

PyroMark™ Q24

Installation and Safety



Biotage

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Legal

Intended Use – United States

PyroMark™Q24 System is designed for Laboratory Use Only, which means it may be used for either research purposes or by high complexity CLIA certified laboratories.

All operations must be performed according to instructions provided through dialogs appearing on the screen, the manuals, instructions for use, and by Pyrosequencing AB's technical support staff, and within limits set by the technical specifications.

Intended Purpose – Europe

PyroMark™Q24 System is a system for detecting changes in specified variable positions in human DNA that may have clinical relevance.

PyroMark™Q24 System is available for research and, in certain European countries*, for *in vitro* diagnostic applications. PyroMark™Q24 System meets the requirements of Annex III of the European Directive for In Vitro Diagnostic Medical Devices 98/79/EC.

For *in vitro* diagnostic medical use, PyroMark™Q24 System may only be operated (i) by personnel who have received special education and training with regard to procedures utilizing *in vitro* diagnostic medical devices, and (ii) accredited medical testing laboratories.

All operations must be performed according to instructions provided through dialogs appearing on the screen, the manuals, instructions for use, and by Pyrosequencing AB's technical support staff, and within limits set by the technical specifications.

* For more information, see www.biotaagebio.com

Warranty and Liability

Pyrosequencing AB warrants for a period of twelve (12) months from the date of shipment ("Warranty Period") that PyroMark™Q24 System (i) meets the published specifications, and (ii) is free from defects in material and workmanship under normal use and service and when used in compliance with the applicable operating instructions. Pyrosequencing AB's sole liability and Buyer's exclusive remedy for a breach of this warranty is limited to replacement, repair or refund at the sole option of Pyrosequencing AB. This warranty does not apply to any consumable items included in PyroMark™Q24 System such as, but not limited to, filter probes, tubing, fittings, o-rings and gaskets.

Limitation of Warranty and Liability

PYROSEQUENCING AB HEREBY EXPRESSLY DISCLAIMS, AND BUYER HEREBY EXPRESSLY WAIVES, ANY WARRANTY REGARDING RESULTS OBTAINED THROUGH THE USE OF THE SOFTWARE, INCLUDING WITHOUT LIMITATION ANY CLAIM OF INACCURATE, INVALID, OR INCOMPLETE RESULTS. ALL OTHER WARRANTIES, REPRESENTATIONS, TERMS AND CONDITIONS (STATUTORY, EXPRESS, IMPLIED OR OTHERWISE) AS TO QUALITY, CONDITION, DESCRIPTION, MERCHANTABILITY, FITNESS FOR PURPOSE OR NON-INFRINGEMENT (EXCEPT FOR THE IMPLIED WARRANTY OF TITLE) ARE HEREBY EXPRESSLY EXCLUDED.

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In view of the risk of trademark degeneration, authors intending to use the trademark designations are respectfully requested to acknowledge the trademark status of the products at least once in each article.

Other Trademarks

Other product and company names mentioned herein may be trademarks or registered trademarks and/or service marks of their respective owners, and are used only for explanation and to the owners' benefit, without intent to infringe.

Copyright

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Pyrosequencing AB is a wholly-owned subsidiary of Biotage AB. Biotage AB is listed on the OMX Nordic Exchange (ticker BIOT), www.biotage.com.

Install PyroMark™Q24 System



WARNING! You must observe all safety requirements on page 15 - 16 when installing and operating PyroMark™Q24 System. Failure to install or use the system in a manner specified by Pyrosequencing may result in personal injury and/or equipment damage.

Note: We recommend that the boxes and packing materials are kept by the customer in case an item needs to be returned for service or moved to another location.

Install and Move PyroMark™Q24 Instrument



WARNING! The total weight of the package including the instrument is 35 kg. Use suitable lifting equipment when moving the package.

WARNING! The instrument weighs 28 kg. Two persons are required when lifting the instrument.

WARNING! Use only power supplies and cords supplied with your instrument. The mains plugs shall be easily accessible in case of the need of quickly disconnecting the instrument from the mains power.

Delivered Items

Check the delivery for completeness and for damage during transportation.
The following items are delivered:

- PyroMark™Q24 Instrument
- PyroMark™Q24 Instrument Software (pre-loaded)
- PyroMark™Q24 Cooling Device (pre-installed)
- 12 VDC power supply
- 24 VDC power supply
- Power cord (2)
- USB memory stick (2)
- Installation and Safety booklet (this publication)
- Quick Guide
- Declaration of Conformity document
- Test report
- Packing list
- PyroMark™Q24 Software package (see page 7)
- PyroMark™Control Oligo (shipped in a separate package)

Note: PyroMark™Q24 User Manual is available on the PyroMark™Q24 Software CD.

Site Requirements

Before installing the instrument, the installation site should be prepared as follows:

Bench	Flat, stable, and able to support the weight of the instrument (28 kg). At least 70 x 60 cm (W x D) free area is required. The free space above the bench should be at least 70 cm to accommodate the instrument with the lid open, and for ventilation. Allow at least 10 cm of free space behind the instrument for cabling.
Environment	Temperature: 15°C to 32°C* Humidity: 20% to 90% relative humidity Draft-free location not close to window. Keep the instrument out of direct sunlight.
Input voltage and current	100–240 VAC, 47–63 Hz, 1.1–0.45 A The instrument must be connected to protective earth. Note: In the event of a power failure, data obtained will still be stored on the instrument's internal memory for later retrieval.

Install the Instrument

1. Before installing the instrument, the installation site should be prepared according to the site requirements above.
2. Place the instrument on a bench (dimensioned according to the site requirements and that are able to support the weight, 28 kg). Lift the instrument by the base plate. Two persons are needed.
3. Remove the transport strap from under the instrument lid (see image below) using a pair of scissors.
4. Ensure that the power switch at the rear of the instrument is in position 0 (off); see image below.
5. Connect the two power supplies to the instrument. Place the supplies in a ventilated area, on the bench or on the floor. Do not cover the supplies with papers or other items that will reduce cooling.



See page 19 for larger image.

6. Connect the two power supplies to properly grounded (earthed) mains outlets with the correct mains voltage and frequency using the supplied power cords. The mains plugs shall be easily accessible in case of the need of quickly disconnecting the instrument from the mains power.
7. At the rear of the instrument, press the light button and check that the coolant level is visible in the window (see image). If not, please contact 1-Point Support before proceeding (see contact details on page 48).
8. Set the correct date and time in the instrument software; see the *System Administration* section in PyroMark™Q24 User Manual.
9. Ensure that the instrument is working properly by using PyroMark™Control Oligo (one package is supplied with the system). Set up the run according to the instructions supplied with the product.

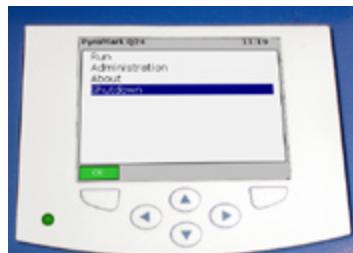


For instructions on how to use the instrument, please read PyroMark™Q24 User Manual (see the *User Documentation* section on page 13).

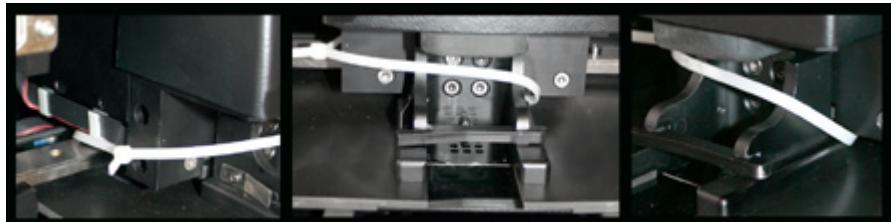
Move the Instrument

Should you need to move the instrument within the laboratory or to a new site, follow the instructions below.

1. When the instrument is not processing, select **Shutdown** in the instrument's main menu (using the ▲ and ▼ screen buttons) and press **Ok**.
2. When the message *It is now safe to turn off the instrument* appears, turn off (O) the instrument. The power switch is located at the rear of the instrument.
3. Disconnect the instrument from the mains power. There are two mains plugs.
4. Disconnect the two power supplies from the instrument.
5. To move the instrument within the laboratory, carefully place the instrument on a trolley and move to the new room. Lift the instrument by the base plate. Two persons are needed.



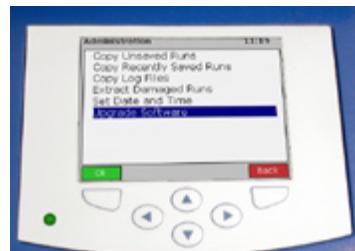
6. To transport the instrument to another site:
 - a. Clean the instrument according to the instructions in the *Maintenance* section in PyroMark™Q24 User Manual.
 - b. Secure the dispensation unit to the metal bar (behind the dispensation unit) using a transport strap; see images below.
 - c. Pack the instrument properly, preferably by using the box and packing materials from the original delivery of the instrument. Lift the instrument by the base plate. Two persons are needed.
 - d. Use suitable lifting equipment when moving the package.
7. Install the instrument at the new location according to the instructions on page 4.



