MagNA Pure 24 System

Safety Manual Version 3.1
Software version 1.2

For in vitro diagnostic use

Publication information

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Revision history

Edition notice

This publication is intended for users of the MagNA Pure 24 System.

Every effort has been made to ensure that all the information contained in this publication is correct at the time of publishing. However, the manufacturer of this product may need to update the publication information as output of product surveillance activities, leading to a new version of this publication.

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Preface

Use this publication together with the MagNA Pure 24 System User Guide.

Operation and maintenance actions are described in the User Guide and User Assistance.

Intended use

The MagNA Pure 24 System is an automated nucleic acid purification system consisting of the MagNA Pure 24 instrument, software, consumables and reagents. The MagNA Pure 24 System is intended for use by professional users for the purification of nucleic acids from biological samples for *in vitro* diagnostic purposes.

Symbols and abbreviations

Product names

Except where the context clearly indicates otherwise, the following product names and descriptors are used.

Product name	Descriptor
MagNA Pure 24 System	system
MagNA Pure 24 Software	software
MagNA Pure 24 Instrument	instrument
MagNA Pure 24 Archive Viewer	archive viewer

Product names

Abbreviations

The following abbreviations are used.

Abbreviation	Definition
ANSI	American National Standards Institute
CSA	Canadian Standards Association
EC	European Community
EN	European standard
FFPE	Formalin-fixed paraffin-embedded
FFPET	Formalin-fixed paraffin-embedded tissue
IC	Internal control
IEC	International Electrical Commission
IVD	In vitro diagnostic
IVDR	In vitro diagnostics regulation
LIS	Laboratory information system
MGP	Magnetic glass particles
n/a	not applicable
PCR	Polymerase chain reaction
UL	Underwriters Laboratories Inc.
WEEE	Waste Electrical and Electronic Equipment

Abbreviations

Introduction

⚠ General attention

To avoid serious or fatal injury, read this publication thoroughly before you use the instrument.

- Pay particular attention to all safety precautions.
- Always follow the instructions in this publication.
- Do not use the instrument in a way that is not described in this publication.
- Keep this publication in a safe place to ensure that it is not damaged and remains available for use.
  This publication must always be easily accessible.

Safety classifications

The safety precautions and important user notes are classified according to the ANSI Z535.6-2011 standard. Familiarize yourself with the following meanings and icons:

⚠ Safety alert

- The safety alert symbol is used to alert you to potential physical injury hazards. Obey all safety messages that follow this symbol to avoid possible damage to the system, injury, or death.

These symbols and signal words are used for specific hazards:

⚠ WARNING

Warning...

- ...indicates a hazardous situation which, if not avoided, could result in death or serious injury.

⚠ CAUTION

Caution...

- ...indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

NOTICE

Notice...

- ...indicates a hazardous situation that, if not avoided, may result in damage to the system.

Important information that is not safety relevant is indicated with the following icon:

Tip...

...indicates additional information on correct use or useful tips.

Safety precautions

⚠ **To avoid serious or fatal injury, read and comply with the following safety precautions.**

In this section

Operator qualification

Insufficient knowledge and skills

As an operator, ensure that you know the relevant safety precaution guidelines and standards and the information and procedures contained in these instructions.

- Do not carry out operation and maintenance unless you have read and understood the information provided in the user documentation.
- Leave installation, repair, and preventive maintenance to trained Roche Service representatives.
- Carefully follow the procedures specified in the instructions for operation and maintenance.
- Follow laboratory best practices, especially when you work with biohazardous material.

Safe and proper use of the system

Missing personal protective equipment

Working without personal protective equipment means danger to life or health.

- Wear appropriate personal protective equipment, including, but not limited to, the following items:
  - Eye protection with side shields
  - Fluid-resistant laboratory coat
  - Approved lab gloves
  - Face shield if there is a chance of splashing or splattering
- Follow laboratory best practices and regularly change lab gloves to minimize the risk of infection and contamination (especially after contact with waste, e.g., consumables, or sample material).

Air-transmitted infection

The instrument is not a fully airtight device. Samples containing infectious material that can be transmitted by air may cause infection.

- Do not use the instrument for such samples without additional appropriate safety measures.
- Ensure safe sample handling according to local regulations.

Exposure to chemicals

- Avoid exposure to chemicals.

