cobas® trace doc software

User Guide

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Software version 1.1.0

Publication information

Publication version	Software version	Revision date	Change description
1.0	1.0.0	June 2019	First version
1.1	1.1.0	December 2021	Service patch 1.1

Revision history

Edition notice

This publication is intended for users of the **cobas**® trace doc 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, leading to a new version of this publication.

Where to find information

The **User Guide** contains all information about the product, including the following:

- Routine operation
- Safety
- Background information

The **Service Manual** contains all information about the product, including the following:

- Configuration and administration
- Safety
- Background information

⚠ General attention

Ensure that you are familiar with the instructions and safety information.

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

Images

The screenshots in this publication have been added exclusively for illustration purposes. Configurable and variable data in screenshots, 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.

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Open-source and commercial software

The product and the **cobas**® trace doc software as a whole may form a regulated software in accordance with the applicable laws – please refer to the user manual and the labeling for details. Please note that the respective authorization in accordance with the applicable laws lapse in case of any unauthorized changes to the **cobas**® trace doc software.

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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 Service representative, should you have any such feedback.

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Intended use

The **cobas**® trace doc software is a stand-alone software solution installed in the laboratory infrastructure in order to collect data that is relevant for the traceability of patient results and that is sent from the instrument.

cobas® trace doc software helps to store data outside the instrument for mid and long term. Based on the stored data, **cobas**® trace doc software provides navigation through the archived data via traces or linkages created by the analyzer.

cobas® trace doc software provides a traceability according to trace or linkage information that is provided by the instrument between measured patient sample result and the parameters that have been used to produce this result, including but not limited to reagent, control and calibration material and measurements.

cobas® trace doc software is a read only archive and does not change, update or manipulate any data except for anonymization to comply with privacy requirements, for example GDPR.. Neither does it offer any possibility to send back data to the instrument, nor send any sample orders or other commands to trigger any actions on the instrument.

The **cobas**® trace doc software is not intended to be used for troubleshooting by the laboratory or Roche Service. It is also not designed to be used for look-back procedures as sometimes used in blood banks.

Symbols and abbreviations

Product names

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

Product name	Descriptor
cobas® trace doc software	trace doc software
cobas® trace doc software application	user application
cobas® trace doc software administration	administration application

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 an action within 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.
	Figure. Used in figure titles and cross-references to figures.
	Table. Used in table titles and cross-references to tables.

 Symbols used in the publication

Abbreviations

The following abbreviations are used.

Abbreviation	Definition
LIS	Laboratory information system

 Abbreviations

Safety

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Safety

In this chapter 1

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Introduction

⚠ General attention

Read this publication thoroughly before you use **cobas**® trace doc softwaretrace doc software.

- Pay particular attention to all safety notices.
- Always follow the instructions in this publication.
- Do not use **cobas**® trace doc software in a way that is not described in this publication.
- Store this publication in a safe and easily retrievable place.

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 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.

Caution messages

⚠ List of caution messages

Failure to observe the caution messages may result in data loss or unavailability of the system.

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

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 recommendation is essential:

- Monitor **cobas**® trace doc software for suspicious activity and report any suspected compromise immediately to your local IT support.

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System description

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Overview

In this chapter 2

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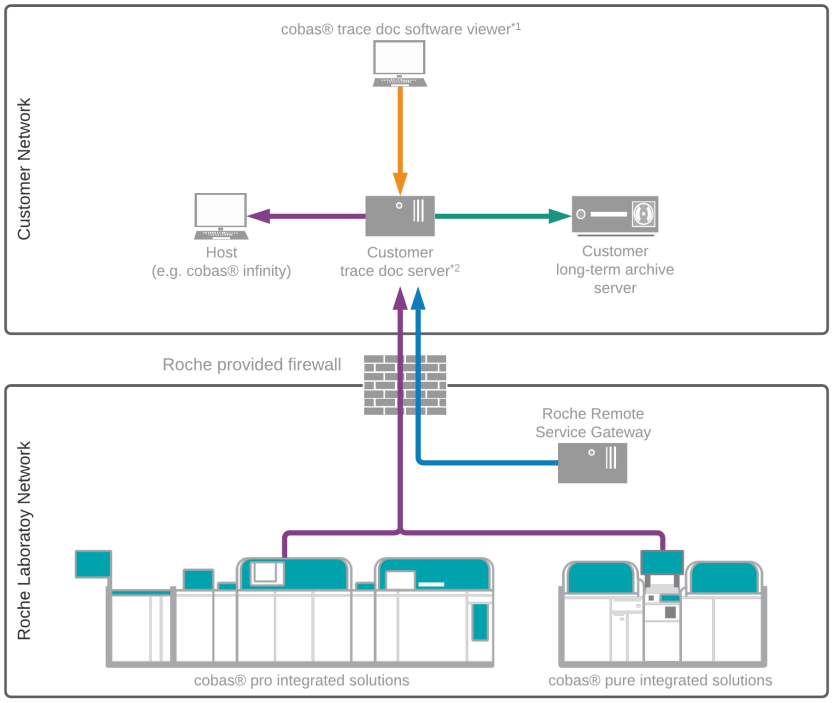
About the cobas® trace doc software