Upgrade the Instrument Software

If you have received a software upgrade from Pyrosequencing, upgrade your instrument as described below.

1. Save the upgrade files on one of the USB memory sticks supplied with the system. The files should be saved in a folder called *Upgrade* at the root of the memory stick.
2. When the instrument is not processing, plug the USB memory stick into the USB port at the front of the instrument. Leave it mounted until the upgrade is finished.
3. Select **Administration** in the main menu (using the ▲ and ▼ screen buttons) and press **Ok**.
4. Select **Upgrade Software** and press **Ok**.
5. Follow the instructions on the screen.



Install and Uninstall PyroMark™Q24 Software

Delivered Items

Check the delivery for completeness and for damage during transportation.
The following items are delivered:

- PyroMark™Q24 Software CD
- Quick Guide

The PyroMark™Q24 Software package is normally included in the instrument package.

Computer Requirements

The office computer used to set up runs and analyze data should be a personal computer with the following recommended minimum specifications:

Operating system	Microsoft Windows XP or Windows Vista, English versions
Processor	Intel Pentium 4, 3 GHz
RAM	1 GB
Hard drive	100 MB free space
Graphics card	Supporting the resolution of the monitor
Monitor	1280 x 1024 pixels
Pointer device	Mouse or similar
Interfaces	USB-port and CD-ROM

Install or Upgrade PyroMark™Q24 Software

Note: If your computer is connected to a network, network policy settings might prevent you from completing this procedure. For more information, contact your system administrator.

1. Ensure that the computer meets the minimum requirements above and that you are logged on as an administrator or a member of the Administrators group on your computer.
2. Close any programs running on the computer.
3. Insert the PyroMark™Q24 Software CD into the CD-drive.

4. In the CD menu that automatically appears, click **Install PyroMark Q24 Software**. If the CD menu does not appear:
 - a. Select **(My) Computer** in the Windows **Start** menu.
 - b. Right-click the CD-drive with the PyroMark™Q24 Software CD and select **Explore**.
 - c. Double-click the file *autorun.exe*.
5. Follow the instructions that appear in the Setup Wizard. When the software has been successfully installed, you will return to the CD menu.
6. To view some of the analysis reports, you must have Adobe Acrobat Reader installed on your computer. To install Adobe Acrobat Reader on your computer, click **Install Acrobat Reader** in the CD menu and follow the instructions that appear in the Setup Wizard. You can also download Adobe Acrobat Reader at www.adobe.com.
7. When you are done installing, click **Exit Setup** in the CD menu.
8. Please use Windows Update (www.update.microsoft.com) to check for any critical updates to the .NET Framework 2.0.
9. To start the software, select **All Programs | Biotage | PyroMark Q24** in the Windows **Start** menu. For instructions on how to set up and analyze a run, see the online help (press the **F1** key when in the software).

Uninstall PyroMark™Q24 Software

1. Select **Control Panel** in the Windows **Start** menu.
2. In the **Control Panel**, click **Add or Remove Programs** (XP) or **Uninstall a program** under the Programs category (Vista).
3. In the list of programs, select **PyroMark Q24**.
4. Click **Remove** (XP) or **Uninstall** (Vista).
5. Repeat steps 3 through 4 for PyroMark Launcher.

Install and Move PyroMark™Q24 Vacuum Prep Workstation



WARNING! The total weight of the package including the vacuum prep workstation is 11 kg. Use suitable lifting equipment when moving the package.

WARNING! The mains plug shall be easily accessible in case of the need of quickly disconnecting the vacuum pump from the mains power.

Delivered Items

Check the delivery for completeness and for damage during transportation.
The following items are delivered:

- PyroMark™Q24 Vacuum Prep Tool
- PyroMark™Q24 Vacuum Prep Worktable
- PyroMark™Q24 Troughs (12)
- PyroMark™Q24 Plate Holder (2)
- Pump
- Waste container and cap with tubing
- Waste filter (2)
- Tubing
- Allen key
- Installation and Safety booklet (this publication)
- Quick Guide
- Declaration of Conformity document
- Test report
- Packing list

Note: PyroMark™Q24 User Manual is available on the PyroMark™Q24 Software CD.

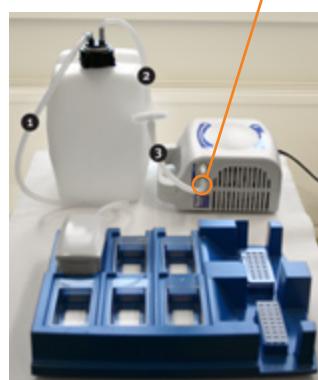
Site Requirements

Before installing the vacuum prep workstation, the installation site should be prepared as follows:

Bench	Flat, stable, and able to support the weight of the vacuum prep workstation (11 kg including all parts and with filled troughs and a full waste container). At least 35 x 70 cm free area is required. The free space above the bench should be at least 40 cm to accommodate working space, and for ventilation.
Environment	Temperature: 15°C to 32°C Humidity: 20% to 90% relative humidity Normal laboratory conditions. Adequate ventilation.
Input voltage and current	100 VAC, 50/60 Hz, 1.7/1.4 A, or 115 VAC, 60 Hz, 1.5 A, or 230 VAC, 50 Hz, 0.6 A

Install the Vacuum Prep Workstation

1. Before installing the vacuum prep workstation, the installation site should be prepared according to the site requirements above.
2. Place the workstation on a bench (dimensioned according to the site requirements and that are able to support the weight, 11 kg).
3. Cut the tubing into three pieces and connect the tubing according to the image below. Ensure that you connect the tubing to the pump's Vacuum fitting. (See page 19 for larger image.)
4. Connect the vacuum pump to a mains outlet with the correct mains voltage and frequency (check the label underneath the pump). The mains plug shall be easily accessible in case of the need of quickly disconnecting the vacuum pump from the mains power.
5. Place six of the troughs supplied with the workstation on the worktable.
6. Ensure that the filter probes are working properly by performing the function test on page 12.



For instructions on how to use the workstation, please read PyroMark™Q24 User Manual (see the *User Documentation* section on page 13).

Move the Vacuum Prep Workstation



WARNING! Irritant. The Denaturation Solution, which is used with the workstation, contains sodium hydroxide that is irritating to eyes and skin. Empty the waste container and tubing and discard any solutions left in the troughs before moving the workstation (see instructions below). Use adequate ventilation. MSDS can be downloaded at www.biotagebio.com.

Should you need to move the vacuum prep workstation within the laboratory or to a new site, follow the instructions below.

Note: Observe all federal, state, and local environmental regulations for disposal of laboratory waste.

Required items: Impermeable gloves, chemical safety goggles, protective clothing, high purity water (Milli-Q 18.2 MΩ x cm, www.millipore.com, or equivalent), a beaker, and lint-free cloths.

1. Ensure that the vacuum switch is closed (OFF) and the vacuum pump is turned off (O).
2. Disconnect the vacuum pump from the mains power.
3. Discard any solutions left in the troughs.
4. Empty the tubing; pull off one end of the tubing and empty it of any liquid waste using an empty beaker.
5. Empty the waste container. Note that the cap can be removed without disconnecting the tubing.



6. To move the workstation within the laboratory, carefully place the workstation on a trolley and move to the new room.
7. To transport the workstation to another site:
 - a. Disconnect the tubing.
 - b. Rinse the waste container, tubing, and troughs with high purity water (Milli-Q 18.2 MΩ x cm, www.millipore.com, or equivalent). Leave them to dry.

- c. Clean the worktable and tool, except for the filter probes, using a clean, lint-free cloth moistened with water or a mild detergent. Do not touch the tips of the filter probes.
 - d. Wipe the worktable and tool, except for the filter probes, dry using a clean, lint-free cloth.
 - e. When all parts are dry, pack the workstation properly, preferably by using the box and packing materials from the original delivery of the workstation.
8. Install the workstation at the new location according to the instructions on page 10.

Installation Test

Instrument – Function Test

Before using the instrument, check that it is working properly by using PyroMark™Control Oligo (one package is supplied with the system). Set up the run according to the instructions supplied with the product. To order PyroMark™Control Oligo, please contact your local sales representative (www.bioteagebio.com).

Vacuum Prep Workstation – Function Test

Before using the vacuum prep workstation, check that the filter probes are working properly by performing the function test below.

Required items: A PCR plate, a trough, and high purity water (Milli-Q 18.2 MΩ x cm, www.millipore.com, or equivalent).

1. Add 100 µl of high purity water to each well of a PCR plate.
2. Fill a trough with 70 ml of high purity water.
3. Start the vacuum pump (l).
4. Apply vacuum to the vacuum prep tool by opening the vacuum switch.
5. Lower the filter probes into the trough with high purity water and hold them there for approximately 20 seconds. Ensure that the water is transported to the waste container, i.e. that vacuum is applied. If not, check the connections.
6. Lower the filter probes into the PCR plate and check that the water is aspirated evenly in all wells and that all wells are empty after a maximum of 10 seconds.
7. If the wells are not empty after 10 seconds, repeat the procedure from step 1. If the test fails twice, replace the failing filter probes (see the *Maintenance* section in PyroMark™Q24 User Manual).



User Documentation

User documentation in other languages can be downloaded at the Pyrosequencing Technical Support website.

