November 2020

QIAcube[®] Connect MDx Safety Instructions and Quick Start Guide

For use with QIAsphere Base



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



Sample to Insight

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Revision History	
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Introduction

QIAcube[®] Connect MDx is designed to perform automated isolation and purification of nucleic acids in molecular diagnostic and/or molecular biology applications. The system is intended for use by professional users, such as technicians and physicians trained in molecular biological techniques and the operation of the QIAcube Connect MDx system.

The QIAcube Connect MDx is intended to be used only in combination with QIAGEN and PAXgene kits indicated for use with the QIAcube Connect MDx for the applications that will be described in the kit handbooks.

Important: The QIAcube 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 at https://www.qiagen.com/de/products/qiacube-connect-mdx/ from the Product Resources tab.

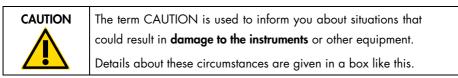
The product name, catalog number, and version number on the Instructions for Use must match the information provided on the product label. If you require a translation that is not available, please contact QIAGEN Technical Services immediately.

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.giagen.com** or contact one of QIAGEN's local distributors at **www.giagen.com**.

Safety Information

Before using the QIAcube Connect MDx, it is essential that you read this guide carefully and pay attention to the safety information. The instructions and safety information in this 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.			



The advice given in this guide is intended to supplement, not supersede, the normal safety requirements prevailing in the user's country.

Proper use

WARNING Risk of personal injury and material damage [W1] Improper use of the QIAcube Connect MDx may cause personal injuries or damage to the instrument. The QIAcube Connect MDx must only be operated by qualified personnel who have been appropriately trained. Servicing of the QIAcube Connect MDx must only be performed by a QIAGEN Field Service specialist.

QIAGEN charges for repairs that are required due to incorrect maintenance.

WARNING	Risk of personal injury and material damage	[W2]
	The QIAcube 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.	
	do not lift the instrument alone.	



Risk of personal injury and material damage

[W3]

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

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

CAUTION Damage to the instrument Avoid spilling water or chemi

[C1]

Avoid spilling water or chemicals onto the QIAcube Connect MDx. Damage caused by water or chemical spillage will void your warranty.

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

CAUTION	Damage to the instrument	[C2]
	Only use QIAGEN spin columns and QIAcube Connect MDx specific consumables with the QIAcube Connect MDx. Damage caused by use of other types of spin columns or chemistries will void your warranty.	

WARNING	Risk of personal injury and material damage	[W4]
	Do not use damaged rotor adapters. The rotor adapters can only be used once. High g forces exerted in the centrifuge can cause damage to used rotor adapters.	

	Risk of material damage Empty the tip disposal container prior to use to prevent a tip jam in the waste drawer. Failure to empty the waste container may block the robotic arm that could cause run failure or instrument damage.	[C3]
WARNING	Risk of personal injury and material damage	[W5]

To prevent plastic crash, load the tubes properly. After a plastic crash, sharp plastic particles could be inside the centrifuge. Be careful when handling items inside the centrifuge.

CAUTION	Damage to the instrument	[C4]
	Only use the correct volume of liquids.	
	Exceeding the recommended volume of liquids may damage	
	the centrifuge rotor or instrument.	

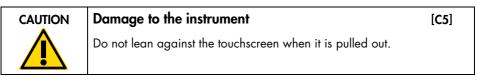
WARNING	Risk of fire or explosion
	When using ethanol or ethanol-based liquids on the QIAcube Connect MDx, handle such liquids carefully and in accordance
	with the required safety regulations. If liquid has been spilled,
	wipe it off and leave the QIAcube Connect MDx hood open to
	allow flammable vapors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

WARNING	Risk of explosion	[W7]
	The QIAcube Connect MDx is intended for use with reagents and substances supplied with QIAGEN kits or other than	
	outlined in respective Information for use. Use of other reagents and substances may lead to fire or explosion.	

[W6]

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

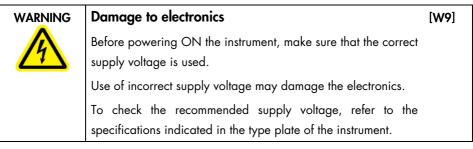
Note: Do not place items on top of the QIAcube Connect MDx hoods.



Electrical safety

Note: Disconnect the line power cord from the power outlet before servicing.

WARNING	Electrical hazard	[W8]
	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	Risk of electric shock	[W10]
	Do not open any panels on the QIAcube Connect MDx.	
	Risk of personal injury and material damage	
	Only perform maintenance that is specifically described in this	
	user manual.	

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

- The line power cord must be connected to a line power outlet that has a protective conductor (earth/ground).
- 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, power OFF the instrument, disconnect it from the power outlet, and contact QIAGEN Technical Services.

