cobas e 411 analyzer

Safety Manual
Version 1.2
Software Version 03-01

Publication information

Publication version	Software version	Revision date	Change description
1.0	02-05, 02-06, & 02-07	November 2016	First version.
1.1	02-08	April 2018	Minor revisions.
1.2	03-01	February 2019	Minor revisions.

Revision history

Edition notice

This publication is for users of the **cobas e** 411 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.

General attention

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

- Pay particular attention to all safety precautions.
- Always follow the instructions in this publication.
- Do not use the analyzer in a way that is not described in this publication.
- Store all publications in a safe and easily retrievable 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 screenshots and hardware 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.

Trademarks

The following trademarks are acknowledged:

COBAS, COBAS C, COBAS E, and ELECSYS are trademarks of Roche.

All other trademarks are the property of their respective owners.

Feedback

Every effort has been made to ensure that this publication fulfills the intended purpose as mentioned above. 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.

Contact addresses

Inside the European Union and EFTA member states

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Outside the European Union and EFTA member states

Manufactured by:	Hitachi High-Technologies Corporation
Manufactured for:	Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim Germany

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Preface

Use this publication together with the **cobas e** 411 analyzer Operator's Manual.

Operation and maintenance actions are described in the Operator's Manual and Online Help.

Intended use

The **cobas e** 411 analyzer is an automated, random-access, multichannel analyzer for immunological analysis. It is designed for both quantitative and qualitative in vitro determination of a wide range of analytes by use of electrochemiluminescence (ECL) technology.

This instrument is designed for clinical immunological test analysis using water-soluble samples and reagents. Other analyses may not be applicable to this instrument. For clinical tests, the instrument should be used under the management of a doctor or clinical inspector.

Symbols and abbreviations

Product names

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

Product name	Abbreviation
cobas e 411 analyzer	analyzer, system
cobas e 411 software	software

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 a user 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.

Symbols used in the publication

Symbol	Explanation
▶	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.
REF	Material reference number
	Search. Used on the search tab.
	Table of content. Used on the table of content tab.
	History. Used on the history tab to show previously viewed topics.
☆	Favorites. Used on the favorites tab and on the content panel.
	Enlarge. Button used on images.
	Settings. Button used to open the settings dialog.
	Contact. Used in the User Assistance. Functionality currently unavailable.

Symbols used in the publication

Symbols used on the analyzer

Symbol	Explanation
GTIN	Global Trade Item Number

Symbols used on the analyzer

Content icon

Symbol	Explanation
Cont.	Quantity in the package

Content icon

Abbreviations

The following abbreviations are used.

Abbreviation	Definition
AD	Amplification and Detection
ANSI	American National Standards Institute
CSA	Canadian Standards Association
EC	European Community
GNU	GNU's Not Unix
EN	European Standard
IEC	International Electrical Commission
IVD	In Vitro Diagnostic

Abbreviations

Abbreviation	Definition
LIS	Laboratory Information System
n/a	Not Applicable
QC	Quality Control
SD	Standard Deviation
13 mm sdta	13 mm sample disk tube adapter
SOP	Standard Operating Procedure
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 analyzer.

- Pay particular attention to all safety precautions.
- Always follow the instructions in this publication.
- Do not use the analyzer 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 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

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 good 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
- Follow good laboratory practices and regularly change lab gloves to minimize the risk of infection and contamination, especially after contact with waste or sample material.

Exposure to chemicals

- Avoid exposure to chemicals.

Exposure to infectious waste

Failure to place an appropriate waste container at the waste outlet can lead to exposure to infectious waste material.

- Always place a waste container at the waste outlet during operation.
- Follow good laboratory practices and regularly change lab gloves to minimize the risk of infection and contamination, especially after contact with waste or sample material.

Regular cleaning

To prevent inaccurate results and unsafe operation of the system:

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

Approved cleaning solutions

- Use only approved cleaning solutions for cleaning.

Errors in installation

Only trained Roche Service representatives may install the system.

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

Exchange or removal of parts

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

- Do not exchange or remove any part of the analyzer.
- Leave replacement of analyzer parts to trained Roche Service representatives.

