

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 format. These documents can be downloaded from the Resources tab of the EZ2 Connect MDx webpage (www.qiagen.com/de/products/ez2-connect-mdx/).


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 Services 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 Services 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 the user manual must be followed to ensure safe operation of the instrument and to maintain the instrument in a safe condition.


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


Note: This Quick Start Guide is supplementary to, not a replacement for, the Instrument User Manual.


Proper use


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| 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 and maintained by qualified personnel who has been appropriately trained. Servicing of the EZ2 Connect MDx must only be performed by QIAGEN Field Service Specialists. |
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| 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. |
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| WARNING  | Risk of personal injury and material damage Do not attempt to move the EZ2 Connect MDx during operation. |
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| 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. |
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| 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. |
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| WARNING  | Risk of explosion The EZ2 Connect MDx is intended for use with reagents and substances supplied with QIAGEN kits as outlined in the 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 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.


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| 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. |
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| CAUTION  | Damage to the instrument Do not lean against the touchscreen. |
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Electrical safety

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

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| 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. |
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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 in 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 Connect MDx.</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 technical service.</p> |
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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 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, and has not been wholly contained in the bottom tray, power OFF the instrument, disconnect it from the power outlet, and contact QIAGEN Technical Services for advice before attempting troubleshooting.

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

The instrument may be electrically unsafe when:

- It 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 come in contact directly with electrical components of the EZ2 Connect MDx.
- The power cord has been exchanged with a non-official power cord.


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| WARNING  | Electric hazard Do not touch the EZ2 Connect MDx with wet hands. |
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| WARNING  | Electric hazard Never install a fuse different from that specified in the user manual. |
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Environment

Operating Conditions

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| WARNING  | Explosive atmosphere The EZ2 Connect MDx 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 Connect MDx. Slits and openings that ensure the ventilation of the instrument must not be covered. |
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| <p>WARNING</p>  | <p>Risk of explosion</p> <p>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.</p> |
| <p>CAUTION</p>  | <p>Damage to the instrument</p> <p>Direct sunlight may bleach parts of the instrument, cause damage to plastic parts. The EZ2 Connect MDx must be located out of direct sunlight.</p> |
| <p>CAUTION</p>  | <p>Damage to the instrument</p> <p>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.</p> |

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/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF).

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.

CAUTION**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., 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 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 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).

Chemicals

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| <p>WARNING</p>  | <p>Hazardous chemicals</p> <p>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.</p> <p>Always wear safety glasses, 2 pairs of gloves, and a lab coat.</p> <p>The responsible body (e.g., 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 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

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


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| <p>WARNING</p>  | <p>Toxic fumes</p> <p>Do not use bleach to clean or disinfect the EZ2 Connect MDx. 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 used can produce toxic fumes.</p> |
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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*.


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| WARNING  | Hazardous chemicals and infectious agents The waste may contain toxic material and must be disposed of properly. Refer to your local safety regulations for proper disposal procedures. |
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Mechanical hazards

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


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

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| 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 Services. |
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| <p>WARNING</p>  | <p>Moving parts</p> <p>Avoid contact with moving parts during operation of the E2Z Connect MDx. Under no circumstances should you place your hands under the pipetting arm during movement. Do not attempt to remove any plasticware from the worktable while the instrument is operating.</p> |
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Heat hazard


The E2Z Connect MDx worktable contains a heating system.

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| <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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Radiation safety

The E2Z 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 must be closed for operation of the UV LED. If the hood sensor or lock is not functioning correctly, contact QIAGEN Technical Services.


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| <p>WARNING</p>  | <p>Risk of personal injury</p> <p>Avoid looking directly into UV light. Do not expose your skin to UV light.</p> |
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| <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> |
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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.










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| WARNING /CAUTION  | Risk of personal injury and material damage Only perform maintenance that is specifically described in the <i>EZ2 Connect MDx User Manual</i> . |
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| 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. |
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| 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. |
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| <p>WARNING</p>  | <p>Damage to the instrument</p> <p>Do not use bleach, solvents, or reagents containing acids, alkalis, or abrasives to clean the EZ2 Connect MDx.</p> |
| <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 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.</p> |
| <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> |
| <p>WARNING /CAUTION</p>  | <p>Risk of personal electric shock</p> <p>Do not open any panels on the EZ2 Connect MDx.</p> <p>Only perform maintenance as described in the <i>EZ2 Connect MDx User Manual</i>.</p> |

Symbols on the EZ2 Connect MDx

| Symbol | Location | Description |
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|  | 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 | Hazard Level 2 laser light — Do not stare into the light beam when using handheld barcode scanner. |
|  | Robotic arm — inside instrument | Crush hazard — The nozzle unit may crush your fingers or hand. |
|  | Type plate 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). |

| Symbol | Location | Description |
|---|--|---|
|  | 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. |
|  | 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
- Quick-start guide and safety instructions (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 Services.
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 at the cut-out area and lift 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 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 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.
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 toward rear direction and pull it 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 that you have received all items. If anything is missing, contact QIAGEN Technical Services.
15. Check that the EZ2 Connect MDx is not damaged and that there are no loose parts. If something is damaged, contact QIAGEN Technical Services. Make sure that the EZ2 Connect MDx has equilibrated to ambient temperature before operating it.
16. Retain the package in case you need to transport the EZ2 Connect MDx in the future. Refer to the Packing the EZ2 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 USB ports located on the front of the instrument or on the rear of the touchscreen.
18. Connect the barcode scanner to one of the 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, first ensure that the hood is closed then press the power button. The startup screen appears, and the instrument is initialized. After the initialization is done, the Login screen appears.

To log in for the first time, enter "Admin" in both User ID and Password fields. After this login, 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, which requires a password between 8 and 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 webpage at www.qiagen.com/de/products/ez2-connect-mdx/.

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 set-up 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.

- From the **Configuration** menu under the **Wi-Fi** tab, you can set up the Wi-Fi network.
- Scan for available networks.
- From the list, select one of the available networks.
- 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 |
|----------|--|
| 03/2024 | Updated the Environment, Maintenance safety, and Symbols subsections, and Installation Procedures section. |
| 03/2022 | First version of the EZ2 Connect MDx Safety Instructions and Quick-Start Guide. |

For further support with technical difficulties, please contact QIAGEN Technical Services 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 Services or your local distributor.

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