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

The instrument may be electrically unsafe when:

- It or the line power cord appears to be damaged.
- It has been stored under unfavorable conditions for a prolonged period.
- It has been subjected to severe transport stresses.
- Liquids come in contact directly with electrical components of the QIAcube Connect MDx.

Environment

Operating Conditions

WARNING	Explosive atmosphere	[W11]
	The QIAcube Connect MDx is not designed for use in an	
	explosive atmosphere.	

CAUTION	Damage to the instrument	[C6]
	Direct sunlight may bleach parts of the instrument and cause damage to plastic parts.	
	The QIAcube Connect MDx must be located out of direct	
	sunlight.	

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 <u>(www.cdc.gov labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF)</u>.

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	[W12]
	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. 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).

* COSHH: Control of Substances Hazardous to Health (United Kingdom).

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

Chemicals

WARNING	Hazardous chemicals	[W13]
WARNING	Hazardous chemicals Some chemicals used with this instrument may be hazardous or may become hazardous after completion of the protocol run. Always wear safety glasses, 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 not exposed to hazardous levels of toxic substances (chemical or biological) as defined in the applicable Material Safety Data Sheets (MSDSs)	[W13]
	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).

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	[W14]
	Do not use bleach to clean or disinfect the QIAcube Connect MDx. Bleach in contact with salts from the buffers can produce toxic fumes.	

WARNING	Toxic fumes	[W15]
	Do not use bleach to disinfect used labware. Bleach in contact	
	with salts from the buffers used can produce toxic fumes.	

Waste disposal

Used labware, such as sample tubes, QIAGEN spin columns, filter-tips, buffer bottle and enzyme tubes, or rotor adapters, may contain hazardous chemicals or infectious agents from the purification process. These hazardous wastes must be collected and disposed of properly according to local safety regulations.



Hazardous chemicals and infectious agents

[W16]

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

Mechanical hazards

The hood of the QIAcube Connect MDx must remain closed during operation of the instrument. Only open the hood when instructed to do so by the instruction for use.

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.



Moving parts

[W17]

Avoid contact with moving parts during operation of the QIAcube Connect MDx. Under no circumstances should you place your hands under the robotic arm when it is lowering. Do not attempt to move any tip racks or tubes whilst the instrument is operating.

WARNING	Moving parts	[W18]
	To avoid contact with moving parts during operation of the	
	QIAcube Connect MDx, the instrument must be operated with	
	the hood closed. If the hood sensor or lock is not functioning	
	correctly, contact QIAGEN Technical Services.	

Centrifuge

Make sure that the rotor and buckets are installed correctly. All buckets must be mounted before starting a protocol run, regardless of the number of samples to be processed. If the rotor or buckets show signs of mechanical damage or corrosion, do not use the QIAcube Connect MDx; contact QIAGEN Technical Services.

CAUTION	Damage to the instrument	[C7]
	The QIAcube Connect MDx must not be used if the centrifuge lid is broken, or if the lid lock is damaged. Make sure that no loose material is inside the centrifuge during operation.	
	Make sure that the rotor is installed correctly and that all buckets are properly mounted, regardless of the number of samples to be processed. Load the rotor only as instructed by the software.	
	Only use rotors, buckets, and consumables designed for use with the QIAcube Connect MDx. Damage caused by use of other consumables will void your warranty.	
	We recommend replacing the centrifuge rotor and buckets after 20,000 cycles, which is equivalent to 9 years of usage with two runs per day for 220 days each year. For more information	
	contact QIAGEN Technical Services.	

In case of breakdown, caused by power failure, the centrifuge lid can be manually opened to remove the samples.

WARNING	Moving parts	[W19]
	In case of breakdown caused by power failure, remove the power cord and wait 10 minutes before attempting to manually open the centrifuge lid.	

CAUTION	Damage to the instrument	[C8]
	After a power failure, do not move the z-module (robotic arm)	
	manually in front of the instrument. Damage may occur if the	
	QIAcube Connect MDx hood is closed and collides with the z-	
	module.	

WARNING	Risk of personal injury and material damage	[W20]
	Raise the centrifuge lid carefully. The lid is heavy and may cause injury if it falls.	

CAUTION	Risk of overheating
	To ensure proper ventilation, maintain a minimum clearance of
	10 cm at the sides and rear of the QIAcube Connect MDx.
	Slits and openings that ensure the ventilation of the QIAcube
	Connect MDx must not be covered.

Heat hazard

The QIAcube Connect MDx worktable contains a heated shaker.

WARNING	Hot surface	[W21]
	The shaker can reach temperatures of up to 70°C (158°F). Avoid touching it when it is hot. Carefully remove the samples after a run.	

