Roche

cobas® Liat® System

User Guide
Publication version 11.0
Software version 3.4

cobas®

US Publication information

Edition notice

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Feedback

This document was created by Roche Diagnostics GmbH (operator manual content) and the Roche Diagnostics Engineering Operations department. Direct questions or concerns regarding the contents of this document :

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Document availability

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Roche provides 24 hour-a-day, 365 day-a-year telephone assistance. In addition, on-site service is provided in a timely manner. In order for us to comply with federal record keeping requirements, if you need to contact your Roche Diagnostics service representative, call the appropriate Customer Support Center number listed below. They, in turn, notify your representative to contact you.

cobas Liat system   **1-800-800-5973 or email to: indianapolis_usa.liatsupport@roche.com**

The Customer Support Center answers all calls pertaining to Roche products. If the Customer Support Center cannot resolve a problem by phone, a Roche representative is dispatched.

Service policy questions   Questions relating to your service policy can be referred to your local Roche representative or the regional service manager by calling number above.

Customer Education

Roche Diagnostics conducts Indianapolis-based operator training courses and/or field-based training depending upon the instrument or system you purchased. Please contact your Roche Diagnostics representative for course availability and scheduling.

Ordering Information

Order replacement parts, consumable materials, reagents, standards, calibrators and controls as necessary from Roche. Please use the catalog number and reference name for each item when placing an order with Roche Order Fulfillment.

Roche Order Fulfillment   **1-800-428-5030**

Contacting Sales Representatives

If you wish to contact your sales representative, he or she may be reached by calling Roche Order Fulfillment or by leaving a message on their voice mail.

Roche Order Fulfillment   **1-800-428-5076**

Voice mail   **1-800-845-7355**

Enter the appropriate mailbox number or press # to spell the name.

OS-00192-04

Customer Communications

As the need arises, you will receive various customer communications concerning information about your system. These updates are usually in one of the following forms.

Customer communications can also be viewed on the internet. Some documentation is available online only. Go to dialog.roche.com > ROCHE DIALOG ESERVICES > eLabDoc.

Bulletins   Bulletins (Reagent, Software, or Analyzer) are printed on Roche Diagnostics letterhead. Bulletins contain information that is vital to the performance of your system. Communicate bulletin information internally to all analyzer operators. Keep bulletins on file until the reagent expires, you receive updated labeling or you are notified by Roche Diagnostics to discard them.

Urgent Medical Device Correction or Removal   Urgent Medical Device Correction or Removal is printed on Roche Diagnostics letterhead with the words **Urgent Medical Device Correction** or **Urgent Medical Device Removal**. These require immediate attention by the analyzer operator and are to be filed for reference until further notice.

Customer Letters   Customer Letters are printed on Roche letterhead and contain general information or attachments that you may place in your files. You may discard Customer Letters after reading and following any applicable instructions contained in them.

Product Announcement   Product Announcements are usually announcing product launches. They contain specific details about a new product such as features and benefits, kit configuration and pricing. Product Announcements may or may not be discarded depending on your laboratory's preference.

CLIA/CLSI Compliance

Roche documentation, which includes this operator's manual, methods sheets and active customer bulletins, conforms with the guidelines in effect at the time of publication listed in the Code of Federal Regulations (CFR) and the Clinical Laboratory Standards Institute (CLSI) General Laboratory Practices and Safety Guidelines. Documentation also meets the Centers for Medicare and Medicaid Services, formerly known as Health Care Financing Administration, interpretation of the requirements for the Clinical Laboratory Improvement Amendments (CLIA '88).

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There are several ways to change your mailing address or the contact name for your account. You may:

- send an email or
- go to dialog.roche.com

Provide your name and account number when contacting us. Your account number is provided to you by a Roche representative when your analyzer is installed.

Email   indianapolis.marcom-tech_pubs@roche.com

dialog.roche.com   Contact > Contact Change Form

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OS-00192-04

cobas® Liat® System

User Guide

Publication version 11.0

Software version 3.4

Publication information

Publication version	Software version	Revision date	Change description
4.0	2.0	March 2015	Clerical updates, text revisions.
5.0	2.1	December 2015	First publication in Roche user documentation format.
6.0	2.1.1	February 2016	Auto lock feature. Branding amendments. Address and intended use amendments.
7.0	3.0	May 2016	Liat images updated.
7.1	3.0	September 2016	Addition of *Consult operating instructions* advisory symbol. Addition of laser transmission cautionary label. Removal of image from *Labels on the analyzer* section.
7.2	3.1	April 2017	Extended intended use for Canada. Audit trail. Extensions for printer installation. Additional features for logon procedures and user management. Logon with badge barcode. Recommendations for inspection of printed barcode labels. Extensions for reviewing results. Extensions for export and delete results. Extensions for DMS connectivity. Color printing. Data migration. Extensions for error codes. Differentiation between software, hardware/firmware, and assay codes. Extensions for troubleshooting. Addition of other environmental conditions. Additional Caution statements. Updates of screenshots and text for changes in user interface.
8.0	3.2	December 2017	Safety instructions updated. Reference to local regulations added to disposal statements. Partial lock of the analyzer added. Locking and unlocking the analyzer restructured. Barcode standards added. System settings updated. Reviewing results, and exporting and deleting results updated. Scanning of activation codes added. Network resources updated. Information for connection interval added. Workflows for changing passwords aligned. Installing and updating assays restructured. Information about data migration deleted. List of error messages updated. Scrolling through the event log by page added. Screenshots updated.

⊞ Revision history

Publication version	Software version	Revision date	Change description
9.0	3.3	October 2019	▪ Publication renamed to User Guide. ▪ License information added. Information for open-source and commercial software added. ▪ TÜV SÜD added to approvals. ▪ Maximum output power of laser barcode reader updated. ▪ Information for data security and electrostatic discharge added. ▪ Advanced Tools replace the functions of the Advanced Tools Key (ATK). Advanced Tools Guide replaces the Advanced Tools Key Guide. ▪ Added/updated information: Symbols and abbreviations Installing the analyzer Storage capacity Analyzer status Power button Title bar Data encryption Starting the analyzer Logging on Changing your password Choosing predefined values Entering text and numbers Shutting down the analyzer Running an assay Result handling Run status Sending status of results Installing and updating assays System settings

⊞ Revision history

Publication version	Software version	Revision date	Change description
9.0 (continued)	3.3	October 2019	▪ Added/updated information (continued): Changing system language Configuring barcode settings Managing users Printer setup Updating the software Viewing system information About the Advanced Tools Archiving data Exchanging data Problem reports Cleaning the USB flash drive Network configuration Roche remote service platform configuration Connecting to a host system Patient verification Share locations configuration Quality control Cleaning the analyzer About troubleshooting List of error messages Lost password for the default administrator account ADMIN Cleaning the window of the barcode reader Restarting an unresponsive analyzer Starndard supplies Barcode specifications Printers USB devices

⊞ Revision history

Publication version	Software version	Revision date	Change description
10.0	3.3	February 2021	Changes for software version 3.3 patch 1:
			▪ The non-associated, introductory sentence was deleted from the Intended use section. The Intended use itself remained unchanged.
			▪ Table with symbols on product updated.
			▪ Information how to use the User Assistance updated.
			▪ Information about the analyzer software added.
			▪ Tilt sensing is always enabled.
			▪ Configuration option for automatic release of results.
			▪ Released results are always sent automatically to the host.
			▪ Control test results of an assay tube lot are only visible on the analyzer where the assay tube lot was added and validated.
			▪ Additional information for troubleshooting and messages can be logged.
			▪ Recommendation to use a lockable USB flash drive for archiving.
			▪ Assay tube lot information is included in problem reports.
			▪ Valid and invalid results, Ct values, and information about aborted runs are sent to a host.
			▪ Network shares use the SMBv2.1 or higher network protocol.
			▪ List of error messages updated.
			▪ Only the last 100 entries of event log are displayed. The full event log is contained in problem reports only.
			▪ Procedure added how to force the change of the ADMIN password.
			▪ Failed sending of results to host is indicated on the analyzer.
10.1	3.3	February 2021	Update for IVDR.

⊞ Revision history

Publication version	Software version	Revision date	Change description
11.0	3.4	August 2022	Added and/or updated information: ▪ Inclusion of part of Intended use applicable solely for Canada and therefore discontinuation of Canadian publications. ▪ Protect attached systems against malicious software and unauthorized access. ▪ Electromagnetic compatibility. Cable lengths. ▪ Contact your local Roche support before disposal. ▪ The analyzer does not require installation and qualification from Roche. ▪ Change time zone before changing time. ▪ Read the package insert or Instructions for Use of the assay. ▪ Extended list of analyzer statuses. ▪ Locking the analyzer. Locking the screen vs. locking the analyzer. ▪ Do not press the power button on the analyzer until the analyzer directs you to. ▪ Read the package insert or the Instructions for Use for the sample type. ▪ Sending status of results. ▪ Printing of assay installation report. ▪ Adding assay tube lots. ▪ Daily restart. ▪ Data collection. ▪ Actions for user roles. Password rules. What is new in publication version 11.0 (19)

⊞ Revision history

Publication version	Software version	Revision date	Change description
11.0 (continued)	3.4	August 2022	Added and/or updated information (continued): ▪ Connect a printer only via USB or network (not both). ▪ Result printing includes printing of run status information. ▪ Updating the software. ▪ The total number of results includes sample and control results. ▪ Connection to remote service. Configuring a proxy server. ▪ Improved connection to the DMS. You can force a connection. Details about last connection are available. ▪ Enhanced patient verification. ▪ Scheduling of automatic tasks. ▪ Archiving. Problem report included in archive file. ▪ Export and import settings, backup and restore functions only with same software version. ▪ Problem reports. ▪ Share lot folder is shared repository for result reports. ▪ Export and import assay tube lots before and after configuring share lot folder, respectively. ▪ Configuration items for network shares and FTP shares. ▪ Updated list of error messages. ▪ Parts and materials. ▪ Unsupported characters for user IDs and sample IDs. ▪ Standard ASCII character set only with the Code 128 barcode standard. ▸▤ What is new in publication version 11.0 (19)

▦ Revision history

Edition notice

This publication is intended for users of the **cobas**® Liat® 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.

Where to find information

The **cobas**® Liat® System **User Guide** contains all information about the product, including the following:
▪ Safety
▪ Installation
▪ Routine operation
▪ Maintenance and calibration
▪ Troubleshooting information
▪ Configuration information
▪ Background information

The **cobas**® Liat® Analyzer **Quick Start Guide** is intended as a reference during the **cobas**® Liat® Analyzer setup.

The **cobas**® Liat® Analyzer **Cleaning Tool Guide** is intended as an instruction for using the **cobas**® Liat® Cleaning Tool with the **cobas**® Liat® Analyzer.

The **cobas**® Liat® Analyzer **Advanced Tools Guide** is intended as a reference for performing various functions, including archiving data and syncing assay tube lots between **cobas**® Liat® Analyzers.

The **cobas**® Liat® Analyzer **Host Interface Manual HL7** contains all necessary information about the HL7 interface.

The **cobas**® Liat® Analyzer **Host Interface Manual POCT1-A (DML)** contains all necessary information about the DML interface.

The **cobas**® Liat® System **User Assistance** is the online help version of the **cobas**® Liat® System User Guide.

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When you use User Assistance online, viewing events (topics viewed and searches performed) and IP addresses are logged.
The data collected is for Roche internal use only and is never forwarded to third parties. It is anonymized, and after one year it is automatically deleted.
Viewing events are analyzed to improve User Assistance content and search functionality. IP addresses are used to classify regional behavior.

⚠ **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.

⚠ **Incident reporting**

‣ Inform your Roche representative and your local competent authority about any serious incidents which may occur when using this product.

Images   The screenshots and images in this publication, including software versions visible therein, 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 analyzer and the use of unauthorized assay tubes or accessories renders the warranty null and void.

Do not open the **cobas**® Liat® Analyzer, change a component, or install unauthorized software.

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This open-source and commercial software and **cobas**® Liat® System as a whole can constitute a device regulated in accordance with applicable law. For more detailed information, refer to the corresponding user documentation and labeling.

Note that the respective authorization is no longer valid according to the corresponding legislation should any unauthorized changes be made to **cobas**® Liat® System.

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In the U.S., call the following number: 1-800-800-5973.

Approvals The **cobas**® Liat® Analyzer meets the requirements laid down in:

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

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 directive(s) is provided by means of the Declaration of Conformity.

The following marks demonstrate compliance:

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TÜV Rheinland	Issued by TÜV Rheinland for Canada and the US.[a]
TÜV SÜD	Issued by TÜV SÜD for Canada and the US.[a]

Equipment de Laboratoire / Laboratory Equipment

'Laboratory Equipment' is the product identifier as shown on the type plate.

(a)   The analyzer features one of the marks.

Contact addresses

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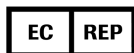
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Table of contents

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Intended use

The **cobas**® Liat® Analyzer is an automated nucleic acid test instrument, that when used together with **cobas**® Liat® assay tubes to perform *in vitro* diagnostic tests, is referred to as the **cobas**® Liat® System. In conjunction with a **cobas**® Liat® assay tube, the instrument performs reagent preparation, target enrichment, inhibitor removal, nucleic acid extraction, polymerase chain reaction (PCR) amplification, real-time detection, and result interpretation to automate the detection or quantification of nucleic acid targets in a biological sample.

Addition for Canada only:
The **cobas**® Liat® System is intended for professional use in a clinical laboratory setting or point-of-care (PoC) location.

Symbols and abbreviations

Names and product names

Except where the context clearly indicates otherwise, the following names, product names, and descriptors are used:

Name	Descriptor
cobas® Liat® System	system
cobas® Liat® Analyzer	analyzer
cobas® Liat® assay	assay
cobas® Liat® assay tube	assay tube
cobas® Liat® Cleaning Tool	cleaning tool
cobas® Liat® Cleaning Tool kit	cleaning tool kit
cobas® Liat® quality control kit	quality control kit

⊞　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.

⊞　Symbols used in the publication

Symbol	Explanation
ℹ	Extra information within a task.
⮕	Result of an action within a task.
📅7	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.
📷	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.
⚙	Code example. Used in code titles and cross-references to codes.

▦ Symbols used in the publication

Symbols used on product

Symbol	Explanation
REF	Catalog number.
GTIN	Global Trade Item Number.
SN	Serial number.
UDI	Unique device identifier.
CONTENT	Quantity contained in the package.
🏭	Manufacturer.
📅	Date of manufacture.

