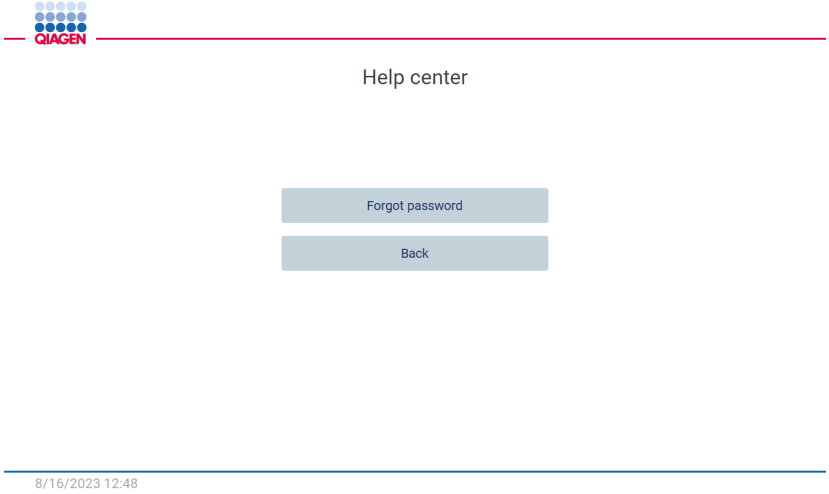



**Figure 25. Help center window.**

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

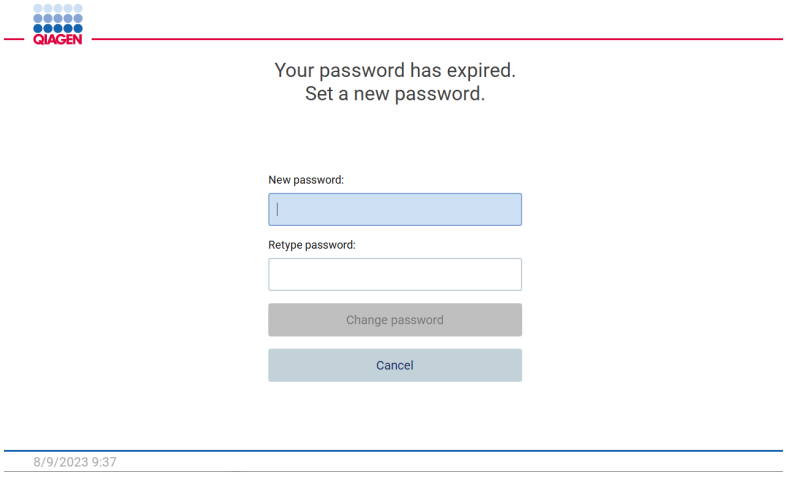



**Figure 26. Set a new password screen after first log in.**

**Note**: Only Administrators can change instrument settings.

**Note**: The system requires a password change for all newly created accounts. The EZ2 default password policy is a strong password, which requires a password between 8 and 40 characters and includes upper and lower case characters, a number, and a special character.

3. From the **Configuration** menu under the **System** tab, you can modify the Device Name, Date, and Time fields. You can also find information on the Software version, Serial number, and Firmware version. For further details, see the “Setting basic system data” section (see page 58).

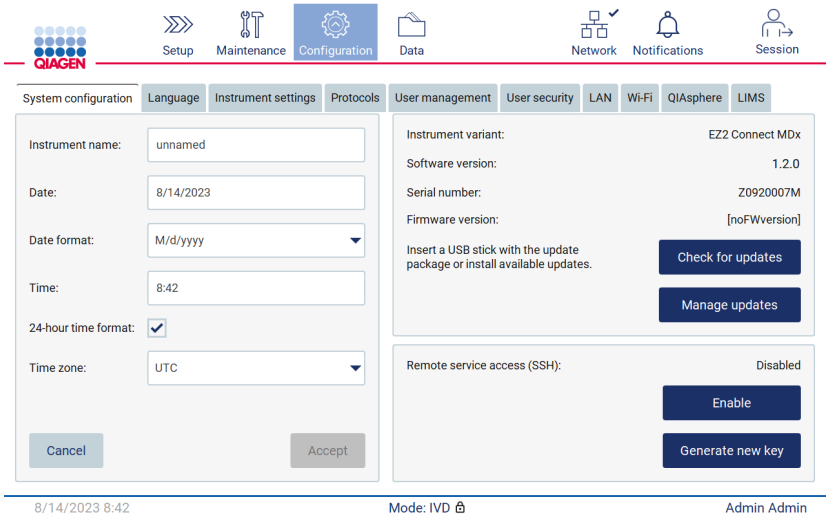



**Figure 27. The System configuration tab.**

4. You may adjust settings of the EZ2 according to your preferences through the **Instrument settings** tab under the **Configuration** menu. For further details see the "Changing Instrument settings" section (see page 59).

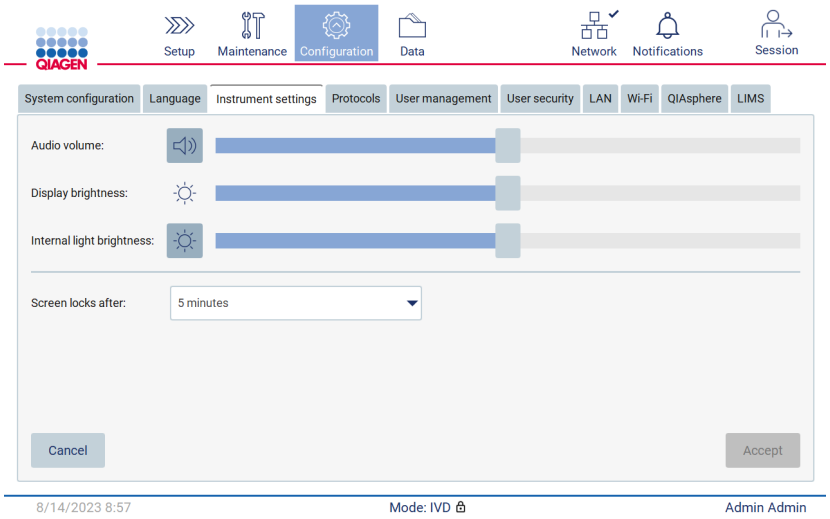



**Figure 28. Details on the Instrument setting tab.**

### 4.3.6 Performing camera exposure calibration

**Note**: Only Administrators can perform the camera exposure calibration.

| WARNING | **Moving parts**<br>To avoid contact with moving parts during the operation of the EZ2, the instrument must be operated with the hood closed.<br>If the hood sensor or lock is not functioning correctly, contact QIAGEN Technical Services. |
|---|---|

1. Before first use in the final installation site, the camera exposure calibration must be performed.
2. From the **Maintenance** menu under the **Camera LED** tab follow the instructions on the user interface.

3. Make sure that you 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 will be displayed:

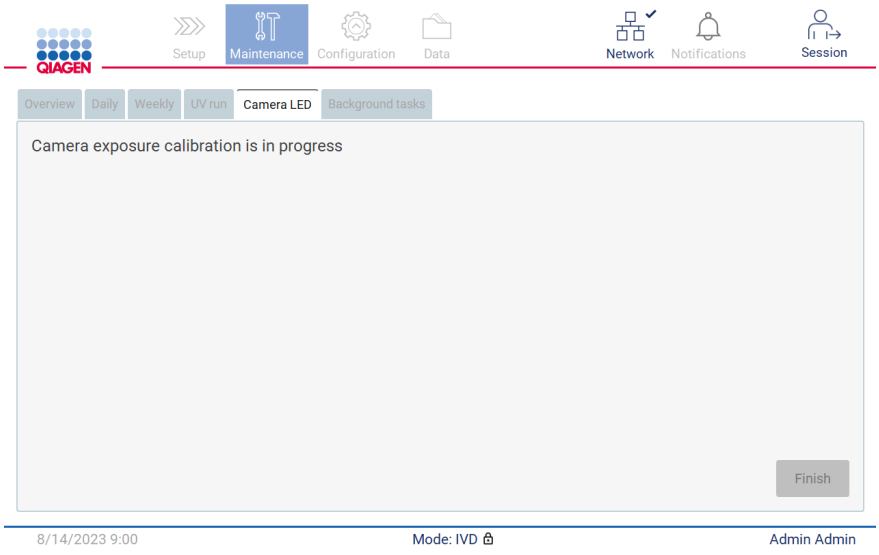



**Figure 30. Camera exposure calibration is in progress message.**

**Note**: For support or technical advice regarding this, please contact QIAGEN Technical Service Department, or see our Technical Support Center at **http://www.qiagen.com/service-and-support/technical-support**

## 4.4 Packaging and transportation of the EZ2 Connect MDx

| WARNING | **Risk of personal injury**<br>The EZ2 is too heavy to be lifted by one person. To avoid personal injury or damage to the instrument, do not lift the instrument alone. |
|---|---|

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

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

   **Important**: Two persons are required to lift the EZ2.

   **Important**: Do not hold the touchscreen display while unpacking or lifting the EZ2; this might damage the instrument.
6. Install outer carton box.
7. Package accessories into the accessories box, place onto the top of the transportation box together with the PE foam at 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.

# 5 Operating Procedures

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

Before proceeding, it is recommended that you familiarize yourself with the features of the instrument as described in the "External features of the EZ2" and "Internal features of the EZ2" sections (see pages 22 and 29, respectively).

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

The hood of the EZ2 must remain closed and will automatically lock during operation of the instrument. Only open the hood when instructed to do so by the instruction for use or GUI.

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

| | |
|---|---|
| **WARNING**  | **Moving parts**<br>To avoid contact with moving parts during the operation of the EZ2, the instrument must be operated with the hood closed.<br>If the hood sensor or lock is not functioning correctly, contact QIAGEN Technical Services. |

| | |
|---|---|
| **WARNING**  | **Moving parts**<br>Avoid contact with moving parts during operation of the EZ2. Under no circumstances should hands be placed under the pipetting arm 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**<br>Do not attempt to move the EZ2 during operation. |

| | |
|---|---|
| **WARNING/ CAUTION**  | **Risk of personal injury and material damage**<br>Improper use of the EZ2 may cause personal injuries or damage to the instrument. The EZ2 must only be operated by qualified personnel who have been appropriately trained. Servicing of the EZ2 must only be performed by QIAGEN Field Service specialists. |

| | |
|---|---|
| **CAUTION**  | **Damage to the instrument**<br>Avoiding spilling water or chemicals onto the EZ2. Instrument damage caused by water or chemical spillage will void your warranty. |

| | |
|---|---|
| **WARNING**  | **Risk of fire or explosion**<br>When using ethanol or ethanol-based liquids on the EZ2, handle such liquids carefully and in accordance with the required safety regulations. If liquid has been spilled, wipe it off and leave the EZ2 hood open to allow flammable vapors to disperse. |

| | |
|---|---|
| **WARNING**  | **Risk of explosion**<br>The EZ2 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**<br>Ensure that the EZ2 is switched off before you manually move the mechanical components of the instrument. |

| | |
|---|---|
| **CAUTION**  | **Damage to the instrument**<br>Do not lean against the instrument or touchscreen. |

| | |
|---|---|
| **WARNING**  | **Samples containing infectious agents**<br>Some samples used with the EZ2 may contain infectious agents. Handle such samples with the greatest of care and in accordance with the required safety regulations.<br>Always wear safety glasses, gloves, and a lab coat.<br>The responsible body (for example, 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 Material Safety Data Sheets (MSDSs) or the OSHA1,* ACGIH,† or COSHH‡ documents.<br>Venting for fumes and disposal of wastes 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)

| | |
|---|---|
| **CAUTION**  | **Hazardous materials and infectious agents**<br>The waste contains samples and reagents. This 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**<br>The heating system can reach temperatures of up to 95°C (203°F). Avoid touching it when it is hot. |

| WARNING | **UV radiation**<br>Avoid looking directly into UV light. Do not expose your skin to UV light. |
|---|---|

| WARNING | **Risk of personal injury**<br>Hazard Level 2 laser light: Do not stare into the light beam when using handheld barcode scanner. |
|---|---|

## 5.1 General information

The EZ2 Connect MDx is operated using a touchscreen display, which 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
- Check the status of the run and the instrument
- Guided maintenance procedures
- Generate, save, and download run reports, support files, sample list templates, and audit trails
- Change instrument settings to customize your EZ2

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

Each screen of the User Interface consists of 3 elements: the toolbar, the main content, and the footer.

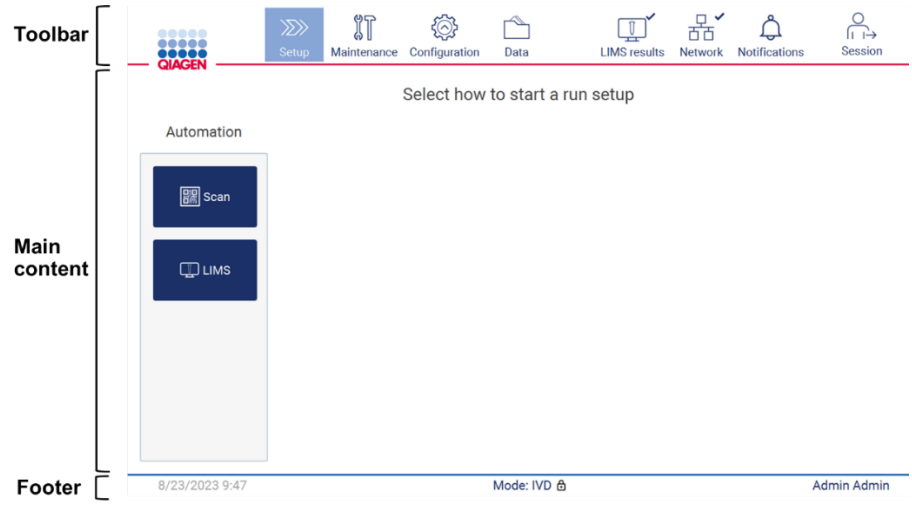



Figure 31. The home screen.

## Toolbar

The toolbar is used to access the main sections of the EZ2 software, to check the connection status of the LAN Wi-Fi, and notifications, and to log out of the application. The toolbar contains the same buttons throughout the whole application, but 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 QIAsphere 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 instrument software. To access the keyboard, tap the field that you want to edit. The keyboard appears.

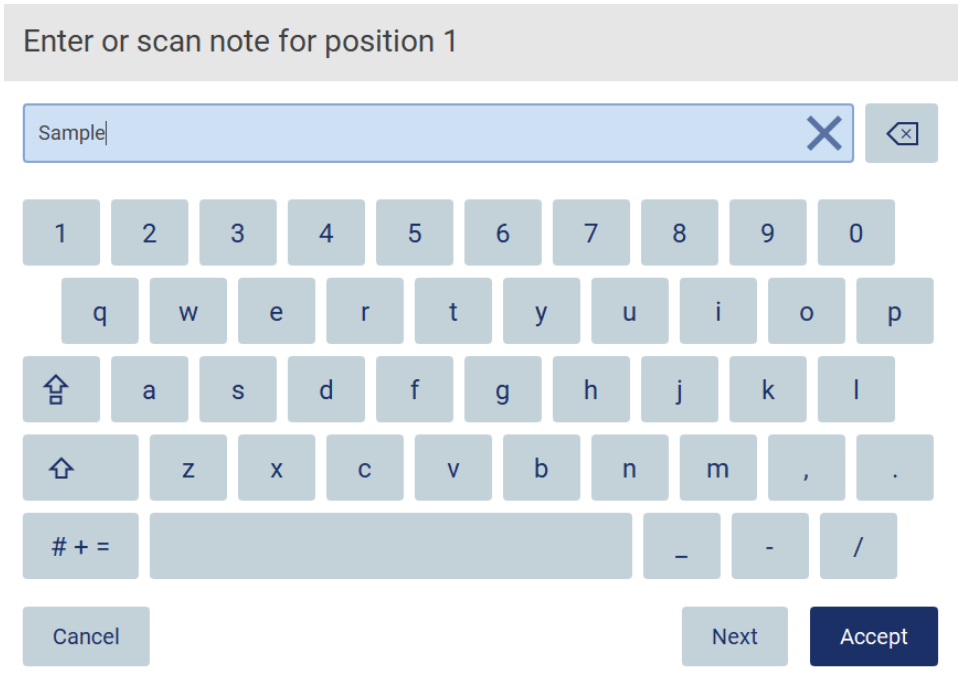



**Figure 32. The on-screen keyboard.**

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.

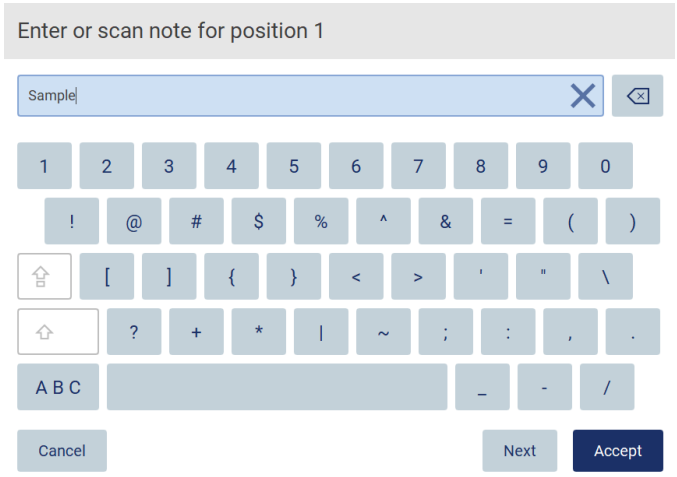



**Figure 33. The on-screen keyboard in special character mode.**

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, so that it follows the requirements.

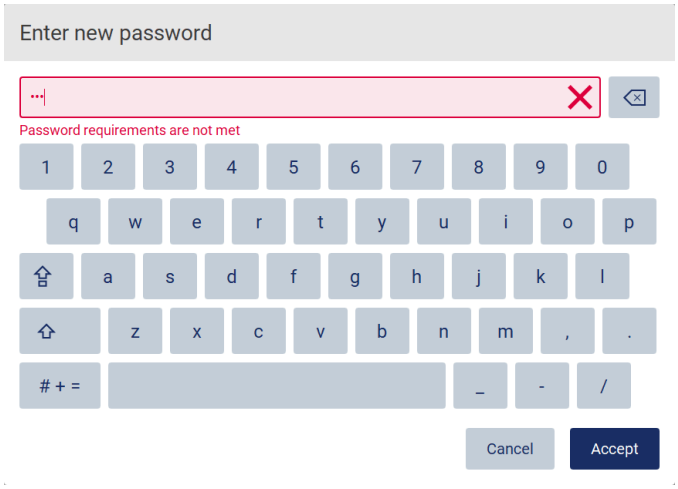



**Figure 34. Example of text field validation.**

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

## 5.2 Starting 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.

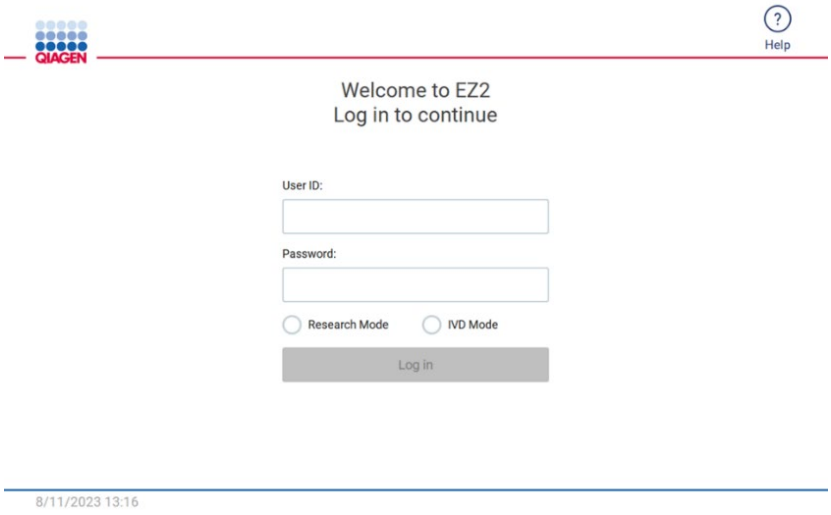



**Figure 35. The login screen.**

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 the "Entering text and numbers" section (see page 54).

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

**Note**: After log in the system will check available disk space and a warning message will appear if insufficient disk space is available for 5 protocol runs. See Section 5.12, Data menu > Run reports, for details on how to download and delete run reports to free up disk space.

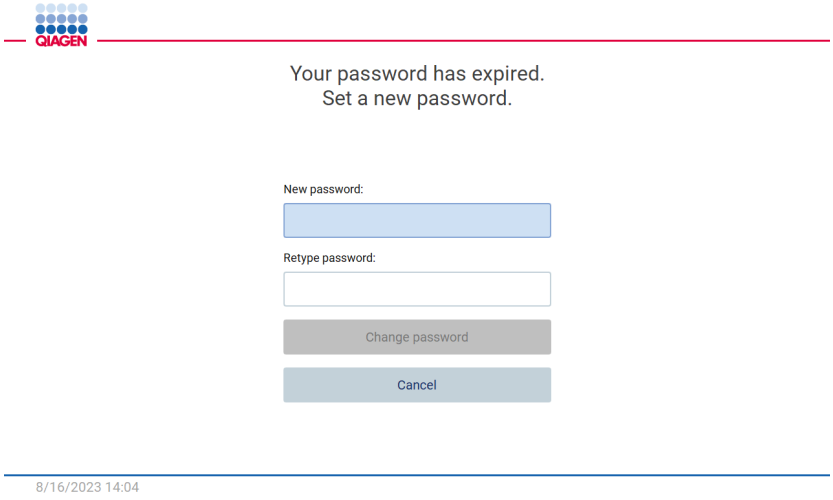



**Figure 36. Set a new password screen after first log in.**

**Note**: After first log in using the default Admin account, the password must be changed according to the Password policy described in the "Managing user security" section (see page 68) and as per instruction in the "Changing password" section (see page 66).

5. Please select the IVD or Research mode to launch. For details of the software modes, please refer to the "General Description: Principle" section (see page 21).
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 (this is set to 3 attempts 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 Administrator role in addition to the default Admin account. In case one administrator is locked due to wrong credentials, the other administrator can unlock the account (see Section 5.3.3).

## 5.3 Configuring the EZ2 Connect MDx

Administrators of the EZ2 Connect MDx can adjust instrument settings, manage users, upload and delete 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.

### 5.3.1 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. System configuration tab.**

2. Tap the **System configuration**.

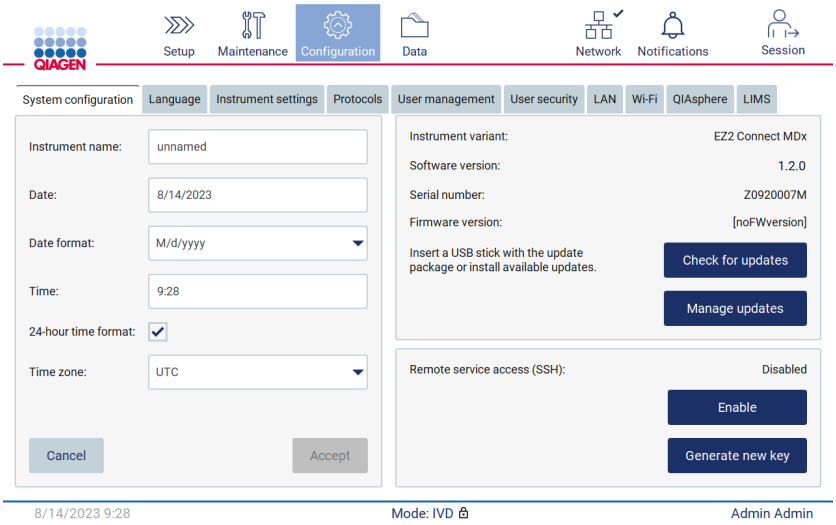



**Figure 38. System configuration tab.**

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.

4. 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**.

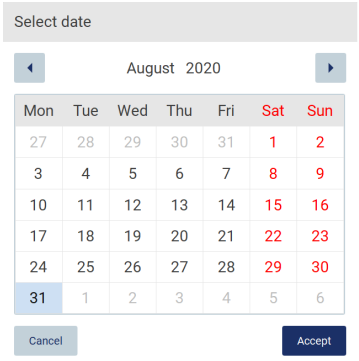



**Figure 39. Select date dialog.**

5. To set the date format, tap the Date format drop-down list and select one of the listed formats.
6. To set the time, tap the Time field and enter the time using the on-screen keyboard.
7. 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.
8. To save the settings, tap Accept.

### 5.3.2 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:

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




**Figure 40. Configuration button on the toolbar.**

2. Tap **Instrument settings**.

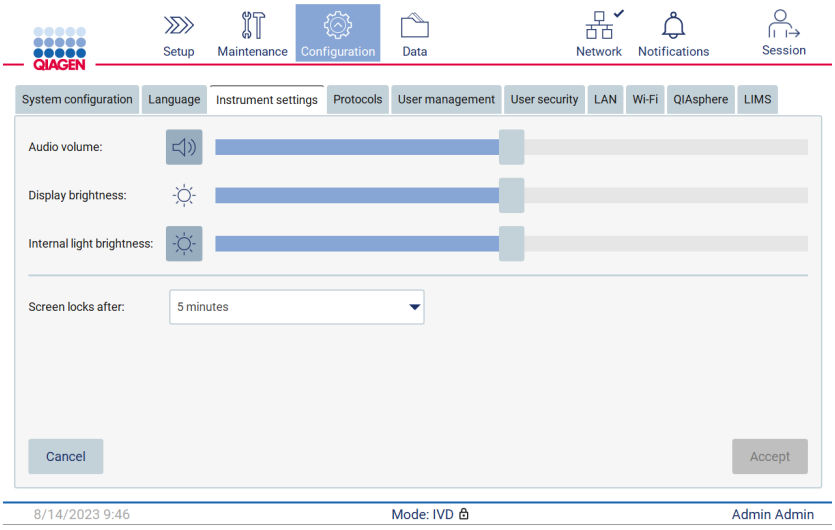



**Figure 41. Configuration button on the toolbar.**

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 will appear 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.

### 5.3.3 Managing users

The EZ2 Connect MDx user management allows you to create and edit user accounts with 2 different roles: administrator and operator. When you use the EZ2 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.

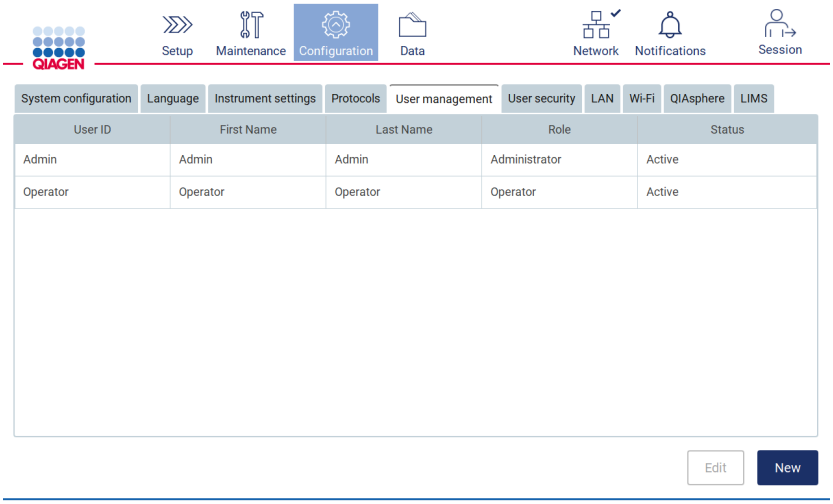



**Figure 43. The User Management tab.**

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

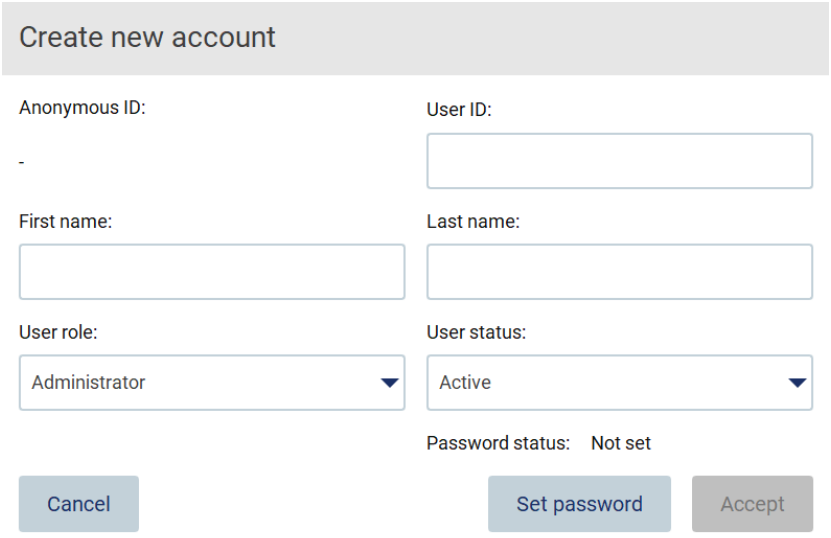



**Figure 44. Create new account dialog.**

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 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. To look up the password policy, refer to the "Managing user security" section (see page 68).

