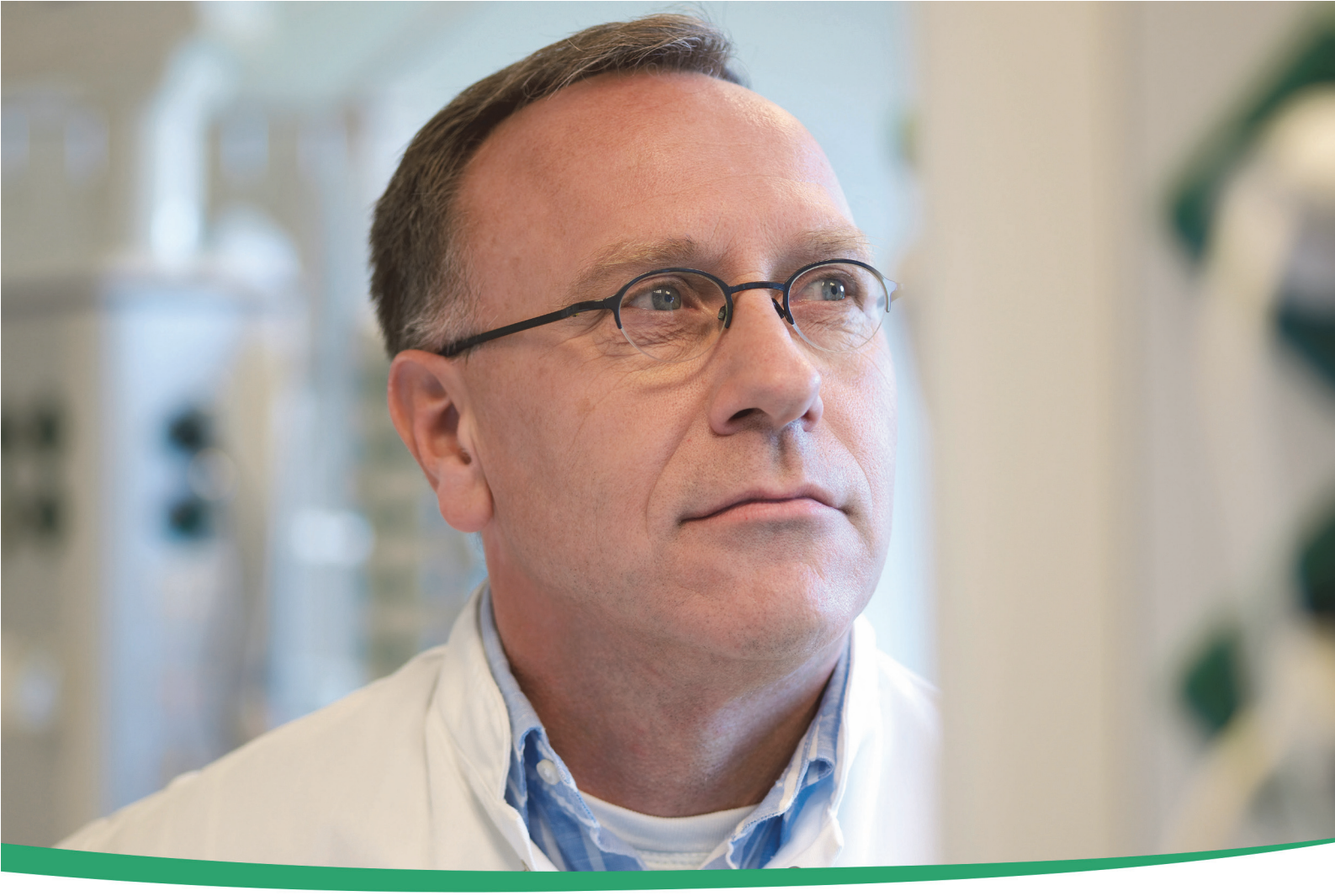

cobas c 111 analyzer

Safety Guide version 1.0
Software version 4.2

Roche

cobas®
Life needs answers

Publication information

Publication version	Software version	Revision date	Change description
1.0	4.2	September 2017	First version

Revision history

Edition notice

This publication is intended for operators of the **cobas c** 111 analyzer with the installed software.

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. This update may lead 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
- A software reference
- Configuration information
- Background information

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

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

Copyright

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Preface

Use this publication together with the **cobas c** 111 analyzer User Guide or User Assistance.

