cobas® t 711 coagulation analyzer

Safety Guide version 6.0
Software version 2.3

Publication information

Publication version	Software version	Revision date	Change description
1.0	1.0	March 2017	• Initial version
1.1	1.0	July 2017	• Updated safety messages
2.0	2.0	August 2018	• Revised for software 2.0 • Update safety labels on the sample area and on the fluid tray
2.1	2.0.2	March 2019	• Update for maintenance action "Cleaning probe assembly" • Update for **cobas**® t development channel cassette handling
3.0	2.1	August 2019	• New work area implemented - Sample and results • New QC initial run type settings • New illustration concept

Revision history

Publication version	Software version	Revision date	Change description
4.0	2.1.1	September 2020	• IVDR Compliance to the Regulation (EU) 2017/746 • Backup system procedure • New safety messages • Handling tubes • Maintenance videos
5.0	2.2	August 2021	• Data alarm detail information • New data alarm • New data upload options • New backup options • Update **E-library** workflows • Update e-barcode handling • Update for LIS security • Encryption at rest - the usage of an encrypted external storage device is recommended. • Specifications for **cobas**® t 711 connection module implemented • Specifications for open tube handling implemented • Cleaning the conductive 5-position rack • Update for cuvette transport troubleshooting
6.0	2.3	March 2023	• Update illustrations that showed wrong information • Update the cleaning of the conductive 5-position rack task • Update list of maintenance actions • New interactive help for replacing a syringe and syringe plunger • New import for a copied CSV file into MS Excel • Update rack release time for QC racks • Open orders cancellation • Syringe for reagent reconstitution • Workflow priority for automated reagent cassette reconstitution • Mandatory Roche special wash rule updates • About the HIL-dependent test result comment • Improved weekly maintenance workflow • QC measurements for calculated tests • QC initial run type • Second measurement unit definition • Correct data alarm information • Configurable data alarm for sample clot or probe blocked For more details, see the section: What is new in publication version 6.0 (19)

Revision history

Edition notice

This publication is intended for operators of the **cobas**® t 711 coagulation 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** contains all information about the product, including the following:

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

The **User Guide** focuses on routine operation and maintenance. The content is organized according to the normal operation workflow.

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

The **Quick Reference Guide** focuses on routine operation. The **Quick Reference Guide** is organized according to the normal operation workflow. It provides information in a concentrated version. For more detailed information, refer to the **User Guide** or the **User Assistance**.

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.

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

eLabDoc

Electronic user documentation can be downloaded using the eLabDoc e-service on the Roche navify Portal:

navifyportal.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**® t 711 coagulation analyzer User Guide or User Assistance.

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

Intended use

The **cobas**® t 711 coagulation analyzer is a fully automated, discrete coagulation analyzer intended for the *in vitro* qualitative and quantitative determination of coagulation analytes in human citrated plasma, the results of which aid in the diagnosis of coagulation abnormalities and in monitoring anticoagulant therapy.

The **cobas**® t 711 coagulation analyzer is a standalone instrument and can also be connected to laboratory automation systems.

Intended use for IVD accessories

	The Intended use of accessories might be not always limited to the **cobas**® t 711 coagulation analyzer.
Insert Sarstedt 8 mm Tube	Rack insert to handle small volume sample tubes on the **cobas**® t 711 coagulation analyzer.

Symbols and abbreviations

Product names

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

Product name	Descriptor
System software for **cobas**® t 711 coagulation analyzer	software
cobas® t 711 coagulation analyzer	analyzer
System Cleaner **cobas**	System Cleaner
HIL Test	HIL test

Product names

Abbreviations

The following abbreviations are used.

Abbreviation	Definition
ANSI	American National Standards Institute
CFR	Code of Federal Regulations
CISPR	*Comité International Spécial des Perturbations Radioélectriques* (International Special Committee on Radio Interference)
FCC	Federal Communications Commission
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
IVD	*In vitro* diagnostic
IVDR	*In vitro* diagnostics regulation
SOP	Standard Operating Procedure

Abbreviations

Introduction

⚠ General attention

To avoid serious or fatal injury, read this publication thoroughly before running 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.
- 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 a user, 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.
- Observe laboratory best practices, especially when you work with biohazardous material.

About safe and proper use of the system

Correct usage

Using the instrument in a way not described by the manufacturer, can impair the protection provided.

- Do not use the analyzer in a way that is not described in the user instructions.

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.

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 lab coat
  - Approved lab gloves
  - Face shield if there is a chance of splashing or splattering
- Follow laboratory best practices and regularly change lab gloves to minimize the risk of infection and contamination (especially after contact with waste or sample material).

Regular cleaning

To prevent inaccurate results and unsafe operation of the system:

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

See section *Cleaning and decontamination* in the user documentation.

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 instrument unless instructed to do so.
- Leave replacement of other instrument 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.

See *Environmental conditions* in 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 analyzer.

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

Factor parallelism analysis

- When performing factor parallelism analysis, you must take full responsibility for test results and validate the test data yourself.

Miscellaneous safety precautions overview

Electromagnetic compatibility

The **cobas**® t 711 coagulation analyzer complies with the emission and immunity requirements described in this part of the IEC 61326-2-6 series.

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

Electromagnetic compatibility (32)

System not used for an extended period

- Follow the procedure for shutting down the analyzer for an extended period.
- Remove and refrigerate any remaining reagents and QC materials.
- For further information, contact your Roche Service representative.

See *Shutting down the analyzer for an extended period* in the user documentation.

Damage in transit

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

Software update

Note the following when updating the system software from version 1.0 to version 2.0:

- Perform calibration and QC measurements for all applications before measuring new test results.
- The following consumables can be reused following a software update:
  - Reagent containers (original but not open reagent bottles)
  - Other containers (diluent or special reagent)
  - Calibrators
  - QC materials
  - Consumables (cleaning solutions, cuvettes, water)
- For applications with lot calibration for software version 1.0 and cassette calibration for software version 2.0, the lot calibrations are not visible on the user interface.
- The format in which the e-barcode version number is displayed in the e-library has changed.