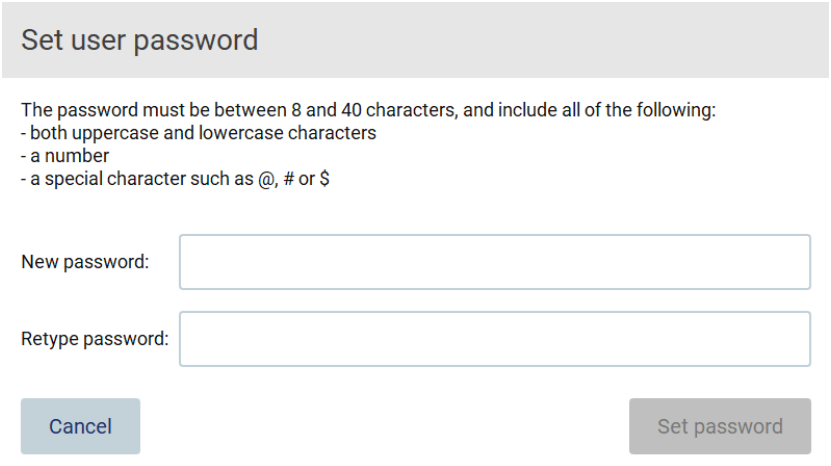



**Figure 45. Set user password dialog.**

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 Administrator role in addition to the default Admin account. In case one administrator is locked due to wrong 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.

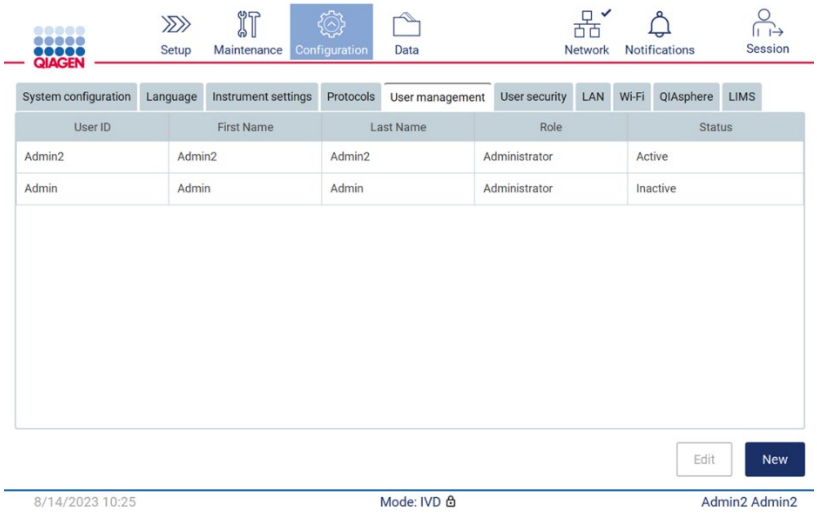



**Figure 47. The User Management tab.**

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

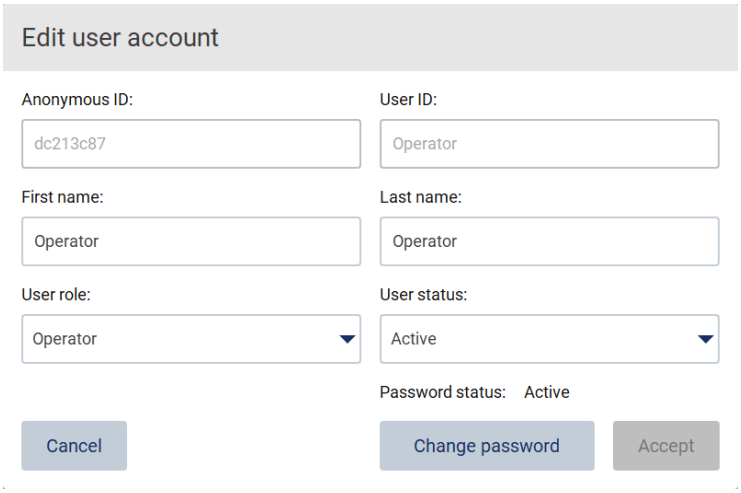



**Figure 48. Edit user account dialog.**

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 appears.

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

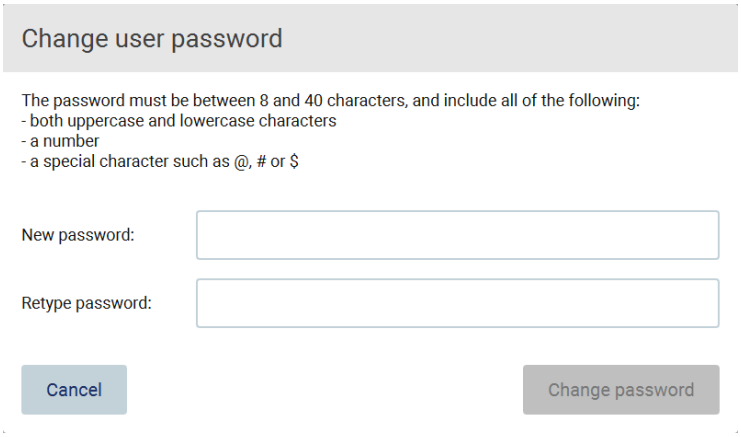



**Figure 49. Change user password screen.**

7. 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 the Managing user security section (see page 68).
8. Tap **Change password**.
9. 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 many wrong login attempts it can be reactivated either by a secondary administrator and the procedure below or by using the help center (see Section 4.3.5).

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




**Figure 50. Configuration button on the toolbar.**

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

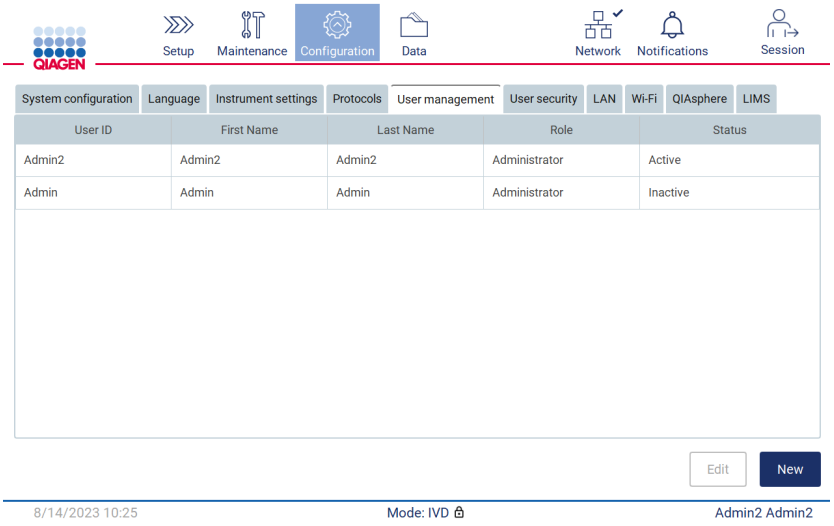



**Figure 51. The User Management tab.**

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

## 5.3.4 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 (see page 63).

**Note**: For cybersecurity reasons, an operator must change the password provided by the administrator upon first login.

**Note**: Although not explicitly prohibited by the software, operators should not re-use 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**.

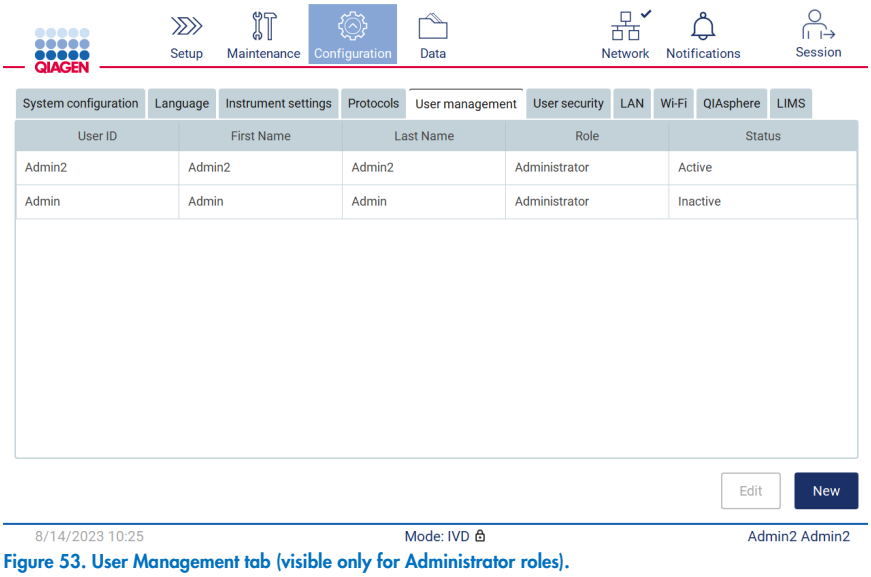



**Figure 53. User Management tab (visible only for Administrator roles).**

3. Tap **Change password**.

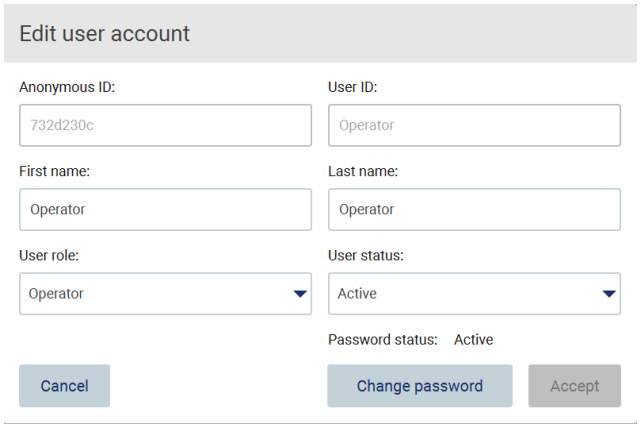



**Figure 54. Change Password screen.**

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.

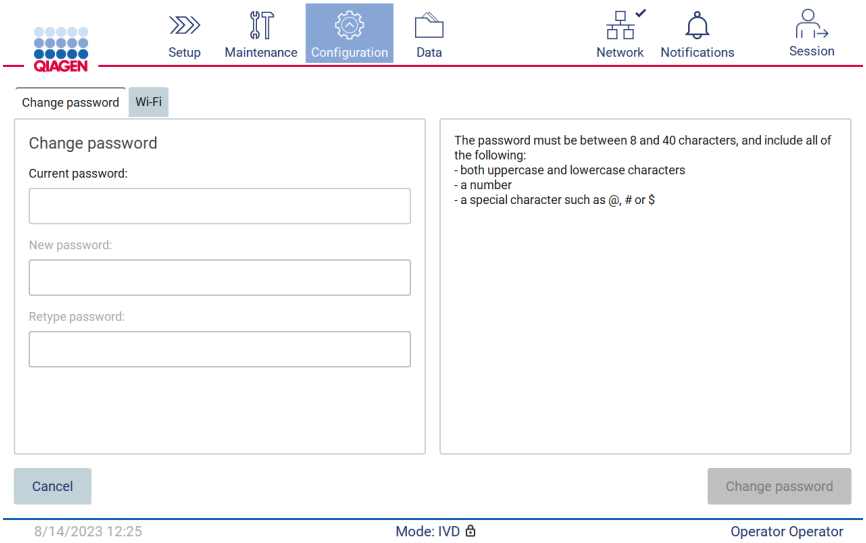



**Figure 55. Configuration screen for Operator role.**

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 4.3.5).

### 5.3.5 Managing user security

Only administrators can change the settings for password expiration 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.

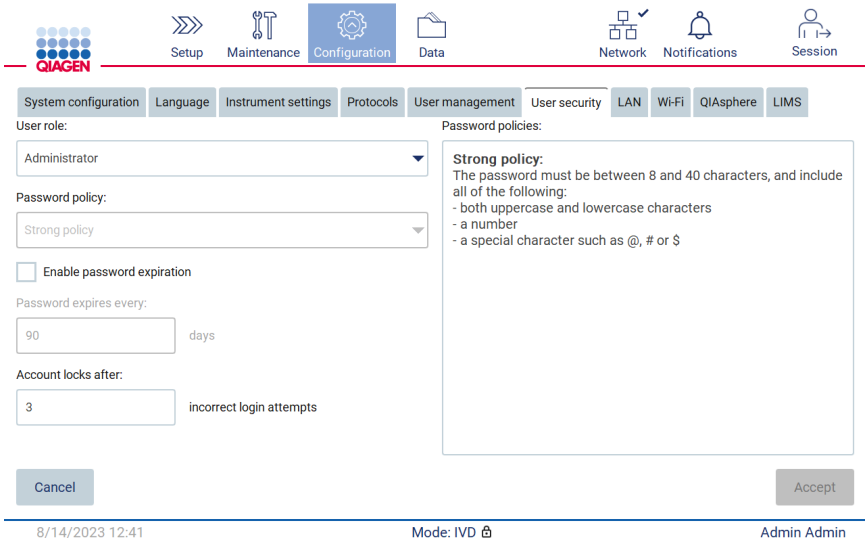



**Figure 57. User security tab.**

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. To enable password expiration, select the "Enable password expiration" checkbox.
5. 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.
6. 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 360. It is recommended to set to at least 2 incorrect attempts. Otherwise, one typographical error will lock your account. Only administrators can unlock locked accounts.
7. Tap **Accept** to save all changes, or tap **Cancel** to restore previously saved settings.

### 5.3.6 Installing new protocols

**Note**: Only administrators can install new protocol packages.

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

The protocols are integrated in the EZ2 Software. However, QIAGEN can provide protocol packs independently from the Software in order to update current or provide new protocols. If there is an updated version of the protocols available, it can be found on the EZ2 Connect MDx product page (**www.qiagen.com**). We recommend to check for the latest protocol package version. Protocols can be installed by using a USB stick or by using the QIAsphere. The QIAsphere will automatically check for the latest version and notify if there is a new package available. During installation via the USB stick, the EZ2 will inform the user if the latest version is already installed or if the package contains newer versions or even new protocols. The system will also show the current installed protocol versions and the new protocol versions.

#### Installing protocols by using a USB stick

**Note**: To ensure that your EZ2 has the latest protocol versions installed, please visit the EZ2 webpage (**www.qiagen.com/EZ2-Connect-MDx**). Protocol versions can be found during the setup wizard, step 2 of 7.

**Note**: The installation of a new protocol package will overwrite all existing protocols. Please make sure you have all previously installed protocols available on a USB stick to allow rollback if required.

**Important**: Use only EZ2 related files downloaded from **www.qiagen.com** or provided by QIAGEN Technical Services.

**Note**: Checksum confirmation is required to secure software integrity after web download was 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 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**.

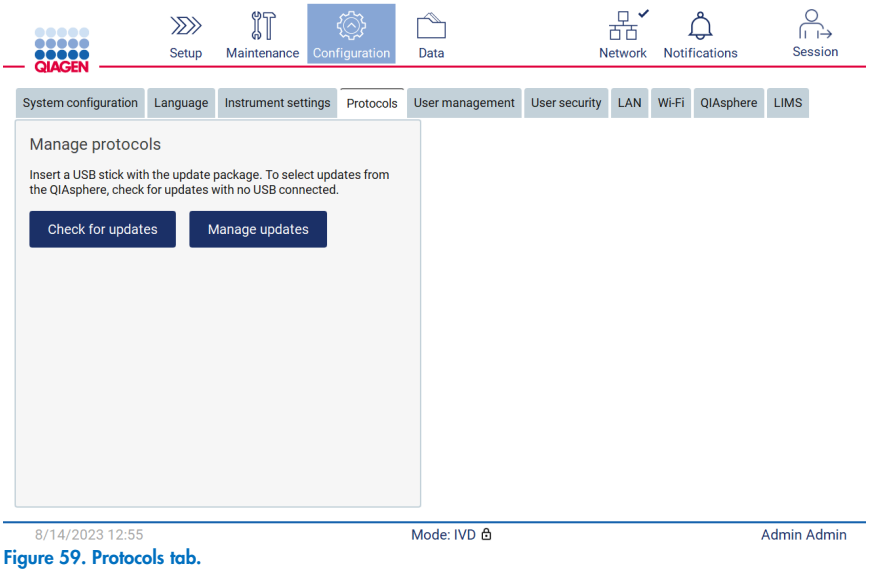



**Figure 59. Protocols tab.**

4. Tap **Check for updates**.
5. If protocol upload packages are detected on the USB stick, a pop-up window appears.

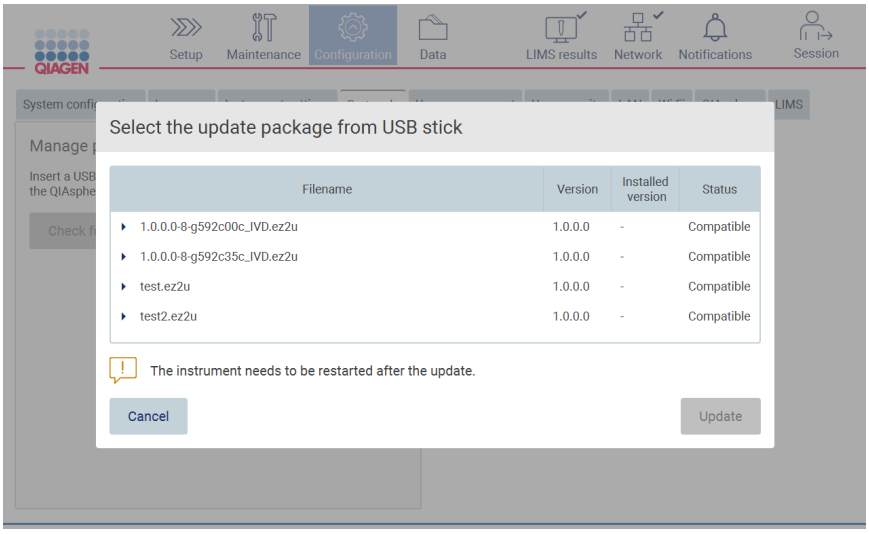



**Figure 60. Update package pop-up window.**

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 at all instrument variants. Those protocols will be 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 by using QIAsphere

1. Ensure that QIAsphere connection is established (see Section 5.3.9).
2. If there is an update available, the QIAsphere will automatically inform the user about an available update.

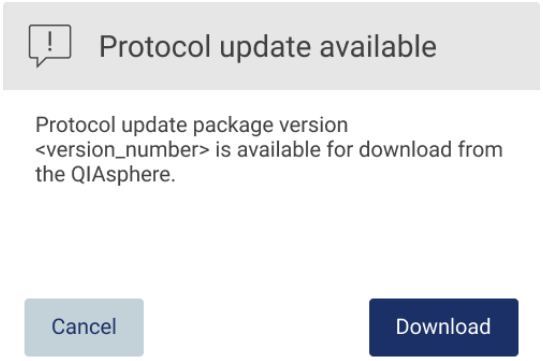



Figure 61. Protocol update available pop-up window.

3. Tap on **Download**. The download process will start.

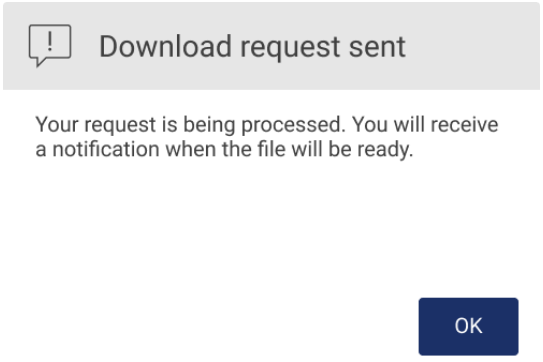



Figure 62. Download request notification pop-up window.

4. Tap **OK**. A notification will be 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 tap **Update**.

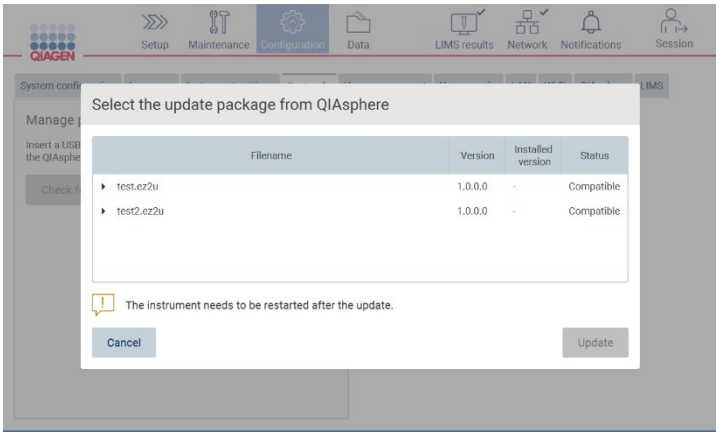



**Figure 63. QIAsphere pop-up window for protocol updates**

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**.

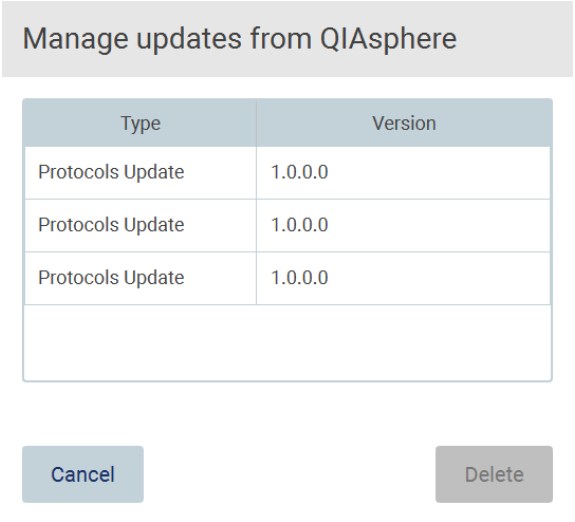



**Figure 64. Manage updates from QIAsphere dialog.**

### 5.3.7 Installing language packages

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

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

**Important**: Use only EZ2 related files downloaded from **www.qiagen.com** or provided by QIAGEN Technical Services.

**Note**: Checksum confirmation is required to secure software integrity after web download was 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 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 in the EZ2 Software. However, QIAGEN can provide language packs independently from 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 product page (**www.qiagen.com**). 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 to change the language settings.

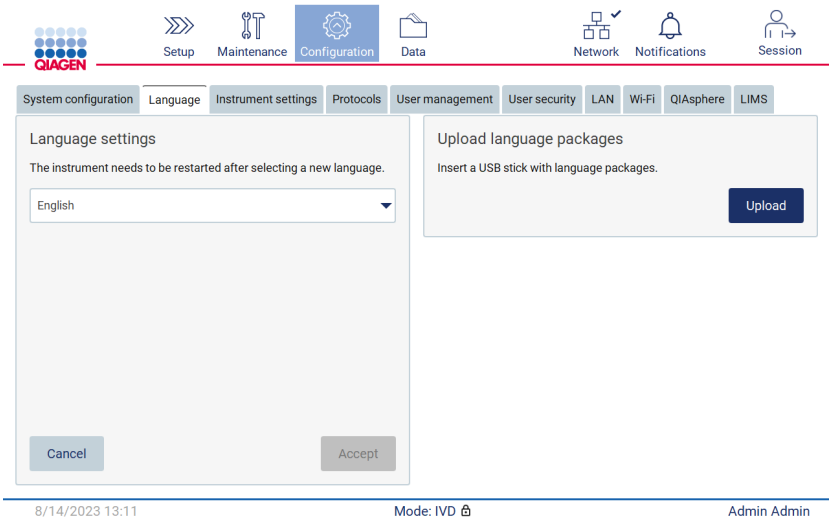



**Figure 66. Language tab.**

5. Tap **Upload** in Upload language packages window.
6. If language upload packages are detected on the USB stick, a pop-up window appears.

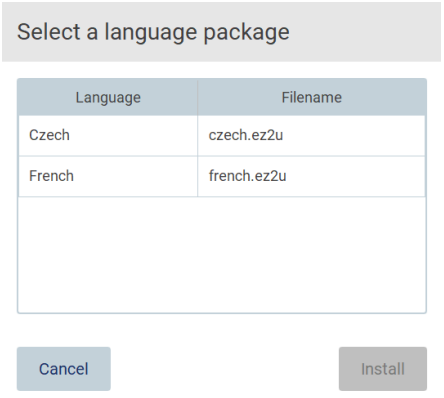



**Figure 67. Language package pop-up window.**

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

**Note**: The EZ2 will need to be restarted to set the selected language.

### 5.3.8 Updating software

**Note**: Only administrators can update the software.

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

**Note**: To ensure that your EZ2 has the latest software versions installed, please visit the EZ2 webpage at **www.qiagen.com/EZ2-Connect-MDx**. Currently installed software version can be found from 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 USB ports.

**Important**: Use only EZ2 related files downloaded from **www.qiagen.com** or provided by QIAGEN Technical Services.

**Note**: Checksum confirmation is required to secure software integrity after web download was 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 can be found on the EZ2 product page (**www.qiagen.com**). We recommend to check for the latest version. Software updates can be installed by using an USB stick or by using the QIAsphere. The QIAsphere will automatically check for the latest version and notify the user if there is a new version available. Current installed software version can be seen in the configuration tab.

#### Installing newest software version by using an 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.

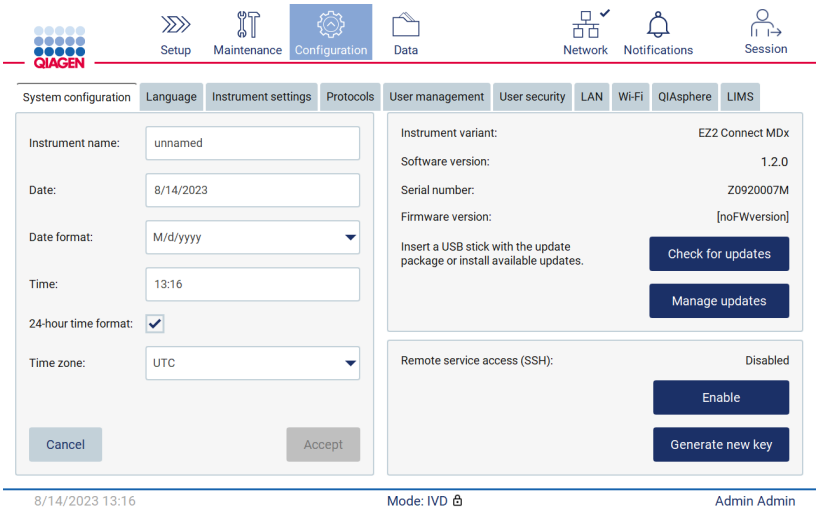



**Figure 69. System Configuration tab.**

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.

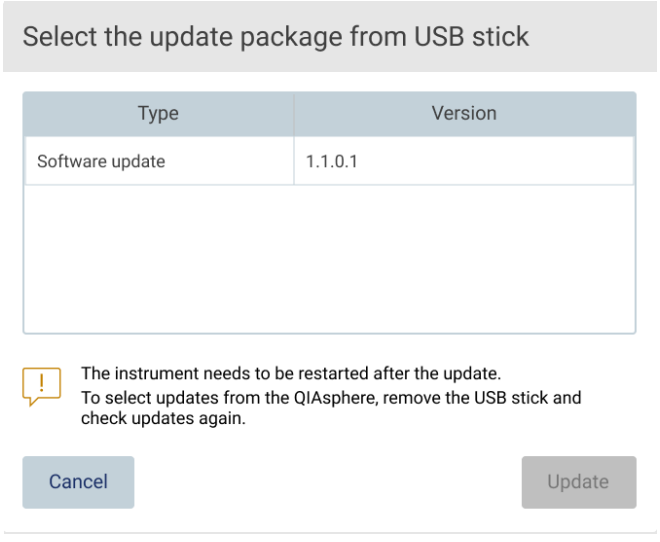



**Figure 70. Update package pop-up window.**

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 by using QIAsphere

1. Ensure that the QIAsphere connection is established (see Section 5.3.9).
2. If there is an update available, the QIAsphere will automatically inform the user about an available update.

