



diaxxoCareM2

Instructions for Use

Issue date: 19/03/2026

Applicable models:

- DXO-CARE-M2V1Rx

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diaxxoCare is an extraction and PCR device for special purposes. Please operate in strict accordance with the *Instructions for Use* to avoid any damage to the device and any incorrect results.



diaxxoCare has a specific purpose and should only be used in combination with *diaxxo*'s consumables. Please operate in strict accordance with both the instruments and the accompanied cartridge's *Instructions for Use* to avoid any damage or incorrect overall results. In case the device is disassembled, or its performance is affected by significant alterations, the warranty will be void.



Thank you for choosing our products. Please make sure to read the operations manual carefully before using the instrument for the first time. Having a clear understanding of the correct usage procedure, instrument setup and precautions to take is required to carry out proper diagnostic experiments.

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1 Safety Information



Before using this device, it is essential that you read this user manual 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.



The following types of safety information appear throughout this manual:

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

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

1.1. Proper Use



<p>WARNING / CAUTION</p> 	<p>Risk of personal injury and material damage</p> <ul style="list-style-type: none"> ▪ Improper use of this device may cause personal injuries or damage to the instrument. If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired. ▪ This device must only be operated by qualified personnel who have been appropriately trained. ▪ Servicing of this device must only be performed by diaxxo specialists. ▪ Do not attempt to move the device during operation. ▪ The robotic arm moves during position. Never touch any moving part while the instrument is in operation.
<p>WARNING / 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 device. Slits and openings that ensure the ventilation of the device must not be covered.</p>

<p>WARNING / CAUTION</p> 	<p>Risk of explosion</p> <ul style="list-style-type: none"> ▪ The device is intended for use with reagents and substances supplied by diaxxo. ▪ Use of other reagents and substances may lead to fire or explosion. ▪ The device is not designed for use in an explosive atmosphere.
<p>CAUTION</p> 	<p>Damage to the instrument</p> <ul style="list-style-type: none"> ▪ Direct sunlight may bleach parts of the instrument and cause damage to plastic parts. The device must be located out of direct sunlight. ▪ Avoid spilling water or chemicals onto the device. Damage caused by water or chemical spillage will void your warranty.

In case of emergency, switch off the device at the power switch at the rear of the instrument and unplug the power cord from the power outlet.

1.2. Electrical Safety

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

<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. Intentional interruption is prohibited.</p>
<p>WARNING</p> 	<p>UV irradiation hazard</p> <p>If the device is equipped with a UV disinfection module, an electronic interlock ensures that the instrument lid must be closed for operation of the UV lamp.</p> <p>Under no circumstances should this interlock be disabled.</p>

To ensure satisfactory and safe operation of the device, please do the following:

- Connect the line power cord 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, switch off the instrument, disconnect it from the power outlet, and contact diaxxo Technical Services.

If the instrument becomes electrically unsafe, prevent other personnel from operating it, and contact diaxxo Technical Services. The instrument may be electrically unsafe when:


- The line power cord appears to be damaged
- It has been stored for a prolonged period of time in conditions which are outside of the “Storage Conditions” described in the dedicated paragraph of this manual
- It has been subjected to severe transport stresses.

1.3. Biological Safety


Specimens and reagents containing biological materials 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/od/ohs/biosfty/biosfty.htm).

Samples

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.

<p>WARNING</p> 	<p>Samples containing infectious agents</p> <p>Samples analysed by this device 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. 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 infectious agents as defined in the applicable Material Safety Data Sheets (MSDSs) or OSHA, ACGIH, or COSHH documents.</p> <p>Disposal of waste must be in accordance with all national, state, and local health and safety regulations and laws.</p>
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Chemicals

<p>WARNING</p> 	<p>Hazardous chemicals</p> <p>Some chemicals used with this instrument may be hazardous or may become hazardous after completion of the protocol run. Always wear appropriate personal protective equipment. 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) or OSHA, ACGIH, or COSHH documents.</p> <p>Disposal of waste must be in accordance with all national, state, and local health and safety regulations and laws.</p>
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1.4. Waste Disposal

Used plastic ware and containers may contain certain hazardous chemicals, or contagious / biohazardous materials. Such waste must be collected and disposed of properly according to national and local safety regulations. Additional information on the disposal of the cartridges and of the device is provided in the dedicated section.

1.5. Mechanical Hazard



<p>WARNING</p> 	<p>Moving parts</p> <p>Avoid contact with moving parts during operation of the device.</p> <p>Do not attempt to move any part of the device whilst the instrument is operating.</p>
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To ensure satisfactory and safe operation of the device, please do the following:

- Only use recommended consumables
- Keep the instrument lid closed whenever possible
- Do not disable the lid interlock (if present)
- Do not place any item (other than the dedicate consumables) inside the device

1.6. Maintenance Safety

Perform the maintenance as described in the dedicated section of this manual. Diaxxo charges for repairs that are required due to incorrect maintenance.