Installation and Safety

PyroMark™Q24 Installation and Safety contains safety requirements and instructions for installing, moving, and re-installing the system.

A printout of the document is supplied with the system. A PDF version of the document is available on the PyroMark™Q24 Software CD and on the Pyrosequencing Technical Support website, but can also be accessed by selecting **All Programs | Biotage | PyroMark Q24 Documentation | PyroMark Q24 Installation and Safety.pdf** in the Windows **Start** menu.

User Manual

PyroMark™Q24 User Manual provides a description of the system, technical specifications, instructions for operation and maintenance, and guides for assay design and validation and troubleshooting.

The manual is available as a PDF document on the PyroMark™Q24 Software CD and on the Pyrosequencing Technical Support website, but can also be accessed by selecting **All Programs | Biotage | PyroMark Q24 Documentation | PyroMark Q24 User Manual.pdf** in the Windows **Start** menu.

Quick Guides

The three quick guides contain short descriptions on how to operate PyroMark™Q24 Instrument, PyroMark™Q24 Software, and PyroMark™Q24 Vacuum Prep Workstation.

Printouts of the guides are supplied with the system (one printout per guide). A PDF version of the guides is available on the PyroMark™Q24 Software CD and on the Pyrosequencing Technical Support website, but can also be accessed by selecting **All Programs | Biotage | PyroMark Q24 Documentation | PyroMark Q24 Quick Guide.pdf** in the Windows **Start** menu.

Online Help

The online help included with PyroMark™Q24 Software contains user instructions for PyroMark™Q24 Software.

Context-sensitive help is accessed by pressing the **F1** key when in a dialog or window in PyroMark™Q24 Software. A PDF version of the online help is available on the Pyrosequencing Technical Support website, but can also be accessed by selecting **All Programs | Biotage | PyroMark Q24 Documentation | PyroMark Q24 Online Help.pdf** in the Windows **Start** menu.

Instructions for Reagents and Consumables

Detailed instructions for use are included with PyroMark™Q24 Gold Reagents, PyroMark™Q24 Cartridge, PyroMark™Control Oligo, and PyroMark™Q24 Validation Oligo. MSDS for PyroMark™Q24 Gold Reagents, PyroMark™Control Oligo, PyroMark™Q24 Validation Oligo, and sample preparation solutions can be downloaded at the Pyrosequencing Technical Support website.

Service Agreements

Service agreements are available for PyroMark™Q24 Instrument. Please contact your local sales representative or refer to Pyrosequencing website (www.bioteagebio.com) for further details.

Safety

Safety Requirements



WARNING! You must observe all safety requirements when installing and operating PyroMark™Q24 System. Failure to install or use the system in a manner specified by Pyrosequencing may result in personal injury and/or equipment damage.

- PyroMark™Q24 System shall be installed in accordance with the *Install PyroMark™Q24 System* section on page 3.
- The mains plugs shall be easily accessible in case of the need of quickly disconnecting the equipment from the mains power.
- PyroMark™Q24 System shall be used in accordance with the instructions provided through dialogs appearing on the screen, the manuals, instructions for use, and by 1-Point Support, and within limits set by the technical specifications (see PyroMark™Q24 User Manual). For more information on user documentation, see page 13.
- Follow all generally accepted laboratory safety procedures and applicable laws and regulations. Use appropriate safety precautions when handling biological material.
- The Denaturation Solution, which is used with the vacuum prep workstation, contains sodium hydroxide that is irritating to eyes and skin. Use adequate ventilation. Use impermeable gloves, chemical safety goggles, and protective clothing. MSDS can be downloaded at www.biotagebio.com. Always empty the waste container and discard any sodium hydroxide left in the troughs at the end of a working day (see PyroMark™Q24 User Manual).
- Use only power supplies and cords supplied with your instrument. Power supplies and cords should be inspected periodically and replaced if damaged or altered. Note: The ground prong on the mains plugs must not be removed and the plugs should only be connected to grounded outlets as per local and national regulations. Use of power supplies that disable the grounding connections to the instrument is dangerous and prohibited.
- Always keep the instrument lid closed while the instrument is processing. An audible warning signal will alert you if the lid is opened when it is not safe.
- Do not remove the cover panels—there are no user serviceable parts inside. If you believe there is a problem with your system, please contact 1-Point Support immediately (www.biotagebio.com).
- Always shut down and disconnect the equipment from the mains power before any maintenance is performed. Note that the power switch does not disconnect the equipment completely from mains power.

- The instrument weighs 28 kg. Two persons are required when lifting the instrument.
- If the system has been damaged or does not function properly, shut down the system and contact 1-Point Support immediately (www.biotaagebio.com).
- Do not touch the sharp needles at the bottom of the reagent cartridge.
- Do not touch the hot surfaces on the plate holder and the heating block.
- Do not connect or use any consumables, accessories, or external equipment other than what is specified in the user documentation. Please refer to Pyrosequencing website (www.biotaagebio.com), or contact your local sales representative, for the latest information on consumables and accessories.

Symbols Used on Pyrosequencing Product Labels

Explanation of symbols used on Pyrosequencing product labels:

Symbol Referent



In accordance with all the essential requirements of all applicable European product directives; see the Declaration of Conformity document supplied with the product



In accordance with both U.S. and Canadian safety standards; see the Declaration of Conformity document supplied with the product



In accordance with FCC (Federal Communications Commission) standards; see the Declaration of Conformity document supplied with the product



Subject to the Waste Electrical and Electronic Equipment (WEEE) Directive; see page 18



In vitro diagnostic (IVD) medical device



Catalog or reorder number



Batch code or lot number



Use by (+ date)



Temperature limitation



Consult accompanying user documentation



Manufacturer



Date of manufacture



Serial number



Warning, consult accompanying user documentation



Irritant substance

Safety Label on the Instrument

The following safety label is attached to PyroMark™Q24 Instrument:

Pinch and impact warning due to moving parts.

Keep the instrument lid closed while the instrument is processing. An audible warning signal will alert you if the lid is opened when it is not safe.

Note: For information on the symbols used on the product label at the rear of the instrument, see page 17.



Symbols Used in the User Documentation



Warning or Caution:

If the symbol is accompanied by “**WARNING!**”, it means that you must follow an instruction in detail to avoid personal injury.

If the symbol is accompanied by “**CAUTION!**”, it means that you must follow an instruction to avoid damage to the product or other equipment.

Do not proceed until you clearly understand the instructions and all stated conditions are met.



Irritant substance

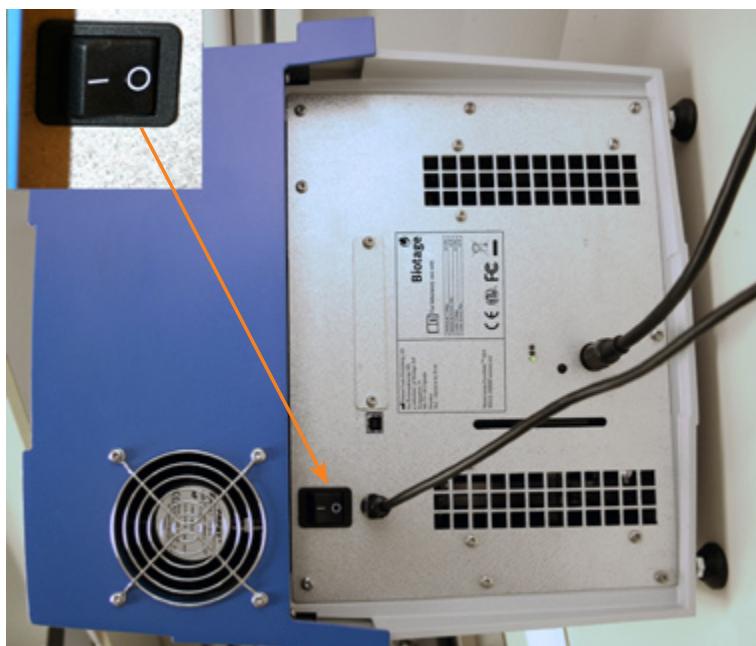
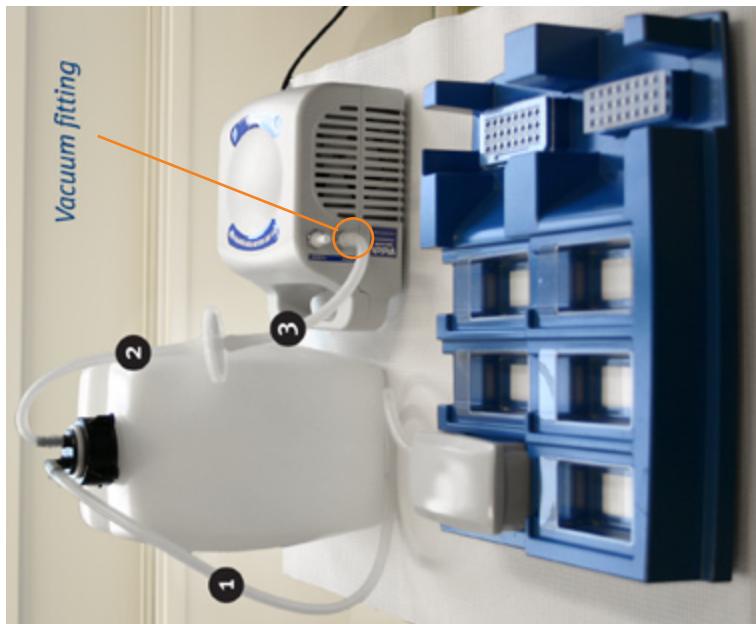
WEEE Compliance Statement

Valid for customers in EU countries



We are committed to being a good corporate citizen. As part of that commitment, we strive to maintain an environmentally conscious manufacturing operation. The European Union (EU) has enacted a directive on product recycling (Waste Electrical and Electronic Equipment, WEEE), and over time this directive will be implemented in the national laws of each EU member state.