Regular cleaning

To prevent inaccurate results and unsafe operation of the system:

- Regularly clean and/or decontaminate the instrument and accessories as required. Follow laboratory best practices for cleaning and decontamination.
- Ensure that the laboratory is regularly cleaned and is maintained in an orderly manner.

Approved cleaning and decontamination solutions

- Use only approved solutions for cleaning and decontamination.

Errors in installation

- Only trained Roche Service representatives shall install the system.

Damage to the instrument

- Connect the system to an earth grounded power outlet only.
- For the electric power supply, see the User Assistance.

Exchange or removal of parts

Unauthorized exchange or removal of instrument parts can damage the instrument or stop it from functioning correctly.

- Do not exchange or remove any part of the instrument not specified in the user documentation.
- Leave replacement of instrument parts to trained Roche Service representatives.

Unsuitable operating conditions

Operation outside of the specified ranges may lead to incorrect results or malfunction of the instrument.

- Use the instrument indoors only, and avoid heat and humidity outside of the specified range.
- Make sure that the instrument's ventilation openings always remain unobstructed.
- Keep the operating instructions undamaged and available for use. Operating instructions must be easily accessible for all users.
- For the allowable environmental conditions, see the User Assistance.

Non-specified accessories and consumables

Use of non-specified accessories and/or consumables can lead to incorrect results.

- Do not use accessories or consumables that are not intended for use with the system.
- For a list of supported materials, see the User Assistance.

Unauthorized access

Unauthorized access to the components of the system can result in loss of data integrity, system damage, or system unavailability.

- Only authorized persons may access system components.

Miscellaneous safety precautions

Power interruption

A power failure or momentary drop in voltage may damage the system or lead to loss of data integrity.

- It is recommended to use an uninterruptible power supply (UPS).
- Ensure regular maintenance of the UPS.
- Perform regular backup and archiving of results.

Electromagnetic compatibility

The system complies with the emission and immunity requirements described in IEC/EN 61326-1:2012 and IEC/EN 61326-2-6:2012.

The system complies with the emission requirements described in this part of the FCC CFR 47, Part 15 Class A.

Electromagnetic compatibility (25)

System not used for an extended period

- Set the power switch to OFF if you do not use the system for an extended period.

Damage in transit

- Do not attempt to relocate or transport the instrument.
- Leave relocation and transportation to Roche Service representatives.

Related topics

• Disposal information (30)

Warning messages

⚠ List of warning messages

Failure to observe warning messages may result in death or serious injury.

- Before operating the system, read the warning messages carefully.

In this section

Electrical safety

Electric shock

Removing the covers of electronic equipment can cause electric shock because there are high-voltage parts inside.

- Do not attempt to manipulate any electronic parts.
- Do not remove any cover of the instrument.
- Only Roche Service representatives may install, service, and repair the system.

Related topics

- Safety labels on the instrument (28)

Optical safety

Eye damage due to intense barcode reader light

The intense light of an LED barcode reader may damage your eyes.

- Do not stare into the beam of an LED barcode reader.
- Do not remove the housing from barcode readers.
- If you experience problems with the barcode readers, contact your Roche Service representative.
- Perform only the procedures described in operating instructions. Performing unauthorized procedures may result in exposure to hazardous radiation.

Safety labels on the instrument (28)

High-energy ultraviolet light

High-energy ultraviolet light may severely damage your eyes and skin, or may expose you to hazardous radiation. The instrument contains a high-energy ultraviolet light for decontamination of the instrument deck.

- Do not remove any components of the housing of the instrument.

Samples and biohazardous materials

Infectious samples

Contact with samples containing material of human origin may result in infection. All human sourced material and all resulting waste should be handled as potentially biohazardous.

- Follow laboratory best practices, especially when working with biohazardous material.
- Wear appropriate personal protective equipment.
- Only personnel proficient in handling biohazardous materials and in the use of the system should work with the system.
- As the sensitivity and titer of potential pathogens in the sample material can vary, the operator must optimize pathogen inactivation and follow the appropriate measures according to local safety regulations.
- If any biohazardous material is spilled, immediately wipe it up, clean with water, and disinfect with a freshly prepared solution of 0.5% sodium hypochlorite in distilled or deionized water (dilute household bleach 1:10), or follow appropriate site procedures.
- If sample or waste comes into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant. Consult a physician.

Operator infection and injury

Contact with instrument mechanisms or with the instrument chassis or cover may result in personal injury and infection.