▦ Symbols used on product

Symbol	Explanation
EC REP	Authorized representative in the European Community.
	Indicates the entity importing the medical device into the European Union.
	Device for near-patient testing.
	Device not for self-testing.
===	Indicates that the equipment is suitable for direct current only; to identify relevant terminals.
	Temperature limits.
%	Humidity limits.
	Keep upright.
This side UP	This side up.
	Fragile handle with care.
	Keep dry.
	Keep away from sunlight.
0kg	Stacking limit by mass.
	Stacking limit by number.
	Recyclable.
i	Consult operating instructions.
!	Caution.

⊞   Symbols used on product

Abbreviations   The following abbreviations are used.

Abbreviation	Definition
AD	Amplification and detection
ANSI	American National Standards Institute
CFR	Code of Federal Regulations
CISPR	Comité International Spécial des Perturbations Radioélectriques (International Special Committee on Radio Interference)
Ct	Cycle threshold
CSA	Canadian Standards Association
DHCP	Dynamic Host Configuration Protocol
DML	Device messaging layer as defined in the POCT1-A standard
DMS	Data management system
DNS	Domain Name System
DOB	Date of birth
EC	European Community
EMC	Electromagnetic compatibility
EN	European standard
FTP	File transfer protocol
HIS	Hospital information system
HL7	Health Level Seven
IEC	International Electrical Commission
IP	Internet protocol
IPC	Internal process control
IVD	In vitro diagnostic
IVDR	In vitro diagnostics regulation
LAN	Local area network
LIS	Laboratory information system
MD5	Message-digest algorithm 5
n/a	not applicable
N/A	Not available
NAT	Nucleic acid test
PCR	Polymerase chain reaction
POCT	Point of Care testing
QC	Quality control
RF	Radio frequency
RUDI	Roche unique device identifier
SD	Standard deviation
SL	Share lot
SMB	Server message block
SNTP	Simple network time protocol

⊞ Abbreviations

Abbreviation	Definition
TCP/IP	Transmission Control Protocol/Internet Protocol
TLS	Transport Layer Security
UPS	Uninterruptible power supply
URI	Uniform resource identifier
USS	Uniform Symbology Specification
UTC	Coordinated Universal Time
WEEE	Waste Electrical and Electronic Equipment
WLAN	Wireless LAN
WPA2	Wi-Fi Protected Access 2

⊞ Abbreviations

What is new in publication version 11.0

Canadian Intended use and Canadian user documentation

The part of the Intended use that solely applies to Canada was added.

The User Guide and the User Assistance are now applicable for Canada as well. The publications that were published for Canada only are discontinued.

⯈▤ Intended use (15)

Data security

Ensure that other computers and services on the network and other systems that are attached to the analyzer are properly secured and protected against malicious software and unauthorized access (for example, by using antivirus software, limiting permissions, keeping system software up to date, backing up systems regularly, etc.).

⯈▤ Data security (36)

Electromagnetic compatibility

The information about electromagnetic compatibility was extended.

⯈▤ Electromagnetic compatibility (38)

Cable lengths

Information about cables was added.

⯈▤ Environmental conditions which are tested (39)

Disposal

Contact your local Roche support before disposal.

⯈▤ Disposal (39)

Installing the analyzer

The analyzer does not require installation and qualification from Roche.

Changing time zone and time

Any change to the time zone should be made first as changing it updates the time.

Running assays

Read the package insert or Instructions for Use of the appropriate assay for use with the **cobas**® Liat® Analyzer before proceeding with the test.

Analyzer status

The list of possible analyzer statuses was extended.

Locking the analyzer

If maintenance tasks must be performed or if the analyzer has a malfunction, you can now lock the analyzer to prevent assay runs. The locked status is indicated in the title bar of each screen.

Locking the analyzer vs. locking the screen

The function to lock the analyzer that prevents assay runs is not the same as the function to lock the screen that secures the analyzer when left unattended.

Loss of power

Do not press the power button on the analyzer until the analyzer directs you to.

Sample type

For transferring the sample to the assay tube during an assay run, read the package insert or the Instructions for Use for the sample type.

Sending status of results

The information about the sending status of results was separated for DMS and HL7.

Assay installation report

After installing an assay, you can print the assay installation report as long as no assay tube lot is added for the assay.

Adding assay tube lots

If you share assay tube lots via a DMS, you cannot use another way to share assay tube lots between analyzers at the same time.

If the negative control and/or positive control was not completed successfully during the add assay lot procedure, refer to the package insert or the Instructions for Use of the assay for further information, and repeat the negative and/or positive control.

Daily restart

To ensure that the automatic daily restart of the analyzer does not interfere with any ongoing activity (e.g., assay runs, scheduled tasks, etc.), schedule the daily restart for a time when the analyzer is not frequently used.

After each daily restart, a message is displayed. The next daily restart (or any scheduled tasks) will only be performed after you have confirmed the message.

Data collection

To gather statistical information and to facilitate product care, the analyzer software contains a data collection function that uses individual data collector plug-ins for each specific data collection purpose.

Data collection requires that the analyzer is connected to the remote service.

You can view a list of data collectors that are installed on the analyzer, and details about each data collector, including the kind of data that it collects.

By default, data collection is disabled on the analyzer.

For data collection to be executed, an administrator or a supervisor has to enable data collection on the analyzer.

‣ Data collection (142)

User management

The actions that a user with supervisor user role or administrator user role can perform on the analyzer were extended for the configuration of data collectors and scheduled tasks.

If the analyzer exchanges user data with a DMS, the following applies:
- Passwords must comply with the rules for passwords on both the analyzer and the DMS. For the password rules on the DMS, contact your DMS administrator.
- If the DMS does not support a separate badge barcode, but a user ID only, do not configure a logon mode on the analyzer that uses a badge barcode.

‣ Overview of user account user roles (148)

‣ About user IDs and passwords (149)

Connecting printers

Do not connect a printer to the analyzer via both USB and network. Printing via USB may not work correctly if the analyzer and the printer are additionally connected to the same network.

‣ About printer setup (156)

‣ Connecting a printer (158)

Printing of run status information

Result printing includes the printing of run status information.

‣ About laser and inkjet printers (156)

Updating the software

When updating the software, always follow the instructions that are displayed on the screen because the specific steps may differ depending on the installed software version. For example, you may be prompted to export and delete results and/or to calibrate the screen.

The procedures for how to update the software were updated.

‣ Updating the software (168)

Total results
The total number of results that is displayed includes the sample and control results. (Results from tube lot validation are not included.)

⇥ Viewing system information (174)

Scheduled tasks
On the new **Scheduled tasks** screen (**Settings > Scheduled tasks**), you can now schedule the following tasks for automatic execution:

- **Archive and delete results** (new)
- **Archive and reduce audit trails** (new)
- **Problem report** (moved from the **Tools** screen)

Alternatively, if the analyzer is connected to a DMS, it can receive the scheduled tasks from the DMS as part of the device configuration.

The configured settings for scheduled tasks are treated as analyzer settings and are therefore included in the following functions from the **Tools** screen:

- **Export settings**
- **Import settings**
- **Back up analyzer**
- **Restore analyzer**

To ensure that the scheduled tasks are performed as configured, observe the following:

- As the execution of scheduled tasks may take some time and you cannot perform any other action meanwhile, schedule them for a time when the analyzer is not frequently used.
- You cannot perform any other action on the analyzer until the scheduled task is finished.
- Do not schedule the daily restart and the different scheduled tasks for the same time. Configure a different time for each action.
- After each daily restart, a message is displayed. Any scheduled tasks (or the next daily restart) will only be performed after you have confirmed the message.
- To prevent the daily restart from interfering with the scheduled tasks, schedule the automatic tasks for earlier in the day than the daily restart.
- Because of data encryption, schedule the archiving and deletion of results and/or the problem report for a time when a user has already logged on after the last startup of the analyzer.

If a scheduled tasks fails, check the connections and the storage location, e.g., the network share. Try again manually and/or wait for the next scheduled execution. If the scheduled task still fails, contact your Roche representative.

▸▤ About data encryption (62)

▸▤ About scheduled tasks (64)

▸▤ Scheduling automatic archiving and deletion of results (189)

▸▤ Scheduling automatic archiving and reduction of audit trails (192)

▸▤ Scheduling automatic problem reports (211)

About archiving

Further information about archiving was added.

Archived data is only deleted from the analyzer if archiving was successful. This applies to the following functions:

- Archive and delete results (manually or automatically)
- Archive and delete audit trails (manually)
- Archive and reduce audit trails (automatically)

When you archive and delete results (manually or automatically), a problem report is automatically created with the same archiving criterion and contained in the archive file.

Storage locations that are accessible for archiving are displayed in black font on the screen.

If manual or automatic archiving fails, check the connections and the storage location, e.g., the network share. Try again manually and/or wait for the next scheduled execution. If archiving still fails, contact your Roche representative.

▸▤ Archiving data (180)

▸▤ About problem reports creation (208)

Exchanging data

Importing settings overwrites the existing exportable settings on the analyzer.

Only export and import settings between analyzers that have the same software version installed.

Only use the backup and restore functions between analyzers that have the same software version installed.

▸▤ About compatibility (179)

Problem reports   If the analyzer is connected to a DMS, problem reports always contain the data synchronization details.

Sample IDs can only be contained in problem reports if sample results are included.

To facilitate diagnostics, it is recommended to include the optional content in problem reports and consider the appropriate data range.

The default values for the problem report content were added.

If manual or automatic problem report creation fails, check the connections and the storage location, e.g., the network share. Try again manually and/or wait for the next scheduled execution. If the problem report still fails, contact your Roche representative.

Remote service   The information about how the analyzer connects to Axeda as remote service was updated.

You can now connect the analyzer to **cobas**® **infinity** edge smart as remote service as an alternative to Axeda.

The information was updated about how to configure a proxy server for access to the internet for connecting to the remote service.

Information was added about which traffic between the analyzer and the remote service is directed through the proxy server.

DMS connection   The connection to the DMS was improved:

- After the daily restart, the analyzer establishes a normal connection.
- You can now manually force a connection to the DMS on demand.
- Details about the connection status and the last synchronizations are available.

QC data and information messages are communicated to the DMS. Ct values are included for detected target results only.

Information was added about which data the analyzer accepts from the DMS depending on analyzer status.

- About problem reports content (205)
- About host connections (236)
- Monitoring host connection (241)
- Forcing a connection to the DMS (242)
- About data exchange with a DMS (243)
- About the timing of communications (244)
- Overview of accepted data for different analyzer statuses (245)
- Viewing details of the last synchronization with a DMS (246)
- List of error messages (272)

Enhanced patient verification

If patient verification takes too long (e.g., due to network performance) you can cancel the patient verification. The next step in the assay run then depends on the analyzer configuration and your user role.

If patient verification is configured, on the **Result report** screen, both the scanned ID (sample ID, patient ID, order ID, or visit ID) and the received patient ID are displayed.

The scanned ID, the outcome of the patient verification (success, fail), the received patient ID (if patient verification successful), and the action taken by the user if patient verification failed (cancel, retry, overrule patient verification) are part of the results that are transferred to the DMS.

- About running an assay with patient verification (248)
- About results with patient verification (249)

Share locations

The share lot folder is also used as a shared repository for result reports.

Before you change the configuration of the share lot folder, export the assay tube lots. After changing the configuration of the share lot folder, import the assay tube lots again.

If DNS resolution is not possible, the server name may not work for the URI of the network share server. Try the IP address of the network share server instead.

The **Type** configuration item for FTP shares is read-only and is displayed automatically.

‣▤ Share locations configuration (253)

‣▤ Configuration items for share locations (253)

‣▤ Configuring the share lot folder (255)

List of error messages

The list of error messages was updated.

‣▤ List of error messages (272)

Parts and materials

The information about parts that are provided and required materials that are not provided was consolidated and updated.

The **cobas**® Liat® Analyzer Advanced Tools Guide is no longer included in the package.

Electronic user documentation can be downloaded using the eLabDoc e-service on Roche DiaLog.

‣▤ eLabDoc (11)

‣▤ Installing the analyzer (45)

‣▤ Parts and materials (298)

Unsupported characters

The list of characters that are not supported for sample IDs and user IDs was extended.

‣▤ Unsupported characters (299)

Barcode specifications

Only use the standard ASCII character set with the code 128 barcode standard. Do not use the extended ASCII character set (code 128-255).

‣▤ Barcode specifications (300)

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Safety

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General safety information

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1 General safety information

Safety instructions

Safety classification

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 symbol**

‣ 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 that, if not avoided, may result in damage to the analyzer.

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

💡 **Tip…**

…indicates additional information on correct use or useful tips.

Safety summary

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

1 General safety information

⚠ WARNING!

Insufficient knowledge and skills

As a user, ensure that you know the relevant safety precaution guidelines and standards and the information and procedures contained in these instructions.

▶ Carefully follow the procedures for operation and maintenance described in the User Guide.

▶ Leave maintenance, installation, or service that is not described in the User Guide to your Roche Service representative.

⚠ WARNING!

Infectious materials

There is a potential risk of infection. Users using the **cobas**® Liat® Analyzer to perform tests on patient samples must be aware that any object coming into contact with biological specimens is a potential source of infection.

▶ Use disposable gloves.

▶ Use a new transfer pipette (provided) for each sample.

▶ Follow all health and safety regulations applicable to your institution.

Laser transmission

Label	Explanation
⚠	There is a danger of contact with laser light or severe damage to the eyes. Do not stare into the laser transmitter.
⚠ **LASER 2** 🚫	

▦ Laser transmitter cautionary labels

⚠ **WARNING!**

Blindness due to intense barcode reader light

The intense light of a laser barcode reader may severely damage your eyes or result in exposure to hazardous radiation.

▸ Do not stare into the beam of the laser barcode reader.

▸ Do not remove covers from the barcode reader.

▸ Do not perform any maintenance actions on the barcode reader. If you experience problems with the barcode reader, contact your Roche representative.

▸ Perform only the procedures described in the User Guide. Performing unauthorized procedures may result in exposure to hazardous radiation.
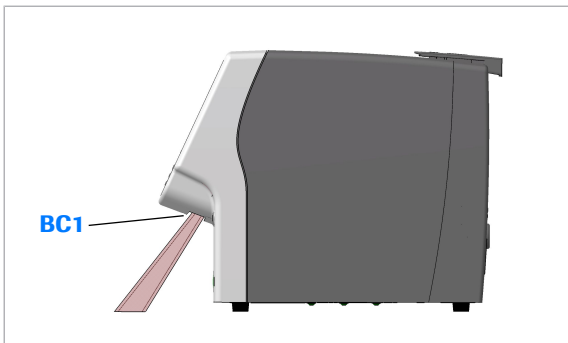
Barcode reader beam localization	Wave-length	Pulse duration	Max. output	Remark
BC1	650 nm	720 µs	2.5 mW	Class 2 laser IEC 60825-1 CFR 21 Part 1040.10

⊞ Laser barcode reader in the **cobas**® Liat® Analyzer

Data security

⚠ CAUTION!

