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EZ2[®] Connect MDx User Manual

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



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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
- Appendix B – EZ2 Connect MDx Accessories — an overview of the accessories available for the EZ2 with required ordering information
- Ordering Information — Ordering information
- 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.)
- Timepoint when the error occurred for the first time
- Frequency of error occurrence (i.e., intermittent or persistent error)
- EZ2 Support Package (see section 7.1.1)

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 Requirements for EZ2 users

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

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 only	Specialists trained, certified, and authorized by QIAGEN

1.5 Materials required

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

- EZ1 DSP DNA Blood Kit (Catalog Number 62124)
- EZ1 DSP Virus Kit (Catalog Number 62724)

The research mode of the software supports the usage of other EZ1&2 or EZ2 kits for life science applications.

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

Other required materials:

- Filter-tips and holders, EZ1 (50) (Catalog number 994900)
- Cartridge rack (Catalog number 9027012)
- Tip and sample rack (Catalog number 9027009)
- USB stick (Catalog number 9026881)
- Silicone grease (Catalog number 9027102)
- Barcode Reader (Catalog number 9027101)

Note: Only use accessories supplied by QIAGEN.

1.6 Materials required but not provided

- Safety glasses
- Gloves
- Lab coat

1.7 Glossary

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

1.8 Accessories

For information about EZ2 accessories, refer to the Appendix B – EZ2 Connect MDx Accessories section (page 170) of this user manual.

2 Safety Information

Before using the EZ2, 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.

<p>WARNING</p> 	<p>The term WARNING is used to inform you about situations that could result in personal injury to you or others.</p> <p>Details about these circumstances are given in a box like this one.</p>
--	--

<p>CAUTION</p> 	<p>The term CAUTION is used to inform you about situations that could result in damage to an instrument or other equipment.</p> <p>Details about these circumstances are given in a box like this one.</p>
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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 the competent authority of the Member State (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

<p>WARNING/ CAUTION</p> 	<p>Risk of personal injury and material damage</p> <p>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 instrument must only be performed by a QIAGEN Field Service Specialist.</p>
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<p>WARNING/ CAUTION</p> 	<p>Risk of personal injury</p> <p>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.</p>
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<p>WARNING</p> 	<p>Risk of personal injury and material damage</p> <p>Do not attempt to move the EZ2 during operation.</p>
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Perform the maintenance as described in the Maintenance Procedures section (see page 141). 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.

<p>CAUTION</p> 	<p>Damage to the instrument</p> <p>Avoid spilling water or chemicals onto the EZ2. Instrument damage caused by water or chemical spillage will void your warranty.</p>
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WARNING 	Risk of fire or explosion 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.
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WARNING 	Risk of fire or explosion The EZ2 is intended for use with reagents and substances supplied with QIAGEN kits as outlined in respective Information for use. Use of other reagents and substances may lead to fire or explosion.
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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 Ensure that the EZ2 is switched off (power OFF) and mains plug removed from power outlet before you manually move the mechanical components of the instrument.
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CAUTION 	Damage to the instrument Do not lean against the instrument or touchscreen.
---	---

2.2 Electrical safety

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

<p>WARNING</p> 	<p>Electrical hazard</p> <p>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.</p> <p>Intentional interruption is prohibited.</p> <p>Lethal voltages inside the instrument</p> <p>When the instrument is connected to line power, terminals may be live and opening covers or removing parts is likely to expose live parts.</p>
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<p>WARNING</p> 	<p>Damage to electronics</p> <p>Before powering ON the instrument, make sure that the correct supply voltage is used.</p> <p>Use of incorrect supply voltage may damage the electronics.</p> <p>To check the recommended supply voltage, refer to the specifications indicated on the type plate of the instrument.</p>
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<p>WARNING</p> 	<p>Risk of electric shock</p> <p>Do not open any panels on the EZ2.</p> <p>Risk of personal injury and material damage</p> <p>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.</p>
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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 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 appear 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.

<p>WARNING</p> 	<p>Electric hazard</p> <p>Do not touch the EZ2 with wet hands.</p>
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WARNING 	Electric hazard Never install a fuse different from that specified in the user manual.
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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 The EZ2 instrument is not designed for use in an explosive atmosphere.
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WARNING 	Risk of overheating To ensure proper ventilation, maintain a minimum clearance of 10 cm at the sides and rear of the EZ2. Slits and openings that ensure the ventilation of the instrument must not be covered.
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WARNING 	Risk of explosion 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.
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CAUTION 	Damage to the instrument Direct sunlight may bleach parts of the instrument, cause damage to plastic parts or interfere with the correct function of the load check. The EZ2 must be located out of direct sunlight.
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CAUTION 	Damage to the instrument 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.
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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.

<p>WARNING</p> 	<p>Samples containing infectious agents</p> <p>Samples used with the EZ2 instrument may contain infectious agents. Handle such samples with the greatest of care and in accordance with the required safety regulations.</p> <p>Always wear safety glasses, gloves, and a lab coat.</p> <p>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.</p> <p>Venting for fumes and disposal of wastes must be in accordance with all national, state, and local health and safety regulations and laws.</p>
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* 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)

2.5 Chemicals

<p>WARNING</p> 	<p>Hazardous chemicals</p> <p>Some chemicals used with the EZ2 instrument may be hazardous or may become hazardous after completion of a purification run.</p> <p>Always wear safety glasses, gloves, and a lab coat.</p> <p>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.</p> <p>Venting for fumes and disposal of wastes must be in accordance with all national, state, and local health and safety regulations and laws.</p>
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* 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

<p>WARNING</p> 	<p>Toxic fumes</p> <p>Do not use bleach to clean or disinfect the EZ2 instrument. Bleach in contact with salts from the buffers can produce toxic fumes.</p>
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<p>WARNING</p> 	<p>Toxic fumes</p> <p>Do not use bleach to disinfect used labware. Bleach in contact with salts from the buffers can produce toxic fumes.</p>
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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 instrument, see Appendix A: Waste Electrical and Electronic Equipment (WEEE).

<p>CAUTION</p> 	<p>Hazardous chemicals and infectious agents</p> <p>Waste may contain toxic or infectious material and must be disposed of properly. Refer to your local safety regulations for proper disposal procedures.</p>
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2.7 Mechanical hazards

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

The worktable of the EZ2 instrument 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.

<p>WARNING</p> 	<p>Moving parts</p> <p>To avoid contact with moving parts during the operation of the EZ2, the instrument must be operated with the hood closed.</p> <p>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.</p>
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<p>WARNING</p> 	<p>Moving parts</p> <p>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 whilst the instrument is operating.</p>
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2.8 Heat hazard

The EZ2 worktable contains a heating system.

<p>WARNING</p> 	<p>Hot surface</p> <p>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.</p>
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2.9 Radiation

The EZ2 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.

<p>WARNING</p> 	<p>UV radiation</p> <p>Avoid looking directly into UV light. Do not expose your skin to UV light.</p>
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The EZ2 instrument has a 2D handheld barcode scanner to allow kit bar code and sample barcode scanning.

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

2.10 Maintenance safety

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

Perform the maintenance as described in the Maintenance Procedures section (see page 141). QIAGEN charges for repairs that are required due to incorrect maintenance.

WARNING/ CAUTION 	Risk of personal injury and material damage Improper use of the EZ2 instrument may cause personal injuries or damage to the instrument. The EZ2 must only be operated by suitably qualified personnel. Servicing of the EZ2 instrument must only be performed by QIAGEN Field Service Specialists.
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Operate the EZ2 instrument only as described in the Operating Procedures section (see page 57). QIAGEN charges for repairs that are required due to incorrect operation.

WARNING 	Risk of fire When cleaning the EZ2 instrument with alcohol-based disinfectant, leave the instrument door open to allow flammable vapors to disperse. Only clean the EZ2 instrument with alcohol-based disinfectant when worktable components have cooled down.
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CAUTION 	Damage to the instrument Do not use bleach, solvents, or reagents containing acids, alkalis, or abrasives to clean the EZ2 instrument.
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<p>CAUTION</p> 	<p>Damage to the instrument</p> <p>Do not use spray bottles containing alcohol or disinfectant to clean surfaces of the EZ2 instrument. Spray bottles should be used only to clean items that have been removed from the worktable and if permitted by local laboratory operating practices.</p>
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<p>CAUTION</p> 	<p>Damage to the instrument</p> <p>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.</p>
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<p>WARNING/ CAUTION</p> 	<p>Risk of personal electric shock</p> <p>Do not open any panels on the EZ2 instrument.</p> <p>Only perform maintenance as described in this user manual.</p>
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2.11 Symbols on the EZ2 Connect MDx instrument

The following symbols appear on the EZ2 Connect MDx instrument.

Symbol	Location	Description
	Heating system — inside instrument	Heat hazard — the temperature of the heating system can reach up to 95°C.
	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 pipettor 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 bar code 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	Catalogue 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 and/or molecular biology applications.

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 non-DSP kits is also supported (in the Research mode of the software).

The EZ2 Connect MDx gives the option to start a protocol either in the IVD mode of the software (for validated IVD applications only) or in the Research mode of the software (for Molecular Biology Applications (MBA) only). 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-software 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 **Product Resources** tab).

EZ2 Connect MDx is preinstalled with various protocols for processing QIAGEN EZ1 DSP and EZ1&2 kits for purification of RNA, genomic DNA, and viral and bacterial nucleic acids, and RNA. The user must first log-in to the software in IVD mode using the touchscreen, then scans a kit barcode and loads labware, samples, and reagents 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 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](#) and [Appendix B - EZ2 accessories](#)), 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, QIA sphere, LIMS)

3.2 External features of the EZ2 Connect MDx



Figure 1. The front of the EZ2 instrument.

- 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 instrument.

- 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 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 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.

<p>WARNING</p> 	<p>Moving parts</p> <p>To avoid contact with moving parts during the operation of the EZ2, the instrument must be operated with the hood closed.</p> <p>If the hood sensor or lock is not functioning properly, contact QIAGEN Technical Services.</p>
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Figure 4. The EZ2 with the hood closed.

3.2.3 Power button

The power button is located on the front of the EZ2, 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 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 128).

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 (5.3.6). For more information on software updates, refer to the Updating software section (see page 82).

The handheld bar code 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 flash drive provided by QIAGEN. Do not connect other USB flash drive 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: Always turn off the EZ2 before you plug or unplug the Wi-Fi USB device. Plug-and-play of the Wi-Fi USB device while the instrument is turned on is not supported.

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 to a local area network.



Figure 6. Location of RJ-45 port.

3.2.6 Power cord socket

The power cord socket is located on the back of the EZ2 (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.

<p>WARNING</p> 	<p>Electrical hazard</p> <p>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.</p> <p>Lethal voltages inside the instrument</p> <p>When the instrument is connected to line power, terminals may be live and opening covers or removing parts is likely to expose live parts.</p>
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<p>WARNING</p> 	<p>Damage to electronics</p> <p>Before turning the instrument on, make sure that the correct supply voltage is used.</p> <p>Use of incorrect supply voltage may damage the electronics.</p> <p>To check the recommended supply voltage, refer to the specifications indicated on the type plate of the instrument.</p>
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<p>WARNING</p> 	<p>Risk of electric shock</p> <p>Do not open any panels on the EZ2.</p> <p>Risk of personal injury and material damage</p> <p>Only perform maintenance that is specifically described in this user manual.</p>
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3.2.7 Ventilation openings

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

<p>CAUTION</p> 	<p>Risk of overheating</p> <p>To ensure proper ventilation, maintain a minimum clearance of 10 cm at the sides and rear of the EZ2.</p> <p>Slits and openings that ensure the ventilation of the instrument must not be covered.</p>
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3.2.8 Bar code 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 Using the bar code scanner section (see page 132).

WARNING 	Risk of personal injury Hazard Level 2 laser light: Do not stare into the light beam when using handheld bar code scanner.
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3.3 Internal features of the EZ2



Figure 8. Interior of the EZ2.

- 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 (50–1000 μ l) 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 9. EZ2 pipettor head.

<p>WARNING</p> 	<p>Moving parts</p> <p>To avoid contact with moving parts during the operation of the EZ2, the instrument must be operated with the hood closed.</p> <p>If the hood sensor or lock is not functioning correctly, contact QIAGEN Technical Services.</p>
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<p>WARNING</p> 	<p>Moving parts</p> <p>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 whilst the instrument is operating.</p>
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3.3.2 Worktable

The EZ2 worktable contains two movable racks (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 10. Cartridge rack with two cartridges inserted.



Figure 11. Removable cartridge rack inside the instrument.

The cartridge rack consists of two separate parts. The left cartridge rack is used for cartridges in positions from 1 to 12. The right cartridge rack is used for cartridges in positions 13 to 24. On the worktable, the cartridge rack is located behind the tip rack. Both parts of the cartridge rack together hold up to 24 reagent cartridges.

For more information on how to load the cartridge rack, refer to the Loading the cartridge rack section (see page 109).

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.

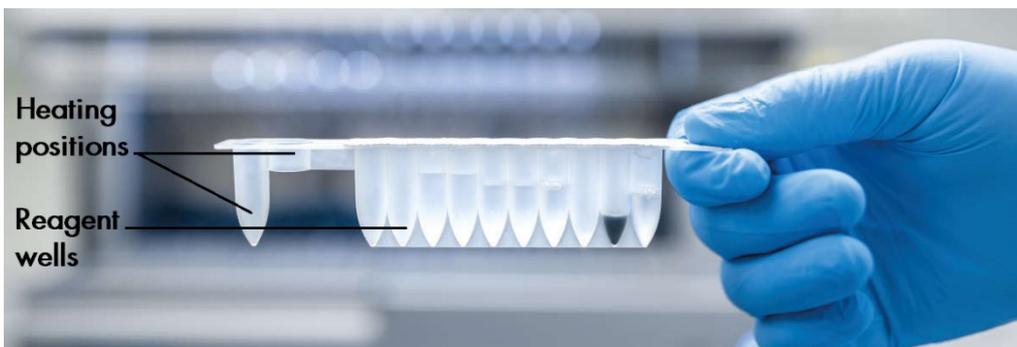


Figure 12. An EZ1/2 cartridge.

Tip rack



Figure 13. Tip rack with four inserted tip holders/filter tips.



Figure 14. Tip racks inside the instrument.

The EZ2 tip rack consists of two separate parts. The left part of the tip rack is used for labware in positions from 1 to 12. The right part of the 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 four 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 15. Tip holders and filter tips.

- Row D – Usually 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 110).

Heating system

The heating system is located under the rear part of the cartridge rack. If required by the used protocol, it heats up the wells in positions 11 and 12 of the cartridge.



Figure 16. Heatable positions in the cartridge rack (marked by white frame).

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

The tray is located underneath the tip and cartridge racks. Its role is to prevent contamination of the EZ2 that could be caused by liquids that are unintentionally spilled. The tray can be removed and cleaned as described in the Daily maintenance section (see page 148).



Figure 17. The EZ2 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 18. The EZ2 magnet module.

3.3.4 Camera

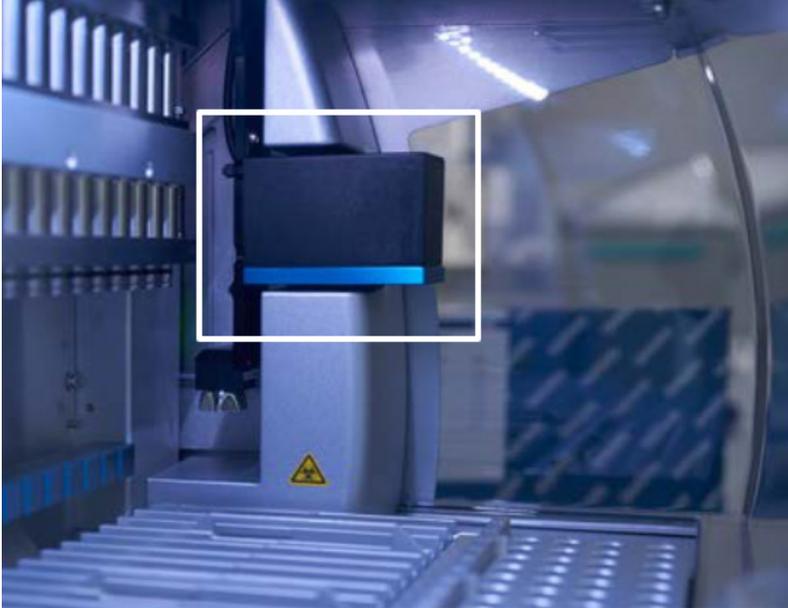


Figure 19. Camera module.

The EZ2 Connect MDx has a built-in camera that is used for load checks and 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 118).

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.

<p>WARNING</p> 	<p>UV radiation</p> <p>Do not expose your skin to UV light from the UV LED lamp.</p>
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<p>WARNING</p> 	<p>Moving parts</p> <p>To avoid contact with moving parts during the operation of the EZ2, the instrument must be operated with the hood closed.</p> <p>If the hood sensor or lock is not functioning correctly, contact QIAGEN Technical Services.</p>
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3.3.6 Internal light

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

- Blinking light – indicates that operator activity is required (for example, 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.

4.1 Installation environment

The EZ2 is a plug-and-play instrument. Unpacking and installation procedures are easy to follow, but a person who is familiar with laboratory equipment should oversee the installation.

4.1.1 Site requirements

The EZ2 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 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.

<p>WARNING</p> 	<p>Explosive atmosphere</p> <p>The EZ2 instrument is not designed for use in an explosive atmosphere.</p>
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<p>CAUTION</p> 	<p>Risk of overheating</p> <p>To ensure proper ventilation, maintain a minimum clearance of 10 cm at the sides and rear of the EZ2.</p> <p>Slits and openings that ensure the ventilation of the instrument must not be covered.</p>
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<p>WARNING</p> 	<p>Risk of personal injury and material damage</p> <p>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.</p>
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<p>CAUTION</p> 	<p>Damage to the instrument</p> <p>Direct sunlight may bleach parts of the instrument, cause damage to plastic parts, and may interfere with the load check.</p> <p>The EZ2 must be located out of direct sunlight.</p>
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<p>CAUTION</p> 	<p>Damage to the instrument</p> <p>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.</p>
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4.1.2 Power requirements

The EZ2 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.

<p>WARNING</p> 	<p>Damage to electronics</p> <p>Before turning the instrument on, make sure that the correct supply voltage is used.</p> <p>Use of incorrect supply voltage may damage the electronics.</p> <p>To check the recommended supply voltage, refer to the specifications indicated on the type plate of the instrument.</p>
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<p>WARNING</p> 	<p>Electrical hazards</p> <p>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.</p> <p>Intentional interruption is prohibited.</p> <p>Lethal voltages inside the instrument</p> <p>When the instrument is connected to line power, terminals may be live and opening covers or removing parts is likely to expose live parts.</p>
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4.1.3 Grounding requirements

To protect operating personnel, the National Electrical Manufacturers' Association (NEMA) recommends that the EZ2 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.

<p>WARNING</p> 	<p>Electrical hazards</p> <p>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.</p> <p>Intentional interruption is prohibited.</p> <p>Lethal voltages inside the instrument</p> <p>When the instrument is connected to line power, terminals may be live and opening covers or removing parts is likely to expose live parts.</p>
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4.2 Unpacking the EZ2

<p>WARNING</p> 	<p>Risk of personal injury</p> <p>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.</p>
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The following items are delivered:

- EZ2 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:

1. Before unpacking the EZ2, 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 Services.
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 20. 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 two pieces of protector 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 which secure the hood to the base panels.
9. Remove the protective film which covers the hood
10. Open the hood and remove the transport lock from the pipetting head by pulling the transport lock from bottom.



Figure 21. 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 transport lock towards rear direction and pull it 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 that you have received all items. 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 Connect MDx section (page 56) 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

<https://www.qiagen.com/de/products/ez2-connect-mdx/>.

4.3.1 Removal of the EZ2 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 flash drive, cartridge racks, and sample/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 47).

4.3.2 Installation of the AC power cord

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

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

2. Ensure that the power button is set to OFF.



Figure 22. Location of the power button.

3. Check that the voltage rating on the label at the back of the EZ2 matches the voltage available at the installation site.
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.

<p>WARNING</p> 	<p>Damage to electronics</p> <p>Before powering ON the instrument, make sure that the correct supply voltage is used.</p> <p>Use of incorrect supply voltage may damage the electronics.</p> <p>To check the recommended supply voltage, refer to the specifications indicated on the type plate of the instrument.</p>
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<p>WARNING</p> 	<p>Electrical hazard</p> <p>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.</p> <p>Intentional interruption is prohibited.</p> <p>Lethal voltages inside the instrument</p> <p>When the instrument is connected to line power, terminals may be live and opening covers or removing parts is likely to expose live parts.</p>
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4.3.3 Installation of external barcode scanner

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 Hazard Level 2 laser light: Do not stare into the light beam when using handheld bar code scanner.
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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 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.



Welcome to EZ2
Log in to continue

User ID:

Password:

Research Mode IVD Mode

1/31/2022 8:29

Figure 23. The login screen.

- To log in for the first time, select IVD Mode, enter **Admin** in both **User ID** and **Password** fields, then press **Log in**. After this login, you will have administrator rights with the option to set up other users. Refer to the Managing users section (see page 69) for further details.

Note: After first log in using the Admin account, the password should be changed according to the Password policy described in the Managing user security section (see page 77) and as per instruction in the Changing password section (see page 75).

- From the **Configuration** menu under the **System** tab, you can modify the Instrument Name, Date and Time fields. You can also find information on Software version, Serial number, and Firmware version. For further details, see the Setting basic system data section (see page 67).

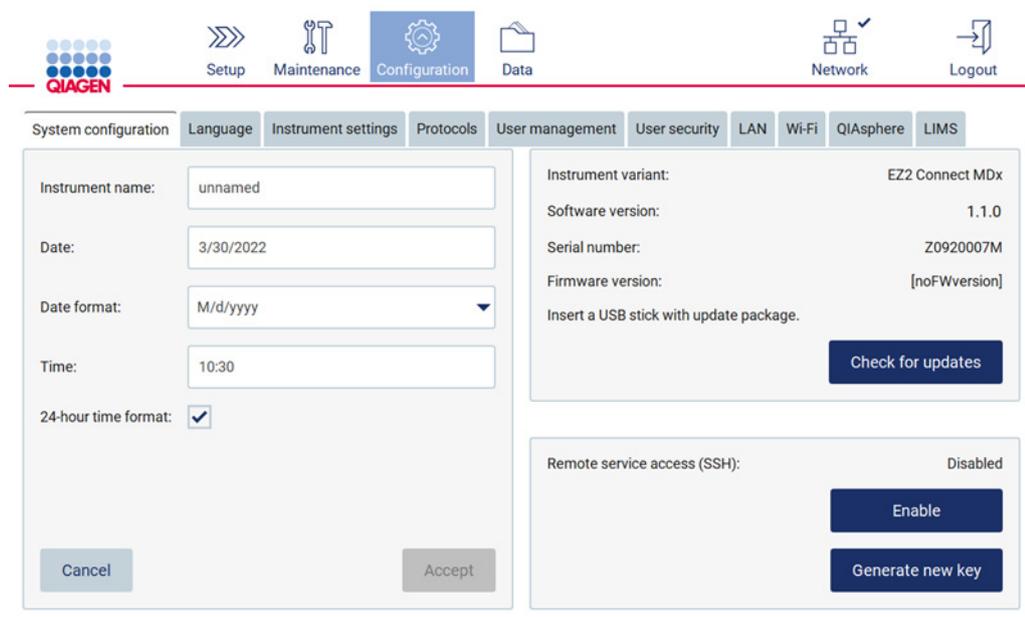


Figure 24. The System configuration tab.

- You may adjust settings of the EZ2 Connect MDx according to your preferences through the **Instrument settings** tab under the **Configuration** menu. For further details see the Changing Instrument settings section (see page 68).

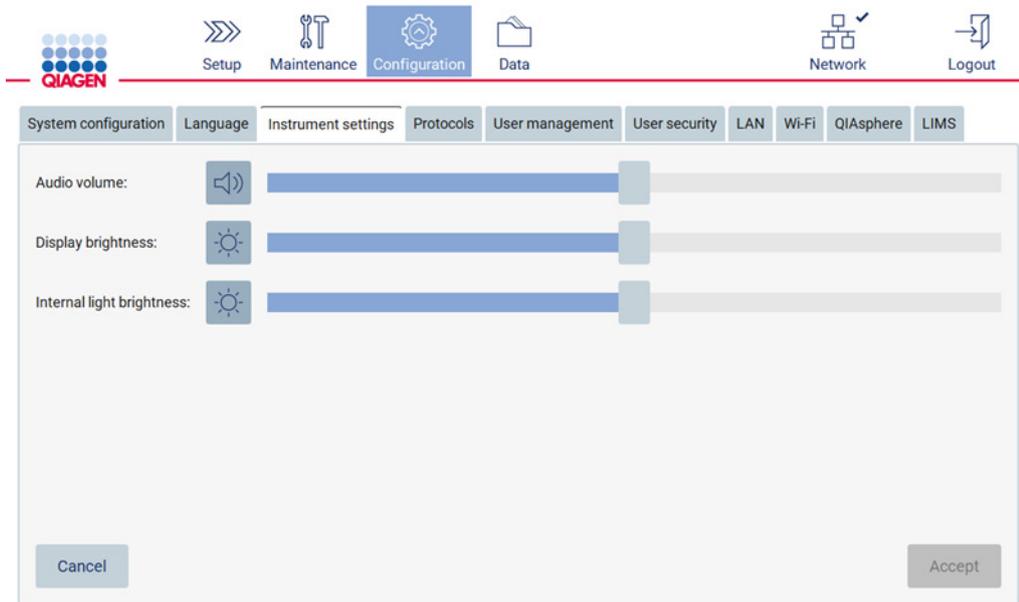


Figure 25. Details on the Instrument settings tab.

Note: The display brightness should not be switched off completely. This will change the screen to black which can only be reverted by a system restart.

4.3.6 Performing camera exposure calibration

Note: Only Administrators can perform the camera exposure calibration.

<p>WARNING</p> 	<p>Moving parts</p> <p>To avoid contact with moving parts during the operation of the EZ2, the instrument must be operated with the hood closed.</p> <p>If the hood sensor or lock is not functioning correctly, contact QIAGEN Technical Services.</p>
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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 same tip racks 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 26. Camera exposure calibration screen.

4. During the calibration routine, the following message will be displayed.

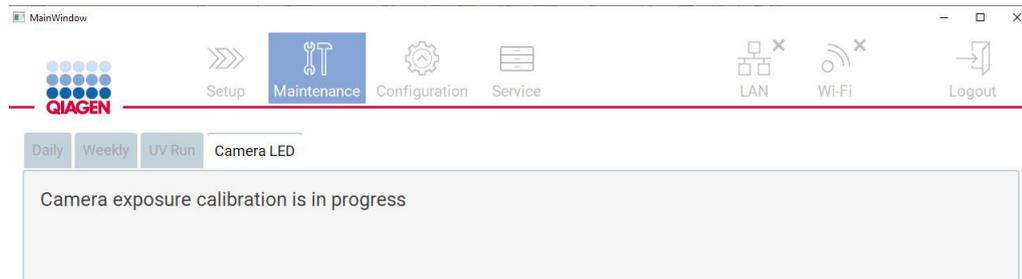


Figure 27. Camera exposure calibration message.

Note: For support or technical advice regarding this, please contact QIAGEN Technical Services or see our Technical Support Centre at <http://www.qiagen.com/service-and-support/technical-support>.