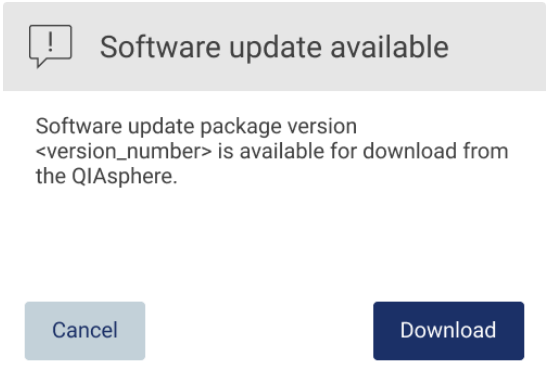



Figure 71. Software update pop-up window.

3. Tap on **Download**. The download process will start.

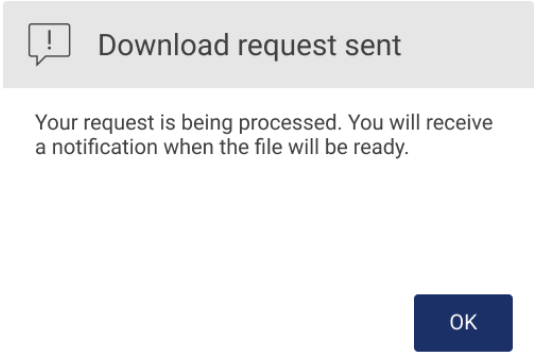
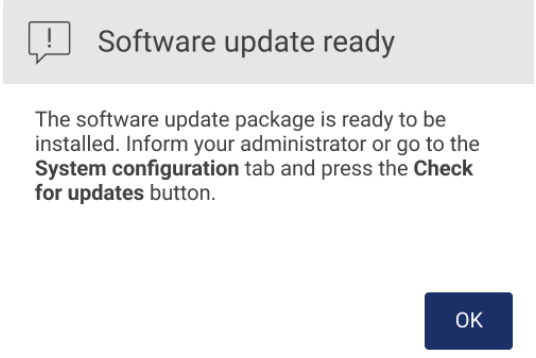



Figure 72. Download request notification pop-up window.

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



5. Tap the **System configuration** tab.
6. Tap **Check for updates**.
7. If a software update package was downloaded, a pop-up window appears.

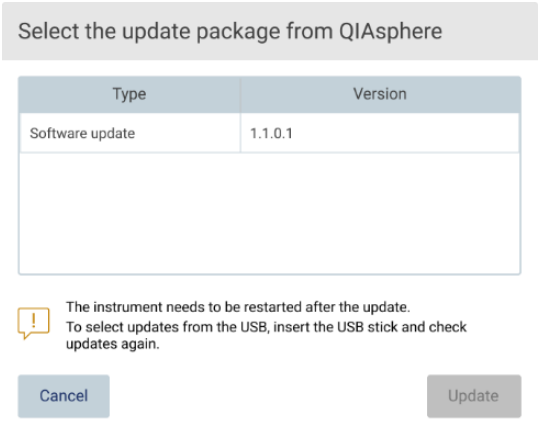



**Figure 73. Update selection pop-up window.**

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

## 5.3.9 Configuring network and QIAsphere Base connections

### Configuring a LAN connection

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

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




**Figure 74. Configuration button on the toolbar.**

2. Tap the **LAN** tab.

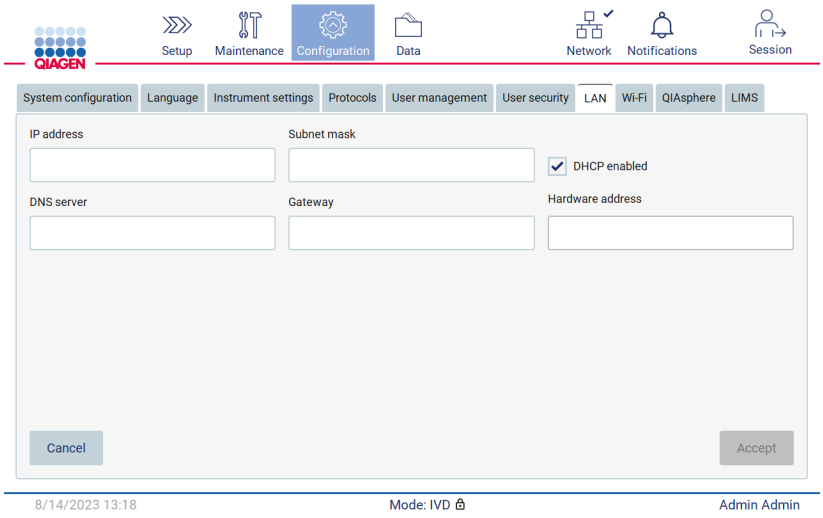



**Figure 75. The LAN tab.**

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

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

   **Note**: Hardware address = MAC address

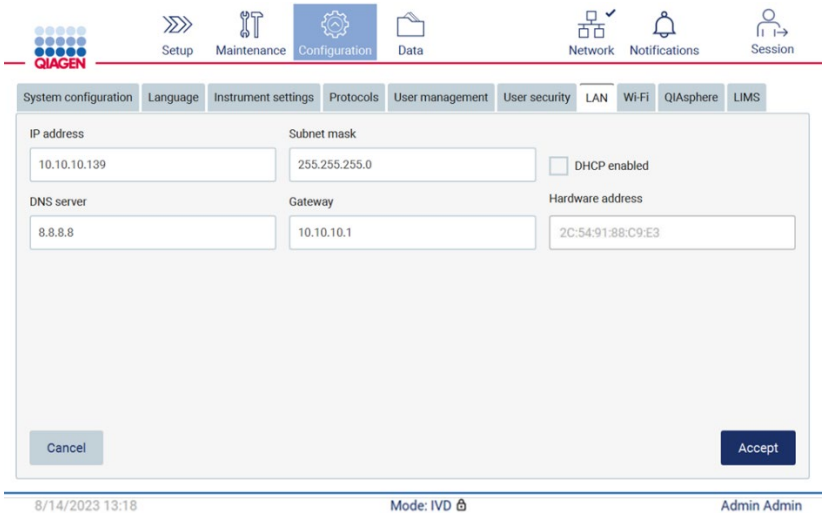



**Figure 76. Configured LAN tab.**

## Configuring a Wi-Fi connection

**Note**: Only administrators can configure Wi-Fi settings.

**Note**: Make sure the Wi-Fi USB device was plugged-in before the machine was started.

The EZ2 can be connected to a Wi-Fi network using the 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, and 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 77. The Wi-Fi tab.**

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




**Figure 78. The Wi-Fi tab.**

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

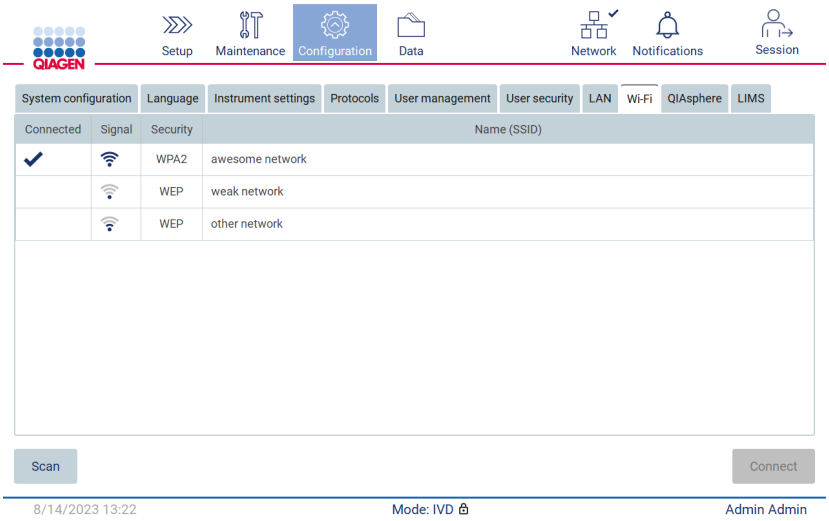



**Figure 79. List of available Wi-Fi networks.**

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.

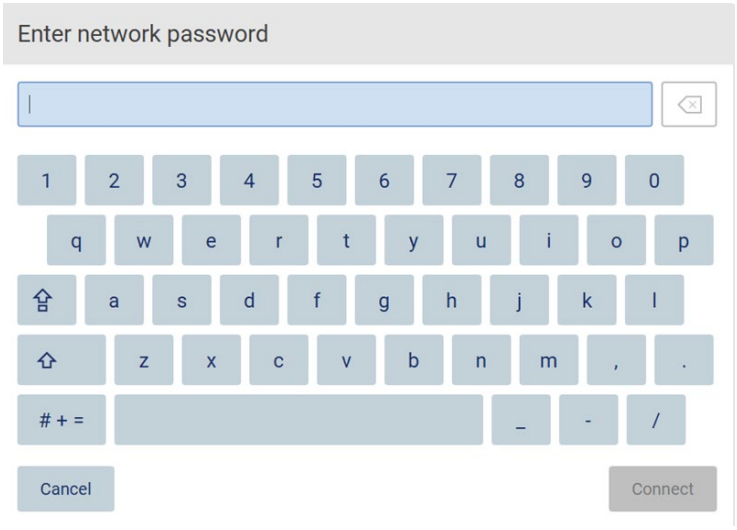



**Figure 80. On-screen keyboard.**

**Note**: If you failed to connect to the network several times despite entering the correct password, it is recommended to restart the instrument.

**Note**: In case of errors, refer to the "Troubleshooting" section (page 159) for more information.

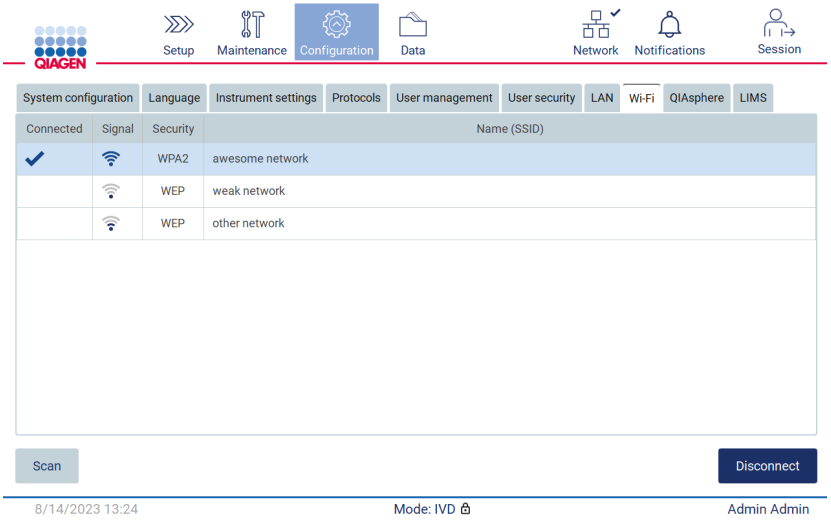



**Figure 81. Successful connection to a Wi-Fi network.**

7. 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 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, refer to the *QIAsphere User Manual* that is available at **www.qiagen.com/qiasphere**.

Only users assigned the role Administrator 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 82. Configuration button on the toolbar.**

2. Tap the **QIAsphere** tab.

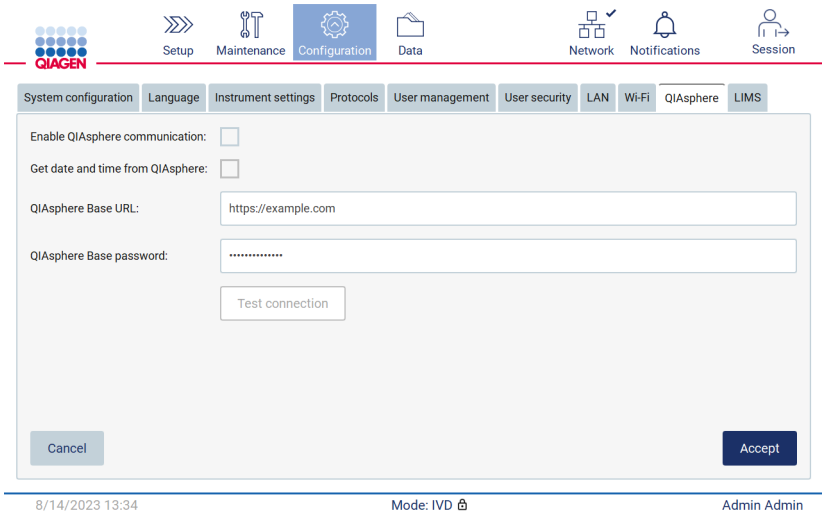



**Figure 83. The QIAsphere tab.**

3. Enter the QIAsphere Base URL.
4. Enter the QIAsphere Base password.
5. Tick the Enable QIAsphere communication box.
6. **Optional**: For time and date synchronization with QIAsphere tick the Get date and time from QIAsphere synchronization box.

   **Note**: The time synchronization will just be executed if the EZ2 is connected with the 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. If you wish QIAGEN to set up such a connection, 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 can be connected with a LIMS system, the connection can be configured from 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 which enables the data transfer between the EZ2 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, you might need to re-upload the QIAGEN LIMS Connector certificate. This certificate was originally generated by the QIAGEN Service Team during the LIMS Connector set up and was saved on a USB drive. The certificate can only be created locally and cannot be provided remotely. If you need 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 84. Configuration button on the toolbar.**

3. Tap the **LIMS** tab.

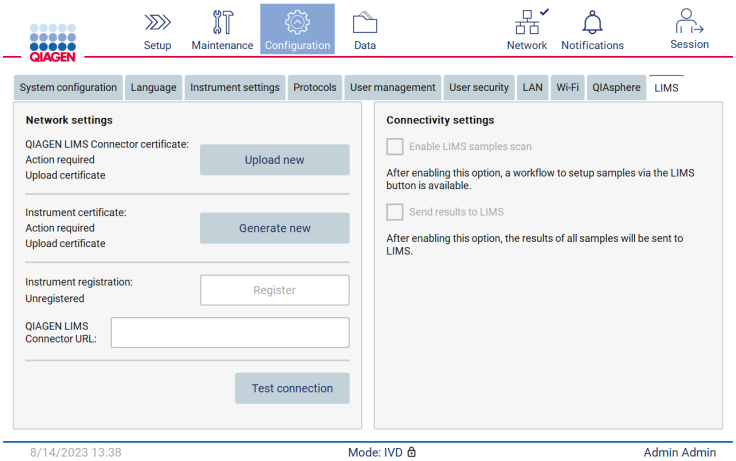



**Figure 85. LIMS configuration tab.**

4. Tap **Upload new**.

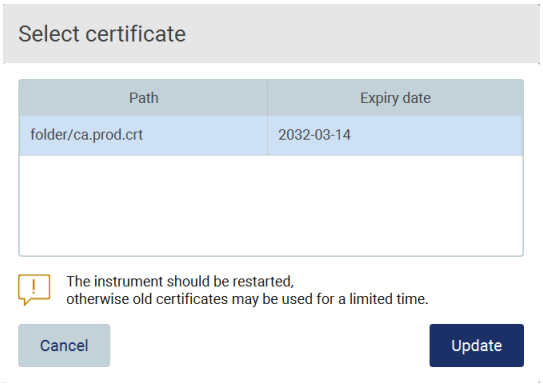



**Figure 86. Select certificate screen.**

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

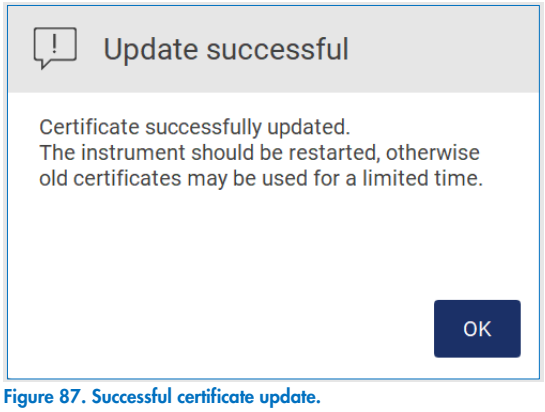



**Figure 87. Successful certificate update.**

6. Tap **OK** and restart the EZ2.
7. From the **LIMS configuration** tab, tap **Generate new**. Certificate will be stored on attached USB stick.

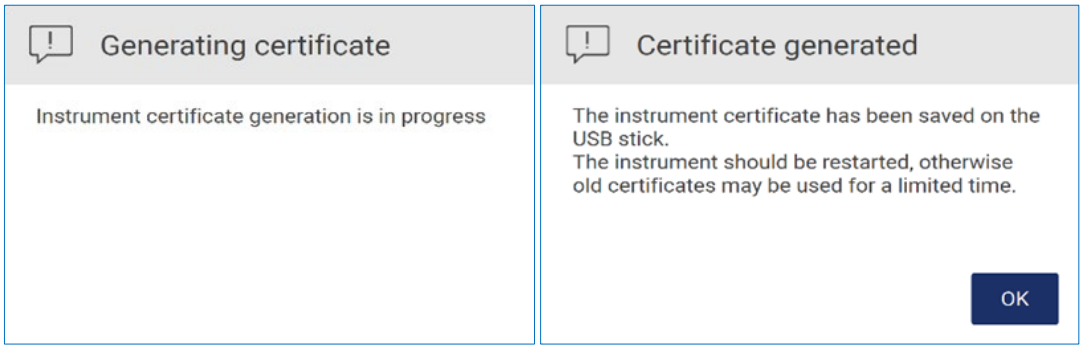



**Figure 88. Generation of Instrument certificate.**

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

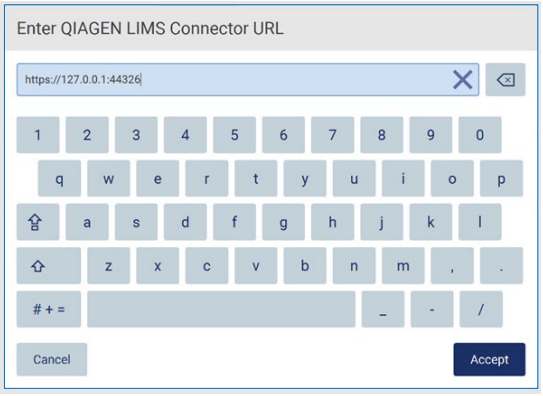



**Figure 89. Enter QIAGEN LIMS Connector URL.**

11. Tap **Accept**.

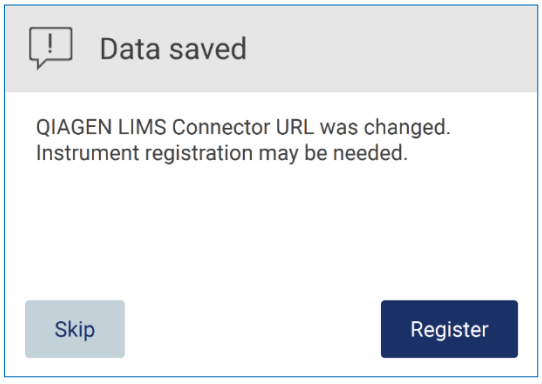



**Figure 90. URL accepted.**

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

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

13. If you want to select a new configuration, you can also tap **Register** in the **LIMS configuration** tab.

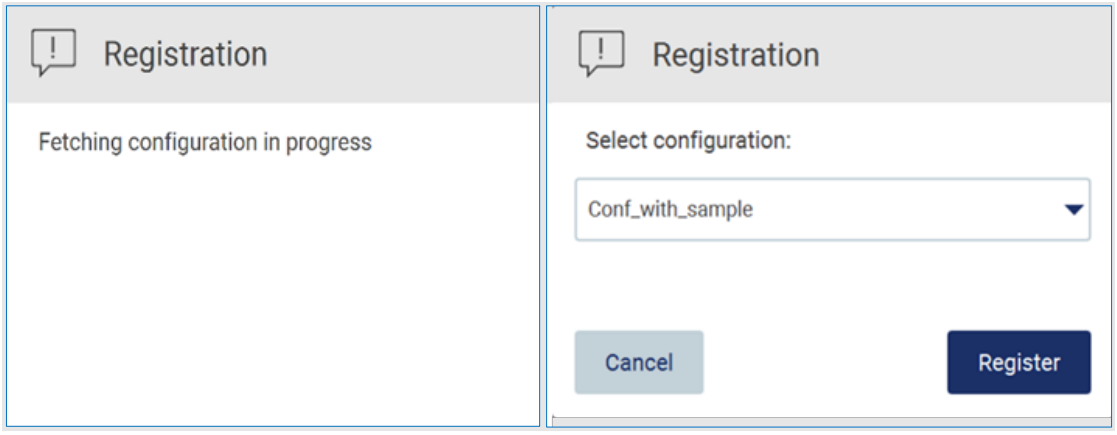



Figure 91. LIMS registration.

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

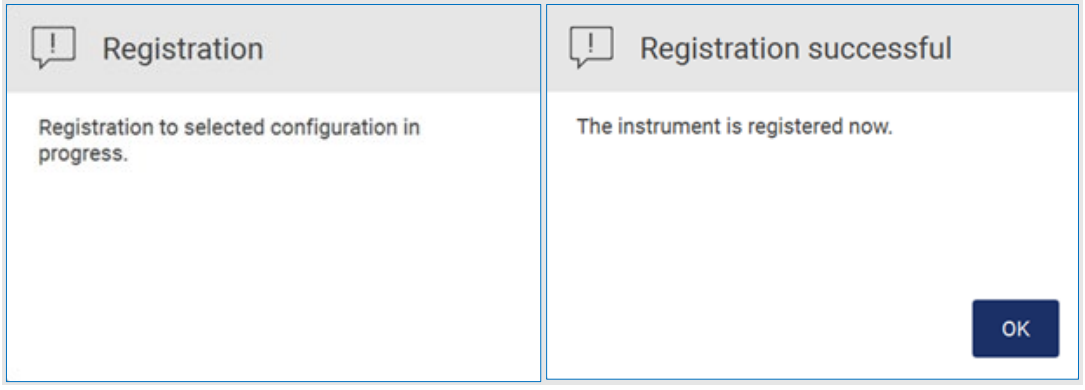



Figure 92. LIMS registration successful.

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

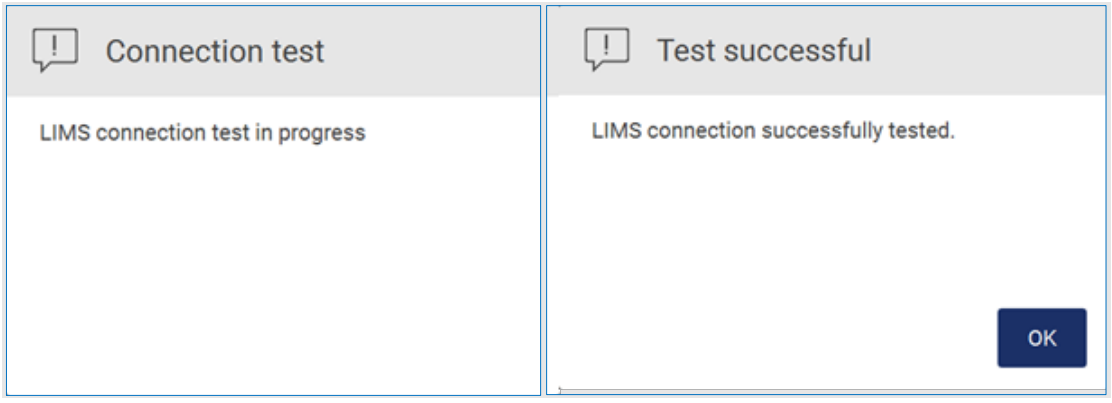



**Figure 93. LIMS connection test.**

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

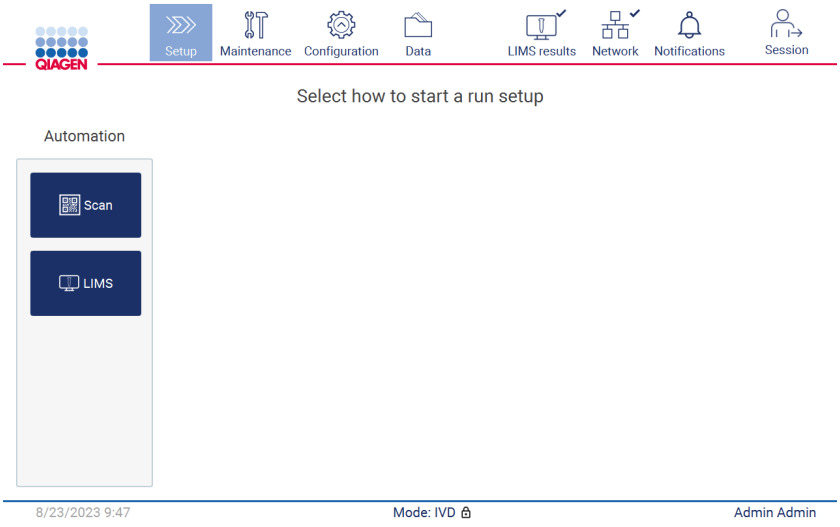



**Figure 94. LIMS button available on the Setup screen.**

**Note**: If the user checks the “Send results to LIMS” checkbox, the LIMS results status will be displayed, and the results for each sample will be 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.

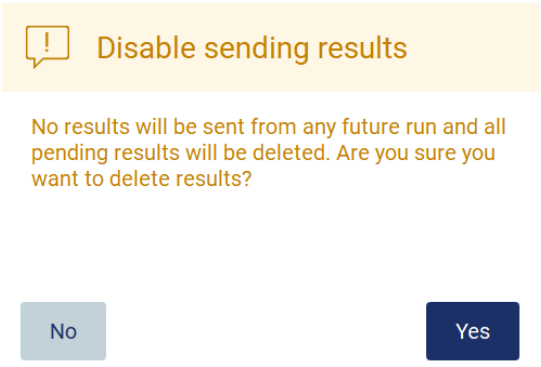



**Figure 95. Disable sending results warning.**

The LIMS results status is shown by an icon in the upper right corner of the screen. This icon has 3 states:

1.  - sending results is in progress,
2.  - results were sent successfully / nothing queued to be sent,
3.  - unsent results.

**Figure 96. LIMS icon status.**

17. Tapping on the icon directs the user to 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 nothing is queued to be sent. The user sees the LIMS results status icon with a checkmark.

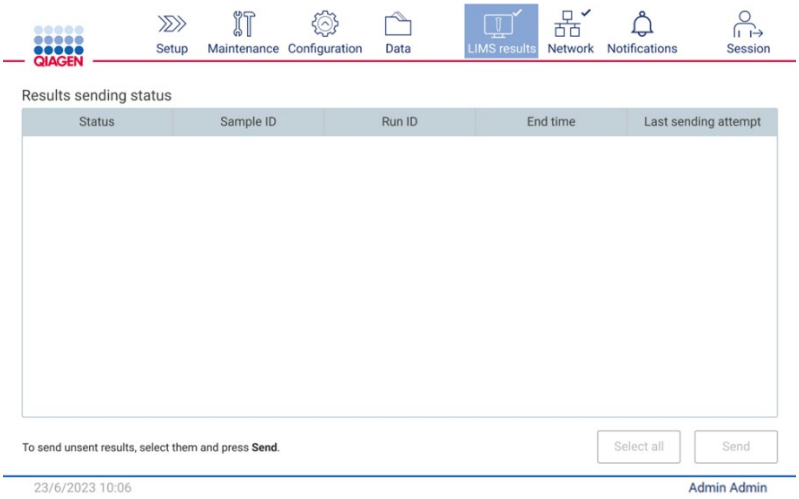



**Figure 97. Results sending status Empty.**

- Status icon:



If the user selects unsent results and taps **Send** button, selected unsent samples will be 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.

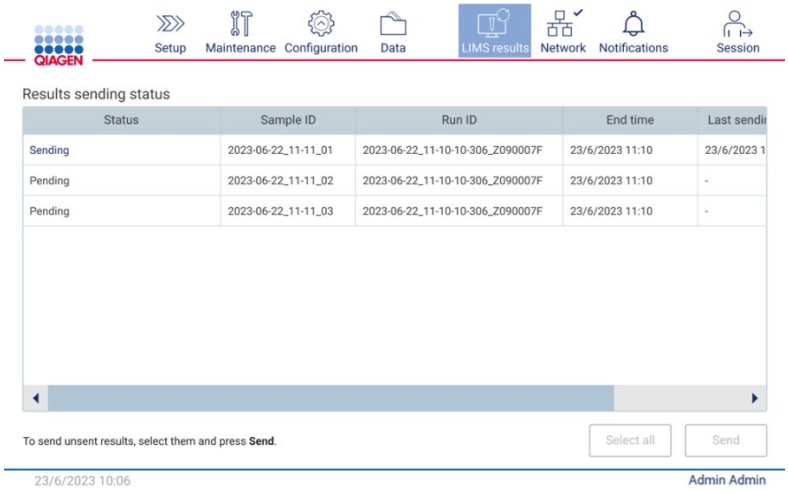



**Figure 98. Results sending status In Progress.**

- 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 resent results to a configured LIMS. Unsent results will be sent automatically only after the instrument restart.