Data loss, unavailability of the analyzer, or unauthorized access to personal information due to malicious software, misuse, or unauthorized access

Infection by malicious software, misuse of the analyzer, or unauthorized access can result in data loss, unavailability of the analyzer, or unauthorized access to personal information.

▶ Do not install and/or execute any other software on the analyzer.

▶ Ensure that attached networks are secure and monitored for security breaches. Customers are responsible for the security of their local 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.

▶ Ensure that other computers and services on the network and other systems that are attached to the analyzer are properly secured and protected against malicious software and unauthorized access (for example, by using antivirus software, limiting permissions, keeping system software up to date, backing up systems regularly, etc.).

▶ Restrict physical access to the analyzer and all attached IT infrastructure (computer, cables, network equipment, etc.).

▶ If parts of your network, which the analyzer uses to exchange data, are connected by WLAN, secure the WLAN with WPA2 encryption.

<div style="background-color: yellow">

⚠ CAUTION!

Data loss, unavailability of the analyzer, or unauthorized access to personal information due to malicious software, misuse, or unauthorized access (continued)

</div>

Infection by malicious software, misuse of the analyzer, or unauthorized access can result in data loss, unavailability of the analyzer, or unauthorized access to personal information.

▸ Ensure that any external storage devices (such as USB flash drives) connected to the analyzer are free of malicious software.

▸ Ensure that any external storage devices (such as USB flash drives) that contain export files and archive files are protected against unauthorized access.

▸ Use a Kensington lock to prevent theft of the analyzer.

▸ Set a short auto lock time on the analyzer (e.g., keep the default value of 3 minutes).

▸ Prevent credential theft:

   ▪ Use strong passwords.

   ▪ Do not share passwords.

   ▪ Do not write passwords down.

   ▪ Do not share user accounts.

▸ If you connect the analyzer to a host, enable TLS encryption to secure the connection.

▸ Ensure that export files and archive files are stored in a secure location and are protected from any unauthorized access and disaster.

1 General safety information

Electromagnetic compatibility

⚠ CAUTION!

Malfunction of system and incorrect results due to interfering electromagnetic fields

If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the system and the source of the interference.

The system complies with the emission and immunity requirements described in IEC 61326-2-6, IEC 61326-1, CISPR 11, and in the FCC CFR 47, Part 15 Subpart B: Class A.

This system is designed and tested to CISPR 11 Class A standard. In a domestic environment it may cause electromagnetic 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 system.

▸ WARNING: Do not use this system in proximity (< 30 cm) to sources of strong electromagnetic radiation (for example, microwave ovens, hand-held radio transmitters, electric motors), as these can interfere with proper operation. The distance of 30 cm for "portable RF devices" (mobile phones, Wi-Fi) is considered as normal electromagnetic fields for the system.

Class A equipment is suitable for use in all establishments other than domestic and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes (CISPR 11, 4.2).

1 General safety information

Environmental conditions which are tested

⚠ **CAUTION!**

Cable lengths with which the system complies with EMC testing

USB 2.0: < 3 m

LAN/Ethernet: < 30 m (longer cable might reduce speed performance)

▸ WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this system could result.

▸ WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this system could result in increased electromagnetic emissions or decreased electromagnetic immunity of this system and result in improper operation.

Disposal

The analyzer must be disposed of in accordance with relevant local regulations and in coordination with your local authorities, as appropriate. The analyzer may potentially be infectious. Contact your local Roche support before disposal.

Safety labels on the analyzer

Safety labels are placed on the analyzer to draw your attention to areas of potential hazard.
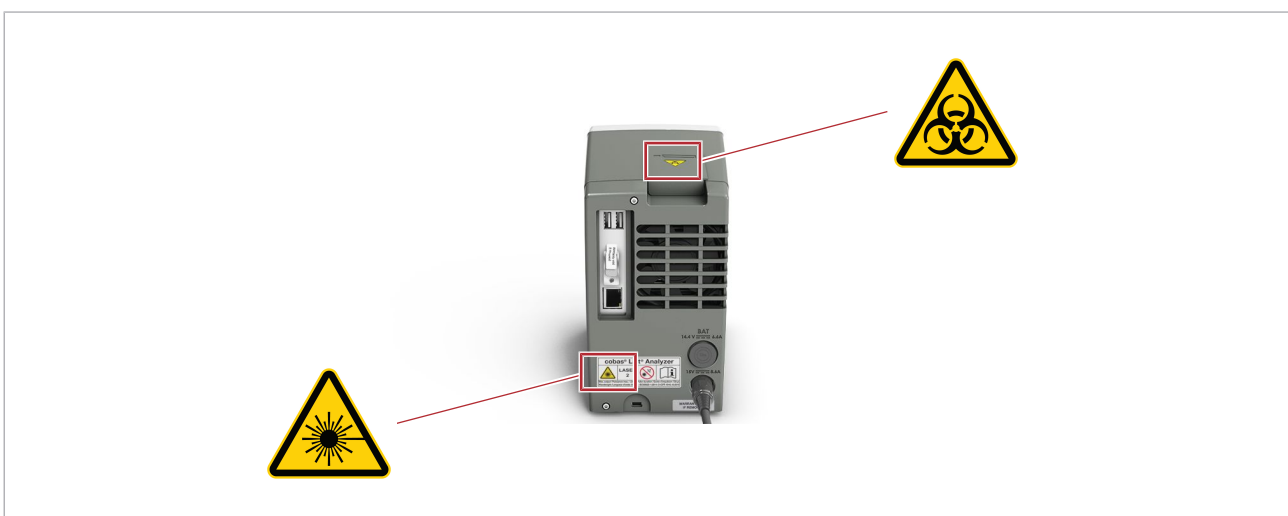
📷 Safety labels on the analyzer (rear view)

Listed below are labels and the definitions according to the location on the analyzer.

1 General safety information

The safety labels on the analyzer comply with the following standards: ANSI Z535, IEC 61010-1, IEC/EN 61010-2-101, or ISO 15223-1.

In addition to the safety labels on the analyzer, there are safety notes in the corresponding parts of this publication.

-ᗩ- For replacement labels, contact your Roche representative.

Biohazard warning
This label indicates that there are potential biohazards within the vicinity of this label. The user is responsible for cleaning the area if biohazardous material was spilled. Follow Good Laboratory Practice for working with biohazardous materials

General warning
Potential hazards located near this label may lead to death or serious injury.

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

Operation

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Installation

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Installing the analyzer

Place the analyzer on a suitable level surface and connect it to the power supply. Connect it to a printer and a network, if required.

When the analyzer is starting up, a series of initialization diagnostic tests are performed automatically.

The analyzer does not require installation and qualification from Roche.

⚠ CAUTION!

Incorrect results or malfunctions due to incorrect installation

Performing installation actions other than those mentioned in the User Guide may lead to malfunction and incorrect results.

▶ Do not carry out any installation actions that are not described in the User Guide.

⚠ CAUTION!

Injury by tripping over cables

Cables between the analyzer and mains outlets cause a potential tripping hazard.

▶ Position the analyzer as close to the mains outlet as possible, taking care to ensure sufficient room for ventilation (at least 10 cm).

▶ Take care not to trip if you must walk behind the analyzer.

⚠ CAUTION!

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.

NOTICE!

Malfunction due to use of inappropriate power supply

Using an inappropriate power supply may cause malfunction.

▶ Only use the supplied power supply.

Make sure that the package includes the following items:

☐ **cobas**® Liat® Analyzer

☐ Power supply

☐ Power cable

☐ Touch screen stylus

☐ User ID card kit

☐ **cobas**® Liat® Cleaning Tool kit

☐ **cobas**® Liat® System Short Instructions

☐ **cobas**® Liat® Analyzer Quick Start Guide

☐ **cobas**® Liat® Analyzer Cleaning Tool Guide

-ᶛ̣- If the packaging is damaged or an item is missing or damaged, immediately contact your Roche representative.

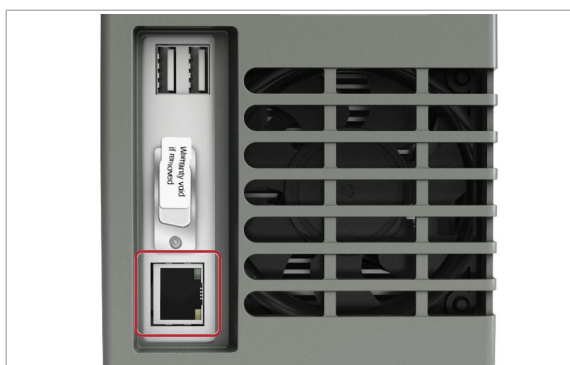-ᶛ̣- Retain the shipping container and packaging materials in case you have to return the analyzer to Roche for service.

☐ **cobas**® Liat® Analyzer

☐ Power supply

☐ Power cable

☐ Ethernet data cable wit RJ-45 connectors, if you intend to connect the analyzer to a data network

☐ USB cable, if you intend to connect the analyzer to a USB printer

☐ Kensington lock, if you intend to secure the analyzer

☐ If the analyzer is cold due to shipping or storage, allow it to come to ambient temperature before opening the package and powering up to avoid possible condensation inside the analyzer.

▶ To install the analyzer

1 Place the analyzer indoors on a solid, level, vibration-free, and non-reflective surface, away from direct sunlight.

2 Installation

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i Allow at least 10 cm (4 inches) of space at the rear of the analyzer for airflow. Ensure that the vents at the rear and at the bottom of the analyzer are not blocked.
Allow at least 6 cm (2.5 inches) of space in front of the analyzer for easy barcode scanning.
Position the analyzer near a grounded mains outlet to avoid creating a trip hazard with the power cable.

2 Optionally, secure the analyzer with a Kensington lock.

3 Connect the power supply with the analyzer.

i Only use voltage of 100-240 V AC, 50-60 Hz.

4 Connect the power supply with the provided power cable to a properly grounded mains outlet.

5 Press and release the power button to power on the analyzer.

6 Optionally, connect the analyzer to the local data network. Use a standard Ethernet data cable and connect the Ethernet port of the analyzer to an appropriate wall connector or switch.

i By default, the analyzer tries to connect to a DHCP server in your network to configure its network settings automatically.

2 Installation
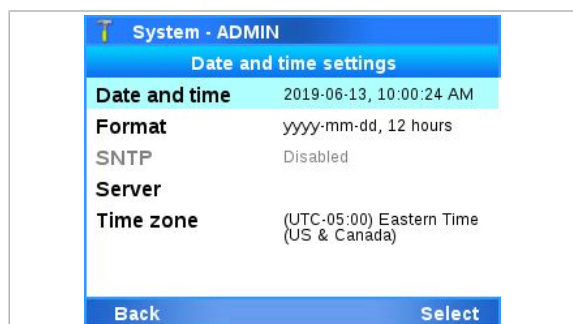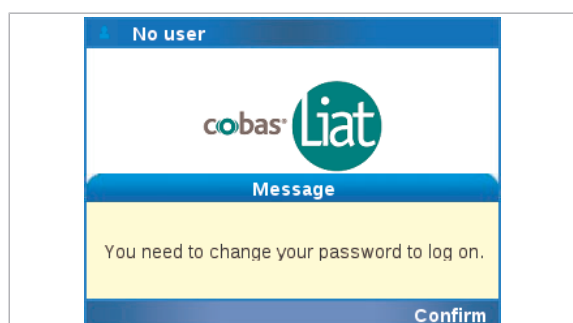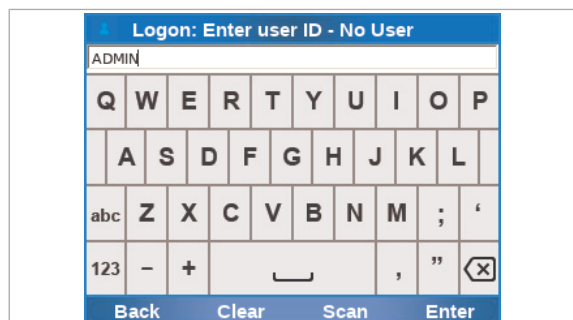
7 Choose the **Log on** button.

8 Manually enter "ADMIN" as user ID. Choose the **Enter** button.

- ℹ You must use the default administrator account ADMIN for the first logon to the analyzer.

9 On the message dialog box, choose the **Confirm** button.

- ℹ When you use a default user account for the first time, you must change the password at logon.

10 Enter the new password for the default administrator account ADMIN and choose the **Apply** button. To confirm the new password, enter the password again and choose the **Apply** button.

- ℹ Take note of the new password. The analyzer uses the password of the default administrator account to encrypt all sensitive data on the analyzer during first logon.

- → The analyzer initializes the data encryption. This may take some time.

11 Choose **Settings > System > Date and time**. Ensure that the time zone, date, and time are set correctly. If necessary, set the correct time zone, date, and time as described in System settings (133).

- ℹ Any change to the time zone should be made first as changing it updates the time.

12 If you connected the analyzer to a network in step **6** but the network settings were not configured automatically, configure the network settings manually as described in Network configuration (219).

2 Installation

13 Optionally, connect and configure a printer as described in Printer setup (156).

14 NOTICE! Risk of data loss in case of lost ADMIN password.

It is recommended to create another administrator account immediately as described in Creating users (150).

ⓘ If the new password for the default administrator account ADMIN is lost and you have no alternative way to change the password, you must reset the analyzer before you can use the account again. The analyzer reset deletes user accounts, passwords, sample IDs, patient IDs, order IDs, visit IDs, and results from the analyzer.

15 To facilitate diagnostics, it is recommended to include the optional content in problem reports and consider the appropriate data range as described in Configuring problem reports content (208).

⊩ **Related topics**

- Logging on (72)
- Changing your password (74)
- System settings (133)
- About data encryption (62)
- Network configuration (219)

2 Installation

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About the analyzer

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About the analyzer functions

The analyzer and the associated disposable assay tubes are for *in vitro* diagnostic use. The analyzer identifies and/or measures the presence of genetic material in a biological sample. The analyzer automates all nucleic acid test (NAT) processes, including reagent preparation, target enrichment, inhibitor removal, nucleic acid extraction, amplification, real-time detection, and result interpretation in a rapid manner.

Overview

The assay tube uses a flexible tube as a sample processing vessel. It contains all assay reagents pre-packed in tube segments separated by seals. Multiple sample processing actuators in the analyzer compress the assay tube to selectively release reagents, move the sample from one segment to another, and control reaction conditions. A detection module monitors the reaction in real time, while an onboard computer analyzes the collected data and outputs an interpreted result.

In a typical assay, a sample is first mixed with an internal control and then with lysis reagents. Magnetic glass particles are incubated with the lysed sample for nucleic acid enrichment, and are then captured and washed to remove possible inhibitors. Subsequently, nucleic acid is eluted from the magnetic glass particles and transferred alternately between tube segments at different temperatures for rapid PCR amplification and real-time detection.