Unsuitable environmental 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 always remain unobstructed.
- To maintain the environmental 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.

For the allowable environmental conditions, see the user documentation.

Non-approved spare parts

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

- Use only spare parts and devices approved by Roche Diagnostics.

Non-specified third-party software

Installation of third-party software is not approved by Roche Diagnostics and may result in malfunction.

- Do not install third-party software.

Non-specified consumables

Use of non-specified consumables can lead to incorrect results.

- Do not use consumables that are not intended for use with the system.

For a list of supported materials, see the user documentation.

Miscellaneous safety precautions overview

Power interruption

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

- It is recommended to use an uninterruptible power supply (UPS).
- Ensure regular maintenance of the UPS.
- Perform regular backup of results.
- Do not switch off power while the control unit accesses the hard disk or storage device.

Electromagnetic compatibility

This analyzer 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 device.
- Do not operate this analyzer in close proximity to sources of strong electromagnetic fields (for example unshielded intentional RF sources), as these may interfere with the proper operation.

The **cobas e** 411 analyzer complies with the emission requirements described in this part of the FCC CFR 47, Part 15 Class A.

System not used for an extended period

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

Damage in transit

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

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 work on any electronic equipment.
- Do not remove any cover of the system except those covers specified in the instructions.
- Do not open the top cover and touch the microbead mixer during operation, or when the analyzer is performing maintenance.
- Only Roche Service representatives may install, service, and repair the system.

Disconnecting power supply

Disconnecting the analyzer incorrectly from the mains power supply can cause an electric shock.

- Set the main circuit breaker switch to OFF, then remove all power supply cords. Rack systems can have more than one power supply cord.

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 good laboratory practices, especially when working with biohazardous material.
- Keep all covers closed while the system is operating.
- Wear appropriate personal protective equipment.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If sample or waste comes into contact with your skin, wash the affected area immediately with soap and water and apply disinfectant.
  Consult a physician.

Operator infection and injury

Contact with system mechanisms, for example, syringes, tubes, waste containers, reservoirs, S/R probe, sipper probe, rinse stations, or with the system chassis or covers, may result in personal injury and infection.

- Whenever possible, keep the top cover and the front cover of the system closed.
- Always ensure that the system is off, or in Maintenance mode or Shutdown status, before you work with an opened cover, for example, for cleaning or maintenance.
- Do not open the top cover while the system is performing maintenance.
- Make sure the covers are fully open to avoid hitting your head.
- Pay attention to the covers during automatic movement, check for obstructions and keep out of reach.
- Do not touch any parts of the system other than those specified.
- Never reach into the analyzer while parts are moving.
- Carefully observe all instructions given in this safety manual.

Sharp objects

Contact with probes may result in infection.

- When you wipe probes, use several layers of lint-free cloth 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. 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 emitting from the analyzer can lead to personal injury.

- If you see smoke coming from the analyzer:
  - Avoid inhaling
  - Disconnect the analyzer from the 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

Infectious waste

Contact with solid waste or waste solution may result in infection. All materials and mechanical components associated with 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 disinfectant.
- If waste comes into contact with your skin, wash the affected area immediately with soap and water and apply disinfectant.
  Consult a physician.

Environmental harm

The system generates liquid and/or solid waste. Liquid waste contains concentrated reaction solutions. 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 laws and regulations. Any substances contained in reagents, calibrators, and controls must be disposed of according to the relevant water discharge facility regulations.
- Contact the reagent manufacturer for information about the concentration of heavy metals and other toxic constituents of reagents, or for legal regulations on water discharge.
- Take extra care when pouring ProCell and CleanCell down the drain, as they may produce toxic gases. Run the tap continuously to ensure that the waste is diluted.

Caution messages

⚠ List of caution messages

- Before operation, 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 station can reach up to 85 °C.

- Avoid contact with hot surfaces inside the analyzer indicated with a warning label.
- Use caution near the heating station and sealing station following an emergency stop.
- Be careful if you open the analyzer covers after an analyzer error. Wait a few minutes to let the heating station cool down before you reach into the analyzer.