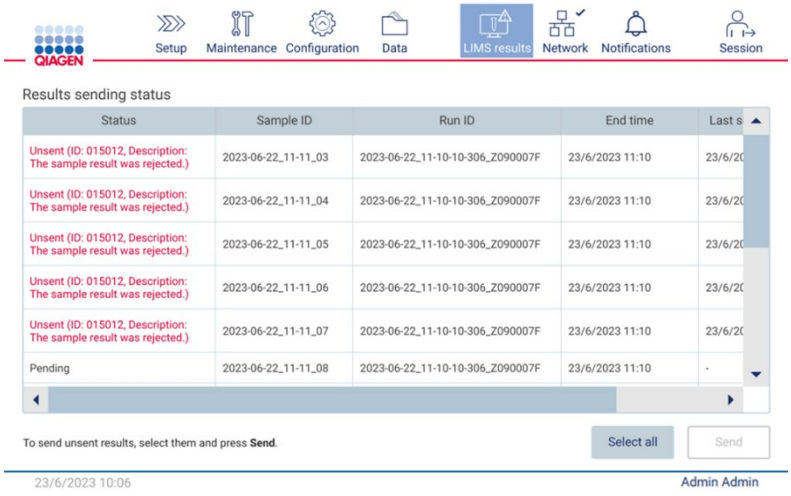



**Figure 99. Results sending status error.**

## 5.4 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 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**: EZ2 does not support protocols obtained from sources other than QIAGEN.

**Note**: The protocol run set up can be aborted at any time by pressing the **Abort** button (see Section 5.6).

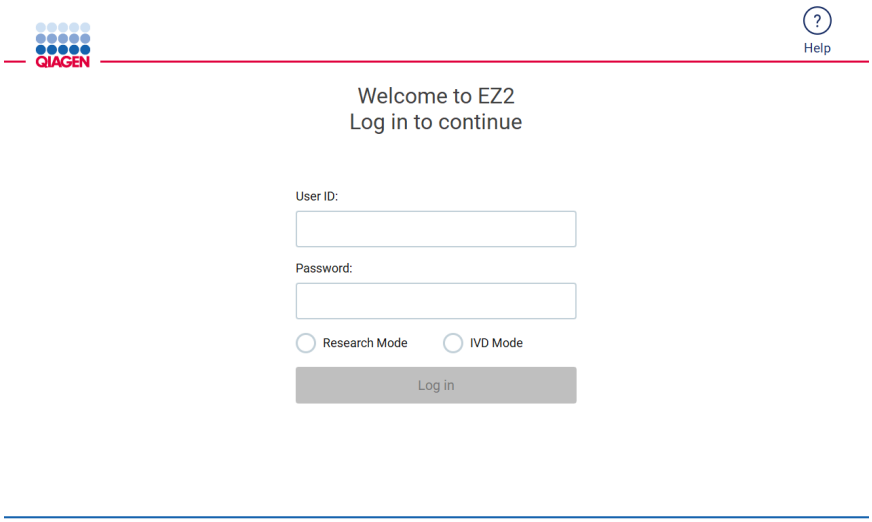



**Figure 100. The log in screen.**

The EZ2 software will guide you through the protocol run setup process. The steps of the protocol wizard vary, depending on the selected protocol and may differ from the figures included in this section. Some descriptions shown on the touchscreen may only be visible by using a scrollbar. Please ensure to read the entire instruction. The process is started by tapping either the **SCAN** or **LIMS** button on the **Set Up** tab. The **LIMS** button only is 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 will appear (Figure 102).

### 5.4.1 Using the barcode scanner

The EZ2 has a 2D handheld barcode scanner which 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 the section “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 101. Scanning the information into the Instrument.**

| | |
|---|---|
| **WARNING** | **Risk of personal injury**<br>Hazard Level 2 laser light: Do not stare into the light beam when using handheld barcode scanner. |

## 5.4.2 Scanning Q-Card bar code

1. 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 will check in the background if there is enough disc space. A warning will appear if the disc space is lower than required for 5 runs. Previous run reports should be downloaded and deleted to free up disk space. Please check Section 5.12.1 about how to delete run reports if this message appears.

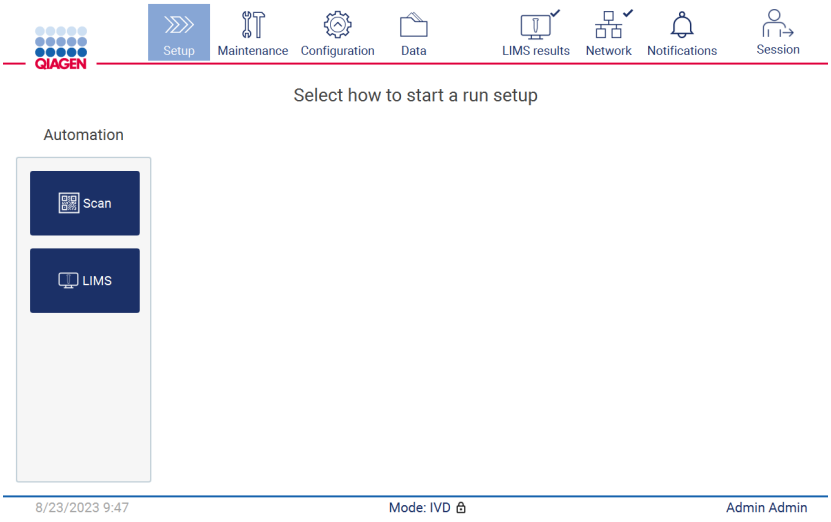



**Figure 102. Setup screen.**

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

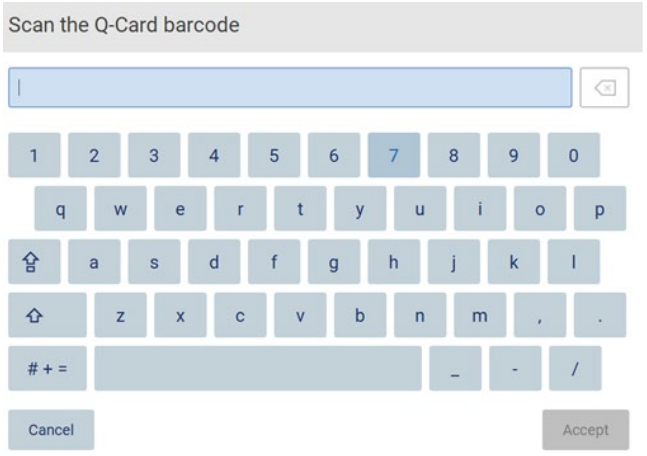



**Figure 103. Scan the Q-Card barcode screen.**

**Important**: If scanning of the Q-Card fails, you can also type the barcode number via the user interface.

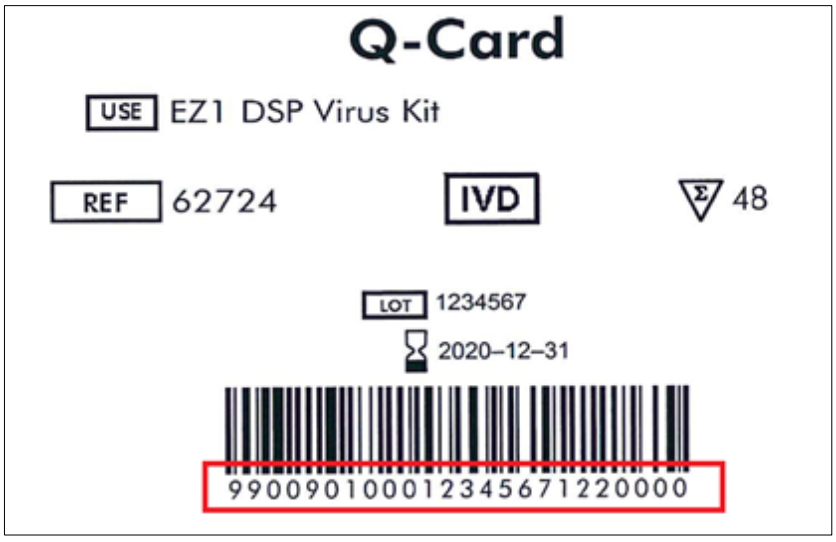



**Figure 104. Q-Card sample.**

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 the "LIMS Workflow" section (see page 118).




**Figure 105. Select protocol screen.**

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

### 5.4.3 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.

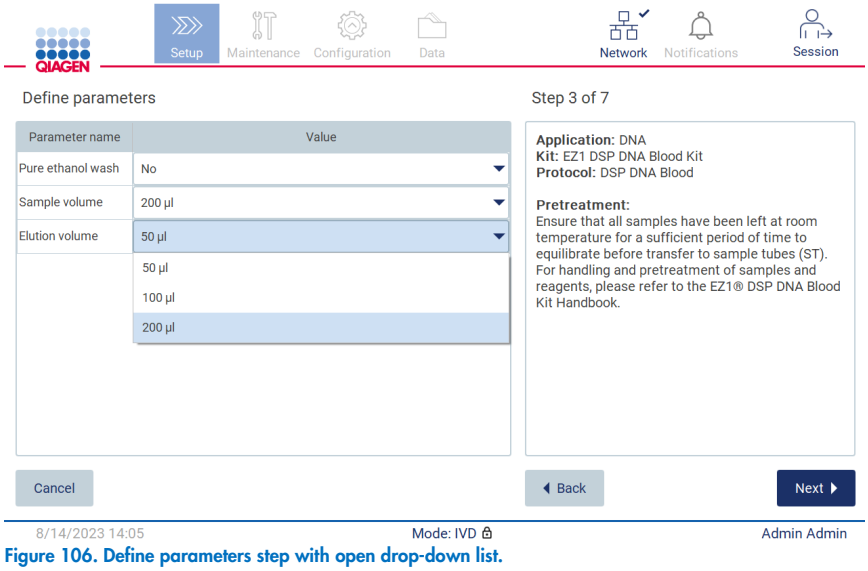



**Figure 106. Define parameters step with open drop-down list.**

Additional information about the protocol is also displayed on the screen, for example, references into the respective kit handbook with respect to sample storage, handling, and pretreatment (if required). Please ensure to read the entire instruction using the scroll buttons (if applicable).

**Note**: The description on the GUI is supportive only. Please ensure you to 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**.

## 5.4.4 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.

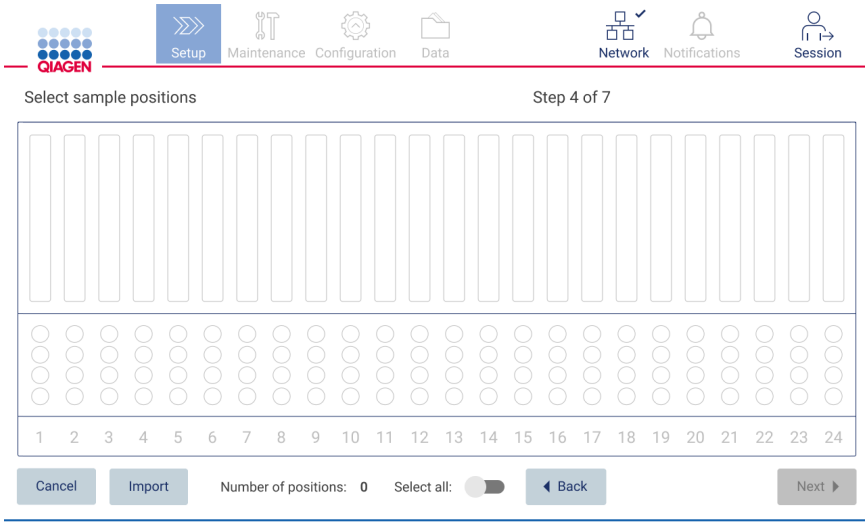



**Figure 107. Select sample positions screen.**

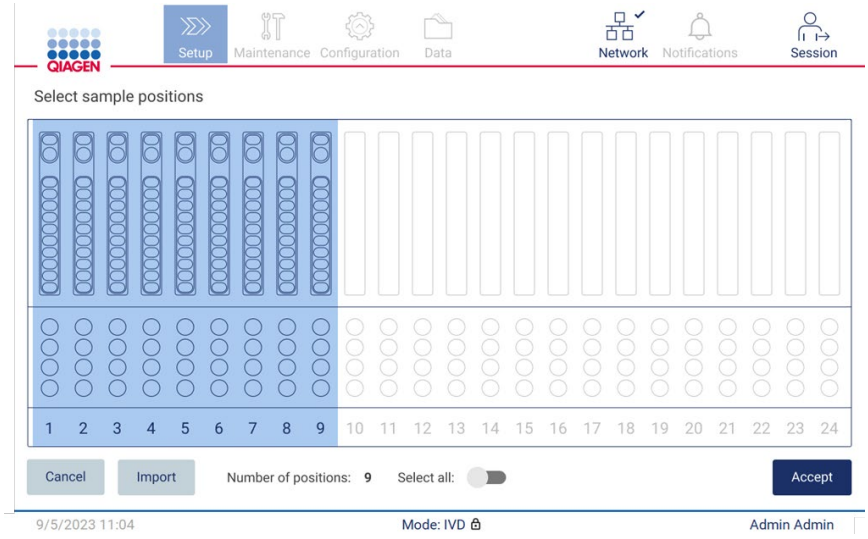



**Figure 108. Select sample positions step.**

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

Alternative option: Instead of manually defining the sample positions via the touchscreen, a pre-filled sample list file can be uploaded to the EZ2. 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. Instructions to download a sample list template can be found in Section 5.12.4. 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 will detect and show all **.xlsx** files on the USB stick. To avoid confusion it is recommended to just have one **.xlsx** file with a meaningful title 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.

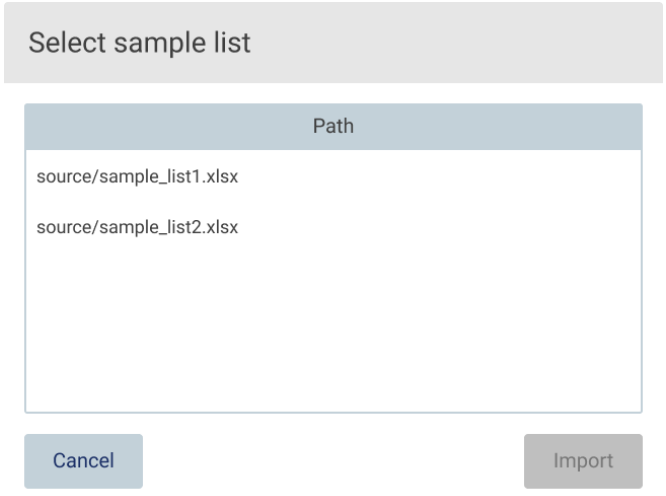



Figure 109. Select sample list dialog.

### 5.4.5 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, by use of the on-screen keyboard, by use of the handheld barcode scanner or by using a sample list. Ensure that the entered sample ID accurately corresponds to the ID of the sample in the respective position.

**Note**: Sample list upload is described in Section 5.4.4. Sample list template download is described in Section 5.12.4.

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

**Note**: The user can enter/edit all sample IDs or notes without the need to manually select the next sample cell from the table. When the user edits the sample ID, and scans the barcode, the input is saved and the new keyboard appears for the next sample ID.

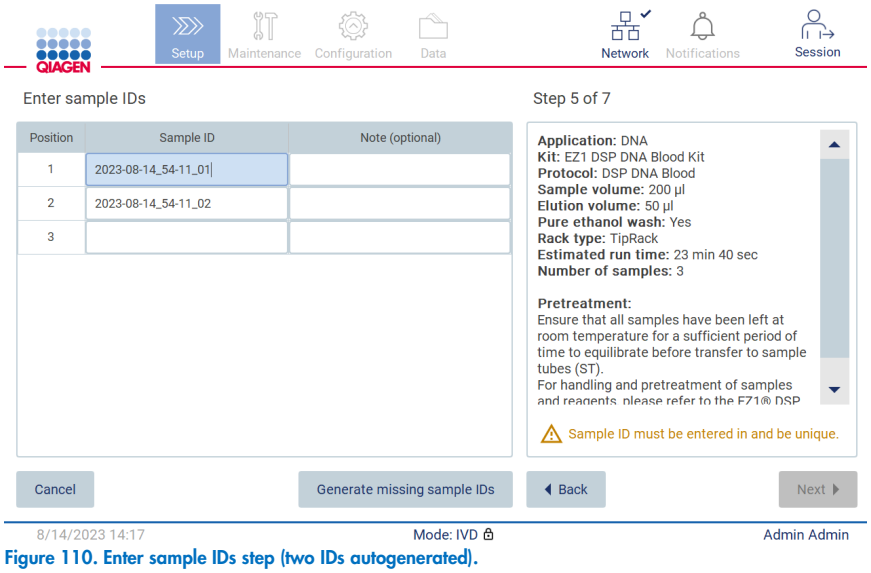



**Figure 110. Enter sample IDs step (two IDs autogenerated).**

## Modifying a sample ID

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

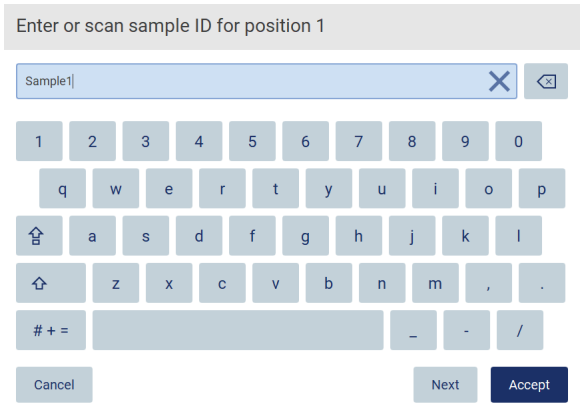



**Figure 111. Changing the sample ID.**

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 to a sample

Optionally, you can add a note to each sample. Tap the **Note (optional)** box next to the relevant sample ID, and use the on-screen keyboard to enter the note.

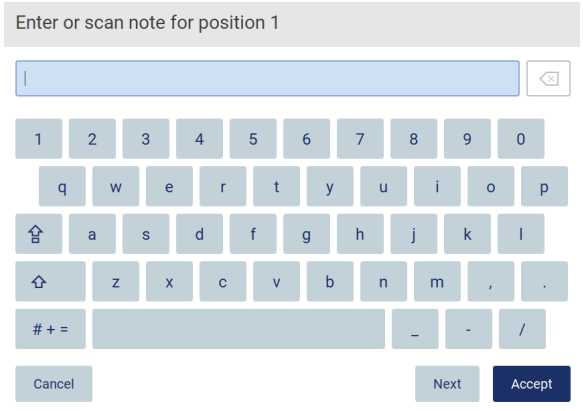



**Figure 112. Adding a note to a sample.**

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**.

## 5.5 Setting up the worktable

This section is about setting up the EZ2 worktable that consists of removing the empty tip rack(s) and the cartridge rack(s) from the instrument, prepare them with respective cartridge(s), consumables and sample(s) and reload 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.

### 5.5.1 Loading the cartridge rack(s)

To load the cartridge rack(s), follow the steps below (also displayed on the GU). 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 4 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 on) 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.

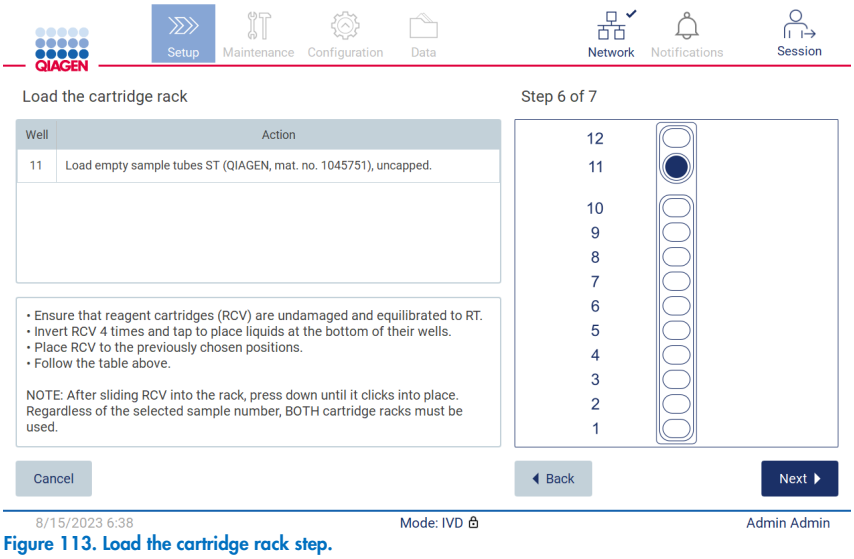



**Figure 113. Load the cartridge rack step.**

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

## 5.5.2 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:

1. Place the tips into their tip holders.
2. Load the labware according to the instructions on the UI.
3. Load the sample tubes onto the tip rack.

   **Note**: Make sure that you follow any protocol-specific directions shown on the screen in the Load the tip rack step of the run setup process. You could be required to perform some additional actions. The instructions can also be found in the kit handbooks.

**Note**: Remove any caps from the labware and store safely. Make sure not to mix up lids between different samples.

4. Once all the labware is loaded, place the tip rack sections onto the worktable.
5. Place the tip racks always after loading the cartridge racks. The rim of the reagent cartridge plastic flag (where the 2D-barcode label is placed on) must sit below the tip rack, but the label itself should not be covered.

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

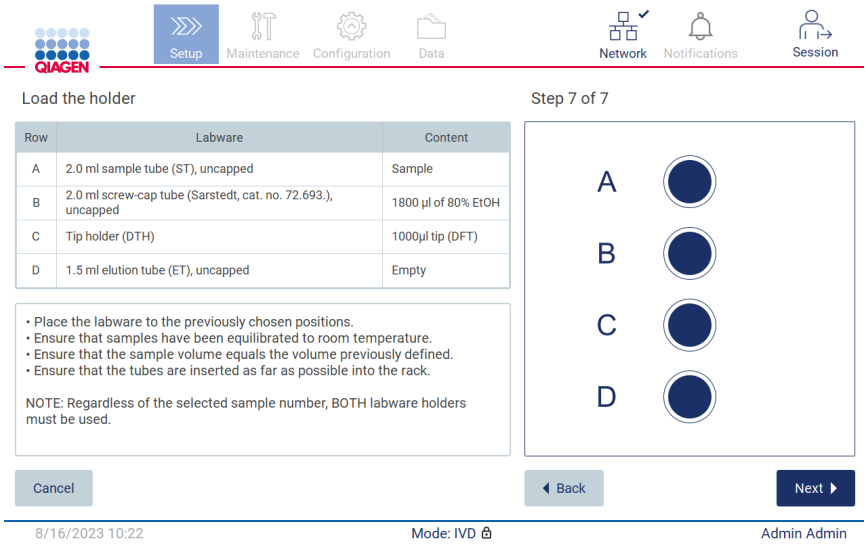



**Figure 114. Load the tip rack step.**

**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, you will see an overview of the selections you made during the run setup process.

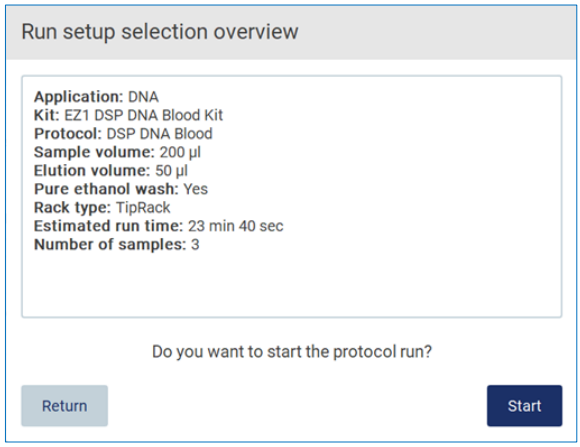



Figure 115. Run set up overview.

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

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

## 5.6 Starting the protocol run and monitoring its progress

After successfully completing all the steps of the protocol run setup, you can start the run. During the protocol run, you can monitor its progress. Ongoing steps, 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 is shown.

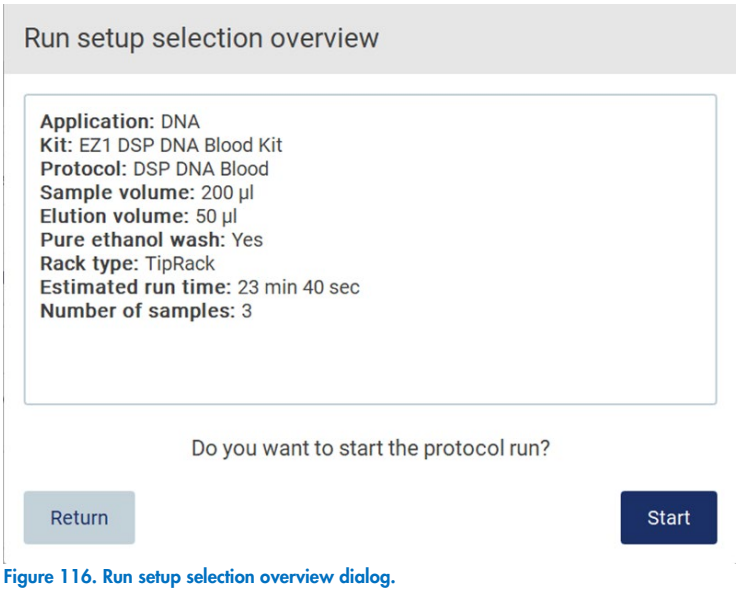



Figure 116. Run setup selection overview dialog.

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 will start.




**Figure 117. Close the hood dialog.**

4. The load check will now be performed. For more information about the load check, refer to the "Load check" section (see page 107). The run will start 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 will not start, and operator action will be required. If the instrument is left unattended for an extended time period, stability of samples and reagents may be impaired.

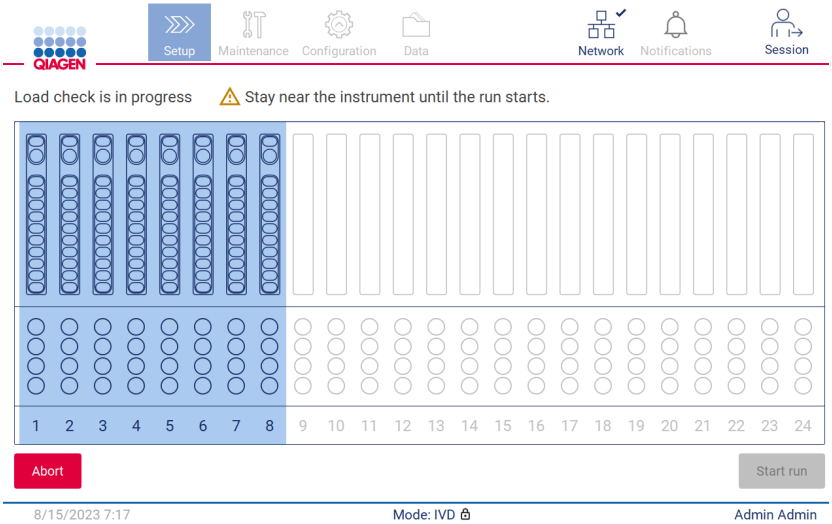



**Figure 118. Load check in progress screen.**

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.