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

Intended use

The **cobas c** 111 analyzer is a continuous random-access analyzer intended for the in vitro determination of clinical chemistry and electrolyte parameters in serum, plasma, urine, or whole blood (HbA1c).

It is important that the operators read this manual thoroughly before using the system.

Symbols and abbreviations

Product names

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

Product name	Descriptor
cobas c 111 analyzer	**cobas c** 111
cobas c 111 with operating software	System
Cuvette Segment	Cuvette segment
Ion selective electrode	ISE
Activator for **cobas c** 111	Activator
Calibrator for automated systems	Cfas
PreciControl ClinChem Multi 1	PCCC1
PreciControl ClinChem Multi 2	PCCC2
ISE Reference Solution	REF

Product names

Symbols used on product

Symbol	Explanation
GTIN	Global Trade Item Number.

Symbols used on product

Acronyms

The following acronyms are used:

Acronym	Definition
ANSI	American National Standards Institute
CFR	Code of Federal Regulations
CISPR	*Comité International Spécial des Perturbations Radioélectriques*
FCC	Federal Communications Commission
IEC	International Electrical Commission
ISO	International Organization for Standardization
SOP	Standard Operating Procedure

Acronyms

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 system in a way that is not described in this publication.
- Keep this publication in a safe place to ensure that it is not damaged and remains available for use. This publication must always be easily accessible.

Safety classifications

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

Safety alert

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

These symbols and signal words are used for specific hazards:

⚠ WARNING

Warning...

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

⚠ CAUTION

Caution...

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

NOTICE

Notice...

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

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

Tip...

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

Safety precautions

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

In this section

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 laboratory best practices, especially when you work with biohazardous material.

Incorrect results due to inappropriate formula

The formula defines how the values of the applications and coefficients are mathematically combined to generate a result.

- It is the responsibility of the user to ensure that the formula is appropriate for the application that is being defined.

About safe and proper use of the analyzer

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 powder-free 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).

Exposure to chemicals

- Avoid exposure to chemicals.

Risk of personal injury or contamination of the instrument

The material used for cleaning might bring you or the instrument in contact with hazardous chemicals.

- Dispose of the cloths used for cleaning according to local regulations.
- Change lab gloves after each cleaning step and dispose of them according to local regulations.

Exposure to infectious waste

Failure to place an appropriate waste container near the **cobas c** 111 analyzer can lead to exposure to infectious waste material.

- Always place the waste container correctly on the external fluid rack during operation.
- 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 analyzer as required. Follow laboratory best practices for cleaning and decontamination.
- Ensure that the laboratory is regularly cleaned and is maintained in an orderly manner.

Incorrect results or processing stops due to skipping maintenance actions

Not performing maintenance actions that are due may lead to situations where the system cannot continue processing orders, or it may lead to incorrect results.

- If possible, perform the maintenance actions when they are due.

Incorrect results or processing stops due to incomplete maintenance actions

You can cancel a maintenance action by choosing the ⊗ button at the end of a step. Cancel a maintenance action may lead to unexpected errors.

If you cancel a maintenance action that was due, its status remains due, and you must fully reperform the action later.

- If possible, complete a maintenance action without interrupting it.
- If you must interrupt the maintenance action, wait until you see confirmation on screen that the current step has been completed.

Maintenance

Not performing maintenance actions may lead to wrong results or instrument damages

- Do not carry out operation and maintenance unless you have been trained by Roche Diagnostics.
- Start all maintenance actions on the screen. Do not perform maintenance actions without the assistance of the user interface.
- Carefully follow the procedures specified in the Operator's Manual for the operation and maintenance of the system.
- Leave maintenance that is not described in the Operator's Manual to a trained service representative.
- Follow Good Laboratory Practices, especially when working with biohazardous material.

Approved cleaning solutions

- Use only approved cleaning solutions for cleaning.

Errors in installation

Incorrect results or damage to the analyzer due to wrong installation

- Follow the specified installation instructions carefully.

Timing error

When the alarm message results from a timing error.

- All tests run or results obtained after the time of the error time stamp should be retested.

Incorrect results due to condensation in the reagent cooler

In ambient conditions of high temperature and humidity, condensation can build up in the reagent cooler. Water can spill on the analyzer unit and get into the cuvettes when removing the reagent disk.

- In ambient conditions of high temperature and humidity, wipe up the condensation water in the reagent cooler periodically.

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.

Water quality

Inadequate water quality may lead to incorrect results.