Mechanical safety

Damaged touchscreen monitor

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

- Do not touch the touchscreen monitor if it is visibly damaged.
- Contact your Roche Service representative.

Touchscreen monitor

Risk of personal injury when moving the touchscreen monitor towards the system housing. Your hand can be pinched between the touchscreen monitor and the housing.

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

Moving parts

Contact with moving parts may result in personal injury or damage to the analyzer.

- Keep all covers closed and in place while the system is operating.
- Always ensure that the system is off, or in Shutdown status, before you work with an opened cover, for example, for cleaning or maintenance.
- Do not touch any parts of the system except those parts specified. Keep away from moving parts during operation.
- Take care not to pinch your fingers or hand when closing the rack sampler cover.
- During operation and maintenance, carefully follow the instructions.
- Before you load or unload items on the reagent disk, sample disk or rack sampler, ensure that the analyzer is not in operation.

Loading and unloading racks and trays

Incorrect loading and unloading of racks and trays may damage the analyzer or cause operation to stop.

- When the analyzer is in operation, ensure that the light on the rack sampler is green before you load samples on the A-Line or unload samples from the C-Line.
- Do not add or remove single AssayCups and AssayTips to a tray when it is on the analyzer.

Reagents and other 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 for the test.
- 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 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 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 use a reagent pack or reagent bottle whose reagent has spilled.

Foam, clots, films, or bubbles

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

- Ensure good sample preparation and reagent handling techniques to avoid the formation of foam, clots, and bubbles in all reagents, samples, 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.

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.
- The system does not allow the use of expired reagents.

Incorrect results due to incorrect handling of reagents

Incorrect handling of reagents or other consumables may lead to incorrect results.

- Do not use reagents that were exposed to heat or to light for an extended time.
- Adhere to the storage conditions defined in the Instructions for Use for the reagents, controls, and consumables. Do not store reagents below 2 °C as the microbeads must not be frozen.
- Do not use reagents or consumables that have been dropped on the floor or compromised in any other way.
- Do not manipulate supplies in any way not specified in the user documentation or Instructions for Use.

Incorrect results due to incorrect handling of wash reagent, lysis reagent, or diluent in containers

Incorrect handling of wash reagent, lysis reagent, or diluent in containers may lead to incorrect results.

- Do not open the containers until they are ready for use on the analyzer.

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.

Incorrect use of barcode labels

Incorrect use of barcode labels may cause incorrect results.

- To prevent undetected barcode read errors, use barcodes with check digits.
- When you attach barcode labels to sample tubes, ensure they are readable.

Fatigue due to long hours of operation

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 laboratory's SOPs or local regulations.

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 the proper operation.
- Evaluate the electromagnetic environment before you operate the system.
- Take measures to mitigate the interference.
- Do not use the following devices in the same room as the analyzer:
  - Mobile phones
  - Transceivers
  - Cordless phones

Wireless interference

Wireless devices in the analyzer may lead to malfunction.

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

Data security

Data loss or unavailability of the system due to malicious software or unauthorized system access

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

To avoid infection by malicious software or the unauthorized access and misuse of the system, follow the recommendations below:

- Do not connect any unauthorized external storage devices, such as USB flash drives or external hard drives, to the system.
- Do not install and/or execute any other software on the system.
- Make sure other computers and services on the network, for example, the LIS, archiving share, or backup share, 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 might include 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 and part of the system.
- 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 and disaster, this includes: remote storage location; disaster recovery sites; secure transfer of backup files.

PC flash memory

The flash memory of the PC of the analyzer may degrade over time.

- If a message from the operating system on the PC indicates a problem with the flash memory, then contact your Roche service representative.

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 **cobas e** 411 analyzer 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.

Heat

Loss of results and reagents due to exposure to heat

Exposure to heat may cause the temperature inside of the system to rise. If the inside temperature is >37 °C or <2 °C, all reagents on board, and all currently measured results become invalid.

- Avoid heat sources close to the system.
- See the system specifications in the user documentation for the allowable environmental conditions.

Incorrect results

Incorrect results due to overfilling the sample tubes

Overfilling the sample tubes can lead to spillage during normal operation and result in contamination and incorrect results.