Products falling under the scope of the WEEE Directive will be identified with a crossed over “wheelie bin” symbol on the product label, as indicated to the left. To forward the products to recycling or proper disposal, use an authorized collection system or return them to Pyrosequencing AB.



Safety in Other Languages

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Sicherheit

Dieses Dokument ist eine Übersetzung des Abschnitts „Safety“ im englischen Originaldokument „PyroMark™Q24 Installation and Safety“. Im Falle von Diskrepanzen hat die englische Originalversion Vorrang.

Sicherheitsanforderungen



WARNUNG! Bei Installation und Betrieb des PyroMark™Q24 Systems müssen alle Sicherheitsvorschriften beachtet werden. Wird das System nicht in der von Pyrosequencing vorgegebenen Weise installiert oder genutzt, kann dies zu Verletzungen und / oder Schäden an der Ausrüstung führen.

- Das PyroMark™Q24 System muss in Übereinstimmung mit dem Abschnitt *Install PyroMark™Q24 System* auf Seite 3 installiert werden.
- Die Netzstecker müssen leicht erreichbar sein, damit im Notfall eine schnelle Trennung der Ausstattung von der Netzstromversorgung möglich ist.
- Das PyroMark™Q24 System muss gemäß den Anleitungen am Bildschirm, in den Handbüchern, in der Bedienungsanleitung und von 1-Point-Support sowie innerhalb der von den technischen Spezifikationen gesetzten Grenzen betrieben werden (siehe PyroMark™Q24 Anwenderhandbuch. Weitere Informationen zur Anwenderdokumentation siehe Seite 13).
- Folgen Sie den allgemein anerkannten Sicherheitsprozeduren für Labors und beachten Sie die geltenden Gesetze und Vorschriften. Treffen Sie beim Umgang mit biologischem Material geeignete Sicherheitsvorkehrungen.
- Die in der Arbeitsstation für die Vakuum-Aufbereitung verwendete Denaturierungslösung (Denaturing Solution) enthält Natronlauge, die Augen und Haut reizen kann. Sorgen Sie für ausreichende Belüftung. Tragen Sie wasserdichte Handschuhe, eine Schutzbrille für den Chemiebereich und Schutzkleidung. Das MSDS (Sicherheitsdatenblatt) kann bei www.bioteagebio.com heruntergeladen werden. Entleeren Sie am Ende einer Arbeitsschicht immer den Abfallbehälter und entsorgen Sie Natronlauge, die eventuell in den Einsätzen zurückgeblieben ist (siehe PyroMark™Q24 Anwenderhandbuch). Weitere Informationen zur Anwenderdokumentation siehe Seite 13.
- Verwenden Sie ausschließlich die mit dem Instrument gelieferten Netzteile und Kabel. Netzteile und Kabel müssen regelmäßig überprüft und bei Anzeichen von Schäden oder Veränderungen ersetzt werden. Hinweis: Der Erdungsstift an den Netzsteckern darf nicht entfernt werden und die Netzstecker dürfen nur gemäß örtlicher und nationaler Vorschriften an geerdeten Steckdosen angeschlossen werden. Die Verwendung von Netzteilen, die zu einer Unterbrechung der Erdungsverbindungen des Instruments führen, kann gefährlich sein und ist verboten.

- Lassen Sie die Klappe des Instruments immer geschlossen, solange ein Verarbeitungszyklus läuft. Ein Warnton weist Sie darauf hin, wenn die Klappe zu einem ungeeigneten, weil unsicheren Zeitpunkt geöffnet wird.
- Entfernen Sie niemals die Verkleidung des Systems. Es befinden sich dahinter keine vom Anwender wartbaren Teile. Wenn Sie glauben, dass eine Störung im System vorliegt, wenden Sie sich bitte sofort an 1-Point Support (www.biotaagebio.com).
- Vor Wartungsarbeiten muss das Gerät immer heruntergefahren und von der Netzstromversorgung getrennt werden. Bitte beachten Sie, dass der Betriebsschalter die Ausrüstung nicht vollständig von der Netzstromversorgung trennt.
- Das Instrument wiegt 28 kg. Zum Anheben werden darum immer zwei Personen gebraucht.
- Wenn das System beschädigt wurde oder nicht einwandfrei funktioniert, fahren Sie es sofort herunter und wenden Sie sich umgehend an 1-Point Support (www.biotaagebio.com).
- Berühren Sie nicht die spitzen Nadeln unten an der Reagens-Kartusche.
- Berühren Sie nicht die heißen Oberflächen von Plattenhalter und Heizblock.
- Verbinden Sie mit dem System kein anderes Zubehör oder andere externe Geräte und benutzen Sie keine anderen Verbrauchsartikel, als in der Anwenderdokumentation angegeben. Für aktuelle Informationen zu Verbrauchsartikeln und Zubehör besuchen Sie bitte die Pyrosequencing Website (www.biotaagebio.com) oder wenden Sie sich an Ihren örtlichen Vertriebsrepräsentanten.

Auf Pyrosequencing Produktschildern verwendete Symbole

Erklärung der auf Pyrosequencing Produktschildern verwendeten Symbole:

Symbol Bedeutung



Erfüllt alle grundlegenden Anforderungen geltender europäischer Produktverordnungen; siehe dem Produkt beiliegende Declaration of Conformity (Konformitätserklärung)



Erfüllt US-amerikanische und kanadische Sicherheitsstandards; siehe dem Produkt beiliegende Declaration of Conformity (Konformitätserklärung)



Erfüllt die Standards der FCC (Federal Communications Commission); siehe dem Produkt beiliegende Declaration of Conformity (Konformitätserklärung)



Unterliegt der EU-Richtlinie zu Elektro- und Elektronik-Altgeräten; siehe Seite 24



In vitro Diagnostikum (IVD)



Katalog- oder Nachbestellnummer



Chargencode oder Fertigungslos-Nummer



Verwendbar bis (+ Datum)



Temperaturbegrenzung



Beiliegende Anwenderdokumentation zu Rate ziehen



Hersteller



Herstellungsdatum



Seriennummer



Warnung: Beiliegende Anwenderdokumentation zu Rate ziehen



Reizstoff

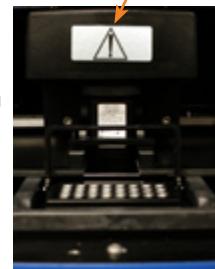
Sicherheitsschild am Instrument

Das folgende Sicherheitsschild ist am PyroMark™Q24 Instrument angebracht:

Quetsch- und Stoßgefahr durch sich bewegende Teile.

Lassen Sie die Klappe des Instruments geschlossen, solange ein Verarbeitungszyklus läuft. Ein Warnton weist Sie darauf hin, wenn die Klappe zu einem ungeeigneten, weil unsicheren Zeitpunkt geöffnet wird.

Hinweis: Informationen zu dem an der Rückseite des Instruments angebrachten Produktschild siehe Seite 23.



In der Anwenderdokumentation verwendete Symbole



Warnung oder Vorsicht:

Ist das Symbol mit dem Zusatz “**WARNUNG!**” oder “**WARNING!**” versehen, müssen Sie die betreffende Anweisung exakt befolgen, um Verletzungen zu vermeiden.

Ist das Symbol mit dem Zusatz “**VORSICHT!**” oder “**CAUTION!**” versehen, müssen Sie die betreffende Anweisung befolgen, um Schäden an Produkt oder anderer Ausstattung zu vermeiden.

Verwenden Sie das System nur, wenn Sie die Anleitungen völlig verstanden haben und alle genannten Nutzungsbedingungen erfüllt sind.



Reizstoff

WEEE-Konformitätserklärung

Gültig für Kunden in EG-Ländern



Wir fühlen uns dazu verpflichtet, als gute Unternehmensbürger zu handeln. Im Rahmen dieser Verpflichtung bemühen wir uns um die Einhaltung einer umweltbewussten Herstellungspraxis. Die Europäische Gemeinschaft (EG) hat eine Richtlinie zum Produktrecycling (WEEE, EG-Richtlinie zu Elektro- und Elektronik-Altgeräten) erlassen. Diese Richtlinie wird mit der Zeit in die nationale Gesetzgebung aller EG-Mitgliedsstaaten übernommen werden.