4.4 Packaging and Transportation of the EZ2 Connect MDx

<p>WARNING</p> 	<p>Risk of personal injury</p> <p>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.</p>
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Before transporting the EZ2 Connect MDx, the instrument must first be decontaminated. Refer to Disinfecting the EZ2 and Removing contamination 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 into 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 Connect MDx.

5 Operating Procedures

This section describes how to operate the EZ2 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 26 and 35, respectively).

The EZ2 is intended to be used only in combination with QIAGEN kits indicated for use with the EZ2 instrument 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 instrument moves during operation of the instrument. Never open the EZ2 hood while the instrument is operating.

<p>WARNING</p> 	<p>Moving parts</p> <p>To avoid contact with moving parts during the operation of the EZ2, the instrument must be operated with the hood closed.</p> <p>If the hood sensor or lock is not functioning correctly, contact QIAGEN Technical Services.</p>
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<p>WARNING</p> 	<p>Moving parts</p> <p>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 whilst the instrument is operating.</p>
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WARNING 	Risk of personal injury and material damage Do not attempt to move the EZ2 during operation.
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WARNING/ CAUTION 	Risk of personal injury and material damage 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.
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CAUTION 	Damage to the instrument 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 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 The EZ2 is intended for use with reagents and substances supplied with QIAGEN kits as outlined in respective Information for use. Use of other reagents and substances may lead to fire or explosion.
---	---

<p>CAUTION</p> 	<p>Damage to the instrument</p> <p>Ensure that the EZ2 is switched off before you manually move the mechanical components of the instrument.</p>
---	---

<p>CAUTION</p> 	<p>Damage to the instrument</p> <p>Do not lean against the instrument or touchscreen.</p>
---	--

<p>WARNING</p> 	<p>Samples containing infectious agents</p> <p>Some samples used with the EZ2 instrument may contain infectious agents. Handle such samples with the greatest of care and in accordance with the required safety regulations.</p> <p>Always wear safety glasses, gloves, and a lab coat.</p> <p>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.</p> <p>Venting for fumes and disposal of wastes must be in accordance with all national, state, and local health and safety regulations and laws.</p>
---	--

* 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)

<p>CAUTION</p> 	<p>Hazardous materials and infectious agents</p> <p>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.</p>
---	--

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

<p>WARNING</p> 	<p>UV radiation</p> <p>Avoid looking directly into UV light. Do not expose your skin to UV light.</p>
--	--

<p>WARNING</p> 	<p>Risk of personal injury</p> <p>Hazard Level 2 laser light: Do not stare into the light beam when using handheld bar code scanner.</p>
---	---

5.1 General information

The EZ2 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 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 three elements: the toolbar, the main content, and the footer.

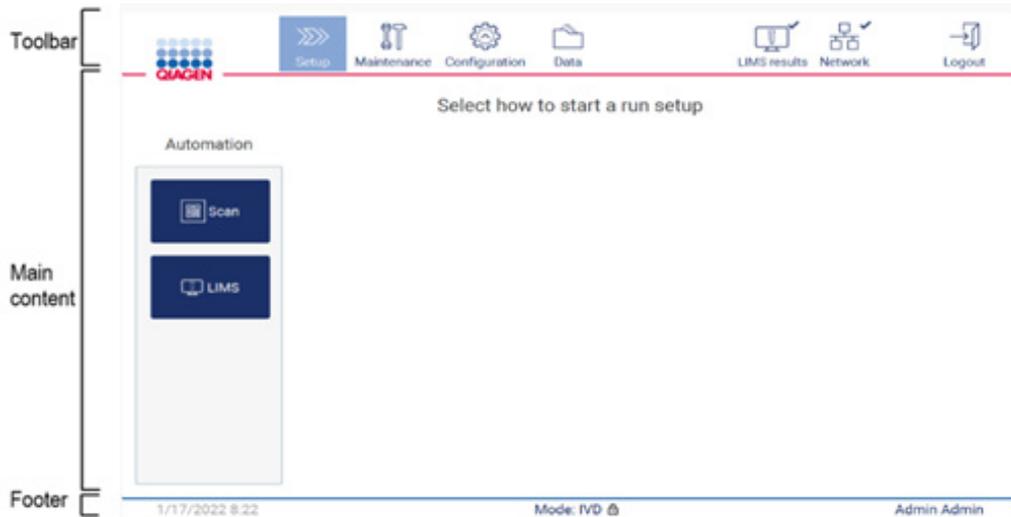


Figure 28. The home screen.

Toolbar

The toolbar is used to access the main sections of the EZ2 software, to check the connection status of the LAN and Wi-Fi, 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:

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.
 LAN	Shows the status of the LAN connection.
 Wi-Fi	Shows the status of the Wi-Fi connection.
 Logout	Tap this button to log out.
 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

Figure 29. Description of elements in the User Interface.

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, the software mode, 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 instrument software. To access the keyboard, tap the field that you want to edit. The keyboard appears.

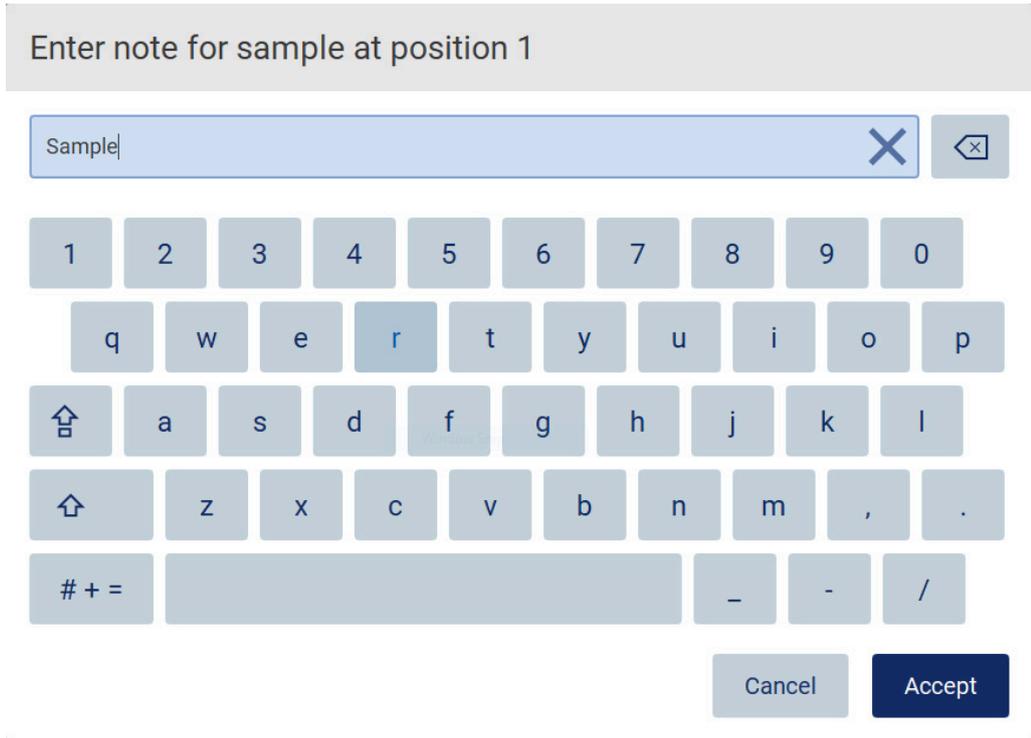


Figure 30. The on-screen keyboard.

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 **ABC** .

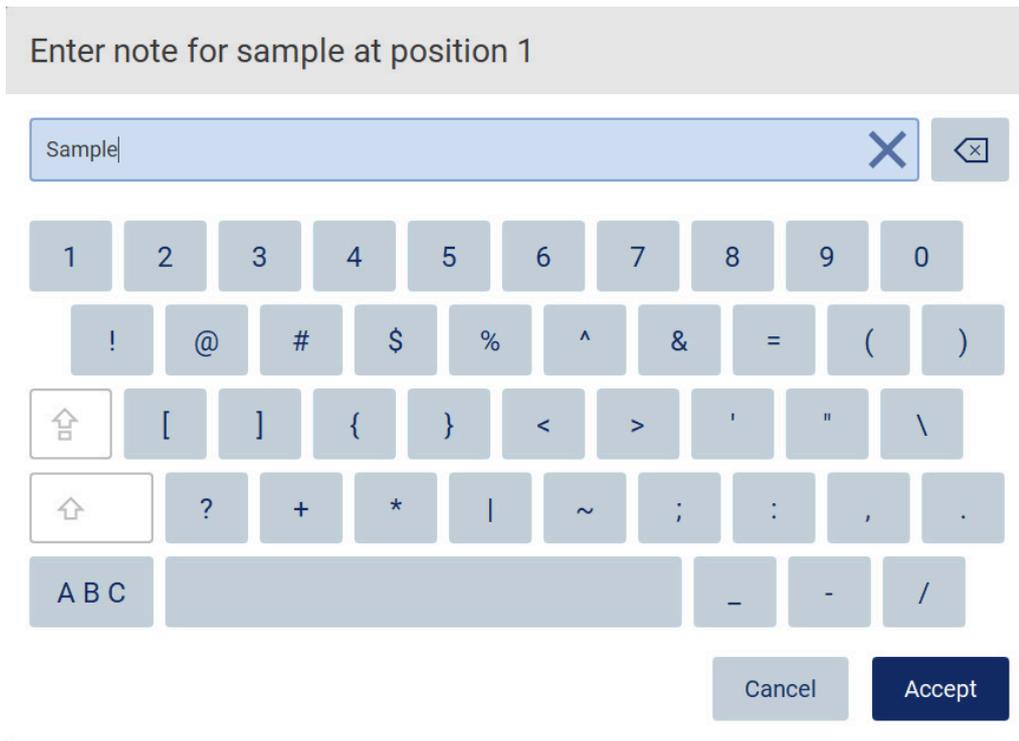


Figure 31. The on-screen keyboard in special character mode.

To remove one character to the left of the cursor, tap **Backspace** . To delete all characters from the field, tap **Clear All** . Please note that press and hold of the Backspace button does not clear all.

Some fields have requirements or restrictions that have 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.

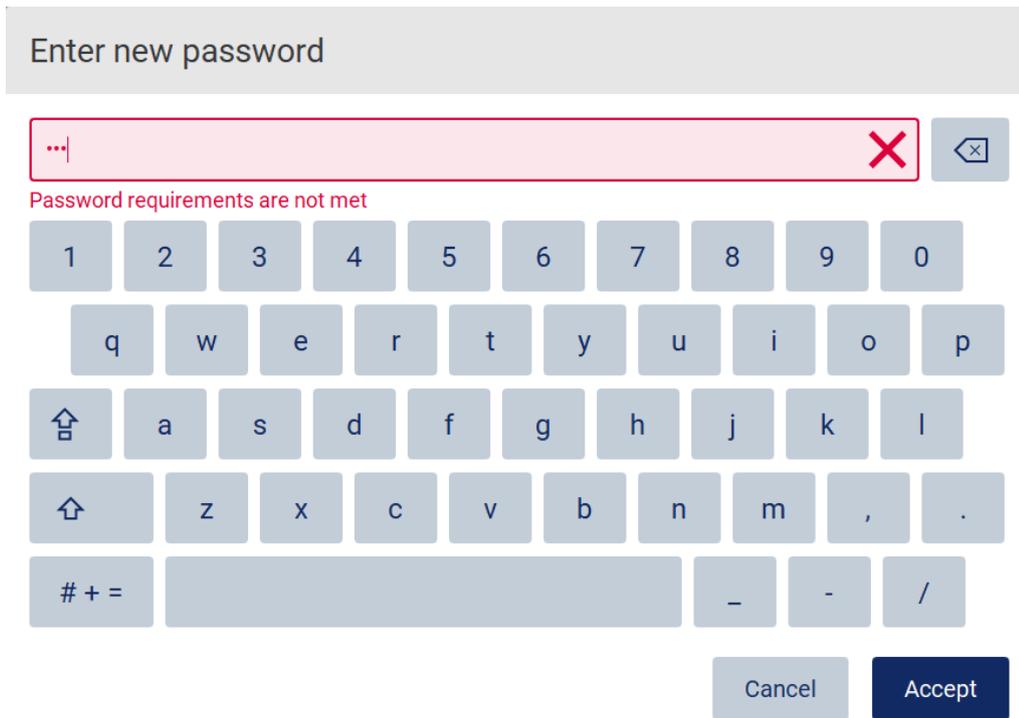


Figure 32. Example of text field validation.

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

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 **Login** screen appears.



Welcome to EZ2
Log in to continue

User ID:

Password:

Research Mode IVD Mode

1/31/2022 8:29

Figure 33. 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 62).

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

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

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

Note: After first log in using the default Admin account, the password should be changed according to the Password policy described in the Managing user security section (see page 77) and as per instruction in the Changing password section (see page 75).

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 25).
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.

5.3 Configuring the EZ2

Administrators of the EZ2 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, date format and time, follow the steps below:

Note: Only Administrators can change system settings.

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



Figure 34. Configuration button on the toolbar.

2. Tap **System configuration**.

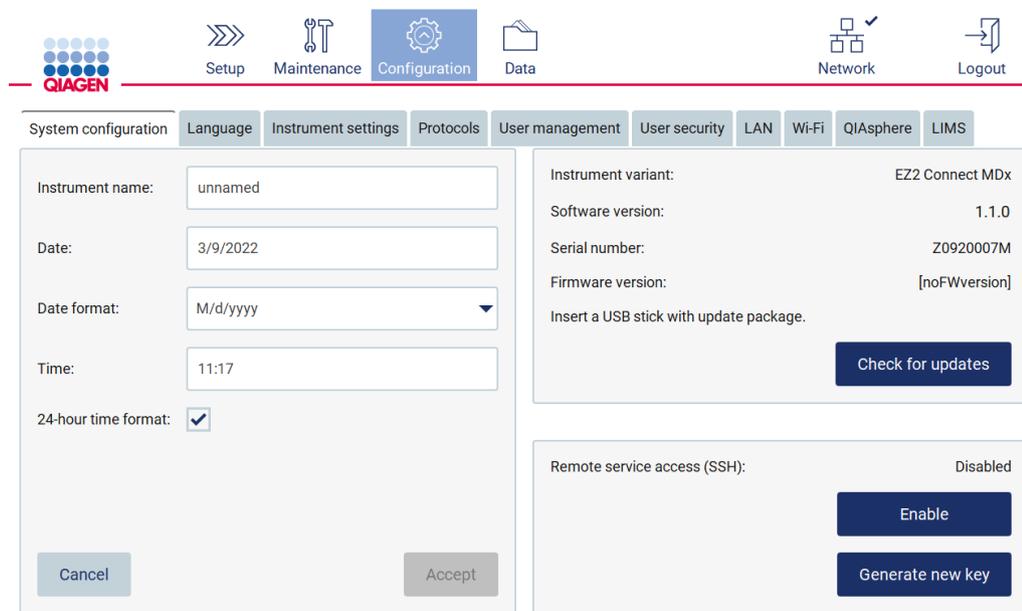


Figure 35. System configuration tab.

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

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

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

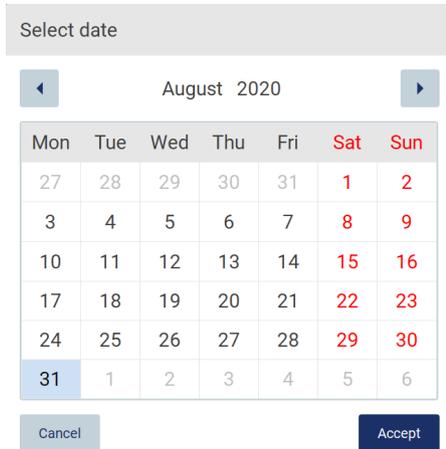


Figure 36. Select date dialog.

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

5.3.2 Changing Instrument settings

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

Note: Only Administrators can change Instrument settings.

To modify Instrument settings, follow the steps below:

- Tap **Configuration** on the toolbar.



Figure 37. Configuration button on the toolbar.

2. Tap **Instrument settings**.

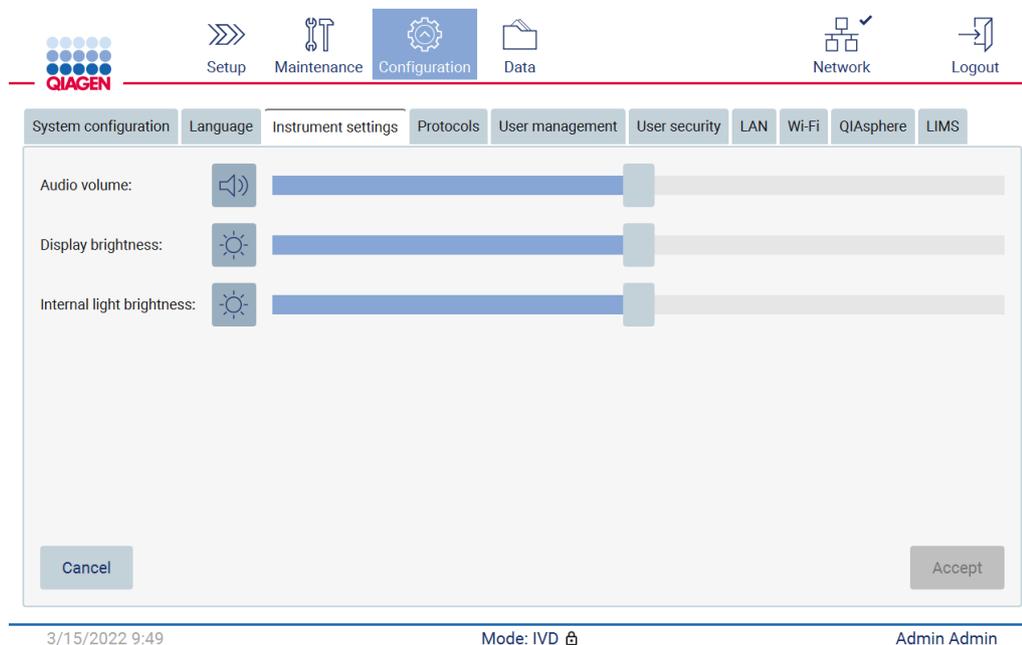


Figure 38. The Instrument settings tab.

3. To adjust the volume of the audio, use the **Audio volume** slider. A sound is played each time you change the volume. To mute the device, tap **Audio** , or move the slider to the far-left position.
4. To adjust the brightness of the touchscreen, use the **Display brightness** slider. It is possible to turn off the backlight of the display by tapping **Display brightness** , or moving the slider to the far-left position. However, this is not recommended as it turns off the backlight of the display, which makes the content on the touchscreen barely visible. If this happens by mistake, a restart of the instrument will make the display bright again.
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. Tap **Accept** to save the modified settings or tap **Cancel** to restore previously saved settings.

5.3.3 Managing users

EZ2 user management allows you to create and edit user accounts with two 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

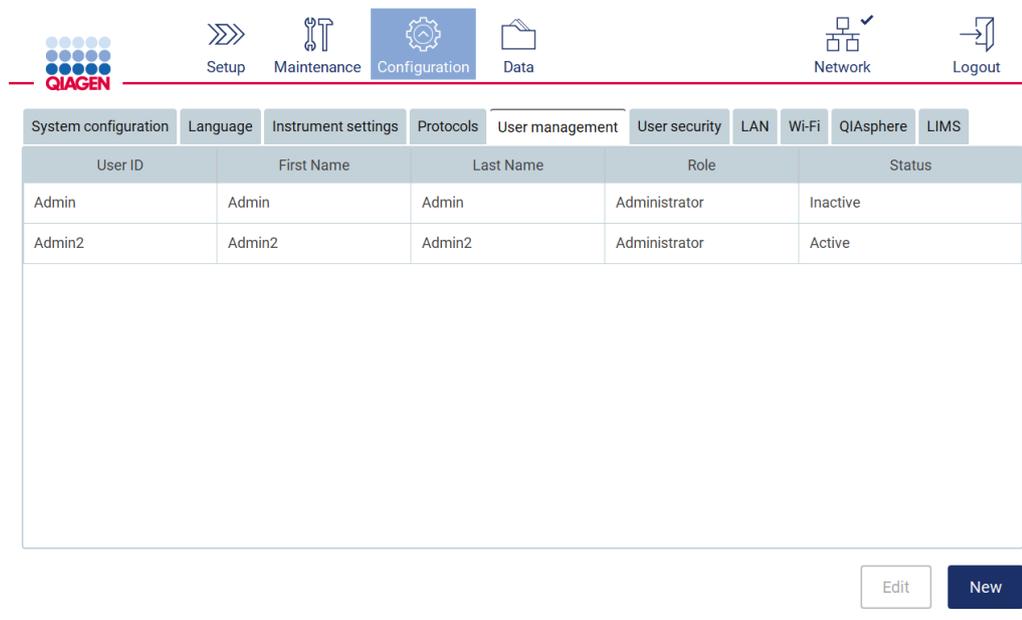
Note: Only administrators can add new users.

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



Figure 39. Configuration button on the toolbar.

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

A screenshot of the 'User management' tab in the application. At the top, there is a horizontal menu with tabs: System configuration, Language, Instrument settings, Protocols, User management (selected), User security, LAN, Wi-Fi, QIAsphere, and LIMS. Below the menu is a table with the following data:

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

Below the table, there are two buttons: 'Edit' and 'New'.

Figure 40. The User Management tab.

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

Create new account

Anonymous ID: d6da443f

User ID:

First name:

Last name:

User role: Administrator

User status: Active

Password status: Not set

Cancel Set password Accept

Figure 41. 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 audit trails when downloaded by service users.

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 modify the password policy, refer to the *Managing user security* section (see page 77).

Set user password

Password must consist of 8-40 characters and have at least one of:

- both upper-case and lower-case letters
- numerical digits
- special characters such as @, # or \$

New password:

Retype password:

Cancel Set password

Figure 42. Set user password dialog.

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

Note: Users can change their password later, see the Changing password section (see page 75).

8. 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 **Configuration** on the toolbar.



Figure 43. Configuration button on the toolbar.

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

The image shows the 'User management' tab selected in the configuration menu. Below the toolbar is a table with the following data:

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

Below the table are two buttons: 'Edit' and 'New'.

Figure 44. 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.

Edit user account

Anonymous ID: User ID:

First name: Last name:

User role: User status:

Password status: Active

Figure 45. 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.

Change user password

Password must consist of 8-40 characters and have at least one of:

- both upper-case and lower-case letters
- numerical digits
- special characters such as @, # or \$

New password:

Retype password:

Figure 46. Change user password screen.

- Enter the password in the **New password** field and again in the **Retype password** field. The password must meet the criteria displayed in the dialog and should be different from the one used before. To modify the password policy, refer to the Managing user security section (see page 77).
- Tap **Change password**.
- To save the changes made to the user account, tap **Accept**.

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

Deactivating/Activating a user

Note: Only administrators can deactivate or activate user accounts. The activating function can be used to re-activate a user which has been inactivated due to too many wrong login attempts.

- Tap **Configuration** on the toolbar.



Figure 47. Configuration button on the toolbar.

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

 A screenshot of the 'User management' tab in the application. At the top, there is a horizontal menu with tabs: System configuration, Language, Instrument settings, Protocols, User management (selected), User security, LAN, Wi-Fi, QIAsphere, and LIMS. Below the menu is a table with the following data:

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

 Below the table, there are two buttons: 'Edit' and 'New'.

Figure 48. 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 72).

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 **Configuration** on the toolbar.



Figure 49. The Configuration button on the toolbar.

2. Tap **Edit**.

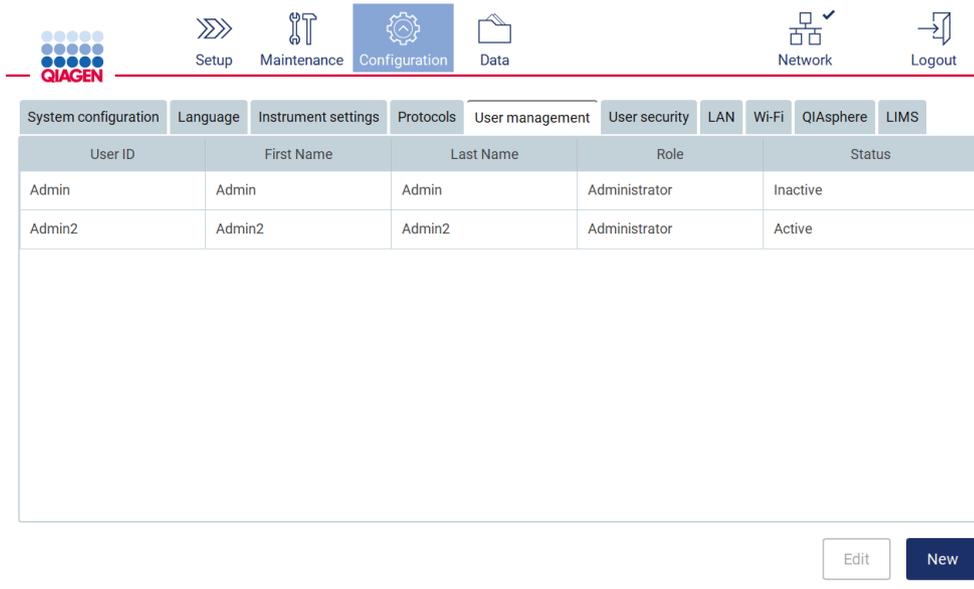


Figure 50. User Management tab (visible only for administrator roles).

3. Tap **Change password**.

Edit user account

Anonymous ID: User ID:

First name: Last name:

User role: User status:

Password status: Active

Cancel
Change password
Accept

Figure 51. 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.

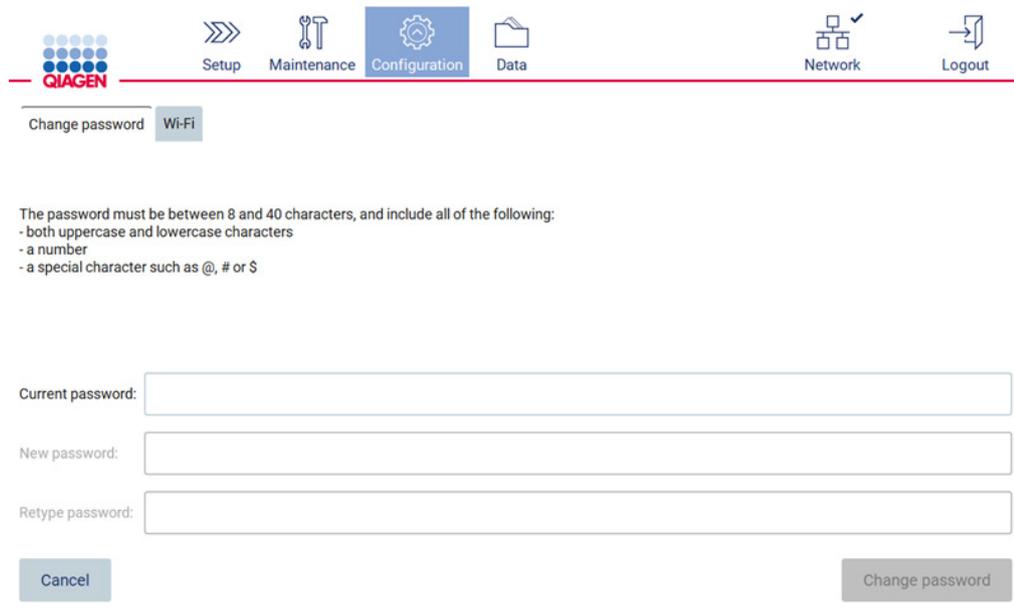


Figure 52. Configuration screen for Operator role.