Insert and test automation

The **cobas**® Liat® System automates all testing processes from sample preparation to amplification and real-time detection. By reducing complex nucleic acid testing to three simple steps, **cobas**® Liat® technology enables non-specialized personnel to conduct sophisticated testing.

When the sample is added to the sample segment of the assay tube, the tube is capped and remains closed for the entire test process. No further materials need to be added or removed from the tube. This approach avoids cross-contamination, reduces biohazard risks, and helps preserve sample integrity.

Rapid testing

This technology uniquely uses liquid flow and mixing to enhance reaction rates while allowing for relatively large reaction volumes. For example, the **cobas**® Influenza A/B

3 About the analyzer

Nucleic Acid Test for use on the **cobas**® Liat® System, using a nasopharyngeal swab sample, takes approximately 20 minutes from sample collection to result generation.

-ᣰ̣- Assay tubes can only be used once.

NOTICE!

Damage to the analyzer due to using unauthorized assay tubes

The use of unauthorized or unapproved assay tubes or accessories may damage the analyzer. Damage caused by unauthorized tubes or accessories voids the analyzer warranty.

▸ Only use assay tubes listed in the parts and materials in the User Guide.

Self-checks

When the analyzer is starting up, a series of initialization diagnostic tests are performed automatically. Furthermore, the analyzer monitors its operations during assay processing, and performs an automated calibration periodically. If an error occurs, a message is displayed on the screen and the event is logged.

-ᣰ̣- If a hardware-related issue occurs during initialization, the analyzer will be partially locked: You can still perform software-related actions on the analyzer, e.g., log on and generate a problem report. However, you cannot perform hardware-related actions (e.g., run an assay or add an assay tube lot).

Running assays

-ᣰ̣- Read the package insert or Instructions for Use of the appropriate assay for use with the **cobas**® Liat® Analyzer before proceeding with the test.

The testing process has been condensed to a few simple steps:

- Preparing a patient sample.
- Transferring the sample into an assay tube.
- Scanning the assay tube barcode label.
- Inserting the assay tube into the analyzer.
- The analyzer automatically runs all the required assay steps and reports the test results.
- Disposing of the assay tube.
- Reviewing the result.

Before using the analyzer for the first time, make sure that it is set up correctly and the required assays are installed and activated.

About the analyzer software

The **cobas**® Liat® software provides workflow management for the *in vitro* diagnostic medical device **cobas**® Liat® Analyzer.

About storage capacity

The analyzer can store at least 5000 results including all related run data.

About the audit trail

The system logs each user action that triggers a system change in an audit trail entry along with user information and time stamp (in UTC).

You can archive the audit trail.

‣ Archiving audit trails manually (185)

‣ Scheduling automatic archiving and reduction of audit trails (192)

About analyzer status

The analyzer can have the following status:

- Ready:
    - A user is logged on.
    - No operation is currently performed on the analyzer.
- Busy:
    - An operation is currently performed on the analyzer.
- Standby:
    - No user is logged on, or the walk-by screen is active.
- Partial lock:
    - One or more assay or the SW registration periods have expired, an error was encountered during initialization, or the maximum audit trail threshold is reached.
- Locked:
    - The analyzer cannot run assays.

‣ About locking the analyzer (67)

‣ **Related topics**

- About setting up the analyzer (113)
- Installing or updating an assay from the USB flash drive (115)

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3 About the analyzer

- Installing or updating an assay from the remote service (117)
- Installing an assay from a local source (119)
- Adding an assay tube lot (124)

Overview of the analyzer operating elements

A Function buttons	**D** Tube entry door	**G** Power button
B Navigation buttons	**E** Touch screen	
C Barcode reader	**F** Power indicator light	

▣   Analyzer components.

Function buttons   The function buttons are located beneath the touch screen and are aligned with the touch screen buttons.

You press a button to perform the same function as when tapping the aligned button on the touch screen.

Navigation buttons   You use the 4 buttons (left, right, up, and down) to highlight an item for selection, scroll through screens, position the cursor, and toggle selections.

Barcode reader   The barcode reader aims the scanning beam down in front of the analyzer. Choosing the **Scan** button on the screen activates the reader for approximately 5 seconds to read barcodes.

Tube entry door	Opens and closes automatically during an assay run so that you can insert and remove the assay tube.

> -ᜣ- Never open or close the tube entry door manually, unless instructed to do so on the screen.

Touch screen	You tap the items on the screen with your finger (also when wearing disposable gloves), or the stylus included with the analyzer.

Power button	Switch on and switch off the analyzer.

To shut down the analyzer, always follow the shutdown procedure. Only switch off the analyzer with the power button when the analyzer has completed shutdown.

About assays

The analyzer runs a specific assay as determined by the scanned barcode of an assay tube.

The analyzer requires a program, called an assay script, to conduct a specific assay.

New assays can be added to the analyzer by installing assay scripts. You need supervisor or administrator user role to install an assay script.

The currently available assays are listed on the **Assay Menu** screen.

Related topics

- Installing an assay from a local source (119)
- Adding an assay tube lot (124)
- Running an assay (95)

Overview of the touch screen

To operate the touch screen, use your finger (even when wearing disposable gloves) or the stylus included with the analyzer.

> **NOTICE!**
>
> **Damage to the touch screen due to using sharp objects**
>
> Using sharp objects on the touch screen may damage the screen and lead to malfunction.
>
> ▸ Do not use sharp objects for operating the touch screen.

Touch screen elements

The touch screen is divided into several information and operating areas.
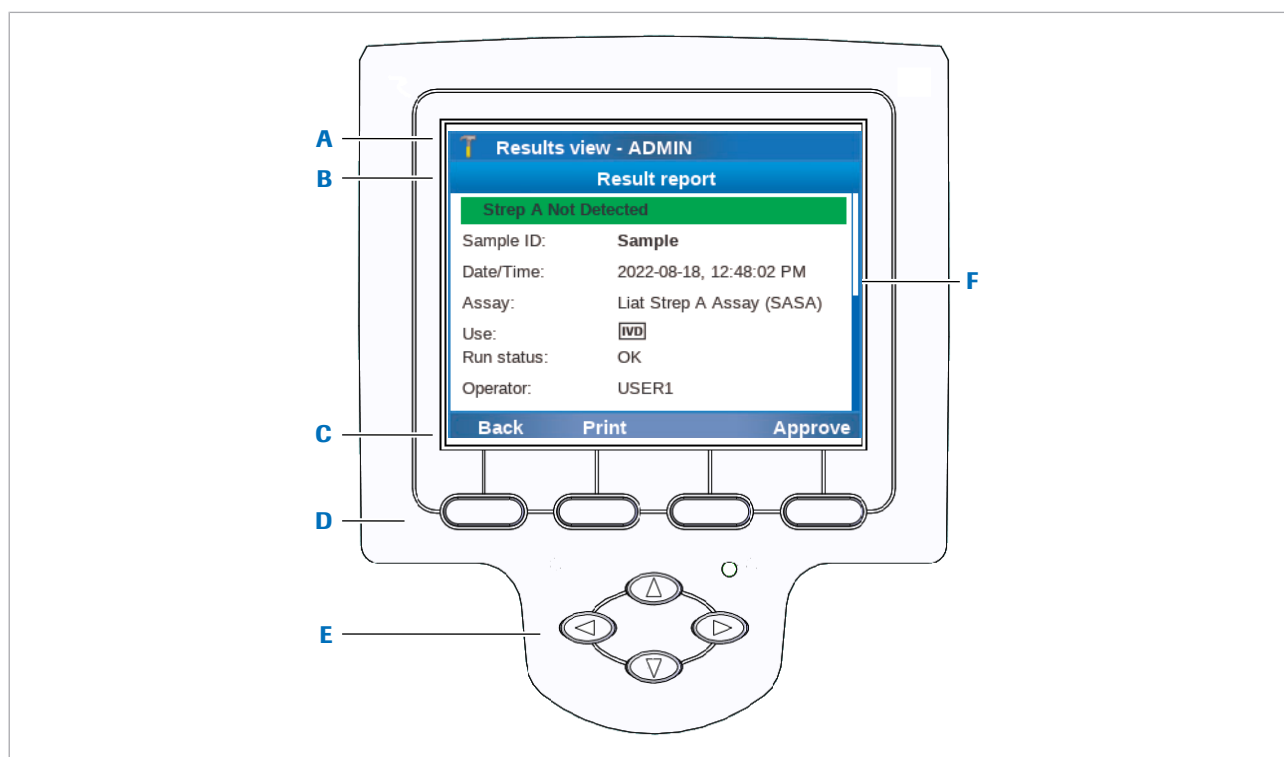
A	Title bar	**D**	Function buttons
B	Subtitle bar	**E**	Navigation buttons
C	Touch screen buttons	**F**	Scroll bar

▣ Overview of touch screen.

⚙️ To choose an item, either tap it directly or use the corresponding function button.

Title bar
Displays
- User role icon:

  🔨 Administrator

  👥 Supervisor

  👤 User

- Current screen name or assay name.
- User ID
  User IDs shown in screenshots in this publication are for illustration purposes only.

In case of a configured DML or HL7 connection, you can also monitor the connection status in the touch screen.

If the share lot folder is enabled, the share lot folder connection status is also indicated in the title bar of the touch screen.

If the log level is set to the **Verbose** value, this is also indicated in the title bar of the touch screen.

If the analyzer is in locked status, the title bar is black and an 🔒 icon is displayed in the top right corner.

> 📖 About locking the analyzer (67)

> 📖 System settings (133)

> 📖 Monitoring host connection (241)

> 📖 Share lot folder connection status (255)

Touch screen buttons
The touch screen buttons vary depending on the current content of the screen.

Function buttons
Perform the same function as the corresponding touch screen buttons.

Navigation buttons
Use to highlight an item for selection, scroll through menus, position the cursor, and toggle selections.

3 About the analyzer

About data encryption

All sensitive data on the analyzer is encrypted.

Data encryption is initialized when you log on to the analyzer for the first time during analyzer installation and may take some time. The encryption uses the new password for the default administrator account ADMIN that you must enter during the first logon.

The following data is encrypted:
- User accounts and password
- Sample IDs, patient IDs, order IDs, and visit IDs

All non-sensitive data is not encrypted, for example:
- Assays
- Assay tube lots
- System settings
- Results
- Log files
- Audit trails

Because of data encryption, a user that must change the password at logon cannot be the first user to log on after starting or restarting the analyzer. At first, a user without a request to change the password must log on and log off again.
This also applies to the default accounts SUPERVISOR, USER1, and USER2, that must change their passwords at first logon.

Because of data encryption, a scheduled task can only access the results on the analyzer if a user has logged on between the last startup of the analyzer (e.g., the configured daily restart) and the execution time of the scheduled task.

Consequently, if no user has logged on between the last startup and the scheduled task, the following applies:
- A scheduled archiving and deletion of results fails.
- A scheduled problem report is created, but it does not contain any results (and therefore no sample IDs either), regardless of the content configuration for the problem report.

NOTICE!

Risk of data loss

If the password for the default administrator account ADMIN is lost and you have no alternative way to change the password, you must reset the analyzer before you can use the account again. The reset deletes user accounts, passwords, sample IDs, patient IDs, order IDs, visit IDs, and results from the analyzer.

▸ You must change the password of the default administrator account ADMIN during analyzer installation. Take note of the new password and store it safely for later use.

▸ If another user account with administrator user role exists on the analyzer, you can avoid the analyzer reset. It is therefore recommended to create another administrator account immediately after analyzer installation.

▸ Always check if you have a way to change the password of the default administrator account ADMIN before you reset the analyzer.

▸ If an analyzer reset is necessary, back up the analyzer before the reset (using an account with supervisor role). Restore the analyzer again after the analyzer reset.

▸▤ **Related topics**

- Installing the analyzer (45)
- Creating users (150)
- Lost password for the default administrator account ADMIN (284)

3 About the analyzer

About scheduled tasks

You can schedule the automatic execution of certain tasks on the analyzer.
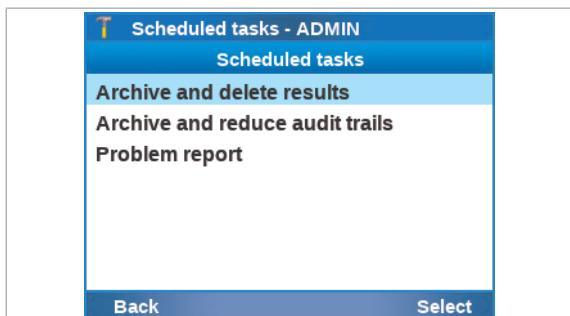
You can schedule the tasks directly on the analyzer on the **Scheduled tasks** screen (**Settings > Scheduled tasks**). Alternatively, if the analyzer is connected to a DMS, it can receive the scheduled tasks from the DMS as part of the device configuration.

You can schedule the following automatic tasks:
- **Archive and delete results**
- **Archive and reduce audit trails**
- **Problem report**

Additionally, you can configure the time of the automatic daily restart on the **Settings > System** screen. However, you cannot disable the daily restart.

> -ᵟ- Do not schedule the daily restart and the different scheduled tasks for the same time. Configure a different time for each action.

As the execution of scheduled tasks may take some time and you cannot perform any other action meanwhile, schedule them for a time when the analyzer is not frequently used.

You cannot perform any other action on the analyzer until the scheduled task is finished.

The configured settings for scheduled tasks are treated as analyzer settings and are therefore included in the following functions from the **Tools** screen:
- **Export settings**
- **Import settings**
- **Back up analyzer**
- **Restore analyzer**

About restrictions for scheduled tasks

To ensure that the analyzer can perform the scheduled tasks as configured, observe the following restrictions.

After each daily restart, a message is displayed. Any scheduled tasks (or the next daily restart) will only be performed after you have confirmed the message.

💡 To prevent the daily restart from interfering with the scheduled tasks, schedule the automatic tasks for earlier in the day than the daily restart.

Because of data encryption, a scheduled task can only access the results on the analyzer if a user has logged on between the last startup of the analyzer (e.g., the configured daily restart) and the execution time of the scheduled task.

Consequently, if no user has logged on between the last startup and the scheduled task, the following applies:

▪ A scheduled archiving and deletion of results fails.

▪ A scheduled problem report is created, but it does not contain any results (and therefore no sample IDs either), regardless of the content configuration for the problem report.

About execution of scheduled tasks

It depends on the analyzer status at the scheduled time if the scheduled task is executed:

▪ Standby:
The scheduled task is executed.

▪ Ready or partial lock:
The analyzer notifies the user about the upcoming scheduled task. If the user does not cancel the action within 30 s of the notification, the analyzer proceeds to execute the scheduled task.