Produkte, die in den Geltungsbereich der WEEE-Richtlinie fallen, sind auf dem Produktschild mit einer durchgekreuzten “Mülltonne auf Rädern” gekennzeichnet, wie links gezeigt. Um das Produkt der Wiederverwertung oder ordnungsgemäßen Entsorgung zuzuführen, nutzen Sie ein entsprechendes zugelassenes lokales Sammelsystem oder senden Sie es zurück an Pyrosequencing AB.

Seguridad

Este documento es una traducción de la sección Seguridad de PyroMark™Q24 Installation and Safety redactado en inglés. En caso de cualquier discrepancia, prevalecerá la versión inglesa

Requisitos de seguridad



ADVERTENCIA Respete siempre todos los requisitos de seguridad al instalar y utilizar el Sistema PyroMark™Q24. Si hace caso omiso a las instrucciones de instalación y uso del sistema proporcionadas por Pyrosequencing, pueden producirse lesiones personales y/o daños en el equipo.

- El Sistema PyroMark™Q24 debe instalarse del modo descrito en la sección de *Install PyroMark™Q24 System* de la página 3.
- Los enchufes de conexión al suministro eléctrico deben estar ubicados de forma que se pueda acceder a ellos con facilidad en caso de que sea necesario desconectar rápidamente el equipo del suministro eléctrico.
- El Sistema PyroMark™Q24 debe utilizarse del modo descrito en las instrucciones proporcionadas en los cuadros de diálogo que se muestran en la pantalla, los manuales, las instrucciones de uso y por el equipo de asistencia de 1-Point Support y dentro de los límites definidos en las especificaciones técnicas (consulte el Manual del usuario de PyroMark™Q24). Si desea obtener más información sobre la documentación del usuario, consulte la página 13.
- Respete siempre todos los procedimientos generales aceptados sobre seguridad en laboratorios y la normativa y legislación aplicables. Aplique las medidas de seguridad necesarias al manipular material biológico.
- La solución desnaturalizante (Denaturing Solution) que se utiliza con la estación de trabajo de la unidad de vacío, contiene hidróxido de sodio que produce irritación de piel y ojos. Asegúrese de que haya una ventilación adecuada. Utilice guantes impermeables, gafas de seguridad para manipulación de productos químicos y ropa de protección. Las hojas de datos sobre seguridad de materiales (MSDS) pueden descargarse en www.bioteagebio.com. Vacíe siempre el depósito de desechos y elimine cualquier resto de hidróxido de sodio que pueda quedar en las bateas al final el turno de trabajo (consulte el Manual del usuario de PyroMark™Q24). Si desea obtener más información sobre la documentación del usuario, consulte la página 13.

- Utilice exclusivamente los cables y las fuentes de alimentación que se suministra con el instrumental. Inspeccionar regularmente los cables y fuentes de alimentación y cambiarlos si están dañados o han sufrido modificaciones.
Nota: La patilla de la toma de tierra de los enchufes de conexión eléctrica no debe eliminarse y los enchufes deben conectarse a tomas de corriente del modo indicado en la normativa nacional y local. El uso de fuentes de alimentación que anulen las conexiones a tierra del instrumental es peligroso y está prohibido.
- Mantenga siempre cerrada la tapa del instrumental mientras esté procesando. Si se abre la tapa del instrumental, dejando de ser seguro, se escuchará una señal acústica de advertencia.
- No desmonte los paneles de cubierta, ya que en su interior no existen piezas que requieran mantenimiento. Si cree que su sistema tiene problemas, póngase en contacto inmediatamente con el equipo de asistencia de 1-Point Support (www.biotaagebio.com).
- Apague y desconecte siempre el equipo del enchufe del suministro eléctrico antes de realizar cualquier tarea de mantenimiento. Recuerde que el interruptor de conexión/desconexión no desconecta completamente el equipo del suministro eléctrico.
- El instrumental pesa 28 kg por lo que serán necesarias dos personas para elevarlo.
- Si el sistema sufre daños o no funciona correctamente, apáguelo y póngase en contacto inmediatamente con el equipo de asistencia de 1-Point Support (www.biotaagebio.com).
- No toque las agujas afiladas que hay en la parte inferior del cartucho de reactivos.
- No toque las superficies calientes del porta-placas, ni el bloque del calentador.
- No conecte ni utilice consumibles, accesorios o equipos externos distintos a los especificados en la documentación del usuario. Si desea obtener información actualizada sobre consumibles y accesorios, consulte el sitio Web de Pyrosequencing (www.biotaagebio.com) o bien, póngase en contacto con su representante local de ventas.

Símbolos utilizados en las etiquetas de producto de Pyrosequencing

Explicación de los símbolos utilizados en las etiquetas de producto de Pyrosequencing:

Símbolo	Explicación
	De acuerdo a todos los requisitos esenciales de todas las Directivas Europeas aplicables. Consulte la documentación Declaration of Conformity (de la Declaración de conformidad) que se suministra con el producto.
	De acuerdo a los estándares de seguridad norteamericanos y canadienses. Consulte la documentación Declaration of Conformity (de la Declaración de conformidad) que se suministra con el producto.
	De acuerdo a los estándares de la Comisión Federal de Comunicaciones de Estados Unidos (FCC, en sus siglas en inglés). Consulte la documentación Declaration of Conformity (de la Declaración de conformidad) que se suministra con el producto.
	Sujeto a la Directiva CE sobre residuos de aparatos eléctricos y electrónicos (RAEE). Consulte la página 28.
	Productos sanitarios para diagnóstico <i>in vitro</i> (IVD).
	Número de catálogo o pedido.
	Código de lote o número de lote.
	Usado por (+ fecha).
	Límites de temperatura.
	Consultar la documentación de usuario adjunta.
	Fabricante.
	Fecha de fabricación.
	Número de serie.
	Advertencia, consultar la documentación de usuario adjunta.
	Sustancia irritante.

Etiqueta de seguridad en el instrumental

El instrumental PyroMark™Q24 porta la siguiente etiqueta de seguridad:

Advertencia sobre impactos y pellizcos por las piezas móviles.

Mantenga siempre cerrada la tapa del instrumental mientras esté procesando. Si se abre la tapa del instrumental, dejando de ser seguro, se escuchará una señal acústica de advertencia.

Nota: Si desea obtener información sobre los símbolos utilizados en la etiqueta de producto que hay en la parte trasera del instrumental, consulte la página 27.



Símbolos utilizados en la documentación del usuario



Advertencia o precaución:

Si el símbolo va acompañado por la palabra “**ADVERTENCIA!**” o “**WARNING!**”, indicará que debe seguir las instrucciones detalladas que se proporcionan para evitar lesiones personales.

Si el símbolo va acompañado por la palabra “**PRECAUCIÓN!**” o “**CAUTION!**”, indicará que debe seguir las instrucciones detalladas que se proporcionan para evitar daños en el producto u otros equipos.

No continúe el procedimiento que esté realizando hasta que no comprenda con claridad y cumpla todas las condiciones indicadas.



Sustancia irritante.

Declaración de conformidad sobre RAEE

Válido para clientes de países de la UE



Estamos muy comprometidos para ser un ciudadano corporativo responsable. Como parte de este compromiso, trabajamos para producir de un modo respetuoso con el medioambiente. La Unión Europea (UE) ha promulgado una directiva sobre el reciclaje de productos, la Directiva sobre residuos de aparatos eléctricos y electrónicos (RAEE) que progresivamente se irá incluyendo en la legislación nacional de todos los países miembros.

Los productos que entran dentro del ámbito de la Directiva RAEE incluirán en la etiqueta del producto una identificación con el símbolo de una “papelera con ruedas” tachada con una cruz, del modo que se muestra a la izquierda. Para un correcto reciclaje o eliminación de estos productos, deberán enviarse a un sistema de recogida adecuado o bien, devolverlos a Pyrosequencing AB.

Sécurité

Ce document est une traduction de la section originale Safety (Sécurité) de PyroMark™Q24 Installation and Safety rédigée en anglais. En cas de différences, la version originale en anglais prévaut.

Exigences de sécurité



AVERTISSEMENT ! Vous devez vous conformer à toutes les exigences de sécurité lors de l'installation et de l'utilisation du système PyroMark™Q24. Toute installation ou utilisation du système effectuée d'une manière non conforme aux spécifications de Pyrosequencing pourrait entraîner des blessures et/ou des dommages matériels.

- Le système PyroMark™Q24 doit être installé conformément au paragraphe *Install PyroMark™Q24 System*, page 3.
- Les fiches d'alimentation électrique doivent être facilement accessibles afin de pouvoir, si nécessaire, mettre rapidement le matériel hors tension.
- Le système PyroMark™Q24 doit être utilisé conformément aux instructions données dans les messages affichés sur l'écran, les manuels, les consignes d'utilisation, l'assistance 1-Point Support et dans le cadre des limites imposées par les spécifications techniques (voir le manuel de l'utilisateur du PyroMark™Q24). Pour plus d'informations sur la documentation de l'utilisateur, reportez-vous à la page 13.
- Conformez-vous à toutes les procédures de sécurité habituellement appliquées dans les laboratoires ainsi qu'aux lois et réglementations en vigueur. Observez les précautions de sécurité adéquates lorsque vous manipulez du matériel biologique.
- La solution de dénaturation (Denaturing Solution) utilisée dans la station de préparation à vide, contient de l'hydroxyde de sodium qui est un produit irritant pour les yeux et la peau. Utilisez un système d'aération adéquat. Portez des gants imperméables, des lunettes de protection contre les produits chimiques et des vêtements de protection. La fiche technique santé-sécurité (MSDS) peut être téléchargée sur www.biotaqebio.com. À la fin de chaque journée de travail, videz le contenu du récipient à déchets et éliminez tout reste d'hydroxyde de sodium dans les cuvettes (voir le manuel de l'utilisateur PyroMark™Q24). Pour plus d'informations sur la documentation de l'utilisateur, reportez-vous à la page 13.

