cobas c 311 analyzer

Safety Guide - Version 1.2
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Publication information

Publication version	Software version	Revision date	Change description
1.0	01-09	2014-10	First version
1.1	01-10 01-11	2016-12 2019-08	License information and regulatory information updated.
1.2	01-13	2021-06	IVDR implemented. GDPR implemented. Safety information added on: • Sharps, rough edges, and/or moving parts. • Immediate action in an emergency situation. • Flammable refrigerant. List of safety labels: Flammable label added. Location of safety labels on rear view: Flammable label added. Disposal information revised.

Revision history

Edition notice

This publication is intended for users of the **cobas c** 311 analyzer.

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.

Where to find information

The **Online Help** contains all information about the product, including the following:

- Routine operation
- Maintenance
- Safety
- Troubleshooting information
- Software reference
- Configuration information

The **Safety Guide** contains important safety information. You must read the Safety Guide before operating the instrument.

The **Operator's Manual** focuses on routine operation and maintenance. The content is organized according to the normal operation workflow.

cobas e-library provides access to important updates, Method Sheets, Value Sheets, and other important documents from Roche.

The original version of this document is in English. All translations of this document have been translated from the original version in English. You can find the original and translated versions of this document at: *www.dialog.roche.com*.

Contact your local affiliate or Roche Service representative for more information.

The **cobas c** 311 analyzer can be used with all released tests. Tests approved for use on the instrument are available under eLabDoc on the Roche DiaLog website: *www.dialog.roche.com*.

Privacy notice When you use the User Assistance online, viewing events (topics viewed and searches performed) and IP addresses are logged. The data collected is for Roche internal use only and is never forwarded to third parties. It is anonymized, and after one year it is automatically deleted. Viewing events are analyzed to improve User Assistance content and search functionality. IP addresses are used to classify regional behavior.

⚠ General attention

To avoid serious or fatal injury, ensure that you are familiar with the system and safety information before you use the system.

- 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.
- Store all publications in a safe and easily accessible place.

Training

Do not carry out operation tasks or maintenance actions unless you have received training from Roche Diagnostics. Leave tasks that are not described in the user documentation to trained Roche Service representatives.

Images

The images in this publication have been added exclusively for illustration purposes. Configurable and variable data in screenshots, such as tests, results, or path names visible therein must not be used for laboratory purposes.

Warranty

Any customer modification to the system renders the warranty or service agreement null and void.

For conditions of warranty, contact your local sales representative or refer to your warranty contract partner.

Always leave software updates to a Roche Service representative or perform such updates with their assistance.

Copyright

Trademarks

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Feedback

Every effort has been made to ensure that this publication fulfills the intended use. All feedback on any aspect of this publication is welcome and is considered during updates. Contact your Roche representative, should you have any such feedback.

Approvals

The **cobas c** 311 analyzer complies with the following directives and regulations:

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances.

Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006.

Compliance of specific instruments with the respective directives or regulations is provided by means of the Declarations of Conformity where applicable.

Check the serial number of the instruments to identify the applicable directives and/or regulations.

Fluorinated greenhouse gases specifications can be found in supporting information identified by serial number of the instruments.

All documents are available under eLabDoc on the Roche DiaLog website: *www.dialog.roche.com*.

If you are unable to access Roche DiaLog, contact your Roche Service representative.

Compliance is provided by means of the Declaration of Conformity.

The following marks demonstrate compliance:

For *in vitro* diagnostic use.

Complies with the provisions of the applicable EU regulations.

Issued by Underwriters Laboratories, Inc. (UL) for Canada and the US.

Contact addresses

Inside the European Union and EFTA member states

Manufacturer of the instrument

Hitachi High-Tech Corporation
1-17-1 Toranomon Minato-ku,
Tokyo, 105-6409 Japan

Authorized representative and Importer

Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany

Outside the European Union and EFTA member states

Manufactured by: Hitachi High-Tech Corporation

Manufactured for: Roche Diagnostics GmbH
Sandhofer Strasse 116
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Distributed in USA by: Roche Diagnostics
9115 Hague Road Indianapolis,
Indiana, USA

Roche affiliates

A list of all Roche affiliates can be found at:

www.roche.com/about/business/roche_worldwide.htm

eLabDoc

Electronic user documentation can be downloaded under eLabDoc on the Roche DiaLog website:

www.dialog.roche.com

For more information, contact your local affiliate or Roche Service representative.

Table of contents

Preface

Use this publication together with the **cobas c** 311 Operator's Manual.

In this section

Intended use

Intended use for US only

The **cobas c** 311 analyzer is a fully automated, discrete clinical chemistry analyzer intended for the in-vitro quantitative and qualitative determination of analytes in body fluids.

Supporting information for US only

The **cobas c** 311 analyzer is intended to be used by trained laboratory technicians. The operational environment for the **cobas c** 311 analyzer are clinical laboratories, hospital laboratories and commercial hospitals, as well as private laboratories.

Intended purpose for EU/EFTA and outside US

The **cobas c** 311 analyzer is an automated analyzer including software, intended for running qualitative, semi-quantitative and quantitative clinical chemistry assays as well as ion-selective measurements.

Supporting information for EU/EFTA and outside US

It is an IVD device intended to be used in combination with assays for screening, monitoring (aid in monitoring), diagnosis (aid in diagnosis) and prognosis.

The specific disorder and testing populations are covered by the applicable assays running on the instrument. The type of specimen to be used includes serum, urine, cerebrospinal fluid, hemolysate, whole blood and plasma that are used for detecting and/or measuring analytes covered by the specific assays.

The intended users of this device are trained laboratory technicians and trained field service engineers (professional use only).