▪ Busy:
The scheduled task is queued until the next status change.

▪ Locked:
The scheduled task is still executed.

If a scheduled task is canceled, fails, or is aborted, the scheduled task will only be executed again at the next scheduled time. The analyzer does not automatically retry to execute a scheduled task.

If a scheduled tasks fails, check the connections and the storage location, e.g., the network share. Try to perform the corresponding action manually and/or wait for the next scheduled execution of the automatic task. If the scheduled task still fails, contact your Roche representative.

▸ About analyzer status (55)

About archiving and reducing the audit trail at logon
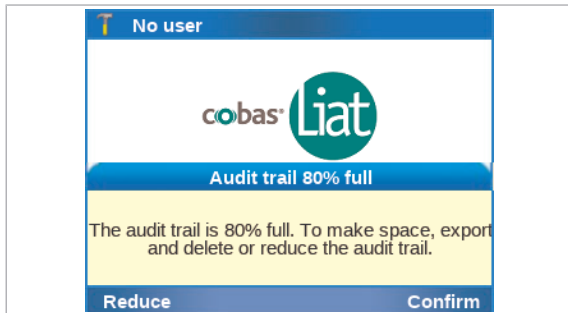
If the internal storage space for the audit trails is almost full, a corresponding message is displayed during logon.

If the scheduled task for audit trails is configured correctly on the analyzer, the **Reduce** button is available on the message and you can trigger the execution directly. The archive file is then saved in the configured archiving location.

As archiving may take some time, consider any time constraints before you choose this option.

The execution during logon does not change the execution of the next scheduled archiving and reduction of audit trails.

Alternatively, you can confirm the message, and later archive and delete the audit trails manually. Only this option is available if the scheduled task for audit trails is not configured on the analyzer.

3 About the analyzer

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About locking the analyzer

If maintenance tasks must be performed or if the analyzer has a malfunction, you can lock the analyzer to prevent assay runs.

About locking the analzyer and locked status

The analyzer can be locked manually by a user with supervisor user role or administrator user role, or with a `LOCK` command from the DMS.

The `LOCK` command from the DMS is only accepted when the analzyer displays the **Log on** or walk-by screen. Any currently logged on user is automatically logged off.

When the analyzer is locked:

- The analyzer is in status locked.
- Only users with supervisor user role or administrator user role can log on.
- It is not possible to run an assay or to add an assay tube lot.
- Scheduled tasks such as archiving and creating problem reports are still performed as scheduled.
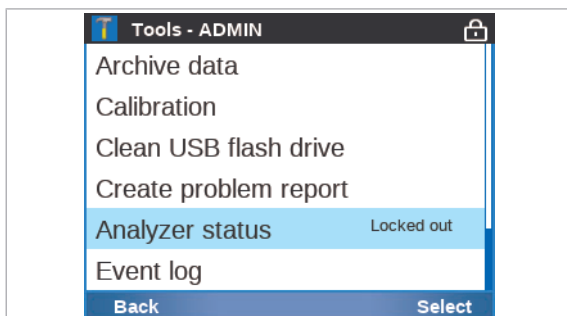
Locked status is indicated on each screen of the analyzer by the following:

- A black title bar
- An 🔒 icon in the top right corner of the screen

▸ To lock the analyzer manually (214)

About unlocking the analyzer

The analzyer can be unlocked manually by a user with supervisor user role or administrator user role, or with a `RELEASE LOCKOUT` command from the DMS.

The `RELEASE LOCKOUT` command from the DMS is rejected by the analyzer if an activity such as archiving or creating problem reports is accessing the analyzer data storage.

If the analyzer is unlocked while a user with supervisor user role or administrator user role is logged on, the analyzer status will change to ready or partial lock (if at least one assay is not yet registered/activated or the

3 About the analyzer

software is expired, not registered, or not activated). If the analyzer is unlocked while no user is logged on, the analyzer status will change to standby.

When the analyzer unlocks:

- The analyzer status changes to standby, ready, or partial lock.
- All users can log on again.
- The analyzer is able to run assays again.

-�- After unlocking the analyzer it is possible that some or all assays cannot be run, for example if software or assays are not registered.

⌸ To unlock the analyzer manually (214)

Locking the analyzer or locking the screen   The function to lock the analyzer that prevents assay runs is not the same as the function to lock the screen that secures the analyzer when left unattended.

⌸ Locking the screen (84)

⌸ Unlocking the screen (86)

3 About the analyzer

Common user actions

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Starting the analyzer

Switching on the analyzer starts an initialization process that ensures the proper functioning of the analyzer.

NOTICE!

Damage to the analyzer due to inappropriate handling

Inserting an assay tube into the analyzer prior to completion of initialization results in damage to the tube, possible damage to the analyzer and failure of the assay tube to provide a result.

‣ Do not insert assay tubes or any other object into the tube chamber while it is starting up.

🕐 Up to several minutes

‣ To start the analyzer

1 Press the power button.

ⓘ If the temperature inside the analyzer is low, the analyzer warms up until the internal temperature reaches the threshold temperature. This may take some time.

→ Power indicator lights up

→ Touch screen lights up

→ Tube entry door opens and closes

→ Actuators inside the analyzer move

→ Self-checks are performed

2 Wait until the **Log on** screen is displayed.

ⓘ The steps displayed during initialization may vary in time and do not reflect a percentage of readiness of the analyzer.
Initialization may take several minutes.

4 Common user actions
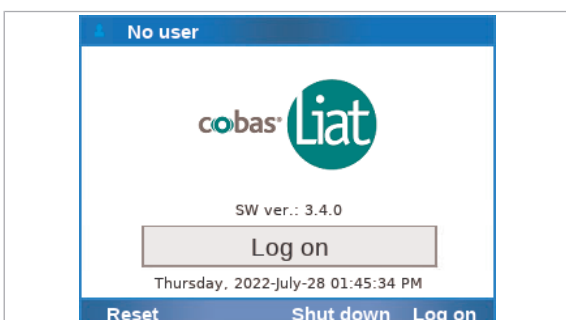
Logging on

At logon, the analyzer prompts you for your user ID and password, for your badge barcode and password, or for your badge barcode only.

A user ID barcode is a barcode representing your user ID (e.g., the barcodes on the cards provided with the user ID card kit). A badge barcode can be any barcode that complies with the system standards.

The type of authentication prompted at logon depends on the logon mode setting on the analyzer.

> 🔅 Independent of the logon mode setting on the analyzer, you can always log on with your user ID and password.

⯈▤ For details on entering information, see Entering text and numbers (81).

⯈▤ Scanning barcodes (83)

⯈▤ About logon modes (137)

First logon after starting the analyzer

Each time when you start or restart the analyzer, the following limitations apply to the first log on:

- ▪ You must log on with your user ID and password, regardless of the logon mode set on the analyzer.
- ▪ You must enter your user ID manually. It is not possible to scan a user ID barcode.
- ▪ You can only log on if you do not have to change your password at logon.
  A user that must change the password at logon cannot be the first user to log on after starting or restarting the analyzer. At first, a user without a request to change the password must log on and log off again.

⯈ **To log on with user ID**

1 On the **Log on** screen, choose the **Log on** button.
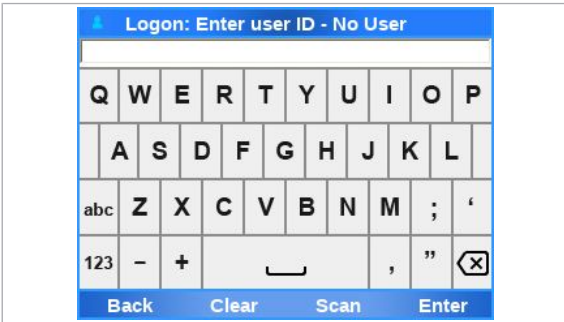
2 To enter your user ID, do one of the following:
- ▪ Enter your user ID manually and choose the **Enter** button.
- ▪ Place your user ID barcode parallel to the analyzer directly beneath the barcode reader. Choose the **Scan** button.
- ❶ The first user that logs on after starting the analyzer must enter their user ID manually. It is not possible to scan a user ID barcode.

3 Enter your password and choose the **Enter** button.
- ➜ In the title bar, your user role and user ID are indicated.

▶ **To log on with badge barcode**

1 On the **Log on** screen, choose the **Log on** button.
- ❶ The first user that logs on after starting the analyzer must log on manually with user ID and password, regardless of the logon mode setting on the analyzer.
  If a badge barcode logon mode is set on the analyzer, the barcode reader is enabled automatically.

2 Scan your badge barcode.
- ❶ If you want to log on with your user ID instead, wait until the time to scan your badge barcode runs out. On the message dialog box, choose the **Manual** button.

3 If required, enter your password and choose the **Enter** button.
- ➜ In the title bar, your user ID and user role are indicated.

▸▤ **Related topics**
- ▪ Scanning barcodes (83)
- ▪ About logon modes (137)

4 Common user actions

Changing your password

All users can change their own passwords.

If users are not exchanged with a connected DMS, you can change your password at anytime.

> 💡 If users are exchanged with a connected DMS, users can only change their passwords based on a request from the DMS.
>
> 📖 About data exchange with a DMS (243)

When prompted by the analyzer, you must change your password at logon. By default, new users have to change their passwords at first logon.

> 💡 When you use a default user account for the first time, you must change the password at logon.
>
> 📖 To change your password at logon (76)

If you must change your password at logon, you cannot be the first user to log on after starting or restarting the analyzer. At first, a user without a request to change the password must log on and log off again.

📖 About user IDs and passwords (149)

📖 Resetting the analyzer (287)

Changing the password of another user

If users are not exchanged with a connected DMS, users with supervisor or administrator user role can do the following:

- Change the password of another user up to their own user role.
- Request a password change at next logon for another user up to their own user role.

📖 Changing user information (152)

▶ **To change your password at anytime**

1 Choose **Settings > User management**.

ⓘ If you are logged on with user user role, only your own user account is listed.

4 Common user actions

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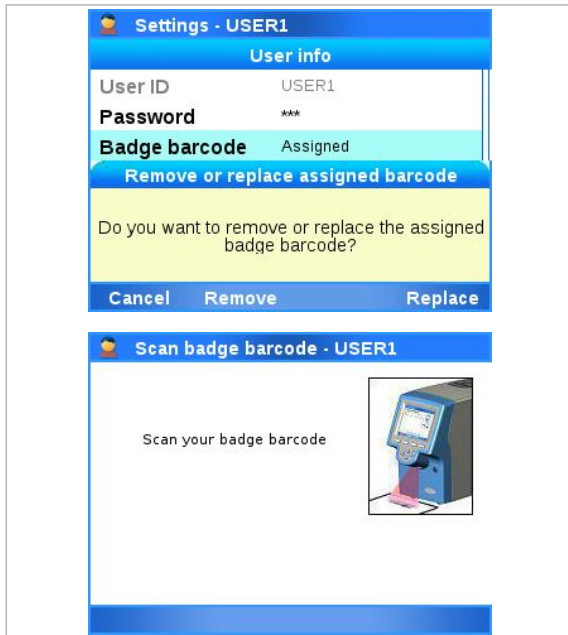VV-07723-04
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2 Choose the **Select** button.

3 Choose the **Password** item and choose the **Edit** button.

- ❶ If you are logged on with user user role, you have access to the **Password** item and the **Badge barcode** item only.

4 Enter your current password and choose the **Enter** button.

- ❶ Your user account is displayed in the password field.

5 Enter your new password and choose the **Apply** button.

- ❶ For passwords, you can use alphanumeric characters, symbols and/or spaces. Passwords are restricted in length to 4–20 characters.
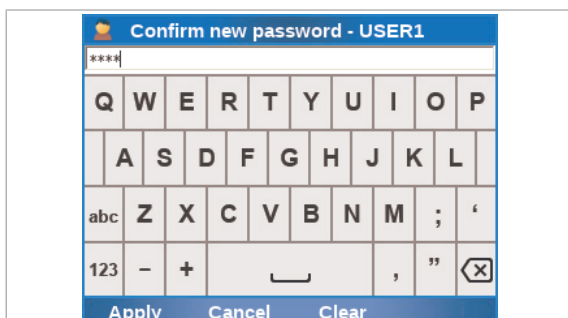
6 To confirm your new password, enter the password again and choose the **Apply** button.

➔ Your password is changed.

7 On the **User info** screen, choose the **Save** button.

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4 Common user actions
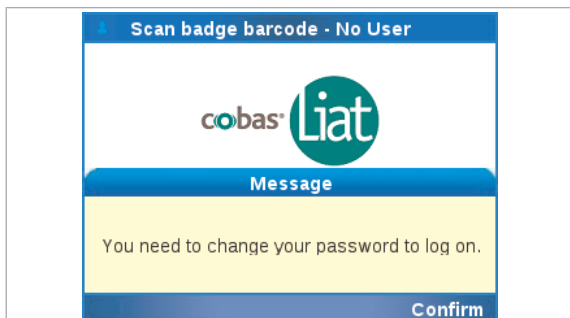
▶ To change your password at logon

1 When prompted to change your password, choose the **Confirm** button.

2 Enter your new password and choose the **Enter** button.

ⓘ For passwords, you can use alphanumeric characters, symbols and/or spaces.
Passwords are restricted in length to 4–20 characters.
Your user account is displayed in the password field.

3 To confirm your new password, enter the password again and choose the **Enter** button.

➜ Your password is changed.

Assigning or changing your badge barcode

All users can assign and change their own badge barcodes.

If users are not exchanged with a connected DMS, you can assign or change your badge barcode at anytime.

> ⌖ If users are exchanged with a connected DMS, users cannot assign or change their badge barcodes directly on the analyzer.
>
> ⊟ About data exchange with a DMS (243)

Changing the badge barcode of another user

If users are not exchanged with a connected DMS, users with supervisor or administrator user role can assign or change the badge barcodes of other users up to their own user role.

⊟ Changing user information (152)

▶ **To assign or change your badge barcode**

1 Choose **Settings > User management**.

   ❶ If you are logged on with user user role, only your own user account is listed.

2 Choose the **Select** button.

3 Choose the **Badge barcode** item and choose the **Edit** button.

   ❶ If you are logged on with user user role, you have access to the **Password** item and the **Badge barcode** item only.

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4 Common user actions
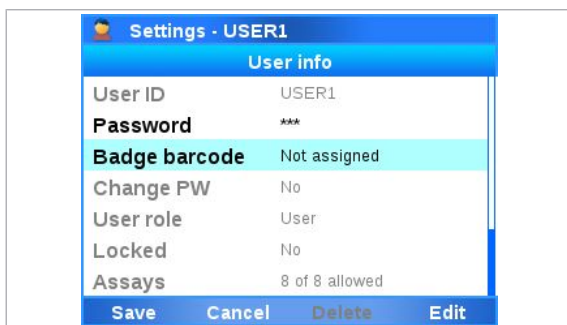
4 To assign a badge barcode, scan your badge barcode twice.