User-defined tests

Roche assumes no responsibility for the correctness of user-defined tests.

- When adding additional dilutions to a test, you must manually validate and release the results.

Related topics

- Disposal information (43)

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

Power interruption

A power failure or momentary drop in voltage can damage the system, interfere with reagent cooling, or lead to data loss.

- To ensure system performance according to the specification, correct reagent cooling, and data integrity, only operate the system with an uninterruptible power supply (UPS). Operation outside of the specified ranges may lead to incorrect results.
- Ensure periodic maintenance of the UPS.
- Regularly backup results.

Electric shock

Risk of personal injury due to electric shock if covers are left open or when touching power supply components during operation.

- Do not remove any cover of the system except those covers specified in the instructions.
- Do not touch power supply components during operation.
- Do not attempt to work on any electronic equipment.
- Only Roche Service representatives are permitted to install, service, and repair the system.

Related topics

- List of safety labels on the analyzer (35)

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 laboratory best 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 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.

User infection and injury

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

- Whenever possible, keep the main cover closed.
- Be careful not to hit your head when the cover is open.
- Pay attention to the main cover during automatic movement of analyzer parts, check for obstructions and keep out of reach.
- Do not touch any parts of the system other than those specified.
- Never reach into the instrument while parts are moving.
- Carefully observe all instructions given in this publication.

Contact with probes

Contact with probes may result in injury and infection.

- Avoid touching the end of the reagent probes and sample probes.
- Avoid contacting the reagent probes and sample probes during operation.
- When cleaning near the probes or replacing probes, 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.

Contaminated sample tubes, racks, and surfaces

Contact with contaminated sample tubes, sample racks, loading positions, and internal surfaces may result in infection.

- Use caution when loading sample tubes.
- Use caution when handling sample racks, loading positions, and internal surfaces.
- Wear appropriate personal protective equipment.

Splashed sample

Contact with splashed sample may result in infection.

- Use caution when cleaning the analyzer surfaces in the sample pipetting area.
- Wear appropriate personal protective equipment.

Contaminated incubator and analyzer area

Contact with contaminated incubator and analyzer area may result in infection.

- Use caution when cleaning the incubator and analyzer area.
- Wear appropriate personal protective equipment.

Rinse mechanism malfunction

Malfunction of the rinse mechanism may result in direct contact with sample and infection when replacing a probe.

- Use caution when replacing probes.
- Wear appropriate personal protective equipment.

Smoke due to electrical malfunction

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

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

Electromagnetic interference

Electromagnetic interference

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

- Evaluate the electromagnetic environment before you operate the system.

Electromagnetic compatibility

The system is tested and complies with international EMC requirements. Operating the system in environments exceeding the EMC requirements can expose the analyzer to harmful interference and impact performance.

- Do not operate this system in close proximity to sources of strong electromagnetic fields (for example, unshielded intentional RF sources).
- Evaluate the electromagnetic environment before you operate the system.
- Take measures to mitigate the interference.

Mechanical safety

Main cover

Risk of personal injury when closing the main cover. Your fingers can be pinched between the main cover and the housing.

- Use caution when closing the main cover.

Moving parts

Contact with moving parts of the incubator, analyzer, transfer arms, sample probes, or reagent probes may result in personal injury.

- Keep all covers closed and in place while the system is operating.
- Do not touch any parts of the system except those parts specified. Keep away from moving parts during operation.
- During operation and maintenance, carefully follow the instructions.
- Observe all safety labels on the analyzer.

Hot surfaces

Risk of personal injury due to touching hot surfaces in the analyzer.

- Use caution near the heated reagent probe. If it is necessary to handle the heated reagent probe, allow time for it to cool down.
- Observe all safety labels on the analyzer.

Racks

Delayed results due to system crash caused by rack wedging on the sample balcony

During peak throughput conditions, system vibration can result in racks becoming wedged on the sample balcony. This can lead to a system crash, causing a delay in results.

- Ensure that racks cannot become wedged in the rack trays on the sample balcony.
- Loosely fitting, wobbly racks are more prone to wedging. Ensure that racks can move freely on the rack trays, but are not wobbly.
- During peak throughput conditions, regularly check the sample balcony to ensure that racks do not become wedged.

Reagents and other working solutions

Carryover due to damaged glass reagent bottles

If a reagent cassette contains damaged reagent bottles, carryover can occur during reagent mixing, leading to incorrect results.

- Ensure that reagent bottles are intact by performing an acoustic check. Manually shake the reagent cassette and listen for any sign of broken reagent bottles.

Incorrect results due to calibration with mixed calibrator material lots

Using different calibrator lots in a single calibration can lead to incorrect results.

- Do not mix different calibrator lots for a single calibration, also for repeat point measurement.
- Visually control the calibration result and graph prior to release. Check the list of used materials.
- Use caution when preparing a calibrator material for measurement and pay particular attention when attaching barcode labels to secondary tubes for calibrators.

Foam, clots, films, or air bubbles

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

- Ensure good sample preparation and reagent handling techniques to avoid the formation of foam, clots, and air bubbles in all reagents, samples, and QC materials.
- Check that there is no foam in calibrator tubes, QC tubes, or sample tubes.
- Make sure that the samples contain no insoluble contaminants, such as fibrin or dust.
- Ensure that no air bubbles are aspirated into the sample pipetting mechanism.

Viscous samples

Delayed results may occur due to samples with viscosity higher than normal. In such cases the systems triggers Samp.C data alarm.

- For sample with Samp.C data alarm please check for viscosity higher than normal.
- For sample with viscosity higher than normal, choose a manual method as a workaround.

Incorrect results due to insufficient sample volumes

Pipetting samples with insufficient volumes can lead to coagulum being aspirated and incorrect results.

- Ensure that there is enough plasma in the sample tube.
- When performing high numbers of measurements from the same sample material (e.g., for precision studies), use a secondary cup on tube.

Evaporation of samples or reagents

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

- If left open, sample material may evaporate. 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, calibrators, or QCs.

