# cobas c 311 analyzer

Safety Manual
Software version 01-09

# Publication information

| Publication version | Software version | Revision date | Change description |
|---|---|---|---|
| 1.0 | 01-09 | 2014-10 | First version |
| 1.0.1 | 01-09 | 2016-07 | Replacement pages with minor additions:<br>• UltraVNC licence agreement<br>• Electromagnetic compatibility statement<br>• RoHS and Content symbol explanation |

Revision history

## Edition notice

This publication is intended for operators of the **cobas c** 311 analyzer.

Every effort has been made to ensure that all the information is correct at the time of publishing. However, Roche Diagnostics reserves the right to change this publication as necessary and without notice as part of ongoing product development.

## Where to find information

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

The **Operator's Manual** focuses on routine operation and maintenance. The chapters are organized according to the normal operation workflow.

The **Online Help** contains the content of the Operator's Manual and additionally:

- Troubleshooting information
- A software reference
- Configuration information
- Background information

### ⚠ General attention

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

- 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.

**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.

**Screenshots**

The screenshots 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.

**Copyright**



**License agreement for UltraVNC software and Linux Kernel**

UltraVNC and Linux Kernel are pieces of free software for all commercial uses, which are installed on the control unit PC.

You can redistribute the software and/or modify it under the terms of the GNU General Public License (version 2 or later), as published by the Free Software Foundation. A copy of the GNU General Public License (version 2) is stored on the control unit PC. The path for the license is C:\Program Files\uvnc bvba\UltraVNC.

The software is distributed without warranty. There is no implied warranty of merchantability or fitness for a particular purpose. For more information, see the GNU General Public License at http://www.gnu.org/licenses.

The source code for the software is stored on the control unit PC. The path for the source code is C:\DriversAndTools\UltraVNC.

**Trademarks**

The following trademarks are acknowledged:

COBAS, COBAS C, COBAS INTEGRA, and LIFE NEEDS ANSWERS are trademarks of Roche.

All other trademarks are the property of their respective owners.

**Feedback**

Every effort has been made to ensure that this publication fulfills the intended purpose as mentioned above. 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** 311 analyzer meets the requirements laid down in:

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

Compliance with the applicable directive(s) is provided by means of 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.

The **cobas c** 311 analyzer complies with the emission and immunity requirements described in the standard IEC 61326-2-6 / EN 61326-2-6.

# Contact addresses

**Inside the European Union and EFTA member states**

| | |
|---|---|
| Manufacturer of **cobas c** 311 instrument | Hitachi High-Technologies Corporation<br>1-24-14 Nishi-Shimbashi<br>Minato-ku Tokyo 105-8717<br>Japan |
| EC REP Authorized representative | Roche Diagnostics GmbH<br>Sandhofer Strasse 116<br>68305 Mannheim<br>Germany |

**Outside the European Union and EFTA member states**

| | |
|---|---|
| Manufactured by: | Hitachi High-Technologies Corporation |
| Manufactured for: | Roche Diagnostics GmbH<br>Sandhofer Strasse 116<br>68305 Mannheim<br>Germany |

## Table of contents

# Preface

Use this publication together with the **cobas c** 311 Operator's Manual.


- Intended use (6)
- Symbols and abbreviations (6)


## Intended use

The **cobas c** 311 analyzer is an automated, software-controlled system for clinical chemistry analysis. It is designed for both quantitative and qualitative in vitro determinations using a large variety of tests for analysis.

The **cobas c** 311 analyzer performs photometric assays and ion-selective electrode measurements and uses serum/plasma, urine, CSF and supernatant sample types.