- Whenever possible, keep the cover of the instrument closed.
- Be careful not to hit your head when the cover is open.
- Pay attention to the cover and check for obstructions.
- Do not touch any parts of the instrument other than those specified.
- Carefully observe all instructions given in this publication.

Sharp objects or edges

Contact with sharp objects or edges may result in personal injury and infection.

- When cleaning near sharp objects, take care not to puncture yourself.
- Wear appropriate personal protective equipment.

  Take extra care when working with lab gloves. They can easily be pierced or cut, leading to infection.

Smoke due to electrical malfunction

Electrical malfunction can result in the emission of hazardous smoke. Inhaling smoke emitted from the instrument can lead to personal injury.

- If you see smoke coming from the instrument:
  - Avoid inhaling.
  - Disconnect from power supply.
  - Contact your Roche Service representative immediately.

Troubleshooting procedures

Corrective measures in troubleshooting procedures can result in exposure to biohazardous materials.

- Always follow the troubleshooting procedures given in software wizards and/or in the user documentation.
- Wear appropriate personal protective equipment when implementing corrective measures.

Waste

Chemical reaction producing cyanide

The system waste contains lysis reagent. Filling bleach or DNA AWAY™ Surface Decontaminant into the liquid waste insert or the liquid waste reservoir can result in a chemical reaction producing cyanide.

- Do not fill bleach or DNA AWAY™ Surface Decontaminant into the liquid waste insert or the liquid waste reservoir of the processing station adapter.

Infectious waste

Contact with waste (liquid and/or solid) may result in infection. All materials associated with waste are potentially biohazardous.

- Wear appropriate personal protective equipment.

  Take extra care when working with lab gloves. They can easily be pierced or cut, leading to infection.
- If any biohazardous material is spilled, wipe it up immediately, clean with water, and apply a disinfectant.
- If waste comes into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant.
  Consult a physician.

For cleaning procedures, see the User Assistance.

Environmental harm

The system generates liquid and solid waste. Liquid waste contains concentrated reaction solution. Liquid and solid waste is potentially biohazardous. Improper disposal may contaminate the environment.

- Treat liquid and solid waste as infectious waste.
- Dispose of waste in accordance with the local regulations.

Related topics

- Safety labels on the instrument (28)
- Disposal information (30)

Caution messages

⚠ List of caution messages

- Before operating, read the caution messages carefully. Failure to observe them may result in minor or moderate injury.

In this section

Burns due to hot surfaces

Hot surfaces inside

Contact with some surfaces may cause burns. The temperature of the heating elements can reach up to 100 °C.

- Avoid contact with hot surfaces inside the instrument indicated with a warning label.
- Use caution near the heating elements following an emergency stop.
- Be careful if you open the cover after an instrument error. Wait a few minutes to let the heating elements cool down before reaching into the instrument.

Safety labels on the instrument (28)

Mechanical safety

Damaged touch screen monitor

Damage to the touch screen monitor can expose sharp edges, which can cause personal injury if touched.

- Avoid touching the touch screen monitor if it is visibly damaged.
- Contact your Roche Service representative.

Touch screen monitor

Risk of personal injury exists when moving the touch screen monitor towards the instrument housing. Your hand can be pinched between the touch screen monitor and the housing.

- Use caution when moving the touch screen monitor in front of the instrument housing.
- Keep your fingers away from the gap between touch screen monitor and instrument housing when moving the touch screen monitor towards the housing.

Cover

Risk of personal injury exists when not opening the cover far enough or when closing the cover.

If you lean into the instrument, you can hit your head with the cover.

Your hand can be pinched between the cover and the housing.

- Use caution when closing the cover.
- Do not lean into the instrument when closing the cover.
- Keep your fingers away from the gap between cover and housing when closing the cover.
- Do not hold the cover at the sides when closing the cover.

Related topics

- Safety labels on the instrument (28)

Reagents and other working solutions

Skin inflammation or injury

Direct contact with reagents or other working solutions may cause skin irritation, inflammation, or burns.

- When you handle reagents, exercise the precautions required for handling laboratory reagents.
- Wear appropriate personal protective equipment.
- Observe the instructions given in the Instructions for Use for the reagent.
- Observe the information given in Safety Data Sheets.
- If reagents come into contact with your skin, wash the affected area immediately with soap and water.
  Consult a physician.

Incorrect results due to incorrect handling of reagents

Incorrect handling or evaporation of reagents may lead to incorrect or invalid results.