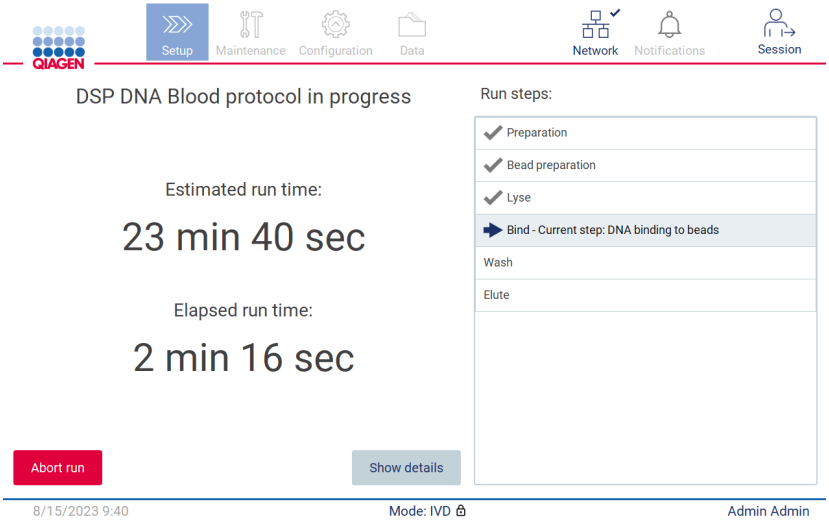



**Figure 119. Run progress screen.**

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

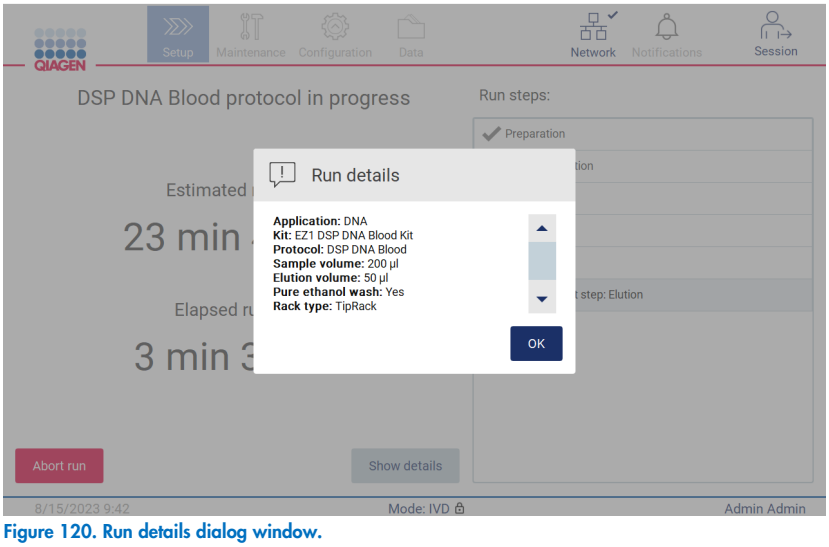



**Figure 120. Run details dialog window.**

### 5.6.1 Load check

The EZ2 comes with a built-in camera, which is designed as an aid to ensure 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.

The load check is mandatory and automatically starts after you tap **Start** in the Run setup selection overview dialog window. For more information on starting a run, refer to the "Starting the protocol run and monitoring its progress" section (page 104).

After the load check starts, the camera moves above the worktable and checks all positions on the cartridge rack and the tip rack, and the **Load check** is in progress screen is shown on the display. The positions that you chose in the Select sample positions screen are highlighted.

**Important**: Operator should confirm completion of load check prior to leaving the EZ2 unattended as in the event of failed load check operator intervention may be required. If the instrument is left unattended for an extended time period, stability of samples and reagents may be impaired.

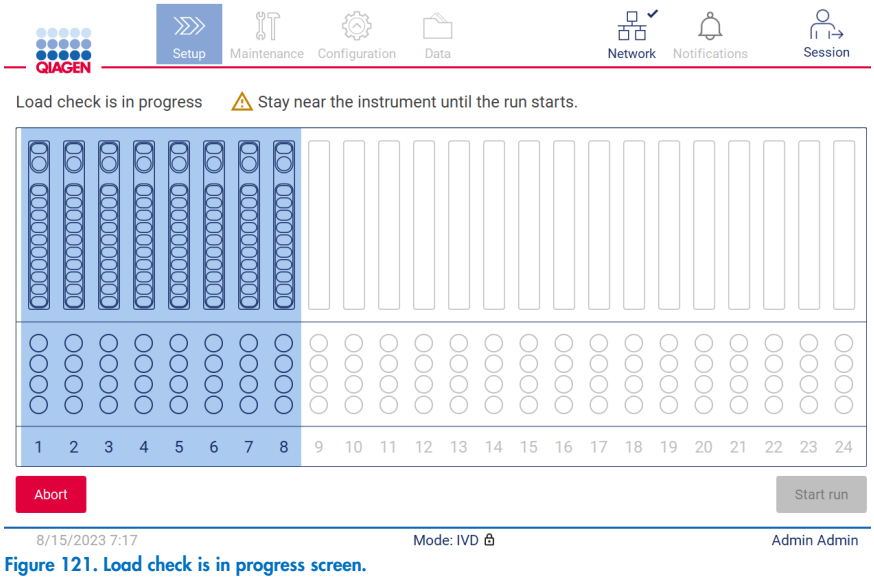



**Figure 121. Load check is in progress screen.**

### 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 repeatedly 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 shown. If you need the instructions from the previous screen, press Back again. Once you have confirmed correct loading of the worktable, tap Next in the Load the tip rack screen. The Run setup selection overview screen will be displayed where a **Skip load check** button will now be available (see "Skip load check option" section). If you have to correct the loading, the load check must be repeated.

**Note**: Only use EZ1 DSP kits within their expiration date. If an expired kit is used, the EZ2 software will show 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 will be marked as invalid sample in the run report.

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

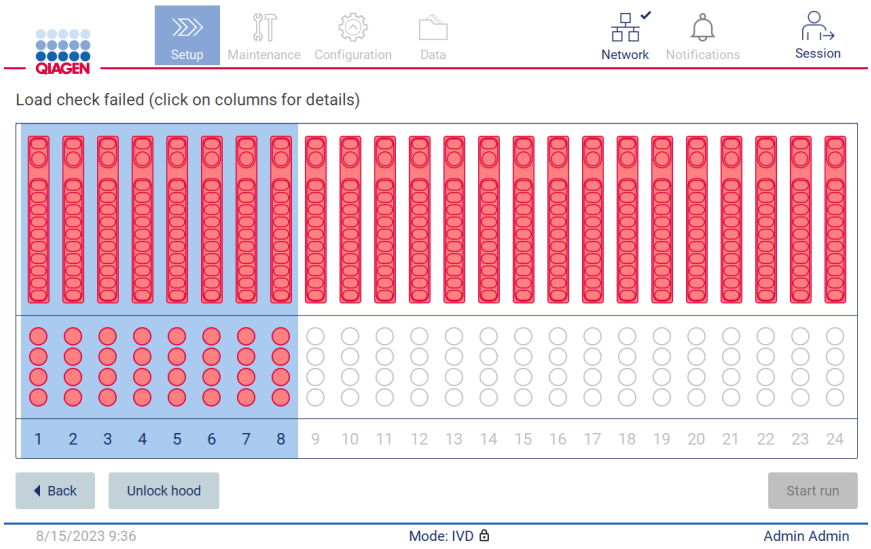



**Figure 122. Load check failed screen.**

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

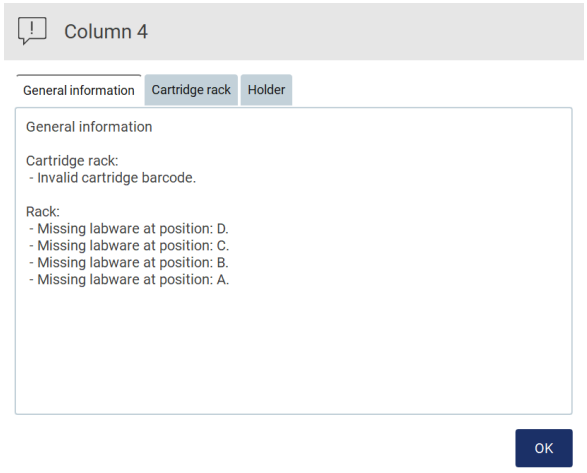



**Figure 123. Pop-up window with faults to be corrected.**

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.

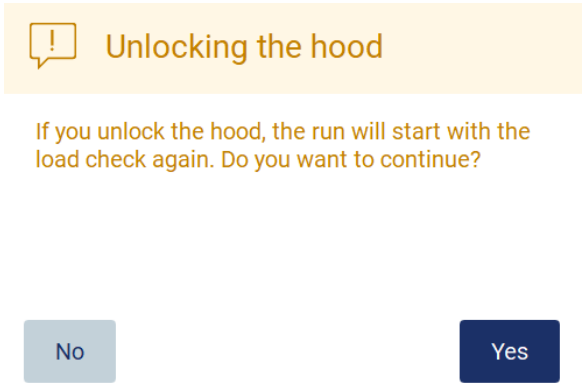



Figure 124. Warning after unlocking the hood.

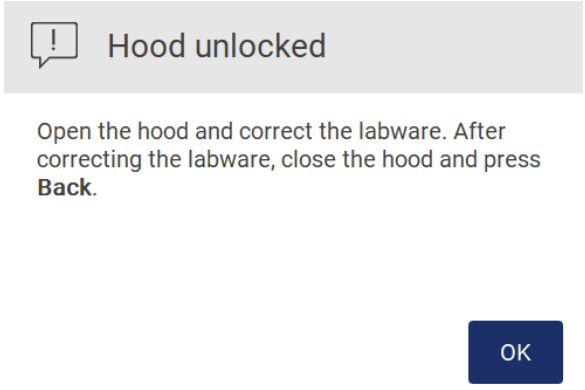



Figure 125. Hood unlocked pop-up window.

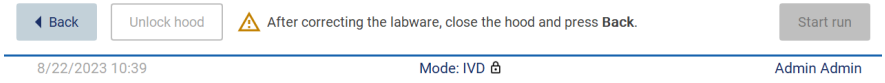



Figure 126. Warning on the Load check failed screen.

### Skip load check option

The first load check is mandatory and cannot be skipped in the **Run setup selection overview** dialog. Following failure of the first load check the operator has an option to 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, it is the responsibility of the operator to visually check and confirm 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 will be unlocked, the load check must be repeated.

It is recommended to perform this check while the **Load check failed** screen (Figure 122) is still open. If you press **Back**, the information about the failed positions will not be visible again. Once correct loading is confirmed, tap **Next** to proceed to the Run setup selection overview screen where the **Skip load check** button will now be available.

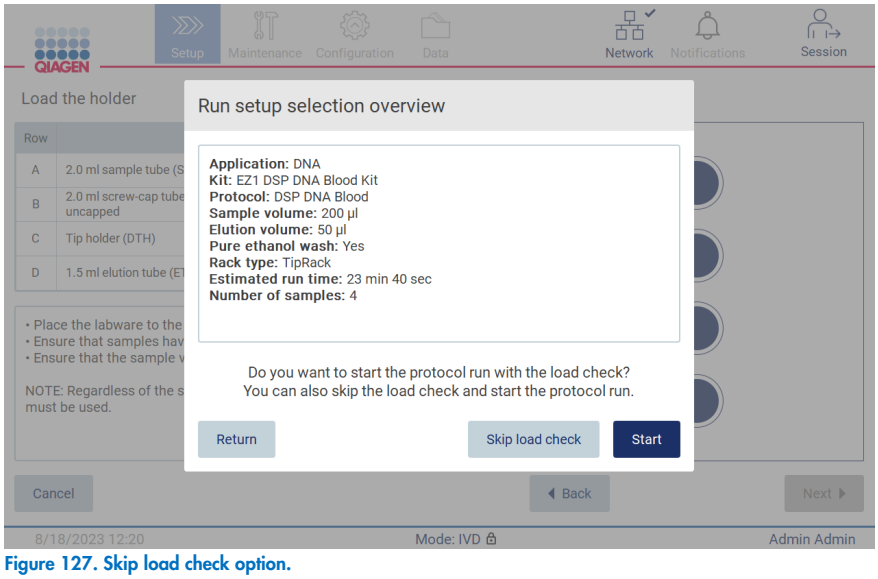



**Figure 127. Skip load check option.**

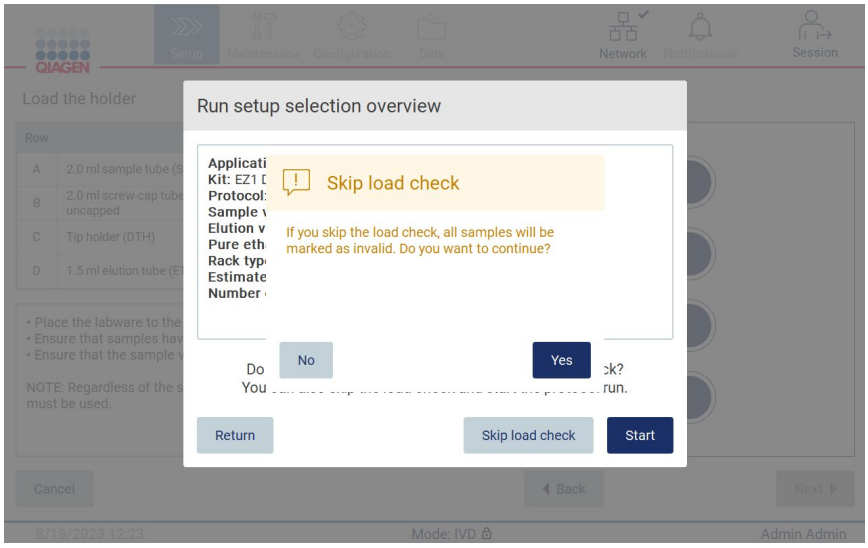



**Figure 128. Confirm skip load check screen.**

When an operator chooses to use the skip load check option following a previously failed load check, this will be recorded in the run report and all samples will be flagged as invalid.

If you find positions with wrong loading, tap Unlock hood button to correct the loading.

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

## 5.7 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.

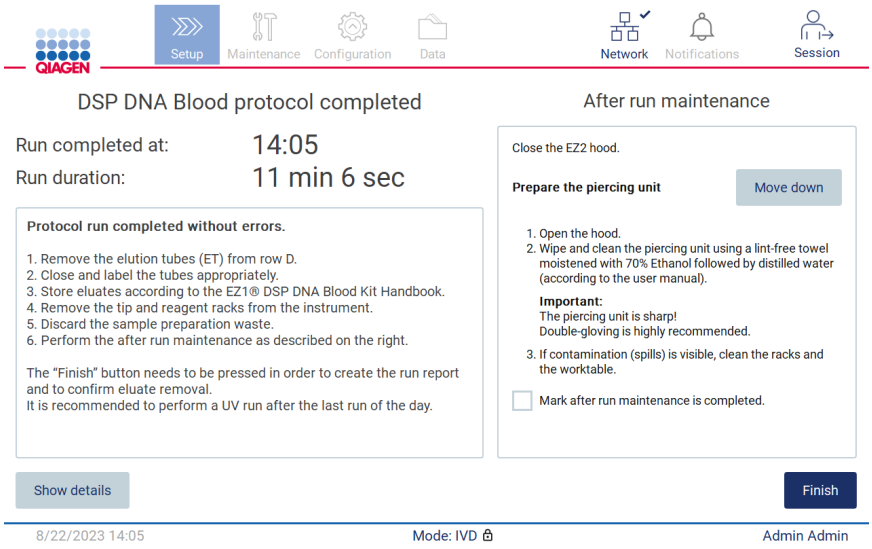



**Figure 129. Protocol run competed screen.**

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

At the end of a protocol run, you must remove the labware. To do so, follow the steps below:

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 carry over 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 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.

| CAUTION | **Hazardous materials and infectious agents**<br>The waste contains samples and reagents. This 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 the "Cleaning agents", "Disinfecting the EZ2", and "Removing contamination" sections.
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.

| CAUTION | **Hazardous materials and infectious agents**<br>The waste contains samples and reagents. This 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 the "Cleaning agents", "Disinfecting the EZ2", and "Removing contamination" sections.
8. Place the cartridge rack sections back in the instrument, followed by the tip rack.

Clean the piercing unit, see the "After run maintenance" section (page 140). 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 the "Saving a run report" section (page 115).

**Note**: Once the **Finish** button is pressed the automatic cooling after run will start (see Section 5.15). 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).

## 5.8 Saving a run report

After a run finishes successfully, fails, or is aborted, a run report will be 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 the "Run report contents" section.

### 5.8.1 Run report contents

An EZ2 run report is created by the software application after a run is completed, aborted, or if it fails, after the user taps the Finish button on the screen that is shown after a run ends.

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

## 5.9 Canceling the protocol run setup

You can cancel the protocol run setup process at any time. If you cancel the run setup, your progress is not saved, and the worktable does not move. If you have loaded anything onto the worktable, remove the labware.

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

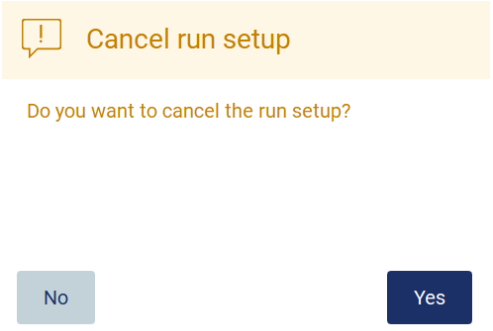



**Figure 130. The Cancel run setup dialog.**

## 5.10 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 appears.
2. Tap **Yes** to stop the run, or tap **No** to go back to the "Protocol run in progress" screen.




**Figure 131. Aborting protocol run dialog.**

3. 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/workdeck in suitable positions to support a safe clean-up procedure. After this is done, a message is shown and the Proceed to the summary button is activated. Tap **Proceed to the summary**.

   **Note**: If you tap Abort during a pause or when the machine is waiting to reach a specific temperature, the run is stopped immediately.

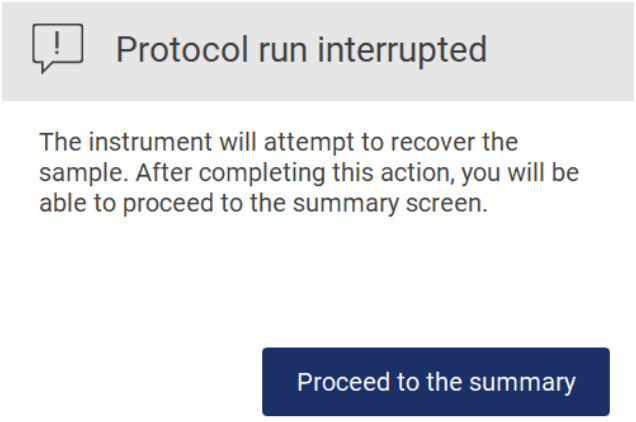



**Figure 132. Protocol run interrupted dialog.**

4. 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 the "Saving a run report" section (page 115).

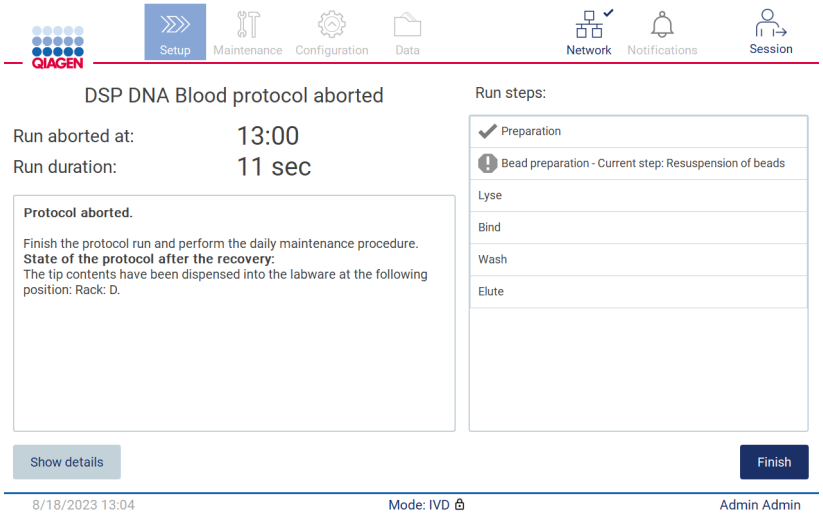



**Figure 133. Protocol run aborted screen.**

5. Also, for aborted protocol runs, the after run maintenance needs to be performed. Please follow the instructions regarding the cleaning of the piercing unit from "Daily maintenance" section (page 143).

## 5.11 LIMS Workflow

**Important**: Before using the LIMS features of the EZ2 Connect MDx for the first time it is needed to contact a QIAGEN representative. The EZ2 Connect MDx has to be integrated with existing LIMS, by setting up and configuring external service called LIMS Connector; this can be done with help from QIAGEN Service Team. To begin set up of a protocol run using the LIMS interface, start at the **Setup** tab, then tap the **LIMS** button.

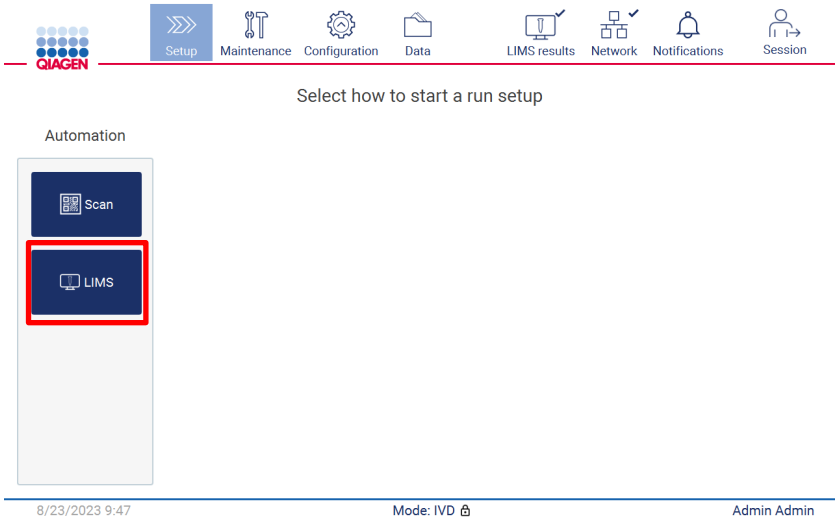



**Figure 134. Setup screen.**

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

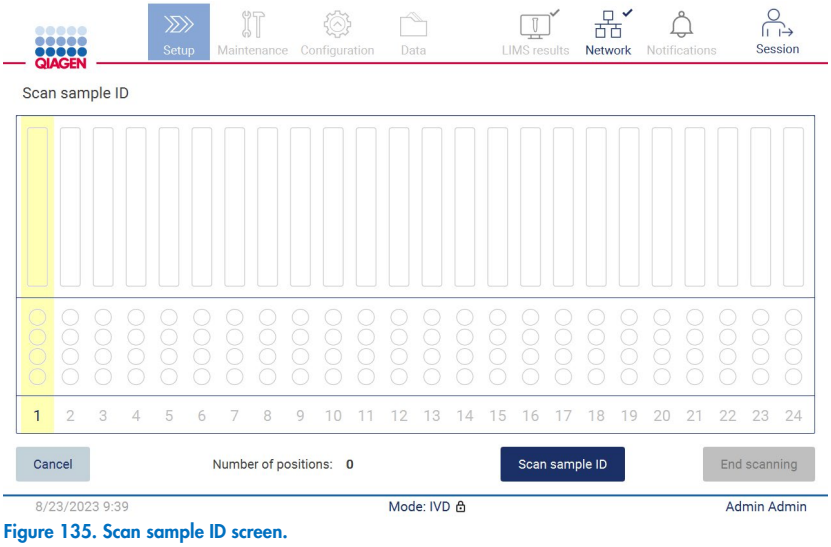



**Figure 135. Scan sample ID screen.**

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




**Figure 136. Scan or enter sample ID.**

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

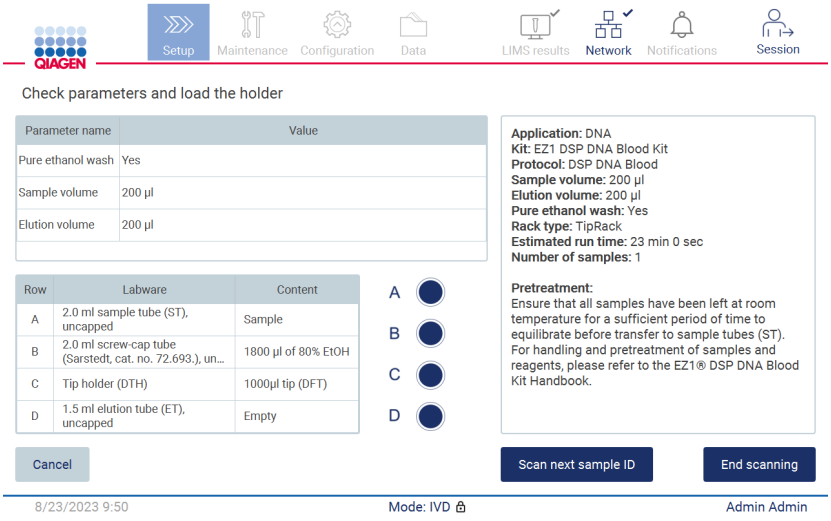



**Figure 137. Check parameters and load holder screen.**

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.

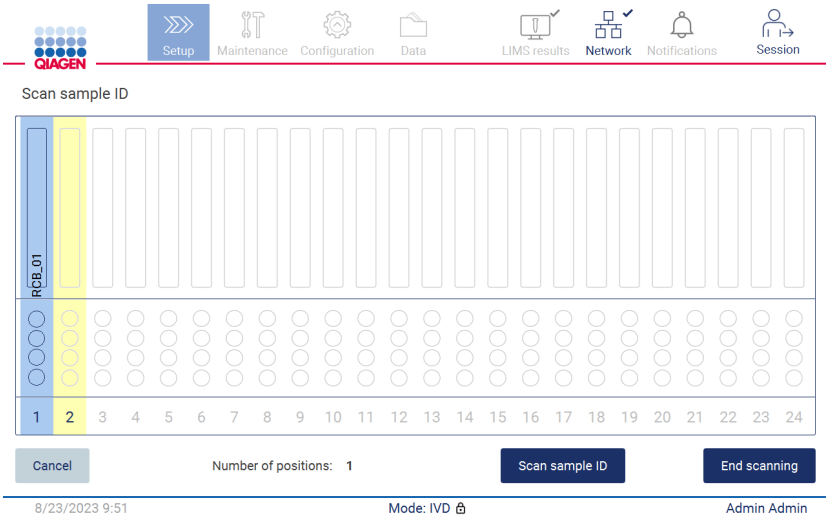



**Figure 138. Scan additional samples or proceed to next step.**

5. **Important**: Information captured in the note field will not be transmitted/transferred to LIMS. After pressing **End scanning**, the "Review collected samples" screen appears. Here, you have the option to review your setup and add notes (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.




**Figure 139. 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.

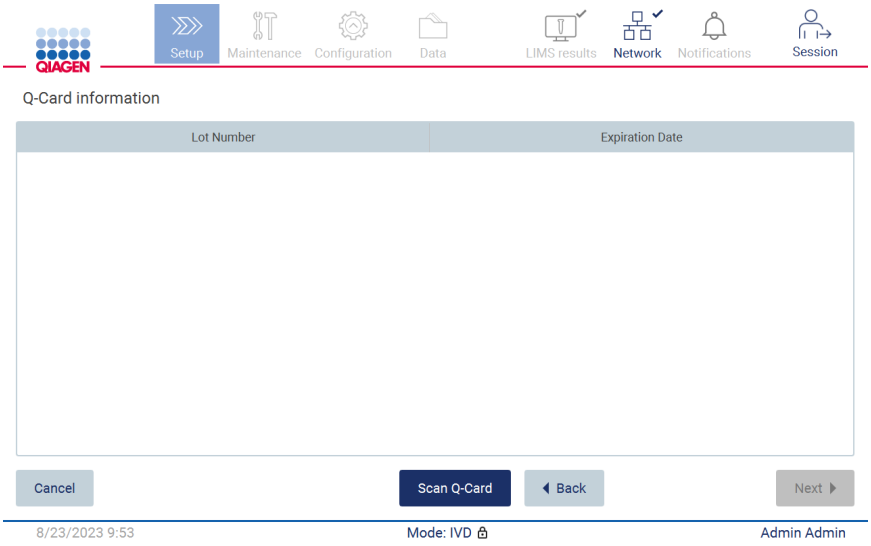



**Figure 140. Scan Q-card.**

The “Load the cartridge rack” steps feature (page 101) 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.

