cobas t 411 coagulation analyzer

Safety Manual
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Revision history

Edition notice

This publication is intended for users of the **cobas t** 411 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.

General attention

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

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

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Preface

Use this publication together with the **cobas t** 411 coagulation analyzer Operator's Manual.

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

Intended use

The **cobas t** 411 coagulation analyzer is a fully automated blood plasma analysis system intended for in vitro determination of coagulation. It performs optical clotting time detection, using chronometric, chromogenic, and immuno-turbidimetric measurement methods. It is designed for 24h/day operation.

Conventions used in this publication

Product names

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

Official product name	Common name in this publication
cobas t 411 coagulation analyzer	analyzer system (if the emphasis is on the software, or on software and hardware as a whole)
cobas t 411 coagulation analyzer Operator's Manual	Operator's Manual

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 Pertubations Radioélectriques*
EC	European Community
FCC	Federal Communications Commission
IEC	International Electrical Commission
ISO	International Organization for Standardization
LIS	Laboratory information system
QC	Quality control
UPS	Uninterruptible power supply
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 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 Z535.6-2011 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 that, 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 solid waste container below the waste chute can lead to exposure to infectious waste material.

- Always place a solid waste container below the waste chute 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 instrument 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 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.
- Leave replacement of 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.

For the allowable environmental conditions, see the Operator's Manual.

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 Operator's Manual.

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.

Electromagnetic compatibility

The **cobas t** 411 analyzer complies with the emission and immunity requirements described in this part of the IEC 61326:2012 series.

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

Electromagnetic compatibility (22)

System not used for an extended period

- Follow the procedure for shutting down the system.
- Shut down and switch off the control unit.
- Remove and refrigerate any remaining reagents and QC materials.
- For further information, call your Roche Service representative.

See the procedure on shutting down the system in the Operator's Manual.

Damage in transit

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

Related topics

- Disposal information (29)

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.
- Only Roche Service representatives may install, service, and repair the system.

Related topics

- List of safety labels on the system (24)

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 in place 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 arm, probe, etc.) or the system chassis or covers may result in personal injury and infection.

- Whenever possible, keep the covers of the system in place.
- Always ensure that the system is off or in standby mode before you remove any cover (for example, for cleaning or maintenance).
- Do not remove any cover while the system is processing samples, QC, or calibration, or while it is performing maintenance.
- Do not touch any parts of the system other than those specified.
- Never reach into the sample pipetting area, reagent area or above the cuvette conveyor while parts are moving.
- Carefully observe all instructions given in this publication.

Sharp objects

Contact with the probe may result in infection.

- When cleaning the probe or near the probe, 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.
- When wiping the probe, use several layers of tissue and wipe from the top down.

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 the Operator's Manual.
- Wear appropriate personal protective equipment when implementing corrective measures.

Waste

Infectious waste

Contact with solid waste may result in infection. All materials and mechanical components associated with the solid 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.
- Use an appropriate solid waste container for the used cuvette bars.

For system decontamination procedures, see the procedures on cleaning in the Operator's Manual.

Environmental harm

The system generates liquid and solid waste. Liquid waste contains concentrated reaction solutions, 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.

Related topics

- List of safety labels on the system (24)
- Disposal information (29)

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

Moving parts

Contact with moving parts may result in personal injury.

- Keep all covers in place while the system is operating. An interlock system prevents operation of moving parts when the reagent area cover is not in place.
- Always ensure that the system is off or in standby mode before you remove a 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.
- Do not put your finger in the waste chute.
- Do not place your hand or any other part of your body in the sample pipetting area, reagent area or above the cuvette conveyor, especially while the analyzer is pipetting.
- Do not manually remove single containers from reagent racks that are placed on the reagent area. If you want to refill a reagent, always first remove the whole reagent rack.
- During operation and maintenance, carefully follow the instructions.