- N'utilisez que les modules d'alimentation et les cordons fournis avec votre instrument. Les modules d'alimentation et les cordons doivent être inspectés régulièrement et remplacés en cas d'usure ou d'endommagement. NB : La prise de terre ne doit pas être retirée des fiches d'alimentation électrique qui ne doivent être raccordées qu'à des prises de courant avec mise à la terre conformément aux réglementations locales et nationales. L'utilisation de modules d'alimentation empêchant le raccordement à la terre de l'instrument est dangereuse et interdite.
- Maintenez toujours le couvercle de l'instrument fermé lorsque celui-ci est en service. Un signal sonore d'alarme vous avertit lorsque le couvercle est ouvert et met en danger la sécurité.
- Ne retirez pas les panneaux protecteurs — Le matériel ne contient aucune pièce nécessitant un entretien de la part de l'utilisateur. Si vous pensez que votre système rencontre un problème de fonctionnement, veuillez immédiatement contacter l'assistance 1-Point Support (www.biotaagebio.com).
- Avant d'effectuer toute opération de maintenance, mettez l'appareil hors tension et débranchez le module d'alimentation. Notez que l'interrupteur Marche/Arrêt ne déconnecte pas entièrement l'équipement de l'alimentation électrique.
- L'instrument pèse 28 kg. Pour le soulever, il faut deux personnes.
- Si le système a été endommagé ou ne fonctionne pas convenablement, éteignez-le et contactez immédiatement l'assistance 1-Point Support (www.biotaagebio.com).
- Ne touchez pas les aiguilles situées en bas de la cartouche de réactif.
- Ne touchez pas les surfaces chaudes du support de plaques et du bloc chauffant.
- Vous ne devez pas installer ou utiliser des consommables, accessoires ou équipements périphériques autres que ceux qui sont spécifiés dans la documentation de l'utilisateur. Veuillez vous reporter au site Internet de Pyrosequencing (www.biotaagebio.com) ou contactez votre représentant local pour obtenir les informations les plus récentes concernant les consommables et les accessoires.

Symboles utilisés sur les étiquettes des produits Pyrosequencing

Explication des symboles utilisés sur les étiquettes des produits Pyrosequencing:

Symbol **Référent**



En conformité avec toutes les principales exigences de l'ensemble des directives européennes applicables à ce produit ; voir le document Declaration of Conformity (Déclaration de conformité) livré avec le produit



En conformité avec les normes de sécurité en vigueur aux États-Unis et au Canada ; voir le document Declaration of Conformity (Déclaration de conformité) livré avec le produit



En conformité avec les normes FCC ("Federal Communications Commission", Commission Fédérale des Etats-Unis pour la communication) ; voir le document Declaration of Conformity (Déclaration de conformité) livré avec le produit



Soumis à la directive Déchets d'Equipements Electriques ou Electroniques (DEEE) ; voir page 32



Dispositif médical de diagnostic *in vitro* (IVD)



Nº de référence catalogue ou réapprovisionnement



Code de lot ou n° de lot



Date de péremption (+ date)



Limites de température



Consultez la documentation de l'utilisateur livrée avec le produit



Fabricant



Date de fabrication



Numéro de série



Avertissement : Consultez la documentation de l'utilisateur livrée avec le produit



Substance irritante

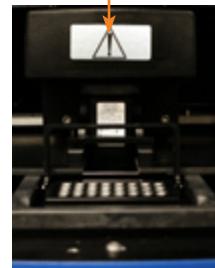
Étiquette de sécurité sur l'instrument

L'étiquette de sécurité suivante est fixée sur l'instrument PyroMark™Q24 :

Pièces en mouvement pouvant occasionner un risque de choc ou de pincement.

Maintenez le couvercle de l'instrument fermé lorsque celui-ci est en service. Un signal sonore d'alarme vous avertit lorsque le couvercle est ouvert et met en danger la sécurité.

NB : Pour plus d'information sur les symboles utilisés sur l'étiquette du produit fixée à l'arrière de l'instrument, voir page 31.



Symboles utilisés dans la documentation de l'utilisateur



Avertissement/Warning ou Attention/Caution :

Si le symbole est accompagné du message “**AVERTISSEMENT !**” ou “**WARNING !**”, cela signifie que vous devez suivre précisément une consigne pour éviter un accident corporel.

Si le symbole est accompagné du message

“**ATTENTION !**” ou “**CAUTION !**”, cela signifie que vous devez suivre une consigne pour éviter d'endommager l'appareil ou un autre équipement.

Arrêtez toute opération jusqu'à ce que vous ayez clairement compris les consignes et que toutes les conditions soient réunies.



Substance irritante

Déclaration de conformité DEEE

Pour les clients des pays de l'Union européenne



Nous avons pris l'engagement d'être une véritable entreprise citoyenne. Cet engagement nous conduit à veiller à maintenir nos opérations de fabrication dans une approche environnementale.

L'Union européenne (UE) a produit une directive portant sur le recyclage des produits (Déchets d'Equipements Electriques ou Electroniques, DEEE) qui sera au cours du temps intégrée dans les lois nationales de chaque pays membre de l'UE.

Les produits concernés par la directive DEEE sont identifiés par un symbole représentant une poubelle sur roues barrée d'une croix, comme indiqué à gauche. Le recyclage ou l'élimination adaptée des produits doit se faire au moyen d'un système de collecte homologué ou par le renvoi direct à Pyrosequencing AB.

Sicurezza

Il presente documento è una traduzione della sezione originale “Safety” di “PyroMark™Q24 Installation and Safety” redatta in inglese. In caso di discrepanze, prevarrà la versione originale inglese.

Requisiti di Sicurezza



ATTENZIONE! Durante l'installazione e il funzionamento del Sistema PyroMark™Q24, osservare tutti i requisiti di sicurezza. Se il sistema viene installato o utilizzato in modo diverso da quello indicato da Pyrosequencing può provocare lesioni alla persona e/o danni all'apparecchiatura.

- Il Sistema PyroMark™Q24 deve essere installato secondo le indicazioni al paragrafo *Install PyroMark™Q24 System* a pagina 3.
- Le principali spine di connessione devono essere facilmente raggiungibili in caso sia necessario scollegare velocemente l'apparecchiatura dalla presa di corrente.
- Il Sistema PyroMark™Q24 deve essere usato secondo le istruzioni fornite nelle finestre di dialogo visualizzate a schermo, nei manuali, nelle istruzioni d'uso e dal servizio di assistenza 1-Point Support, nonché entro i limiti stabiliti dalle specifiche tecniche (consultare il manuale d'uso PyroMark™Q24). Per maggiori informazioni sulla documentazione d'uso, vedere pagina 13.
- Seguire tutte le procedure di sicurezza di laboratorio generalmente accettate e le leggi e regole applicabili. Adottare misure di sicurezza appropriate quando si utilizza materiale biologico.
- La soluzione di denaturazione (Denaturing Solution) usata con il terminale di preparazione sottovuoto contiene idrossido di sodio, una sostanza irritante per occhi e pelle. Accertarsi che la ventilazione sia adeguata. Indossare guanti impermeabili, occhiali di protezione contro gli agenti chimici e l'apposito abbigliamento protettivo. La scheda di sicurezza dei materiali (MSDS) può essere scaricata dal sito www.biotaagebio.com. Al termine della giornata lavorativa , svuotare sempre il contenitore rifiuti e disfarsi dell'eventuale rimanenza di idrossido di sodio presente nei canali (vedi manuale d'uso del PyroMark™Q24). Per maggiori informazioni sulla documentazione d'uso, vedere pagina 13.

- Usare solo fonti di alimentazione e fili elettrici forniti con lo strumento. Le fonti di alimentazione e i fili elettrici devono essere controllati periodicamente e sostituiti se danneggiati o alterati. Nota: il cavo di messa a terra delle spine di alimentazione non deve essere rimosso e le spine devono essere collegate solo a prese messe a terra come da regole locali e nazionali. È pericoloso e proibito l'uso di fonti di alimentazione che disabilitano le connessioni di messa a terra dello strumento.
- Tenere sempre chiuso il coperchio dello strumento quando questo è in uso. Un distinto segnale di avvertenza avverte che il coperchio è aperto qualora non sia sicuro.
- Non rimuovere i pannelli di copertura: all'interno non vi sono parti d'uso utili. Nel caso si ritenga che vi sia un problema con il sistema, contattare tempestivamente il servizio di assistenza 1-Point Support (www.biotaagebio.com).
- Arrestare e scollegare sempre l'apparecchiatura dalle principali fonti di corrente prima di qualsiasi procedura di manutenzione. Si tenga presente che il pulsante di accensione non scollega totalmente l'apparecchiatura dalla corrente.
- Lo strumento pesa 28 Kg; per sollevarlo sono quindi necessarie due persone.
- Se il sistema è stato danneggiato o non funziona bene, arrestare il sistema e contattare tempestivamente il servizio di assistenza 1-Point Support (www.biotaagebio.com).
- Non toccare gli aghi appuntiti all'estremità della cartuccia di reagente.
- Non toccare le superfici calde del portapiastre e il blocco di riscaldamento.
- Non collegare, né usare consumabili, accessori o apparecchiature esterne diverse da quelli specificati nella documentazione d'uso. Per informazioni più aggiornate sui consumabili e sugli accessori far riferimento al sito della Pyrosequency (www.biotaagebio.com) o contattare l'agente di vendita di riferimento.