The **cobas**® trace doc software is an archiving software. It hooks into the communication between instrument and host and captures all result messages.

The **cobas**® trace doc software stores test, QC and calibration results. The results include details about the used substance (e.g. control code, sample ID), the used reagents (e.g. reagent lot number) as well as information about the module and system on which the measurements were performed.

The main **cobas**® trace doc software functions are:

- Collecting and processing of host messages from the following solutions in conjunction with or without a host system:
  - **cobas**® **pro** integrated solutions
  - **cobas**® **pure** integrated solutions
- Access to short-term archive via the web based **cobas**® trace doc software viewer.
- Advanced search based on various criteria (e.g. test name, sample ID, QC material, calibrator).
- Export of signed archive packages for the customer long-term archive server.
- Communication between user application and **cobas**® trace doc software is encrypted.
- Import of archive packages with authentication and integrity checks.



*1 cobas® trace doc software viewer can be used on a customer work station or on the customer trace doc server
*2 cobas® trace doc software can either be installed on a customer virtual machine or hardware

cobas® trace doc software workflow

cobas® trace doc software viewer

The **cobas**® trace doc software viewer provides access to the archive. It runs in a web browser and is used by the archive client user.

A set of criteria allows you to search the archive for specific results. The archive is read-only.

The **cobas**® trace doc software can be accessed from any computer that has a connection to the customer trace doc server.

Customer trace doc server

The virtual machine or computer with an installed operating system on which the **cobas**® trace doc software will be installed.

Prerequisites

Roche provided firewall

The Roche provided firsewall (e.g. Fortigate 50E) protects the Roche Laboratory Network (RLN) including the connected devices. It must be configured to allow outbound connection to the **cobas**® trace doc software.

Customer long-term archive server

In order to be compliant with local law and regulation, the signed archive packages exported by the **cobas**® trace doc software must be safely stored by the customer on a suitable long-term archive server (e.g. network attached storage, backup server).

Roche Remote Service Gateway

The Roche Remote Service Gateway provides remote access for support and troubleshooting purposes to the customer trace doc server via the Remote Desktop Protocol (RDP) from Microsoft.

Host

The **cobas**® trace doc software intercepts the host messages and stores them before forwarding them to the connected host (e.g. middleware, LIS, HIS). The **cobas**® trace doc software can also be operated without a connected host.

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Operation

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Operation

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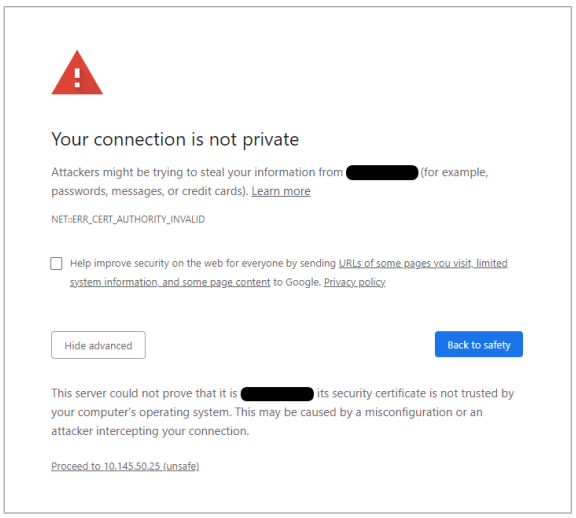
Logging on to the user application

The user application runs in a web browser.

The user application has been tested and optimized for the Google Chrome web browser.