System water leakage in sample pipetting mechanism

System water leakage in the sample pipetting mechanism can lead to incorrect results.

- Regularly perform QCs and visual checks for system water leakage.

Incorrect results due to incorrect handling of reagents, QCs, calibrators, or consumables

Incorrect handling of reagents, QCs, calibrators, or consumables may lead to incorrect results.

- Only load cassettes as described in the user documentation.
- Opening and closing a sample tube, QC tube, or calibrator tube can influence the inside pressure. Use caution when opening and closing tubes.
- Do not use reagents, QCs, calibrators, or other consumables that were exposed to heat or to light for an extended time.
- The system does not support the use of expired reagents, calibrators, or QCs.
- Adhere to the storage conditions defined in the *Instructions for Use*.
- 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 using expired reagents, QC materials, and calibrators

Using expired reagents, QC materials, and calibrators can lead to incorrect results.

- The system does not support the use of expired reagents, QC materials, and calibrators.
- Do not change the QC expiry date. Changing the expiry date can lead to incorrect QC evaluation and the responsibility for any consequences of doing so falls entirely on the operator.

Exchanging reagent cassettes between systems

Exchanging reagent cassettes between systems can lead to incorrect results and is not supported.

- Do not exchange reagent cassettes between systems.
- If using multiple analyzers in the laboratory, mark the labels of any unloaded reagent cassettes to avoid reloading the reagent cassette onto another instrument.

Incorrect results due to hemolysis, icterus, and lipemia

The presence of hemoglobin, bilirubin, and lipids in the sample can affect the result quality.

- Ensure good sample preparation and handling techniques.

Multiple analyzers: Reagent cassettes

- Never load the same reagent cassette onto more than one analyzer.
- If there are multiple analyzers in the same laboratory, manually mark unloaded reagent cassettes such as follows:
  - Instrument:
  - Operator:
  - Date/Time:

Quality controls

- To ensure correct results, perform QCs regularly.

Reagent probe/flow path

Incorrect cleaning or rinsing of the probe/flow path of the reagent pipetting mechanism can lead to incorrect results.

- Perform QCs regularly.

Sample carryover

Sample or rinse water carryover in the pipetting mechanism can lead to incorrect results.

- Regularly check instrument performance to prevent incorrect results due to carryover.

Sample preparation and sample integrity

Incorrect sample preparation can cause sample integrity issues, contaminated probes, or false sample tube filling volumes, leading to incorrect results.

- Observe relevant laboratory best practices for preparing samples.
- During the sample preparation process, perform a check for any sample integrity issues.

Sample tube filling volume

Incorrect filling volume can lead to incorrect results.

- Perform a visual check to ensure correct sample tube filling volume.

Empty water containers

Performing maintenance actions with empty water containers can cause air in the fluid system leading to wrong results.

- Before performing maintenance actions, ensure that at least one water container is full.
- If air in the fluid system is detected, you must perform the **Fill fluid system** maintenance action.

Waste

Infectious waste

Contact with liquid waste or solid waste 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.

Liquid waste tubing clogging

Risk of infection due to contact with liquid waste when removing clogging in the liquid waste tubing.

- Use caution when unclogging the liquid waste tubing.
- Wear appropriate personal protective equipment.

Solid waste bags

Attempting to empty and reuse solid waste bags can result in spillage. Spilled solid waste can lead to contamination, risk of slipping, and risk of personal injury during instrument cleanup.

- Do not attempt to empty and reuse solid waste bags.
- When disposing of solid waste, dispose of the entire bag.

Environmental harm

The system generates liquid and solid waste which is potentially biohazardous. Improper disposal may contaminate the environment.

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

Related topics

- List of safety labels on the analyzer (35)
- Disposal information (43)

Data security

Data loss or unauthorized access to system data

Unsecured system backup and archive files can result in data loss or unauthorized access to system data.

- Make sure that system backup and archive files exported by the system are physically secured and are protected from any unauthorized access.

Data loss due to a database crash

A database crash may lead to reagent loss and a potential result delay.

- n/a

Aged or damaged hard disk

Age or damage to the hard disk caused by power failure or incorrect usage (e.g. incorrect system shutdown) can lead to incorrect results.

- Use an uninterruptible power supply (UPS).
- Avoid shutting off the main power switch while the analyzer is operating.
- Take care when restarting or reinitializing the system.
- Regularly backup database.

Patient sensitive information

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

Do not write any patient-sensitive information into the following fields:

- Sample-level comments
- Result-level comments
- QC result comments
- Calibration result comments
- Calibration measurement point comment
- Sample ID field, or any other field

Replacing a heated reagent probe

Heated reagent probes must be tight to avoid carry-over and ensure correct results

⚠ WARNING

Incorrect results due to insufficiently tightened heated reagent probe

An improperly tightened heated reagent probe can cause carryover and thus incorrect results.

- Apply the maximum reasonable force you can apply with the fingers (as tight as possible without causing pain in the finger). Do not worry about applying force, nothing will break.

Caution messages

⚠ List of caution messages

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

In this section

Mechanical safety

Damaged touch screen monitor

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

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

Open drawers

Risk of personal injury by tripping over open drawers.

- When leaving the instrument for an extended time, ensure that all drawers are closed.

Sample balcony

Placing heavy loads or sitting on the sample balcony can damage the analyzer.

- Do not place any heavy loads or sit on the sample balcony.

Slippery surfaces due to condensation

Risk of personal injury due to slipping on wet surfaces caused by condensation.

- Use caution if condensation water is present.
- Take measures to prevent any condensation water from accumulating on the floor.

Related topics

- List of safety labels on the analyzer (35)

Reagents and other working solutions

Skin inflammation or injury

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

Eye irritation or injury

Contact with fumes from evaporating reagents or cleaning solutions can lead to eye irritation or injury.

- 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 Safety Data Sheets (available for Roche Diagnostics reagents and cleaning solutions).
- If fumes from reagents or cleaning solutions come into contact with your eyes, thoroughly rinse your eyes with water immediately and consult a physician.