- Do not overfill sample tubes.

Instrument damage

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 your Roche Service representative.

Collision with moving parts

Contact with moving parts may bend the probes or damage other components. 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.

Damage to motorized parts

Manually moving motorized components while the power is on can damage them.

- Power off the analyzer before attempting to move any motorized components.

Damage to the measuring cell unit

Opening the detection unit cover while the power is on can damage the photomultiplier.

- Power off the analyzer before attempting to open the detection unit cover.

Damage to the system or consumables from organic solvents

Organic solvents may damage the system and consumables.

- Do not use organic solvents to clean or dry AssayCups, AssayTips, or the waste solution path.
- Do not use organic solvents, other than isopropyl alcohol or ethanol, for performing system checks or maintenance.

Damage to the system due to mechanical stress

Shock, vibration, or pressure can damage the system.

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

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 follow the applicable decontamination procedure. Wear appropriate personal protective equipment.
  Dispose of waste according to the local regulations.

Safety labels on the system

In this section

List of safety labels on the system

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

The safety labels on the system 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 system, there are safety notes in the corresponding parts of the user documentation.

Only Roche service personnel are to replace damaged labels. For replacement labels, contact your local Roche 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.

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

Moving parts
There is a risk of hand injuries from moving parts near this label.
Keep hands away from moving parts.

Laser transmitter
There is a danger of contact with laser light or severe damage to the eyes.
Do not stare into the laser transmitter.

Corrosive materials
There is a danger of contact with corrosive or caustic material.
Wear appropriate personal protective eye protection and gloves.

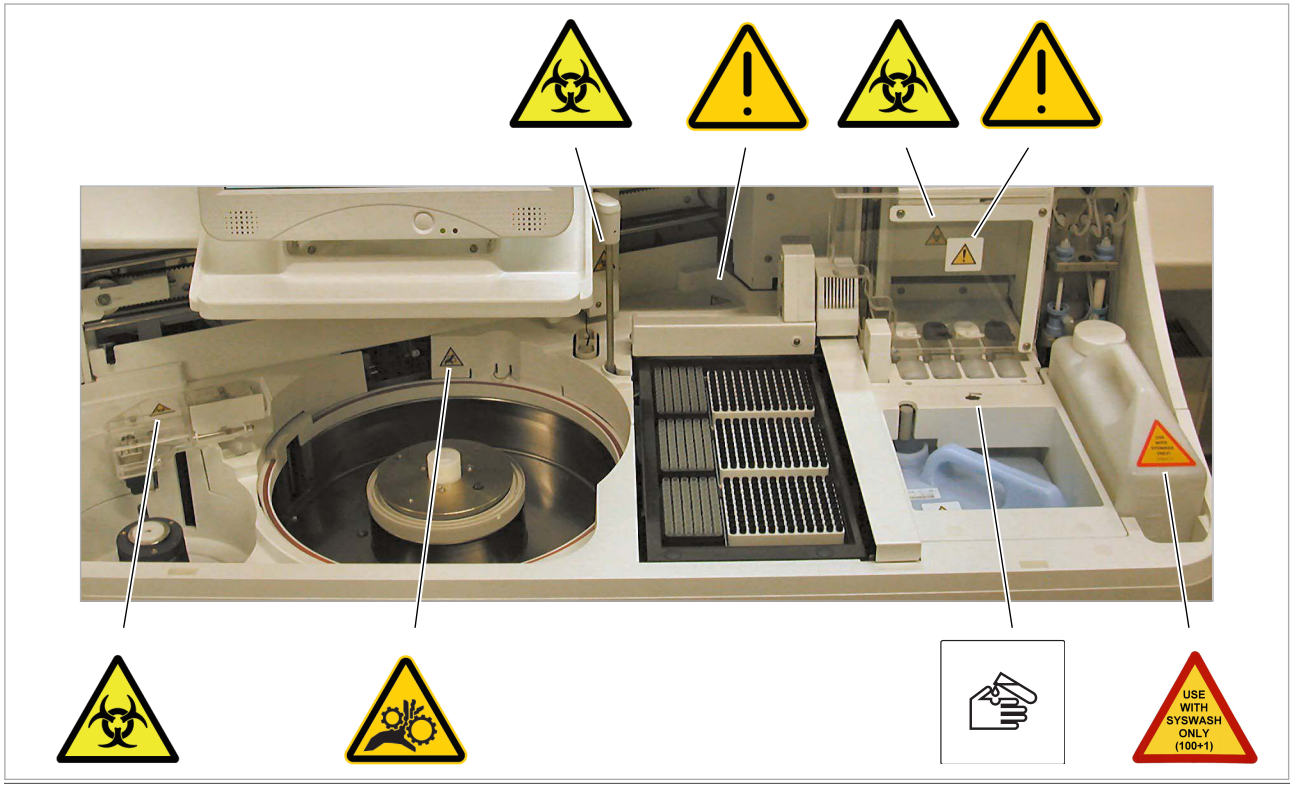
STAT rack orientation
There is a risk of damage to the system if the rack in the STAT port is inserted backwards.
Position the rack into the STAT port with the same orientation as on the label.