Related topics

- List of safety labels on the system (24)

Reagents and other working solutions

Skin inflammation or injury

Direct contact with reagents, ethanol, 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 of the reagent, ethanol, cleaning solution, or other working solution.
- Observe the information given in Material Safety Data Sheets (available for Roche Diagnostics reagents and cleaning solutions).
- If reagents, ethanol, 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 reagent volume

Incorrect reagent handling may cause an undetectable loss of reagent.

- Always store reagents according to the specified storage conditions as stated in their instructions for use.

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 QC materials.

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.

Contaminated sample tube caps

Dust, blood or other substances on sample tube caps may contaminate the probe during cap piercing, leading to incorrect results.

- Only use sample tubes with clean caps.
- If the cap of a sample tube is contaminated, clean it before loading the sample tube on the analyzer.

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 leave samples, calibrators, or QC materials that have been pipetted into a cuvette for any length of time.
- Do not use improperly stored reagents. Ensure that reagents are stored according to their 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 expired reagents that were exposed to heat or to light for an extended time.
- Do not use expired reagents.
- Adhere to the storage conditions defined in the instructions for use for the reagents, QC materials, or 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 instructions for use.

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.

Wireless interference

Wireless devices in the instrument may lead to malfunction.

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

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 connect external hard drives to the system.
- Do not install and/or execute any other software on the system.
- Make sure other computers, USB flash drives, and services on the network (for example, the LIS, archiving, backup share, or service) are properly secured and protected against malicious software and unauthorized access.
- Customers are responsible for the security of their local area network, especially in protecting it against malicious software and attacks. This protection might include measures, such as a firewall, to separate the device from uncontrolled networks as well as measures that ensure that the connected network is free of malicious code.
- The use of a firewall is mandatory.
- Restrict physical access to the system and all attached IT infrastructure (computer, cables, network equipment, etc.).
- Make sure that system backup and archive files are protected from any unauthorized access and disaster, this includes: remote storage location; disaster discovery 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

Moving parts

Contact with moving parts

Contact with moving parts may bend the probe or damage some other components. If the analyzer detects a collision, an alarm is issued and operation is stopped immediately.

- Keep away from moving parts during operation.
- Do not touch any parts of the analyzer other than those specified in the Operator's Manual.

Circuit breakers and fuses

Circuit breakers and fuses

Improper use may result in damage to the system.

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

Electromagnetic compatibility

Class A equipment (industrial areas)

- The system 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.

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.

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 too high or too low, the analyzer stops measuring and displays the message [er19], [er20], [er21], or [er22].

- Avoid heat sources close to the system.
- For the allowable environmental conditions, see the Operator's Manual.

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.

  For decontamination procedures, see the procedures on cleaning Operator's Manual.

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 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 the 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 a Roche Service representative is 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.