## Symbols and abbreviations

### Product names

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

| Product name | Abbreviation |
|---|---|
| **cobas c** 311 analyzer | analyzer |
| **cobas c** pack | reagent pack |

Product names

### Symbols used in the publication

| Symbol | Explanation |
|---|---|
| • | List item |
| | Related topics containing further information |
| | Tip. Extra information on correct use or useful hints. |
| | Start of a task |
| | Extra information within a task |
| → | Result of a user action within a task |
| | Frequency of a task |
| | Duration of a task |
| | Materials that are required for a task |
| | Prerequisites of a task |
| | Topic. Used in cross-references to topics. |
| | Task. Used in cross-references to tasks. |

Symbols used in the publication

| Symbol | Explanation |
|---|---|
| | Figure. Used in figure titles and cross-references to figures. |
| | Table. Used in table titles and cross-references to tables. |
| $\sqrt{xy}$ | Equation. Used in cross-references to equations. |

Symbols used in the publication

## Symbols used on products

| Symbol | Explanation |
|---|---|
| GTIN | Global Trade Item Number |
| Cont. | Quantity contained in the package |
| CONTENT | Quantity contained in the package |
|  | Orientation of the package during transportation |
| RoHS | Complies with the directive 2011/65/EU on RoHS |

Symbols used on products

## Abbreviations

The following abbreviations are used.

| Abbreviation | Definition |
|---|---|
| ANSI | American National Standards Institute |
| COBI | Compendium of Background Information |
| CSV | comma separated values |
| EC | European Community |
| EFTA | European Free Trade Association |
| EN | European standard |
| IEC | International Electrical Commission |
| IVD | In vitro diagnostic |
| LIS | Laboratory information system |
| n/a | not applicable |
| QC | Quality control |

Abbreviations

| Abbreviation | Definition |
|---|---|
| SBS | scan before sample stop |
| SD | Standard deviation |
| WEEE | Waste Electrical and Electronic Equipment |

Abbreviations

# 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 that, 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 which, 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.**

Keep in mind that the hazard warnings in this manual, in the Operator´s Manual, in the Online Help, and on the instrument cannot cover every possible case, as it is impossible to predict and evaluate all circumstances beforehand.

Just following the given directions may, therefore, be inadequate for operation. Always be alert and use your common sense.


- About operator qualification (9)
- About safe and proper use of the system (10)
- About installation and deinstallation (11)
- About operating conditions (12)


## 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 standard 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

**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 local regulations.

**System not used for an extended period**

- Follow the decommissioning procedure if available.
- Set the power switch to OFF if you do not use the system for an extended period.
- Remove and refrigerate any remaining reagents.
- For further information, call your Roche Service representative.

**Abnormal condition**

During operation, always check for any abnormal sound, water leakages or other abnormal condition.

- If a trouble occurs, take suitable safety measures according to the condition and contact your Roche Service representative.

**Non-approved parts**

Use of non-approved parts or devices may result in malfunction of the system and may render the warranty null and void.

- Use only parts and devices approved by Roche Diagnostics.

# About installation and deinstallation

**Errors in installation**

Only trained Roche Service representatives may install the system.

- Leave installation that is not described to trained Roche Service representatives.

**Damage in transit**

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

**Disposal**

A biohazardous system may lead to infection.

- If you must dispose of the system, read the following information.

Disposal information (35)

# About operating conditions

**Unsuitable operating 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 remain unobstructed always.
- To maintain the operating 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.

**Power interruption**

A power failure or momentary drop in voltage may damage the system or lead to data loss.

- Operate only with an uninterruptible power supply (UPS).
- Ensure regular maintenance of the UPS.
- Perform regular backups of results.
- Do not switch off power while the control unit accesses the hard disk or storage device.

**Electromagnetic compatibility**

This instrument complies with the standard IEC 61326-2-6/EN 61326-2-6. It has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

- The electromagnetic environment should be evaluated prior to operation of the instrument.
- Do not operate this instrument in close proximity to sources of strong electromagnetic fields (for example, unshielded intentional radio frequency sources), as they may interfere with proper operations.
- Do not operate the following devices in close proximity to the instrument:
  - Mobile phones
  - Transceiver
  - Cordless phones
  - Other electrical devices that generate strong electromagnetic fields