Symbols and abbreviations

Product names

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

Product name	Descriptor
cobas c 311 analyzer	analyzer
cobas c pack	reagent pack

Product names

Symbols used in the publication

Symbol	Explanation
•	List item
	Related topics containing further information
	Tip. Extra information on correct use or useful hints.
▸	Start of a task
	Extra information within a task
➔	Result of an action within a task
	Frequency of a task
	Duration of a task
	Materials that are required for a task
	Prerequisites of a task
	Topic. Used in cross-references to topics.
▶	Task. Used in cross-references to tasks.
	Figure. Used in figure titles and cross-references to figures.
	Table. Used in table titles and cross-references to tables.
√xy	Equation. Used in cross-references to equations.

Symbols used in the publication

Abbreviations

The following abbreviations are used.

Abbreviation	Definition
ACN	Application code number
ADC	Analog-digital converter
ANSI	American National Standards Institute
CellCln 1	Basic reaction cell wash solution (NaOH-D)
CellCln 2	Acid reaction cell wash solution
CFAS	Calibrator for automated systems (CFAS)
CFR	Code of Federal Regulations
COBI	Compendium of Background Information
CSA	Canadian Standards Association
CSV	Comma-separated values

Abbreviations

Abbreviation	Definition
CV	Coefficient of variation
DCCT	Diabetes control and complications trial
DIL	ISE Diluent
EC	European Community
ECO-D	EcoTergent, additive to the incubation bath to reduce surface tension
EFTA	European Free Trade Association
EN	European standard
EU	European Union
GNU	GNU's Not Unix!
HIS	Hospital information system
ICVC	Initial cassette volume check
IEC	International Electrotechnical Commission
IFCC	International Federation of Clinical Chemistry and Laboratory Medicine
IS	ISE internal standard
ISE	Ion-selective electrode
ISE COMP	ISE Standard High, used as calibrator 3
ISE HIGH	ISE Standard High, used as calibrator 2
ISE LOW	ISE Standard Low, used as calibrator 1
ISO	International Organization of Standardization
IVD	In vitro diagnostic
IVDR	In vitro diagnostics regulation: Regulation (EU) 2017/746
LED	Light-emitting diode
LIS	Laboratory information system
LLD	Liquid level detection
n/a	Not applicable
NACL	NaCl solution, used as diluent
NAOHD	Wash solution for reagent probes and reaction cells (D1)
QC	Quality control
RCM	Reaction calculation mode
REF	ISE Reference Electrolyte solution
RoHS	Restriction of Hazardous Substances
SBS	Scan before sample stop
SCCS	Additive to prevent reaction cell carryover in long HbA1c batches (D3)
SD	Standard deviation

Abbreviations

Abbreviation	Definition
SmpCln 1	Basic sample probe wash solution
SmpCln 2	Acid sample probe wash solution
SMS	Wash solution for reagent probes and reaction cells (D2)
STAT	Short turn-around time
SysClean	ISE Cleaning Solution/Elecsys SysClean
UL	Underwriters Laboratories Inc.
USB	Universal serial bus
WEEE	Waste Electrical and Electronic Equipment

Abbreviations

Safety classifications

The safety precautions and important user notes are classified according to the ANSI Z535.6 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 that, if not avoided, could result in death or serious injury.

⚠ CAUTION

Caution…

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

NOTICE

Notice...

...indicates a hazardous situation which, 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.**

Keep in mind that the hazard warnings in this manual, in the Operator´s Manual, in the Online Help, and on the instrument cannot cover every possible case, as it is impossible to predict and evaluate all circumstances beforehand.

Just following the given directions may, therefore, be inadequate for operation. Always be alert and use your common sense.

In this section

About 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 Roche Diagnostics has trained you to do so.
- Leave maintenance, installation, or service that is not described to trained Roche Service representatives.
- Carefully follow the procedures specified in the instructions for operation and maintenance.
- Follow standard laboratory practices, especially when you work with biohazardous material.

About 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

Fatigue due to long hours of operation

Looking at the monitor over an extended time may lead to eye strain or body fatigue.

- Take a break to relax, in accordance with your local regulations.

System not used for an extended period

- Follow the decommissioning procedure if available.
- Set the power switch to OFF if you do not use the system for an extended period.
- Remove and refrigerate any remaining reagents.
- For further information, call your Roche Service representative.

Abnormal condition

During operation, always check for any abnormal sound, water leakages or other abnormal condition.

- If a trouble occurs, take suitable safety measures according to the condition and contact your Roche Service representative.

Non-approved parts

Use of non-approved parts or devices may result in malfunction of the system and may render the warranty null and void.

- Use only parts and devices approved by Roche Diagnostics.

About installation and deinstallation

Errors in installation

Only trained Roche Service representatives may install the system.

- Leave installation that is not described to trained Roche Service representatives.

Damage in transit

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

Disposal

A biohazardous system may lead to infection.

- If you must dispose of the system, read the following information.

Disposal information (43)

About operating conditions

Unsuitable operating conditions

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

- Use the system indoors only, and avoid heat and humidity outside of the specified range.
- Make sure that the system's ventilation openings remain unobstructed always.
- To maintain the operating conditions of the system, perform maintenance in accordance with the specified intervals.
- Keep the operating instructions undamaged and available for use. Operating instructions must be easily accessible for all users.

Power interruption

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

- Operate only with an uninterruptible power supply (UPS).
- Ensure regular maintenance of the UPS.
- Perform regular backups of results.
- Do not switch off power while the control unit accesses the hard disk or storage device.

Electromagnetic compatibility

This instrument complies with the standard IEC 61326-2-6/EN 61326-2-6. It 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.

- The electromagnetic environment should be evaluated prior to operation of the instrument.
- Do not operate this instrument in close proximity to sources of strong electromagnetic fields (for example, unshielded intentional radio frequency sources), as they may interfere with proper operations.
- Do not operate the following devices in close proximity to the instrument:
  - Mobile phones
  - Transceiver
  - Cordless phones
  - Other electrical devices that generate strong electromagnetic fields

About the protection of personal data and software security

The General Data Protection Regulation (GDPR) is a regulation in EU law on data protection and privacy for all citizens of the European Union (EU) and the European Economic Area (EEA). The regulation also covers the processing of personal data outside the EU and EEA.