SysWash
Incorrect SysWash dilution could affect test results.
When refilling the system water container, add 35 mL of SysWash to the deionized water, for a 100+1 dilution ratio.

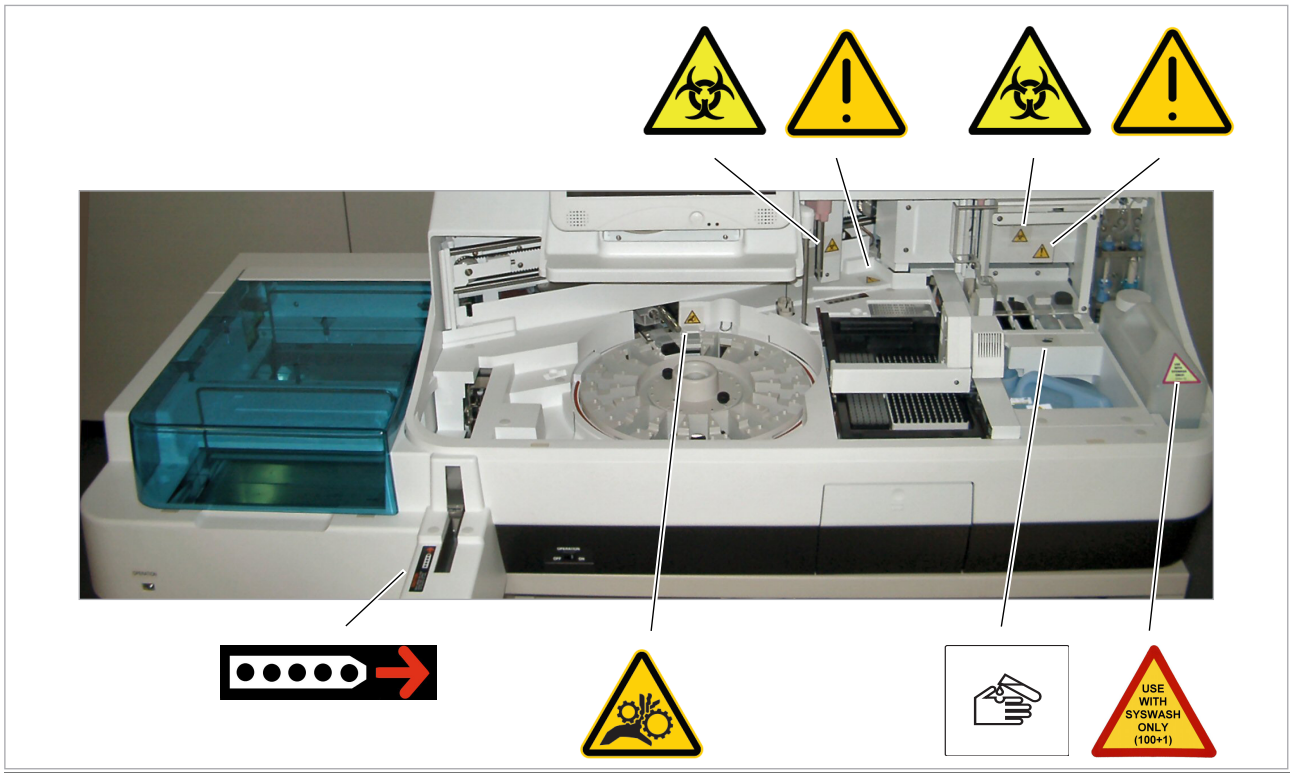
The safety messages give more detailed information about potentially hazardous situations that may arise during daily operation, or when carrying out maintenance actions.

