

EZ2[®] Connect MDx Safety Instructions and Quick-Start Guide

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



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Introduction

Note: This quick-start guide is supplementary to, not a replacement for, the instrument user manual.

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 for the applications described in the kit handbooks.

The EZ2 Connect MDx 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.

Important: The *EZ2 Connect MDx User Manual*, this quick-start guide, and the available translations for both documents are electronically available in PDF. These documents can be downloaded from the Resources tab of the EZ2 Connect MDx webpage (www.qiagen.com/EZ2ConnectMDx).

The product name, catalog number, and version number on the instructions for use (user manual and quick-start guide) must match the information provided on the product label. If you require a translation that is not available, please contact QIAGEN Technical Support immediately.

If you encounter any issues with downloading the instructions for use, QIAGEN will send you the relevant translation by e-mail, fax, or post. For assistance, please contact QIAGEN Technical Support at support.qiagen.com or contact one of QIAGEN's local distributors at www.qiagen.com

Safety Information

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

WARNING



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

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

CAUTION



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

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

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

Note: This quick-start guide is supplementary to, not a replacement for, the instrument user manual.

Proper use

WARNING/ CAUTION



Risk of personal injury and material damage

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

WARNING



Risk of personal injury

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

WARNING



Risk of personal injury and material damage

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

CAUTION



Damage to the instrument

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

WARNING**Risk of fire or explosion**

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

WARNING**Risk of explosion**

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

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

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

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

CAUTION**Damage to the instrument**

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

CAUTION**Damage to the instrument**

Do not lean against the instrument or touchscreen.

Electrical safety

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

WARNING



Electrical hazard

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

Intentional interruption is prohibited.

Lethal voltages inside the instrument

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

WARNING



Damage to electronics

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

Use of incorrect supply voltage may damage the electronics.

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

WARNING



Risk of electric shock

Do not open any panels on the EZ2 Connect MDx.

Risk of personal injury and material damage

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

To ensure satisfactory and safe operation of the EZ2 Connect MDx, follow these guidelines:

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

If the EZ2 Connect MDx becomes electrically unsafe, prevent other personnel from operating it and contact QIAGEN Technical Support.

The instrument may be electrically unsafe when:

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

WARNING

Electrical hazard



Do not touch the EZ2 Connect MDx with wet hands.

WARNING

Electrical hazard



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

Operating environment

WARNING

Explosive atmosphere



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

WARNING

Risk of overheating



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

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

WARNING

Risk of explosion



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

CAUTION

Damage to the instrument



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

CAUTION

Damage to the instrument



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

Biological safety

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

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

WARNING



Samples containing infectious agents

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

Always wear safety glasses, 2 pairs of gloves, and a lab coat.

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

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

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

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

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

Chemicals

WARNING



Hazardous chemicals

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

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

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

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

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

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

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

Toxic fumes

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

WARNING



Toxic fumes

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

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 on how to dispose of the EZ2 instrument, see Appendix A: Waste Electrical and Electronic Equipment (WEEE) of the *EZ2 Connect MDx User Manual*.

WARNING



Hazardous chemicals and infectious agents

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

Mechanical hazards

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

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

WARNING



Moving parts

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

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

WARNING



Moving parts

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

Heat hazard

The EZ2 Connect MDx worktable contains a heating system.

WARNING



Hot surface

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

Radiation safety

The EZ2 Connect MDx has a UV LED lamp. The wavelength of the UV light produced by the UV LED lamp is 270 to 285 nm. This wavelength corresponds to ultraviolet light type C, which can be used to support decontamination procedures. A mechanical lock ensures that the hood is closed for operation of the UV LED. If the hood sensor or lock is not functioning correctly, contact QIAGEN Technical Support.

WARNING



Risk of personal injury

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

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

WARNING



Risk of personal injury

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

Maintenance safety

Perform the maintenance as described in the Maintenance Procedures section of the *EZ2 Connect MDx User Manual*. QIAGEN charges for repairs that are required due to incorrect maintenance.

Operate the EZ2 instrument only as described in the Operating Procedures section of the *EZ2 Connect MDx User Manual*. QIAGEN charges for repairs that are required due to incorrect operation.