- Always use purified water of the quality specified in section

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

Not from Roche Diagnostics approved third-party software installations 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 **cobas c** 111 analyzer.

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 periodic maintenance of the UPS.
- Perform regular backup of results.

Electromagnetic compatibility

The **cobas c** 111 analyzer comply with the emission and immunity requirements described in particular requirements for IVD medical equipment of the EN/IEC 61326-2-6 standard.

- The electromagnetic environment should be evaluated before operating the device.

The **cobas c** 111 analyzer comply with the emission requirements described in this part of the FCC rule, Part 15 Class B.

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.
- Only Roche Service representatives may install, service, and repair the system.
- Connect the analyzer to grounded power outlets only (IEC protection class 1). All peripheral devices that are connected to the **cobas c** 111 analyzer must comply with safety standard IEC 60950 for information technology equipment, or with IEC/UL 61010-1 for laboratory use instruments.

Optical safety

Incorrect results through soiled lamp

Touching the lamp with bare fingers reduces the life of the bulb and may affect the consistency of measurements made with the absorbance photometer.

- Hold the lamp assembly by its screw.

Incorrect results due to scratched or soiled cuvettes

Scratches and impurities on the cuvettes distort the measurements.

- Do not touch the cuvettes and make sure that they do not touch other items when handling them.

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.

Operator infection and injury

Contact with system mechanisms (for example, transfer head) or with the system chassis or covers may result in personal injury and infection.

- Whenever possible, keep the cover and flaps of the analyzer closed.
- Always ensure that the system is off or in **Maintenance** status before you work with an opened cover (for example, for cleaning or maintenance).
- Do not open the cover or flaps while the system is performing maintenance.
- 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 parts that are specified.
- Never reach into the analyzer while parts are moving.
- Carefully observe all instructions given in this publication.

Sharp objects

Contact with probes may result in infection.

- When cleaning near the 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.

Calibrators, QCs, and samples

Incorrect results due to expired calibration

Calibrations are performed to compensate for changes over time in reagents and in the measurement systems. Failing to perform calibrations when they are due may lead to incorrect results.

- Make sure to perform calibrations when they are due.

Incorrect results when using old calibration results

Calibrations are performed to compensate for changes over time in reagents and in the measurement systems. Failing to perform calibrations when they are due may lead to incorrect results.

- Roche recommend performing a QC measurement before you continue working with the old calibration results.
- In the application definitions, choose the **On** option for the **QC After Cal** parameter.

  Utilities > Applications > Laboratory Parameters > Control > QC After Cal

Incorrect results due to declining sample quality

Evaporation of sample fluid may lead to incorrect results. In ambient temperatures of more than 25°C, be sure to start processing immediately after placing the sample and defining the order.

- When processing of the order is finished, remove the sample from the sample area.

Contaminated samples

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

- Make sure that the samples contain no insoluble contaminants, such as fibrin or dust.

Carryover of sample

Incorrect results due to carryover. Traces of analytes or reagents may be carried over one test to the next.

- Take adequate measures (e.g. sample aliquoting) to safeguard additional testing and to avoid potentially false results.

Incorrect results due to insufficient fluid

Insufficient fluid may lead to inaccurate pipetting and so to incorrect results.

- Always fill the tubes with sufficient fluid that at the end of the pipetting process at least the dead volume of fluid is left.

Incorrect results due to not placing the identified sample

The system assumes that the operator places the sample that was identified. Failing to do so might lead to wrong results.

- Always place the sample tube when ordered.

Incorrect results due to inappropriate tube and cup placement

Inappropriate tube and cup placement may lead to inaccurate pipetting and so to incorrect results.

- Ensure that the primary tubes are placed centrally and perfectly vertically in the holders in the sample area and that they are inserted firmly.
- Ensure that secondary tubes are placed centrally on the primary tubes and that they rest fully on them.

Incorrect results due to build-up of contaminants

During use, contaminants may adhere to the probe. As a result, traces of analytes or reagents may be carried over to the next.

- Make sure to perform the probe maintenance actions as soon as they are due in order to prevent potentially false results.

Reagents and other working solutions

Incorrect results due to declining reagent quality

If the application definitions (see Method Sheet) recommend the use of chimneys, the corresponding calibration intervals apply to conditions when working with chimneys.

- Roche recommend using chimneys whenever the use is recommended on the test insert.