8. If you are logged in with an operator role, you can change your password directly in the **Configuration** screen.

5.3.5 Managing user security

Administrators **only** can change the password policy for all user roles, as well as change the settings for password expiration and limit incorrect login attempts.

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

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



Figure 53. The Configuration button on the toolbar.

2. Tap **User security**.

System configuration Language Instrument settings Protocols User management User security LAN Wi-Fi QIAsphere LIMS

User role: Administrator

Password policy: Strong policy

Enable password expiration

Password expires every: 90 days

Account locks after: 2 incorrect login attempts

Strong policy:
The password must be between 8 and 40 characters, and include all of the following:
- both uppercase and lowercase characters
- a number
- a special character such as @, # or \$

Cancel Accept

3/10/2022 10:01 Mode: IVD Admin Admin

Figure 54. User security tab.

3. To change the password settings, select the user role whose policy you want to change 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 acceptable range 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 acceptable range 1 to 50. 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.

Note: To ensure that your EZ2 has the latest protocol versions installed, please visit the EZ2 Connect MDx webpage at <https://www.qiagen.com/de/products/ez2-connect-mdx/>. Protocol versions can be found during the set-up 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: Download software upgrades, protocol files, language packs, and other EZ2 related files only from www.qiagen.com.

Important: Use only the USB flash drive provided by QIAGEN. Do not connect other USB flash drive 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 flash drive with a protocol package.
2. Tap **Configuration** on the toolbar.



Figure 55. Configuration button on the toolbar.

3. Tap **Protocols**.

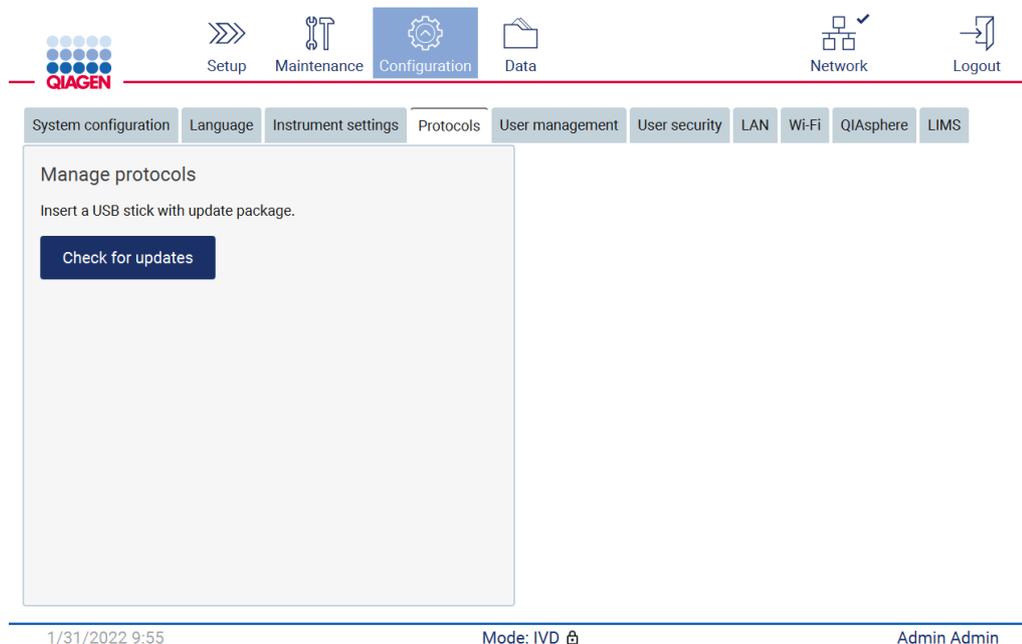


Figure 56. Protocols tab.

4. Tap **Check for updates**.

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

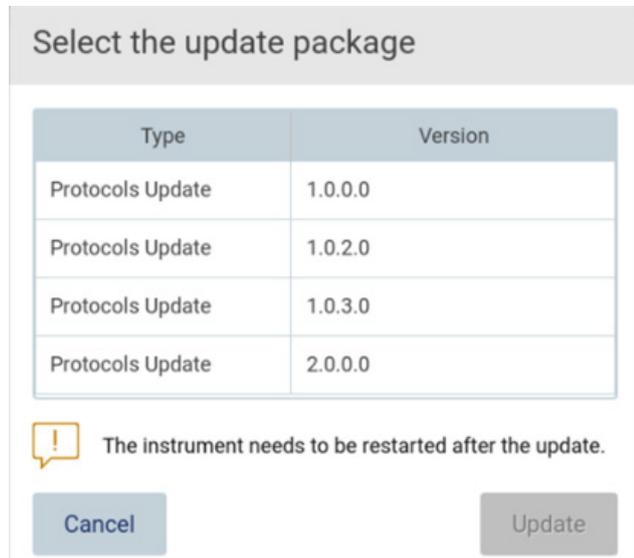


Figure 57. Update package pop-up window.

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

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

5.3.7 Language Settings

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

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

Important: Download software upgrades, protocol files, language packs, and other EZ2-related files only from www.qiagen.com.

Important: Use only the USB flash drive provided by QIAGEN. Do not connect other USB flash drive 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 flash drive with a language package.
2. Tap **Configuration** on the toolbar.



Figure 58. 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.

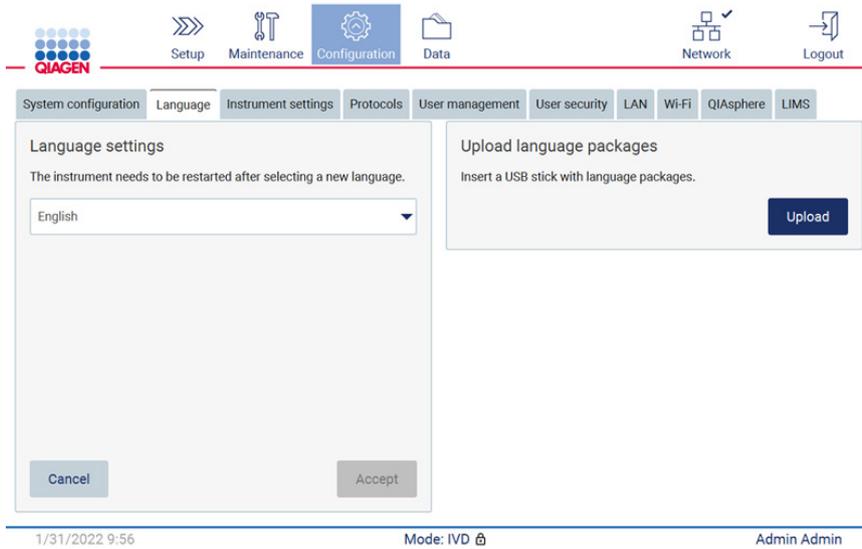


Figure 59. Language Tab.

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

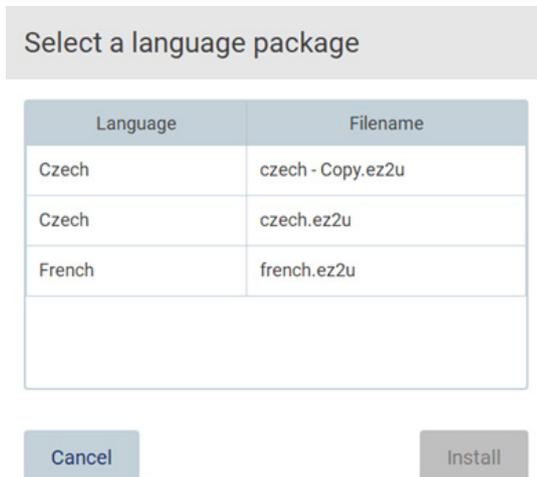


Figure 60. Language package pop-up window.

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 Connect MDx webpage at <https://www.qiagen.com/de/products/ez2-connect-mdx/>. Currently installed software version can be found from the **Configuration** menu, under the **System configuration** tab.

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

Important: Download software upgrades, protocol files, language packs, and other EZ2-related files only from www.qiagen.com. Before installation, verify that the package comes from the original QIAGEN source you downloaded it from. You can do this by comparing the checksum of the package with the checksum on the QIAGEN webpage from where you downloaded it.

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

1. Plug in a USB flash drive with the newest software version.
2. Tap **Configuration** on the toolbar.



Figure 61. Configuration button on the toolbar.

3. Tap **System configuration**.

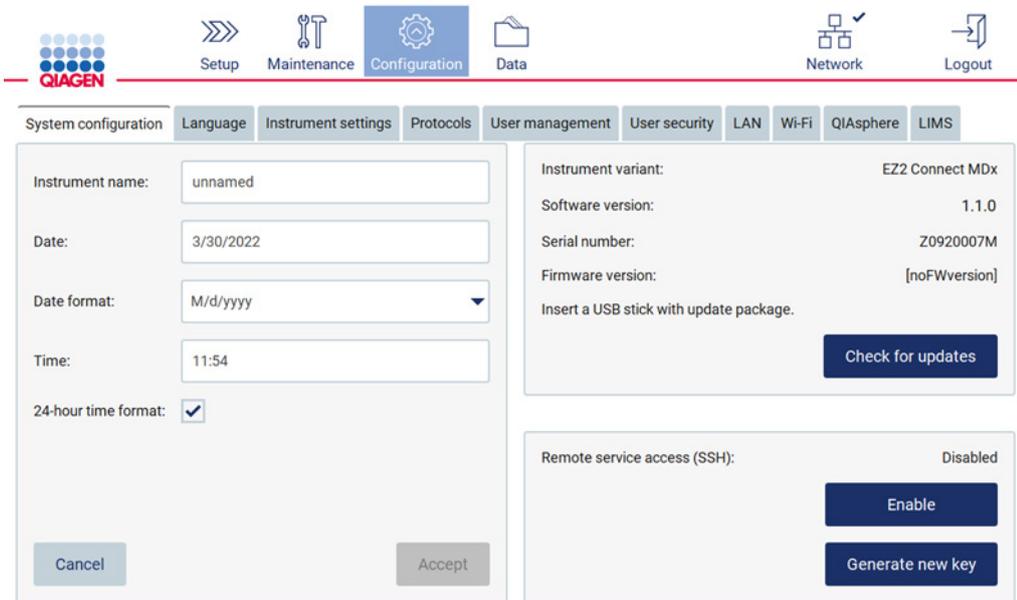


Figure 62. System Configuration tab.

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.

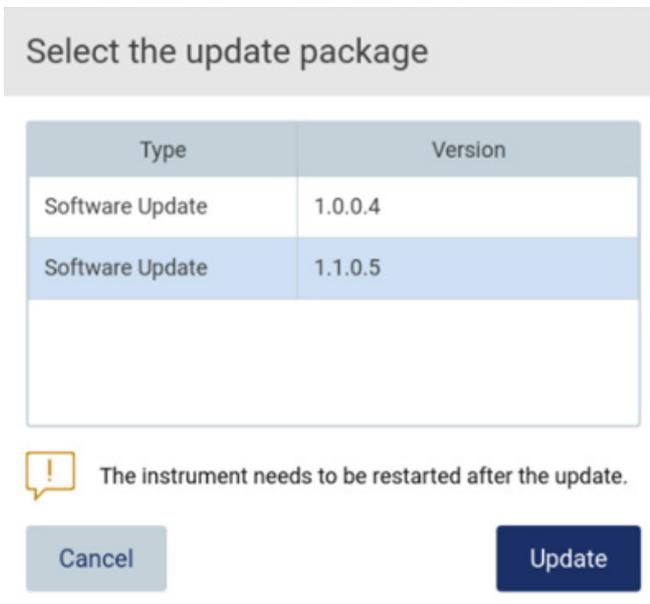


Figure 63. Update package pop-up window.

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

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 **Configuration** on the toolbar.



Figure 64. Configuration button on the toolbar.

2. Tap **LAN**.

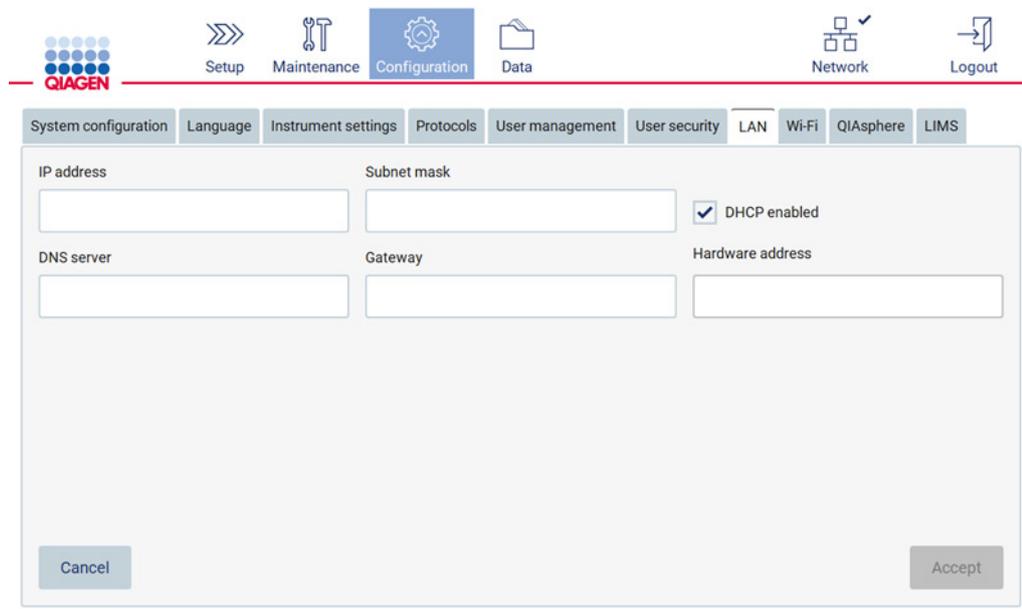


Figure 65. The LAN tab.

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

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

Note: Hardware address = MAC address

The screenshot displays the EZ2 instrument's configuration interface. At the top, there is a navigation bar with icons for Setup, Maintenance, Configuration (highlighted), and Data. To the right, there are icons for Network and Session. Below this is a secondary menu with tabs for System configuration, Language, Instrument settings, Protocols, User management, User security, LAN (selected), Wi-Fi, QIASphere, and LIMS. The main content area shows the LAN configuration form with the following fields: IP address (10.10.10.139), Subnet mask (255.255.255.0), DNS server (8.8.8.8), Gateway (10.10.10.1), and Hardware address (2C:54:91:88:C9:E3). A checkbox for 'DHCP enabled' is present and unchecked. At the bottom of the form are 'Cancel' and 'Accept' buttons. The footer of the interface shows the date and time '3/23/2022 9:48' on the left and the user name 'John Doe' on the right.

Figure 66. 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 **Configuration** on the toolbar.



Figure 67. The Configuration button on the toolbar.

2. Tap **Wi-Fi**.

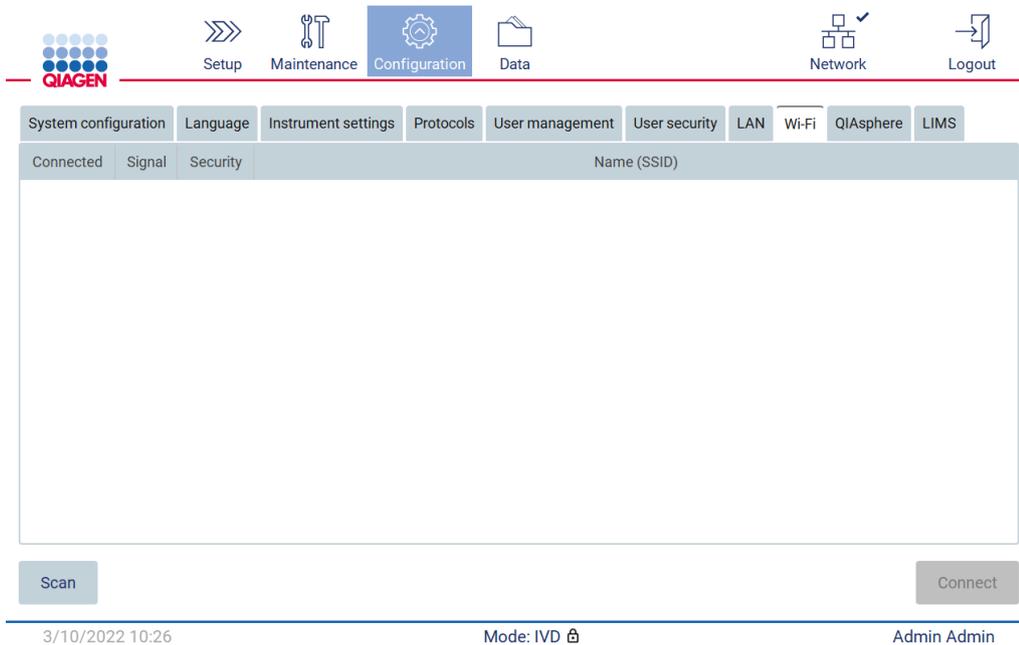


Figure 68. The Wi-Fi tab.

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

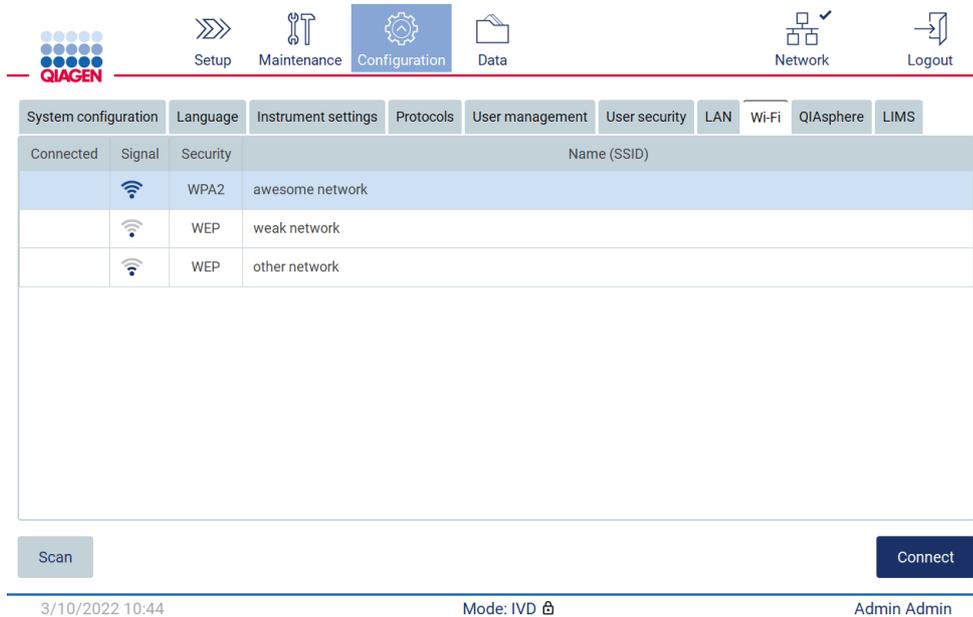


Figure 69. List of available Wi-Fi networks.

- To select a network, tap the row that corresponds to the network you want to select.
- To connect to the selected network, tap **Connect**.
- 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 70. 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.

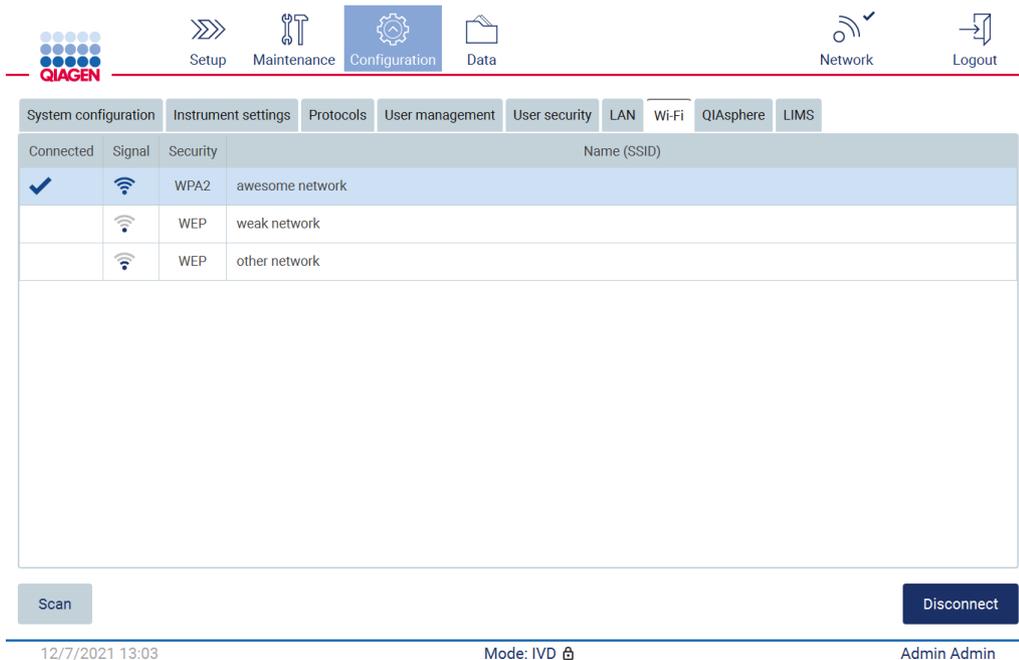


Figure 71. Successful connection to a Wi-Fi network.

- To disconnect from a network, tap the row that represents the network that the instrument is connected to. Then, tap **Disconnect**.
- To view additional information about the network, or to change its password, tap **Advanced**. To go back to the Wi-Fi tab, tap **Back**. To change the password, tap **Change password**. To disconnect from the network, tap **Disconnect**.

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

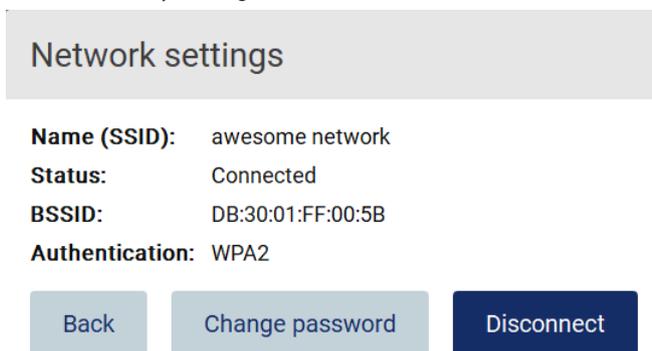


Figure 72. Network settings dialog.

Configuring QIASphere Base connection

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

For more details on the QIASphere Base network configuration and how to connect to the EZ2, refer to the QIASphere Base user manual which is available at www.qiagen.com.

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 **Configuration** on the toolbar.



Figure 73. Configuration button on the toolbar.

2. Tap **QIASphere**.

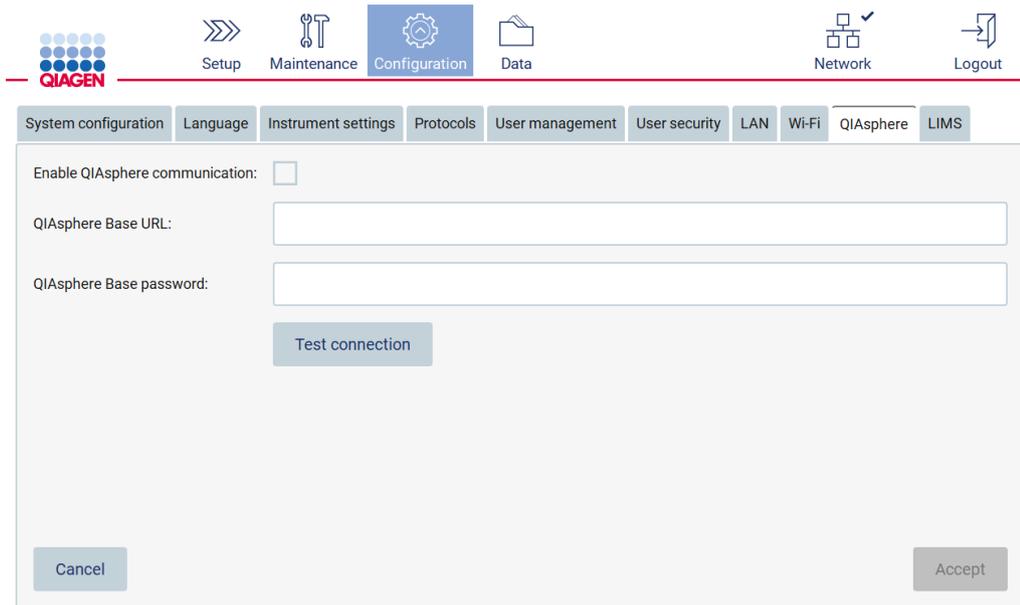


Figure 74. The QIASphere tab.

3. Enter the QIASphere Base URL.
4. Enter the QIASphere Base password.
5. Tick the **Enable QIASphere communication** box.

6. Tap **Accept**.

7. Tap **Test connection**.

Note: If you have any trouble regarding the QIASphere Base, please refer to the QIASphere Base user manual or contact the QIAGEN support.

Configuring LIMS connection

Note: Only administrators can configure the LIMS connection.

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

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

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

The EZ2 Connect MDx can be connected 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. 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.

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 is designed 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 flash drive with the **QIAGEN LIMS Connector** certificate.
2. Tap **Configuration** on the toolbar.



Figure 75. Configuration button on the toolbar.

3. Tap the **LIMS** tab.

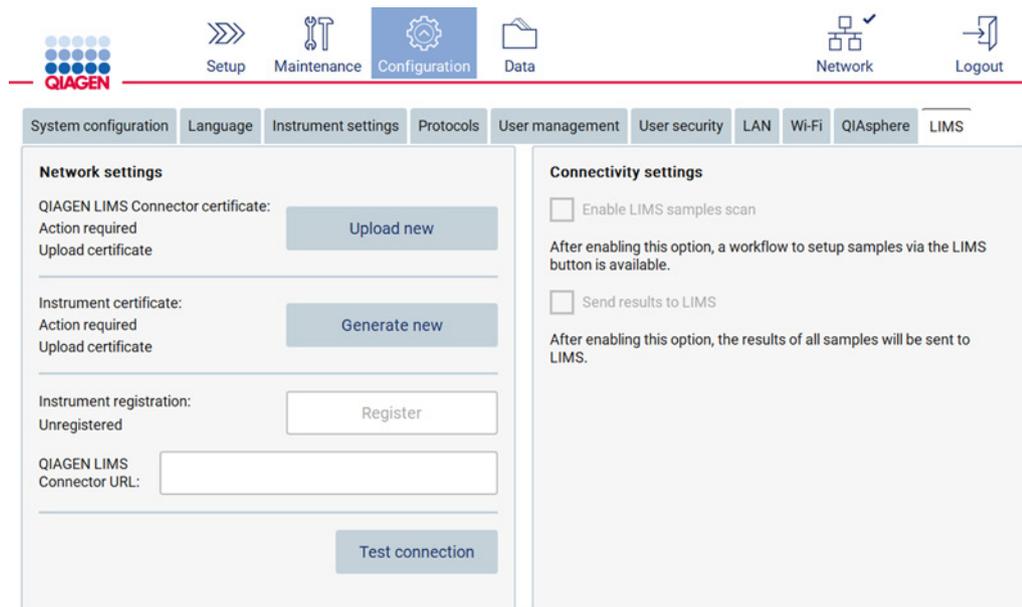


Figure 76. LIMS configuration tab.