If this regulation or any other privacy protection regulation is applicable for your country, observe the following safety messages to prevent data breaches and to meet the GDPR:

Access control

Unauthorized access may lead to data breaches.

- Implement physical access controls to ensure that only authorized laboratory staff operate the system at all times.
- Assign a personal, unique user ID to each user for system access.
- Assign access rights to each user only as high as required for the tasks of the user.
- Delete user IDs from the system for users who no longer work on the system.

Corrupt data due to a disclosed password

The security of the system and its data depends on the password-protected access. If an unauthorized person discovers your user ID and password, they could compromise this security.

- Always enter your password unobserved.
- Do not write down your password anywhere, including in a contact form, in the address book, or in a file on the computer.
- Do not disclose your password to anyone. Roche will never ask you for your password.
- If you ever disclose your password to anyone, change it immediately afterwards.
- Contact your local Roche affiliate if you think your account has been compromised.

Network security

Malicious software and hacker attacks may impair IT security. The laboratory is responsible for the IT security of their IT infrastructure.

- To protect and separate Roche systems from other laboratory infrastructure, the Roche-provided firewall must be used.
- Secure all devices and services used in the lab infrastructure against malicious software and unauthorized access.
- Secure the network environment to be resilient against traffic redirection and eavesdropping.

Data entry and data transfer

Writing patient sensitive information in comment fields can violate protection laws for protected health information.

- Do not write any patient sensitive information into comment fields.
- Do not download patient identifiers from any host system (e.g., LIS, middleware, or HIS) onto the system. Data transfer using any host protocol (e.g., ASTM) is not encrypted; data is transferred as plain text and readable with IT tools like sniffer.

Secure data storage

Unauthorized access to data backups and archive files can violate data protection laws.

- Any data backup or data archive that has been exported from the instrument must be physically stored in a secured location.
- Ensure only authorized persons may access the secure data storage. This includes the data transfer to remote storage locations and disaster recovery.
- Data backups must not be taken from the secure data storage. Do not take storage media outside the lab environment.

Cybersecurity and privacy awareness

Insufficiently informed employees can endanger security.

- Perform regular cybersecurity and privacy awareness trainings for laboratory staff handling personal data. Instruct laboratory staff how to handle data in a compliant way and according the privacy principles as mandated by customer regulations.
- Check your instrument for suspicious activity and report any suspected compromise to your local Roche representative immediately.
- Update to the latest software versions provided by Roche as soon as possible.
- Do not use external storage devices or storage media (e.g., USB flash drives or DVDs) on the system that have been used on public or private computers. Failure to do so may result in data loss and render the instrument unusable.

Use of storage media

Incorrect handling of storage media may result in data loss or system malfunction.

- Only insert or remove a DVD or USB flash drive when the instrument is in **Standby** mode.
- Do not use low quality or damaged DVDs (e.g., scratches, dirt, or dust on disks).
- At any one time only one storage medium can be in use. Before inserting a USB flash drive into a USB port, check that no other USB flash drive is connected and no DVD is inserted.
- Before removing a USB flash drive, safely disconnect it from the system using the corresponding button.

Computer viruses

If you detect an unexpected operation or program/data damage, the PC may be infected with a computer virus.

- To avoid virus infections, scan removable storage media by an antivirus software before using them on the system.
- Never use a program or storage medium that is suspected of containing a virus.
- If you think your PC is infected with a computer virus, call your local Roche Service representative. Your local Roche Service representative will check your system for proper functionality.

Data backup

Data may get lost due to hard disk failures or damages.

- Back up your data (measurement results and system parameters) at regular intervals.
- Use the backup function daily to store relevant data on the hard disk.
- Make a backup copy if you have changed any system parameters.

Non-approved third-party software

Installation of any third-party software that is not approved by Roche Diagnostics may result in incorrect behavior by the system.

- Do not copy or install any software or software patches on the system unless it is part of the system software or your Roche Service representative advises it.
- Do not change any PC settings.

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

Sharps, rough edges, and/or moving parts

Personal injury and infection due to sharps, rough edges, and/or moving parts

Good Laboratory Practice can reduce the risk of injury. Be aware of your laboratory environment, well-prepared, and follow the instructions for use.
Some areas of the instrument may have sharps, rough edges, and/or moving parts.

- Wear personal protective equipment to minimize the risk of injury from bodily contact with such parts, especially in less accessible areas, or while cleaning the instrument.
- Your personal protective equipment should be appropriate to the degree and type of potential hazard, e.g. suitable lab gloves, eye protection, lab coat, and footwear.

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 work in any electronic equipment.
- Do not remove any cover of the system except those covers specified in the Operator's Manual.
- Do not open the top cover and touch the ultrasonic mixing unit during operation or when the analyzer performs maintenance.
- Only Roche Service representatives may install, service, and repair the system.

Immediate action in an emergency situation

If an unexpected emergency situation appears and the instrument cannot be controlled, this can lead to injury of the operator.

- Turn off the operation main switch or circuit breaker of the instrument.

Flammable material

Flammable refrigerant

In certain instruments, the cooling unit contains flammable refrigerant.

- The corresponding instruments can be identified by a *Risk of Fire* safety label.
- Do not remove any cover of the system except those specified in the instructions.
- Leave maintenance, installation, or service that is not described to trained Roche Service representatives.

Biohazardous materials

Infectious samples

Contact with samples containing material of human origin may result in infection. All materials and mechanical components associated with samples containing material of human origin are potentially biohazardous.

- Follow standard laboratory practices, especially when working with biohazardous material.
- Keep all covers closed while the system is operating.
- Always switch off the system or go to maintenance mode, if available, before you work with an opened cover (for example, for cleaning or maintenance).
- Wear appropriate personal protective equipment.
- If any biohazardous material is spilled, wipe it up immediately and apply a disinfectant.
- 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.