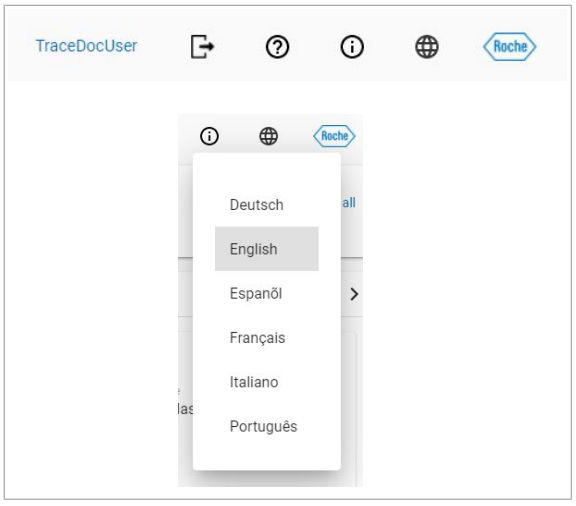
To log on to the user application



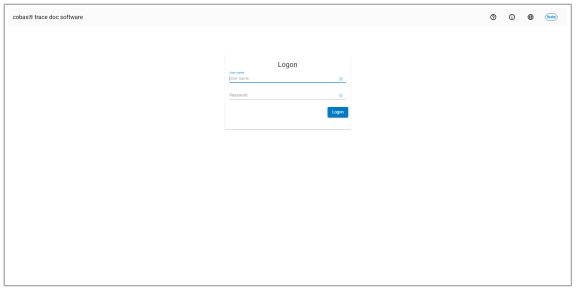
1 Double-click the **cobas**® trace doc software shortcut on the desktop or enter the URL into a web browser.

- https://<TraceDoc server IP address>:9002
  for example, https://192.168.1.4:9002

The browser might show a warning message indicating that the connection is not secure. This depends on the transport layer security certificate installed on the **cobas**® trace doc software server. For guidance, contact the **cobas**® trace doc software administrator.



2 From the drop-down list, choose your preferred language.



3 Enter your user name and password.

4 Choose the **Logon** button.

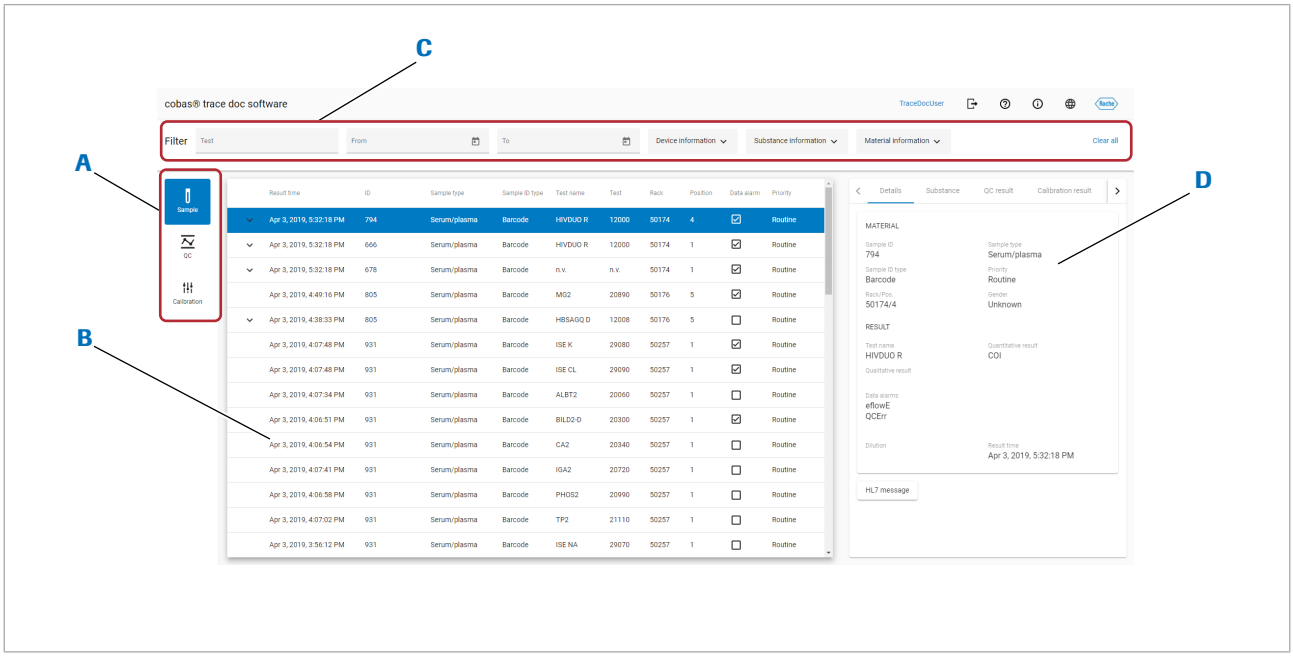
Searching and viewing results

The user application displays all archived results from the connected instruments. The results are grouped according to the specimen types (**Sample**, **QC**, and **Calibration**). Simple filters can be applied to search for specific results. Result details are displayed in a detail panel.