4. Tap **Upload new**.

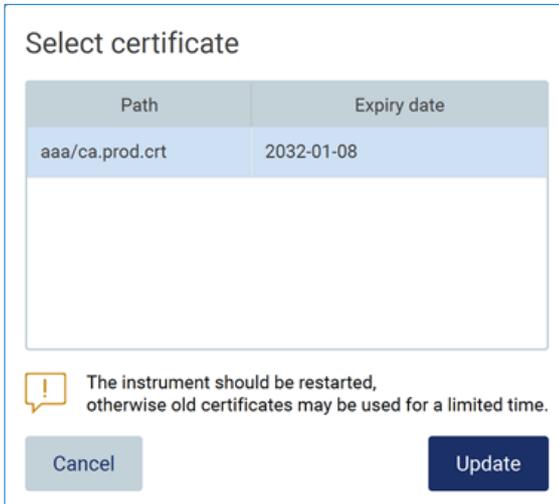


Figure 77. Select certificate screen.

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

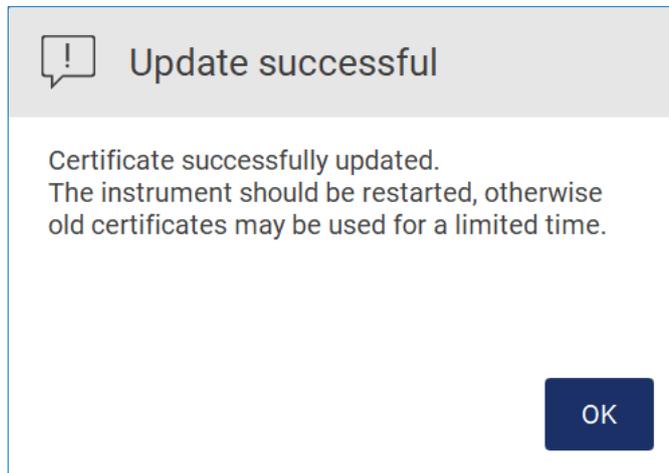


Figure 78. Successful certificate update.

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

- From the **LIMS configuration** tab, tap **Generate** new. Certificate will be stored on attached USB stick.

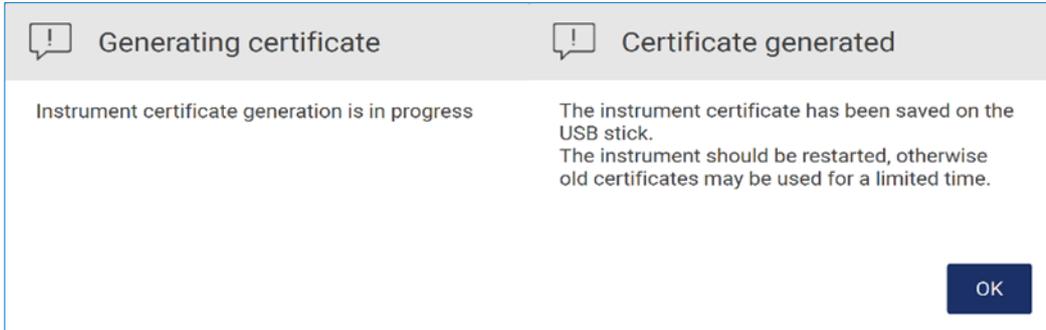


Figure 79. Generation of Instrument certificate.

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

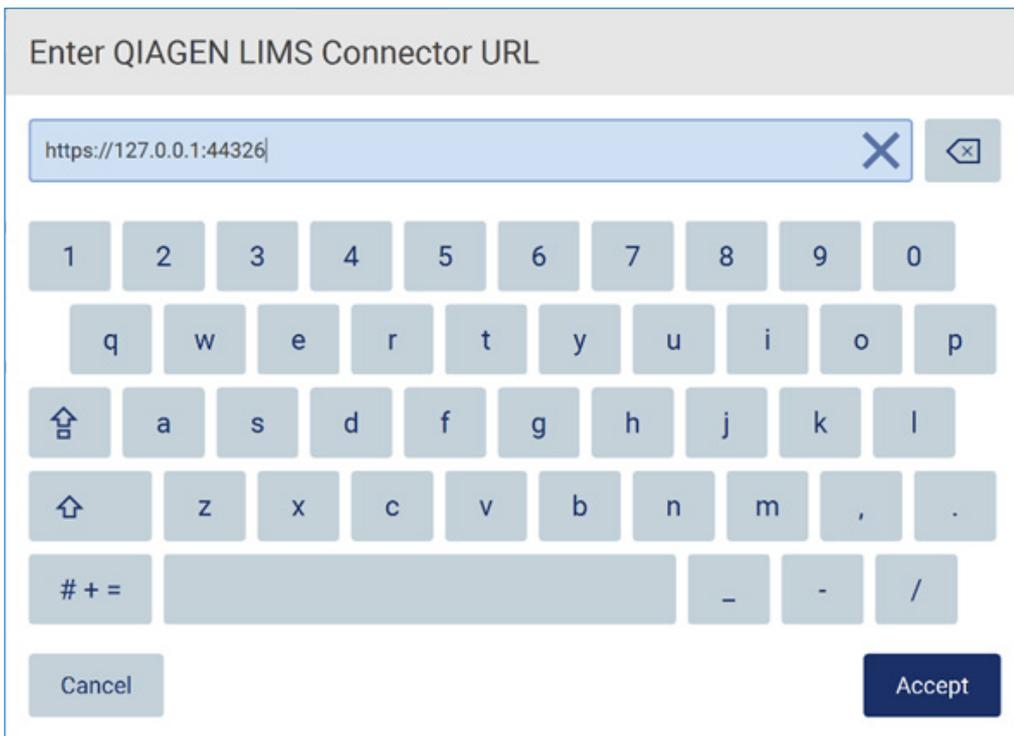


Figure 80. Enter LIMS Connector URL.

11. Tap **Accept**.

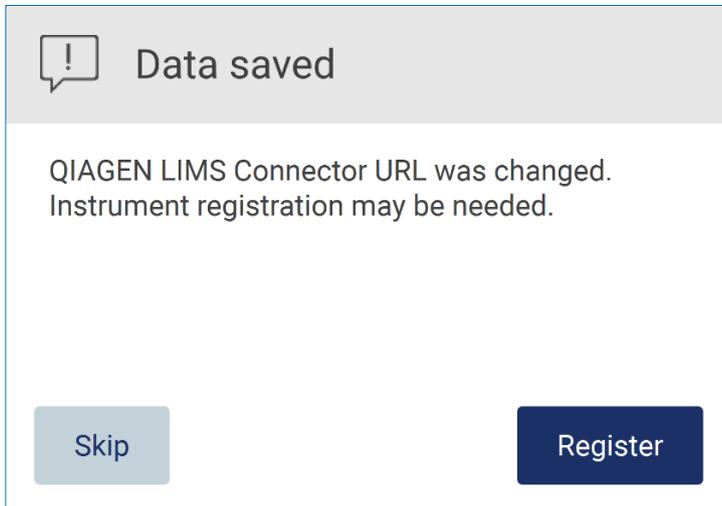


Figure 81. URL accepted.

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.

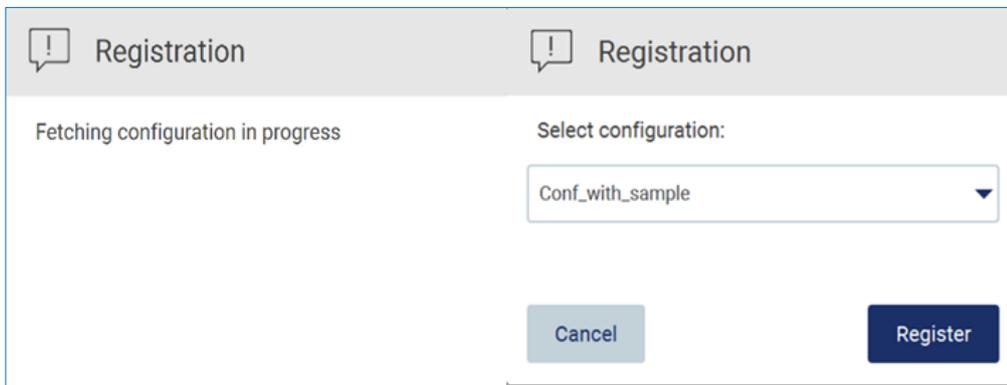


Figure 82. LIMS registration.

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

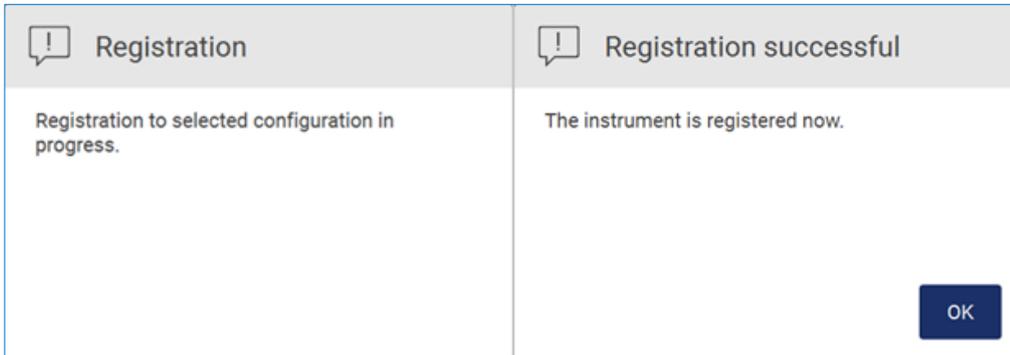


Figure 83. LIMS registration successful.

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

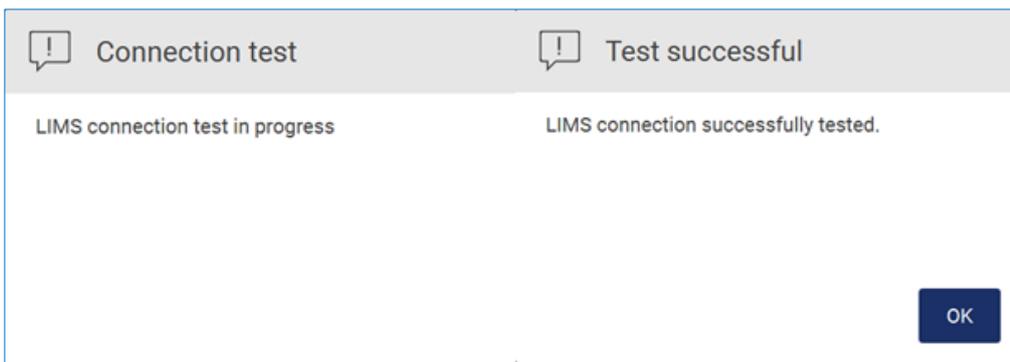


Figure 84. LIMS connection test.

16. If the **Enable LIMS sample scan** box and **Send results to LIMS** are active, the **LIMS** button is available on the **Setup** screen.

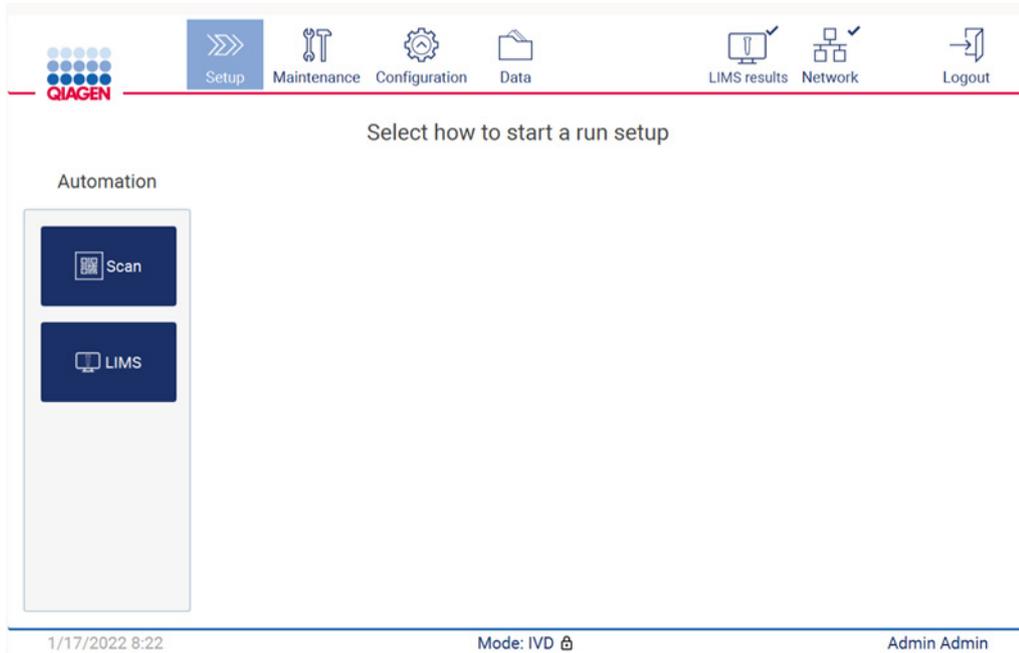


Figure 85. LIMS button available on the Setup screen.

Note: If the user checks the **Send results to LIMS** box, 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** box the following warning is displayed.

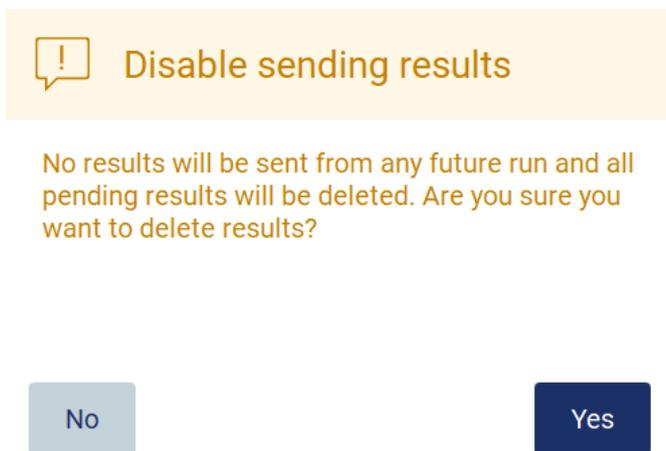


Figure 86. Disable sending results warning.

The LIMS results status is shown by an icon in the upper right corner of the screen.

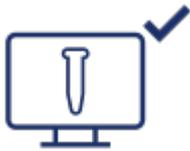
This icon has three states:

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

Figure 87. 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.

18. 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.

The screenshot shows the QIAGEN LIMS interface. At the top, there is a navigation bar with icons for Setup, Maintenance, Configuration, Data, LIMS results (highlighted in blue), Network, and Logout. Below the navigation bar, the page title is 'Results sending status'. The main content area contains a table with the following columns: Status, Sample ID, Run ID, End time, and Last sending attempt. The table is currently empty. At the bottom of the page, the date and time '1/18/2022 13:23' are displayed on the left, and the user name 'Admin Admin' is displayed on the right.

Figure 88. Results sending status Empty.

19. Status icon:



If the sending results is in progress, the 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.



Setup



Maintenance



Configuration



Data



LIMS results



Network



Logout

Results sending status

Status	Sample ID	Run ID	End time	Last
Sending	2022-01-18_13-23_02	2022-01-18_13-23-57-078_Z0920007L	1/18/2022 1:23 PM	1/18/2
Pending	2022-01-18_13-23_03	2022-01-18_13-23-57-078_Z0920007L	1/18/2022 1:23 PM	-
Pending	2022-01-18_13-23_04	2022-01-18_13-23-57-078_Z0920007L	1/18/2022 1:23 PM	-
Pending	2022-01-18_13-23_05	2022-01-18_13-23-57-078_Z0920007L	1/18/2022 1:23 PM	-
Pending	2022-01-18_13-23_06	2022-01-18_13-23-57-078_Z0920007L	1/18/2022 1:23 PM	-
Pending	2022-01-18_13-23_07	2022-01-18_13-23-57-078_Z0920007L	1/18/2022 1:23 PM	-
Pending	2022-01-18_13-23_08	2022-01-18_13-23-57-078_Z0920007L	1/18/2022 1:23 PM	-
Pending	2022-01-18_13-23_09	2022-01-18_13-23-57-078_Z0920007L	1/18/2022 1:23 PM	-
Pending	2022-01-18_13-23_10	2022-01-18_13-23-57-078_Z0920007L	1/18/2022 1:23 PM	-
Pending	2022-01-18_13-23_11	2022-01-18_13-23-57-078_Z0920007L	1/18/2022 1:23 PM	-
Pending	2022-01-18_13-23_12	2022-01-18_13-23-57-078_Z0920007L	1/18/2022 1:23 PM	-

1/18/2022 13:24

Admin Admin

Figure 89. Results sending status In Progress.

20. 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.



Setup



Maintenance



Configuration



Data



LIMS results



Network



Logout

Results sending status

Status	Sample ID	Run ID	End time	Last
Unsent (ID: 014032, Description: The remote hostname was not found (invalid hostname).)	2022-01-18_13-25_22	2022-01-18_13-25-53-013_Z0920007L	1/18/2022 1:25 PM	1/18/2
Sending	2022-01-18_13-26_05	2022-01-18_13-26-54-466_Z0920007L	1/18/2022 1:26 PM	1/18/2
Pending	2022-01-18_13-26_06	2022-01-18_13-26-54-466_Z0920007L	1/18/2022 1:26 PM	-
Pending	2022-01-18_13-26_07	2022-01-18_13-26-54-466_Z0920007L	1/18/2022 1:26 PM	-
Pending	2022-01-18_13-26_08	2022-01-18_13-26-54-466_Z0920007L	1/18/2022 1:26 PM	-
Pending	2022-01-18_13-26_09	2022-01-18_13-26-54-466_Z0920007L	1/18/2022 1:26 PM	-
Pending	2022-01-18_13-26_10	2022-01-18_13-26-54-466_Z0920007L	1/18/2022 1:26 PM	-
Pending	2022-01-18_13-26_11	2022-01-18_13-26-54-466_Z0920007L	1/18/2022 1:26 PM	-
Pending	2022-01-18_13-26_12	2022-01-18_13-26-54-466_Z0920007L	1/18/2022 1:26 PM	-
Pending	2022-01-18_13-26_13	2022-01-18_13-26-54-466_Z0920007L	1/18/2022 1:26 PM	-

1/18/2022 13:27

Admin Admin

Figure 90. 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. For MDx applications, choose the IVD mode when logging in. For other applications, choose Research mode. For details on all protocols, refer to the respective instructions for use/kit handbooks.

Note: EZ2 does not support protocols obtained from sources other than the QIAGEN website.



Welcome to EZ2.
Please log in.

User ID:

Password:

Research Mode IVD Mode

Log in

3/19/2021 12:07

Figure 91. The login 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., on sample storage, handling, and preparation) provided in the handbook.

5.4.1 Scanning Q-Card bar code

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

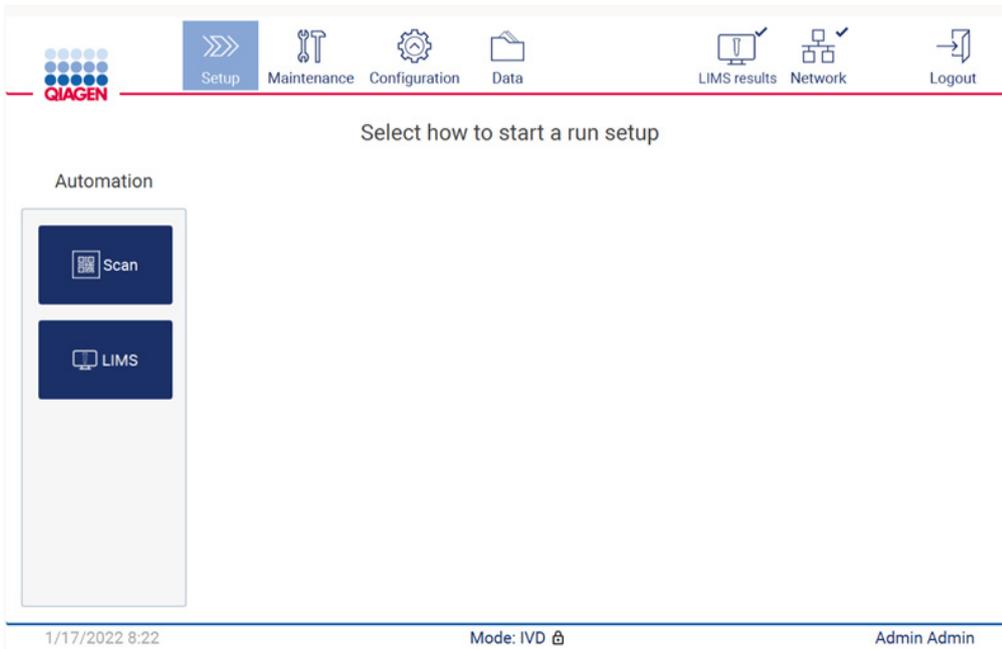


Figure 92. Setup screen.

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

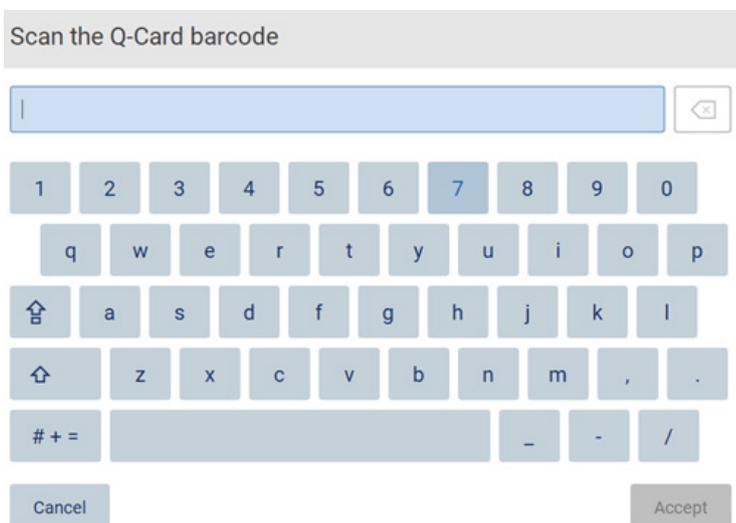


Figure 93. Scan the Q-Card barcode screen.

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

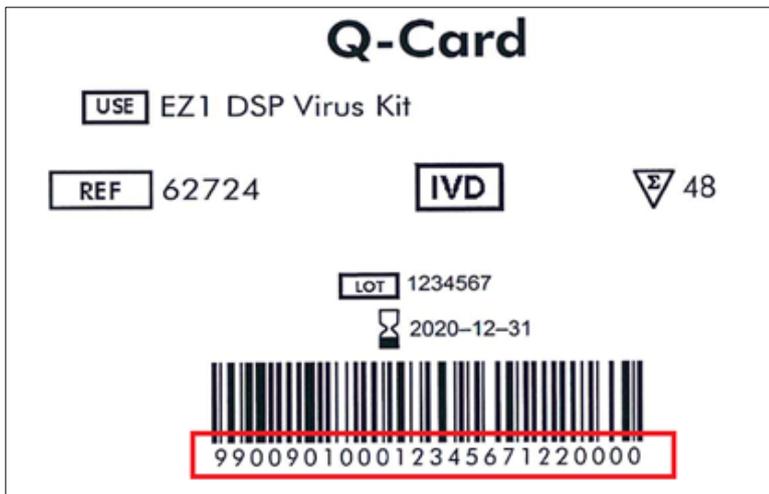


Figure 94. Q-Card sample.

By scanning the 1D Barcode on the Q-Card provided with the kit, the application type is selected and information on script options is given. See the Using the bar code scanner section (see page 132).

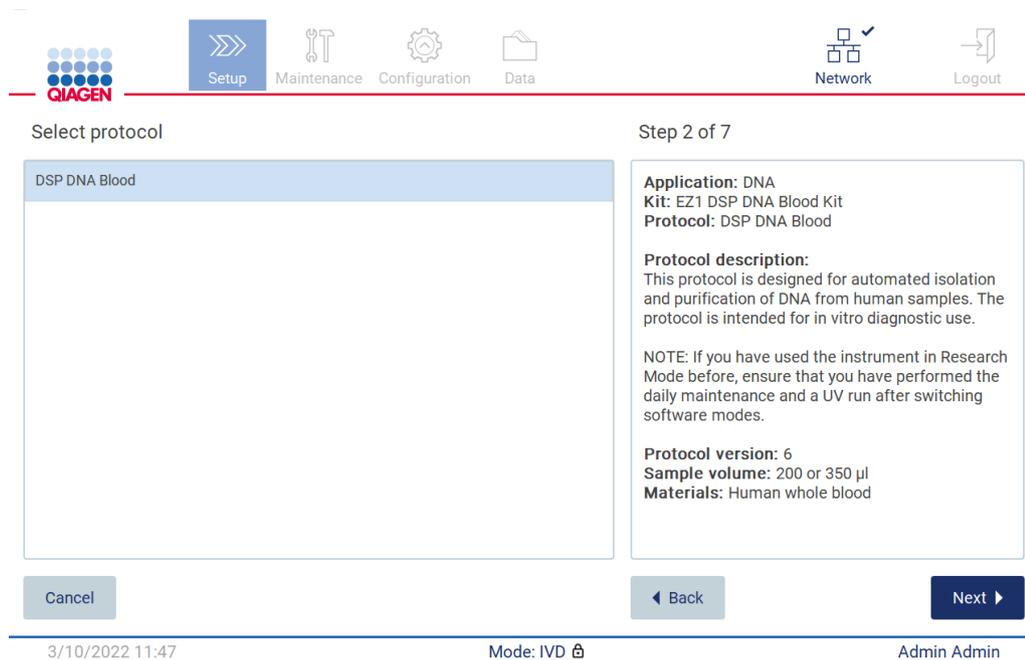


Figure 95. Select protocol screen.

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

5.4.2 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.

Note: If you use language files for translation of the touchscreen, the protocol parameters are not translated into the target language. Choose **No** if the ethanol wash is not desired, or choose **Yes** if the ethanol wash is desired.

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

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

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

Figure 96. Define parameters step with open drop-down list.

Additional information about the protocol is also displayed on the screen, e.g., 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**.

5.4.3 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.

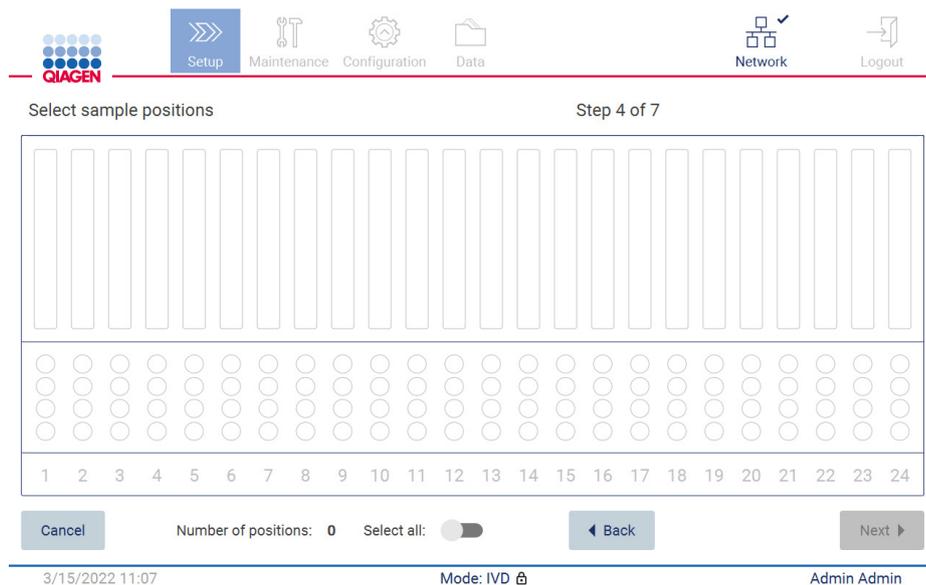


Figure 97. Select sample positions screen.