<p>WARNING / CAUTION</p> 	<p>Risk of personal injury and material damage</p> <p>Only perform maintenance that is specifically described in this user manual.</p> <p>Do not use reagents containing acids, alkalis, or abrasives to clean the device.</p>
<p>WARNING / CAUTION</p> 	<p>Risk of electric shock</p> <p>Do not open any panels on the device. Risk of personal injury and material damage.</p> <p>Only perform maintenance that is specifically described in this user manual.</p>


1.7. Symbols on the device or in this manual

Symbol	Location	Description
	On the back of the instrument (laser engraved, white on black background)	Warning Symbol
	On the back of the instrument (laser engraved, white on black background)	Caution! Power supply
	On the back of the instrument (laser engraved, white on black background)	Ethernet port
	On the tray	Biohazard symbol
	In the Instructions for Use	Flammable material
	On the front panel	Squeezing symbol
	On the back of the instrument	Caution! Documentation of equipment must be consulted
	On the back of the instrument	CE mark for European Conformity
	On the back of the instrument	Legal manufacturer
	On the back of the instrument	Waste Electrical and Electronic Equipment (WEEE)

	On the back of the instrument	Serial number (alphanumeric)
	On the packaging	Fragile
	On the packaging	Keep dry
	On the packaging	Do not use if package is damaged
	On the packaging	Storage and transport temperature range
	On the packaging	Storage and transport humidity range

2 Introduction

Thank you for choosing this diaxxo instrument. We are confident it will become an integral part of your laboratory. Before using the device, it is essential that you read this user manual 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

<p>WARNING</p> 	<p>This system is limited to trained laboratory technicians proficient with molecular techniques and instruments to operate and use.</p>
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2.1. General Information

General information provided in the document *R1285-Technical_Specifications*.

Technical Assistance

If you have any questions or experience any difficulties regarding the device, do not hesitate to contact us. We therefore encourage you to contact us also if you have any suggestions about product performance or new applications and techniques.

Policy statement

It is the policy of diaxxo to improve products as new techniques and components become available. diaxxo reserves the right to change specifications at any time. In an effort to produce useful and appropriate documentation, we appreciate your comments on this user manual. Please contact [diaxxo](#) Technical Services.

2.3. Requirements for the users of this device

This table covers the general level of competence and training necessary for transportation, installation, use, maintenance, and servicing of this device.

Task	Personnel	Training and Experience
Delivery	No special requirements	No special requirements
Installation	Laboratory technicians or equivalent	Appropriately trained and experienced personnel familiar with use of computers and automation in general
Routine use	Laboratory technicians or equivalent	Appropriately trained and experienced personnel familiar with use of computers and automation in general

Servicing and maintenance	diaxxo specialist only	Training and authorization by diaxxo
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2.4. Theory of operation

The diaxxoCare device automates and integrates magnetic beads-based nucleic acid extraction, liquid handling operations and detection of the DNA or RNA target sequences in biological samples using quantitative real-time PCR (qPCR).

Nucleic acid extraction

This instrument is designed to efficiently isolate nucleic acids from biological samples. The extraction process involves three key automated steps: combined sample lysis, washing, and elution of purified nucleic acids. In this process, the user adds the sample to a lysis and binding buffer. Here, the buffer initiates cell lysis, breaking down cell membranes and releasing nucleic acids into the solution. Simultaneously, specialized magnetic beads coated with a high-affinity binding material are introduced to selectively bind with the released nucleic acids. The system's automation ensures thorough mixing during this combined lysis and binding step, enhancing the efficiency of nucleic acid capture. Subsequently, the wash steps remove impurities and contaminants, further purifying the captured nucleic acids. The automated mixing mechanism ensures consistent and effective washing across multiple samples. Finally, in the elution step, the purified nucleic acids are released from the magnetic beads.

qPCR amplification and detection

The diaxxoCare device operates by executing pre-defined qPCR programs, facilitating the amplification and detection of specific DNA and RNA target sequences. In the course of the qPCR, if present, these target sequences undergo exponential amplification, concurrently generating a fluorescence signal. This emitted fluorescence intensifies with successive qPCR cycles, which is captured by the device's recording mechanism. Based on the fluorescence signal change, the instrument's software calculates the quantification cycle (Cq) value to determine the presence/absence of target specific nucleic acids.

The systems require the use of single-use disposable application-specific pods that hold the qPCR reagents and host the qPCR process. The pods are preloaded with all required enzymes and reagents.

3 General Description

This device executes nucleic acid extraction, amplification and detection of the target sequences in simple or complex samples using real-time PCR assays. The systems consist of an automated instrument with moving mechanical parts, a computer, and preloaded software for running tests and viewing the results.

3.1. Consumables

The systems require the use of single use disposable consumables called: *diaxxoExtract*, *diaxxoSleeve*, *diaxxoTips*, and *diaxxoPod*.

- *diaxxoExtract*: holds the chemical reagents which allow nucleic acids extraction from biological specimens by means of magnetic beads.
- *diaxxoSleeve*: protects and prevents the magnets from contamination and allows the magnets to be used multiple times. In addition, *diaxxoSleeve* is used for mixing the reagents of the *diaxxoExtract*.
- *diaxxoTips*: pipetting tips used by the pipetting module to load the extracted samples in the wells of the *diaxxoPod*.
- *diaxxoPod*: holds the qPCR reagents and hosts the qPCR process. Because the cartridges are self-contained, cross-contamination between samples is minimized.
- *diaxxoTubes*: holds the cover fluid for *diaxxoPod*

3.2. Instrument details

The device has a parallelepiped shape; it has a front door, a touch-screen display and a back panel for the connections (e.g. to the power supply).