In this section

User interface of the user application

The user interface of the user application lists the results and shows all details. To search for specific results, use the filter options.



A Specimen type (**Sample**, **QC**, and **Calibration**)

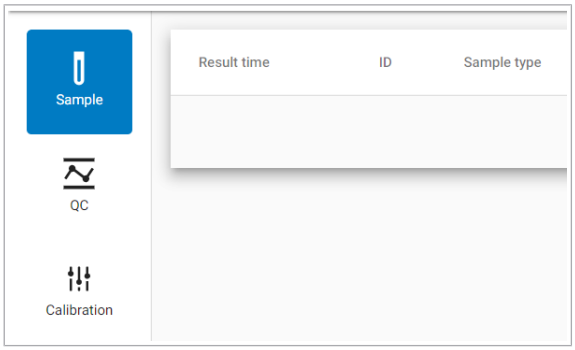
B Result list

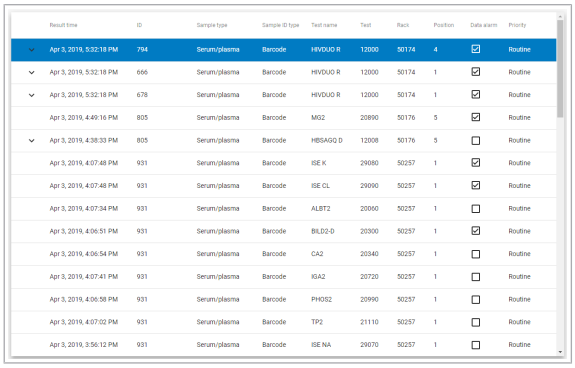
C Filters options

D Detail panel

User interface

Viewing results





To view results

1 Enter your filter criteria.
- The results are automatically reloaded every time you change the filter.
- Choose the **Clear all** button to load the available results without applying a filter.

ⓘ After logging on, the result list is empty.

2 Choose the specimen type:
- **Sample**
- **QC**
- **Calibration**

3 Select a result in the result list.
- A result can have sub-results. To view associated sub-results choose the ⌄ button to expand the main result entry and select a sub-result.

4 In the detail panel, use the tabs on the top to see detailed result information of the selected result:
- **Details**
- **Substance**
- **QC result**
- **Calibration result**

ⓘ Depending on the specimen type, not all tabs are available.

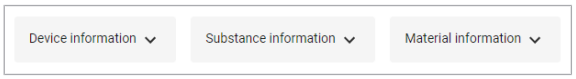
Filtering results

You can apply filters to search for specific results. Combinations of the filters are possible.

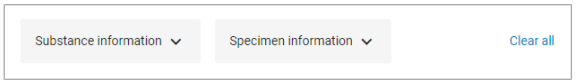
To apply filters to the result list

1 To search for a specific test, enter a test code in the **Test** field.

2 To restrict the result list to a specific date or date range,, enter a date in the **From** and /or **To** date fields. Alternatively, you can select the date with the date picker.



3 To further filter the result list, enter filter criteria in the drop-down lists:
   - **Device information**: choose the module and submodule type from the drop-down lists and enter serial numbers for the analyzer and the analytical unit.
   - **Substance information**: choose the substance type from the drop-down list (for example **R1** or **DIL**), enter code and lot number of the substance, and enter the analytical unit serial number.
   - **Material information**: choose one of the specimen types from the drop-down list (**Sample**, **QC**, or **Calibrator**).



4 To clear the filter, choose the **Clear all** button.

Accessing the User Guide

The User Guide is accessible as PDF document from the user application.

To access the User Guide

1 Choose the ⓘ button in the top right corner of the user application,

➔ A PDF of the User Guide is displayed in a separate window.

Logging off from the user application

If you are idle for too long, the software logs you off automatically.

To log off manually from the user application

1 Choose the **Logoff** button.

2 Close the web browser.

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