- Do not remove the foil of the reagent containers in the reagent cassette when loading reagent cassettes onto the instrument.
- Do not use reagents that were exposed to heat or to light for an extended time.
- The system does not allow the use of expired reagents.
- Always handle and store reagents according to the specified storage conditions as stated in the Instructions for Use for the reagent.
- Store reagents in an upright position.
- Ensure good reagent handling techniques to avoid the formation of foam and bubbles in all reagents.
- Do not use a reagent vessel whose reagent has spilled.
- Do not use reagent vessels that have been dropped on the floor or compromised in any other way.
- Do not manipulate reagents in any way not specified in the user documentation or Instructions for Use.
- Do not use a reagent vessel on different instruments.

Incorrect results due to incorrect handling of consumables

Reuse of consumables can lead to contamination, resulting in an incorrect result.

- Do not reuse consumables.
- Do not use consumables that have been dropped on the floor or compromised in any other way.
- Handle consumables carefully to avoid contaminating them during unpacking and loading.
- Store all consumables protected from light.

Incorrect results

Contaminated samples

Insoluble contaminants, bubbles, or films in samples may cause clogging or pipetting volume shortage, leading to incorrect results.

- Make sure that the samples contain no insoluble contaminants, such as fibrin or dust.
- Ensure good sample preparation techniques to avoid the formation of foam, clots, and bubbles in all samples.

Contamination

Contamination of the instrument, accessories, or consumables with sample material, controls, or reagents may lead to incorrect results.

- Follow laboratory best practices.
- Follow the instructions for operation and maintenance of the instrument given in the User Assistance.
- Follow the instructions given in the Instructions for Use of the reagents.
- In case of suspected contamination (e.g., because of spillage), follow the cleaning procedures provided in this publication for the instrument and accessories. Dispose of consumables according to local regulations.

For cleaning procedures, see the User Assistance.

Incorrect identification

Changing positions of samples, controls, MGP tubes, reagent tubes, or reagent bottles after they have been loaded and identified by the barcode readers may lead to incorrect results.

- Leave all positions of samples, controls, MGP tubes, reagent tubes, and reagent bottles unchanged after they have been loaded and identified by the barcode readers.

Handling of output consumables

Incorrect handling of output tubes or 8-tube strips may cause contamination and may lead to incorrect results.

- Cap and decap output tubes and 8-tube strips with care. Make sure to place 8-cap strips in the right direction (A–H).
- Do not shake or turn upside down output tubes or 8-tube strips.
- Discard output tubes or 8-tube strips that have been dropped on the floor or compromised in any other way. Repeat the runs.
- Do not reuse 8-cap strips; if you decap 8-tube strips for use, always recap with a new 8-cap strip.

Electromagnetic interference

Electromagnetic interference

Strong electromagnetic fields (originating from unshielded radio frequency sources) can interfere with proper operation and may lead to malfunction of the system and incorrect results.

- Do not use this system near sources of strong electromagnetic fields because these fields can interfere with proper operation.
- Evaluate the electromagnetic environment before you operate the system.
- Take measures to mitigate the interference.

Wireless interference

Wireless devices in the instrument may lead to malfunction.

- Do not leave mobile phones or other wireless devices inside the instrument.

Data security

Loss of data integrity or unavailability of the system due to malicious software or unauthorized system access

Malicious software or unauthorized system access can result in loss of data integrity or system unavailability.

To avoid infection with malicious software or the unauthorized access and misuse of the system, the following recommendations are essential:

- Do not install and/or execute any other software on the system.
- Make sure other computers and services on the network (e.g., the host, archiving share, backup share, or service) are properly secured and protected against malicious software and unauthorized access.
- Customers are responsible for the security of their local area network, especially in protecting it against malicious software and attacks. This protection includes measures, such as a firewall, to separate the device from uncontrolled networks as well as measures that ensure that the connected network is free of malicious code.
- The Roche-provided firewall is mandatory.
- Restrict physical access to the system and all attached IT infrastructure (computer, cables, network equipment, etc.).
- Make sure that system backup and archive files are protected from any unauthorized access or disasters. Measures include remote storage locations and secure transfer of backup and archive files.

Attached systems

Malicious software or unauthorized system access on attached systems can result in loss of data integrity or system unavailability.

To avoid infection with malicious software or the unauthorized misuse of the system, the following recommendations are essential:

- Check all external storage devices (e.g., CDs, DVDs, or USB flash drives) with an anti-virus scanner (on another computer) to ensure that they are free of malicious software before using them on the system.
- Make sure other computers and services on the network (e.g., the host, archiving/backup share or service) are properly secured and protected against malicious software and unauthorized access.