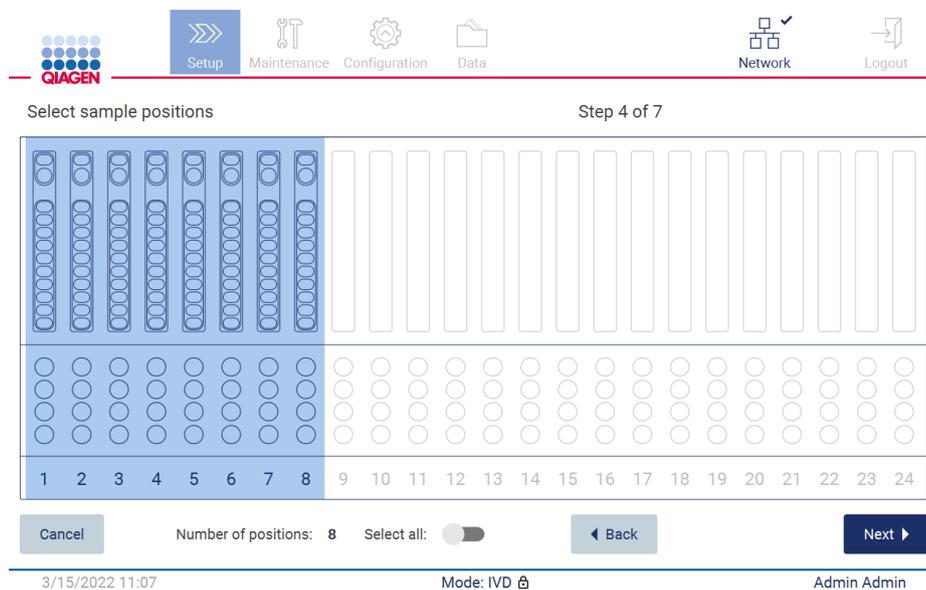


Figure 98. Select sample positions step.

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

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

To cancel the protocol, tap **Cancel**.

5.4.4 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, and by use of the handheld barcode scanner. Ensure that the entered sample ID really corresponds to ID of the sample in the respective position.

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.

The screenshot shows the 'Enter sample IDs' step (Step 5 of 7) in the QIAGEN software interface. The top navigation bar includes icons for Setup, Maintenance, Configuration, Data, Network, and Logout. The main area is divided into two sections: a table for entering sample IDs and a sidebar with protocol details.

Position	Sample ID	Note (optional)
1	2022-03-10_11-54_01	
2	2022-03-10_11-54_02	
3		

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

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

Warning: Sample ID must be entered in and be unique.

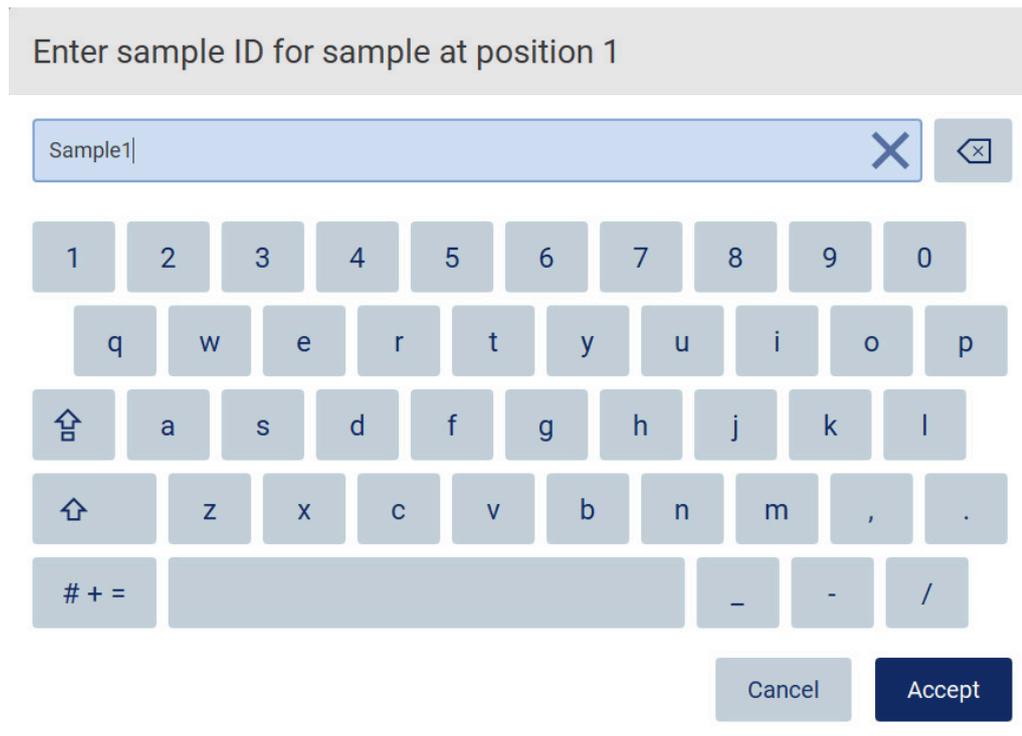
Buttons at the bottom: Cancel, Generate missing sample IDs, Back, Next.

Footer: 3/10/2022 11:54, Mode: IVD, Admin Admin

Figure 99. Enter sample IDs step (two IDs auto generated).

Modifying a sample ID

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



The screenshot shows a dialog box titled "Enter sample ID for sample at position 1". Inside the dialog, there is a text input field containing the text "Sample1". To the right of the input field are two icons: a blue 'X' for clearing the text and a grey square with a white 'X' for closing the keyboard. Below the input field is a full QWERTY on-screen keyboard. At the bottom right of the dialog, there are two buttons: a grey "Cancel" button and a dark blue "Accept" button.

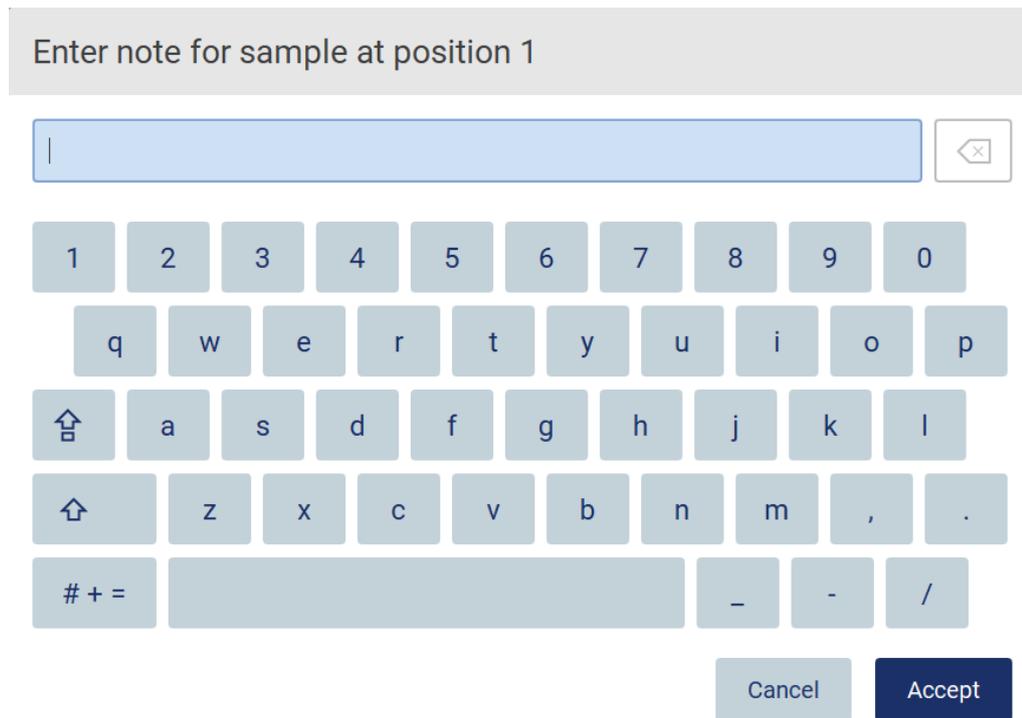
Figure 100. Changing the sample ID.

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.



The screenshot shows a mobile application interface for adding a note to a sample. At the top, a grey header bar contains the text "Enter note for sample at position 1". Below this is a light blue text input field with a vertical cursor on the left and a clear button (a square with a left-pointing arrow and an 'x') on the right. Underneath the input field is a full QWERTY on-screen keyboard with light blue keys. The keyboard includes a home key on the left, a spacebar, and a hyphen/underscore key on the right. At the bottom right of the screen, there are two buttons: a light blue "Cancel" button and a dark blue "Accept" button.

Figure 101. 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**.

5.4.5 Loading the cartridge rack

Remove the cartridge rack from the instrument and place it safely onto the bench. See the Loading and unloading the cartridge rack section (page 130).

The **Load the cartridge rack** steps (page 130) features 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. In the IVD mode of the software, only the protocols for the DSP Virus Kit use the loading instruction for the additional well in the table.

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

Well	Action
11	Load empty sample tubes ST (QIAGEN, mat. no. 1045751), uncapped.

• Ensure that reagent cartridges (RCV) are undamaged and equilibrated to RT.
• Invert RCV 4 times and tap to place liquids at the bottom of their wells.
• Place RCV to the previously chosen positions.
• Follow the table above.

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

Figure 102. Load the cartridge rack step.

To proceed to the **Load the tip rack** step, tap **Next**.

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

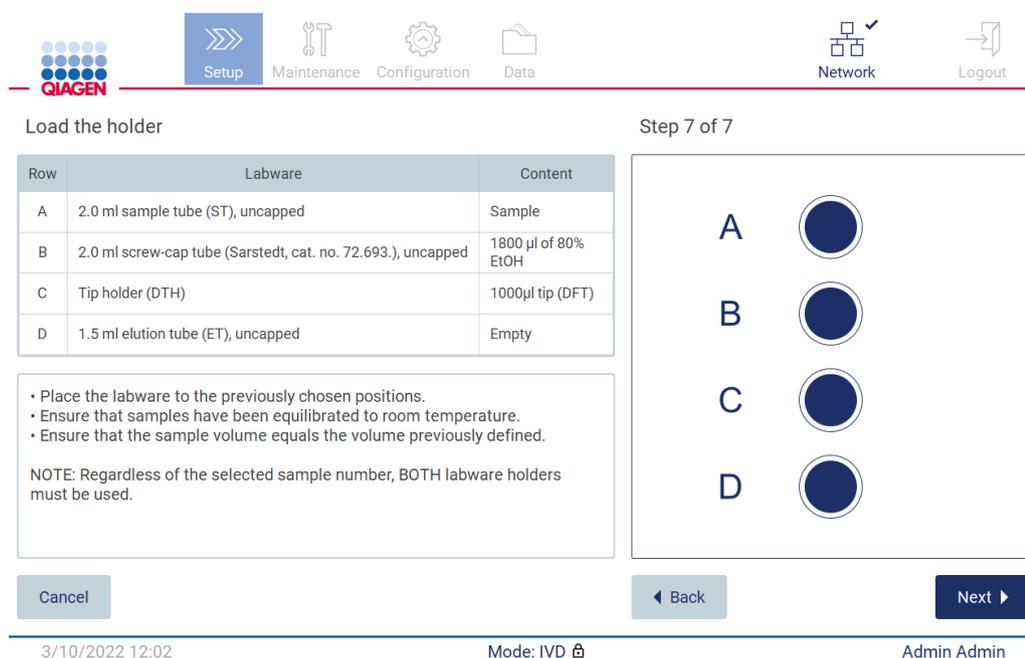
To cancel the protocol, tap **Cancel**.

5.4.6 Loading the tip rack

Remove the tip rack from the instrument and place it safely onto the bench. See the Loading and unloading the tip rack section (see page 131).

The **Load the tip rack** steps (see page 131) 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.



QIAGEN

Setup Maintenance Configuration Data Network Logout

Load the holder Step 7 of 7

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

- Place the labware to the previously chosen positions.
- Ensure that samples have been equilibrated to room temperature.
- Ensure that the sample volume equals the volume previously defined.

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

Cancel Back Next

3/10/2022 12:02 Mode: IVD Admin Admin

Figure 103. Load the tip rack step.

Note: In some applications, not all positions of the labware holder 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.

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.

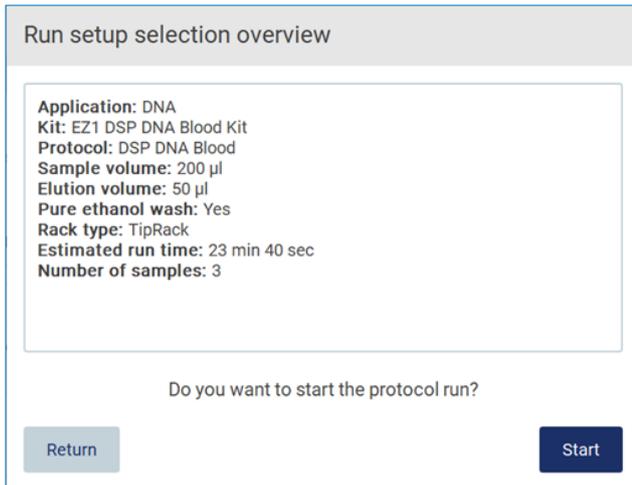


Figure 104. Run set up overview.

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

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

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.

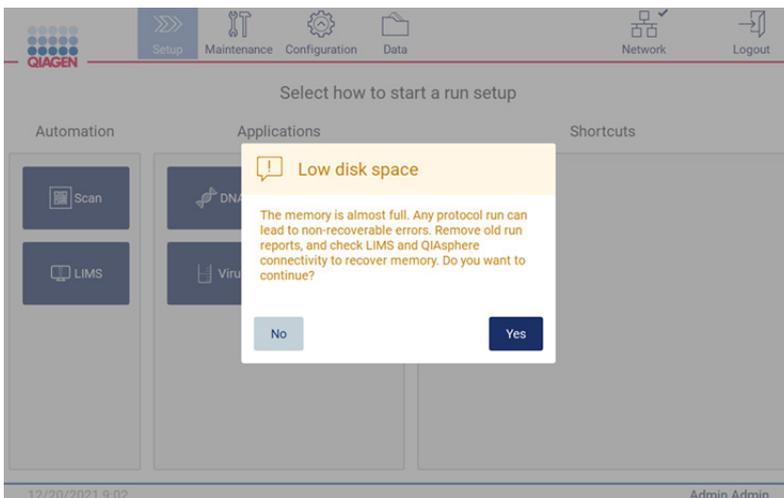


Figure 105. Low disk space.

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

5.4.7 LIMS Workflow

Important: Before starting a run with the LIMS workflow, a specific application layer needs to be created and set up for each protocol which will be run in your lab routinely. This application layer contains all specific parameters of the respective protocol. During the LIMS connection set-up service, ensure that you cover with the QIAGEN service person all protocols you intend to use, to get the needed application layers created during this setup.

1. To begin set up of a protocol run using the LIMS interface, start at the **Setup** tab, then tap the LIMS button.

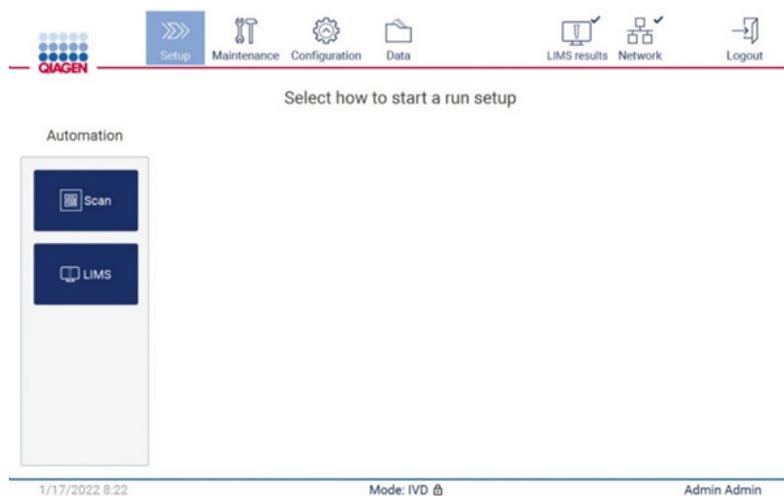


Figure 106. Setup screen.

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

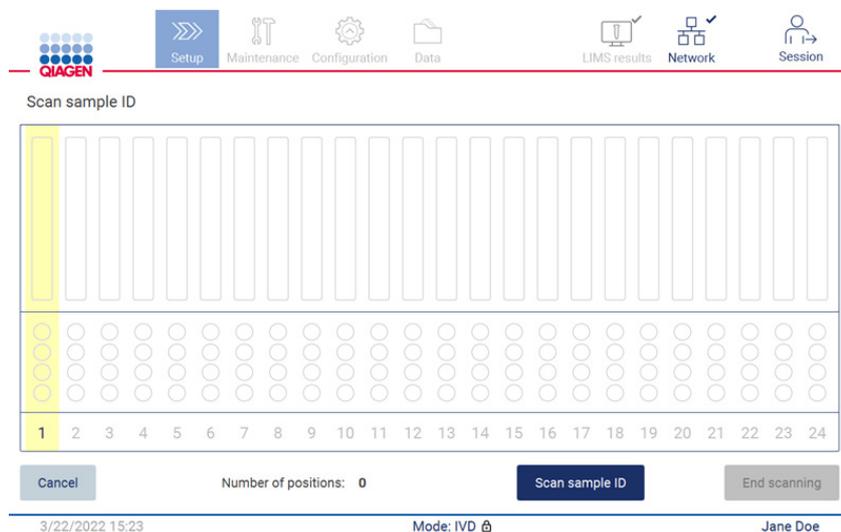


Figure 107. Scan sample ID screen.

3. Tap **Scan sample ID** to either scan using the handheld barcode scanner or by use of the onscreen keyboard.



Figure 108. Scan or enter sample ID.

4. After scanning the first sample the check parameters and load the holder screen is displayed.

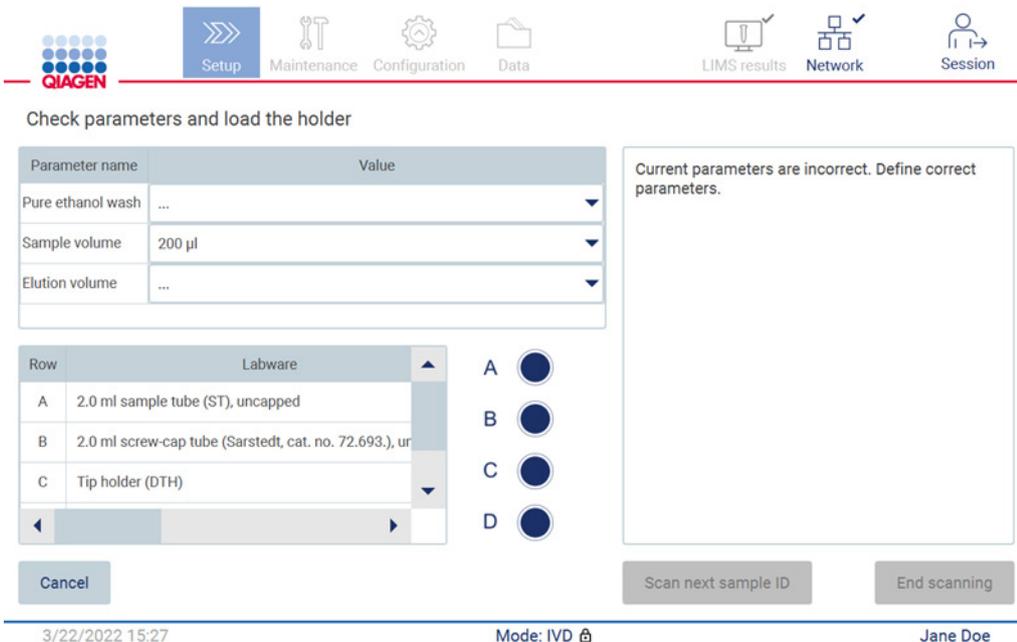


Figure 109. Check parameters and load the holder screen.

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

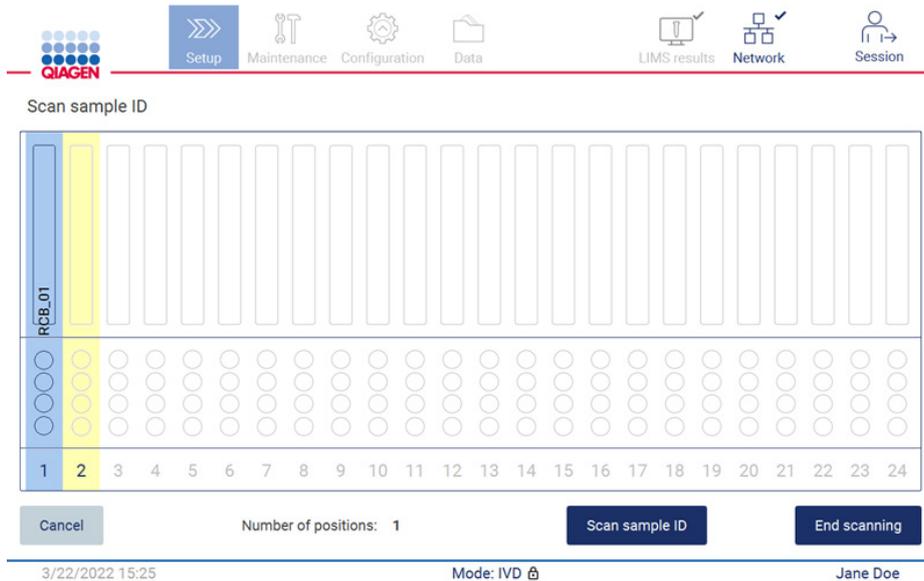


Figure 110. Scan additional samples or proceed to next step.

- 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 which 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.

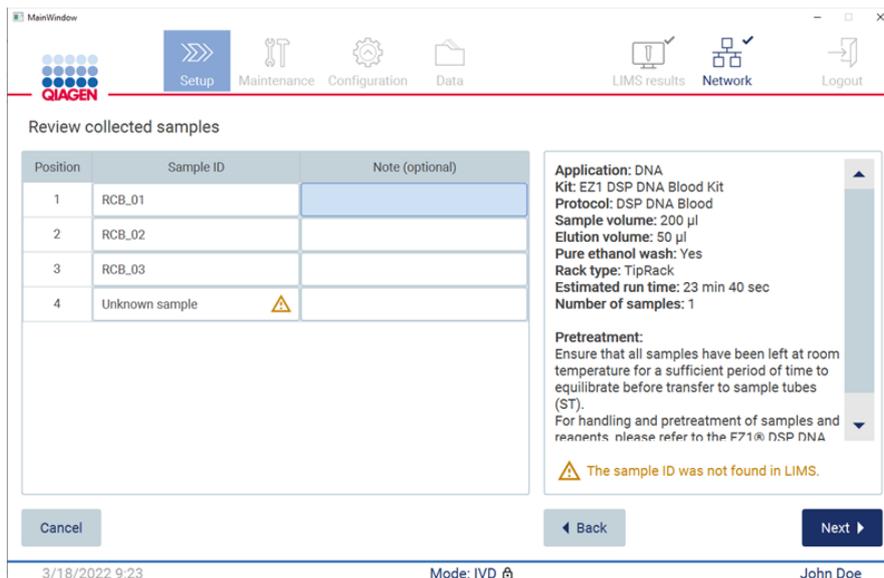


Figure 111. Review collected samples.

- 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 onscreen keyboard. Tap **Next** when complete.

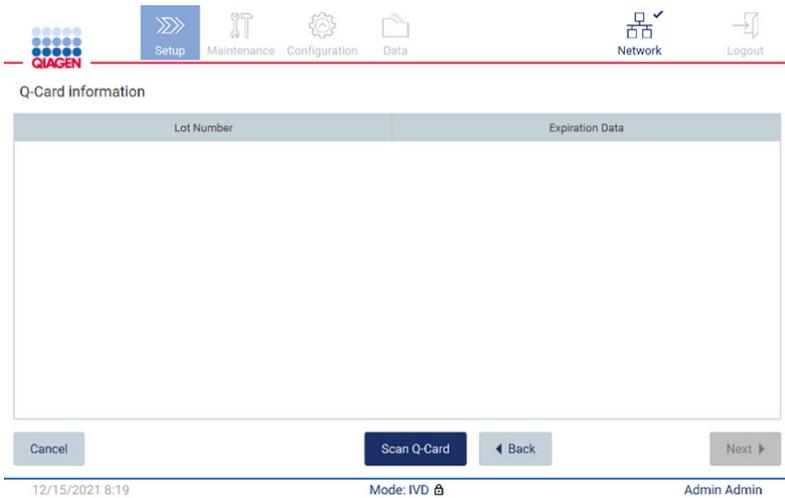


Figure 112. Scan Q-card.

The **Load the cartridge rack** steps (page 130) features 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.

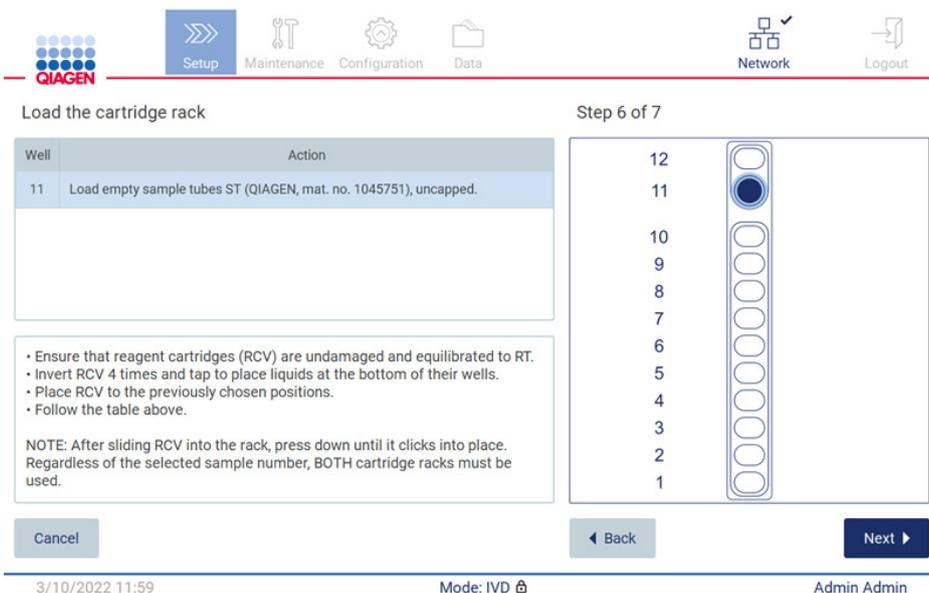


Figure 113. Load the cartridge rack.