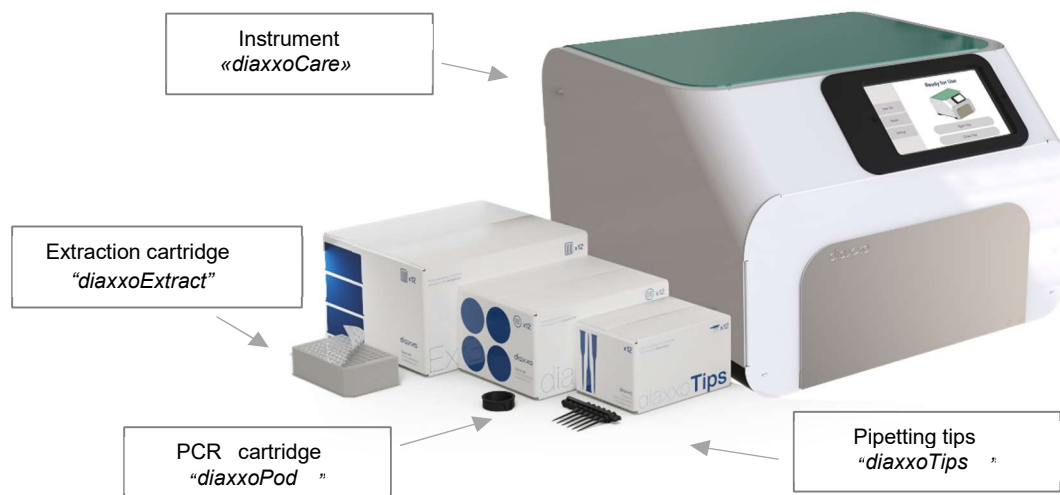




Figure 1: diaxxoCare and its consumables

Instrument lid

The lid of the instrument provides both an isolated enclosure for performing purification and a safety mechanism.

The instrument lid must be closed after loading the consumables and before starting a test. Opening the instrument lid while the device is running is forbidden.

<p>CAUTION</p> 	<p>Damage to the instrument lid</p> <p>Do not use reagents containing acids, alkalis, or abrasives to clean the instrument lid.</p>
<p>WARNING</p> 	<p>Protective function of the lid</p> <p>The user must ensure that all the screws fixing the front window of the lid are properly installed and secured in order to maintain the safety of the instrument during normal operation.</p> <p>The front window of the lid of the instrument can be removed with a common mechanical tool (hex wrench, size 2). In order to prevent unauthorized removal of the front window, the user must ensure that access to this tool is controlled.</p>

Feet

The feet of the instrument have a non-slip silicone base to ensure that the device remains securely positioned on a laboratory bench. Do not attempt to slide the instrument on a bench. Always lift the instrument to avoid damage to the silicone base of the feet.

Back panel

The device connection ports of the back panel are pictured in Figure 2. The power plug of the power supply has to be inserted in the dedicated socket on the back of the device, with the right orientation. The Lan Cable must be plugged in on the second-lowest port, with the right orientation.



Figure 2: Connection ports. From the top: DC Switch, USB ports, Lan Cable, Power Plug

3.3. Internal features

Extraction module

The extraction module consists of magnets and holders for the magnetic beads extraction procedure.

Liquid-handling module

The automated robotic arm equipped with a liquid handler guarantees accurate and consistent sample dispensing, eliminating human variability. Its controlled volume settings facilitate meticulous transfer, supporting reproducible results.

qPCR module

It consists of a heating module and an optical detection module for the execution of real-time quantitative PCR reactions.

Device tray

The device's tray has several slots marked with an identifier, according to the following table:

Identifier	Description
1	Holder for extraction cartridge (<i>diaxxoExtract</i>)
2A, 2B	Indicator for positioning the sleeves inside <i>diaxxoExtract</i> (<i>diaxxoSleeves</i>)
3A, 3B	Holder for the pipetting tips (<i>diaxxoTips</i>)
4	Holder for the PCR cartridge (<i>diaxxoPod</i>)
5, 6, 7 (if present)	Holder for additional laboratory tubes (if part of the test kit)

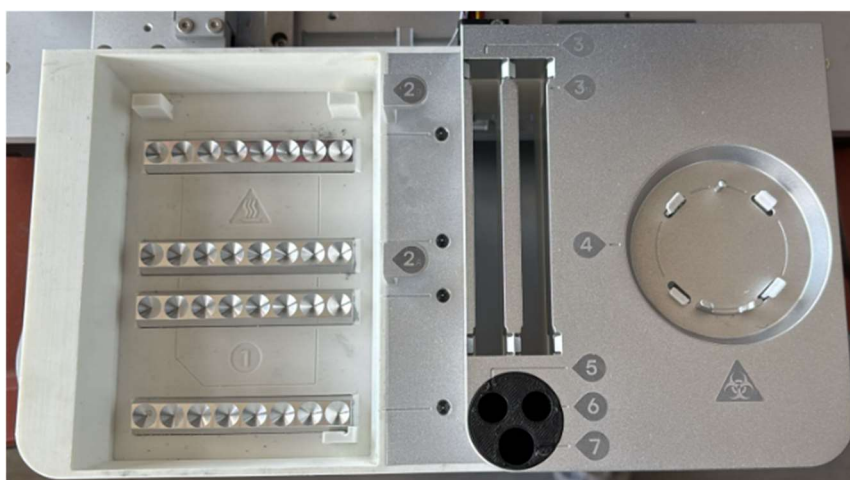


Figure 3: Device's tray and slots for the cartridges

3.5. External Power Supply

Use only the external power supply provided by the manufacturer to ensure optimal performance and safety. This power supply is specifically designed to meet the electrical and safety standards required for your device, including proper insulation, voltage regulation, and overload protection.