[C9]

Maintenance safety

WARNING/	Risk of personal injury and material damage	[W22]
	Only perform maintenance that is specifically described in the user manual.	

WARNING	Risk of explosion	[W23]
	When cleaning the QIAcube Connect MDx with alcohol-based disinfectant, leave the QIAcube Connect MDx hood open to allow flammable vapors to disperse. Only clean the QIAcube Connect MDx when worktable components have cooled down.	

WARNING	Risk of fire	[W24]
	Do not allow cleaning fluid or decontamination agents to come into contact with the electrical parts of the QIAcube Connect MDx.	

WARNING	Risk of personal injury and material damage	[W25]
	To prevent the rotor nuts from loosening during operation of the centrifuge, securely tighten the nuts using the rotor key supplied with QIAcube Connect MDx.	

A	UV irradiation hazard	[W26]
	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.	

WARNING	Risk of personal injury and material damage	[W27]
	Make sure that lids from spin columns and 1.5 ml microcentrifuge tubes are in the correct position and pushed all the way down to the bottom of the slots on the sides of the rotor adapter. Incorrectly positioned lids can break off during centrifugation.	

WARNING	Risk of personal injury and material damage	[W28]
	Be sure the lid is completely removed from the spin column. Spin columns with partially removed lids may not be removed properly from the rotor, causing the protocol run to crash.	

CAUTION	Damage to the instrument(s)	[C10]
	Do not use bleach, solvents, or reagents containing acids,	
	alkalis, or abrasives to clean QIAcube Connect MDx.	

CAUTION	Damage to the instrument(s)	[C11]
	Do not use spray bottles containing alcohol or disinfectant to clean surfaces of the QIAcube Connect MDx. Spray bottles	
	should be used only to clean items that have been removed from the worktables.	

Radiation safety

WARNING	Risk of personal injury	[W29]
	Do not expose your skin to UV-C light from the UV LED lamp.	

WARNING	Risk of personal injury	[W30]
	Hazard Level 2 laser light: Do not stare into the light beam when using handheld barcode scanner.	

Symbols on the QIAcube Connect MDx

Symbol	Location	Description
	Next to the Shaker	Heat hazard — the temperature of the shaker can reach up to 70°C (158°F).
	Near the centrifuge; near the robotic arm	Mechanical hazard — avoid contact with moving parts.
\wedge	On the instrument, near bottle rack	Fire hazard – Usage of ethanol in bottle rack.
	In front of worktable	Biological hazard - Some samples used with this instrument may contain infectious agents and must be handled with gloves.
	Inside the waste drawer	Biohazard — the waste drawer may be contaminated with biohazardous material and must be handled with gloves.
CE	Type plate at the back of the instrument	CE mark for European Conformity
	Type plate at the back of the instrument	CSA listing mark for Canada and the USA
F©	Type plate at the back of the instrument	FCC mark of the United States Federal Communications Commission

Symbol	Location	Description
	Type plate at the back of the instrument	RCM mark for Australia and New Zealand
25	Type plate at 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
Ĩ	At the back of the instrument	Consult instructions for use
\wedge	Type plate at the back of the instrument	See warnings and precautions
IVD	Type plate at the back of the instrument	In vitro diagnostic medical device

Installation Procedures

QIAGEN brings the QIAcube Connect MDx customer experience to the next level with remote instrument monitoring through the QIAsphere Base (an IoT gateway) and the QIAsphere App.

The gateway can be connected to one or more QIAcube Connect instruments. QIAsphere Base enables users to connect the QIAsphere App running on a computer or a mobile device (e.g. a tablet) to their QIAcube Connect instrument(s) via local intranet. The QIAsphere Base interface manages the instrument data transfer from QIAcube Connect to the QIAsphere App. QIAsphere Base is connected to the user's intranet, for example via Wi-Fi.

Important: The QIAsphere Base communicates with the newly launched QIAsphere App, and it also communicates with QIAsphere cloud. The QIAsphere App helps to monitor the instrument status, e.g., instrument is running; instrument is available or the instrument requires maintenance. If your QIAsphere Base is connected to the QIAsphere cloud, run reports generated by the QIAcube Connect MDx (including sample IDs) are transferred to the QIAsphere cloud. In case this transfer of information would not be in accordance with your local regulations or with your laboratory regulations, the connection between the QIAsphere Base and the QIAsphere Base and the QIAsphere cloud, please refer to the instructions provided in the QIAsphere User Manual. Please note that sample IDs must not contain any personal data.