8. 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.

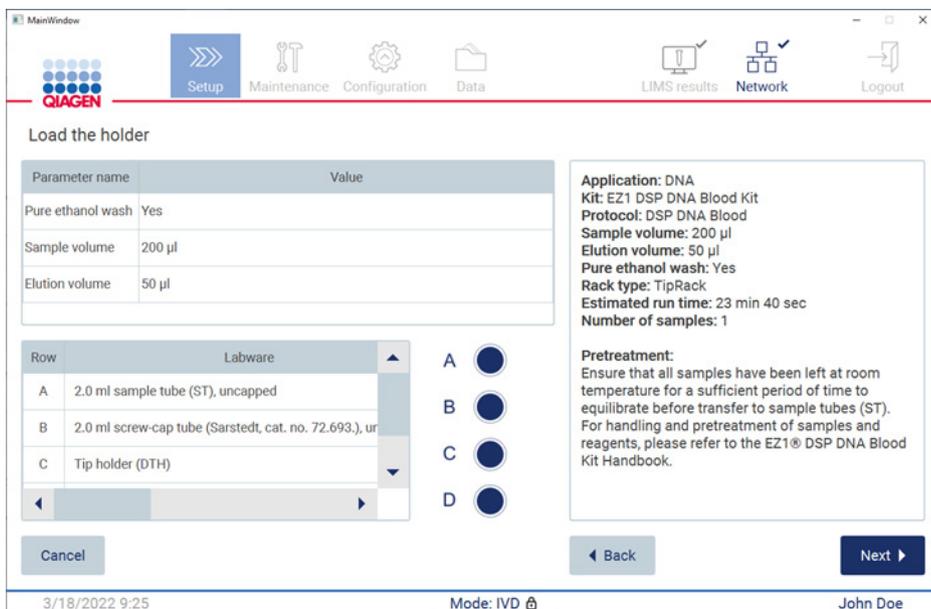


Figure 114. Load the holder.

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

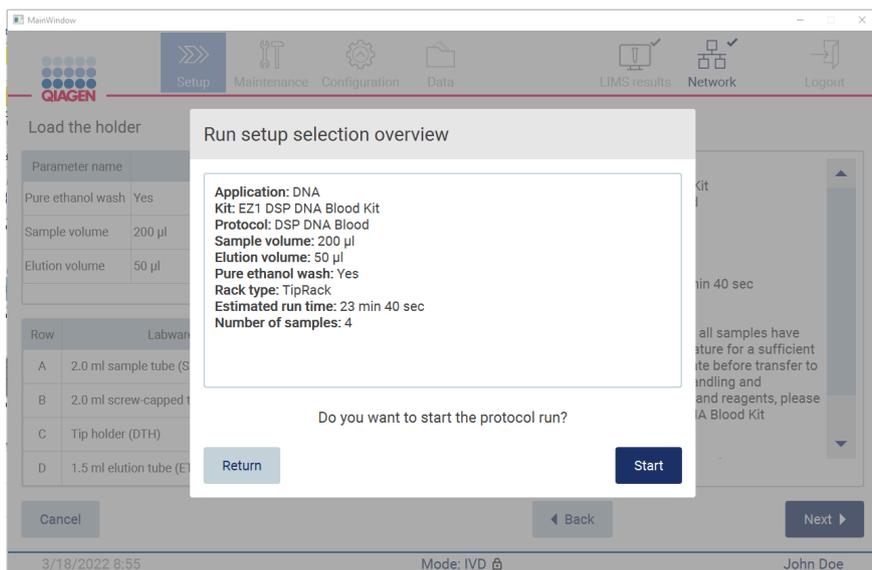


Figure 115. Run set-up overview.

10. 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:

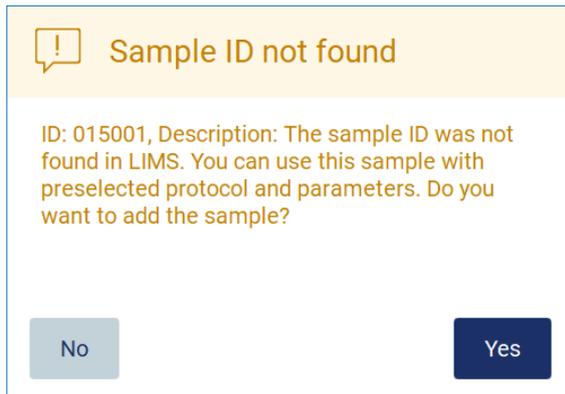


Figure 116. LIMS Sample ID not found dialogue.

11. 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.

12. 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.

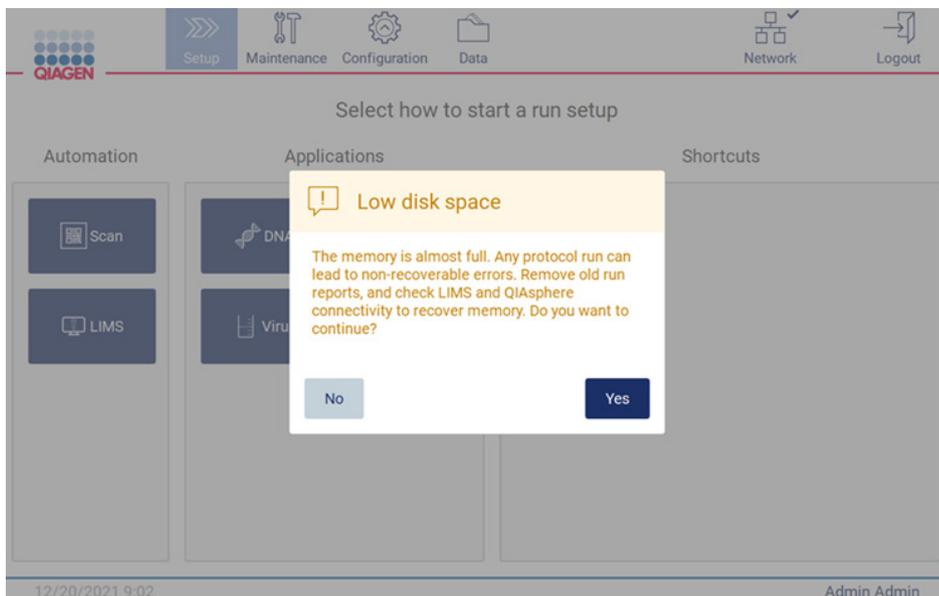


Figure 117. Low disk space.

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

5.5 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.

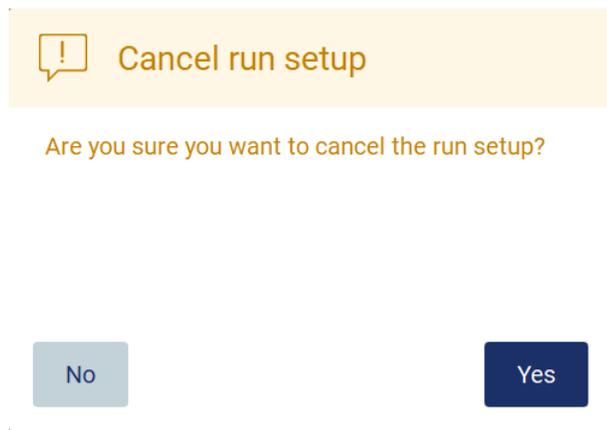


Figure 118. The Cancel run setup dialog.

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.

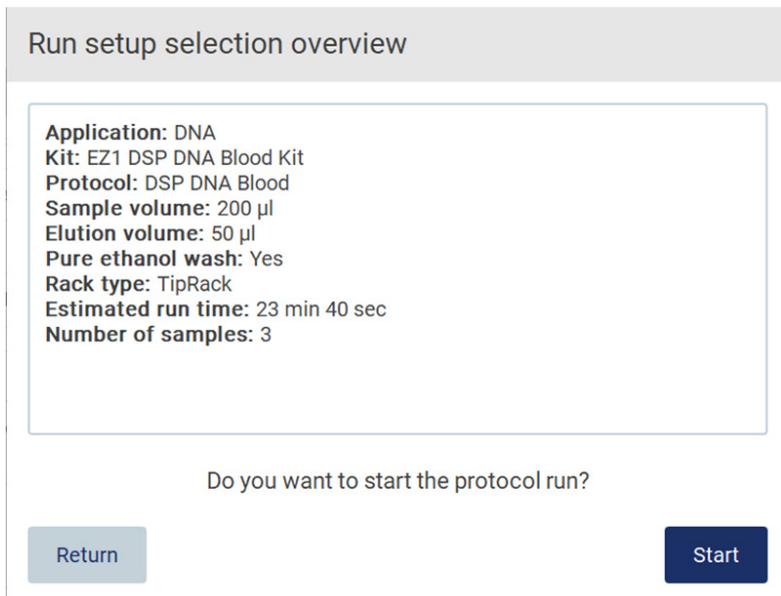


Figure 119. Run setup selection overview dialog.

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.

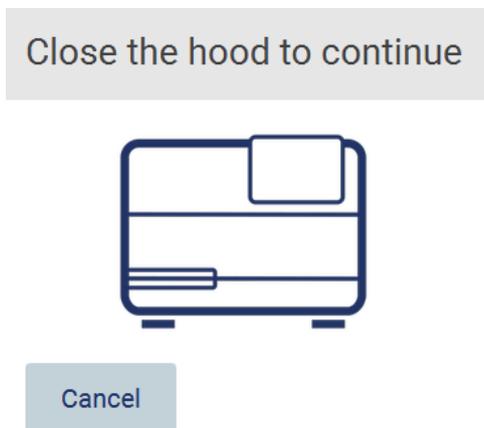


Figure 120. Close the hood dialog.

- The load check will now be performed. For more information about the load check, refer to the Load check section (see page 121). The run will start after the check is successfully completed. To stop the load check, tap **Abort**.

Note: 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.

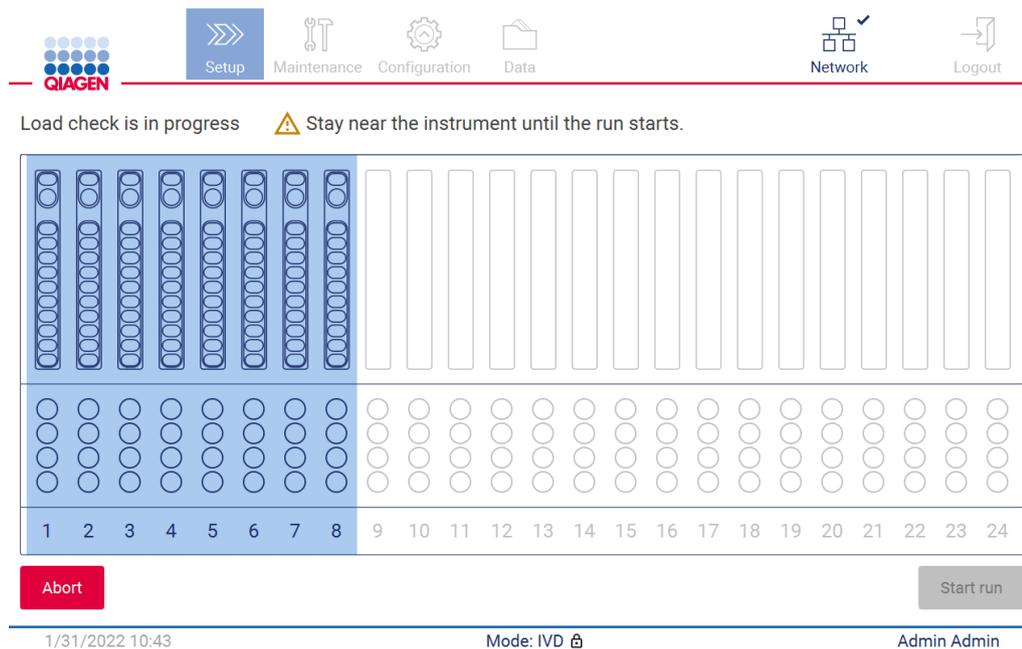


Figure 121. Load check in progress screen.

- 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.

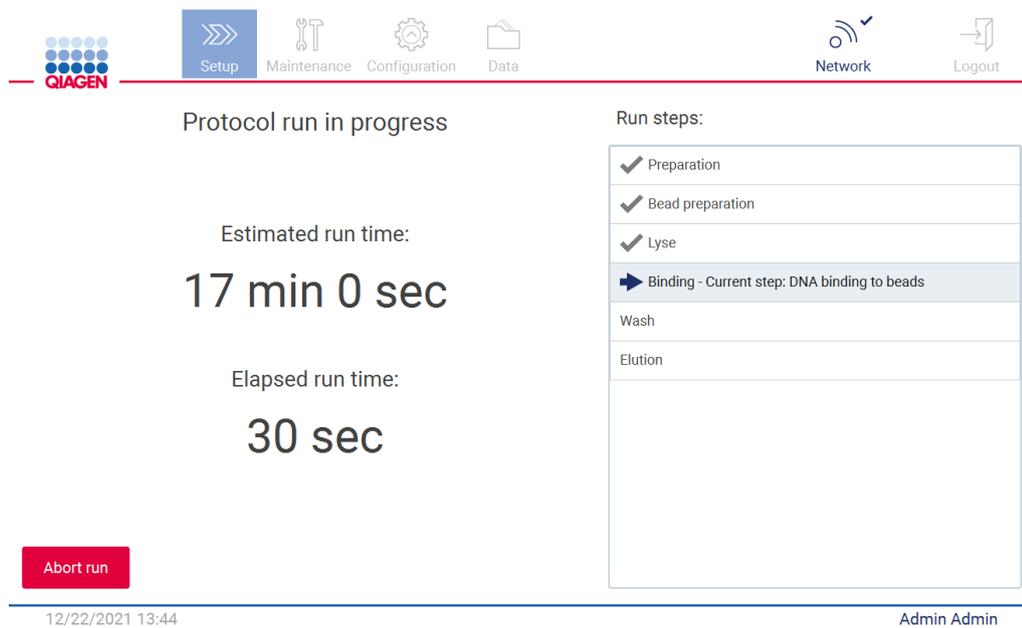


Figure 122. Run progress screen.

5.6.1 Load check

The E22 Connect MDx 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 118).

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.

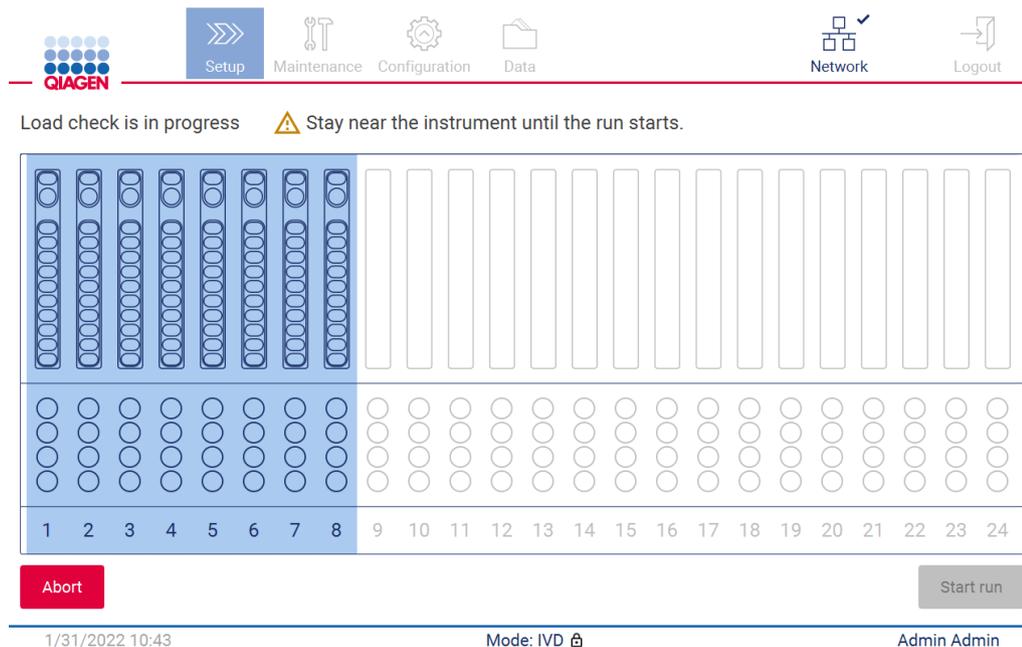


Figure 123. Load check is in progress screen.

Load check Limitations

Important: The load check is designed to support the operator to ensure that the worktable is correctly set up as detailed on the GUI interface. 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 empty tip holder and elution/reagent/sample tube
- Distinguish between capped tube and tip holder with tip
- Distinguish between tip holder (without tip) and tube
- Distinguish between tip holder (without tip) and tip holder with tip

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. If you have to correct the loading, the load check must be repeated.

Note: Only use EZ1&2 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 anymore valid 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, 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.

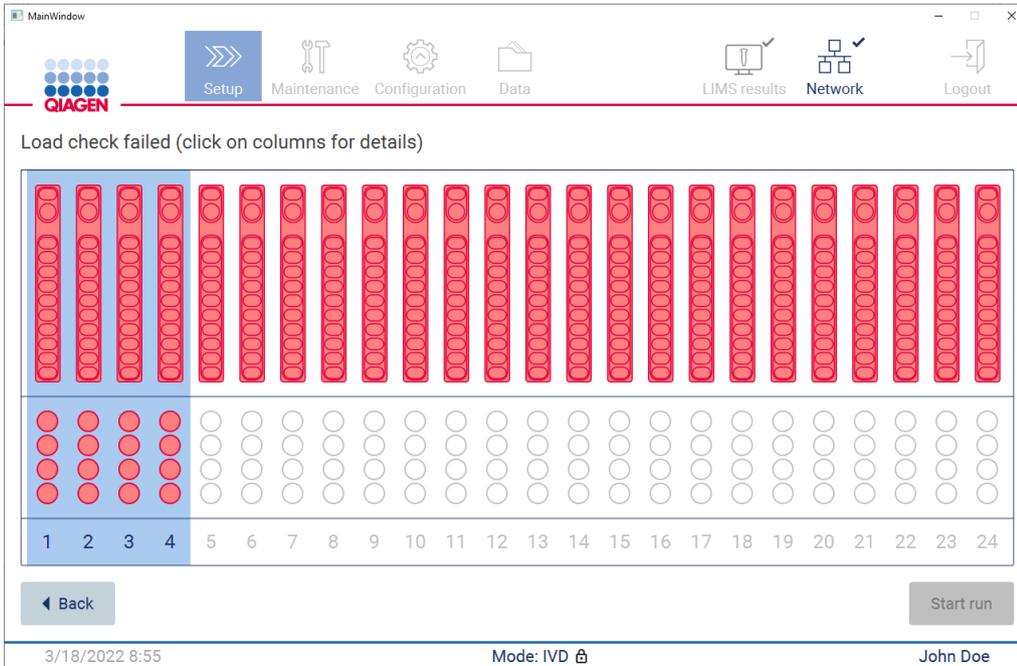


Figure 124. Load check failed screen.

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 to confirm correct placement of ALL consumables in ALL worktable positions in accordance with the instructions detailed in the loading the worktable GUI wizard. It is recommended to perform this check while the Load check failed screen (Figure 123) 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.

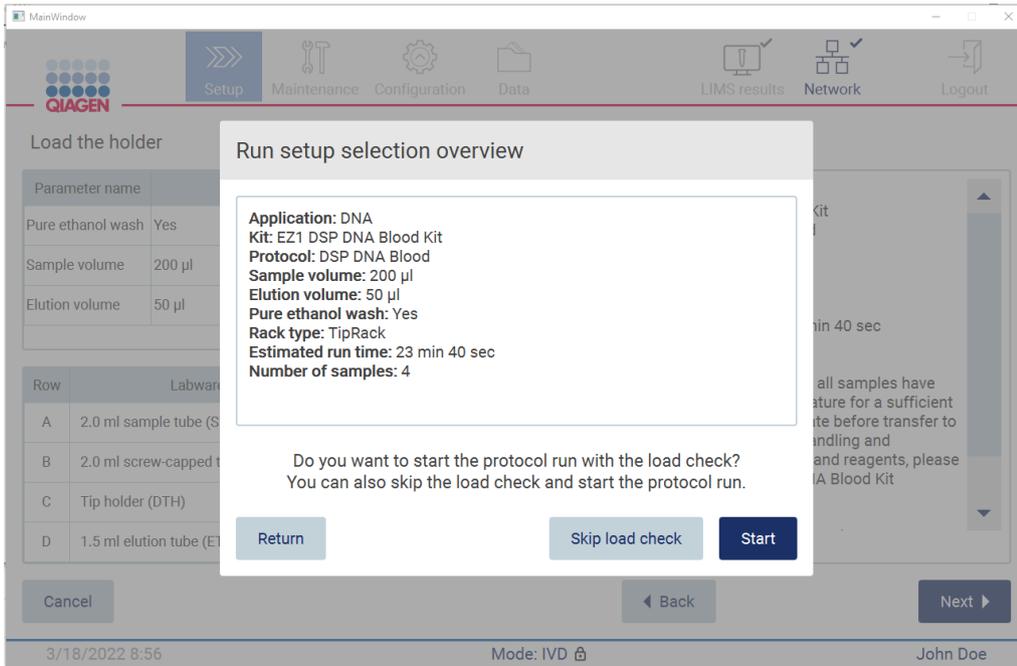


Figure 125. Skip load check option.

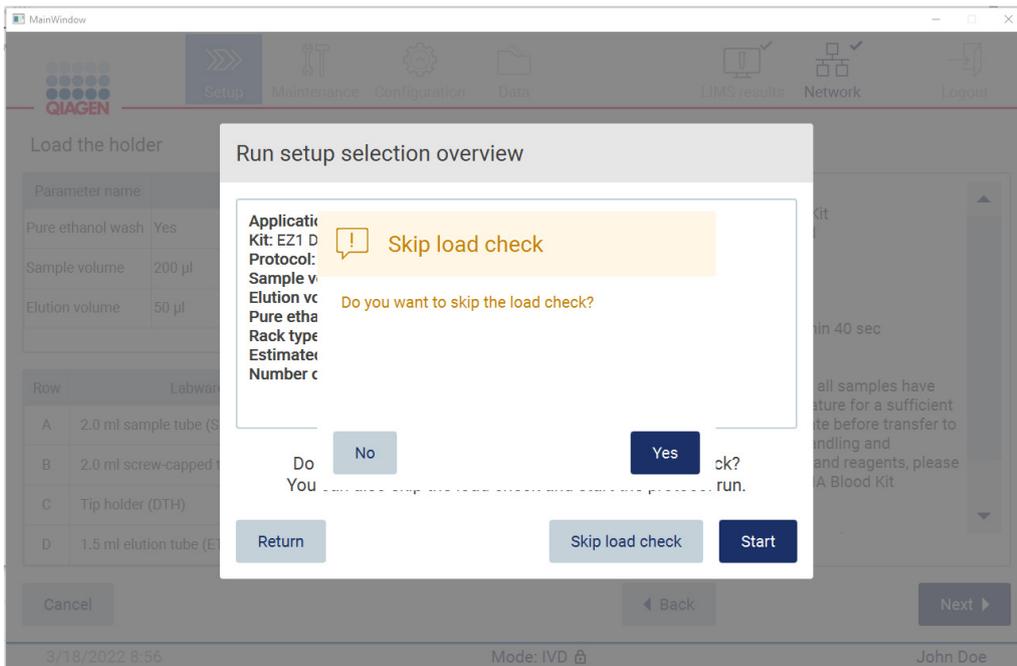


Figure 126. Confirm skip load check screen.

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, you have to press the **Back** button until you reach the **Select sample positions** screen. This will unlock the hood and allow correction of the wrong positions.

Note: If the operator goes back to the Select sample positions screen (standard workflow) 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. First, remove the eluates and store them according to the kit handbook of the used application. Follow the instructions to properly remove all labware from the instrument and clean the piercing unit, see the After run maintenance section (see page 145). If after run maintenance is completed, tap the check box to transfer the maintenance status into the run report. Tap **Finish** to end the run, to create the report file and 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 128).

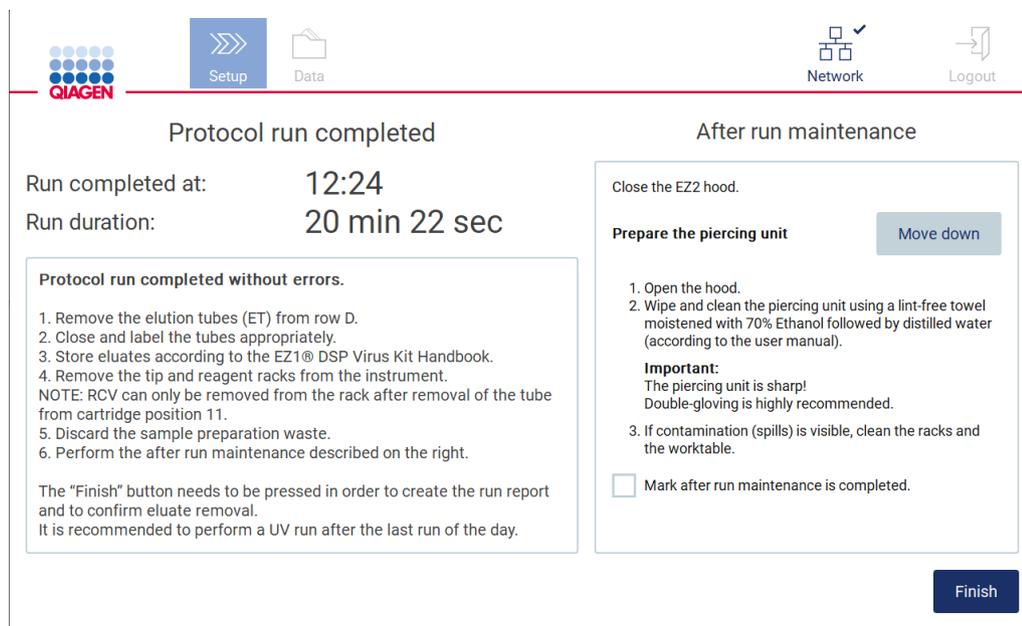


Figure 127. Protocol run completed screen.

5.8 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 128. 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. 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.

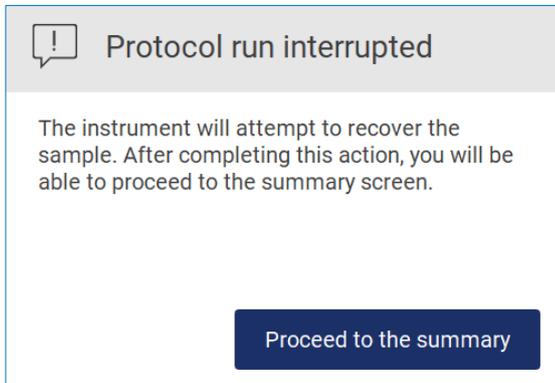


Figure 129. Protocol run interrupted dialog.

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 (see page 128).