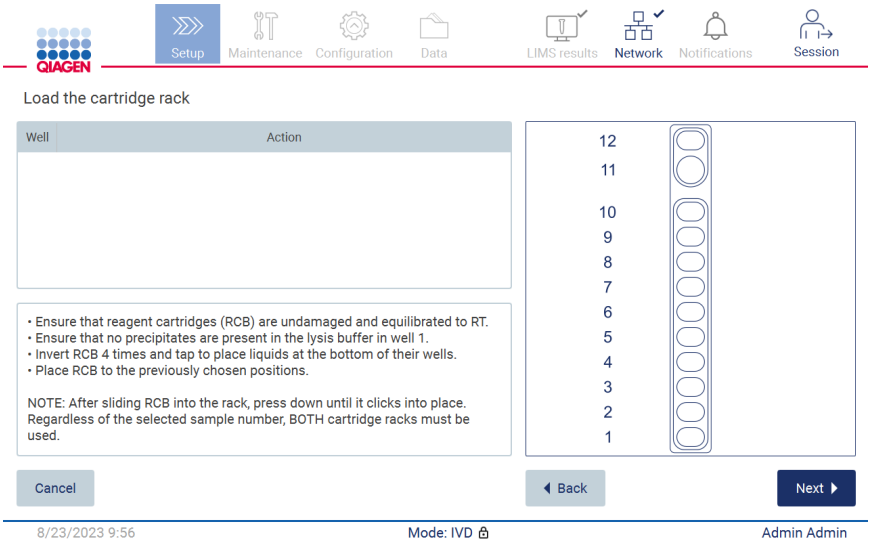



**Figure 141. Load the cartridge rack.**

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.

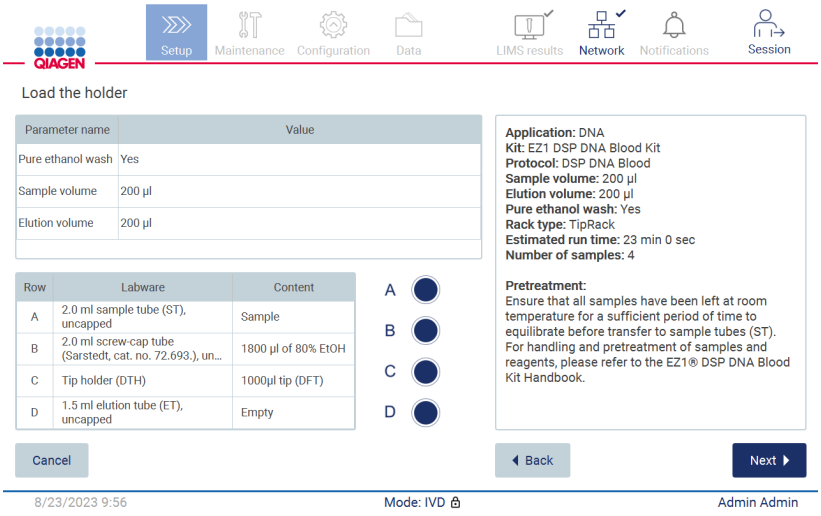



**Figure 142. Load the holder.**

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

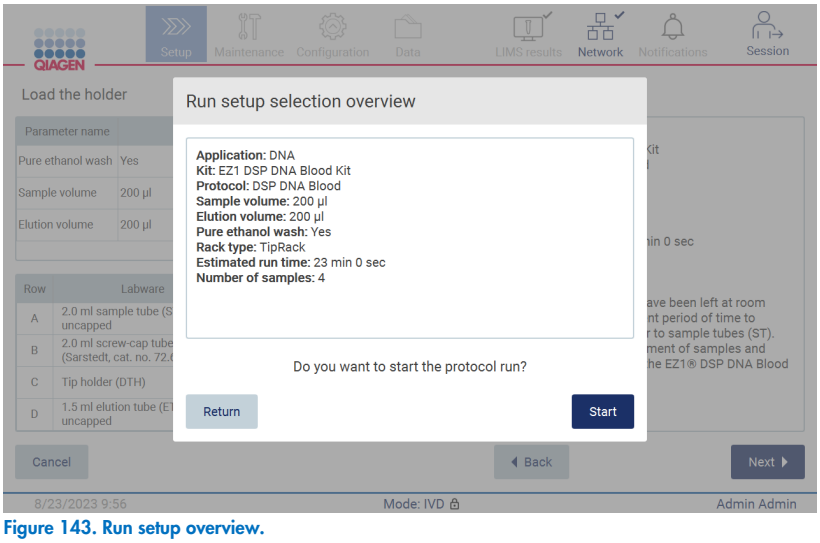



**Figure 143. Run setup overview.**

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 appears:

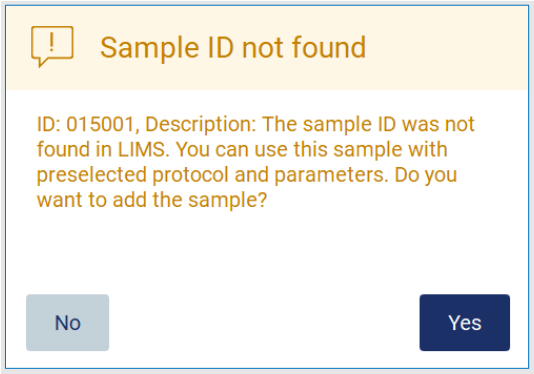



**Figure 144. LIMS Sample ID not found dialogue.**

10. To process the unknown sample along with the sample IDs found in LIMS, tap **Yes**. Previously scanned ID will be 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 5 runs, a warning message is displayed.

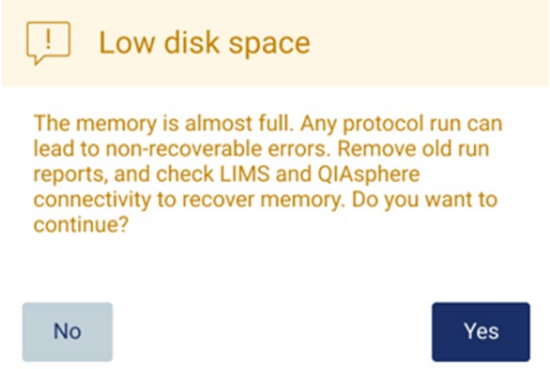



**Figure 145. Pop-up window with Low disk space after attempting to start a run.**

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

## 5.12 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 146. Data button on the toolbar.**

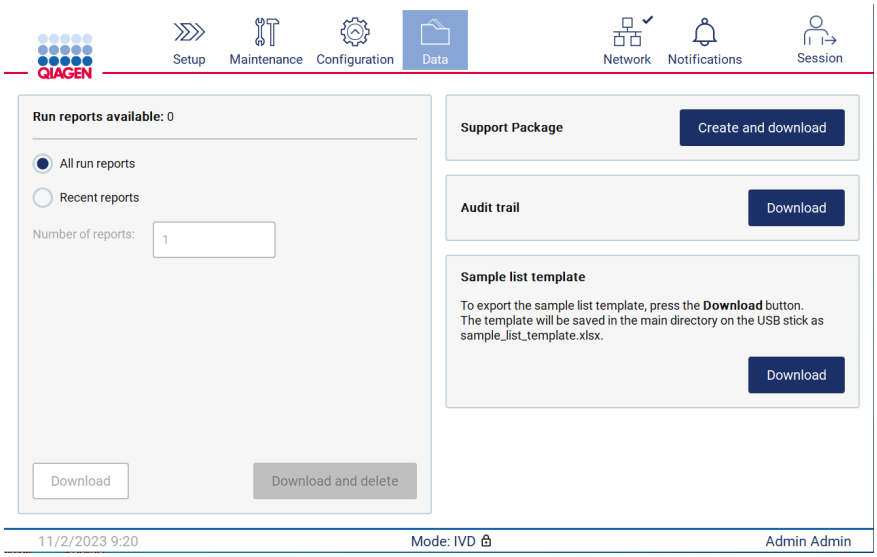



**Figure 147. Data screen.**

### 5.12.1 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.

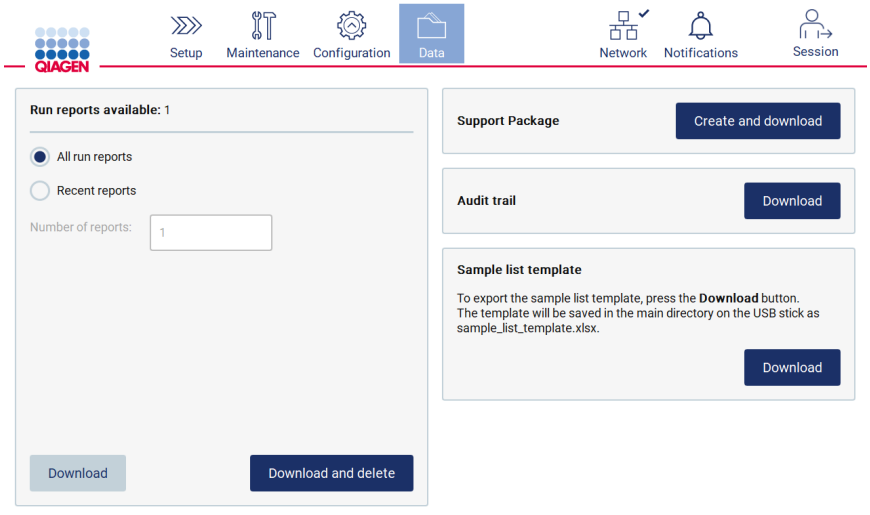



**Figure 148. Data tab.**

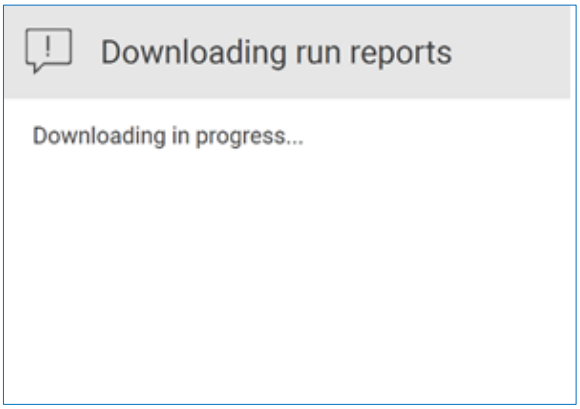



**Figure 149. Download reports in progress.**

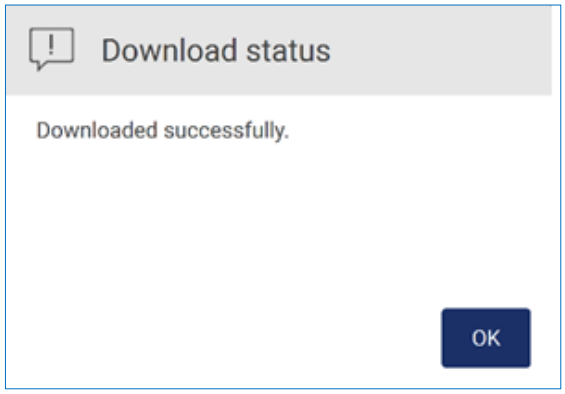



Figure 150. Report download successful.

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

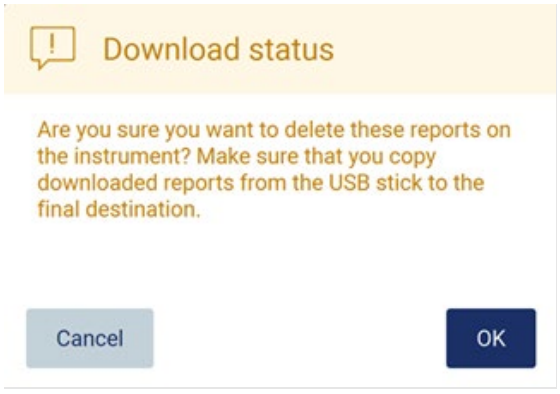



Figure 151. Confirm delete run reports.

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.

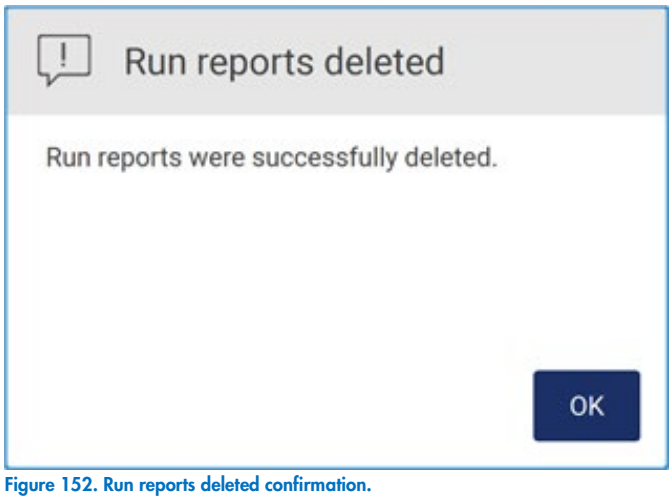



Figure 152. Run reports deleted confirmation.

Tap **OK** to complete process.

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

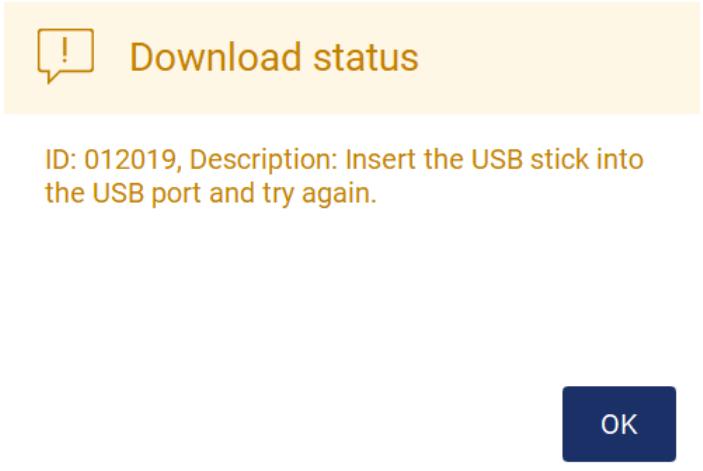



Figure 153. USB drive not inserted.

Insert a USB drive and attempt the process again.

### 5.12.2 Support package

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

### 5.12.3 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:

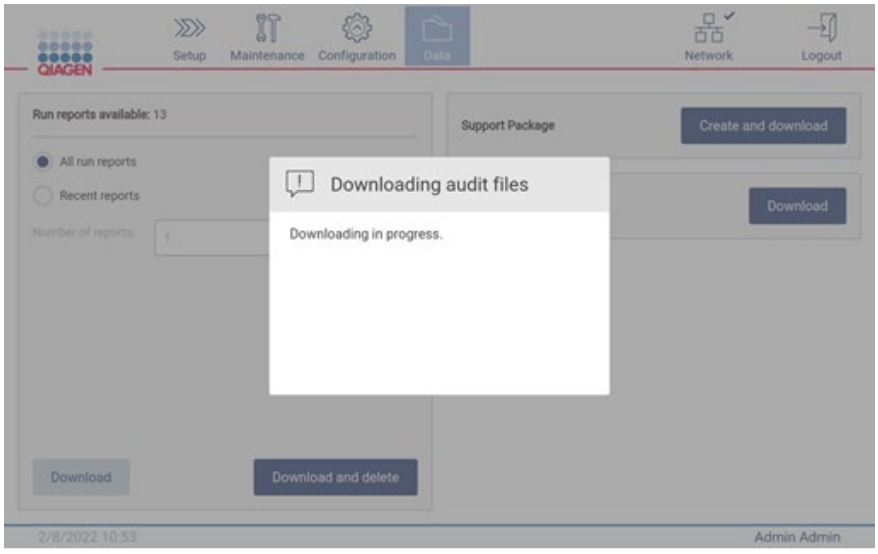



**Figure 154. Download audit trail in progress.**

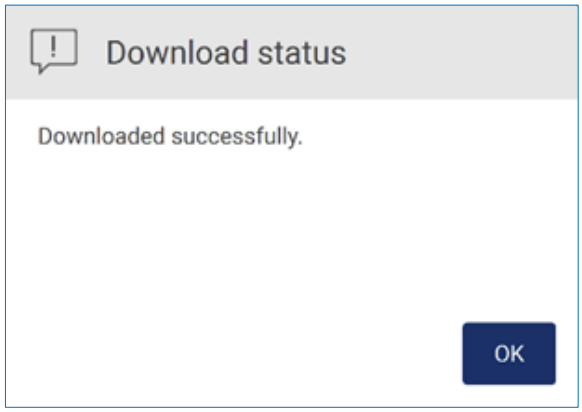



**Figure 155. Audit trail download successful.**

If no USB drive is inserted the following is displayed:

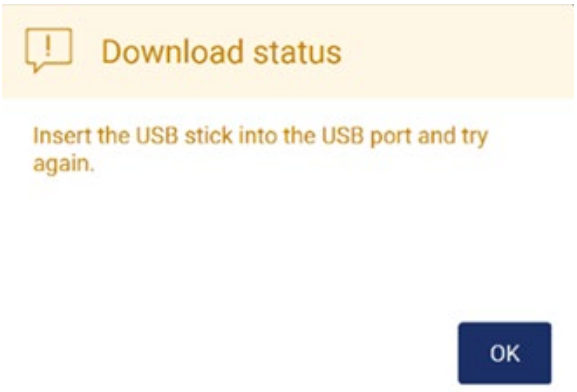



**Figure 156. USB drive not inserted.**

Insert a USB drive and attempt the process again.

## 5.12.4 Sample list template

The sample list template is a .xlsx file which can be used to pre-define 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 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.

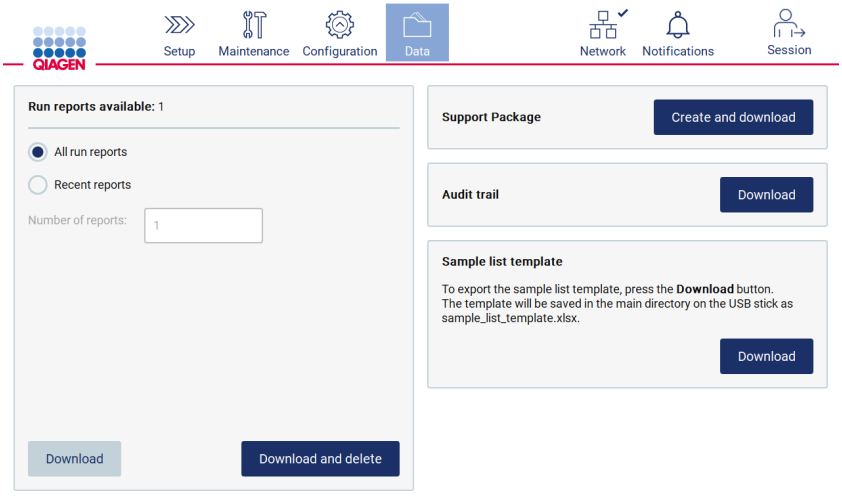



**Figure 157. Data screen.**

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

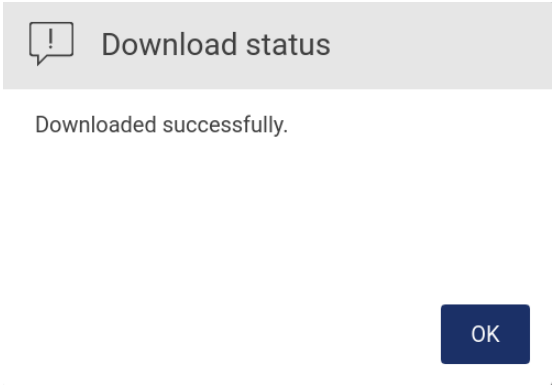



Figure 158. Download successful pop-up window.

3. Use an external PC with a spreadsheet calculation software to open and edit the template.
4. 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 159. Sample list template.

## 5.13 Session handling

Tap the **Session** button to open the Session handling window (Figure 160). The Session handling dialog offers two options: **Screen Lock** and **Logout** (Figure 161).

**Screen Lock** 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, or 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 160. Location of the Session button.

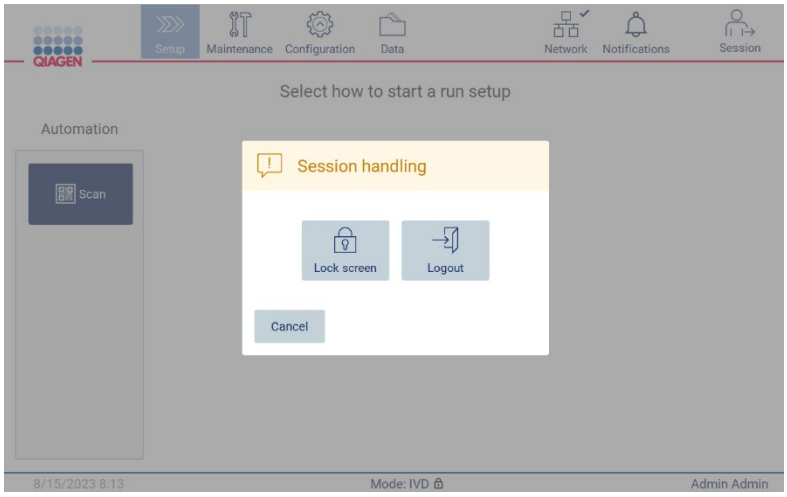



Figure 161. Session handling dialog window.

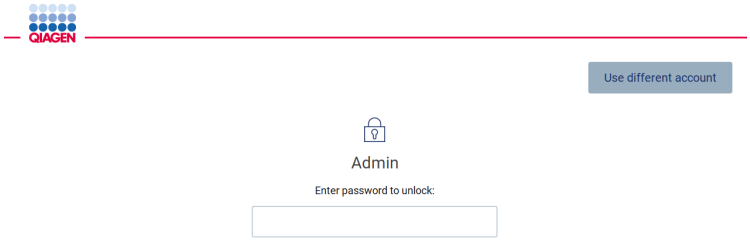



Figure 162. Lock screen.

## 5.14 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.

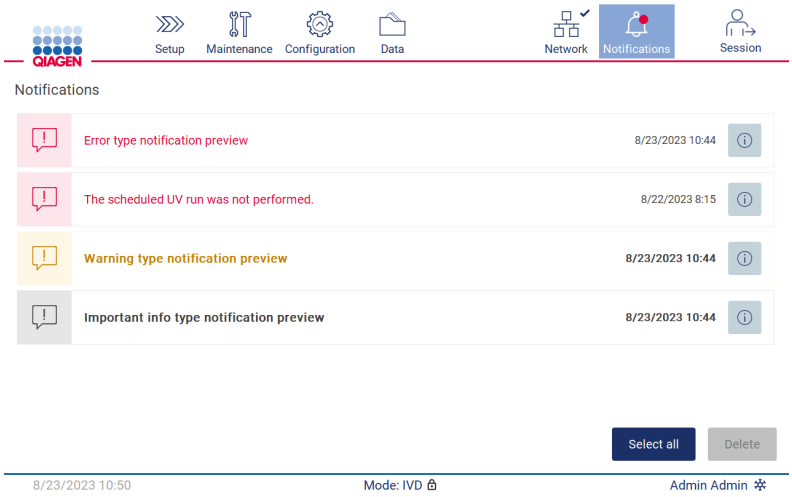



**Figure 163. Notification center.**

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

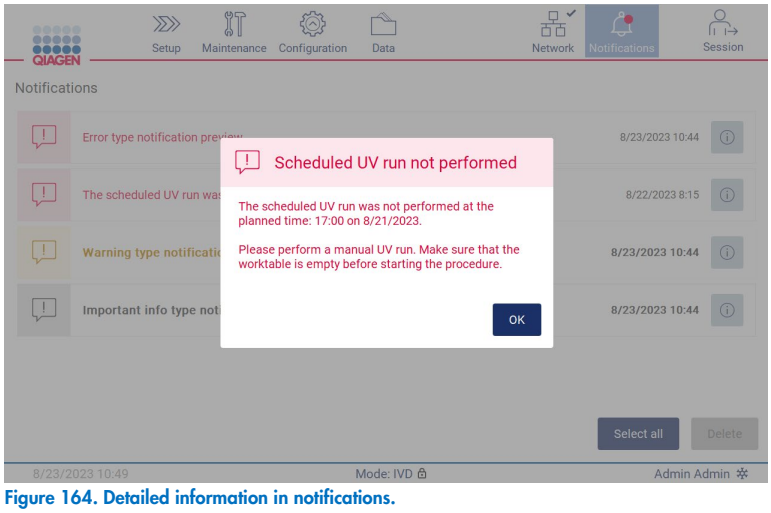



**Figure 164. Detailed information in notifications.**

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.

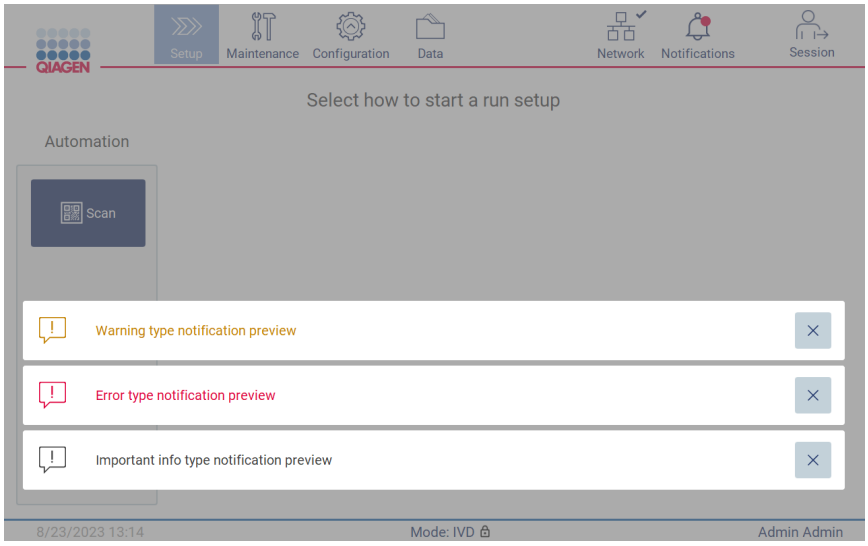



**Figure 165. Notification banners on the startup page.**

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**.

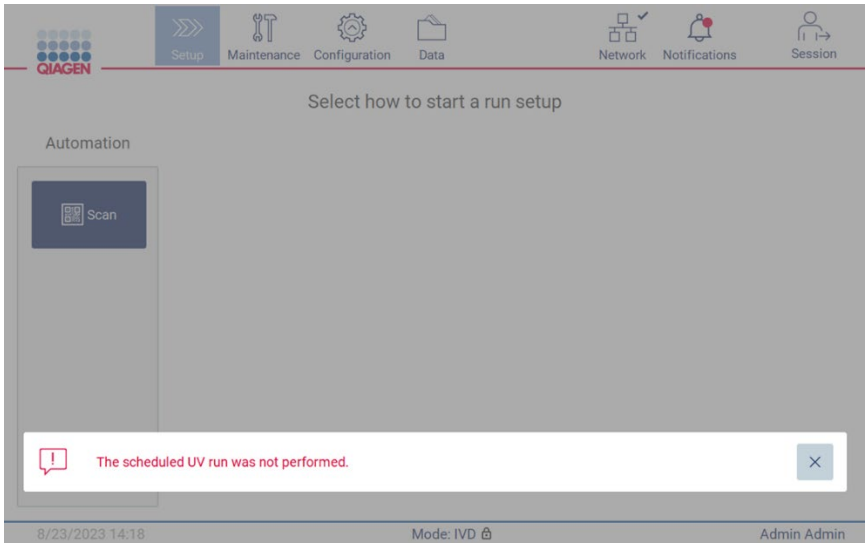



**Figure 166. Background task banner.**

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

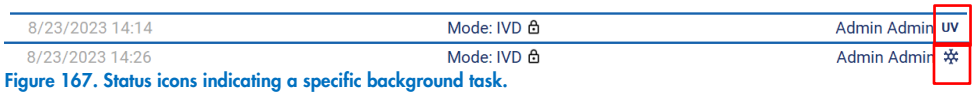



**Figure 167. Status icons indicating a specific background task.**

## 5.15 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 will start 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.

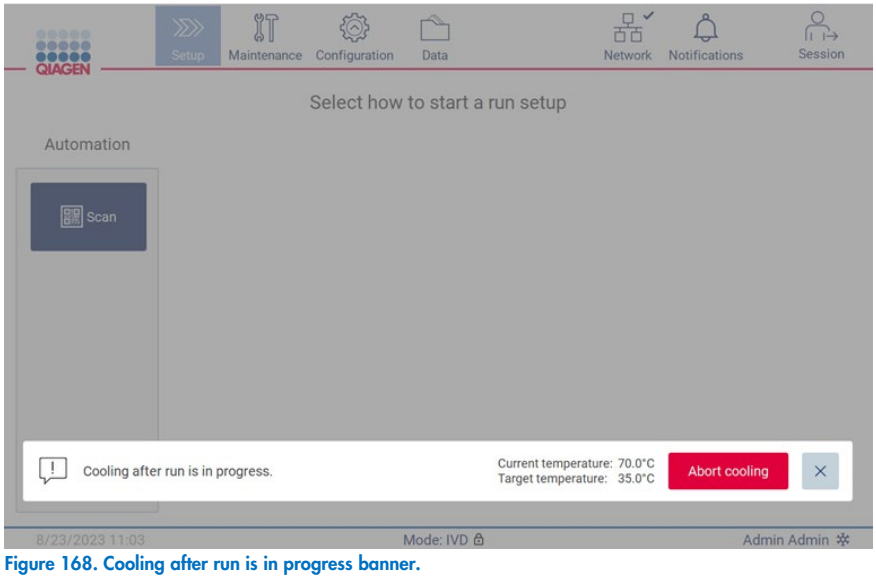



**Figure 168. Cooling after run is in progress banner.**

**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.
The cooling can be aborted when there is a timeout or by tapping **Abort cooling**.

