cobas e 411 analyzer

Safety Guide - Version 1.3
Software Version 03-02

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Publication information

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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.
1.3	03-02	June 2021	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.

Where to find information

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

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

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

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 e** 411 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 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 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 accessible place.

⚠ Incident reporting

- Inform your Roche representative and your local competent authority about any serious incidents which may occur when using this product.

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.

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 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 e** 411 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.

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.

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.

Complies with the provisions of the applicable EU regulations.

For *in vitro* diagnostic use.

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

Issued by CSA Group for Canada and the US.

Instrument approvals

Furthermore, the instrument is manufactured and tested according to the following international safety standards:

- IEC 61010-1
- IEC 61010-2-101

The instrument complies with the emission and immunity requirements described in standard IEC 61326-2-6/ EN 61326-2-6.

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
68305 Mannheim
Germany

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.

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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 and intended purpose

Intended use for US only

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.

Supporting information for US only

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

Intended purpose for EU/EFTA and outside US

The **cobas e** 411 analyzer is an automated analyzer including software, intended for running qualitative, semi-quantitative and quantitative immunochemistry assays.

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; additionally, the device can be used to run companion diagnostic tests.

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, oral fluid, hemolysate 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 e 411 analyzer	analyzer, system
cobas e 411 software	software

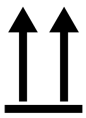
Product names

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.
	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 products

Symbol	Explanation
GTIN	Global Trade Item Number
	Consult instructions for use on this website: *www.dialog.roche.com*
Cont.	Quantity contained in the package
CONTENT	Quantity contained in the package
Prod. Order	Product order
SN	Serial number
	Date of manufacture
	Manufacturer
	Orientation of the package during transportation
EC REP	Authorized representative in the European Community
	Indicates the entity importing the medical device into the European Union
RoHS	Complies with the directives on the restriction of hazardous substances

Symbols used on products

Symbol	Explanation
	Unique device identifier
	Indicates that the equipment is suitable foralternating current only
	Catalogue number
	Lot number
	Single use
	Use by date
	Humidity limit
	Temperature limit
	Caution

Symbols used on products

Abbreviations

The following abbreviations are used.

Abbreviation	Definition
AD	Amplification and detection
ADC	Analog-digital converter
ANSI	American National Standards Institute
CFR	Code of Federal Regulations
CSA	Canadian Standards Association
CSV	Comma-separated values
CV	Coefficient of variation
DIL	Diluent
EC	European Community
ECL	Electrochemiluminescence
EFTA	European Free Trade Association
EN	European standard
EU	European Union
FCC	Federal Communications Commission
GNU	GNU's Not Unix!
HIS	Hospital information system
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
IVD	In vitro diagnostic
IVDR	In vitro diagnostics regulation: Regulation (EU) 2017/746
LIS	Laboratory information system
LLD	Liquid level detection
n/a	Not applicable
PSM	Pre-analytics system manager
QC	Quality control
RoHS	Restriction of Hazardous Substances
SD	Standard deviation
sdta	Sample disk tube adapter
SLLD	Sample liquid level detection
SOP	Standard operating procedure
STAT	Short turn-around time
UL	Underwriters Laboratories Inc.
USB	Universal serial bus
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.

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 external 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.

- Insert or remove a DVD only 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.

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

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 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 guide.

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.

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.

Analyzer 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.