Sharp objects

Contact with probes or needles may result in infection.

- When you wipe probes or needles, use several layers of gauze and wipe from the top down.
- Take care not to puncture yourself.
- Wear appropriate personal protective equipment.
  Take extra care when working with lab gloves, which can easily be pierced or cut, leading to infection.

Moving parts

Contact with moving parts may result in personal injury.

- Keep all covers closed and in place while the system is operating.
- Always switch off the system or go to maintenance mode, if available, before you work with an opened cover (for example for cleaning or maintenance).
- Only trained personnel should have access to the keys to the protective covers of the instrument.
- Do not touch any parts of the system except those parts specified. Keep away from moving parts during operation.
- Only load samples onto the sample disk when the green Access Sample Disk lamp next to the sample disk is on. This indicates that the sample disk will not rotate until renewed operation is actively initiated by the operator.
- During operation and maintenance, carefully follow the Operator´s Manual.

Waste

Infectious waste

Contact with waste (liquid and/or solid) may result in infection. All materials and mechanical components associated with the waste systems 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 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.

Waste must be treated in accordance with the relevant laws and regulations. Any substances contained in reagents, calibrators, and quality controls, which are legally regulated for environmental protection, must be disposed of according to the relevant water discharge facility regulations. For the legal regulations on water discharge, please contact the reagent supplier.

Two kinds of liquid waste are discharged by the analyzer:

- Concentrated waste solution that contains highly concentrated reaction solution. This waste must be treated as infectious waste as specified by the relevant regulations.
- Dilute waste: A non-concentrated waste solution diluted with rinsing water from cell wash or water from the incubation bath. When using NaOH-D for washing the reaction cells, alkaline concentration is 0.1 to 1.0 mmol/L.

Environmental harm

The system generates liquid and/or solid waste. This waste contains concentrated reaction solutions and is potentially biohazardous. Improper disposal may contaminate the environment.

- Treat this waste as infectious waste.
- Dispose of waste in accordance with the local regulations.

Reagents and working solutions

Skin inflammation or injury

Direct contact with reagents, detergents, cleaning solutions, 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.
- Observe the information given in Material Safety Data Sheets (available for Roche Diagnostics reagents and cleaning solutions).
- If reagents, detergents, or other cleaning solutions come into contact with your skin, wash the affected area immediately with soap and water and apply a disinfectant.
  Consult a physician.

Fire and burns

Alcohol is a flammable substance.

- Keep all sources of ignition (such as sparks, flames, or heat) away from the system when you perform maintenance or checks that involve alcohol.
- When you use alcohol on or around the system, use no more than 20 mL at a time.

Incorrect results

Poor accuracy and precision

Incorrect results may lead to errors in diagnosis, posing danger to the patient.

- For proper use of the system, run QC tests and monitor the system during operation.
- Do not use reagents or consumables that have exceeded their expiry date, otherwise you may obtain inaccurate data.
- For diagnostic purposes, always assess the results with the patient's medical history, clinical examination, and results from other consultations.

Position mismatch

Putting a sample container with a manually entered ID on a wrong position may lead to incorrect results.

- Check the manually entered ID against the sample ID on the sample container.
- Be sure that the samples are loaded in the correct positions on the sample disk.

Exchange of sample positions

Exchanging of sample positions during interruption may lead to incorrect results.

- When operating in barcode mode, do not exchange any samples highlighted in green on the **Sample Tracking** screen.
- When operating in non-barcode mode, do not move or exchange any samples that are already on the disk.

Foam, clots, films, or bubbles

Incorrect results may occur due to foam, fibrin clots, films, or bubbles in reagents or samples.

- Avoid the formation of foam, clots, and bubbles in all reagents, samples, calibrators, and controls.

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.

Carryover

Traces of analytes or reagents may be carried over from one test to the next.

- Take adequate measures (for example, extra wash cycles) to avoid extra testing and potentially incorrect results.

Evaporation of samples or reagents

Evaporation of samples or reagents may lead to incorrect or invalid results.

- Sample material may evaporate if left open. Do not leave samples open for any length of time.
- Do not use improperly stored reagents. Ensure that reagents are stored according to the Instructions for Use.

Incorrect reagent volume

Incorrect reagent handling may cause an undetectable loss of reagent.

- Always store reagents according to the specified storage conditions as stated in the Instructions for Use for the test.
- Do not reuse a reagent cassette whose reagent has spilled.
- Do not use a reagent cassette for different systems.

Expired reagents or mixing reagents

Data obtained using expired reagents is not reliable. Mixing new reagents with residues of old reagents may also lead to incorrect results.

- Do not use reagents that have exceeded their expiry dates.
- Do not mix old reagents with new reagents. When a bottle is empty, replace it with a new one.

Expired calibrators or controls

Data obtained using expired calibrators or controls is not reliable.

- Perform QC and calibration only with unexpired material.
- Do not use calibrators or controls that have exceeded their expiry dates.

Missing covers of the ISE measuring system

If the cover of the ISE measuring compartment or the cover of the sipper nozzle are not reinstalled after maintenance, the temperature level or the noise level may be affected, leading to incorrect results. Touching any ISE component or opening the front doors may also affect the noise level and lower measurement precision.

- Only perform measurements if the cover of the ISE compartment system is closed.
- Do not open the front doors during measurement.
- Do not touch the ISE REF tube, the ISE unit, or the sipper nozzle cover during measurement.

Aspiration of air

Incorrect pipetting of the probes as well as incorrect adjustment of the probe position may result in aspiration of air, leading to incorrect results.

- Check the instrument performance by performing control measurements.
- Perform maintenance procedures regularly.

Incorrect mixing volume

The permissible volume of reaction solution to be mixed by the ultrasonic mixer is 100 to 250 µL. If the volume is outside this range, the reaction solution may not be mixed correctly, leading to incorrect results.