Simboli usati sulle etichette dei prodotti Pyrosequencing

Spiegazione dei simboli usati sulle etichette dei prodotti Pyrosequencing:

Simbolo Riferimento



Conforme a tutti i requisiti essenziali di tutte le direttive applicabili per i prodotti europei; consultare il documento Declaration of Conformity (di Dichiarazione di conformità) fornito con il prodotto.



Conforme sia agli standard di sicurezza americani sia canadesi; consultare il documento Declaration of Conformity (di dichiarazione di conformità) fornito con il prodotto.



Conforme agli standard della FCC (Commissione Federale delle Comunicazioni); consultare il documento Declaration of Conformity (di dichiarazione di conformità) fornito con il prodotto.



Soggetto alla direttiva per gli scarichi di apparecchiature elettriche ed elettroniche (WEEE); vedere pagina 36



Dispositivo medico di diagnostica *in vitro* (IVD)



Catalogo o numero di riordine



Codice batch o numero di lotto



In uso da (+ data)



Limite di temperatura



Consultare la documentazione d'uso accompagnatoria.



Produttore



Data di produzione



Numero seriale



Avvertenza, consultare la documentazione d'uso accompagnatoria.



Sostanza irritante

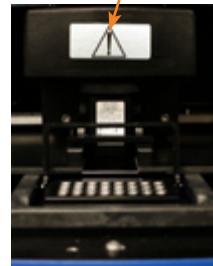
Etichetta di sicurezza sullo strumento

La seguente etichetta di sicurezza è affissa sullo strumento PyroMark™Q24:

Avviso pericolo di morsa ed urto dovuto a parti in movimento.

Tenere chiuso il coperchio dello strumento quando questo è in uso. Un distinto segnale di avvertenza avverte che il coperchio è aperto qualora non sia sicuro.

Nota: per informazioni sui simboli usati sull'etichetta prodotto sul retro dello strumento, consultare pagina 35.



Simboli usati nella documentazione d'uso



Avvertenza o Attenzione:

Se il simbolo è accompagnato da “**AVVERTENZA!**” o “**WARNING**”, significa che si deve seguire dettagliatamente un’istruzione per evitare lesioni alla persona.

Se il simbolo è accompagnato da “**ATTENZIONE!**” o “**CAUTION!**”, significa che si deve seguire un’istruzione per evitare danni al prodotto o ad altre apparecchiature.

Non procedere fino alla completa comprensione delle istruzioni e al riscontro di tutte le condizioni stabilite.



Sostanza irritante

Dichiarazione di conformità WEEE

Valido per clienti di paesi della Comunità europea



La nostra società si impegna a rispettare i principi della buona convivenza. Come parte di questo impegno, la società cerca di fare in modo che le proprie attività di produzione siano svolte nel massimo rispetto dell’ambiente. L’Unione Europea (EU) ha emanato una direttiva sul riciclaggio dei prodotti (Apparecchiatura per gli scarichi elettrici ed elettronici, WEEE) che sarà implementata sempre nelle leggi nazionali di ogni Stato membro della Comunità Europea.

I prodotti che rientrano nella sfera della direttiva WEEE saranno identificati con un simbolo barrato sul “bidone con le ruote” sull’etichetta prodotto, come indicato a sinistra. Per fare in modo che i prodotti siano riciclati o smaltiti correttamente, affidarsi a un sistema di raccolta autorizzato o renderli alla Pyrosequencing AB.

Veiligheid

Dit document is een vertaling van de oorspronkelijke veiligheidsparagraaf in PyroMark™Q24 Installation and Safety, die in het Engels is gesteld. Bij verschillen heeft de oorspronkelijke Engelstalige versie voorrang.

Veiligheidseisen



WAARSCHUWING! U dient bij installatie en bediening van het PyroMark™Q24 Systeem alle veiligheidseisen in acht te nemen. Als u nalaat het systeem op de door Pyrosequencing omschreven wijze te installeren, kan dat tot persoonlijk letsel en/of aan schade aan de uitrusting leiden.

- Het PyroMark™Q24 Systeem moet geïnstalleerd worden volgens de paragraaf *Install PyroMark™Q24 System* op pagina 3.
- De netstekkers moeten goed bereikbaar zijn voor het geval dat de apparatuur snel van de netvoeding ontkoppeld moet kunnen worden.
- Het PyroMark™Q24 Systeem moet in overeenstemming met de instructies in de vorm van dialogen op het scherm, handleidingen, gebruiksaanwijzingen en 1-Point Support worden gebruikt, en wel binnen de grenzen die door de technische specificaties worden gesteld (zie de PyroMark™Q24 Gebruikershandleiding). Zie pagina 13 voor meer informatie over gebruikersdocumentatie.
- Handel volgens algemeen aanvaarde veiligheidsprocedures voor laboratoria en de geldende wet- en regelgeving. Neem bij het hanteren van biologisch materiaal altijd passende veiligheidsmaatregelen.
- De denaturatie-oplossing (Denaturing Solution) die met het werkstation vacuümpreparatie wordt gebruikt, bevat natronloog dat irriterend is voor ogen en huid. Pas de juiste ventilatie toe. Draag ondoorlatende handschoenen, een veiligheidsbril geschikt voor gebruik met chemicaliën en beschermende kleding. De MSDS kan gedownload worden op [www.biotaagebio.com](http://www.biotagebio.com). Leeg aan het eind van de werkdag altijd de afvalbak en gooi eventuele natronloog die nog in de bakken zit weg (zie de PyroMark™Q24 Gebruikershandleiding). Zie pagina 13 voor meer informatie over gebruikersdocumentatie.
- Gebruik uitsluitend de stroombronnen en kabels die met uw instrument worden meegeleverd. Deze moeten met enige regelmaat worden gecontroleerd en vervangen worden als ze beschadigd zijn of als er veranderingen in zijn aangebracht. Let op: de aardpen in de netstekkers mag niet worden verwijderd en de stekkers mogen uitsluitend op geaarde contacten worden aangesloten. Zie de plaatselijke en landelijke regelgeving. Het gebruik van stroombronnen die de aardverbindingen met het instrument uitschakelen is gevaarlijk en verboden.

- Houd het deksel van het instrument altijd gesloten als dit in bedrijf is. Er klinkt een geluidssignaal om u te waarschuwen als het deksel geopend wordt terwijl dit niet veilig is.
- Verwijder de afdekpanelen niet – er zitten aan de binnenzijde geen onderdelen die voor de gebruiker van nut zijn. Als u meent dat uw systeem een mankement vertoont, neemt u dan a.u.b. onmiddellijk contact op met 1-Point Support (www.biotaagebio.com).
- U moet altijd de apparatuur uitschakelen en losnemen van de netvoeding alvorens onderhoud uit te voeren. Denk eraan dat de stroomschakelaar de apparatuur niet volledig van de netvoeding loskoppelt.
- Het instrument heeft een gewicht van 28 kg. Om het op te tillen zijn twee personen nodig.
- Schakel het systeem onmiddellijk uit en neem contact op met 1-Point Support (www.biotaagebio.com) als dit beschadigd is of niet goed werkt.
- Raak de scherpe naalden op de bodem van de reagenspatroon niet aan.
- Raak de hete oppervlakken op de plaathouder en het verwarmingsblok niet aan.
- U mag alleen die verbruiksartikelen, accessoires of externe apparaten aansluiten en gebruiken die in de gebruikersdocumentatie worden gespecificeerd. Zie a.u.b. de website van Pyrosequencing (www.biotaagebio.com) of neem contact op met uw plaatselijke vertegenwoordiger voor de laatste informatie over verbruiksartikelen en accessoires.

Op productlabels van Pyrosequencing gebruikte symbolen

Verklaring van de op productlabels van Pyrosequencing gebruikte symbolen:

Symbool Verwijst naar



Conform alle essentiële vereisten van alle geldende Europese productrichtlijnen: zie Declaration of Conformity (de Verklaring van Overeenstemming bij het product)



Conform Amerikaanse en Canadese veiligheidsnormen: zie Declaration of Conformity (de Verklaring van Overeenstemming) bij het product



Conform de normen van de FCC (Federal Communications Commission): zie Declaration of Conformity (de Verklaring van Overeenstemming) bij het product



Valt onder de AEEA-richtlijn inzake afgedankte elektrische en elektronische apparatuur, zie pagina 40



In vitro diagnosticum (IVD)



Catalogus- of herbestellingsnummer



Batchcode of partijnummer



Uiterste gebruiksdatum



Temperatuurbegrenzing



Zie de begeleidende gebruikersdocumentatie



Fabrikant



Fabricagedatum



Serienummer



Waarschuwing. Zie de begeleidende gebruikersdocumentatie



Irriterend

Veiligheidsetiket op het instrument

Op de PyroMark™Q24 is het volgende veiligheidsetiket aangebracht:

Wees bedacht op beknellen en schokeffecten ten gevolge van bewegende onderdelen.