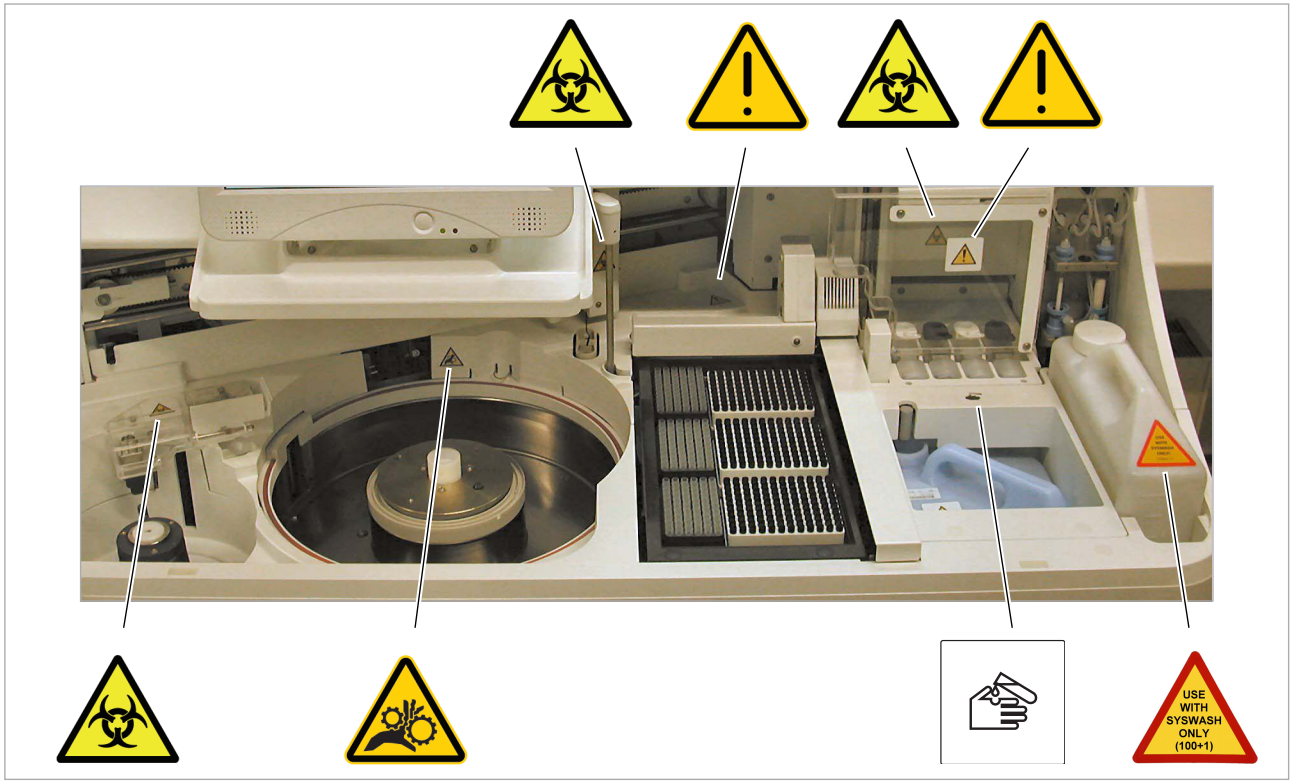
STAT rack orientation
There is a risk of damage to the system if the rack in the STAT port is inserted backwards.
Position the rack into the STAT port with the same orientation as on the label.

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.