Using unapproved power supplies can result in electrical hazards, device malfunction, and voided warranties.

If you encounter any issues with your power supply, contact our technical support team for assistance and replacement options.

4 Installation Procedure

4.2. Delivery list

Please check the provided delivery list (separate sheet).

4.3. Materials Required but Not Provided

This device should only be used in combination with Diaxxo’s consumables, which are provided separately. No other accessories are required for the operation of the instrument.



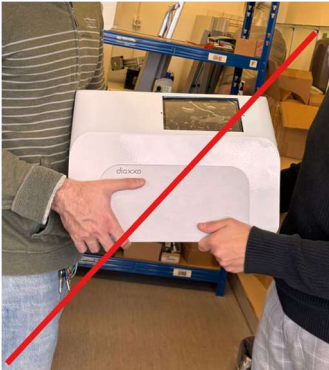

4.4. Environmental requirements

This device is intended for indoor use. Ensure that the installation site is maintained under the conditions specified in the dedicated section of the document *R1285-Technical_Specifications*.

4.5. Unpacking


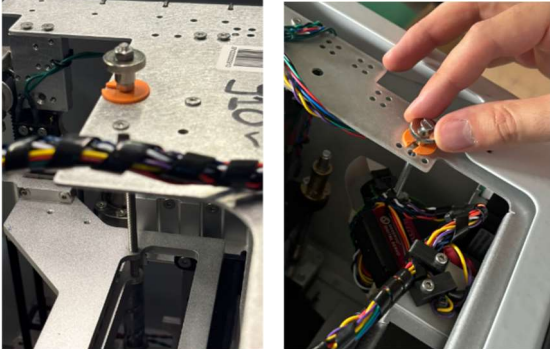
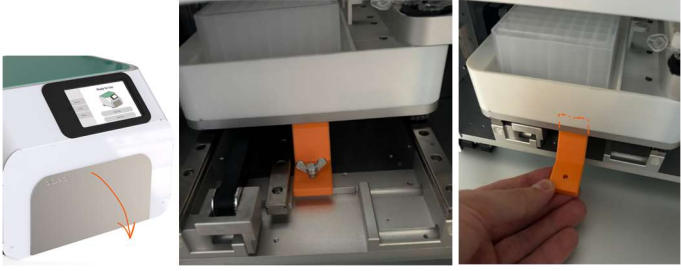


Before unpacking the device, move the package to the site of installation and check that the arrows on the package point upwards. In addition, check whether the package is damaged. In case of damage, contact the transporter of the package.

When lifting up the device, slide your fingers under both sides of the instrument and keep your back straight.

<p>WARNING</p> 	<p>Heavy</p> <p>The device has considerable weight. Remove it from the box with the help of a second person.</p>
<p>WARNING / CAUTION</p> 	<p>Risk of personal injury and material damage</p> <p>The device is heavy. To avoid personal injury or damage to the instrument, do not lift the instrument alone. Always lift the device from the bottom base with two hands.</p> <p><u>Do not lift</u> from the door.</p> <div style="display: flex; justify-content: space-around; align-items: center;">   </div>

In order to unpack the device, please follow the steps in the table below. The same steps can also be executed in opposite order when re-packing the device.

Step	Action	Image
1	<p>Please check the shipment-control stickers placed on the primary packaging (e.g. wooden box or cardboard box). This will indicate the conditions of the shipment (tilting, acceleration).</p> <p>If any sticker shows damage or has been triggered, please contact diaxxo immediately.</p>	
2	<p>Open the box (cut the zip tie, if present). Inside the box, you will find several items wrapped in protective material:</p> <ul style="list-style-type: none"> • The power supply • Power chord (country-specific) • WIFI antenna • Plastic bag containing: 5x screws (M3x8 CS) and corresponding Allen key • IFU (if not shared electronically) 	
3	<p>Remove the top foam</p>	
4	<p>Extract the device with the help of a second person. Lift as shown in the picture.</p> <p>Carry the device on top of the dedicated desk.</p> <p>We suggest you to keep the original shipping box and foam.</p>	