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 cassette or reagent bottle whose reagent has spilled.
- Do not decant leftover reagent from two or more reagent cassettes.

Incorrect results due to reuse of consumables

Reuse of consumables can lead to contamination, resulting in a false positive result.

- Do not reuse consumables.

Incorrect results due to overfilling sample tubes, calibrator tubes, and QC tubes

Overfilling sample tubes, calibrator tubes, or QC tubes can lead to spillage during routine operation and result in contamination and incorrect results.

- Do not overfill sample tubes, calibrator tubes, or QC tubes.

Incorrect results due to reuse of sample tubes, calibrator tubes, and QC tubes

Reuse of sample, QC, or calibrator tubes can lead to contamination, resulting in an incorrect result.

- Do not reuse tubes.

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.

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, the following recommendations are essential:

- Ensure that any external storage devices (such as USB flash drives or external hard drives) connected to the system are free of malicious software.
- Do not install and/or execute any other software on the system.
- Make sure other computers and services on the network (e.g., the LIS, archiving share, backup share, or service) are properly secured and protected against malicious software and unauthorized access.
- Ensure that attached networks are secure. Customers are responsible for the security of their local 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.).

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.

- Prevent credential theft:
  - Use strong passwords.
  - Do not share passwords.
  - Do not write down passwords.
  - Do not use the same credentials on multiple instruments.
  - Do not share user accounts.
- Make sure that system backup and archive files are physically secured and are protected from any unauthorized access and disaster. This includes: remote storage location; disaster recovery sites; secure transfer of backup files.

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

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 up, do not attempt to operate the system before contacting your Roche Service representative.

Electromagnetic compatibility

Class A equipment (industrial areas)

- The **cobas**® t 711 coagulation analyzer has been designed and tested to CISPR 11 Class A. In a domestic environment this may cause radio interference, in which case you may need to take measures to mitigate the interference.

Mechanical stress

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.
- Do not apply excessive force to instrument parts.

Temperature

Loss of results and reagents due to exposure to heat

Exposure to heat may cause the temperature inside of the system to rise.

- Avoid heat sources close to the system.

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

  Decontamination procedures are described in the *Decontamination* section in the user documentation.

Maintenance

Log off during maintenance

Logging off during maintenance can lead to system errors.

- Do not log off or shut down the analyzer during maintenance.

Data security

External storage device

Disconnecting external storage devices from the system during writing process can lead to data loss.

- Only disconnect external storage devices after performing the safe removal process on the operating system.

Safety labels on the analyzer

In this section

List of safety labels on the analyzer

Safety labels are placed on the system to draw your attention to areas of potential hazard. Labels and definitions referring to the location on the system are listed below.

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 representatives are permitted to replace damaged labels. For replacement labels, contact your local Roche representative.

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

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 laboratory best practices 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 user documentation for instructions on safe operation.

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

Important information
Read the operating instructions before handling.

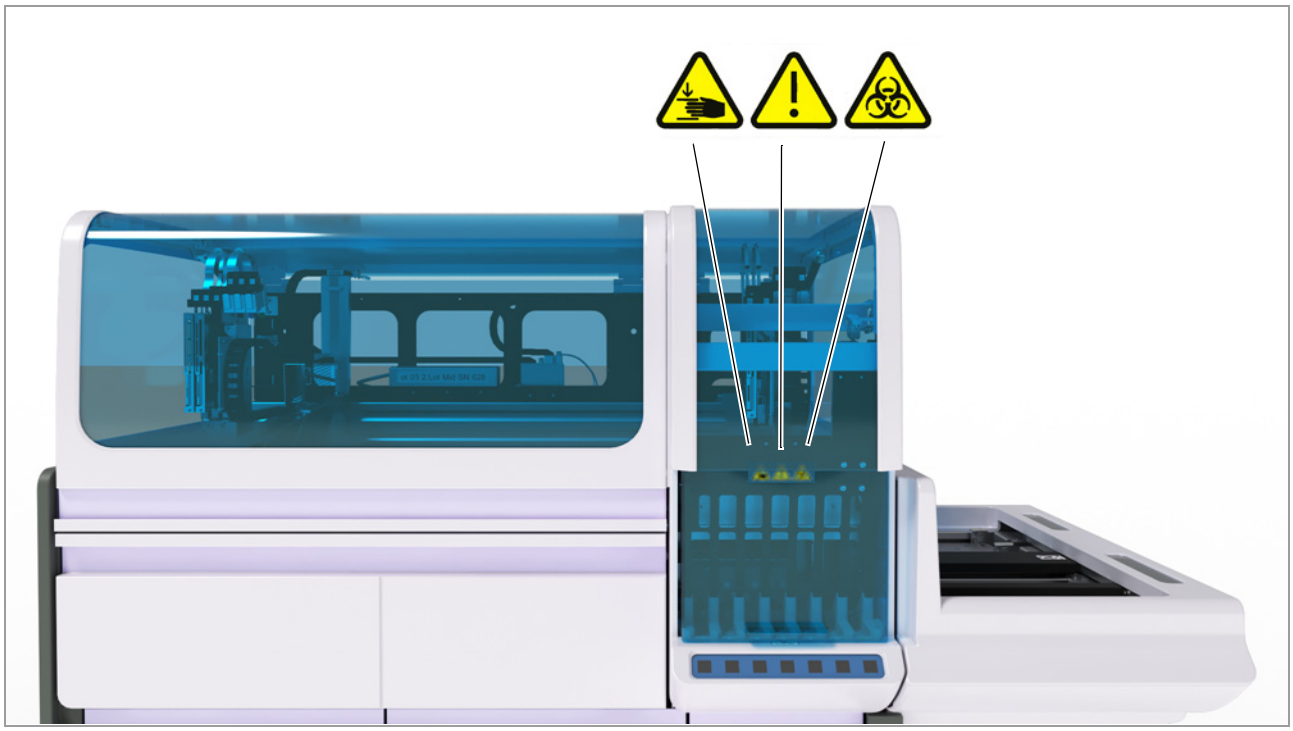
No heavy loads
Placing a heavy load in this location can result in damage to the analyzer. Observe the upper load limit indicated next to the label.