- Make sure that the volume of reaction solution stays in the range of 100 to 250 µL, especially when loading a new application onto the analyzer.
- For information on analytical parameters of each reagent, contact its manufacturer.

Low level of incubator bath

If the water supply insufficient, the incubator bath can not be filled up properly. An alarm will be issued.

- Check that the tap at the outlet of the water tank is open.
- Check that the external water supply is turned on and that the water pressure meets requirements.
- When the cause is eliminated, perform maintenance item (4) Incubation Water Exchange to refill the incubator bath.

Undetected scanning errors

Barcode scanning errors could potentially go undetected when a check digit is not used.

- Use only barcodes with check digits.
- Use only barcode labels of a good printout quality.
- Do not move any samples that have already been scanned.
- Do not add a non-barcoded sample into the position of a sample with an unreadable barcode.

Caution messages

⚠ List of caution messages

Failure to observe caution messages may result in minor or moderate injury.

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

In this section

Mechanical safety

Top cover dropping suddenly

Be careful when opening or closing the top cover. If you let go of the handle, the top cover may drop onto your fingers.

- Always keep a firm grip on the handle and do not let go when opening or closing the top cover.
- If the top cover does not stay open properly, please contact your local Roche Service representative.

Notices

⚠ List of notices

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

- Before operating the system, read the notices carefully.

In this section

Circuit breakers and fuses

Circuit breakers and fuses

Improper use may result in damage to the system.

- If one of the circuit breakers or fuses blows, do not attempt to operate the system before contacting either your Roche Service representative or technical support.

Collision with moving parts

Collision with moving parts

Contact with moving parts may bend the probes or needles or damage some other component. If the system detects a collision, an alarm is raised, stopping the operation immediately.

- Keep all covers closed and in place during operation.
- Do not touch any parts of the system except those parts specified. Keep away from moving parts during operation.
- Only load samples onto the sample disk when the green Access Sample Disk lamp next to the sample disk is on. This indicates that the sample disk will not rotate until renewed operation is actively initiated by the operator.

Spillage

Spilled liquid

Any liquid spilled on the system 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 the covers or other surfaces of the system.
- When you remove or replace consumables, do not spill any liquid on the system.
- If liquid does spill on the system, wipe it up immediately and apply a disinfectant. Wear appropriate personal protective equipment.
  Dispose waste according to the local regulations.

Safety labels on the system

In this section

List of safety labels on the system

The system has warning labels to draw your attention to areas of potential hazard. The following list explains the meanings of the labels at the locations where you find the labels.

The safety labels on the system comply with the following standards: ANSI Z535, IEC 61010-2-101, IEC 61010-1, IEC 60417, ISO 7000, or ISO 15223-1.

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

Spillage
Spillage near this label may damage the system.
Do not place liquids in this area.

Infection
Touching the system mechanism may cause infection.
Do not open the covers while the system is in operation.
Stop every mechanism before you open a cover.

Personal protective equipment
Contact with corrosive material located near this label may harm you.
Wear appropriate personal protective equipment (such as eye protection and lab gloves).

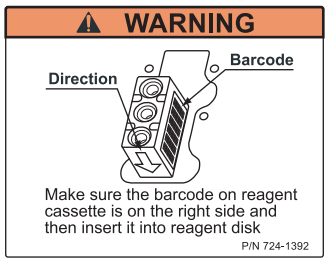
General warning
Potential hazards located near this label may lead to death or serious injury.
Refer to the manual for instructions on safe operation.

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

Electrical
If you access a part of the system marked with this label, contact with electrical components may cause an electric shock.
Refer to the manual for instructions on safe operation.

Flammable
In certain instruments, the cooling unit contains flammable refrigerant.
The corresponding instruments can be identified by a *Risk of Fire* safety label.
Do not remove any cover of the system except those specified in the instructions.
Leave maintenance, installation, or service that is not described to trained Roche Service representatives.