<p>5</p>	<p>The device is provided with the top panel (green) disassembled and wrapped in protective material, in order to allow you to remove the shipping locks (under the top panel).</p>	
<p>6</p>	<p>Remove the orange screws that are holding the internal modules of the machine (extraction, pipetting).</p> <p><i>Note in case of re-packing: make sure that the limit switches of the modules are not compressed when fixing the screws (if unsure, contact diaxxo technical support).</i></p>	
<p>7</p>	<p>Open the front door by hand</p> <p>A L-shaped orange shipping lock is fixed in a slot under the tray. Please unscrew the butterfly screw. Slide the tray forward, then slide the orange part out of the tray</p>	
<p>8</p>	<p>Fix the top panel (green) with 3x screws (M3x8 CS) provided in the plastic bag. The corresponding L Allen key is also provided.</p> <p>Two additional spare screws are also provided.</p>	
<p>9</p>	<p>Plug in:</p> <ul style="list-style-type: none"> - WIFI antenna (if provided) - Power supply <p>The device is then ready.</p> <p><i>Note in case of re-packing: please remove all consumables from the machine (extraction, tips, pod).</i></p>	

Following unpacking, please ensure the completeness of the delivered package and that no damage occurred during its transportation. In case any of the parts is missing please contact diaxxo directly. Keep the packaging in case you need to transport or ship the device in the future. Using the original package minimizes damage during transportation of the instrument.

4.6. Installation on the bench

When the instrument is removed from the packing box, keep the machine stable following the following precautions:

- The instrument must be placed on a non-inclined, clean, stable and flat surface. To ensure the normal operation of the instrument, please choose an indoor workplace that meets the storage requirements.
- The device 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. We recommend that the device does not share a wall socket with other laboratory equipment, and that the instrument is plugged directly into its own wall socket.
- The instrument should not be exposed to direct sunlight, large amounts of dust nor strong electromagnetic radiation. The device should be installed in a laboratory environment that is free of excessive airborne dust.
- The device should be placed in a well-ventilated place that allows easy operation of the device and optimizes the workflow of the working area. The site of installation should be free of excessive drafts, excessive moisture, excessive dust, and should not be subject to large temperature fluctuations. The device should be protected from heat sources such as radiators and heat-producing instruments.
- The device shall not be placed in locations with violent vibrations and shocks occurring due to the surrounding devices.

<p>CAUTION</p> 	<p>Wait before using the instrument</p> <p>Wait at least 1 hour before using the instrument after installation on the bench. During this time, temperature and humidity of the instrument will settle to the values of the surrounding environment. This is particularly important after transportation or shipment (e.g. by truck / car / air).</p>
<p>WARNING / 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 device. Slits and openings that ensure the ventilation of the instrument must not be covered.</p>
<p>CAUTION</p> 	<p>Damage to the instrument</p> <p>Direct sunlight may bleach parts of the instrument and cause damage to plastic parts. The device must be located out of direct sunlight.</p>

4.7. Electrical ratings and requirements

External power supply ratings and device ratings are specified in the document *R1285-Technical_Specifications*.


The external power supply ensures proper insulation, stable voltage regulation, and overload protection. Using an unapproved power supply can lead to electrical hazards, device malfunctions, and voided warranties.

Please follow the following recommendations:

- Ensure that the network power supply and grounding environment of the instrument is good and stable
- The device's overcurrent protection and the non-symmetric power plug ensure a safe connection to the grid by the user.
- When installing the instrument, make sure to use the dedicated power supply. Ensure that it is well grounded and placed in a position where it is easy to operate. Failure to do so may cause fire or electric shock.
- The device is meant to be used only with the provided mains power supply. Do not use any other mains power supply, any other detachable mains supply cord with inadequate rating or any other mains power supply type

Grounding requirements

To protect operating personnel, and for correct functioning of the device, a correct grounding (earth) is recommended. 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>CAUTION</p> 	<p>Electromagnetic compatibility</p> <ul style="list-style-type: none"> ▪ The user is responsible for ensuring the electromagnetic compatibility environment of the device so that the equipment operates properly without interferences. It is recommended to evaluate the electromagnetic environment before using the instrument. Detailed test results can be requested to diaxxo. ▪ It is forbidden to use this equipment near strong radiation sources (such as unshielded radio frequency sources), or it may interfere with the normal operation of the equipment.
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4.8. Re-packing

If the user needs to re-pack and ship the device, they should first switch off the device, remove any cartridges, and clean any residual liquids or spills using the recommended decontamination procedures. The instrument should then be secured by installing the transport lock and re-packed by following the unpacking operations described in Chapter 4.5 in the opposite order.

Before packing, the original transport box should be inspected for any damage; if damage is found, technical support should be contacted.

When lifting the device, fingers should be slid under both sides of the instrument, and the back should be kept straight while handling heavy objects.

4.9. Disposal information

If there is a need to recycle the instrument, please follow the disposal guidelines of your institute and the local rules and regulations regarding electronic equipment. Follow your institution's environmental waste procedures for proper disposal of used cartridges and unused reagents. These materials may exhibit characteristics of chemical hazardous waste requiring specific disposal. If country or regional regulations do not provide clear direction on proper disposal, biological specimens and used cartridges should be disposed per WHO (World Health Organization) medical waste handling and disposal guidelines.

5 Operating Procedures

This section describes how to operate the device.

5.1. Preliminary operations

Before operating the device, the user should do the following:

1. Plug in the power supply
2. Turn on the power switch located on the back of the device
3. Open the device lid with the dedicated handle
4. Ensure that the tray surface is clean and free of dirt

5.2. Loading the consumables

The device's tray should be fully accessible after opening the lid of the machine. If this is not the case, the user may press "HOME" on the Graphical User Interface.