Incorrect results due to changes in fluids

The chemical composition in fluids changes over time. The assigned onboard stability is the interval within which the quality of the fluid remains within the prescribed tolerances. Using fluids whose interval has expired may lead to incorrect results.

- Always exchange the fluids when an interval has expired. Follow the instructions given on the screen.

Incorrect results due to impurities and carryover

Traces of analytes or reagents may be carried over one test to the next when reusing bottle caps.

- Do not remove reagent bottles that are not empty with the purpose of loading them again later.

Incorrect results due to reagent dilution through condensation

In ambient conditions of high temperature and humidity, condensation can build up inside the reagent bottles. This condensation water leads to dilution of the reagent.

- In such conditions and when not performing tests, remove the reagent disk from the analyzer. Place the reagent disk in the reagent disk container. Close the container with its lid and place it in a refrigerator.

Incorrect results due to inappropriate reagent handling

Removing and loading reagents while the reagent disk is outside the analyzer may lead to inconsistencies between the recorded and the physically loaded reagents. This reagent handling may lead to incorrect results.

- Always remove and load reagents while the reagent disk is on the analyzer and by using the software supported procedures.

Incorrect results due to not placing the identified reagent

The system assumes that the operator places the reagent that was identified.

- Failing to do so might lead to wrong results.

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

Transport

Injury from heavy loads

You may injure your hands, fingers, or back when putting the system in place.

- Carry the system according to the transport instructions.

Damage in transit

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

Mechanical safety

Damaged touch screen monitor

To touch a damaged touch screen monitor that can expose sharp edges, can cause personal injury.

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

Moving parts

Contact with moving parts may result in personal injury.

- Keep the cover and flaps closed and in place while the system is operating.
- Always ensure that the system is off or in **Maintenance** 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.
- During operation and maintenance, carefully follow the instructions.

Burns due to hot surfaces

Hot surfaces inside

Contact with the hot absorbance photometer lamp may cause burns.

- Avoid contact with hot surfaces inside the analyzer.

Optical safety

Loss of sight

The intense light of the LEDs may severely damage you eyes. Scanning equipment using LED technology is covered by the international standard EN/IEC 60825-1 LED Safety: Class 1.

- Do not stare into the LEDs.

Blindness due to intense barcode reader light

The intense light of a laser or LED barcode reader may severely damage your eyes or result in exposure to hazardous radiation. Scanning equipment using LED technology is covered by the international standard EN/IEC 60825-1 LED Safety: Class 1.

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

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:

- 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) 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. Ensure that the connected network is free of malicious code.
- 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 instruction includes: remote storage location; disaster recovery sites; secure transfer of backup files.

For further information, contact your Roche Service representative

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.

Class B equipment (industrial areas)

- The **cobas c** 111 analyzer has been designed and tested to CISPR 11, 4.2 Class B. In a domestic environment, it may cause radio interference, in which case you may need to take measures to mitigate the interference.

Malfunction of analyzer and incorrect results due to interfering electromagnetic fields

Devices that emit electromagnetic waves may cause the analyzer to malfunction.

- Do not use this device close to sources of strong electromagnetic radiation (for example, mobile phone, transceiver, cordless phone). These items can interfere with the proper operation.

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.

Reagents and other working solutions

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 Method Sheet for the test.
- Do not use a 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.

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.
- Do not use improperly stored reagents. Ensure that reagents are stored according to the Method Sheet.
- Do not use expired reagents.

Reagent carryover

Spillage through tipping reagent disk may lead to wrong test results.

- When handling the reagent disk, make sure not to tilt it.

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

Incorrect results due to incorrect handling of reagents

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

- Do not use reagents or consumables that were exposed to heat or to light for an extended time.
- Do not use expired reagents or consumables.
- Adhere to the storage conditions defined in the Method Sheet for the reagents, controls, and consumables.
- 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 Method Sheet.

Spillage through tipping reagent disk

If the reagent disk container is not placed on an even horizontal surface, it can slip off or tip over.

- When storing the reagent disk container, make sure to place it on a firm, even, horizontal surface that is easily accessible.
- When handling the reagent disk, make sure not to tilt it.

Waste

Instrument contamination

The internal waste tank overflow may lead to an instrument contamination. Condensation can build up in the cooling unit while the system is in **Standby** mode.

- The internal waste is periodically pumped to the external waste container in **Standby** mode.

Infectious waste

Contact with liquid waste may result in infection. All materials and mechanical components associated with the waste system 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.