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



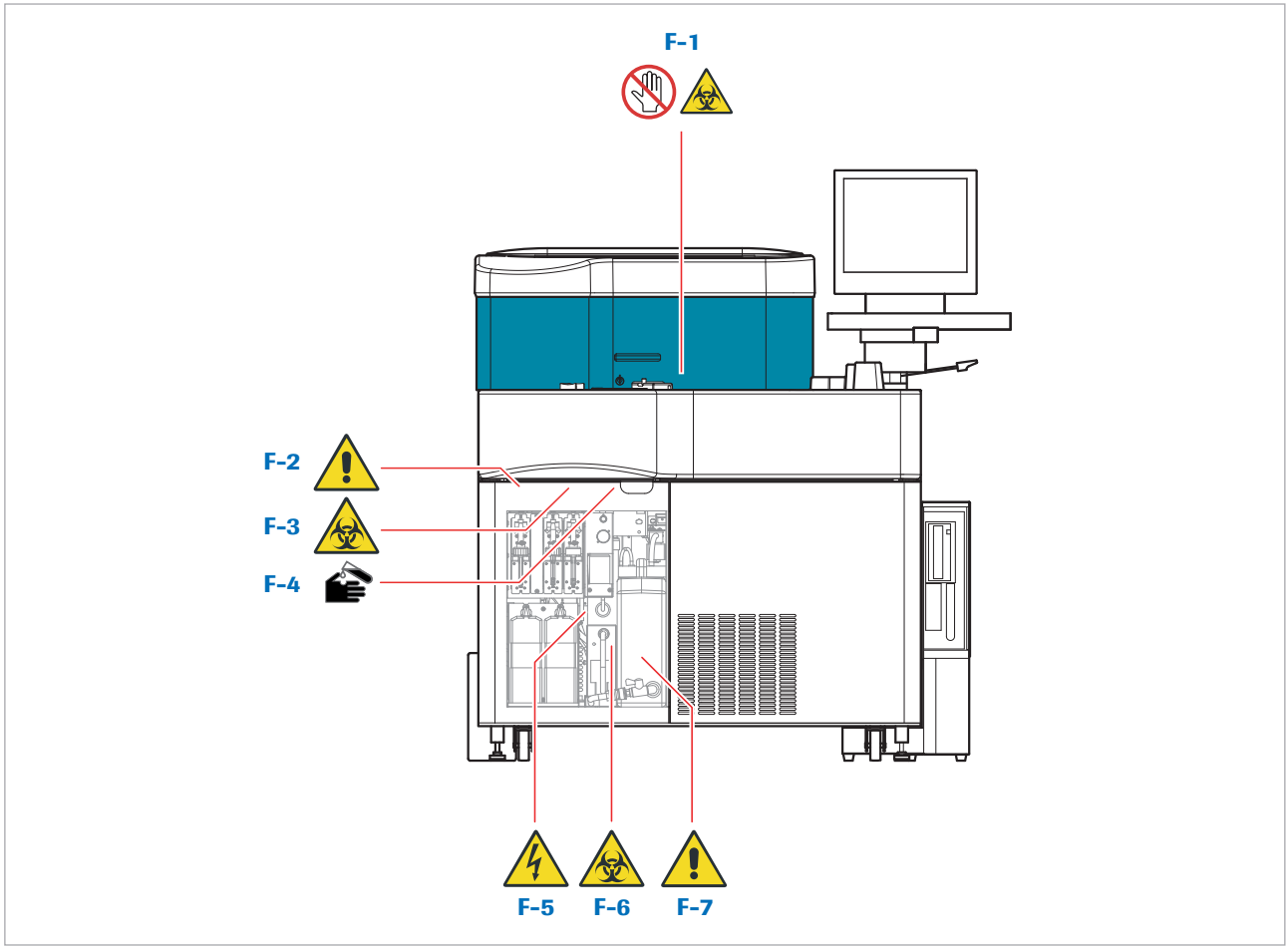
Barcode label direction
The barcode label must be on the right side when you insert the reagent pack into the reagent compartment.
To avoid damage to the system, do not insert the reagent pack the other way around.

Safety labels and safety notes

The following sections briefly describe the meaning of the safety labels at the locations where they are labeled on the system.

When working with the system, observe the safety labels on the system, the safety notes in this manual, and the safety notes in operating instructions.

Location of safety labels on the front view



Front view of the analyzer

F-1
Warning: Possibility of infection or injury due to contact with operating mechanisms!
Keep top cover closed whenever possible.

F-2
Warning: Fingers or skin may be pinched by syringe (when plunger is moving).
Do not touch any moving parts.
Caution: Loose tube connector may lower measurement precision.
After performing maintenance, tighten connector securely.

F-3
Warning: Possibility of infection due to contact with sipper syringe!
Keep front cover closed during operation.

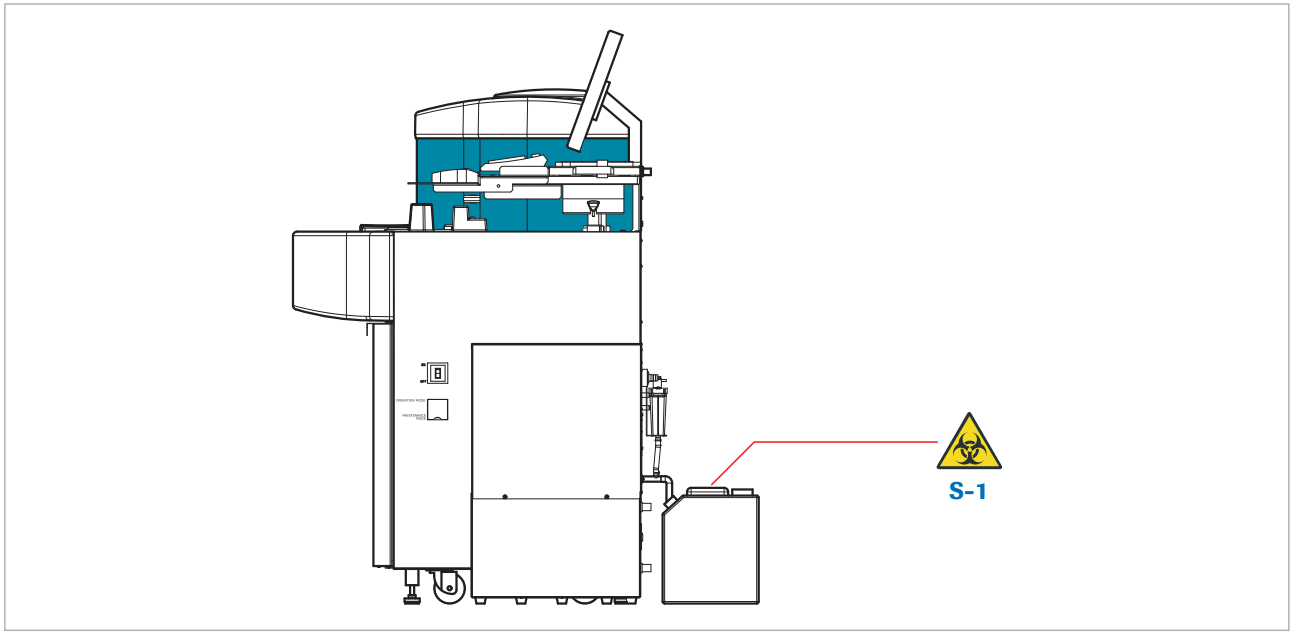
F-4
Caution: Detergent and/or reagent may cause skin irritation!
Observe safety precautions. Wear protective equipment.

F-5
Warning: Possibility of electrical shock inside the instrument.
Do not remove the cover!

F-6
Warning: Possibility of infection due to contact with waste from the vacuum tank!
Follow standard laboratory practices for working with biohazardous materials.