Loading the extraction cartridge (*diaxxoExtract*)

These steps should be carried out when the user intends to execute a program that includes sample extraction (stand-alone or in combination with a qPCR test):

1. Remove the sealing foil from the extraction cartridge and load your sample into the first row. Please refer to *diaxxoExtract - Instruction For Use* for additional information on how to load the sample.
2. Insert *diaxxoExtract* in the corresponding holder on the tray of the device. Please, make sure that cartridge is oriented with the cut corner facing the left side of the tray.
3. Insert *diaxxoSleeves* in the 6th and 12th row of the extraction cartridge. Please, make sure that the extension of the sleeves (made for holding purposes) are on the right side of the tray.

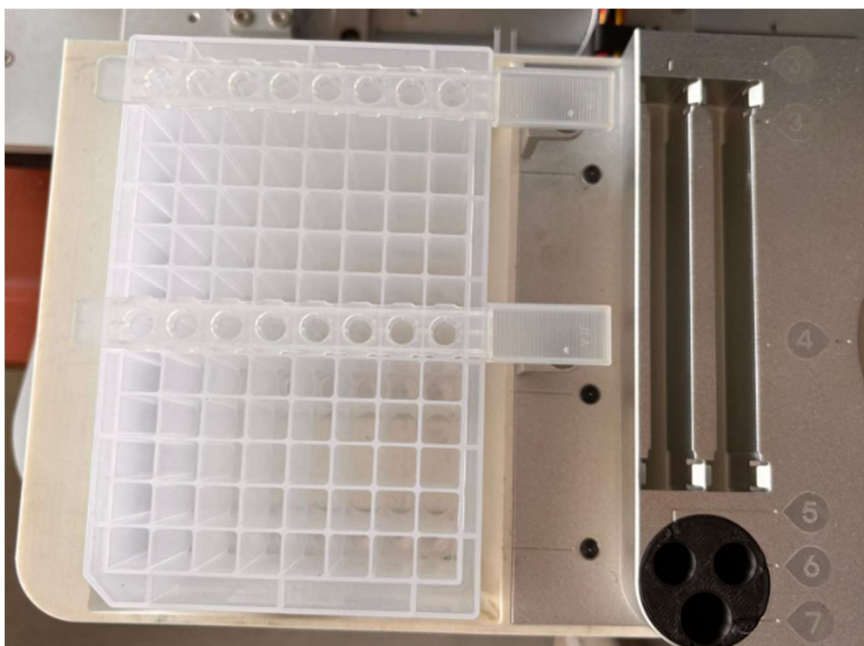






Figure 4: Loading the extraction cartridge and the sleeves

<p>CAUTION</p> 	<p>Do not run an extraction without first inserting the extraction cartridge</p> <p>Please make sure that the extraction cartridge is correctly installed before running a program comprising sample extraction</p> <p>Degradation of the chemicals</p> <p>Please insert the extraction cartridge into the machine no longer than 5 minutes before starting the test.</p> <p>Please check the cartridge's <i>Instruction for Use</i> for additional information about the stability of the reagents once the protective foil has been removed.</p>
<p>CAUTION</p> 	<p>Do not move the tray back and forth manually</p> <p>Please do not move the tray of the device manually. Use the GUI buttons if needed (e.g. to bring the tray to the consumables loading position)</p>
<p>CAUTION</p> 	<p>Prevention of ignition and spread of fire</p> <p>The extraction cartridge contains small amounts of flammable liquids. To prevent ignition and the spread of fire, users should avoid improper handling, such as flipping the cartridge or pouring the liquid onto the device</p>
<p>WARNING</p> 	<p>Handling Spills and Decontamination</p> <p>If any sample or liquid contained in the extraction cartridge is spilled onto or into the equipment, promptly carry out appropriate decontamination. First, ensure the device is powered off and unplugged. Use absorbent materials to contain and remove the spill. Clean the affected area a 70% isopropyl alcohol solution to disinfect.</p> <p><u>Avoid Hazardous Reaction</u> Do not use decontamination or cleaning agents that could cause a hazard due to a reaction with parts of the equipment or with the materials contained in it. Specifically, avoid using bleach, ammonia, or any strong oxidizers which can damage the device or create harmful reactions.</p> <p><u>Consult the Manufacturer</u> If there is any doubt about the compatibility of decontamination or cleaning agents with parts of the equipment or with the material contained in it, consult the manufacturer or its authorized agent.</p>

Loading the pipetting tips (*diaxxoTips*)

These steps should be carried out when the user intends to execute a program that comprises both sample extraction and PCR test, or PCR stand-alone:

1. Take one strip of tips from the corresponding box.
2. Insert the pipetting tips (*diaxxoTips*) in the corresponding tray holder.