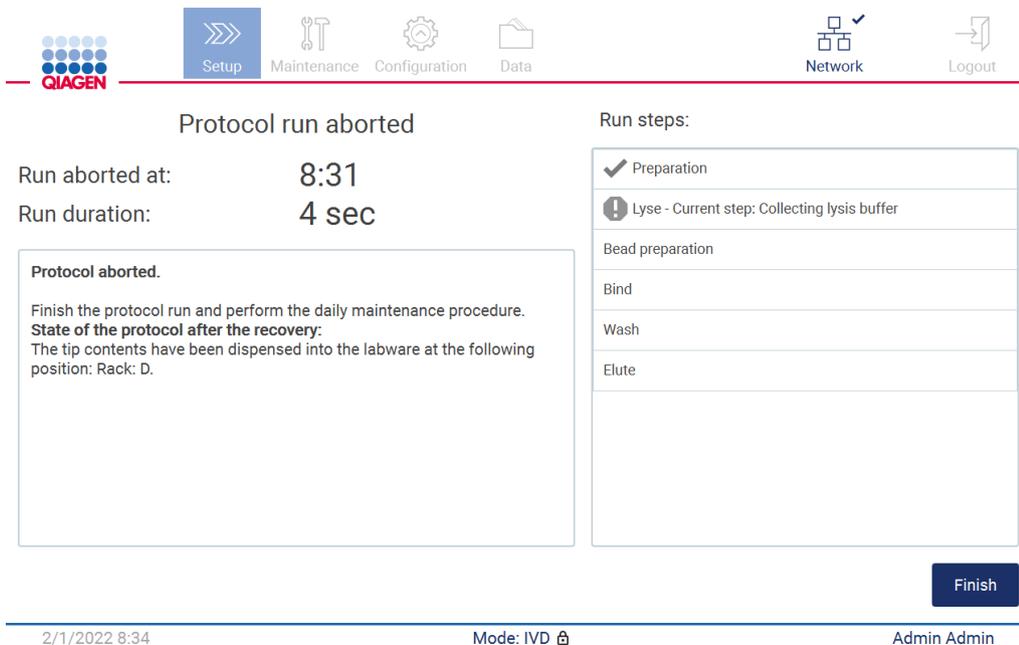


Figure 130. Protocol run aborted screen.

5. Also, for aborted protocol runs, the after daily maintenance needs to be performed. Please follow the instructions regarding the cleaning of the piercing unit from Daily maintenance section (see page 148).

5.9 Saving a run report

After a run ends successfully, fails, or is aborted, a run report can 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** screens.

For more information on what the run report contains, refer to the Run report contents section (see page 128).

5.9.1 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 title of the run report file, which includes the date when the run ended and the serial number of the instrument
- The status of the run, which indicates if the run was completed successfully, if it failed, or if it was aborted
- Errors (if occurred)
- The status of the cleanup procedure that is required after a run ends
- Information about the samples: their positions, names and any notes that were added by the user
- Information on sample flags
- Maintenance information (due, executed, etc.)
- Validity status of samples

5.10 Setting up the worktable

Setting up the EZ2 worktable consists of removing the tip rack and the cartridge rack from the instrument, loading the cartridges, tubes, tip holders and tips, and placing the racks back into the instrument. Some protocols require additional actions to be done before the start of a run, e.g., inversion of the cartridge to mix the magnetic beads. These actions are described in the Loading the cartridge rack and Loading the tip rack screens of the protocol run setup process, and in the kit handbooks.

5.10.1 Loading and unloading the cartridge rack

To load the cartridge rack, follow the steps below:

1. Follow the instructions of the respective kit handbook on how to treat the reagent cartridges before loading onto the cartridge rack.

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 the cartridge 4 times to ensure the magnetic beads are resuspended.
3. Tap the reagent cartridges until the reagents are deposited at the bottom of the wells. No droplets should remain on the walls and sealing of the cartridge.
4. 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.
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, position numbers are engraved onto the rack. Numbering reads 1 to 24 from left to right.

At the end of a protocol run, you must remove the reagent cartridges from the cartridge rack. To do so, follow the steps below:

1. First remove the tip rack.
2. 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.

Note: If the additional tube position was used in the reagent cartridge, these tubes have to be removed before removing the cartridge rack

3. Slide out the reagent cartridges and dispose of them properly, according to local safety regulations.

CAUTION



Hazardous materials and infectious agents

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 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.
5. Place the cartridge rack sections back in the instrument, followed by the tip rack.

5.10.2 Loading and unloading the tip rack

To load the tip rack, follow the steps below:

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. Place the tips into their tip holders.
3. Load the tip holders with tips into Row C.
4. Load the labware into Rows B and D.

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.

5. Once all the labware is loaded, place the tip rack sections onto the worktable.
6. 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.

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

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 instrument and extended time before removal may cause nucleic acid degradation.

1. Remove one or both sections of the tip rack from the worktable. To remove a tip rack section, grab both sides of the section and gently pull up.
2. Cap and remove eluate tubes from the rack and store accordingly.
3. Remove the labware from the tip rack and dispose according to local safety regulations.

<p>CAUTION</p> 	<p>Hazardous materials and infectious agents</p> <p>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.</p>
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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. Place the tip rack sections back in the instrument.

5.11 Using the bar code scanner

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

- Kit Q-Cards
- Sample Bar Codes

Details of readable barcode types can be found in the information supplied with the barcode scanner.

Direct the handheld scanner at the required Q-Card/Barcode or sample bar code to scan the information into the Instrument when prompted by the User Interface.

Note: Barcode information may also be entered manually.



Figure 131. Scanning the information into the Instrument.

<p>WARNING</p> 	<p>Risk of personal injury</p> <p>Hazard Level 2 laser light: Do not stare into the light beam when using handheld bar code scanner.</p>
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5.12 Data menu

Important: Use only the USB flash drive provided by QIAGEN. Do not connect other USB flash drive 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 element:

- Download and/or delete run files
- Create support package
- Download audit trail

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



Figure 132. Data button on the toolbar.

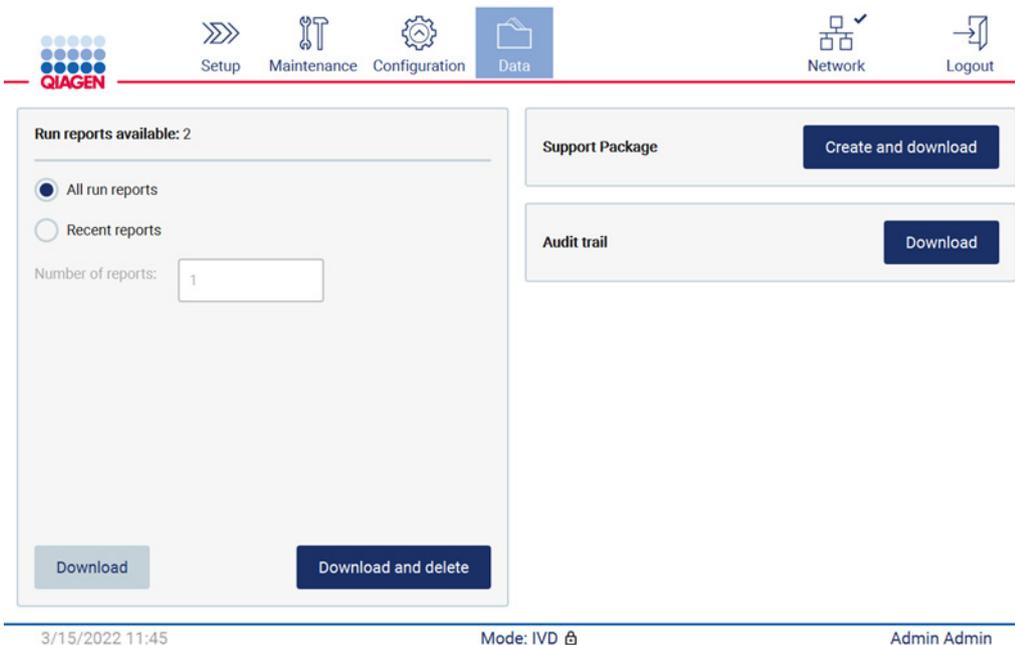


Figure 133. Data screen.

Run reports

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

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**.

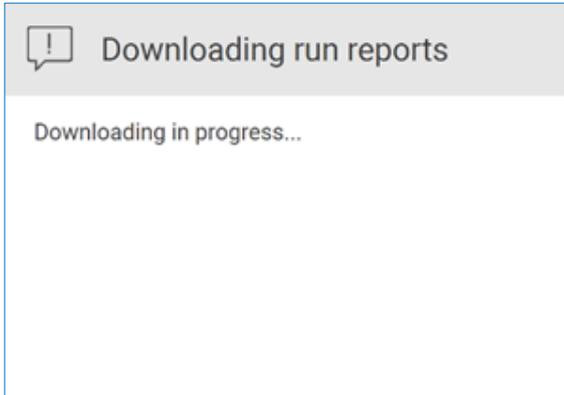


Figure 134. Download reports in progress.

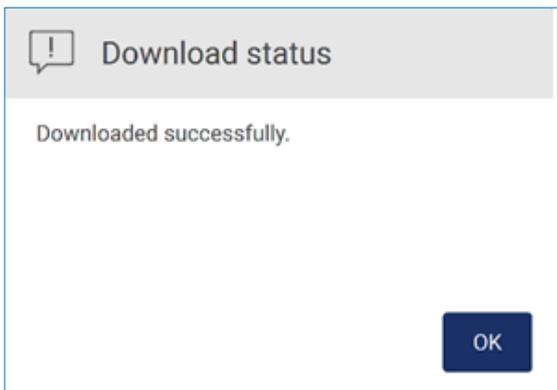


Figure 135. Report download successful.

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

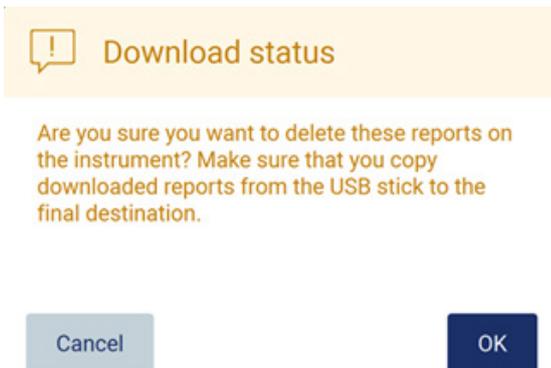


Figure 136. Confirm delete run reports.

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 choosing.

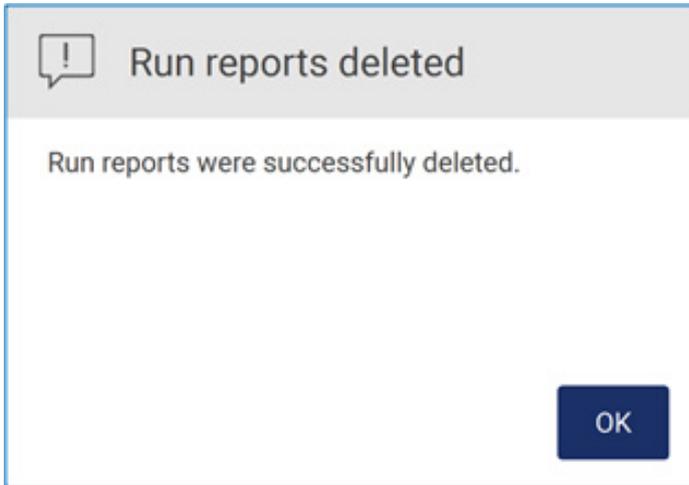


Figure 137. Run reports deleted confirmation.

Tap **OK** to complete process.

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

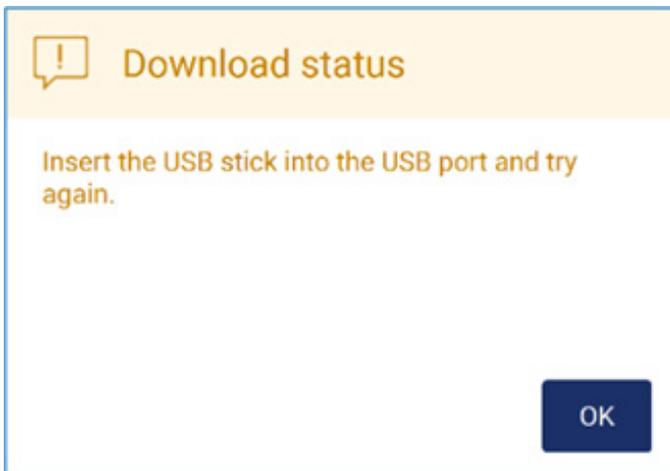


Figure 138. USB drive not inserted.

Insert a USB drive and attempt the process again.

Support package

Detailed instruction can be found in Section 7.1.1, Creating a support package.

Audit trail

Note: Download of Audit trail file is only available to Admin users.

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

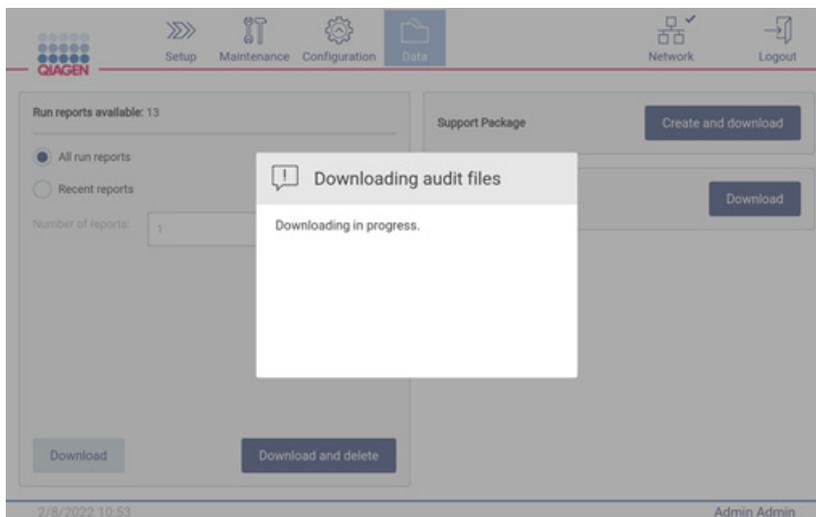


Figure 139. Download audit trail in progress.

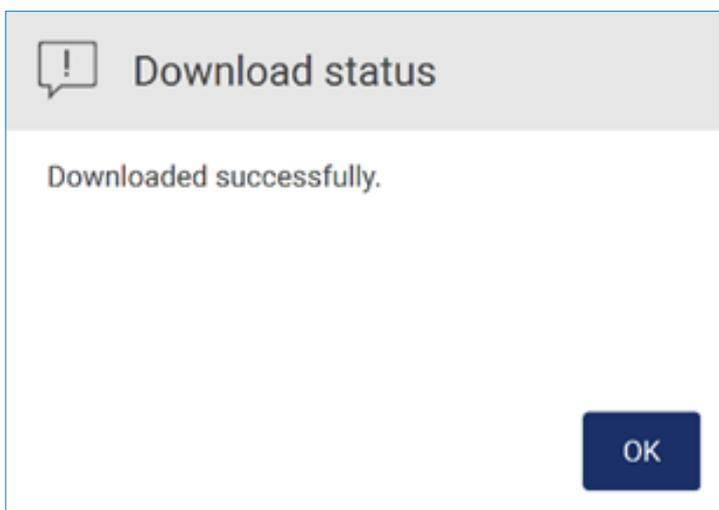


Figure 140. Audit trail download successful.

If no USB drive is inserted the following is displayed:

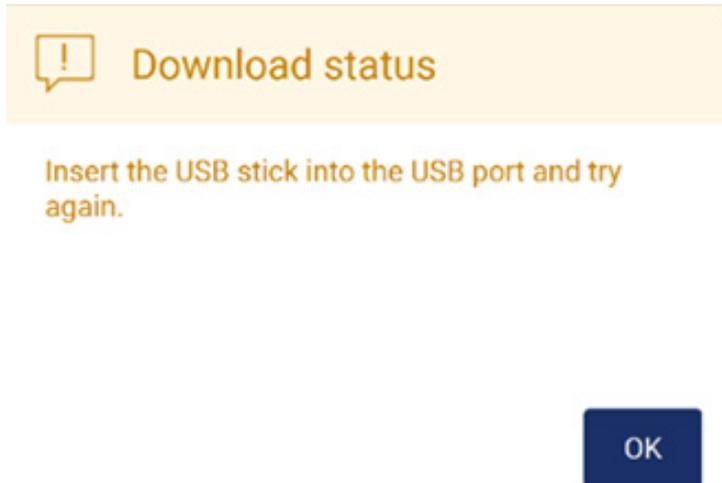


Figure 141. USB drive not inserted.

Insert a USB drive and attempt the process again.

5.13 Logging out and switching the instrument off

To log out of the Software, tap the **Log out** button on the toolbar.

To switch the instrument off, press the power button.

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



Figure 142. Location of the Log out button.

5.14 Research mode

The EZ2 Connect MDx gives the option to start a protocol either in the IVD mode of the software (for validated IVD applications only) or in 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 **Product Resources** tab).

- 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

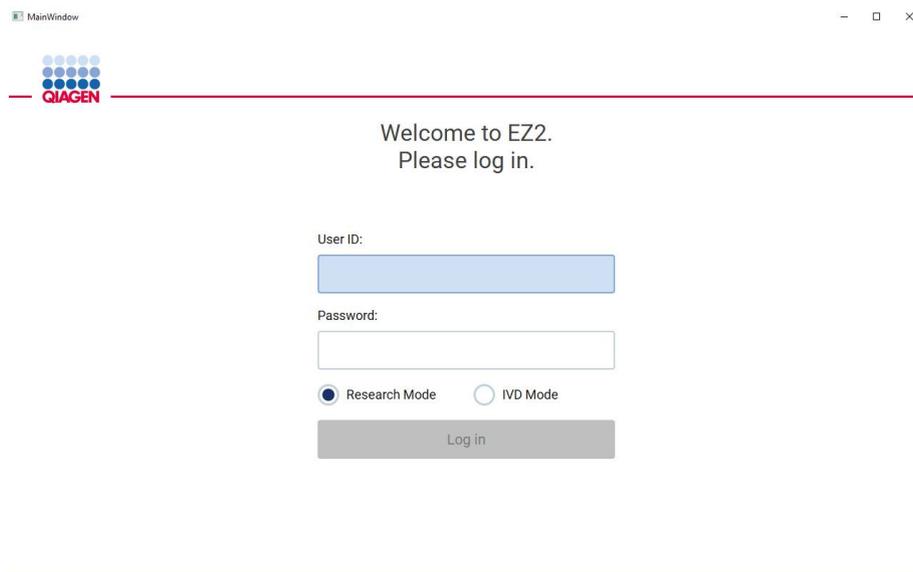


Figure 143. The login screen.

- The set-up screen will open to display available applications
- To start an application either:
 - Tap **Scan** in the **Applications** pane. By scanning the 2D Barcode on the Q-Card provided with the kit, the application type is selected and information on script options is given. Depending on the scanned Q-Card barcode, the software will automatically skip selections screens if the required information is provided by bar code scanning. See the Using the bar code scanner section (page 132).
 - Tap an application in the **Applications** pane, the software will automatically proceed to the protocol selection screen.

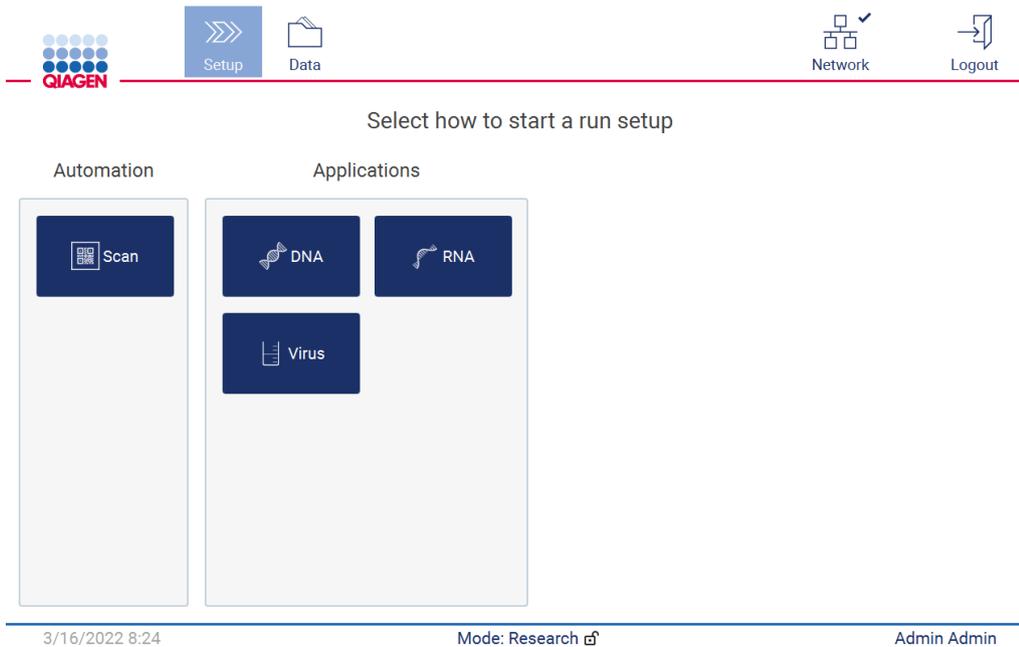


Figure 144. Select an application screen.

- Select and 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 100) 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: When reverting the EZ2 Connect MDx to IVD mode it is important to thoroughly clean and decontaminate the instrument. The following maintenance should be completed:

- Section 6.3 Daily maintenance (if not already completed)
- Section 6.5 UV decontamination

6 Maintenance Procedures

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

To ensure reliable operation of the EZ2, 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 1. Maintenance schedule

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

Optionally, a UV decontamination procedure may be performed as required to reduce pathogen and nucleic acid contamination. See section UV decontamination (page 155) for further details.

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

	Maintenance task	Last	Due
	Daily Maintenance	09/07/2021	10 hours
!	Weekly Maintenance	09/01/2021	0 hours
	UV Run	09/02/2021	-
	Camera LED maintenance	09/06/2021	-

Figure 145. Maintenance overview

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 and touchscreen, can be done using mild detergents/disinfectant, such as the Mikrozyd® AF sensitive (www.schuelke.com), or 70% ethanol. 70% ethanol can be used on the worktable. The hood and touchscreen should **ONLY** be cleaned with lint free tissue moistened with water.

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

CAUTION 	Damage to the instrument Do not use spray bottles containing alcohol or disinfectant to clean surfaces of the EZ2. Spray bottles should be used only to clean items that have been removed from the worktable and if permitted by local laboratory operating practices.
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WARNING 	Risk of fire Do not allow cleaning fluid or decontamination agents to come into contact with the electrical parts of the EZ2.
--	---

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

WARNING 	Risk of fire or explosion 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

Alcohol-based disinfectants can be used for disinfecting surfaces such as the worktable. An example of an 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 (e.g., Cat. no. 109203 or 109160). For countries where Mikrozid® Liquid is not available, the 70% Ethanol can be used.

Disinfectants based on quaternary ammonium salt can be used for submerging worktable items. An example of such disinfectants are the Lysetol® AF or Gigasept® Instru AF (Gigasept Instru AF in Europe, cat. no. 107410, or DECON-QUAT® 100, Veltek Associates, Inc., in the USA, cat. no. DQ100-06-167-01). These disinfectants consist of 14 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 should **ONLY** be cleaned with lint free tissue moistened with water.

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

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

<p>WARNING/ CAUTION</p> 	<p>Risk of personal injury and material damage</p> <p>Improper use of the EZ2 may cause personal injuries or damage to the instrument.</p>
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<p>WARNING</p> 	<p>Samples containing infectious agents</p> <p>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.</p> <p>Some chemicals used with the EZ2 instrument may be hazardous or may become hazardous after completion of a purification.</p> <p>Always wear safety glasses, gloves and a lab coat.</p> <p>Venting for fumes and disposal of waste must be in accordance with all national, state, and local health and safety regulations and laws.</p>
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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; page 144).

After running a protocol, perform after run maintenance as described below. You can run another protocol only once the after run maintenance procedure is done.

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

1. Remove all sample preparation waste and discard it according to your local safety regulations.
2. Close the hood.

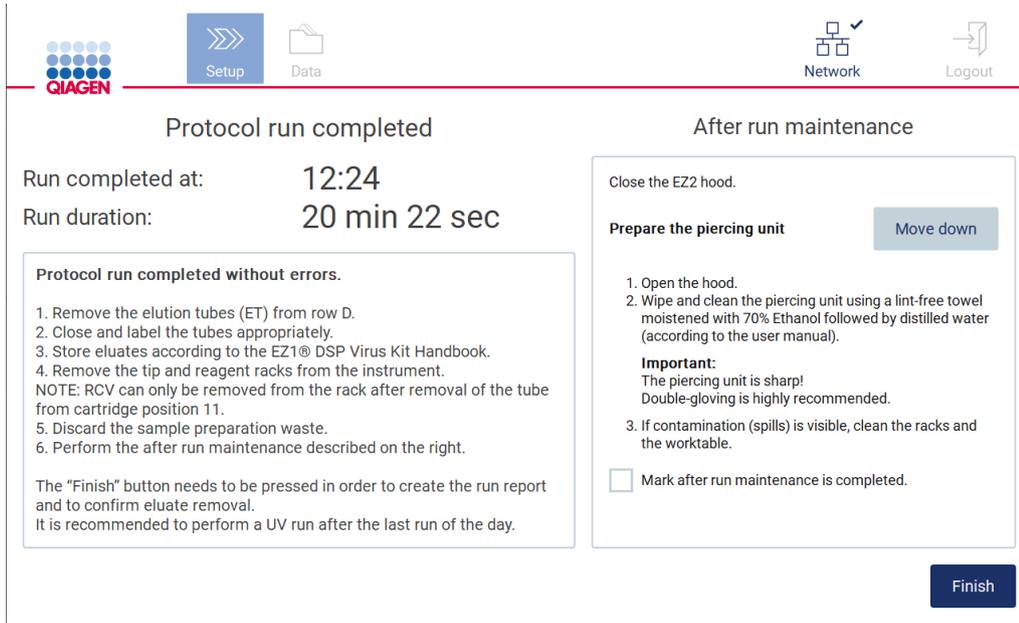


Figure 146. Protocol run completed screen.

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



Figure 147. Cleaning the EZ2 piercing unit.

7. 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.
8. Close the hood.
9. To document the cleaning procedure in the run report, confirm that the maintenance has been completed by activating the checkbox on the touchscreen.
10. On the touchscreen, tap **Finish**. The piercing unit returns to its home position.
11. Open the hood.
12. 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.

<p>WARNING</p> 	<p>Moving parts</p> <p>To avoid contact with moving parts during the operation of the EZ2, the instrument must be operated with the hood closed.</p> <p>If the hood sensor or lock is not functioning correctly, contact QIAGEN Technical Services</p>
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<p>WARNING</p> 	<p>Moving parts</p> <p>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 whilst the instrument is operating.</p>
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<p>WARNING/ CAUTION</p> 	<p>Risk of personal injury and material damage</p> <p>Improper use of the EZ2 may cause personal injuries or damage to the instrument.</p>
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<p>WARNING</p> 	<p>Samples containing infectious agents</p> <p>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.</p> <p>Some chemicals used with the EZ2 instrument may be hazardous or may become hazardous after completion of a purification.</p> <p>Always wear safety glasses, gloves and a lab coat.</p> <p>Venting for fumes and disposal of waste must be in accordance with all national, state, and local health and safety regulations and laws.</p>
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1. On the touchscreen, tap **Maintenance**.
2. Tap **Daily**. The date of the last finished procedure is shown on the screen.