Compromised system

Malicious software or unauthorized system access can result in loss of data integrity or system unavailability.

Typical signs of malicious software or unauthorized access to the system include:
Unexpected warning messages from the instrument.
Unexpected new files in working folders.
Unexpected audit trail and system log entries like multiple failed logon attempts.
Significantly degraded user interface performance.
Seemingly random crashes of the system.
Automated typing of text, automatic cursor movement, etc.

- Monitor the system for suspicious activity and report suspected compromise.
- If you suspect malicious activity on the system:
  - Physically disconnect the system from the network
  - Contact the laboratory IT responsible to report and verify the finding.
  - Mistrust results produced while the system has been compromised (if necessary, re-verify already released results).
  - Contact your Roche Service representative to initiate next steps in system recovery.

Unauthorized access due to incautious password handling

Disclosing passwords may lead to unauthorized system access.

- Always use strong passwords.
- Do not disclose passwords to unauthorized users.
- Do not write down passwords.

Packaging material

Environmental harm

Improper disposal of packaging material may contaminate the environment.

- Dispose of any packaging material in accordance with the local regulations.

Notices

⚠ List of notices

Failure to observe the notices may result in damage to the system.

- Before operating, read the notices contained in this summary carefully.

In this section

Electromagnetic compatibility

Class A equipment (industrial areas)

- The system has been designed and tested to CISPR 11 Class A. In a domestic environment, it may cause radio interference, in which case you may need to take measures to mitigate the interference.

Mechanical stress

Damage to the instrument due to mechanical stress

Shock, vibration, or pressure can damage the instrument.

- Keep sources of vibration away from the instrument.
- Do not place objects on the instrument.

Unspecified temperature conditions

Loss of results and reagents due to exposure to unspecified temperature conditions

If the temperature inside of the instrument is above 37°C or below 15°C, all reagents on board and all current results become invalid.

- Keep heat sources away from the instrument. Exposure to heat may cause the temperature inside of the instrument to rise.

For the allowable environmental conditions, see the User Assistance.

Spillage

Spilled liquid

Any liquid spilled on the instrument may result in malfunction or damage.

- Place samples, reagents, or any other liquid only at the intended positions.
  Do not place samples, reagents, or any other liquid on other surfaces of the instrument.
- When you remove or replace consumables, do not spill any liquid on the instrument.
- If liquid does spill on the instrument, follow the applicable cleaning procedure. Wear appropriate personal protective equipment. Dispose of waste according to the local regulations.

Incorrect results due to spilled liquid during normal operation

Overfilling tubes, 8-tube strips, or processing cartridges, or insufficient sample quality can lead to spillage during normal operation, and can result in contamination and incorrect results.

- Do not overfill tubes, 8-tube strips, or processing cartridges.
- Ensure good sample quality. Incompatible samples (e.g., too high cell density) may lead to spillage during normal operation.

Fan openings

Damage to the instrument due to blocked fan openings

Blocking the instrument fan openings may damage the instrument.

- Always keep the instrument fan openings free.
- Leave sufficient free space around the instrument.

For the space required around the system, see the User Assistance.

Safety labels on the instrument

In this section

List of safety labels on the instrument

Warning labels are placed on the instrument to draw your attention to areas of potential hazard. Listed below are labels and the definitions according to the location on the instrument.

The safety labels on the instrument comply with the following standards: ANSI Z535, IEC 61010-1, IEC 60417, ISO 7000, or ISO 15223-1.

In addition to the safety labels on the instrument, there are safety notes in the corresponding parts of the user documentation.

Only Roche Service representatives are to replace damaged labels. For replacement labels, contact your Roche Service representative.

General warning
Potential hazards located near this label may lead to death or serious injury.
Refer to the user documentation for instructions on safe operation.