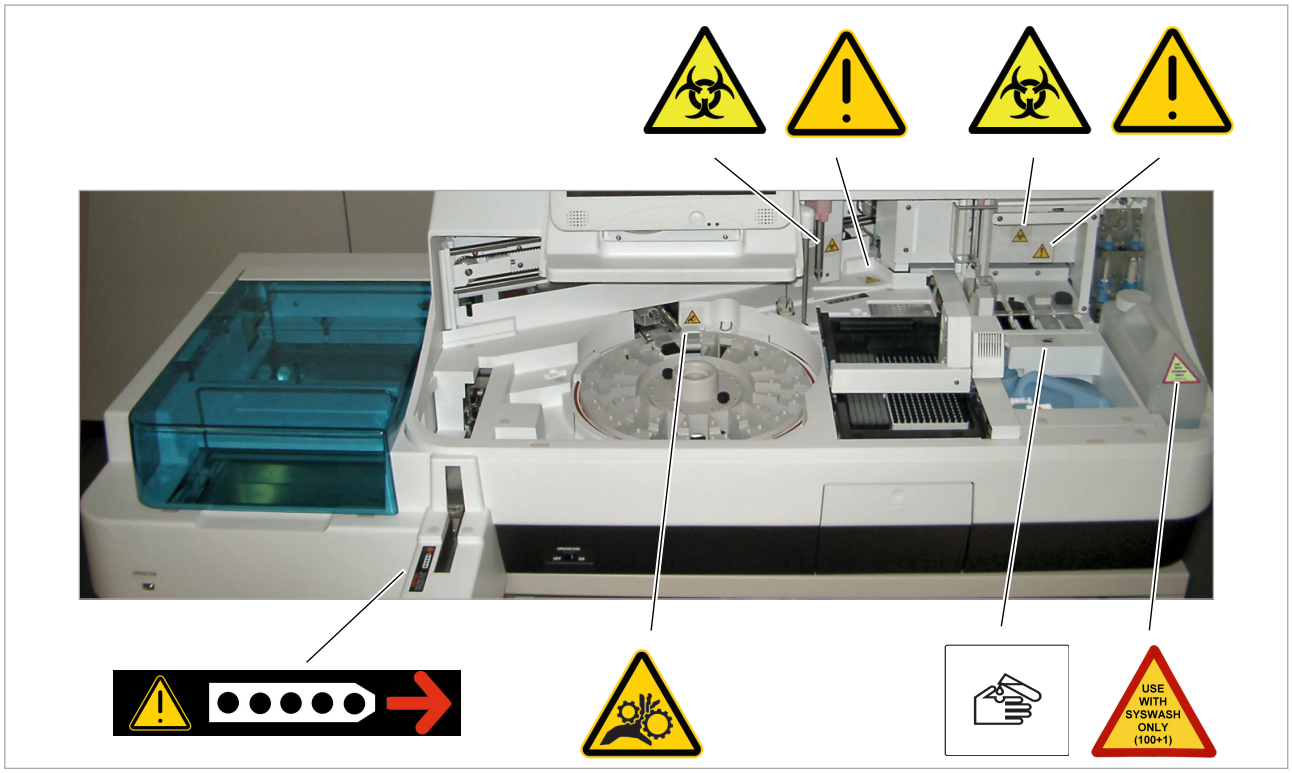
The safety messages give more detailed information about potentially hazardous situations that may arise during daily operation, or when carrying out maintenance actions.

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

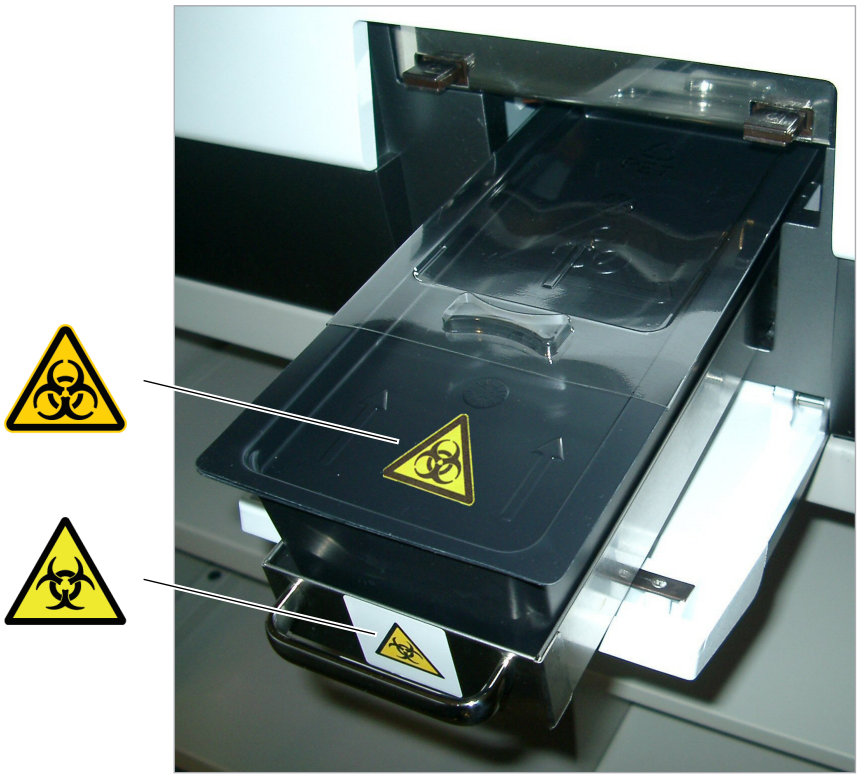
Location of safety labels on the system



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 label on the circuit breaker of the analyzer

Safety labels on the circuit breaker of the analyzer (rack system)

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 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.

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.