5 To change your badge barcode, do one of the following:
- To remove an assigned badge barcode, choose the **Remove** button.
- To replace your badge barcode, choose the **Replace** button. Scan your badge barcode twice.

Related topics
- Scanning barcodes (83)

Choosing items on the screen
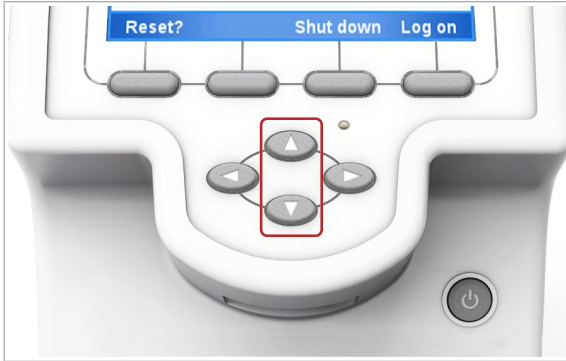
▶ **To choose an item using the buttons**

1 Use the ⬆ and ⬇ navigation buttons to choose the desired item.

ⓘ Alternatively, you can tap the item on the screen.

2 Choose the **Select** button.

➔ Detailed information on the chosen item or a new screen is displayed, or an action is confirmed.

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4 Common user actions

Choosing predefined values

Some items can take one of several predefined values.
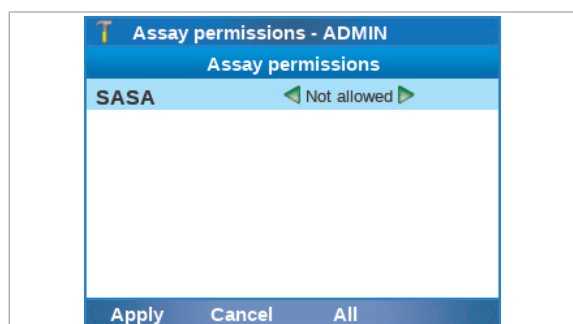
Green arrows frame predefined values that can be chosen.
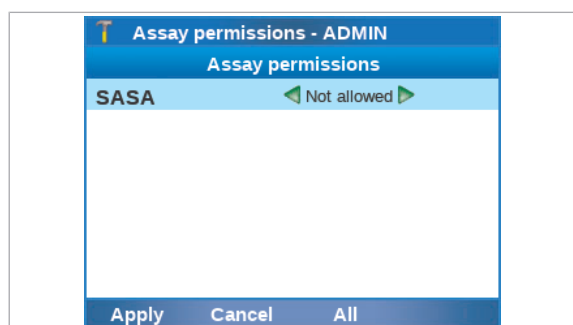
▶ **To choose a predefined value**

1 Use the ⬆ and ⬇ navigation buttons to choose the item you want to change.

2 If required, choose the **Edit** button.

3 Use the left ◀ and right ▶ navigation buttons to choose the desired value.

   ⓘ Green arrows frame predefined values that can be chosen, for example ◀ Allowed ▶ .

4 Choose the **Apply** button or the **Save** button, whichever is available.

4 Common user actions

Entering text and numbers

When you have to enter text or numbers, either the alphanumeric or the numeric keyboard is displayed.
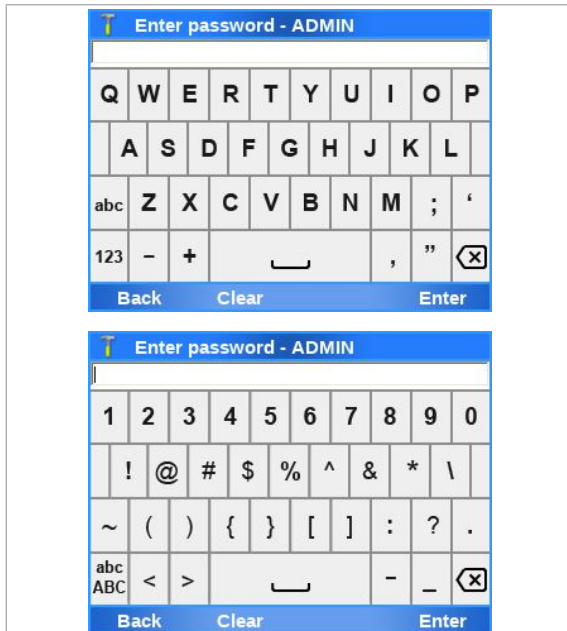
| Key	Function
ABC	Enter capital letters.
abc	Enter lower case letters.
123	Switch to number/symbol entry.
abc ABC	Switch to letter entry.
⬅	Delete the character to the left of the cursor.
⌨	Selected keys on the alphanumeric keyboard

To confirm the entered information, choose the **Enter** button.
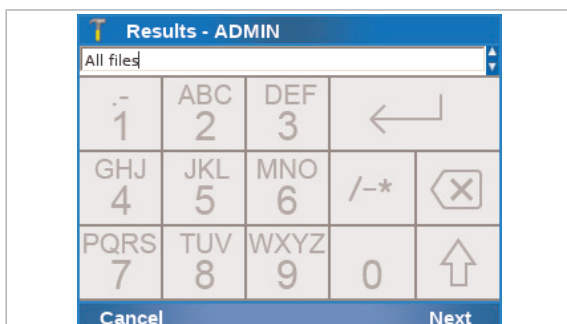
Key	Function
CLR	Delete the character to the left of the cursor.
Caps	Switch to letter entry.
Symb	Switch to symbol entry.
Enter	Confirm the entered information and close the numeric keyboard.
⌨	Selected keys on the numeric keyboard

To confirm the entered information, choose the **Enter** button or the **Next** button.

▸ **To enter text**

1 Use the ⬆ and ⬇ navigation buttons to choose the item.

2 Choose the appropriate button, typically the **Select** button.
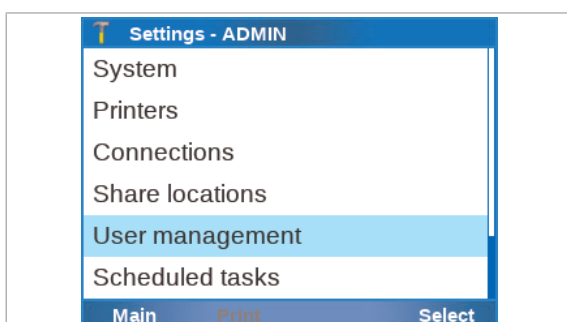
3 Use the ⬆ and ⬇ navigation buttons to choose the specific item that you want to define. Choose the appropriate button, typically the **Edit** button.

➔ The alphanumeric keyboard or the numeric keyboard is displayed.

4 Enter the information and to confirm choose the **Enter** button.

➔ The screen is displayed again where you last chose the item.

➔ If the entered information is not valid, a message informs you about this fact.

Scanning barcodes

You use the barcode reader for scanning barcode labels, e.g., assay tube barcodes, sample barcodes, package insert barcodes, control barcodes, user ID barcodes, and badge barcodes.

> 🔅 To maintain patient confidentiality and privacy standards, do not use protected health information (e.g., patient name, social security number) as the sample ID.

▶ To scan an assay tube barcode

1 Choose the **Scan** button.
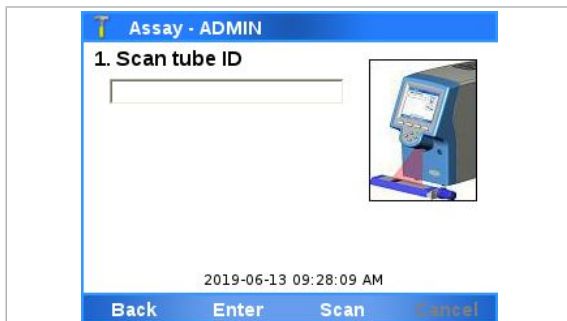
2 NOTICE! Placing the barcode inappropriately may lead to reading errors or malfunction.

Place the barcode parallel to the analyzer directly beneath the barcode reader and make sure that the scanner light extends beyond the barcode on both sides.

3 If the barcode cannot be read, try again.

4 If the barcode still cannot be read, choose the **Enter** button and enter the barcode text manually.

📑 **Related topics**

- Barcode specifications (300)
- Configuring barcode settings (138)

Locking the screen

Locking the screen ensures that the analyzer is secured when inactive or left unattended.

The screen locks *automatically* or you can lock it *manually*. In each case, the walk-by screen is displayed.

About locking the screen manually

Lock the screen to secure the analyzer when you leave it unattended.

You can lock the screen manually at any time with the following exceptions:
- When a message dialog box is displayed
- When a process is running (e.g., an assay run)
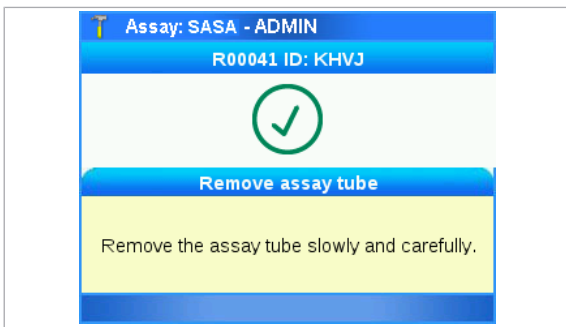
Auto lock and assay runs

The auto lock function locks the screen automatically after a predetermined period of inactivity called the auto lock time. You define the auto lock time in **Settings > System > Auto lock time**. It must be set to 1-1440 minutes. The default value is 3 minutes.

NOTICE!

Unauthorized access

An unlocked screen may be accessed by unauthorized persons.

‣ Set the auto lock time short enough to prevent unauthorized access to the analyzer.

‣ It is recommended to keep the default value of 3 minutes for the auto lock time.

4 Common user actions

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During an assay run, the auto lock function is suspended until the sample preparation, amplification, and detection have completed. It is not possible to lock the screen manually until the assay run is finished.

A message is displayed when the assay tube can be removed from the analyzer. The auto lock function starts again at this point.

If the assay tube remains in the analyzer for longer than the auto lock time, the screen locks and the walk-by screen is displayed.
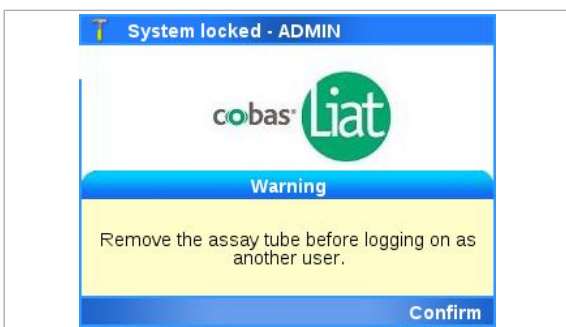
To log on and use the analyzer when a tube is inserted, you must first remove the assay tube.

A red flashing message at the top of the screen indicates that the assay run completion is in progress. The assay run finishes a short time after the assay tube is removed and you can log on.
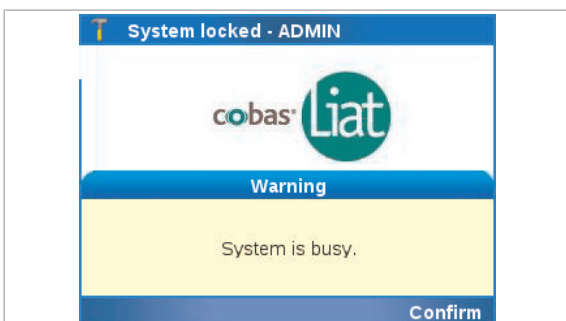
If you try to log on before the assay run finishes, the system indicates that it is busy.

Confirm the message and log on.

▸ Unlocking the screen (86)

▶ To lock the screen manually

1 In the top left corner of the screen, choose the user role icon.
   ➔ The walk-by screen is displayed.

▸ **Related topics**
   - Logging on (72)
   - Unlocking the screen (86)
   - Running an assay (95)
   - System settings (133)

Unlocking the screen

The walk-by screen is displayed when the screen is locked.

Unlocking the screen

When your own account is locked, you must unlock it to continue working. You are returned to the screen in which you were working when the screen locked.

⬦ To unlock the screen by entering your password (86)

⬦ To unlock the screen by scanning your badge barcode (87)

Logging on to use the analyzer

When another user's account is locked, you must log on to use the analyzer. If the previous user has unsaved data, it is lost when you log on.

⬦ To unlock the screen by logging on as another user (87)

☐ The walk-by screen is displayed.

▶ **To unlock the screen by entering your password**

1 On the walk-by screen, choose the **Unlock** button.

2 Enter your password and then choose the **Enter** button.
→ You are returned to the screen in which you were working when the screen locked.

To unlock the screen by scanning your badge barcode

1 On the walk-by screen, choose the **Unlock** button.

   ℹ If the **Barcode and password** logon mode or the **Barcode** logon mode is set on the analyzer, the barcode reader is enabled automatically.
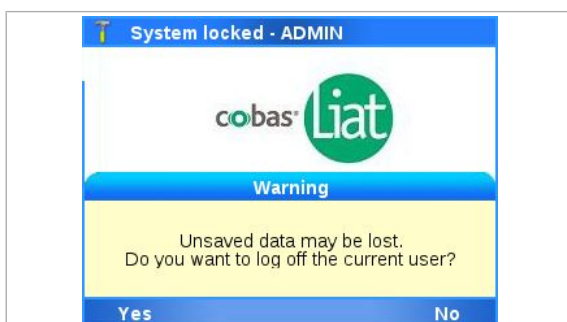
2 Scan your badge barcode.

   ➔ You are returned to the screen in which you were working when the screen locked.

To unlock the screen by logging on as another user

1 On the walk-by screen, choose the **Log on** button.

   ➔ A warning message is displayed.

2 To continue and log on, choose the **Yes** button.

   ℹ Choosing the **No** button, returns you to the walk-by screen.

3 Follow the normal logon procedure Logging on (72).

⊟ **Related topics**

- Locking the screen (84)

Shutting down the analyzer

To shut down the analyzer, shut down the software and turn off the power.

Do not turn off the power using the power button nor disconnect the power cable before the analyzer has completed shutdown.

⚠ CAUTION!

Loss of power

‣ Do not press the power button on the analyzer until the analyzer directs you to.

‣ In the event of power failure while an assay is running, do not attempt to remove the assay tube.

‣ When power is restored, power on the analyzer and only remove the assay tube when the message **Remove the assay tube slowly and carefully.** is displayed.

☐ There is no activity on the analyzer.

‣ **To shut down the analyzer**

1 On the **Log on** screen, choose the **Shut down** button. To confirm shutdown, choose the **Yes** button.

2 Wait until an image is displayed to turn off the power or the screen appears empty.

ⓘ Because of the shutdown, the analyzer cannot display the image longer than approx. 90 seconds. The image is then replaced with an empty screen.