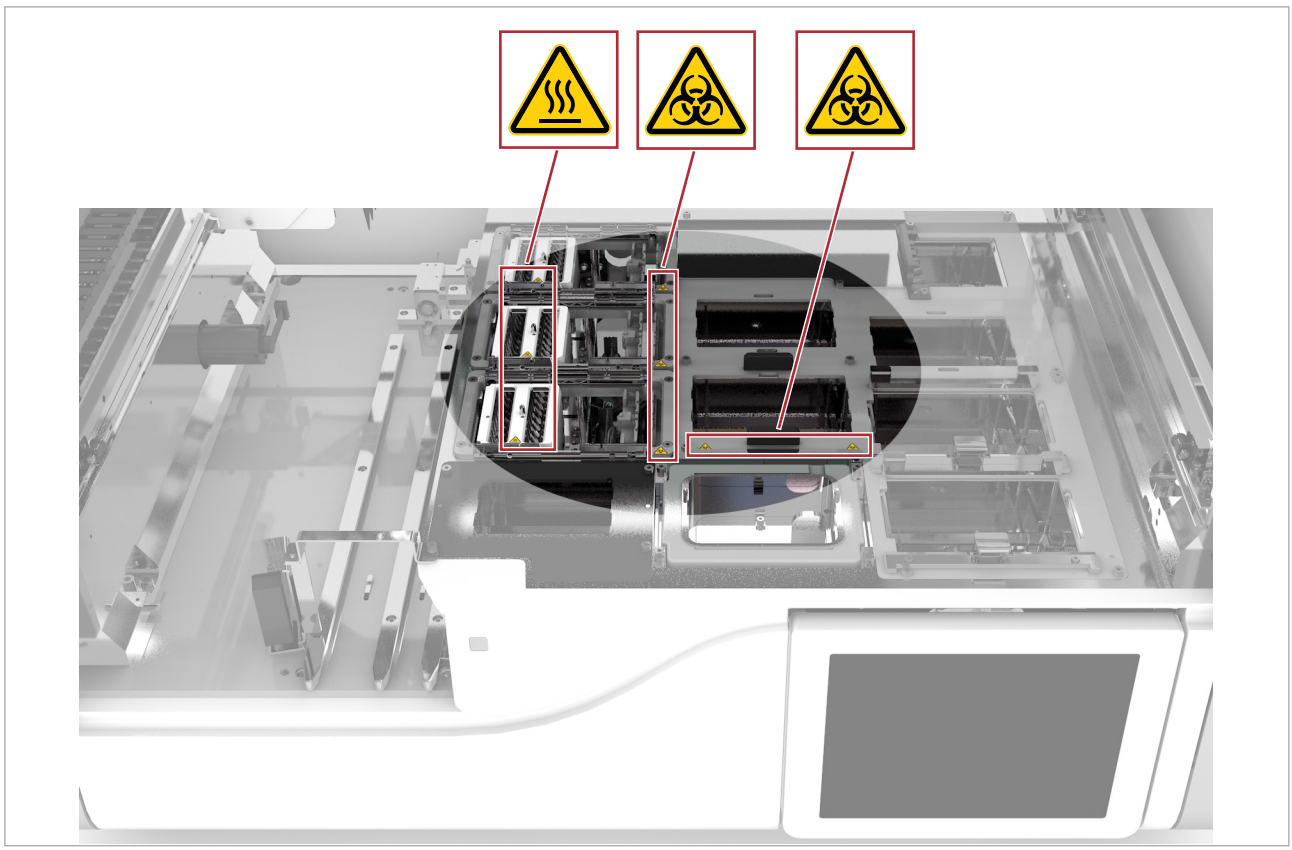
Hot surface
The area near this label may be hot.
To avoid burns, do not touch this area.

Biohazard
Potentially biohazardous materials are used near this label.
Observe relevant laboratory best practices on safe usage.

The safety messages give more detailed information about potentially hazardous situations that may arise during daily operation, or when carrying out maintenance actions.

When working with the instrument, observe both the safety labels on the instrument and the safety messages in the user documentation.

Location of safety labels on the instrument



Location of safety labels on the instrument

Safety information for disposal

Disposal information

Infection by a biohazardous instrument

- Treat the instrument as biohazardous waste. Decontamination (the combination of processes including cleaning, disinfection, and/or sterilization) is required before reuse, recycling, or disposal of the instrument.
- Dispose of the instrument according to local regulations. For more information, contact your Roche Service representative.

Electronic equipment

Disposal of electronic equipment
This symbol appears on any component of the instrument that is covered by the European Directive on Waste Electrical and Electronic Equipment (WEEE).

You must dispose of these items through designated collection facilities appointed by government or local authorities.

Contact your city office, waste disposal service, or your Roche Service representative for more information about disposal of your old product.

Constraint:
It is left to the responsible laboratory organization to determine whether electronic equipment components are contaminated or not. If contaminated, treat them in the same way as the instrument.