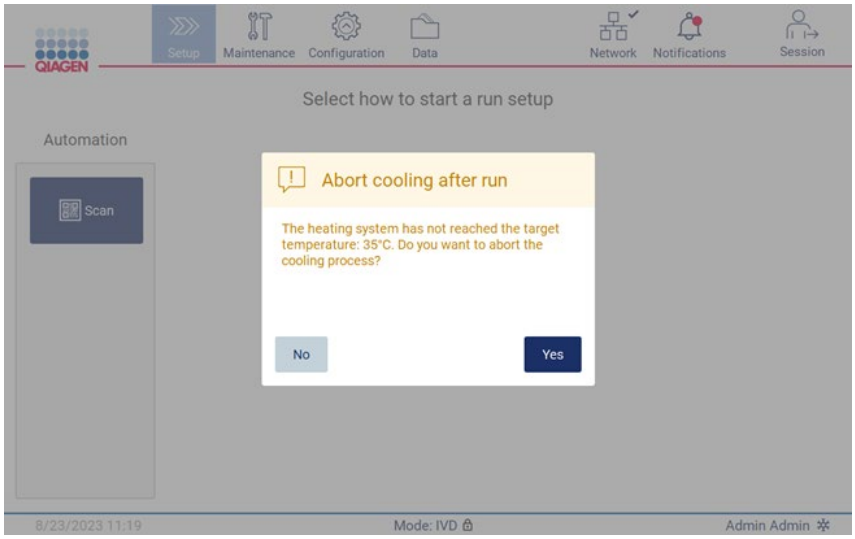



Figure 169. Pop-up window with aborted cooling after run.

# 6 Maintenance Procedures

| WARNING/ CAUTION | **Risk of personal injury and material damage**<br>Only perform maintenance that is specifically described in this user manual. |
|---|---|

To ensure reliable operation of the EZ2, 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.<br>Note: Perform this procedure after you are done with the after run maintenance. | Laboratory technicians or equivalent |
| Weekly maintenance | Once a week.<br>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 Service). | QIAGEN authorized Service Specialists only |

Optionally, a UV decontamination procedure may be performed as required to support pathogen and nucleic acid decontamination. See “UV decontamination” section (page 149) 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.

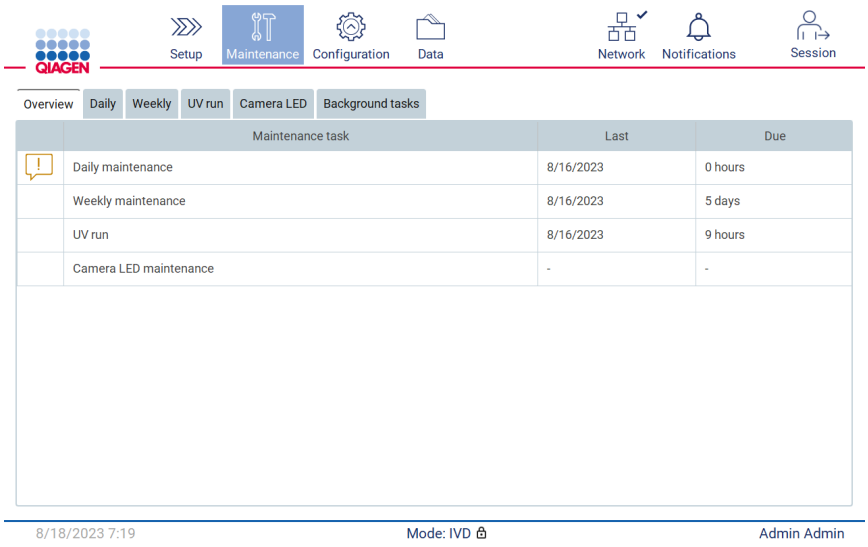



**Figure 170. Maintenance overview.**

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 171). A scheduled UV run is indicated by a UV sign.

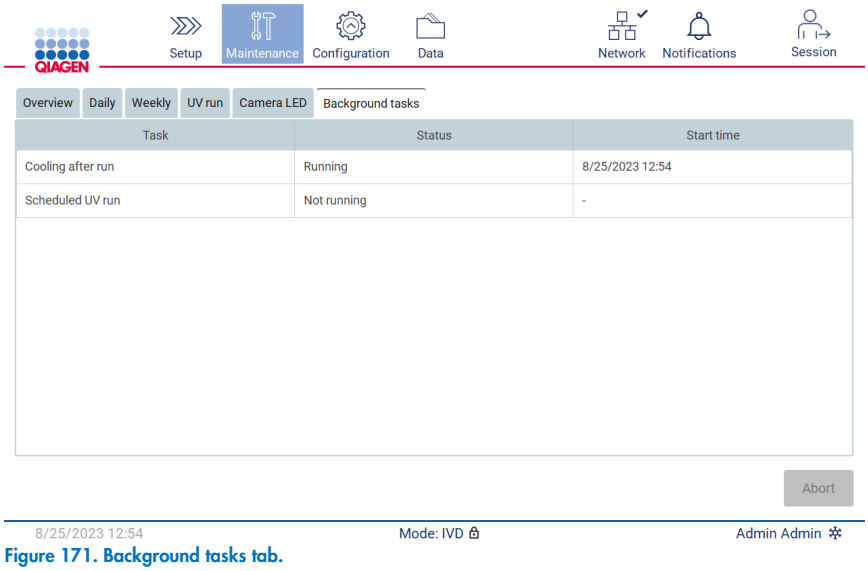



**Figure 171. Background tasks tab.**

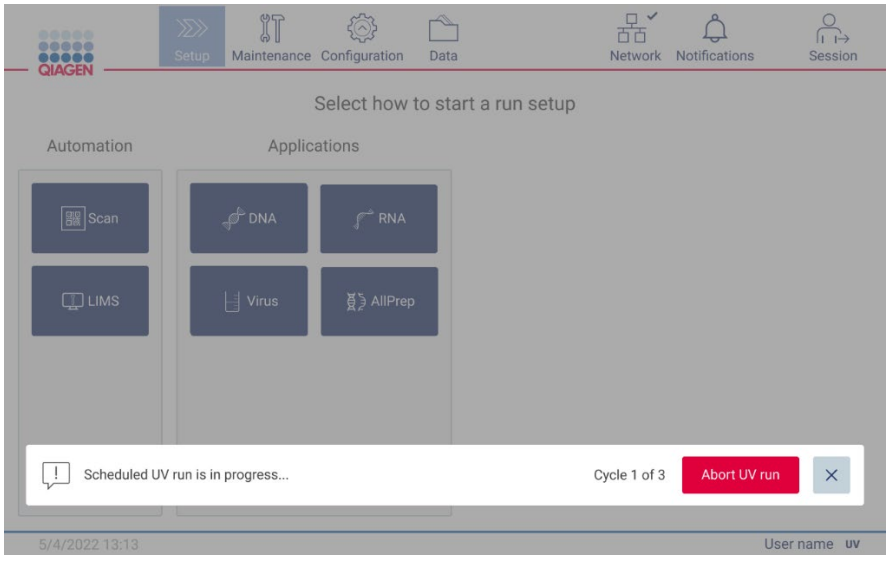



**Figure 172. Scheduled UV run is running.**

## 6.1 Cleaning agents

The surfaces and removable parts of the EZ2 must be cleaned and disinfected with compatible detergents and disinfectants. Please 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, do not use them.

General cleaning of the EZ2, 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**<br>Do not use bleach to clean or disinfect the EZ2 or used labware. Bleach in contact with salts from the buffers can produce toxic fumes. |

| | |
|---|---|
| **CAUTION**  | **Damage to the instrument**<br>Do not use spray bottles containing alcohol or disinfectant to clean surfaces of the EZ2. Spray bottles should be used only to clean items that have been removed from the worktable and if permitted by local laboratory operating practices. |

| | |
|---|---|
| **WARNING**  | **Risk of fire**<br>Do not allow cleaning fluid or decontamination agents to come into contact with the electrical parts of the EZ2. |

| WARNING | **Risk of electric shock**<br>Do not open any panels on the EZ2.<br><br>**Risk of personal injury and material damage**<br>Only perform maintenance that is specifically described in this user manual. |
|---|---|

| WARNING | **Risk of fire or explosion**<br>When using ethanol or ethanol-based liquids to clean the EZ2, handle such liquids carefully and in accordance with the required safety regulations. If any liquid spills, wipe it off and leave the EZ2 hood open to allow flammable vapors to disperse. |
|---|---|

### 6.1.1 Disinfecting the EZ2

Ethanol-based disinfectants can be used for disinfecting surfaces such as the worktable. An example of ethanol-based disinfectant are the Mikrozid Liquid (Mikrozid Liquid consists of 25 g ethanol and 35 g 1-propanol per 100 g) or Mikrozid AF wipes. These are available from Schülke & Mayr GmbH, see (e.g., cat. no. 109203 or 109160). For countries where Mikrozid 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 phenoxypropanols, 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**<br>Do not use spray bottles containing alcohol or disinfectant to clean surfaces of the EZ2. 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 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.

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

Servicing of the EZ2 must only be performed by QIAGEN Field Service specialists.

| | |
|---|---|
| **WARNING**  | **Moving parts**<br>To avoid contact with moving parts during the operation of the EZ2, the instrument must be operated with the hood closed.<br>If the hood sensor or lock is not functioning correctly, contact QIAGEN Technical Services. |

| | |
|---|---|
| **WARNING**  | **Moving parts**<br>Avoid contact with moving parts during operation of the EZ2. Under no circumstances should hands be placed under the pipetting arm 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**<br>Improper use of the EZ2 may cause personal injuries or damage to the instrument. |

| WARNING  | **Samples containing infectious agents**<br>Some samples used with this instrument may contain infectious agents. Handle such samples with the greatest of care and in accordance with the required safety regulations.<br>Some chemicals used with the EZ2 may be hazardous or may become hazardous after completion of a purification.<br>Always wear safety glasses, gloves, and a lab coat.<br>Venting for fumes and disposal of waste must be in accordance with all national, state, and local health and safety regulations and laws. |
|---|---|

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

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

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

**Note**: You need to conduct the after run maintenance (as displayed on the GUI) before you press 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.

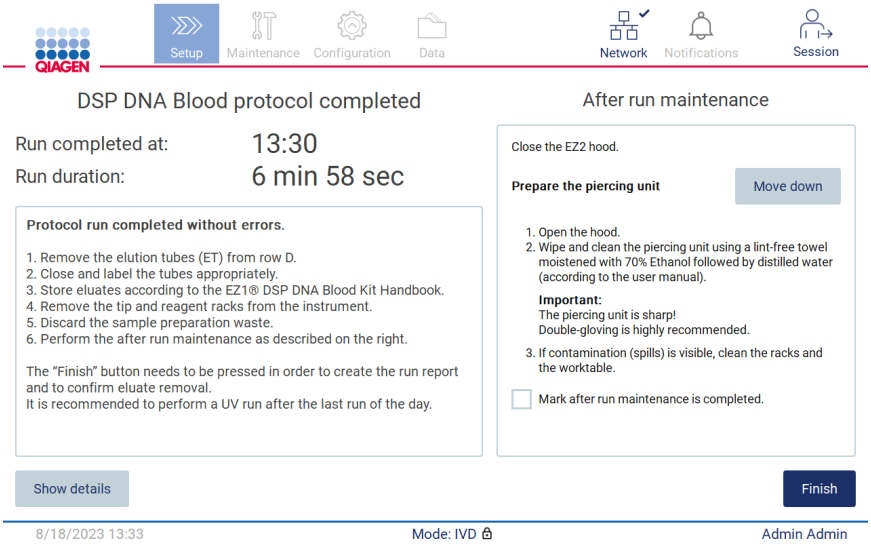



**Figure 173. Protocol run completed screen.**

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 174. Cleaning the EZ2 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**<br>To avoid contact with moving parts during the operation of the EZ2, the instrument must be operated with the hood closed.<br>If the hood sensor or lock is not functioning correctly, contact QIAGEN Technical Services |

| | |
|---|---|
| **WARNING**  | **Moving parts**<br>Avoid contact with moving parts during operation of the EZ2. Under no circumstances should hands be placed under the pipetting arm 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**<br>Improper use of the EZ2 may cause personal injuries or damage to the instrument. |

| | |
|---|---|
| **WARNING**  | **Samples containing infectious agents**<br>Some samples used with this instrument may contain infectious agents. Handle such samples with the greatest of care and in accordance with the required safety regulations.<br>Some chemicals used with the EZ2 may be hazardous or may become hazardous after completion of a purification.<br>Always wear safety glasses, gloves, and a lab coat.<br>Venting for fumes and disposal of waste must be in accordance with all national, state, and local health and safety regulations and laws. |

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

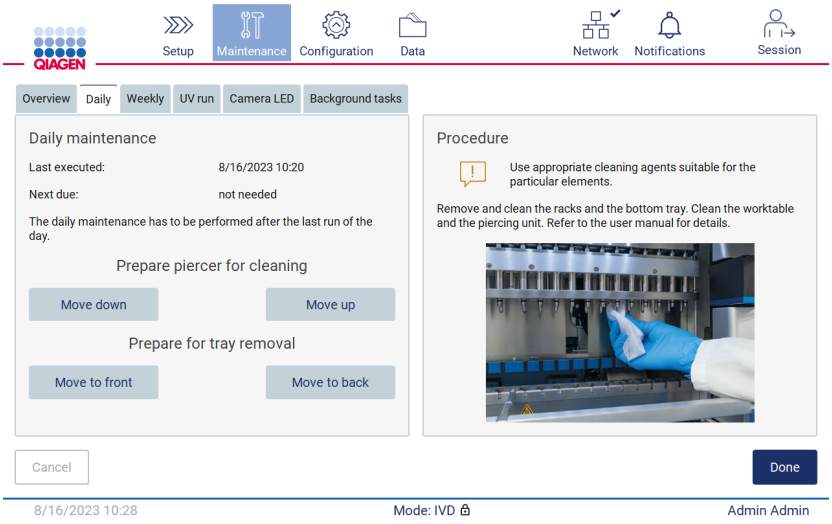



**Figure 175. Daily maintenance screen.**

3. Put on gloves.
4. Clean the piercing unit (if this is not yet done during after run maintenance).
   4a. To prepare the piercing unit for cleaning, tap **Move down**.
   4b. Open the hood.
   4c. Clean the piercing unit as recommended for “After run maintenance” (see page 140).
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**: Left 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 right bottom tray must be inserted first.

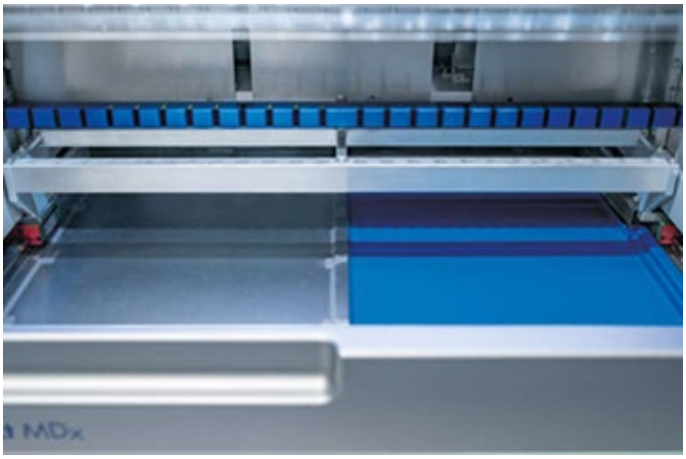


Figure 176-A. Right side of the bottom tray installed.



Figure 176-B. Installing left side of the bottom tray.

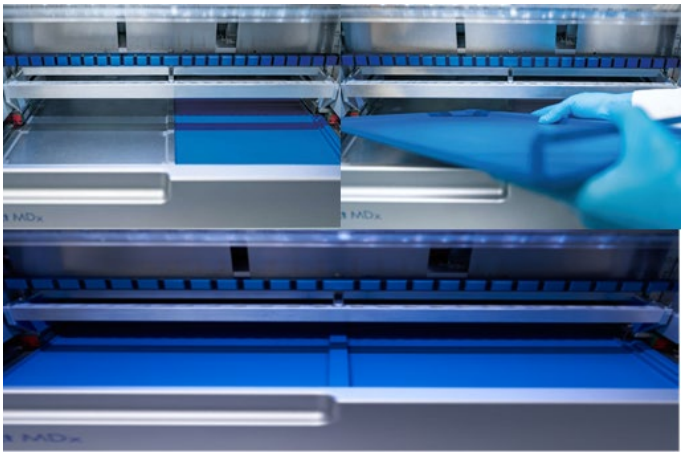


Figure 176-C. Correct installation of the bottom trays.

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**<br>Improper use of the EZ2 may cause personal injuries or damage to the instrument. |

| | |
|---|---|
| **WARNING**  | **Samples containing infectious agents**<br>Some samples used with this instrument may contain infectious agents. Handle such samples with the greatest of care and in accordance with the required safety regulations.<br>Some chemicals used with the EZ2 may be hazardous or may become hazardous after completion of a purification.<br>Always wear safety glasses, gloves, and a lab coat.<br>Venting for fumes and disposal of waste must be in accordance with all national, state, and local health and safety regulations and laws. |

**Important**: Before starting the weekly maintenance procedure, complete the "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 177. 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.

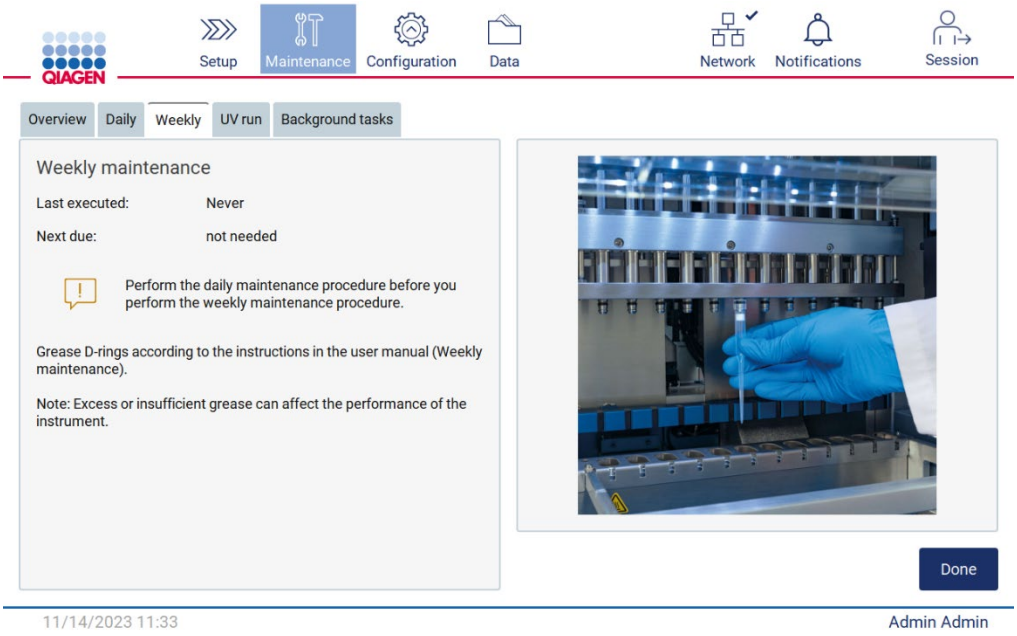



**Figure 178. Weekly maintenance screen.**

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, page 170) onto the inner wall of the large end of a fresh filter-tip by using the fine end of a second fresh tip.

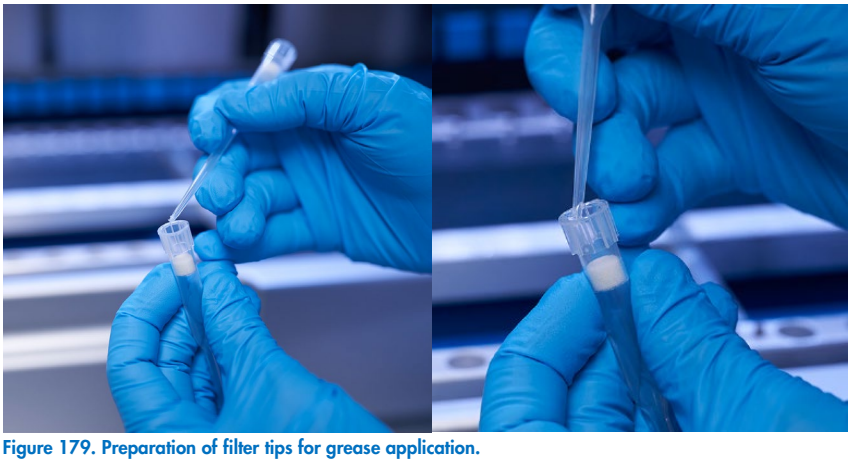


**Figure 179. Preparation of filter tips for grease application.**

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 180, below).

   **Note**: Excess or insufficient grease can affect the performance of the EZ2.

   **Note**: The opening in the nub of the pipettor should be checked after greasing to ensure no grease is present within the opening.

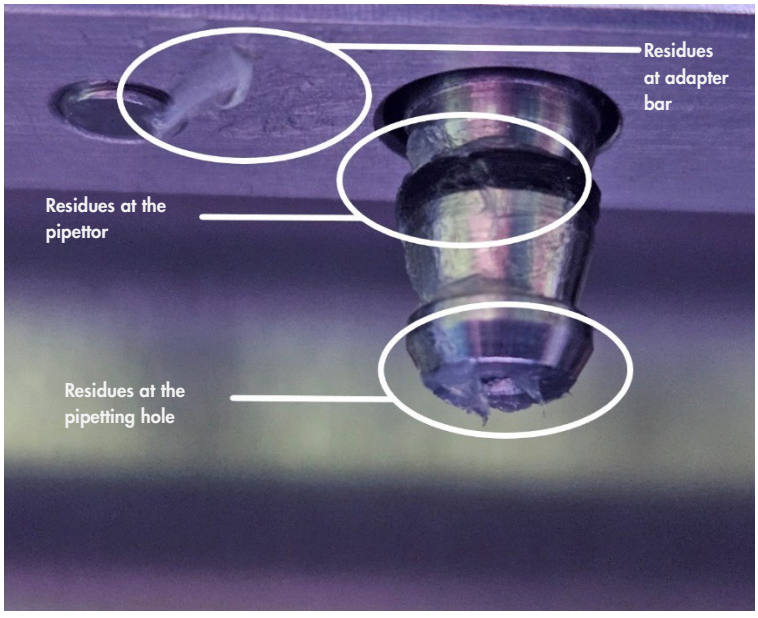



**Figure 180. Example of an overgreased tip adapter. All marked spots should be checked and all visible grease residues should be removed.**

## 6.5 UV decontamination

| | |
|---|---|
| **WARNING/ CAUTION**  | **Risk of personal injury and material damage**<br>Improper use of the EZ2 may cause personal injuries or damage to the instrument. |

| | |
|---|---|
| **WARNING**  | **Samples containing infectious agents**<br>Some samples used with this instrument may contain infectious agents. Handle such samples with the greatest of care and in accordance with the required safety regulations.<br>Some chemicals used with the EZ2 may be hazardous or may become hazardous after completion of a purification.<br>Always wear safety glasses, gloves, and a lab coat.<br>Venting for fumes and disposal of waste must be in accordance with all national, state, and local health and safety regulations and laws. |

| | |
|---|---|
| **WARNING**  | **UV radiation**<br>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.

The UV run can be set manually (for all users) or in scheduled mode (only for administrator and service users).

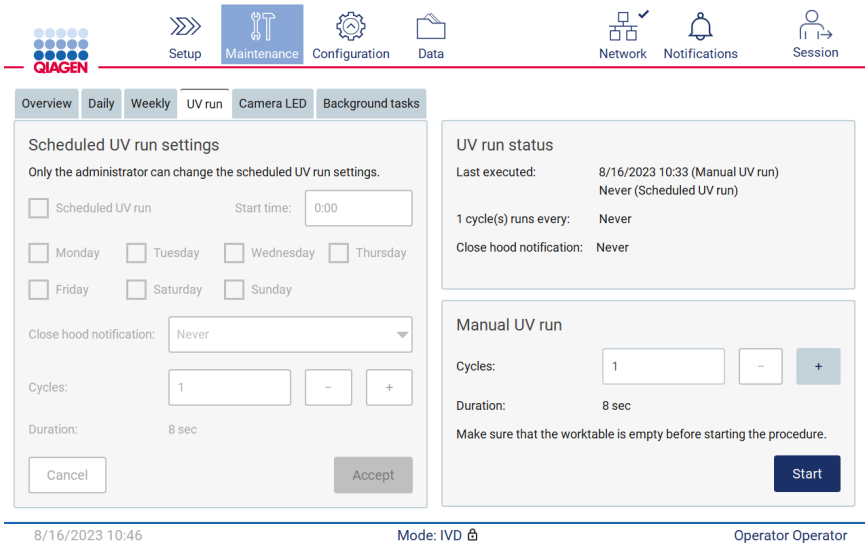



**Figure 181. UV run maintenance tab with manual UV run settings (for all user).**

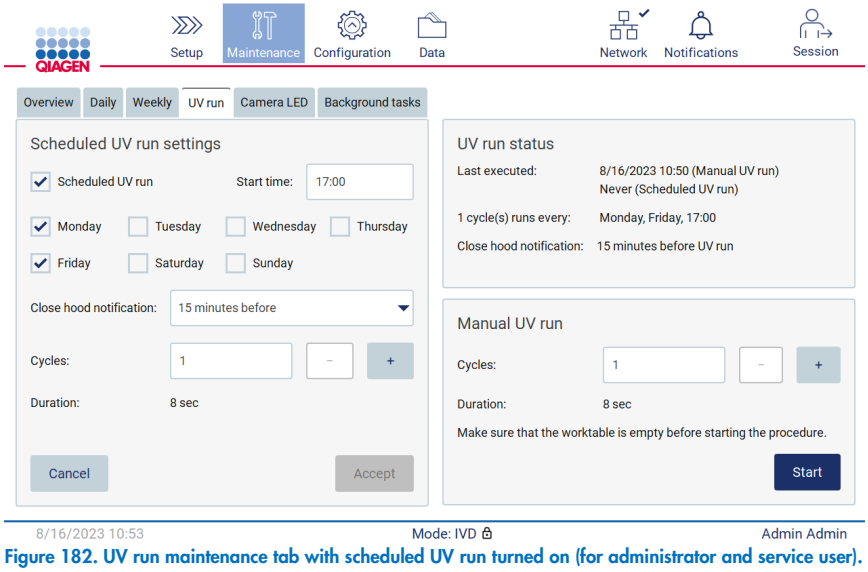



**Figure 182. UV run maintenance tab with scheduled UV run turned on (for administrator and service user).**

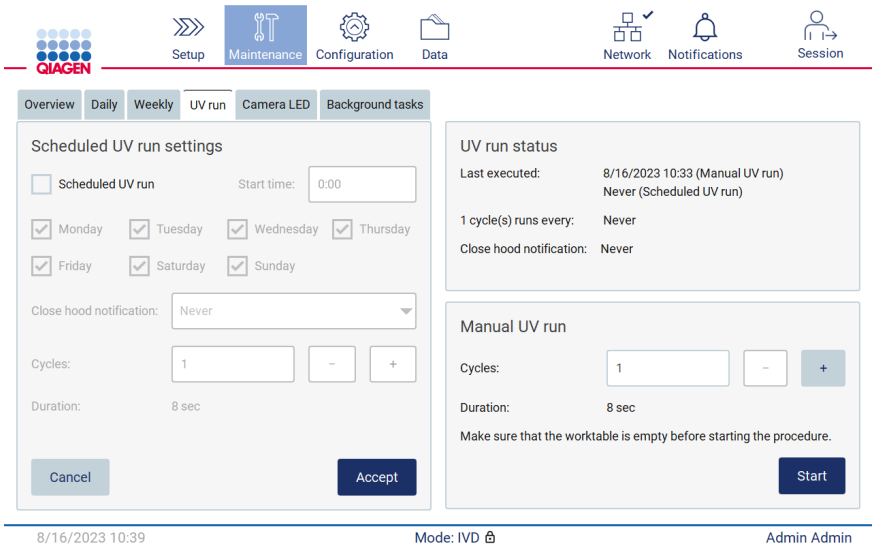



**Figure 183. UV run maintenance tab with scheduled UV run turned off (for administrator and service user).**

## 6.5.1 Manual UV run

1. Close the hood.
2. On the touchscreen, tap **Maintenance**.

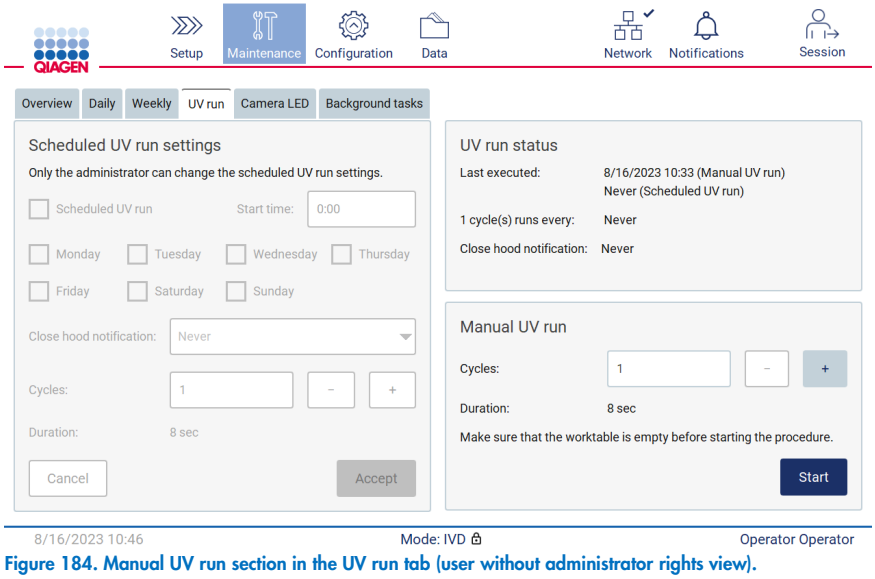



**Figure 184. Manual UV run section in the UV run tab (user without administrator rights view).**

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**.