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

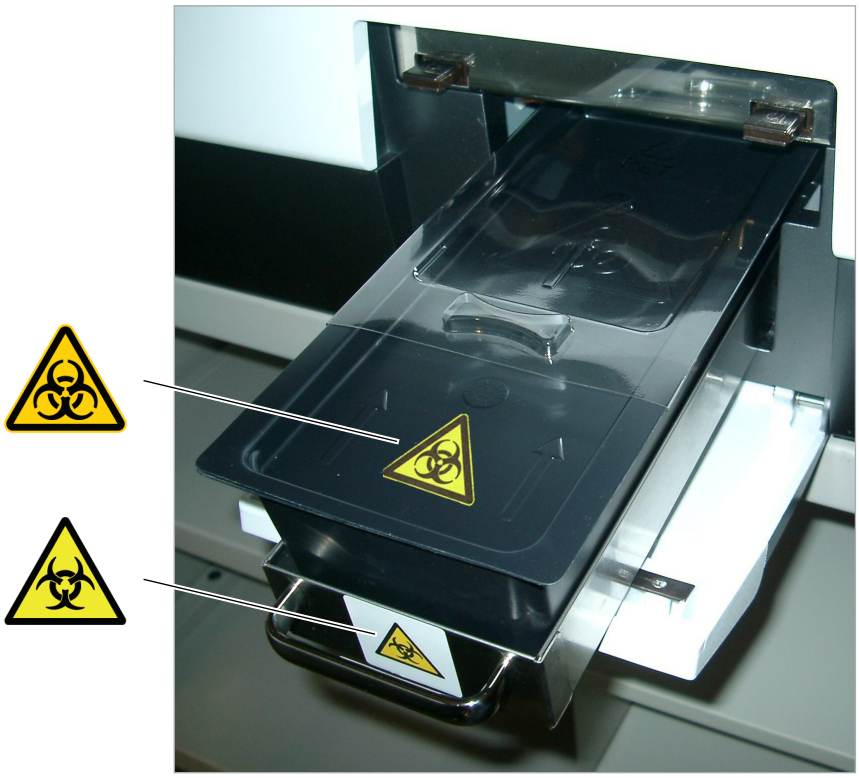
Location of safety labels on the system



Safety labels on the analyzer unit (disk system)



Safety labels on the analyzer unit (rack system)



Safety labels on the solid waste tray and Clean-Liner

Safety labels on the circuit breaker of the analyzer

Safety labels on the rack sampler circuit breaker

Safety information for lasers

The **cobas e** 411 analyzer has two laser barcode readers.

- A laser barcode reader (class B) is used to scan barcodes on primary sample tubes, calibrators, controls, and reagents.
- A laser barcode reader (class 2) is used to scan sample barcodes and rack ID barcodes.

Barcode reader

The barcode readers are class 2 laser products, lowest class.

The mentioned classes refer to the standard IEC 60825-1:

- Class 1: Eye-safe under normal operating conditions.
- Class 2: Visible lasers. Eye-safe for accidental viewing. It may not be safe to deliberately stare into the laser beam for longer than 0.25 s, overcoming the natural aversion response to the bright light.

Wavelength	Operating voltage	Max. output	Remark
650 nm	10-30 V(DC)	0.81 mW	Class 1 laser
655 nm	10-30 V(DC)	1.7 mW	Class 2 laser

Lasers on the system

Safety information for disposal

Infection by a biohazardous system

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

Electronic equipment

Disposal of electronic equipment
This symbol appears on any component of the system 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 system.