F-7
Caution: Malfunction due to spilled liquid
Follow all instructions for water tank maintenance carefully!

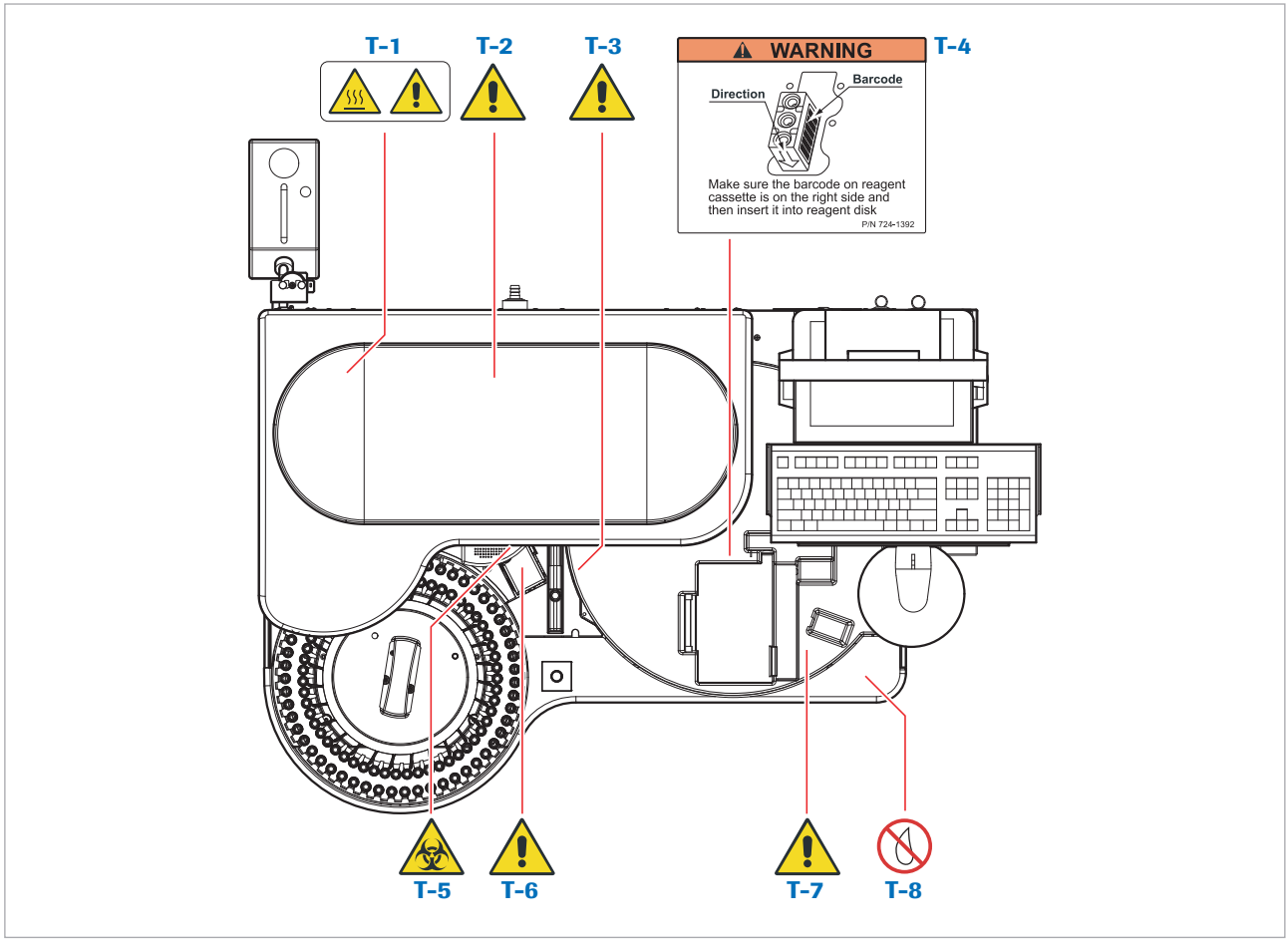
Location of safety labels on the side view



Right side of the analyzer

S-1
Warning: Possibility of infection due to contact with waste solution in waste solution tank!
Follow standard laboratory practices for working with biohazardous materials.

Location of safety labels on the top view

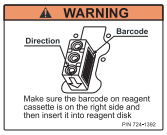


Top view of the analyzer

T-1
Warning: Possibility of burning yourself on the lamp or the lamp housing when replacing the photometer lamp!
Wait until the lamp housing has cooled down.

T-2
Warning: Possibility of injury or infection due to contact with moving mechanism!
Keep top cover closed whenever possible.

T-3
Caution: Touching the ISE Ref. tube during analysis may lower measurement precision!
Do not touch ISE Ref. tube during analysis.



T-4
Incorrect results due to incorrect placement of reagent
Make sure the **cobas c** pack is facing in the right direction when inserting cassettes!