Safety messages and safety labels

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 analyzer

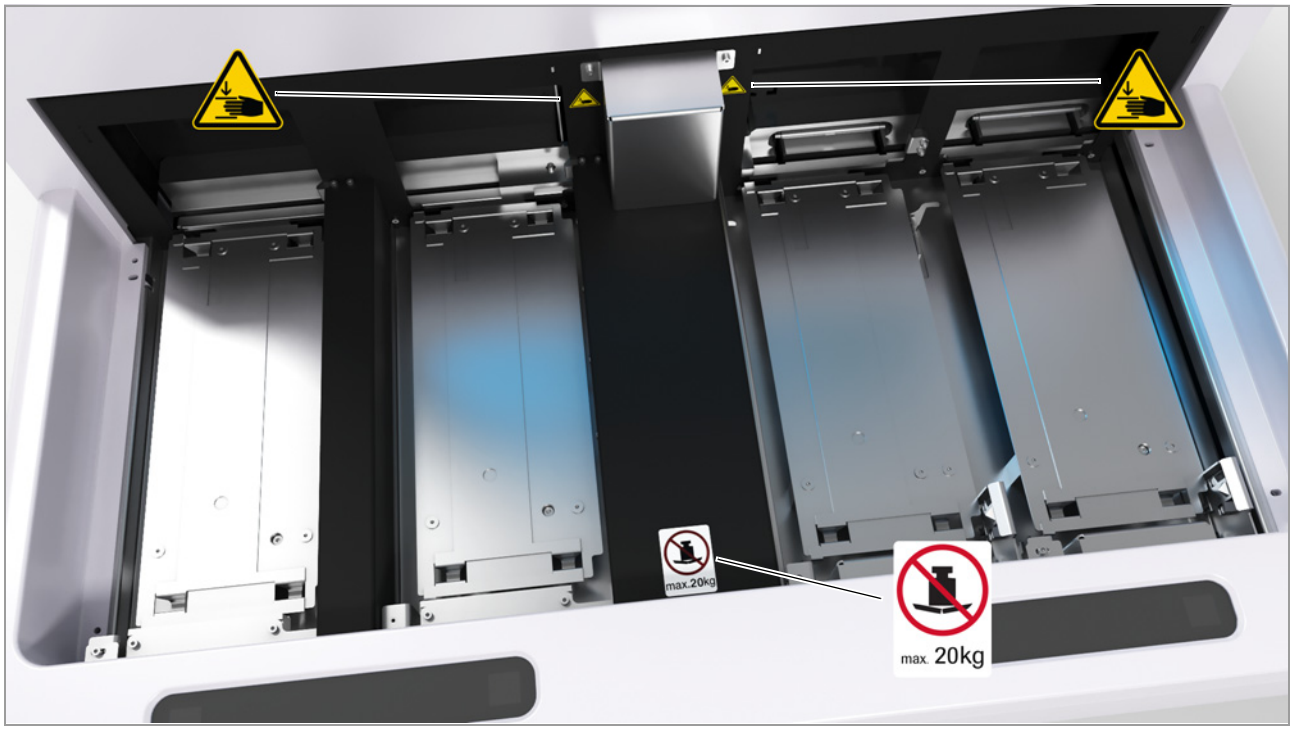


Front view

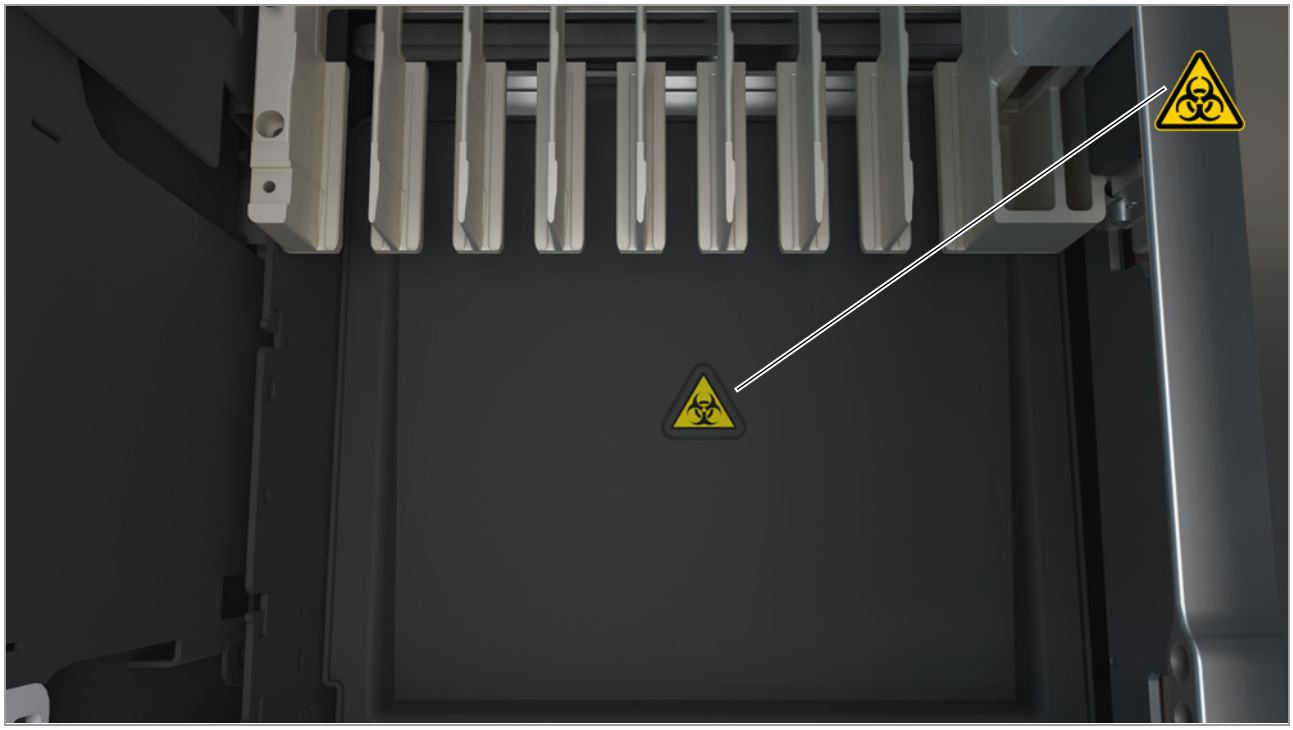
⚠ WARNING

Risk of damage to the analyzer or spillage due to overheight tube.