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4 Common user actions
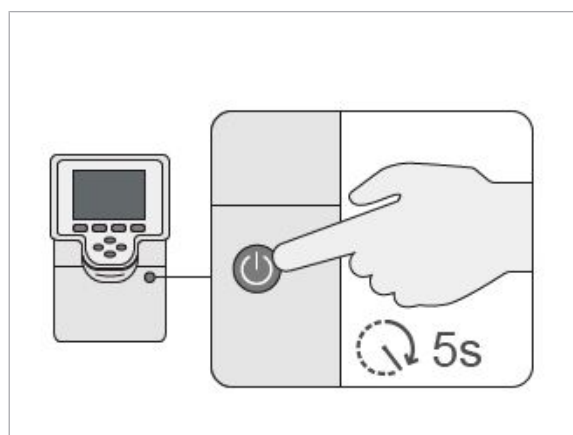
3 Press and hold the power button for approx. 5 seconds until both the power indicator and the touch screen turn dark.

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Performing a run

In this chapter **5**

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Safety

‣ Make sure that you are familiar with the safety instructions in Safety instructions (33).

⚠ CAUTION!

Incorrect results due to using inappropriate assay tubes

Using non certified assay tubes may lead to incorrect results.

▸ Only use **cobas**® Liat® assay tubes.

▸ Never reuse assay tubes.

⚠ CAUTION!

Incorrect results or malfunction due to inappropriate handling of assay tubes

Inappropriate handling of assay tubes may lead to incorrect results or malfunction.

▸ Do not remove or insert an assay tube while the analyzer is performing an assay.

▸ Always use the barcode of the assay tube sleeve that belongs to the assay tube that you are using.

▸ Do not break any seals of the assay tube. Take particular care when adding sample.

▸ Do not force or rotate the assay tube when inserting it.

▸ Do not reuse spent assay tubes.

NOTICE!

Malfunction due to inappropriate handling of the analyzer

Inappropriate handling of the analyzer may lead to malfunction.

▸ Do not manually open or handle the tube entry door, unless instructed to do so on the screen.
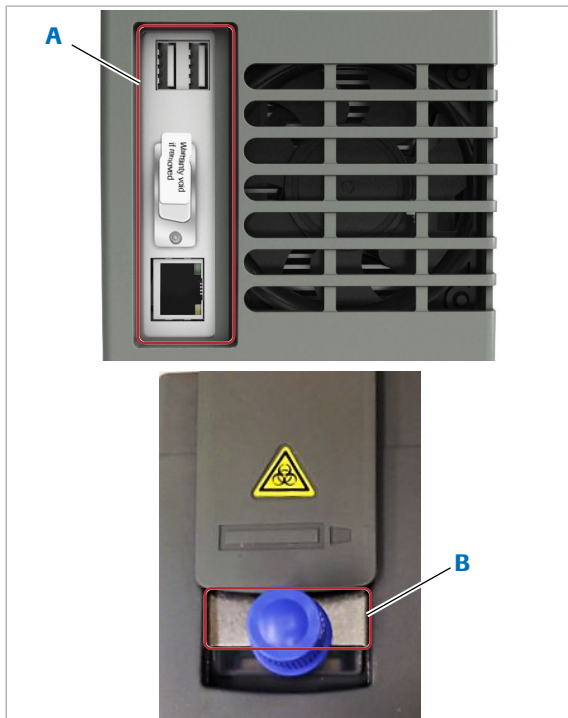
A Connector plate at the rear of the analyzer
B Metal plate on the sample entry

NOTICE!

Instrument error due to electrostatic discharge

Electrostatic discharge on the connector plate at the rear of the analyzer may cause an instrument error.

In the analyzer models where the tube entry has a metal plate, electrostatic discharge on the tube entry metal plate may cause an instrument error.

‣ While running an assay, avoid touching the connector plate at the rear of the analyzer or the metal plate on the tube entry (for models where the tube entry has the metal plate).

5 Performing a run

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Running an assay

The analyzer runs a specific assay as determined by the scanned barcode of an assay tube.

Running an assay comprises the following actions:

- ▪ Transferring sample into an assay tube and capping the tube.
- ▪ Scanning the assay tube barcode and the ID barcode (sample ID, patient ID, order ID, or visit ID depending on analyzer configuration):
  - – To maintain patient confidentiality and privacy standards, do not use protected health information (e.g., patient name, social security number) as the sample ID.

  - – If you must enter the ID barcode manually, do not use spaces.

- ▪ Inserting the assay tube into the analyzer.
- ▪ The analyzer performs the required assay steps and reports the test results.

-ᗺᗅ- For information on transferring sample into the assay tube, see the instructions in the package insert or the Instructions for Use for the assay you are running.

-ᗺᗅ- Make sure that you use the correct sample type as indicated on the screen.

-ᗺᗅ- The auto lock function is suspended during an assay run. It starts again when the message asking you to remove the assay tube is displayed.
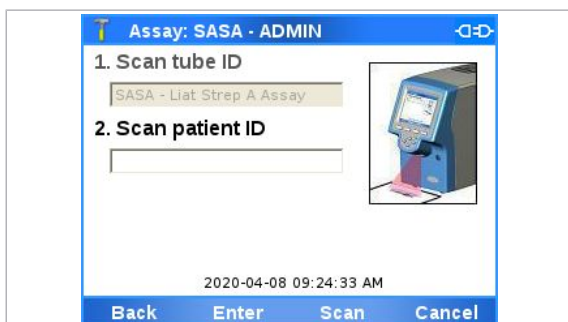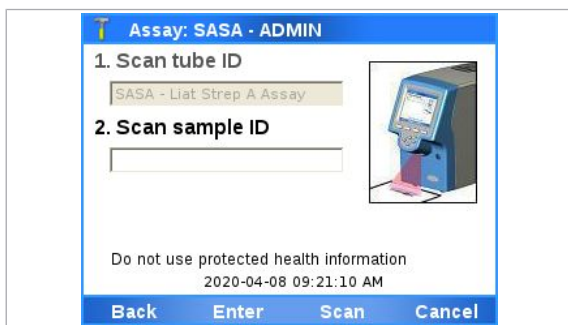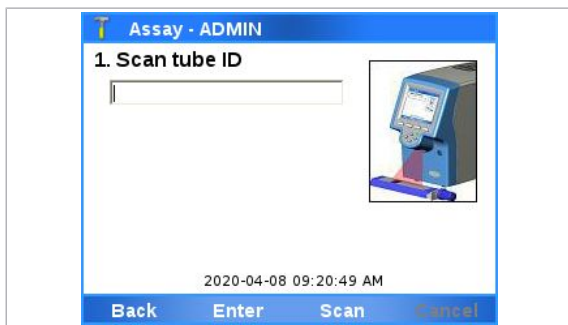
⟩🔖 Locking the screen (84)

🧰   ☐ Assay tube
   ☐ Transfer pipette supplied with the assay tube
   ☐ Sample ID barcode

▶ **To run an assay**

1 Tear open the assay tube pouch of the assay tube.

ⓘ Follow the instructions in the package insert or the Instructions for Use of the assay.
Make sure not to break the first seal at the top of the assay tube.
Do not remove the assay tube sleeve until you insert the assay tube in the analyzer.

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2 Check the assay tube for possible damage, such as leaks or broken seals.

3 On the **Main** screen, choose the **Run Assay** item and choose the **Select** button.

4 Choose the **Scan** button.

5 Scan the assay tube barcode.

ⓘ Do not remove the assay tube sleeve.

6 Choose the **Scan** button again and then scan the sample ID barcode.

ⓘ If necessary, you can enter the sample ID manually. No spaces should be used when you enter the values.

7 Alternatively, if the analyzer is connected to a DMS and patient verification is enabled, scan the requested ID barcode:

- ▪ Sample ID barcode
- ▪ Patient ID barcode
- ▪ Order ID barcode
- ▪ Visit ID barcode

ⓘ If necessary, you can enter the ID manually. No spaces should be used when you enter the values.

→ The ID is verified with the DMS.

→ It depends on the analyzer configuration and your user role if you can overrule a failed patient verification.

**8** If required to confirm the received patient information, choose the **Confirm** button.
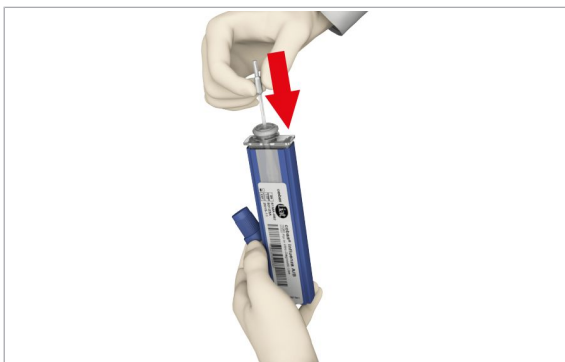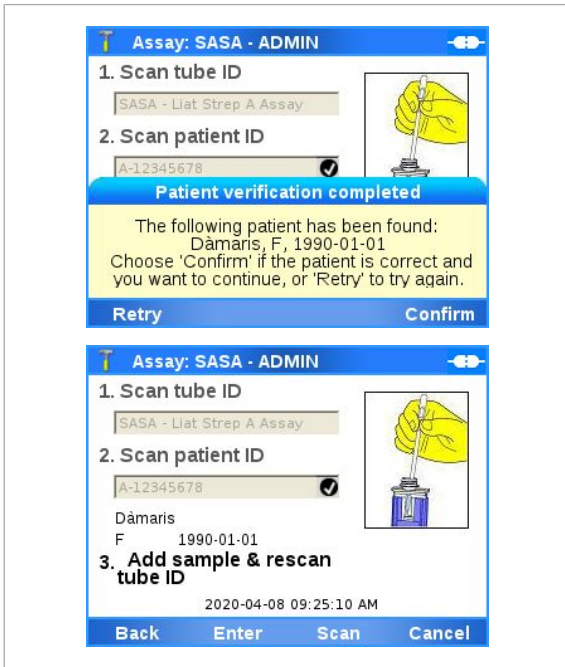
9 Transfer the correct type of sample:

▪ Decap the assay tube.

▪ Transfer sample into the assay tube.

▪ Recap the assay tube.

ⓘ Do not remove the assay tube sleeve.
Dispense the sample to the first seal at the top of the assay tube without an air gap to prevent large bubbles.
Do not break the first seal at the top of the assay tube.
Read the package insert or the Instructions for Use for sample type.

10 Dispose of all used transfer pipettes in accordance with the disposal policy of your institution and according to local regulations.

11 Choose the **Scan** button.
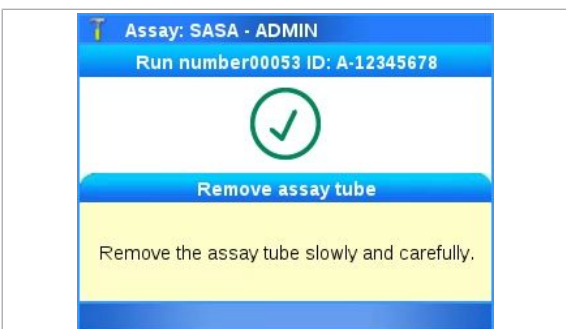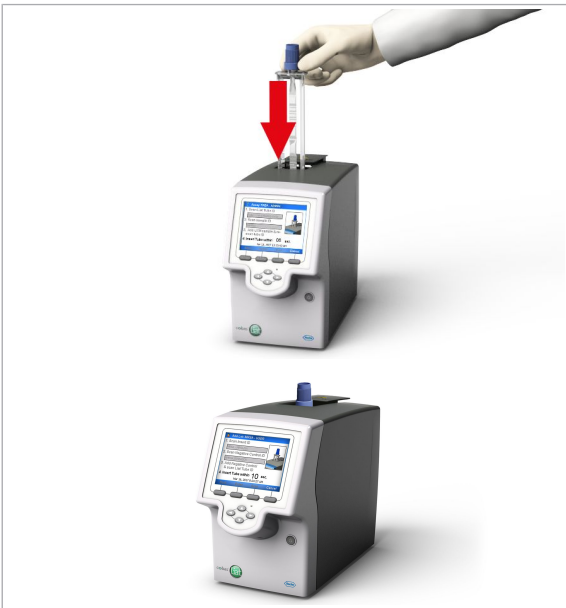
12 Scan the assay tube barcode again.

> ❶ If by mistake you removed the assay tube sleeve completely, make sure that the serial numbers and the lot numbers on the assay tube and on the sleeve match, before you scan the barcode.

13 Remove the assay tube sleeve and insert the assay tube into the analyzer until the tube clicks into place.
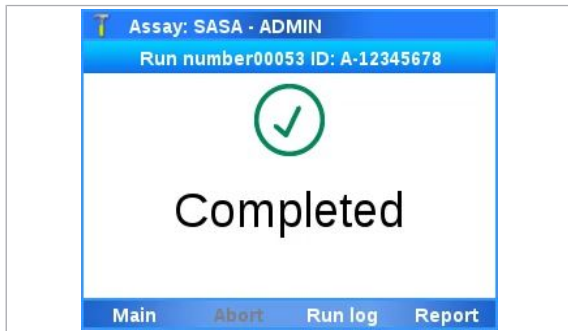
> ❶ The assay tube only fits in one way.

> ➔ The tube entry door closes automatically and processing begins.

14 Check the progress, if required.

> ❶ In the subtitle bar, a run number (for example "00053") and the sample ID are displayed. Choose the **Run log** button to view messages. To abort the assay run, choose the **Abort** button.

15 When the assay run is complete, the tube entry door opens. A message asks you to remove the assay tube. Remove the assay tube and dispose of it in accordance with the disposal policy of your institution and according to local regulations.

> ➔ If configured, results are released and sent to a host automatically.

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16 Do one of the following:

- ▪ To view the result report, choose the **Report** button.
- ▪ To return to the **Main** screen – and, for example, to start another assay – choose the **Main** button.
- ▪ To view messages, choose the **Run log** button.

⊡ **Related topics**

- ▪ Reviewing results (104)
- ▪ About assays (59)
- ▪ Scanning barcodes (83)
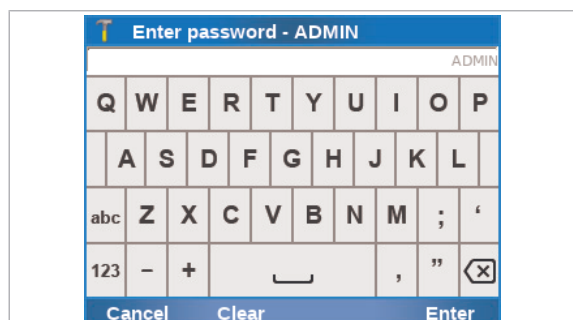- ▪ Aborting an assay run (100)

Aborting an assay run

▶ **To abort an assay run**

1 On the assay run status screen, choose the **Abort** button.

2 On the confirmation message, choose the **Yes** button.

3 Enter your password and choose the **Enter** button.
- Depending on the setting of the analyzer, scan your badge barcode to abort the run.