Environmental harm

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

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

Notices

⚠ List of notices

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

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

In this section

License

Malfunction of analyzer and incorrect results due to software modifications by the customer

Portions of the **cobas c** 111 software might include one or more open source or commercial software programs.

- For copyright, notices, and licensing information regarding such software programs included with **cobas c** 111 software refer to the USB flash drive provided with the product.

The **cobas c** 111 analyzer is designed to operate with the unmodified software as shipped. The operator assumes full responsibility for changing any part of the open source software, which excludes any liability of Roche Diagnostics Ltd.

This program is distributed without any warranty; without even the implied warranty of merchantability or fitness for a particular purpose.
For details, see document **cobas c** 111 analyzer License Notes.

Circuit breakers and fuses

Damage to the system due to use of wrong fuses

Improper use may result in damage to the system.

- Always replace fuses with new ones of the same type and specifications.

Legal liability

Roche Diagnostics Ltd assumes only limited liability when using the **cobas c** 111 analyzer with the **cobas c** 111 Development Channel Programming Software.

For detailed information on this matter, refer to the latest version of the Development Channel Registration Form **cobas c** 111 and the **cobas c** 111 Development Channel Operator's Manual.

You are responsible to determine whether you activate the **TRL Check** feature. If you do so, define the lower measuring range in accordance with the country-specific requirements. If you activate the **TRL Check** feature, you are also responsible for validation of the ranges you define.

Mechanical safety

Damage to the reagent disk

The reagent disk is designed to handle reagents while it is loaded on the analyzer. The cover is equipped with a locking mechanism.

- Always remove and load reagents while the reagent disk is on the analyzer and by using the software supported procedures.

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.

Probe damage due to not removing primary tube caps

The probe is not designed to pierce tube caps. It can get damaged when trying to pierce tube caps.

- Always remove the caps of primary tubes before placing them on the analyzer.

Probe damage and analyzer malfunction due to inappropriate probe handling

Applying unilateral side pressure on the probe can lead to its deformation and so to analyzer malfunction.

- Make sure to apply equal pressure on both sides and to move exactly in the direction of the probe when wiping it.

Damage to the reagent disk

The reagent disk is designed to handle reagents while it is loaded on the analyzer. The cover is equipped with a locking mechanism.

- Always remove and load reagents while the reagent disk is on the analyzer and by using the software supported procedures.

Incorrect results or damage to the analyzer due to dust and soiling

When you leave the main cover open, while the system is in **Standby** status or while the analyzer is shut down. This condition can cause dust and dirt being collected in the cuvette ring, which in turn might decrease the quality of the cuvettes.

- Keep all covers closed. Open them only to perform operation actions.

Damage to electrodes and possible tubing blockage

Periodic flow of solutions must be performed always.

- Do not unplug or switch off the ISE power supply.
- If you intend not to use the ISE unit for more than 1 week, you should deactivate it. This deactivation saves ISE fluids, reduces wear and tear of the tubing, and lowers the likelihood of malfunctions and errors occurring.

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.

Spillage

Risk of instrument damage due to spilled liquid or unsuitable material

Unsuitable liquids, or liquid spilled on the system may result in malfunction or damage.

- Do not use technical or denatured ethanol for preparation of the cleaning solution.
- Moisten the lint-free cloths outside the system and wipe the surfaces and parts as described in these procedures.
- Take care when applying liquid to the lint-free cloth. The cloth should be damp, but not saturated to prevent drops of liquid from falling onto 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.
- Make sure that you do not tilt the bottle or sample tube when scanning its barcode.

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.