WARNING/ CAUTION



Risk of personal injury and material damage

Only perform maintenance that is specifically described in the *EZ2 Connect MDx User Manual*.

WARNING/



Risk of personal injury and material damage

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

The EZ2 Connect MDx must only be operated by suitably qualified personnel. Servicing of the EZ2 Connect MDx must only be performed by QIAGEN Field Service Specialists.

WARNING



Risk of fire

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

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

WARNING



Damage to the instrument

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

CAUTION



Damage to the instrument

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

CAUTION



Damage to the instrument

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

WARNING/ CAUTION



Risk of personal electric shock

Do not open any panels on the EZ2 Connect MDx.

Only perform maintenance as described in the *EZ2 Connect MDx User Manual*.

Symbols on the EZ2 Connect MDx

Symbol	Location	Description
	Heating system — inside instrument	Heat hazard — The temperature of the heating system can reach up to 95°C (203°F).
	Near the tip rack	Biohazard — The tip rack may be contaminated with biohazardous material and must be handled with gloves.
	On the back of the instrument	UV radiation hazard — Avoid looking directly into UV light. Do not expose your skin to UV light.
	On the handheld barcode scanner	Class 2 Laser — Do not stare into the light beam when using a handheld barcode scanner.
	Robotic arm — inside instrument	Crush hazard — The nozzle unit may crush your fingers or hand.
	Type plate at the back of the instrument	CE mark for Europe.
	Type plate at the back of the instrument	CSA listing mark for Canada and the USA.
	Type plate at the back of the instrument	RCM (former C-Tick) mark 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 at the back of the instrument	Waste Electrical and Electronic Equipment (WEEE) mark for Europe
	Type plate at the back of the instrument	Legal manufacturer
	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	Catalog number
	Type plate on the back of the instrument	Serial number
	Type plate at the back of the instrument	In vitro diagnostic medical device
	Type plate at the back of the instrument	Consult instructions for use.

Symbol	Location	Description
	Type plate at the back of the instrument	See warnings and precautions
	Type plate at the back of the instrument	Date of manufacture

Installation Procedures

This section provides you with important information on how to install the EZ2 Connect MDx, including the required instrument setup and network settings. For detailed unpacking and installing information, refer to the respective user manual.

Unpacking and installation procedures are easy to follow, but a person who is familiar with laboratory equipment should oversee the installation.

Site requirements

The EZ2 Connect MDx must be located out of direct sunlight, away from heat sources, and away from sources of vibration and electrical interference. Refer to the *EZ2 Connect MDx User Manual* for the operating conditions (temperature and humidity) and detailed site, power, and grounding requirements.

Unpacking and setting up the EZ2 Connect MDx

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

The following items are delivered:

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

To set up the EZ2 Connect MDx

1. Before unpacking the EZ2 Connect MDx, move the package to the site of installation and check that the arrows on the package point upward. In addition, check whether the package is damaged. In case of damage, contact QIAGEN Technical Support.
2. Open the top of the transportation box to remove the top layer (PE foam).
3. Remove the accessories box together with the PE foam at its perimeter.
4. Remove the outer carton box by holding it at the cut-out area and lifting the outer carton box.
5. Remove the two pieces of protective foam from the unit.
6. Move the unit to the workbench or trolley from the packaging. When lifting the EZ2 Connect MDx, slide your fingers under the side of the instrument and keep your back straight.

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

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

7. Remove the foam strip that is placed in the gap between the hood and the front top cover.
8. Remove the pieces of tape that secure the hood to the base panels.
9. Remove the protective film that covers the hood.
10. Open the hood and remove the transport lock from the pipetting head by pulling the transport lock from the bottom.
11. Remove the silica gel package from the unit.
12. Remove the transport lock for Y-axis (front to back) by pushing the bottom of the transport lock toward the rear direction and pulling the transport foam out from the rear. There is a total of two transport locks for Y-axis.
13. Check if the packing list document is included after unpacking the EZ2 Connect MDx.
14. Read the packing list to check if all items have been received. If anything is missing, contact QIAGEN Technical Support.
15. Check that the EZ2 Connect MDx is not damaged and that there are no loose parts.

If anything is damaged, contact QIAGEN Technical Support. Make sure that the EZ2 Connect MDx has equilibrated to ambient temperature before powering on.