- Only use specified tubes.
- Place the tubes containing the calibrator, QC, or sample into the appropriate racks.

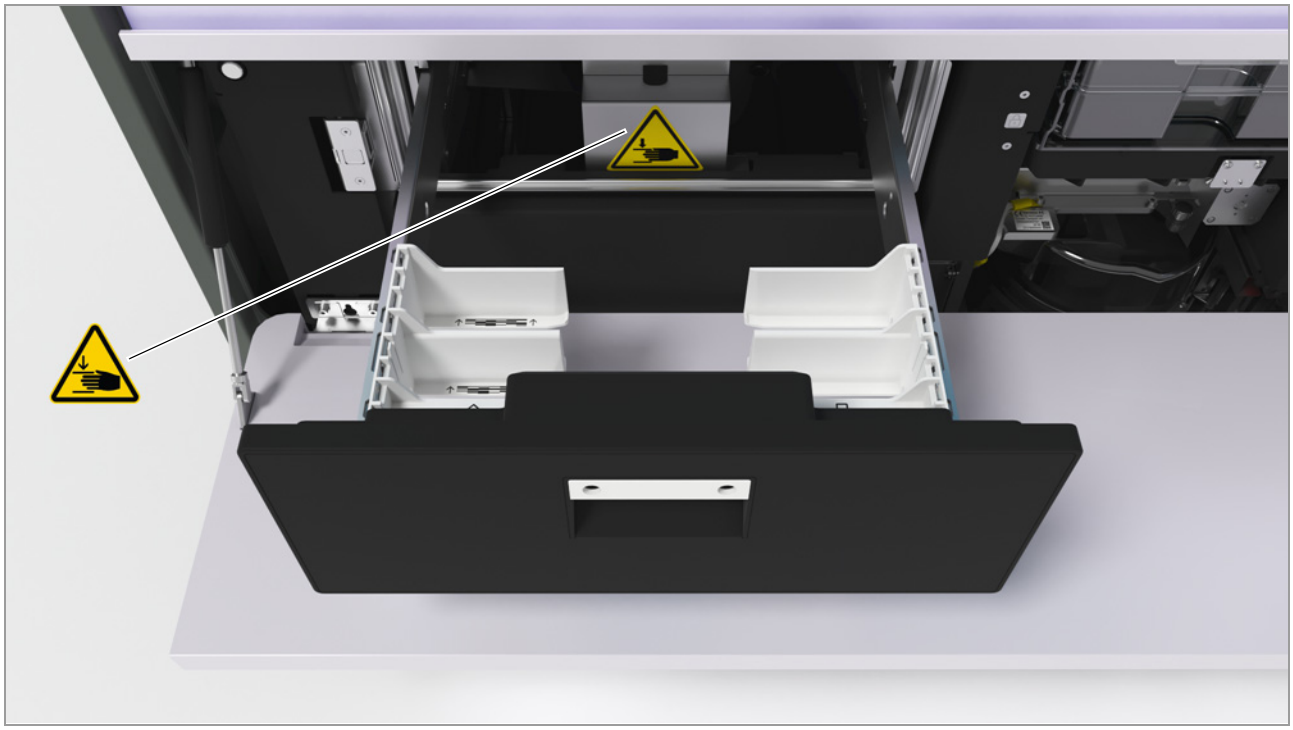


Sample balcony view

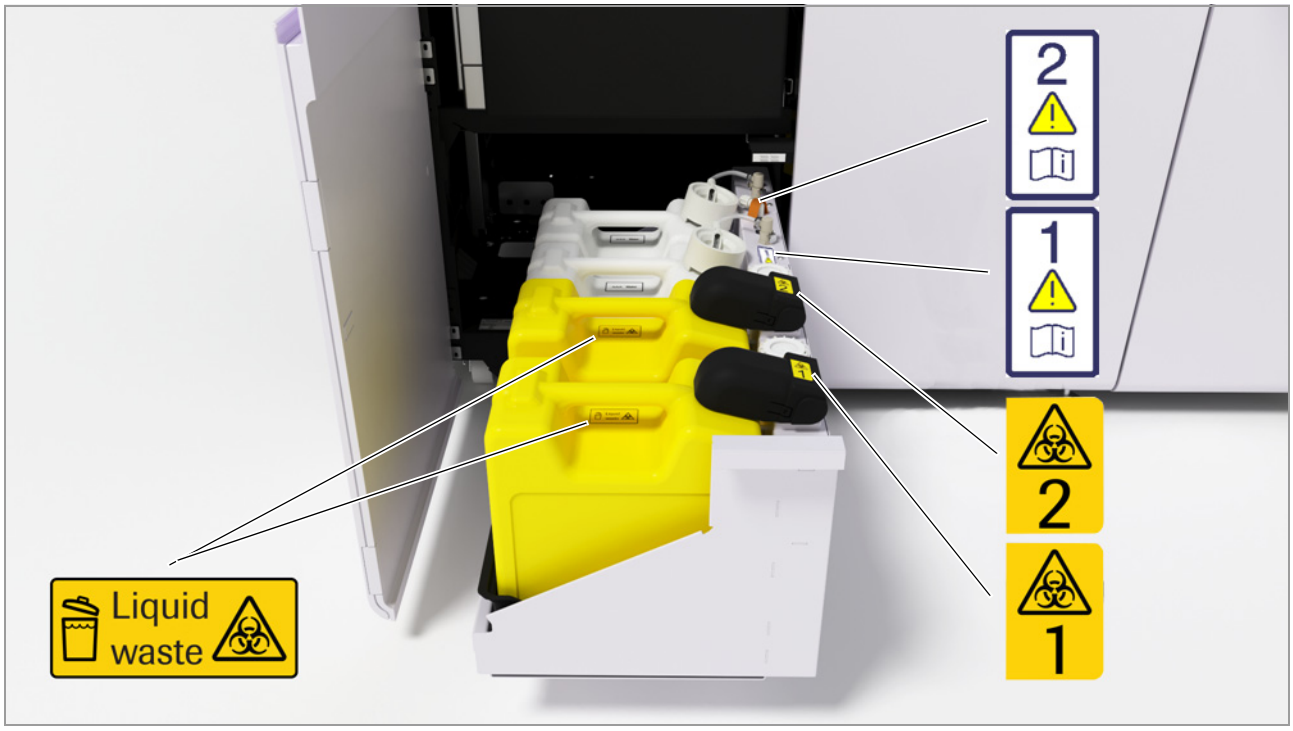


Rack platform

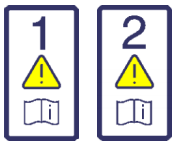
Front panel



Reagent cassette drawer



Water/liquid waste drawer

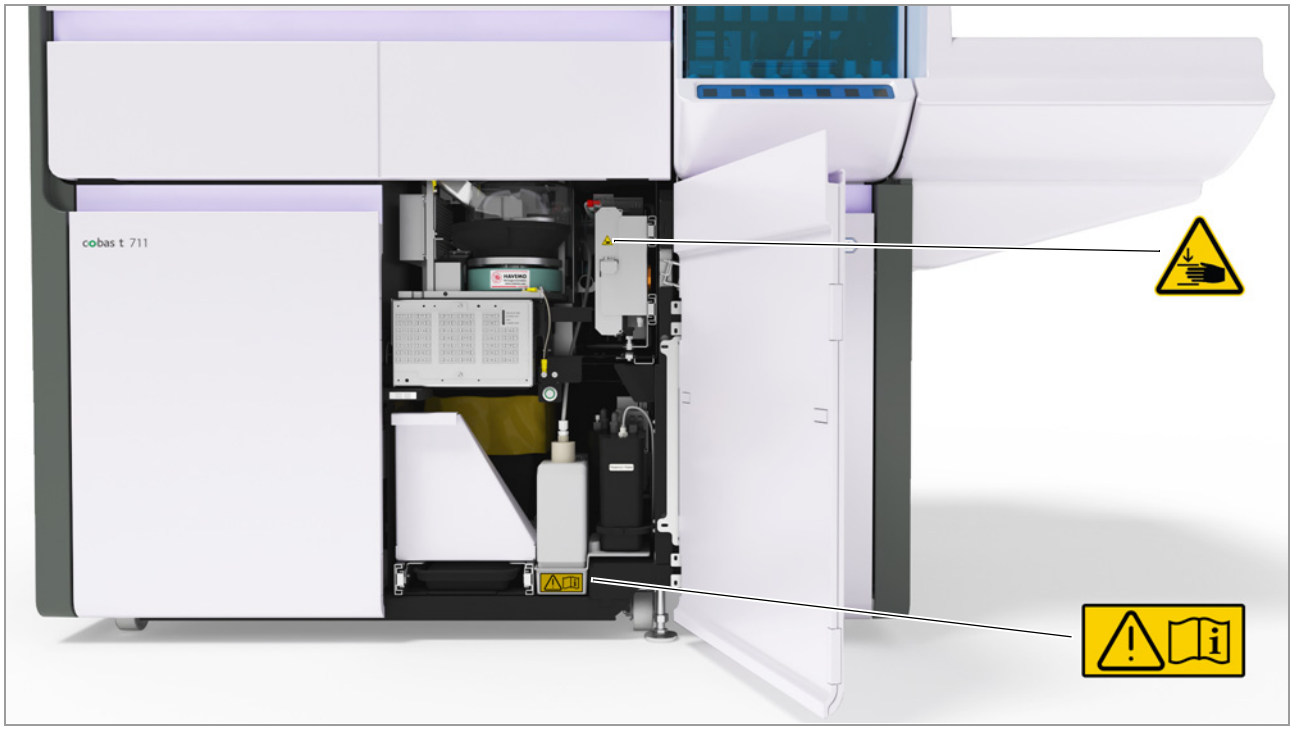


⚠ WARNING

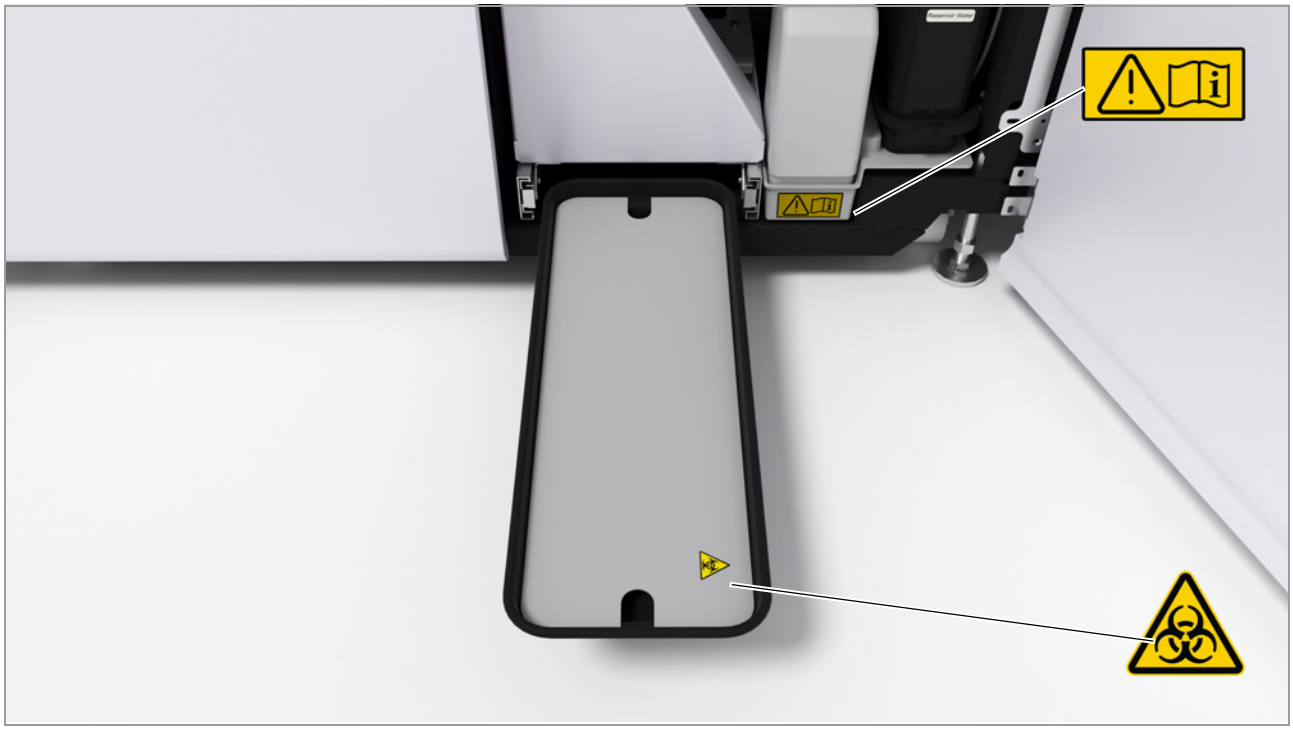
System water

The system water must be reagent grade or higher, and meet the following specifications:

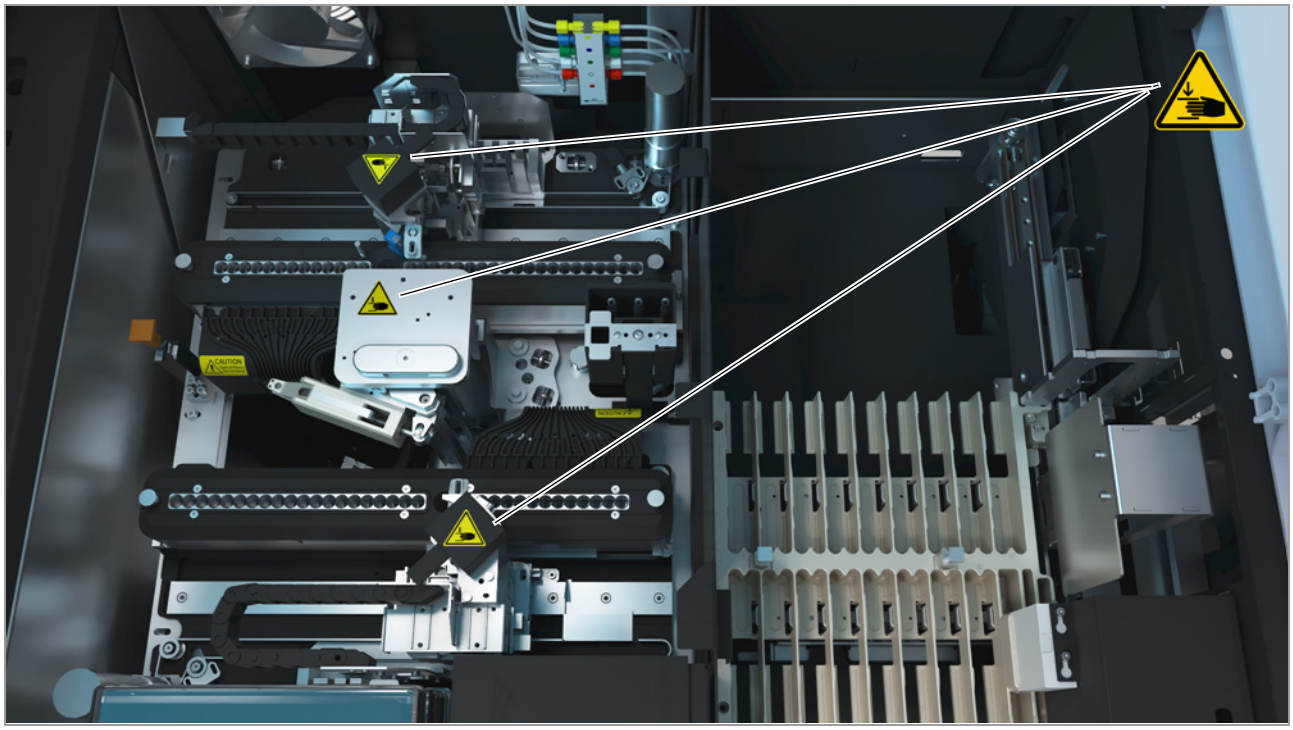
- Conductivity: ≤1.0 µS/cm at 25°C
- Microbiological impurities: ≤ 100 CFU/ml



Solid waste door



Waste tray



Analyzer unit

Other labels on the system

Additional information is provided by labeling on the analyzer.

System Cleaner bottle

Labeling: Required information

⚠ WARNING

Replacing the System Cleaner bottle requires special information and is described in the user documentation.

- Never replace the System Cleaner bottle while the analyzer is operating.

Rack loading area

Labeling: Supported racks

⚠ WARNING

The rack loading area is labeled to indicate that the system only supports specified racks.

Reagent cassette drawer

Labeling: Cassette handling and restrictions

⚠ WARNING

The reagent cassette drawer includes labeling indicating correct reagent cassette loading.

Water and liquid waste containers

Labeling: Container color

⚠ WARNING

To prevent misplacement, the water container is white and the liquid waste container is yellow.

Water container

Labeling: Water label

⚠ WARNING

The water container is labeled so that only reagent grade water or higher is used.

Safety information for disposal

Disposal information

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.