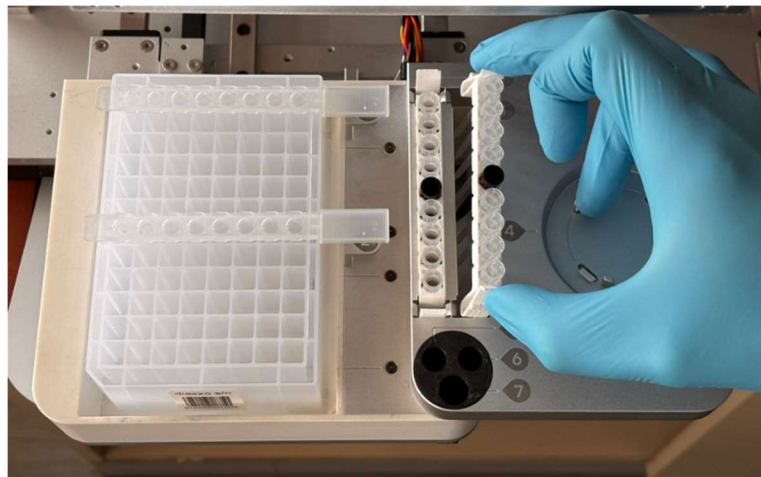


Figure 5: Loading diaxxoTips

CAUTION



Do not run a PCR test without first inserting the pipetting tips

Please make sure that the pipetting tips are correctly installed before running a program comprising both sample extraction and PCR amplification.

Loading the PCR cartridge (*diaxxoPod*)

These steps should be carried out when the user intends to execute a program that comprises a PCR test (stand-alone or in combination with a sample extraction):

1. Extract the PCR cartridge from its protective pouch.
2. Insert the cartridge in the corresponding holder on the tray of the device.

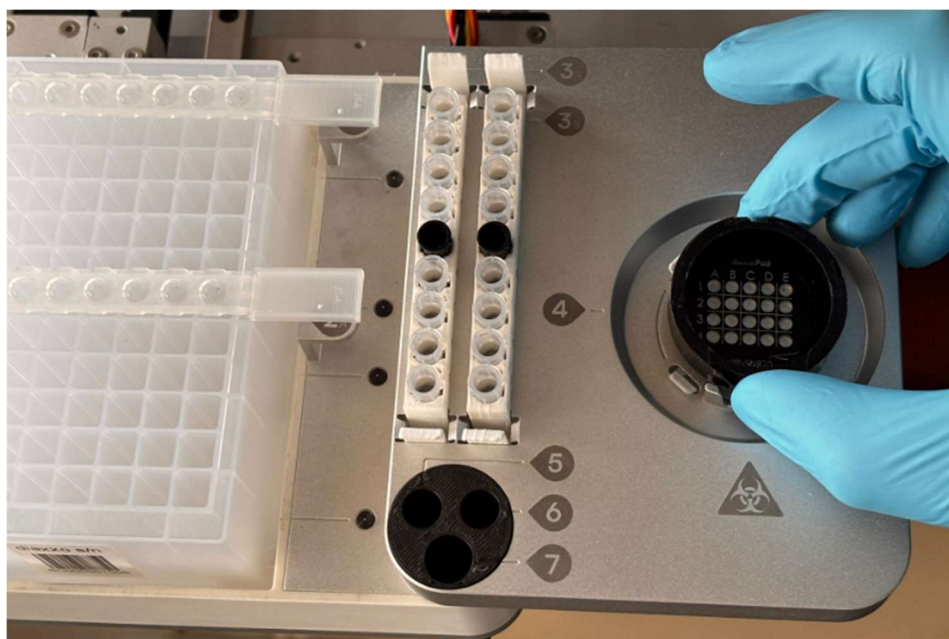




Figure 6: Loading diaxxoPod

<p>CAUTION</p> 	<p>Degradation of the chemicals</p> <p>Please insert the PCR cartridge into the machine no longer than 5 minutes before starting the test.</p> <p>Please check the cartridge's <i>Instruction for Use</i> for additional information about the stability of the reagents once the protective pouch has been opened.</p>
<p>CAUTION</p> 	<p>Do not run a PCR test without first inserting the PCR cartridge</p> <p>Please make sure that the PCR cartridge is correctly installed before running a program comprising PCR amplification.</p>

5.3. Tray overview

The fully loaded tray will look as follows:

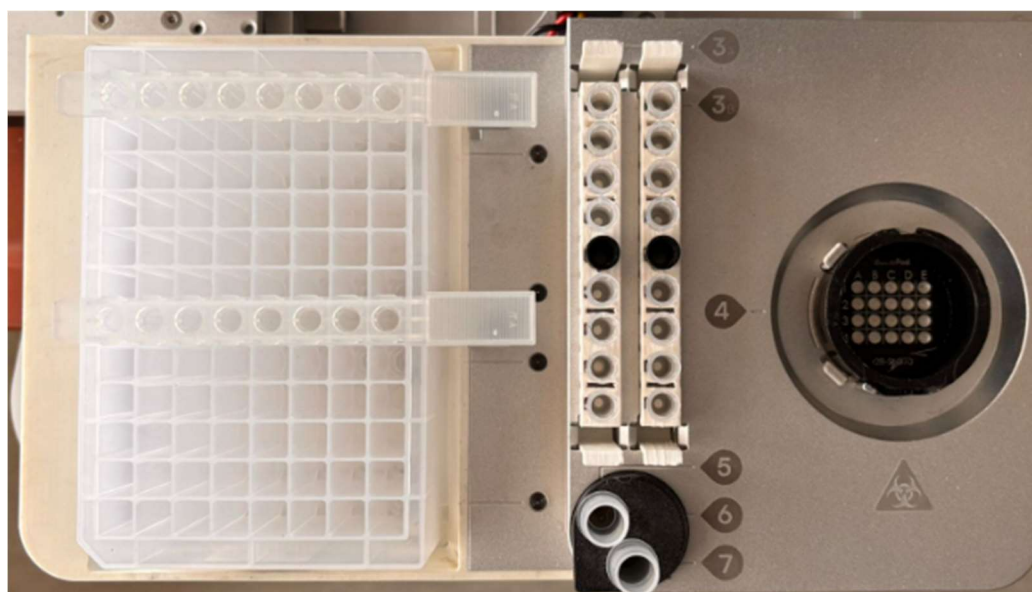




Figure 7: Device tray and consumables (before the test is started) from left to right: diaxxoExtract with two sleeves, two diaxxoTps (top), diaxxoTubes (bottom), diaxxoPod

Depending on the desired program, the following combination of consumables may be present:

- a) Extraction cartridge and sleeve only, for programs comprising only sample extraction.
- b) PCR cartridge only, for programs comprising only PCR amplification and manual loading of the cartridge. If a PCR is to be run with samples on a previously used diaxxoExtract, please also insert diaxxoTps.
- c) Extraction cartridge (with sleeves), pipetting tips and PCR cartridge, for program comprising sample extraction and PCR amplification

5.4. Closing the lid of the device

After loading the consumables, pull the lid handle to close the device's lid. Please note that the device's lid must remain closed during operation of the instrument. Only open the lid when the instrument is not operating or when instructed to do so by the software.

<p>WARNING / CAUTION</p> 	<p>Risk of personal injury and material damage</p> <p>Do not attempt to move the device during operation.</p>
<p>WARNING</p> 	<p>Moving parts</p> <p>To avoid contact with moving parts during operation of the device, the instrument must be operated with the lid closed.</p>

5.5. Device Interfaces

The device has a Graphical User Interface (GUI) displayed on the touch screen, as well as a browser interface accessible by means of a standard browser (e.g. Google Chrome).

Detailed instructions can be found in the corresponding IFU: *diaxxo-R048-diaxxoDashboard*.

5.6. Connectivity

The device offers several connectivity options.

Detailed instructions can be found in the corresponding IFU: *diaxxo-R047-Connectivity*.

5.7 Re-test

Reasons to repeat a diagnostic test

A program shall be re-executed (with new consumables) in the following cases:

- An error occurred during the program (shown on the display).
- The operator stopped a test that was in progress.
- A power failure occurred

When running a new program please always use new consumables. You may use the leftover samples from the original specimen tube (if available in sufficient quantity) or new samples from the same source.

5.8 Switching off the device

After program completion, the device will automatically become idle (state: "READY"). To switch off the instrument, flip the switch located at the back of the device. Please remove the consumables from the tray when not using the device.

5.9 Cleaning

Exterior surfaces

The exterior surfaces should be cleaned on a regular basis in order to remove any dust or dirt that might interfere with proper function:



1. Clean the air vents: remove dust with a soft brush, damp cloth, or keyboard computer vacuum cleaner. Cleaning the vents allows sufficient air flow for precise thermal control during a run.
2. Clean the touch screen: remove dust and traces on the control panel with a soft cloth. Do not use abrasive detergents or rough material which might scratch the display. Do not use ethyl acetate or acetone.
3. Clean the outside case and the handle of the device with a damp cloth or tissue.

Internal surfaces

Clean the tray of the device weekly to prevent the accumulation of any dirt that might interfere with the correct functioning of the instrument:

1. Clean spilled liquids immediately; use wet paper towels with water (recommended), 95% ethanol or 99% isopropyl alcohol.
2. In case of suspected contamination across experiments, clean external components with a lint-free cloth lightly moistened with a DNA/RNA decontamination solution (e.g., DNA/RNA-ExitusPlus™ or equivalent). Do not immerse components in liquid. Avoid prolonged contact of cleaning agents with the plastic parts. Allow all parts to dry completely before use. Do not use strong oxidizing agents, concentrated alcohols, or abrasive cleaning materials.

If contamination persists or additional assistance is required, please contact diaxxo's technical support team.

<p>WARNING</p> 	<p>Risk of electrical shocks</p> <p>To prevent electrical shock, always turn off, unplug the instrument, and let it cool for 5-10 minutes before cleaning it. Do not start a program if the device is still wet after the use of cleaning agents. Always make sure the device (and especially the tray) is dry.</p>
<p>WARNING</p> 	<p>Disposal of chemicals</p> <p>For instructions on handling, disposing, and cleaning biohazardous materials in case of a spillage, consult the guidelines for biosafety provided by your institution.</p>

5.10 Maintenance

Daily maintenance and “good practices”

- Remove and discard used consumables after the program has finished
- Keep the device's lid closed; keep the device off when not needed
- Make sure the tray of the device is clean and free from droplets / dirt

If other or additional maintenance or a service of the equipment is required, the maintenance operation shall only be performed by diaxxo's technical support.