This section provides you with important information on how to install the QIAcube Connect MDx and the QIAsphere Base, including the required instrument setup and network settings. For detailed unpacking and installing information, refer to the respective user manual. **Note**: Before using the QIAsphere Base, it is essential that you read the supplier's user manual carefully and pay attention to the safety information. The safety information for QIAsphere Base can be found at https://www.eurotech.com/en/products/iot/multi-service-iot-edge-gateways/reliagate-10-12.

Site requirements

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

Setting up the QIAcube Connect MDx instrument

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

To set up the QIAcube Connect MDx instrument

- 1. Remove the power cord and the quick-start guide from the foam packing material on top of the QIAcube Connect MDx.
- 2. Remove the USB flash drive, rotor key, rotor nut, Allen key, S2 shaker adapter, and shaker rack plugs from the waste drawer.
- Carefully peel off the protective film from the QIAcube Connect MDx hood. To remove the protective film, gently pull it towards you. Ensure to close the QIAcube Connect MDx hood after removing the protective film.
- 4. To remove the foam protectors above the centrifuge, gently pull the top foam protector towards you. After removal of top foam protector, gently pull the middle foam protector towards you and find the barcode reader enclosed within middle foam. Gently remove the bottom foam protector above centrifuge.
- To remove the foam protector around the robotic arm, gently pull the foam protector towards you. After removing the protector for the robotic arm, ensure to close the QIAcube Connect MDx hood.
- 6. Before turning on the instrument, plug the Wi-Fi adapter into one of the USB ports behind the touchscreen.
- 7. Connect the QIAcube Connect MDx to a power outlet using the provided power cord.

8. The centrifuge rotor and buckets are pre-installed in the QIAcube Connect MDx. When setting up the QIAcube Connect MDx for the first time, switch on the instrument (see step 10) and remove the transportation foam inserts from the centrifuge after it opens. In case the centrifuge rotor and buckets have been manually removed (e.g., during maintenance), follow the procedures below to install the centrifuge rotor and buckets:

Note: The rotor can be mounted in only one orientation. The pin on the rotor shaft fits into a notch on the underside of the rotor, directly underneath rotor **Position 1**.

- Line up **Position 1** of the rotor with the pin on the rotor shaft and carefully lower the rotor onto the shaft.
- 8b. Install the rotor nut on top of the rotor and tighten using the provided rotor key supplied with the QIAcube Connect MDx. Make sure that the rotor is securely seated. Check that all buckets are properly suspended and can swing freely. Note: To help prevent buckets from being loaded incorrectly, the side of the rotor bucket that must face towards the rotor shaft is marked with a grey line. Check that all buckets are properly suspended and can swing freely.

Mount all centrifuge buckets before starting a protocol run, even if fewer than 12 samples are to be processed.

- 9. Optional: Refer to the instrument user manual if you need to change the shaker adapter.
- To power on the QIAcube Connect MDx instrument, close the hood and press the power button. A beeper sounds and the startup screen appears.
- 11. To log in for the first time, enter Admin in both User ID and Password fields. After this login, you will have Admin rights with the option to set up other users. Refer to the instrument user manual for more details on user management.
- 12. From the **Configuration** menu under the **System** tab, you can modify the **Set Date**, **Time** and **Name Settings** fields.

13. Follow the instructions below to connect the QIAcube Connect MDx instrument to a network. This can only be done by a user with an Admin role.

Connecting the QIAcube Connect MDx via Wi-Fi

Note: The QIAcube Connect MDx supports only WPA-PSK and WPA2-PSK modes. Additionally, the SSID of the Wi-Fi hotspot must be visible. A connection to a hidden SSID is not supported.

- 13a. From the **Configuration** menu under the **Wi-Fi** tab, you can set up the Wi-Fi network.
- 13b. Scan for available networks.
- 13c. From the list, select one of the available networks.
- 13d. Enter the Wi-Fi password and connect.

Connecting the QIAcube Connect MDx via LAN cable

13e. 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 QIAsphere Base

The QIAsphere Base must be connected to the same network as the QIAcube Connect MDx instrument. The QIAsphere Base does not need to be in proximity with the QIAcube Connect MDx instrument to be connected.

Note: The name **QIAsphere Base** is abbreviated as **Q-Base** in the QIAcube Connect MDx instrument software and in the QIAcube Connect app.

The installation procedures for QIAsphere Base can be found in the QIAsphere Connectivity Package Quick Start Guide. Go to the **Download Resources** link at **www.qiagen.com/qiasphere**. The installation procedures will provide you the important information on how to install the QIAsphere Base, including the required instrument setup and network settings.

If you need detailed installation information or if you need to use your laptop for configuration via cable instead of Bluetooth[®]/Wi-Fi adapter, refer to the respective user manual.

Note: To enter detailed network settings, you might need the help of an IT professional.

Revision History

Revision	Description	
11/2020	First version of the document.	

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 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.

Notes

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