Safety labels on the cobas c 111 analyzer

In this section

List of safety labels on the analyzer

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

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

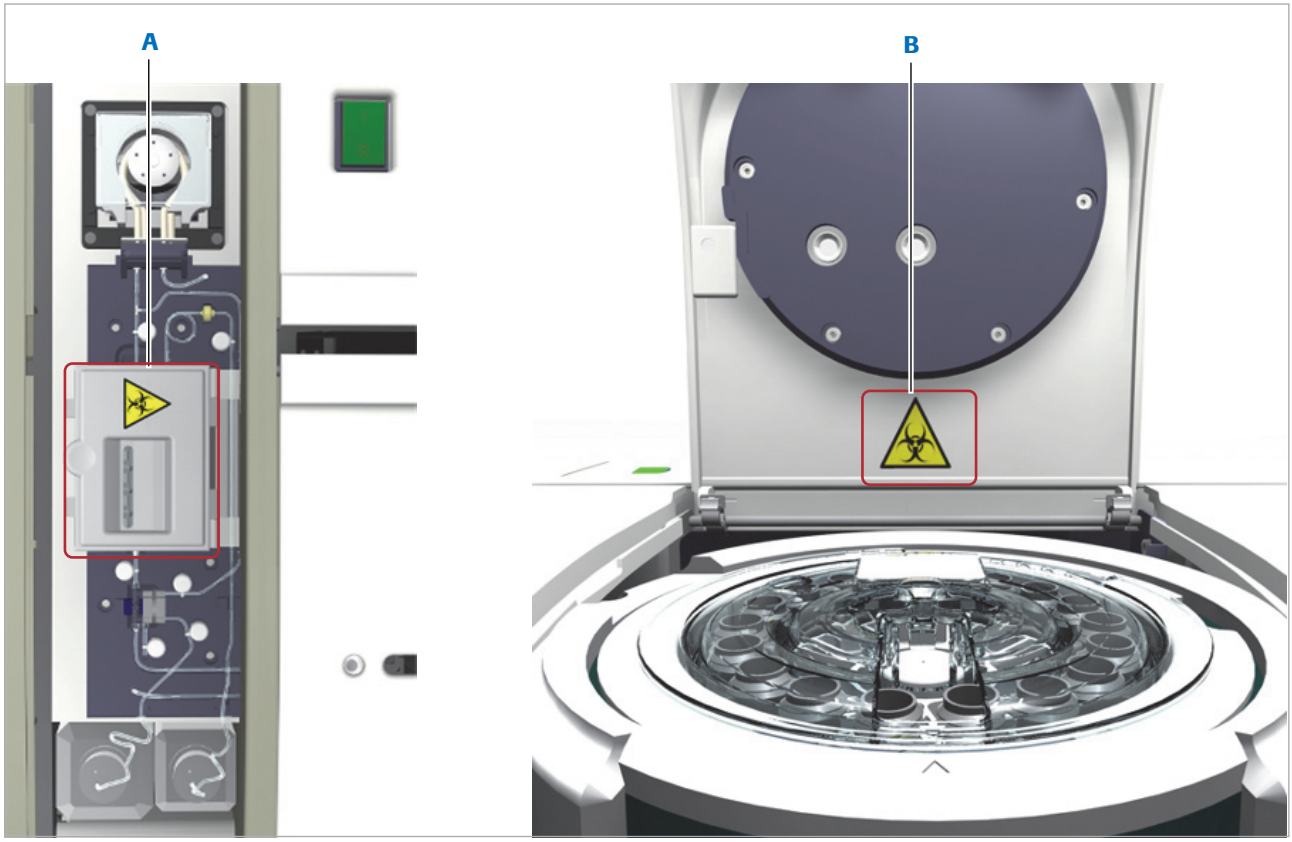
Only Roche Service representative replaces damaged labels. For replacement labels, contact your local Roche representative.

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

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

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

Location of safety labels on the cobas c 111 analyzer



A ISE unit:
This label on the electrode block of the ISE unit indicates that there is a danger of hazardous situations arising within the vicinity of this label, which may result in death or serious injury. The relevant laboratory procedures on safe use must be observed. (You will find this label only if an ISE unit is installed.)

B Main cover:
This label on the main cover indicates that there are potential biohazards within the vicinity of this label, which may result in death or serious injury. The relevant laboratory procedures on safe use must be observed.

Safety labels on the **cobas c** 111 analyzer

In addition to safety labels on the analyzer, there are safety notes in the corresponding parts of the Operator's Manual.

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

When working with the analyzer, be sure to observe both the safety labels on the analyzer and the safety notes in the Operator's Manual.

Safety information for disposal

Disposal information

All electrical and electronic products should be disposed of separately from the municipal waste. Proper disposal of your old appliance prevents potential negative consequences for the environment and human health.

Infection by a biohazardous analyzer

- Treat the analyzer as biohazardous waste. Decontamination (the combination of processes including cleaning, disinfection, and/or sterilization) is required before reuse, recycling, or disposal of the analyzer.
- Dispose of the analyzer 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.

Disposal of external components

External components such as the scanner and the ISE power supply, which are marked with the crossed-out wheeled bin symbol, are covered by the European Directive (WEEE).

These items must be disposed of via designated collection facilities appointed by government or local authorities.

For more information about disposal of your old products, contact your city office, waste disposal service, or your local service representative.