16. Retain the package in case you need to transport the EZ2 Connect MDx in the future. Refer to “Packaging and transportation of the EZ2 Connect MDx” section of the *EZ2 Connect MDx User Manual* for more details. Using the original package minimizes the possibility of damage during transportation of the EZ2 Connect MDx.
17. Before turning on the instrument and if you intend to use the Wi-Fi function on the EZ2, plug the Wi-Fi adapter (supplied with the Connectivity package in certain regions) into one of the three USB ports located on the front of the instrument or on the rear of the touchscreen.
18. Connect the barcode scanner to any of the three USB ports located on the front of the instrument or on the rear of the touchscreen.
19. Connect the EZ2 Connect MDx to a power outlet using the provided power cord.

20. To power on the EZ2 Connect MDx, ensure that the hood is closed. Press the power button. The startup screen appears on the touchscreen, and the instrument is initialized. After the initialization is done, the Log in screen appears.

To log in for the first time, enter "Admin" in both User ID and Password fields, then press **Log in**. The "Set a new password" screen appears and you will have administrator rights with the option to set up other users. Refer to the instrument user manual for more details on user management.

Note: The system requires a password change for all newly created accounts. The EZ2 Connect MDx default password policy is a strong password of 8–40 characters and includes upper- and lower-case characters, a number, and a special character. For further instructions, see "Managing User Security" and "Changing Password" sections of the *EZ2 Connect MDx User Manual*.

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

21. From the **Configuration** menu under the **System configuration** tab, you can modify the Device Name, Date, and Time fields.
22. You may adjust the settings of the EZ2 Connect MDx according to your preferences through the **Configuration** menu, **System Configuration**, **Language** and **Instrument Setting** tabs.
23. Before first use in the final installation site, the camera exposure calibration must be performed through the **Maintenance** menu, **Camera LED** tab.
24. To ensure that your EZ2 Connect MDx has the latest software and protocol versions installed, please visit the EZ2 Connect MDx product page and check out the Resources section at www.qiagen.com/EZ2ConnectMDx

For detailed instructions on how to update software and install/update protocols, refer to the *EZ2 Connect MDx User Manual*.

Note: From the **Configuration** menu under the **System configuration** tab, the software version can be found. Protocol versions can be found during the setup wizard, step 2 of 7.

Connecting the EZ2 Connect MDx via Wi-Fi

The EZ2 Connect MDx can be connected to a Wi-Fi network using the Wi-Fi adapter (supplied with the Connectivity package in certain regions) inserted into one of the USB ports. The adapter supports the 802.11b, 802.11g, and 802.11n Wi-Fi standards, and WEP, WPA-PSK, and WPA2-PSK encryption.

1. From the **Configuration** menu under the **Wi-Fi** tab, you can set up the Wi-Fi network.
2. Scan for available networks.
3. From the list, select one of the available networks.
4. Enter the Wi-Fi password and connect.

Connecting the EZ2 Connect MDx via LAN cable

From the **Configuration** menu under the **LAN** tab, enter the local network settings to set up the LAN network.

Note: You might need the help of an IT professional to enter detailed network settings.

Connecting the EZ2 Connect MDx with LIMS system

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:

1. Upload the LIMS connector certificate.
2. Generate new instrument certificate.
3. Enter the LIMS connector URL.
4. Register the instrument in the LIMS connector.

For detailed instructions on how to connect to LIMS, refer to the *EZ2 Connect MDx User Manual*.

Document Revision History

Revision	Description
03/2022	First version of the EZ2 Connect MDx Safety Instructions and Quick-Start Guide.
03/2024	Updated the Environment, Maintenance safety, and Symbols subsections; and Installation Procedures section.
03/2026	Safety information update to not wash instrument parts in the dishwasher. Laser warning updated. Symbols for mechanical hazard, hazardous chemicals and heat hazard were updated for consistency.

For further support with technical difficulties, please contact QIAGEN Technical Support at www.qiagen.com

For up-to-date licensing information and product-specific disclaimers, see the respective QIAGEN kit handbook or user manual. QIAGEN kit handbooks and user manuals are available at www.qiagen.com or can be requested from QIAGEN Technical Support or your local distributor.

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