cobas c 111 analyzer

Data Protection, Privacy, and Security Guide
Version 1.0
Software version 3.0 and higher

cobas c 111

cobas®

Publication information

Publication version	Software version	Revision date	Change description
1.0	≥3.0	July 2019	First edition

⊞ Revision history of Data Protection, Privacy, and Security Guide

Edition notice

This publication is intended for operators of the **cobas c** 111 analyzer with the installed software version 3.0 or higher.

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
- ▪ A software reference
- ▪ Configuration information
- ▪ Background information

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

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

The **Operator's Manual** contains information about safety, hardware and software, operating the system as well as maintenance and troubleshooting.

⚠️ **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 retrievable place.

The Online Help is a context-sensitive feature. For help information in the **cobas c** 111 software, choose the ⑦ to display Help text that relates to the work area of the software. The Online Help offers a quick and convenient way of finding information, such as explanations of screens, dialog boxes, and on how to perform particular tasks.

To help you find information quickly, there is a table of contents at the beginning of the manual and each chapter. In addition, a complete index can be found at the end.

Training Do not carry out operation tasks or maintenance actions unless you have received training from Roche Diagnostics. Leave tasks that are not described in the user documentation to trained Roche Service representatives.

Images The screenshots and hardware images in this publication have been added exclusively for illustration purposes. Configurable and variable data, such as tests, results, or path names visible therein must not be used for laboratory purposes.

Warranty Any customer modification to the system renders the warranty or service agreement null and void.

For conditions of warranty, contact your local sales representative or refer to your warranty contract partner.

Always leave software updates to a Roche Service representative, or perform such updates with their assistance.

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Feedback Every effort has been made to ensure that this publication fulfills the intended use. All feedback on any aspect of this publication is welcome and is considered during updates. Contact your Roche representative, should you have any such feedback.

Approvals The **cobas c** 111 analyzer meets the requirements laid down in the following directives:

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Compliance with the applicable directives is provided with the Declaration of Conformity.

The following marks demonstrate compliance:

For *in vitro* diagnostic use.

Complies with the provisions of the applicable EU directives.

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

Disclaimer This publication may contain information and references to products that may not be available in your country or sold by Roche Diagnostics. This publication makes no claims regarding the use or performance of those products. Selected third-party products are available for use with the **cobas c** 111 analyzer.

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Intended use

Intended use of the Data Protection, Privacy, and Security Guide

This compliance guide explains the provisions to help your laboratory or medical organization as data controller or processor comply with its requirements while using the **cobas c** 111 analyzer. It is intended for those individuals in your organization, whose responsibility is data protection.

Intended use of the cobas c 111 analyzer

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 optimized for small throughput workloads of up to 50 samples per day, utilizing photometric analysis and an optional unit for ion selective electrodes (ISE).

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
Ion selective electrode	ISE

⊞ Product names

Symbols used in the publication

Symbol	Explanation
•	List item
⊞	Table. Used in table titles and cross-references to tables.

⊞ Symbols used in the publication

Abbreviations

The following abbreviations are used.

Abbreviation	Definition
EU	European Union
IT	Information Technology
LAN	Local Area Network
LIS	Laboratory Information System

⊞ Abbreviations

Data Protection, Privacy, and Security Regulation

Cybersecurity and data privacy for Roche systems installed at customer sites are a shared responsibility between Roche and each customer. Roche provides products with adequate protection. Customers are expected to operate Roche products in a privacy-compliant way.

Access control

For security reasons and for patient confidentiality, all users must exit the software or lock their computer before leaving their workplace. The physical access to all hardware and servers (including analyzer, computer systems, cables, network equipment, etc.) should be protected.

Use the software's operator management functionality as intended.

▪ Do not use shared user accounts for laboratory staff.
▪ It is recommended to have individual accounts with appropriate operator level, to access the software and the laboratory's credentials.
▪ It is recommended to delete any obsolete user accounts from the Roche systems.

Network Security

The laboratory network and any laboratory infrastructure must be secured against unauthorized access, malicious software, and cyber-attacks.

All devices and services used in the customer laboratory infrastructure must be safe and secured against malicious software and unauthorized access.

A secure network environment which is resilient to traffic redirection and eavesdropping must be installed.

Data transfer and data entry on analyzers

Do not download from any host system (e.g. LIS, middleware) any patient-sensitive data to the analyzer.

Data transfer using any host protocol (e.g. HL7, ASTM) is not encrypted; data is transferred as plain text and readable with IT tools (e.g. sniffer).

Secure data storage

Any data backup and data archive that has been exported from the analyzer must be securely stored and protected from any unauthorized access.

Data access to any data backup or data archive is permitted to authorized persons only.

Make sure that system backups and archive files are protected from any unauthorized access and disaster. Do not take any patient identification data outside of the laboratory.

Implement controls for handling and disposal of media and assets (e.g., hard disks). Media and assets containing data from Roche products must be securely destroyed.

Cybersecurity and Privacy awareness

Perform regular security and privacy awareness training for staff handling personal data and according the data privacy principles that are mandatory according to regulations.

Check your analyzer for suspicious activity and report any suspected compromise immediately to your Roche representative.

Always leave software updates to a Roche Service representative, or perform such updates with their assistance. New software updates should be implemented as soon as possible.

Read carefully and follow the recommendations and advice written in the safety guide.