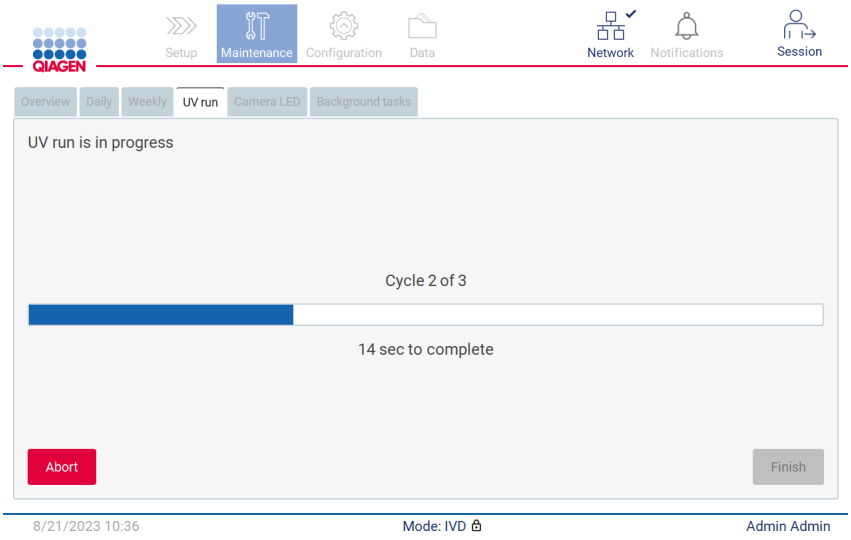



**Figure 185. UV run is in progress screen.**

6. If there is a need to abort the UV cycle prior to completion, tap the **Abort** button.

   **Important**: The UV cycle will not stop immediately upon selecting Abort; the system will need to complete the currently running step of the cycle, this can take up to 2 minutes.

7. A message (see the Figure 186 below) is displayed after execution of the UV run. Tap **Finish** to complete the UV run.

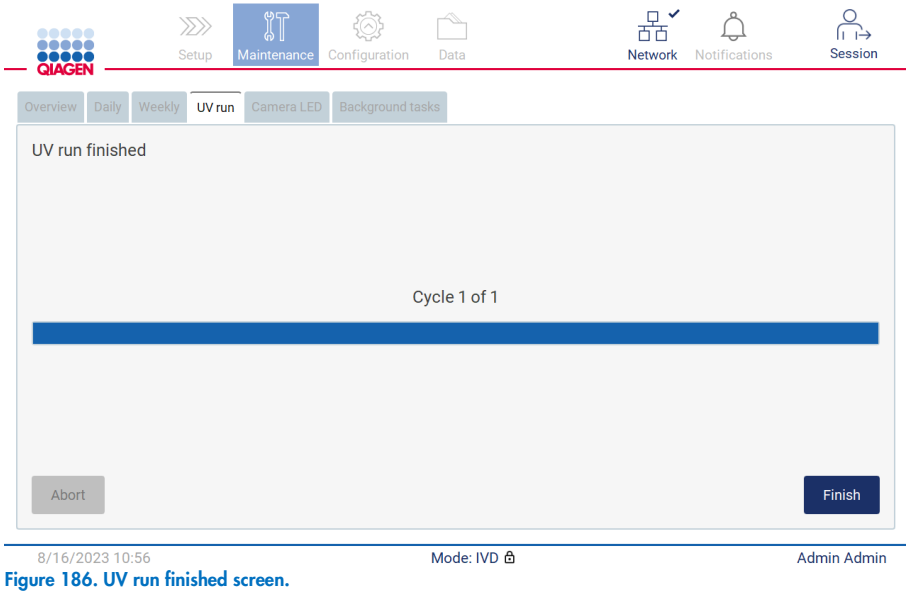



**Figure 186. UV run finished screen.**

### 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.

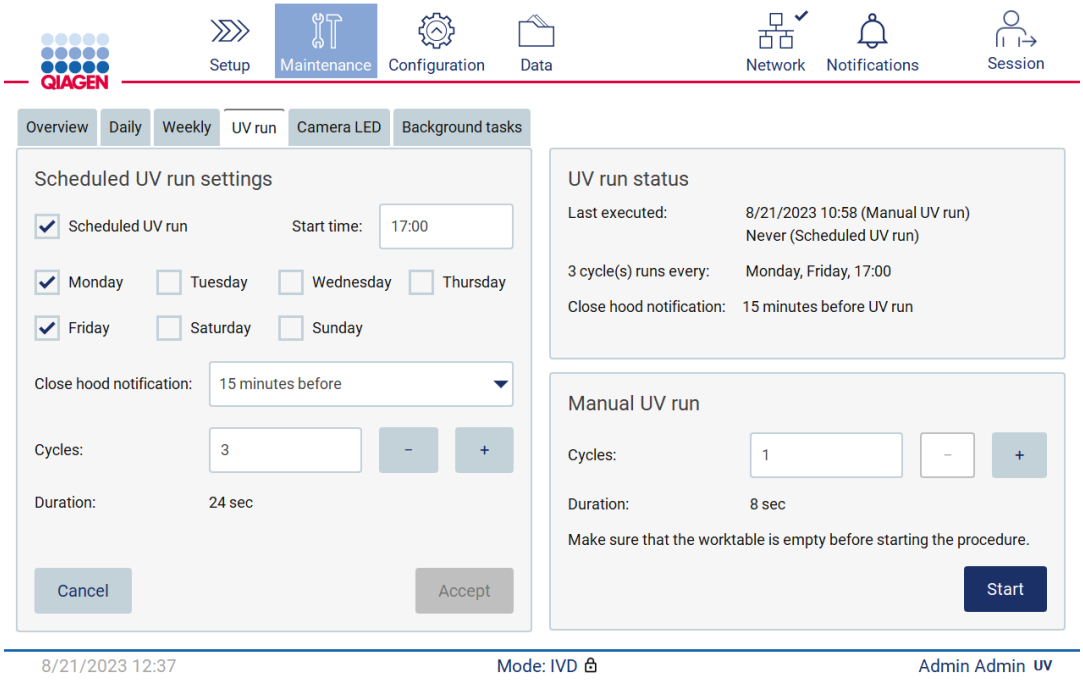



**Figure 187. Scheduled UV run settings.**

The Close hood notification will inform 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 will not be performed. The user will receive a notification that the UV run was not performed.

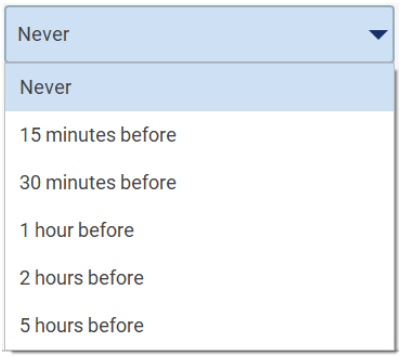



Figure 188. Timeout selection for Close hood notification.

If the Close hood notification is turned on, it will appear 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.

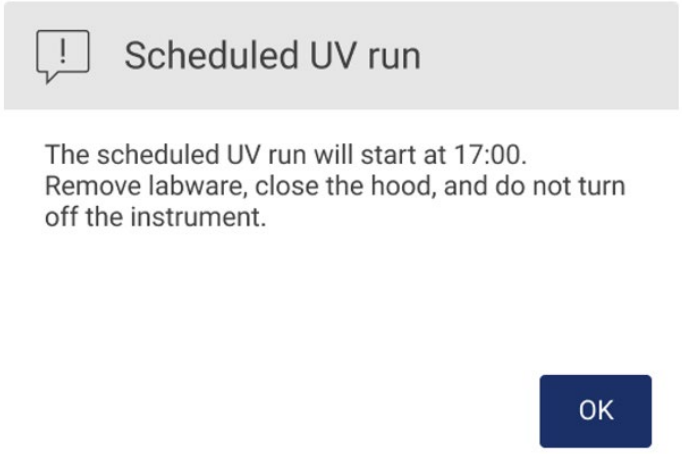



Figure 189. Close the hood notification.

When the UV run starts the scheduled UV run banner appears at the bottom of the screen. Additionally, a UV sign will appear in the lower right corner during the UV run. This sign can be tapped for more information.

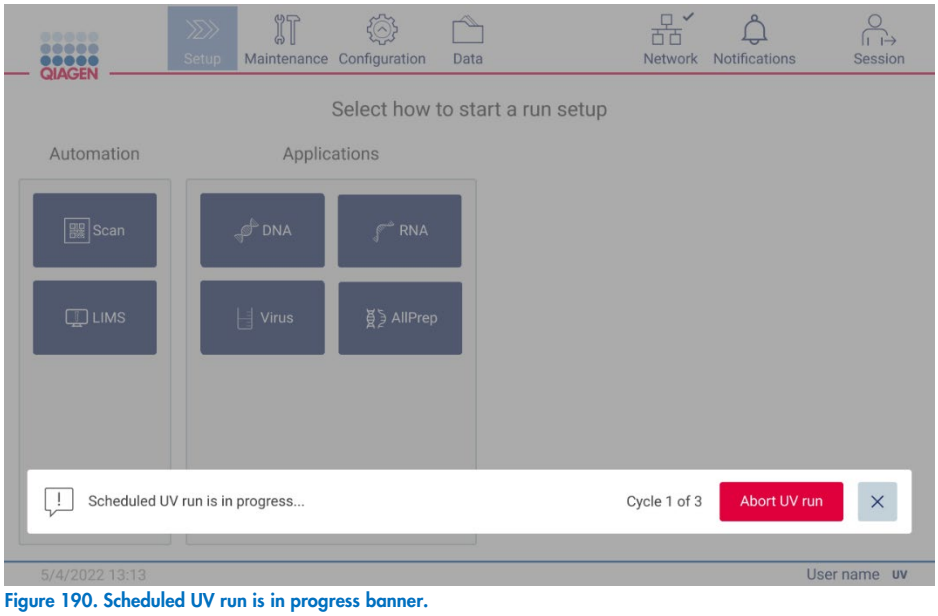



**Figure 190. Scheduled UV run is in progress banner.**

## 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**.

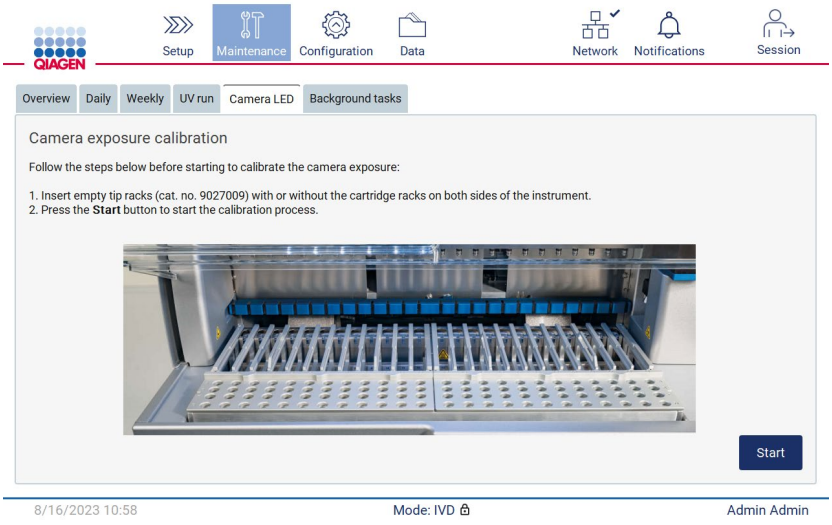



**Figure 191. Camera exposure calibration screen.**

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 will commence 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 Services 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 "Disinfecting the EZ2" and "Removing contamination" sections (pages 139 and 140, respectively).

| | |
|---|---|
| **WARNING/ CAUTION**  | **Risk of personal injury and material damage**<br>Improper use of the EZ2 may cause personal injuries or damage to the instrument. The EZ2 must only be operated by qualified personnel who have been appropriately trained.<br>Servicing of the EZ2 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 of the software (for validated IVD applications only) and the Research mode of the software (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 of the software (with MBA protocols or any customized protocols), please 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.

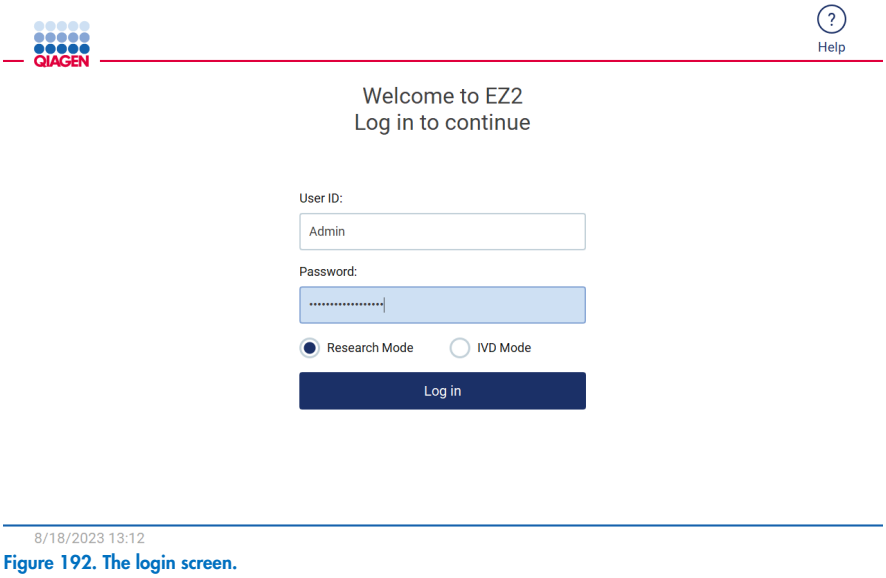



**Figure 192. The login screen.**

- A password change screen will open to request a password change after first login.
- Change your password according to the screen instructions.
- The Setup screen will open 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 will automatically display the protocol options for the corresponding kits. See the "LIMS Workflow" section (see page 118); or

- Tap an application in the Applications pane. The software will automatically proceed to the protocol selection screen.

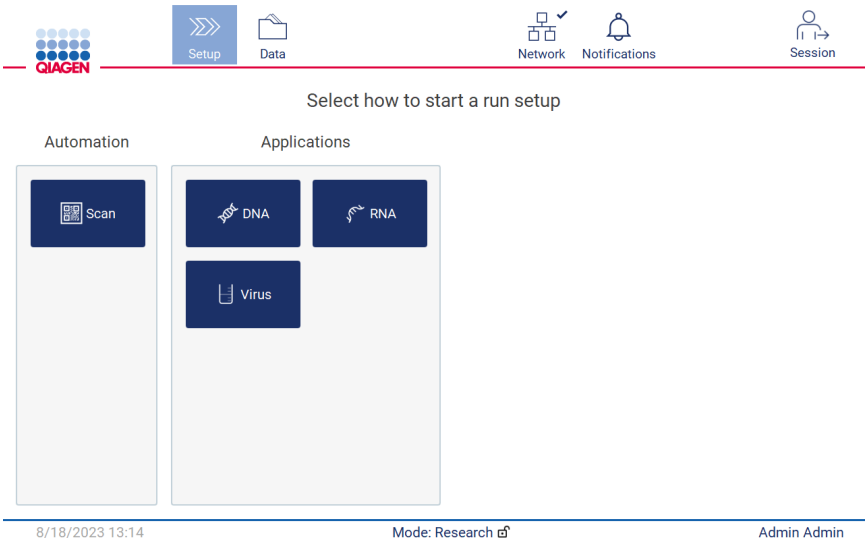



**Figure 193. Select an application screen.**

- Select a protocol and follow the instructions given on the User Interface to progress through the various steps to fully set up the protocol. See subsections within the "Setting up a protocol run" section (see page 92) 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 will 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 maintenance environment of the software is only available in IVD mode. 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.

## 8.1 Contacting QIAGEN Technical Services

Whenever encountering an EZ2 error, be sure to 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, this can be 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
- Kit name and lot number
- Photos of the error conditions (if appropriate)

This information will help you and your QIAGEN Technical Service Specialist to deal most efficiently with your issue.

Note: Information about the latest software and protocol versions can be found at **www.qiagen.com**. In some cases, updates may be available for addressing specific problems.

### 8.1.1 Creating a support package

The EZ2 can create a support package containing information about the device and the device status. This information will help QIAGEN Technical Services 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 194. Data button on the toolbar.**

4. Tap **Create and download** in the Support Package section.

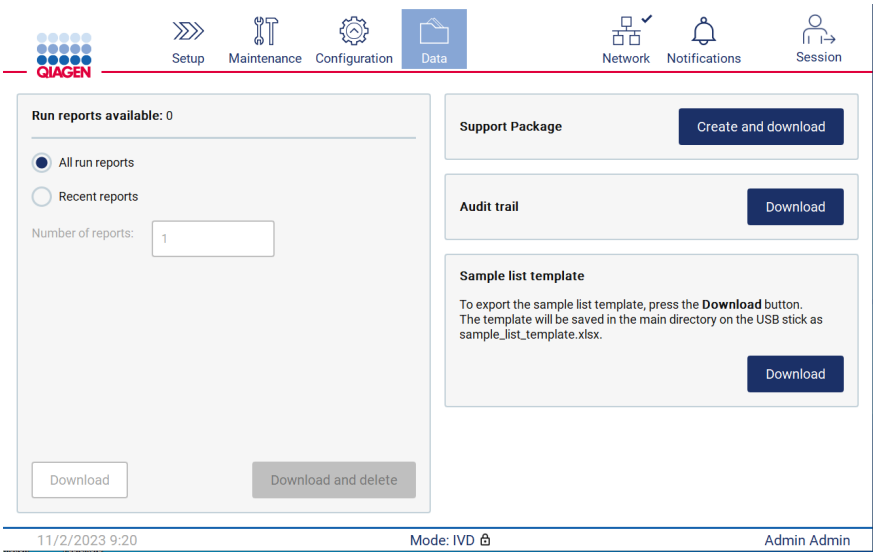



**Figure 195. Data tab.**

5. The support package is now saved on the USB stick. The download successful screen is displayed. Tap **OK** to close.

   **Note**: The support package contains information about the last performed runs and hence can contain sensitive information (e.g., sample IDs).

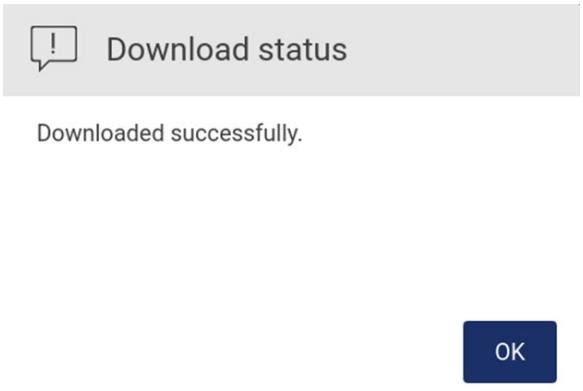



**Figure 196. Download successful status.**

6. If creation of the support package is not possible, the screen below is displayed and the creation should be attempted again.

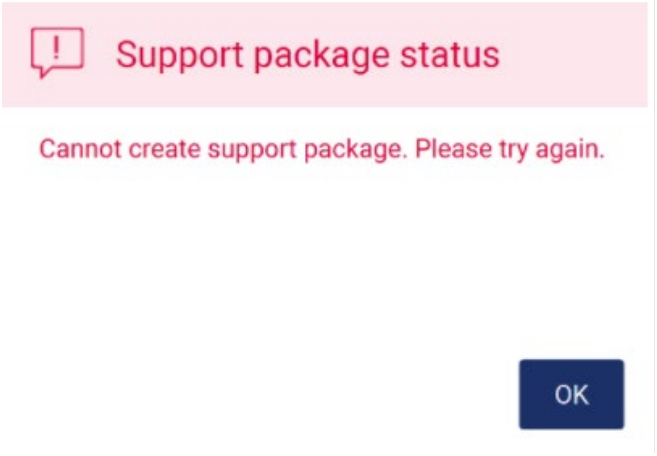



**Figure 197. Support package creation failure status.**

**Note**: The support package contains information about the last performed runs and hence can contain sensitive information.

## 8.2 Operation

| | Comments and suggestions |
|---|---|
| Load check failed | Perform camera exposure calibration according to Section 4.3.6.<br>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 of the same type rack is used. Racks have to be the same type.<br>Check if there is no contamination (e.g., drops) on the labware.<br>**Note**: Avoid strong environmental light changes and direct sunlight.<br>Exchange failing consumable with a different new consumable.<br>Perform load check again. |
| Restricted Mode | In case the instrument turns into restricted mode, the functionality is limited. It is not possible to start a protocol run in this mode. It is still possible to download a support package to support the troubleshooting procedure. One possible root cause is that the hood was not properly closed. In that case ensure that the hood was closed properly by pressing it down with light force and restart the device. |
| Filter insight the tips is dirty / wet | Dirty / wet filter can be caused by:<br>o Incorrect Sample volume: Ensure the used sample volume is according to the protocol instructions<br>o Incorrect Sample pre-treatment: Pre-treat samples according to the kit handbook<br>o Sample condition (clotted, thick, etc.): According to the kit handbook<br>o Incorrect tubes: Just use the tubes delivered with the kit or explicitly mentioned in the kit handbook / loading screen<br>If the liquid passed through the filter, please reach out to QIAGEN Technical Services. |
| Hood lock Error | Check if the hood is firmly closed. Confirm by pressing down the hood with light force. |
| Heater Fuse Error | Please install the latest software update. If software update is not possible, ensure that the hood is closed during start up and restart the device. If error still persists contact QIAGEN Technical Services. |

| | Comments and suggestions |
|---|---|
| Pipetting tips sticking to pipettor | Use lab tissue to wipe the D-rings and make sure weekly maintenance was performed correctly. There should be no visible grease residues after the weekly maintenance. Eventually remove grease residues with a lint free tissue. Check and clean all positions shown in Figure 180. |
| Pipette tip was crushed | Pipetting tip may stick to pipettor. See “pipetting tip sticking to pipettor”. Ensure that correct and compatible tubes were used. Tubes from the appropriate kit or tubes that are specified by the kit handbook shall be used. Check the worktable set up and tip rack type. |
| Imprecise pipetting | If imprecise pipetting appears over several runs (elution volume): Make sure weekly maintenance was performed. Check if the tips sit firmly at the pipettor adapter. Ensure that correct sample volume was used. |
| Leaking pipette tips | Ensure weekly maintenance was performed. Install the latest protocol update package. |
| Pipette tips not picked up by pipettor | Make sure that the tip rack is not damaged and is correctly positioned on the worktable. Check if there are no grease residues at the pipette adapter. |
| Cross-contamination | Ensure maintenance was performed. Clean the piercing unit and worktable with 70% ethanol. Start UV decontamination. Make sure samples and cartridge rack were handled properly. |
| Software/protocol update fails | Restart the device and try to start the update again. Use only the QIAGEN USB stick. USB stick should stay plugged in 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 Services. |
| LAN Connection problem | Check if the ethernet cable is connected correctly. Check the LAN settings (Section 5.3.9). |
| No W-LAN connection | Check the Wi-Fi setting (Section 5.3.9). W-LAN adapter should be connected before you start the device. Reboot the device. |
| 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 Services 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. |

# 3 Glossary

| Term | Definition |
|---|---|
| Barcode reader | A handheld device that enables scanning of bar codes and conversion of them into data that is transmitted to the EZ2. |
| 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. 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. |
| EZ2 kits | Kits supplied by QIAGEN containing reagents, reagent cartridges and plasticware for use with EZ2 instruments. |
| Filter-tip | Labware that is picked up by a tip adapter during operation of the EZ2. 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 that accommodates the heating positions of the reagent cartridges and heats samples. |
| Hood | The main door at the front of the EZ2. When open, it provides complete access to the worktable. |
| Pipettor head | The component of the EZ2 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 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 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, 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 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. |

# 9 Technical Specifications

QIAGEN reserves the right to change specifications at any time.

## 9.1 Operating conditions

| | |
|---|---|
| Power | 100–240 V AC, 50/60 Hz, 1000 VA<br>Mains supply voltage fluctuations are not to exceed 10% of nominal supply voltages. |
| Fuse | AC Inlet: T4A H 250 V<br>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)<br>3M11 (IEC 60721-3-3) |
| Average noise level (over 8 hours) | Max. 70 dBA |
| IP Code (IEC 60529) | IP20 |

## 9.2 Transport conditions

| | |
|---|---|
| Air temperature | –25°C to 60°C (–13°F to 140°F) in manufacturer's package<br>**Note**: If the EZ2 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)<br>2M4 (IEC 60721-3-2) |

## 9.3 Storage conditions

| | |
|---|---|
| Air temperature | 5–40°C (41–104°F) in manufacturer's package |
| Relative humidity | 5–85% RH |
| Environmental class | 2K11 (IEC 60721-3-2)<br>2M4 (IEC 60721-3-2) |

## 9.4 Mechanical data and hardware features

| | |
|---|---|
| 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 at 60°C is ± 2°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 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 x 800 pixels. |
| Camera | Monochrome camera. The USB interface provide power and communication.<br>Sensor resolution is 0.34 MP.<br>Width: 24 mm (0.94 in)<br>Height: 34 mm (1.34 in)<br>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.<br>Supports LAN<br>If network functionality is used: the administrator must ensure that the instrument is not visible to the outside of the network |

## 9.5 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.

## 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 is equipped with an Ethernet port and a Wi-Fi USB device. The Purchaser of the EZ2 Connect MDx is solely responsible for preventing any and all computer viruses, worms, trojans, malware, hacks, or any other type of cybersecurity breaches. QIAGEN assumes no liability for computer viruses, worms, trojans, malware, hacks, or any other type of cybersecurity breaches.

## License Information

The EZ2 Connect 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 |
| **Parts and components** | | |
| EZ2 Connect Tip Rack | One spare part Tip Racks (left and right) for EZ2 Connect | 9027009 |
| EZ2 Connect Cartridge Rack | One spare part Cartridge racks (left and right) for EZ2 Connect | 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 Services or your local distributor.

# Document Revision History

| Date | Changes |
|---|---|
| 03/2024 | Update according to new SW 1.2 functionalities: Cooling after run, UV run scheduler, patch management via QIAsphere, screen lock, time synchronization with QIAsphere, time zone support, notification center. Improved description of the weekly maintenance procedure. Improved structure. |
| 04/2022 | Initial version of the EZ2 Connect MDx User Manual |

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