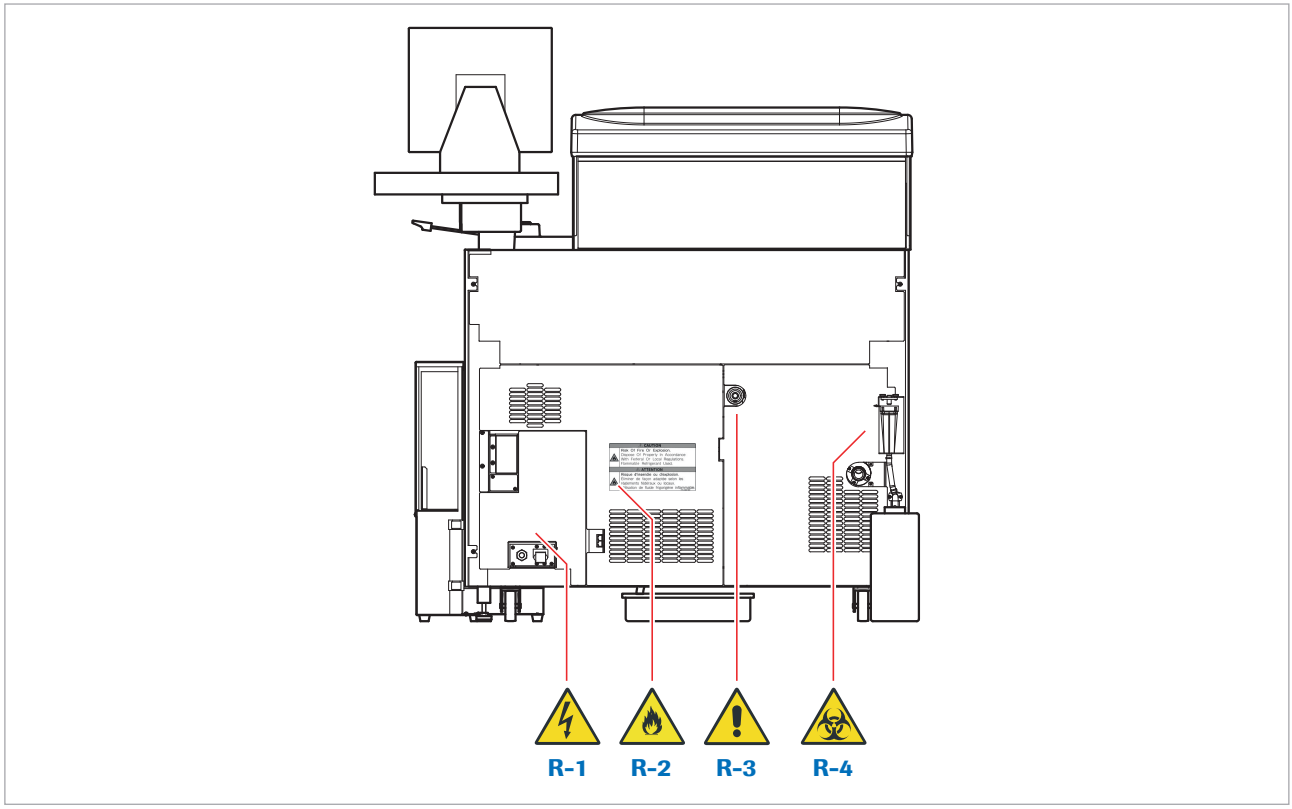
T-5
Warning: Possibility of infection due to contact with parts of the ISE measuring compartment!
Follow standard laboratory practices for working with biohazardous materials.

T-6
Caution: Opening the cover of the ISE measuring compartment may lower measurement precision!
Keep ISE cover closed during analysis.

T-7
Warning: Your fingers or hand may be pinched by the reagent disk during operation!
Do not reach into the reagent disk during operation.

T-8
Spilled liquids, e.g. samples or detergents, may cause instrument damage.
Wipe up spilled liquids immediately.

Location of safety labels on the rear view



Rear view of the analyzer

R-1
Warning: Possibility of electrical shock.
Do not remove the cover!

R-2
Warning: Possibility of fire or explosion due to flammable refrigerant.
Newer instruments use a flammable refrigerant in the cooling unit.
Follow all safety instructions carefully!

R-3
Caution: Incorrect results due to loose tube sockets
Follow instructions for inlet water filter maintenance carefully!

R-4
Warning: Possibility of infection due to contact with ISE waste solution!
Follow standard laboratory practices for working with biohazardous materials.

Safety information for barcode readers

The instrument uses barcode readers to scan the barcodes on samples and reagent packs.

The barcode readers use LED technology with low output power. The barcode readers and the instrument comply with the lowest laser class (Class 1).

⚠ WARNING

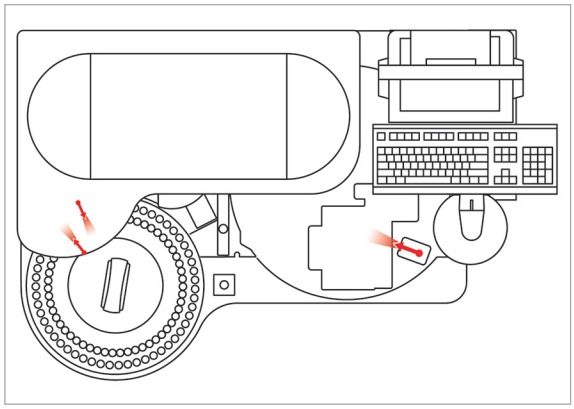
Blindness due to intense barcode reader light

The intense light of a barcode reader may severely damage your eyes or result in exposure to hazardous radiation.

- Do not stare into the beam of a barcode reader.
- Do not remove covers from barcode readers.
- Do not perform any maintenance actions on 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.

Position of barcode readers

The figure shows the position of the LED barcode readers and the directions of their apertures.



Position	Wavelength	Output power
Sample barcode readers at inner and outer ring	655 nm	10 µW
Reagent barcode reader	655 nm	10 µW

LED barcode readers

Safety information for disposal

Disposal information

Infection by an infectious instrument

- Treat the instrument as infectious waste. Decontamination (the combination of processes including cleaning, disinfection, and/or sterilization) is required before reuse, recycling, or disposal of the instrument.
- After decontamination, still treat the instrument as potentially infectious as there might be a remaining risk.
- Dispose of the instrument according to the local regulations. For more information, contact your Roche Service representative.

Collection of fluorocarbons

The cooling unit of the instrument contains fluorocarbons. In some countries, fluorocarbons must be disposed of by designated collection facilities.

- For the disposal of the cooling unit, refer to local regulations and authorities.

Electronic equipment

Disposal of control unit components
This symbol appears on any component of your control unit (such as the computer, monitor, or keyboard) 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 control unit components are contaminated or not. If contaminated, treat them in the same way as the system.