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

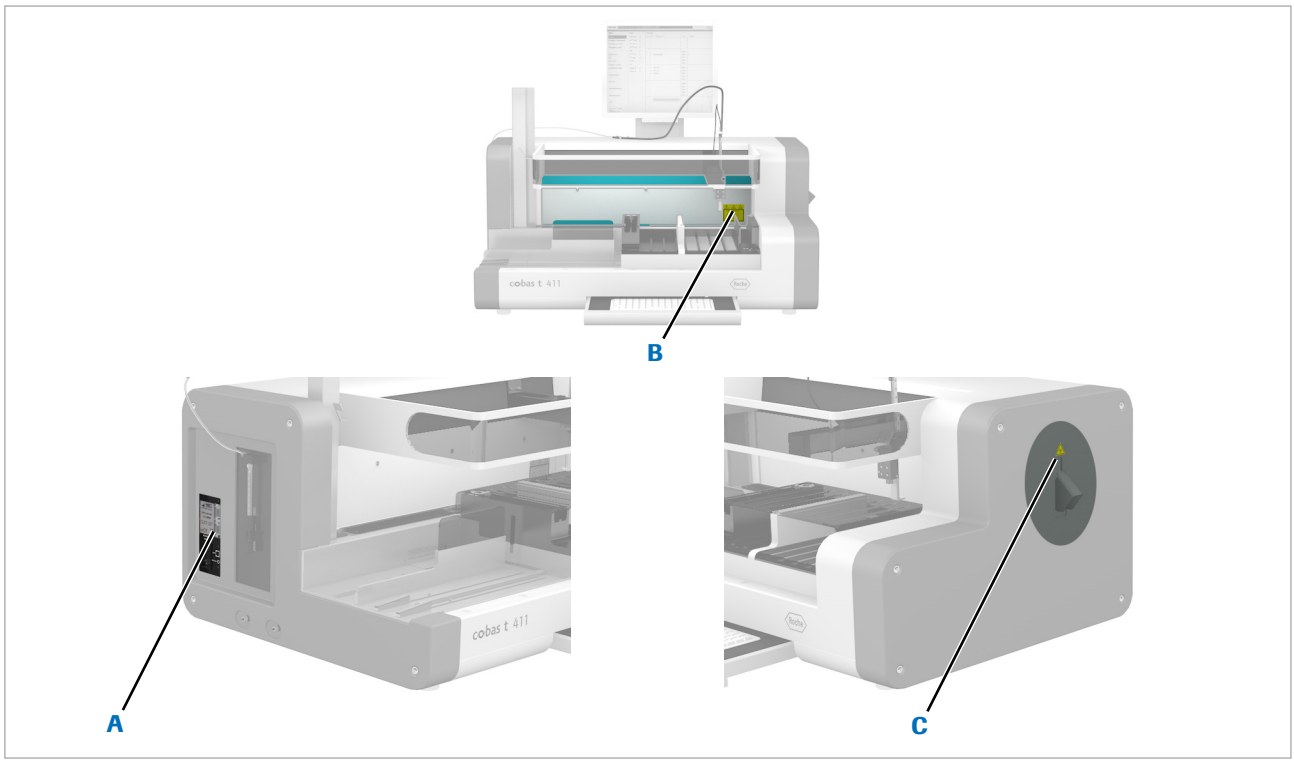
Biohazard
Potentially biohazardous materials are used near this label.
Observe relevant good laboratory practices on safe usage.

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.

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



A Disposal of analyzer components

B Warning, Biohazard warning, Moving parts, Laser transmitter

C Biohazard warning

Safety labels on the analyzer

	Label	Hazard definition
B, C		**Biohazard warning** This label indicates that there are potential biohazards within the vicinity of this label. • Follow standard laboratory practices for working with biohazardous materials.
A		**Disposal of analyzer components** Components of your analyzer (such as the computer, monitor, keyboard) which are marked with this symbol are covered by the European Directive on Waste Electrical and Electronic Equipment (WEEE, 2002/96/EC). • These items must be disposed of via designated collection facilities.

Description of the safety labels

	Label	Hazard definition
B		**Moving parts** This label indicates that there is a danger of moving parts within the vicinity of this label. • Keep hands away from moving parts.
B		**Laser transmitter** This label indicates that there is a danger of coming into contact with laser light within the vicinity of this label. • Do not stare into the laser transmitter.
B		**Warning** This label indicates that there is a danger of hazardous situations arising within the vicinity of this label, which may result in death or serious injury. • Refer to the Operator's Manual for instructions on safe operation.

Description of the safety labels

Safety information for lasers

The system includes laser barcode readers:

- A laser barcode reader (class 2 laser) is used to scan the barcodes on sample racks.
- A laser barcode reader (class 2 laser) is used to scan the barcodes on reagent racks.

Laser barcode readers

Class 2 laser barcode readers

The **cobas t** 411 coagulation analyzer is a class 2 laser product. It is equipped with barcode readers that contain class 2 laser diodes.

The laser light is 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.

- ▶ Do not stare into laser transmitter beam.

Related topics

- List of safety labels on the system (24)

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.