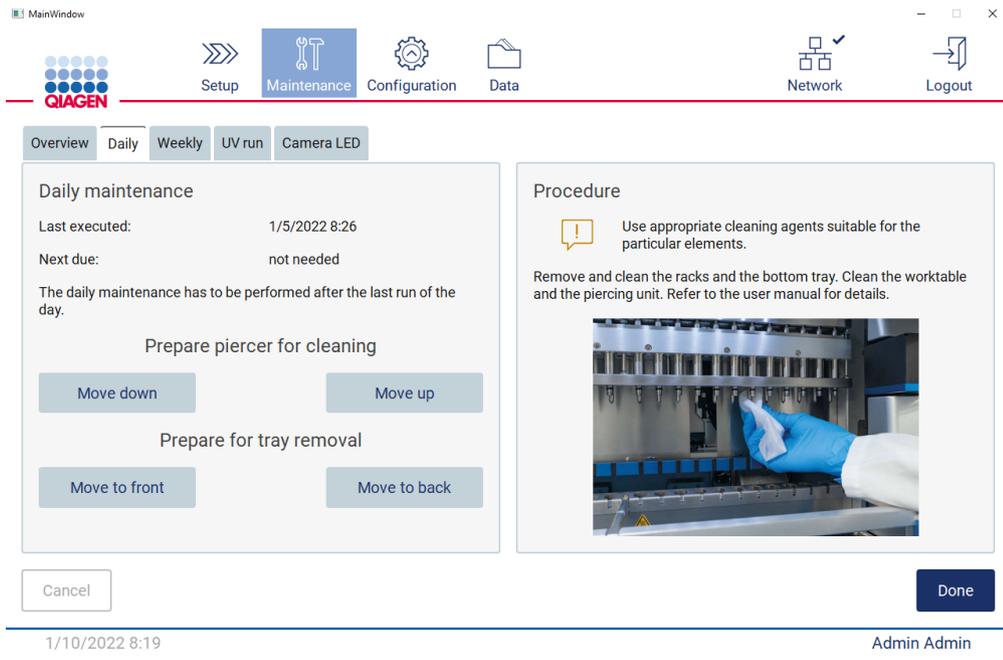


Figure 148. Daily maintenance screen.

3. Put on gloves
4. Clean the piercing unit (if this is not yet done during after run maintenance).
 - To prepare the piercing unit for cleaning, tap **Move down**.
 - Open the hood.
 - Clean the piercing unit as recommended for After run maintenance (see page 145).
5. Clean the worktable with 70% ethanol, 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 tray removal, tap **Move to back**.
9. Clean the tray with 70% ethanol, and then with distilled water.

Note: After removal of the tray for cleaning purposes, ensure it is correctly reinstalled.

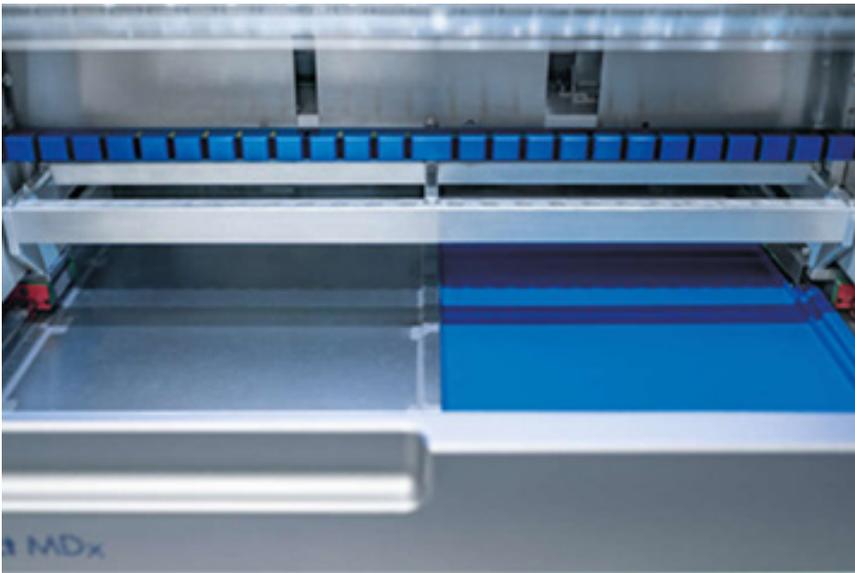


Figure 149-A Right side tray installed.



Figure 149-B. Installing left side tray.

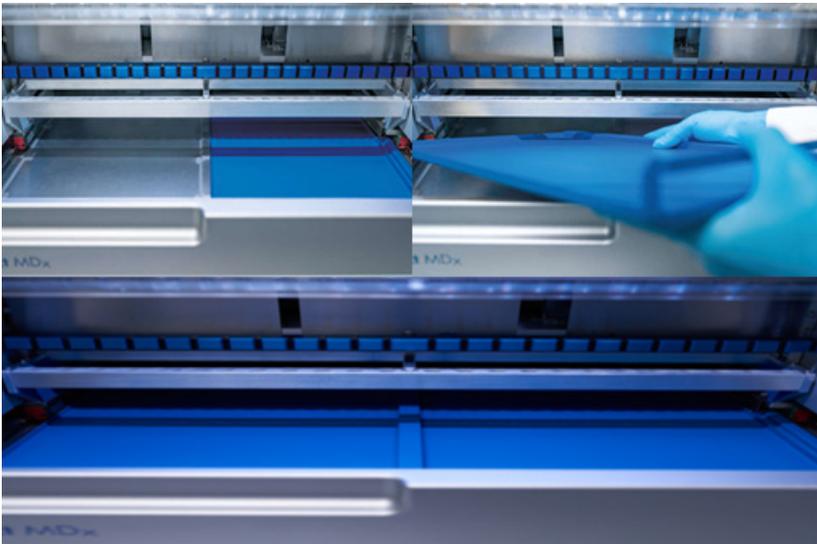


Figure 149-C. Correct installation of the trays.

10. Wipe the cartridge and tip racks with 70% ethanol, and then with distilled water.
11. Wipe the surface of the instrument using a lint-free tissue moistened with 70% ethanol.

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

6.4 Weekly maintenance

<p>WARNING/ CAUTION</p> 	<p>Risk of personal injury and material damage</p> <p>Improper use of the EZ2 may cause personal injuries or damage to the instrument.</p>
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<p>WARNING</p> 	<p>Samples containing infectious agents</p> <p>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.</p> <p>Some chemicals used with the EZ2 instrument may be hazardous or may become hazardous after completion of a purification.</p> <p>Always wear safety glasses, gloves and a lab coat.</p> <p>Venting for fumes and disposal of waste must be in accordance with all national, state, and local health and safety regulations and laws.</p>
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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 O-rings of the tip adapters every week.

1. On the touchscreen, tap **Maintenance**.
2. Tap **Weekly maintenance**. The date of the last procedure, and the date of the next due date of the weekly maintenance are shown on the screen.

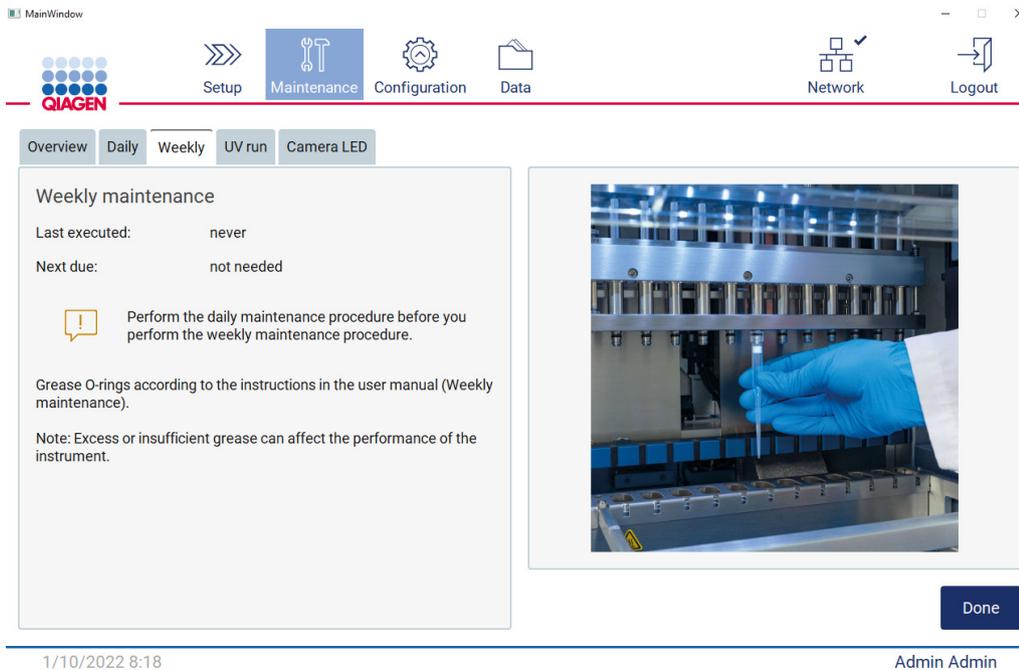


Figure 150. Weekly maintenance screen.

3. Put on gloves.
4. Clean the O-rings with a lint free tissue to remove any previously applied grease.
5. Using a fresh glove, apply a small amount of silicon grease onto the surface of the O-rings (shown in Figure 150), by just using a fingertip moistened with grease. Care should be taken not to allow grease to be applied to, or cover the opening in the nub of the pipettor.
6. Apply a small amount of silicon grease (see Appendix B – EZ2 Connect MDx Accessories, 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.

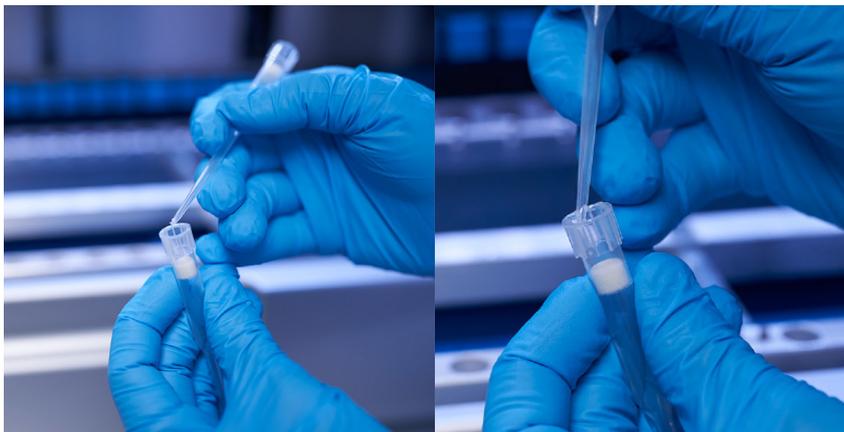


Figure 151. Preparation of filter tips for grease application.

7. Place the previously prepared filter-tip with grease applied to the inner wall at the wide end onto the pipettor head, and rotate the filter-tip on the pipettor head to distribute the silicon grease evenly.
8. Make sure that the O-rings are only moistened with grease and that there are no clumps of grease visible. These could be removed with lint free cloth and greasing restarted.
9. Make sure that there is no grease present on parts other than the O-rings, especially on the bar on top and the opening of the pipettors.

Note: The filter-tips should sit flush against the upper metal bar if the O-rings are properly greased. There should be no gap (when a tip is attached manually). There should not be a gap. 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.

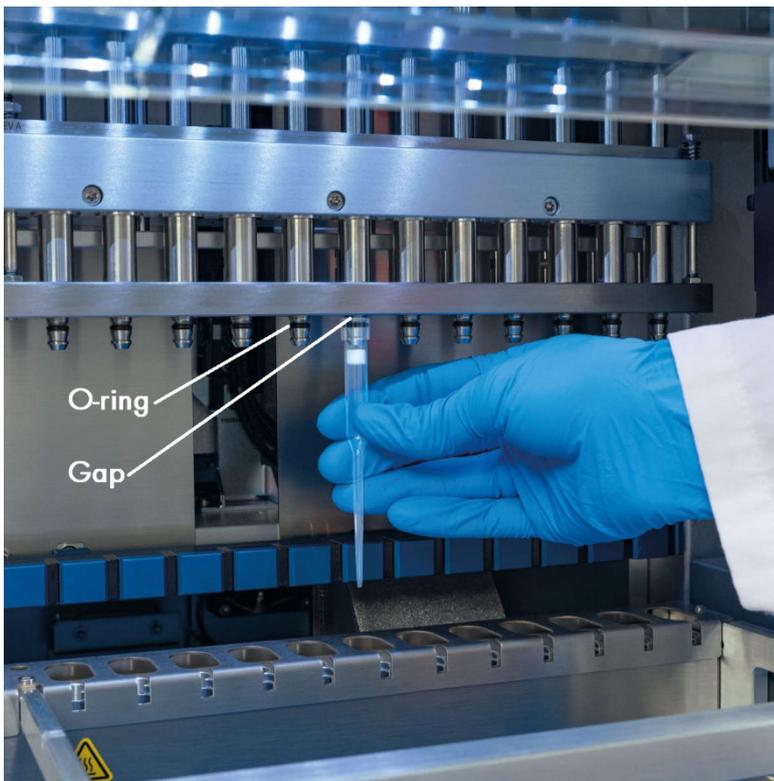


Figure 152. Placing a filter-tip onto the pipettor head.

6.5 UV decontamination

<p>WARNING/ CAUTION</p> 	<p>Risk of personal injury and material damage</p> <p>Improper use of the EZ2 may cause personal injuries or damage to the instrument.</p>
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<p>WARNING</p> 	<p>Samples containing infectious agents</p> <p>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.</p> <p>Some chemicals used with the EZ2 instrument may be hazardous or may become hazardous after completion of a purification.</p> <p>Always wear safety glasses, gloves and a lab coat.</p> <p>Venting for fumes and disposal of waste must be in accordance with all national, state, and local health and safety regulations and laws.</p>
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<p>WARNING</p> 	<p>UV radiation</p> <p>Avoid looking directly into UV light. Do not expose your skin to UV light.</p>
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Important: Before starting the UV decontamination, complete the Daily maintenance (see page 145).

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

3. Tap **UV Run**. The date of the last procedure is shown on the screen.

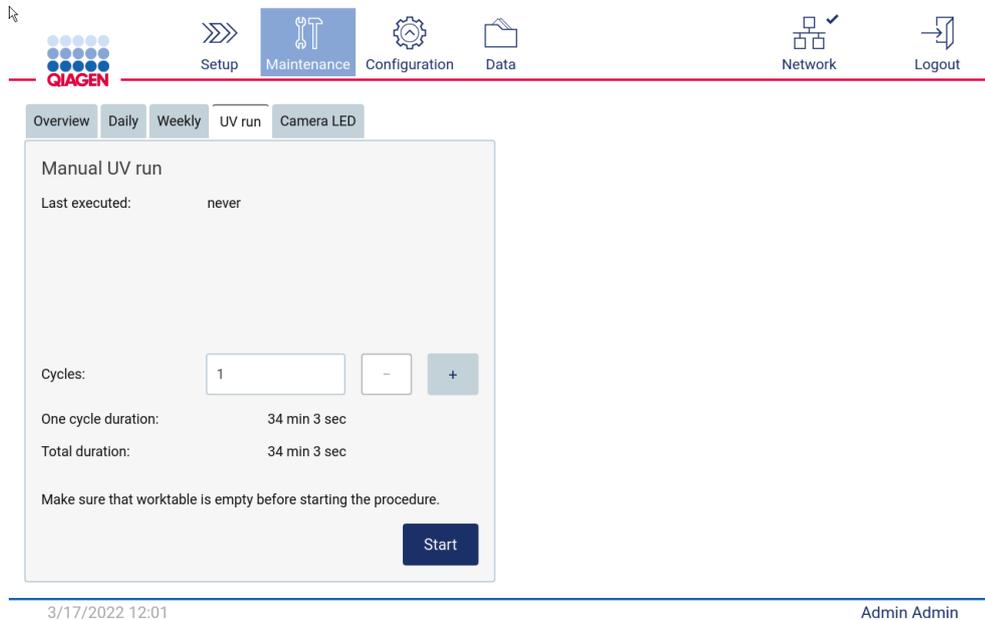


Figure 153. Manual UV Run screen.

4. Select the number of decontamination cycles. The required decontamination time depends on the biological material processed on the device.

5. To begin the procedure, tap **Start**.

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 1 or 2 min.

7. A message (see the figure hereafter) is displayed after execution of the UV Run. Tap **Finish** to complete the UV Run.

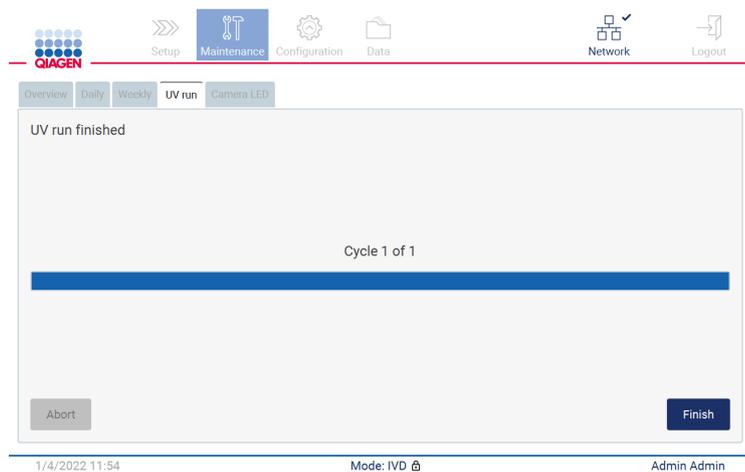


Figure 154. UV run finished screen.

6.6 Camera calibration

The EZ2 Connect MDx provides an internal camera which allows 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 155. Camera exposure calibration screen.

3. Follow the instructions displayed on the screen.
4. Close the hood.
5. To begin the procedure, tap **Start**.

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 144 and 144, respectively).

<p>WARNING/ CAUTION</p> 	<p>Risk of personal injury and material damage</p> <p>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.</p> <p>Servicing of the EZ2 must only be performed by a QIAGEN Field Service specialist.</p>
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7 Troubleshooting

This section contains information about what to do if an error occurs when using the EZ2 instrument.

7.1 Contacting QIAGEN Technical Services

Whenever encountering an EZ2 instrument error, be sure to have the following information at hand:

Note: Much 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 or in each run report
- Sample input material and sample pre-treatment
- Detailed description of the error situation
- Support package

This information will help you and QIAGEN Technical Services 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.

7.1.1 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. Power off the EZ2 and plug in a USB flash drive.
2. Re-instate the power and log in.
3. Tap **Data** on the toolbar.



Figure 156. Data button on the toolbar.

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

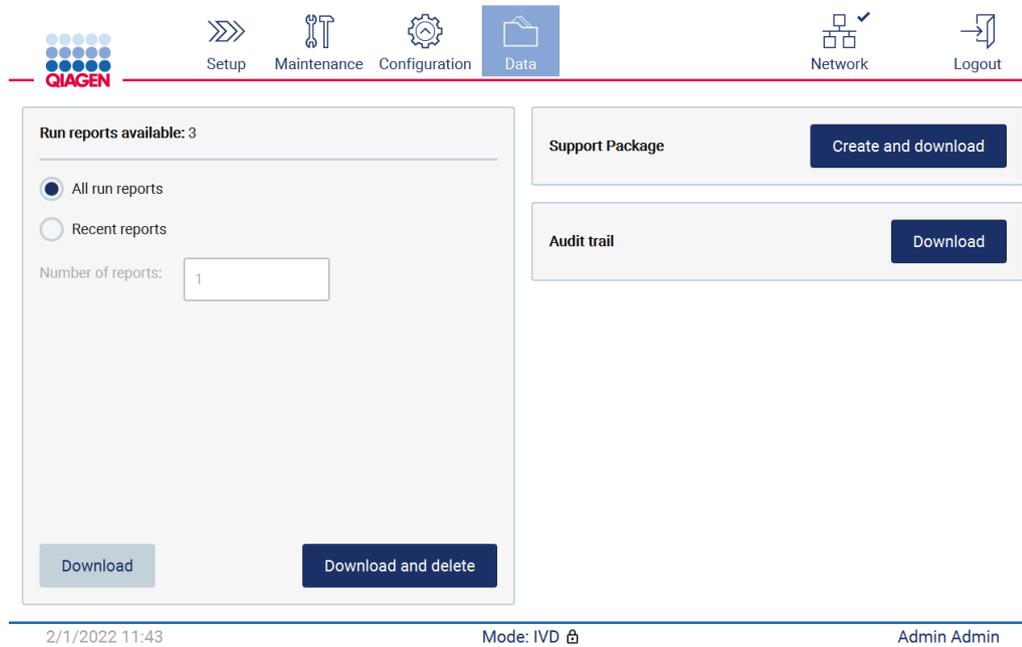


Figure 157. Data tab.

5. The support package is now saved on the USB flash drive. 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.

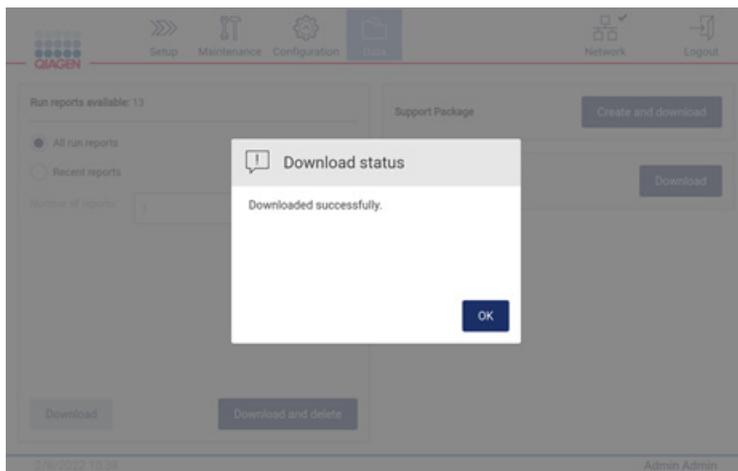


Figure 158. Download successful status.

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

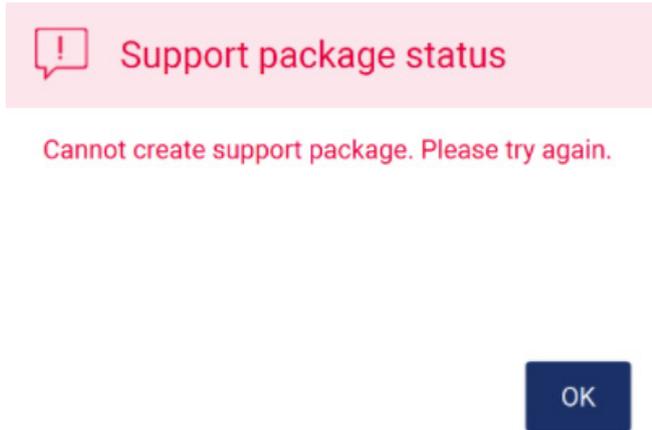


Figure 159. Support package creation failure status.

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

7.2 Operation

	Comments and suggestions
Load check failed	<p>Perform camera exposure calibration according to Section 4.3.6.</p> <p>Both racks must be loaded, even if just one rack is used. Racks have to be the same type.</p> <p>Check if there is no contamination (e.g., drops) on the labware.</p> <p>Note: Avoid strong environmental light changes and direct sunlight.</p> <p>Perform load check again.</p>
Hood lock Error	Check if the hood is firmly closed. Confirm by pressing down the hood with light force.
Heater Fuse Error	Restart the device.
Pipetting tips sticking to pipettor	Use lab tissue to wipe the O-rings and make sure weekly maintenance was performed correctly.
Pipette tip was crushed	Pipetting tip may stick to pipettor. See "pipetting tip sticking to pipettor".
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.
Leaking pipette tips	Ensure weekly maintenance was performed. Check if the tips sit firmly at the pipettor adapter.
Pipette tips not picked up by automatic pipettor	Make sure that the tip rack is not damaged and is correctly positioned on the worktable.
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. Make sure you use the QIAGEN USB flash drive. USB flash drive should stay plugged in during the whole update procedure.
USB device not detected	Restart the device. Save the file(s) to the USB stick again. Try using a different USB port. Check the USB stick on a PC to ensure it is functional. If the error persists, contact QIAGEN Technical Services.
Connection problem	Check if the ethernet cable is connected correctly. Check the LAN settings (Section 5.3.8).
No W-LAN connection	Check the Wi-Fi setting (Section 5.3.8). 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.
Surface damaged	Ensure that only the cleaning agents as assumed 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.

8 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.
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.
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.
O-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.
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.
Tray	A metal tray that is located under the worktable. It collects any drops of liquid that may spill.
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 Mains supply voltage fluctuations are not to exceed 10% of nominal supply voltages.
Fuse	AC Inlet: T4A H 250 V Heater block (temperature fuse): 10A 250V 117C
Overvoltage category	II
Air temperature	18–30°C (64–86°F)
Relative humidity	10–75% RH
Altitude	Up to 2000 m (6500 ft.)
Place of operation	For indoor use only
Pollution level	2
Environmental class	3K21 (IEC 60721-3-3) 3M11 (IEC 60721-3-3)
Average noise level (over 8 hours)	Max. 70 dBA
IP Code (IEC 60529)	IP20

9.2 Transport conditions

Air temperature	–25–60°C (–13–140°F) in manufacturer's package 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) 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) 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 $\pm 2^\circ\text{C}$.
Filter tips	Attach to the tip adapters of the pipettor head to allow liquid aspiration and dispensation. Capacity of 50–1000 μl . Capacity of 50–1000 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	<p>Reagents are loaded onto the worktable in reagent cartridges. These cartridges are already prefilled by QIAGEN.</p> <p>Up to 24 reagent cartridges can be placed in the cartridge rack.</p> <p>Samples are loaded onto the worktable in 2 ml sample tubes.</p> <p>Steps that require heating occur on the heating system, which accommodates the heating positions of the reagent cartridges.</p> <p>Purified nucleic acids are collected in 1.5 ml elution tubes.</p>
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	<p>Monochrome camera. The USB interface provide power and communication.</p> <p>Sensor resolution is 0.34 MP.</p> <p>Width: 24 mm (0.94 in.)</p> <p>Height: 34 mm (1.34 in.)</p> <p>Depth: 39 mm (1.54 in.)</p>
Network	<p>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.</p> <p>Supports LAN</p> <p>If network functionality is used: the administrator must ensure that the instrument is not visible to the outside of the network</p>

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.

The EZ2 does not fully support standard UL-2900-1 as it does not provide a (configurable) inactivity-timeout.

Appendix B – EZ2 Connect MDx Accessories

Ordering Information

Product	Contents	Cat. no.
EZ2 Connect MDx	Instrument and 1-year warranty on parts and labor	9003230
Accessories		
EZ2 Connect Tip Rack	Tip Rack for EZ2 Connect, for use with screw-cap tubes	9027009
EZ2 Connect Tip Rack - Flip Cap Tube	Tip Rack for EZ2 Connect, for use with flip-cap tubes	9027010
EZ2 Connect Cartridge Rack	Cartridge rack for EZ2 Connect, for use with prefilled kit cartridges	9027012
USB Flash Drive		9027254
Barcode Reader		9027101
Silicone Grease		9027102

For up-to-date licensing 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
04/2022	Initial version of the EZ2 Connect MDx User Manual

Trademarks: QIAGEN[®], Sample to Insight[®], EZ2[®], (QIAGEN Group); Gigasepl[®], Lysetol[®], Mikrozyd[®] (Schülke & Mayr GmbH). Registered names, trademarks, etc. used in this document, even when not specifically marked as such, are not to be considered unprotected by law.

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