Houd het deksel van het instrument gesloten als dit in bedrijf is. Er klinkt een geluidssignaal om u te waarschuwen als het deksel geopend wordt terwijl dit niet veilig is.

Let op: zie pagina 39 voor informatie over de symbolen die op het productetiket aan de achterkant van het instrument worden gebruikt.



In de gebruikersdocumentatie gebruikte symbolen



Waarschuwing of Voorzichtig:

Als het symbool vergezeld gaat van “WAARSCHUWING!” of “WARNING!”, betekent dat dat u een voorschrift nauwgezet moet opvolgen om persoonlijk letsel te vermijden.

Gaat het symbool vergezeld van “VOORZICHTIG!” of “CAUTION!”, dan betekent dat dat u een voorschrift moet opvolgen om schade aan het product of andere apparatuur te vermijden.

Ga pas verder als u de voorschriften heeft begrepen en als aan alle aangegeven voorwaarden is voldaan.



Irriterend

Verklaring van overeenstemming AEEA

Geldig voor klanten in EU-landen



Wij hebben ons verplicht tot maatschappelijk verantwoord ondernemen. Als onderdeel van die verplichting streven wij naar een milieubewuste fabricagewijze. De Europese Unie (EU) heeft een richtlijn vastgesteld inzake de recycling van producten (afgedankte elektrische en elektronische apparatuur, AEEA) en in de loop van de tijd zal deze richtlijn geïmplementeerd worden in de nationale wetgeving van de afzonderlijke lidstaten van de EU.

Products falling under the scope of the WEEE Directive will be identified with a crossed over “wheelie bin” symbol on the product label, as indicated to the left. To forward the products to recycling or proper disposal, use an authorized collection system or return them to Pyrosequencing AB.

Säkerhet

Det här är en översättning av Safety i PyroMark™Q24 Installation and Safety. Vid eventuella avvikelser gäller det engelska originalet.

Säkerhetskrav



WARNING! Du måste iaktta alla säkerhetskrav när du installerar och använder PyroMark™Q24 System. Underlätenhet att installera och använda systemet på det sätt som anges av Pyrosequencing kan resultera i personskada och/eller skador på utrustningen.

- PyroMark™Q24 System skall installeras i enlighet med avsnittet *Install PyroMark™Q24 System* på sidan 3.
- Strömkontakterna skall vara lättillgängliga i den händelse att utrustningen snabbt måste kopplas bort från elnätet.
- PyroMark™Q24 System skall användas i enlighet med instruktionerna som tillhandahålls via dialogrutor som visas på skärmen, handböcker, bruksanvisningar och av 1-Point Support, och inom gränserna som anges i tekniska specifikationer (se användarhandboken för PyroMark™Q24). För mer information om användardokumentation, se sidan 13.
- Följ alla allmänt godkända laboratoriesäkerhetsprocedurer samt tillämpliga lagar och bestämmelser. Vidta nödvändiga skyddsåtgärder vid hantering av biologiskt material.
- Denatureringslösningen (Denaturing Solution), som används ihop med arbetsstationen Vacuum Prep Workstation, innehåller natriumhydroxid som irriterar ögon och hud. Använd tillräcklig ventilering. Använd skyddshandskar, kemiska skyddsglasögon och skyddande klädsel. Datablad om materialsäkerhet (MSDS) kan laddas ned på www.biotopebio.com. Töm alltid avfallsbehållaren och kassera natriumhydroxid som finns kvar i trågen efter arbetsdagens slut (se användarhandboken för PyroMark™Q24). För mer information om användardokumentation, se sidan 13.
- Använd endast eltillbehör och sladdar som medföljer instrumentet. Eltillbehör och sladdar ska undersökas regelbundet och bytas ut om de har skadats eller ändrats. Obs! Jordledaren på strömkontakterna ska inte tas bort och kontakterna ska endast anslutas till jordade uttag enligt lokala och nationella bestämmelser. Användning av eltillbehör som inaktiverar jordningsanslutningarna till instrumentet är farlig och otillåten.
- Håll alltid instrumentlocket stängt medan instrumentet arbetar. En varningssignal ljuder om locket är öppet när det inte är säkert.

- Ta inte bort skyddspanelerna – det finns inga delar inuti som är servicebara för användaren. Om du tror att det är något fel på ditt system, kontakta 1-Point Support direkt (www.biotagebio.com).
- Stäng alltid av och koppla från utrustningen från elnätet innan du utför något underhåll. Observera att strömbrytaren inte kopplar från utrustningen helt från elnätet.
- Instrumentet väger 28 kg. Två personer krävs för att lyfta instrumentet.
- Om systemet har skadats eller inte fungerar som det ska, stäng av systemet och kontakta 1-Point Support direkt (www.biotagebio.com).
- Rör inte vid de vassa nälarna på undersidan av reagenskassetten.
- Rör inte vid de heta ytorna på plathållaren och värmefacket.
- Anslut inte och använd inte några förbrukningsartiklar, tillbehör eller extern utrustning annat än vad som anges i användardokumentationen. För den senaste informationen om förbrukningsartiklar och tillbehör se Pyrosequencing-webbplatsen (www.biotagebio.com) eller kontakta din lokala säljrepresentant.

Symboler som används på Pyrosequencing-produktetiketter

Förklaring av symboler som används på Pyrosequencing-produktetiketter:

Symbol Referens



I enlighet med alla grundläggande krav i alla tillämpliga Europeiska produktdirektiv; se dokumentet Declaration of Conformity (Försäkran om överensstämmelse) som medföljer produkten



I enlighet med både amerikanska och kanadensiska säkerhetsstandarder; se dokumentet Declaration of Conformity (Försäkran om överensstämmelse) som medföljer produkten



I enlighet med FCC-standarder (Federal Communications Commission); se dokumentet Declaration of Conformity (Försäkran om överensstämmelse) som medföljer produkten



I enlighet med direktivet Avfall från elektriska och elektroniska produkter (WEEE), se sidan 44



Medicinteknisk produkt för in *vitro-diagnostik* (IVD)



Katalog- eller beställningsnummer



Batch- eller lotnummer



Bäst-före-datum



Temperaturgräns



Se medföljande användardokumentation



Tillverkare



Tillverkningsdatum



Serienummer



Varning, se medföljande användardokumentation



Irriterande ämne

Säkerhetsetikett på instrumentet

Följande säkerhetsetikett finns på instrumentet PyroMark™Q24:

Kläm- och stötvarning på grund av rörliga delar.

Håll instrumentlocket stängt medan instrumentet arbetar. En varningssignal ljuder om locket är öppet när det inte är säkert.

Obs! För information om symbolerna som finns på produktetiketten på baksidan av instrumentet, se sidan 43.



Symboler som används i användardokumentationen



Varning eller försiktighet:

Om symbolen åtföljs av ”**WARNING!**” eller ”**WARNING!**”, betyder det att du måste följa en instruktion i detalj för att undvika personskada.

Om symbolen åtföljs av ”**FÖRSIKTIGHET!**” eller ”**CAUTION!**”, betyder det att du måste följa en instruktion för att undvika skador på produkten eller annan utrustning.

Fortsätt inte förrän du klart och tydligt har förstått instruktionerna och alla angivna villkor har uppfyllts.



Irriterande ämne

Förklaring av WEEE-överensstämmelse

Gäller kunder i EU-länder



Vi har lovat att vara bra företagsmedborgare. Som del av det löftet strävar vi efter att upprätthålla en miljömedveten tillverkningsverksamhet. Europeiska unionen (EU) har antagit ett direktiv om produktåtervinning (Avfall från elektriska och elektroniska produkter (WEEE)), och snart kommer detta direktiv att införas i de nationella lagarna i varje EU-medlemsland.

Produkter som omfattas av direktivet om avfall från elektriska och elektroniska produkter (WEEE) kommer att märkas med en överkryssad sotunnesymbol på produktetiketten, som visas på vänster sida. För att skicka produkterna till återvinning eller kassera dem på lämpligt sätt, använd ett godkänt insamlingssystem eller returnera dem till Pyrosequencing AB.

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Contact Information



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E-mail: pyrosequencing@biotage.com

Website: www.biotaagebio.com

Sales Offices and Distributors

Please visit www.biotaagebio.com for contact information.

Technical Support

Europe: 1-pointsupport@eu.biotaage.com

U.S. & Canada: 1-pointsupport@biotaage.com

Rest of the world: Please contact your local distributor.

For phone numbers and more information, please visit www.biotaagebio.com.

Revision History

Version	Revision date
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AA	March 2008
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AB	April 2008
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April 2008
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