ⓘ You can choose the **Back** button to return to the previous screen.

→ The analyzer stops assay processing.
→ The analyzer writes a result report.
→ If configured, information about the aborted run is sent to a host automatically.
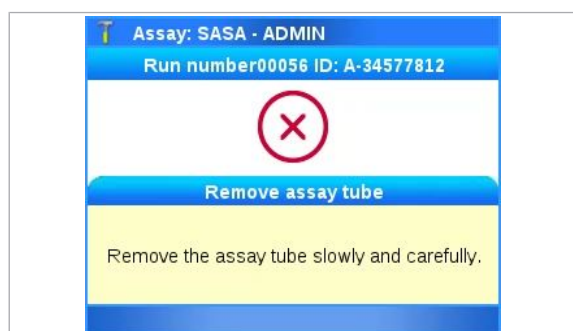
4 When asked to do so, remove the assay tube.

5 Dispose of the assay tube in accordance with the disposal policy of your institution and according to local regulations.

6 Do one of the following:

  ▪ To view the result report, choose the **Report** button.

  ▪ To return to the **Main** screen, choose the **Main** button.

  ▪ To view messages, choose the **Run log** button.

Result handling

About results

The way results are calculated and displayed depends on the intended use of each individual assay.

Result reports

Result report

Results view - ADMIN
Result report
Strep A Not Detected
Sample ID: Sample
Date/Time: 2022-08-18, 12:48:02 PM
Assay: Liat Strep A Assay (SASA)
Use: IVD
Run status: OK
Operator: USER1
Back   Print   Approve

Printed result report

Result Report

Strep A Not Detected

Sample ID:Sample
Date/Time:2022-08-18, 12:48:02 PM
Assay:Liat Strep A Assay (SASA)
Use:IVD
Run status:OK
Operator:USER1
Approved by:ADMIN
Analyzer S/N:M1-E-00003
Assay version:1.29
Software version:3.4.0
Run No.:00001
Tube S/N:7A8B-03D53
Tube lot:71108B
Tube exp. date:2032-08-31

If the analyzer is connected to a DMS and patient verification is configured, rows and columns displaying ID data have an **ID** label instead of a **Sample ID** label.

About run status
The run status is determined by the software and is not associated to the assay script or assay result interpretation.

A run can have the following status:
▪ OK
Run completed without error.
▪ Warning
Run completed with warnings.
▪ Aborted
Run was aborted by system, script, or user.

The run status is displayed on the **Result report** screen and included in the result report.

Refer to the package insert or the Instructions for Use of the assay you are running for information on the assay result interpretation, i.e., the result symbols displayed on the **Results** screen.

About sending status of results
If the analyzer is connected to a host, the sending status of results is indicated on the **Results** screen.

For DMS:

Icon	Description
No icon:	Not sent
✉ (yellow)	Sent to host, but not yet confirmed by host
✉	Sent to host successfully

⊞ DMS: Sending status of results

For HL7:

Icon	Description
No icon:	Not sent or sending failed

⊞ HL7: Sending status of results

Icon	Description
✉	Sent to host successfully

⊞ HL7: Sending status of results

Reviewing results

Users with supervisor or administrator user role can accept or reject results except if automatic release of results is enabled at the end of the respective runs.

You typically review results as part of assay processing. Alternatively, you can choose results on the **Results** screen and review them.

You can also archive the result report directly from the **Results** screen.

By default, on the **Results** screen, all results of the last 7 days are displayed sorted by date in descending order.

> ☀ If the analyzer is configured to release results automatically and is connected to a host, reviewing is not done on the analyzer.
>
> ▸⊟ About data exchange with a DMS (243)

🧰   ☐ To archive the result report to a USB flash drive: USB flash drive

🗐   ☐ To archive the result report to a share location: Network share or FTP share configured

☐ Supervisor user role or administrator user role

▸ **To review results from the assay status screen**

1 From the assay status screen, you can do the following:

▪ Display and print run status information (see steps **2** to **3**).

▪ Review and print the result report (see steps **4** to **12**).

ⓘ You can perform these actions when the assay run is complete.
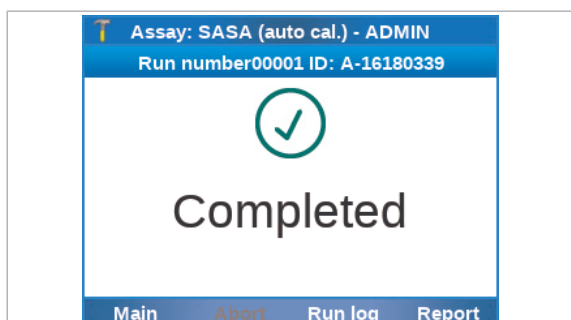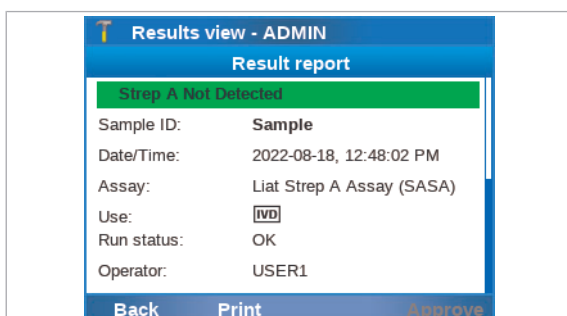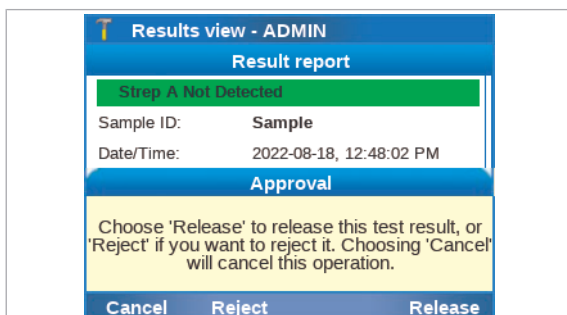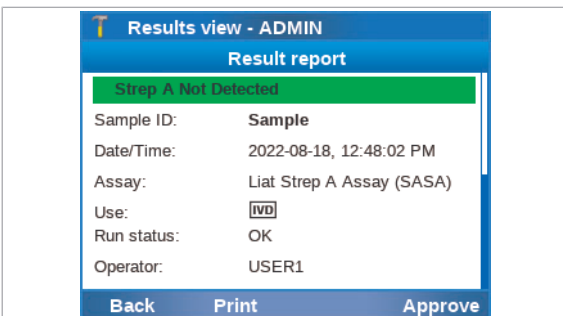
2 To display run status information, on the assay status screen, choose the **Run log** button.

3 On the **Message** screen, do the following:
- To print the messages, choose the **Print** button.
- To return to the assay status screen, choose the **Back** button.

4 To view the result report, on the assay status screen, choose the **Report** button.

5 On the **Result report** screen, if the result information does not fit into one screen, use the ⬆ and ⬇ navigation buttons to display the rest of the information.

6 From the **Result report** screen, you can do the following:
- Approve or reject the result (see steps **7** to **9**), except if automatic release of results was enabled at the end of the run.
- Print the result report (see steps **10** to **12**).

7 To approve or reject the result, on the **Result report** screen, choose the **Approve** button.

🛈 The **Approve** button is only available if automatic release of results was disabled at the end of the run.

8 On the **Approval** message, choose the **Release** button to accept the result or the **Reject** button to reject it.

9 On the confirmation message, choose the **Yes** button.
→ On the result report, your user ID is added to the **Approved by:** line.

10 To print the result report, on the **Result report** screen, choose the **Print** button.

🛈 If the analyzer is set up to print the results automatically, this step is not required.
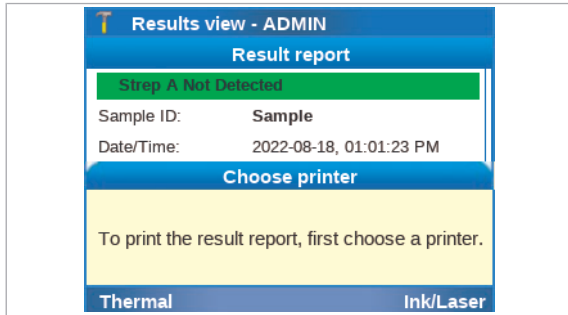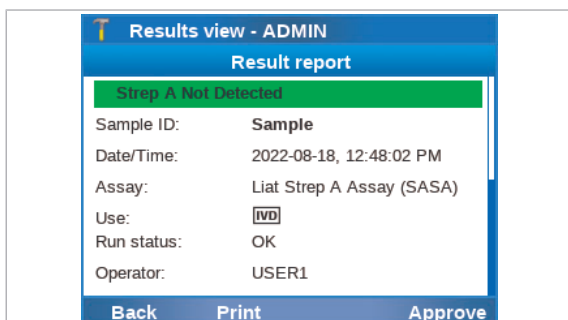
11 If a message is displayed to choose the printer, do one of the following:

- ▪ To print the result report on the connected thermal printer, choose the **Thermal** button.
- ▪ To print the result report on the connected inkjet printer or laser printer, choose the **Ink/Laser** button.

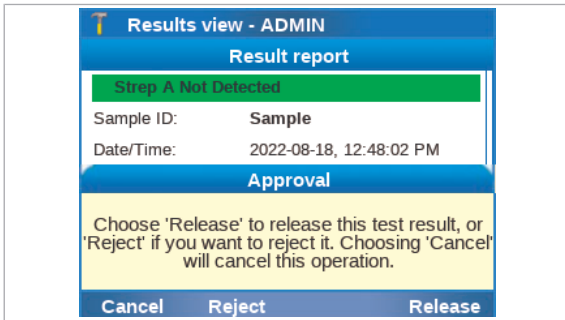12 On the **Print queued** message, choose the **Confirm** button.

▶ **To review results from the Results screen**

1 On the **Main** screen, choose the **Results** item and choose the **Select** button.

➜ The **Results** screen is displayed. By default, all results of the last 7 days are displayed sorted by date in descending order.

2 Optionally, sort and/or filter the results as described in Sorting and filtering results (108).

3 On the **Results** screen, choose the desired result entry.

- ▪ Double-tap an entry to choose a result and to sort the table by the corresponding column.
- ▪ A sorting indicator marks the sorting column.

🛈 For information on the result symbols, see the instructions in the package insert or the Instructions for Use for the corresponding assay.

4 From the **Results** screen, you can do the following:

- ▪ Review and print the result report (see steps **5** to **13**).
- ▪ Archive the result in a share location or on a USB flash drive, or send the result to a host (see steps **14** to **16**).

5 To review the result report, on the **Results** screen, choose the **View** button.

6 On the **Result report** screen, if the result information does not fit into one screen, use the ⬆ and ⬇ navigation buttons to display the rest of the information.

7 From the **Result report** screen, you can do the following:

- ▪ Approve or reject the result (see steps **8** to **10**), except if automatic release of results was enabled at the end of the run.
- ▪ Print the result report (see steps **11** to **13**).

8 To approve or reject the result, on the **Result report** screen, choose the **Approve** button.

5 Performing a run

ⓘ The **Approve** button is only available if automatic release of results was disabled at the end of the respective run.

9 On the **Approval** message, choose the **Release** button to accept the result or the **Reject** button to reject it.

10 On the confirmation message, choose the **Yes** button.

→ On the result report, your user ID is added to the **Approved by:** line.
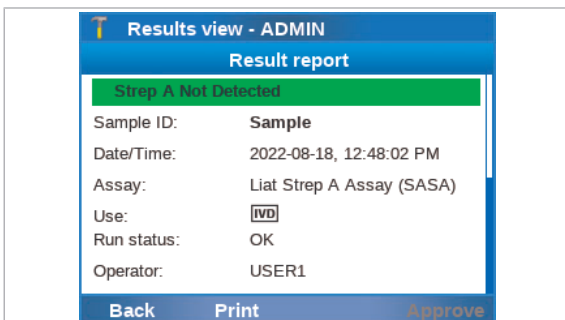
11 To print the result report, on the **Result report** screen, choose the **Print** button.

ⓘ If the analyzer is set up to print the results automatically, this step is not required.
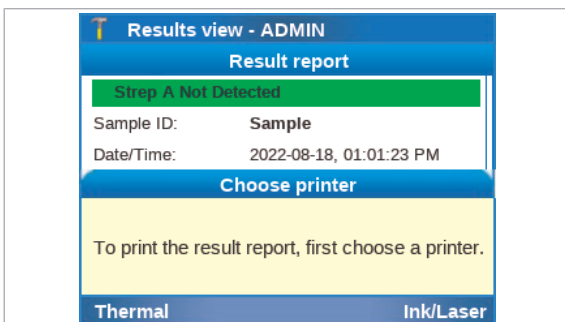
12 If a message is displayed to choose the printer, do the following:

▪ To print the result report on the connected thermal printer, choose the **Thermal** button.

▪ To print the result report on the connected inkjet printer or laser printer, choose the **Ink/Laser** button.
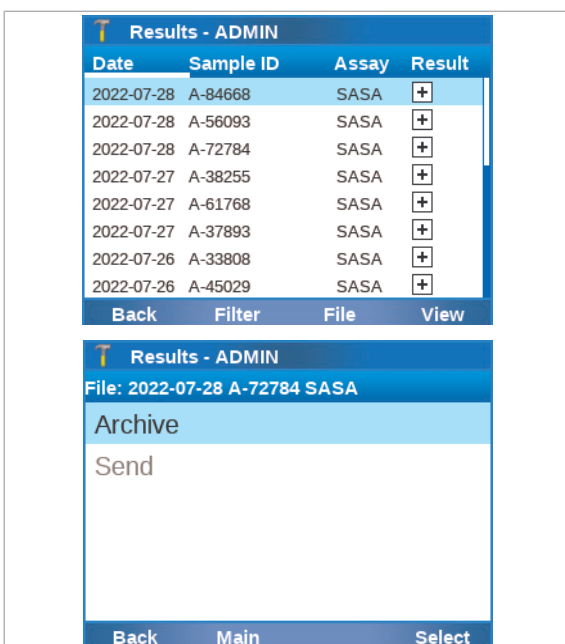
13 On the **Print queued** message, choose the **Confirm** button.

14 To archive the result report or to send the result to a host, on the **Results** screen, choose the **File** button. From the **File** screen, you can do the following:

▪ Archive the result report in a share location or on a USB flash drive (see step **15**).

▪ Send the result to a host (see step **16**).

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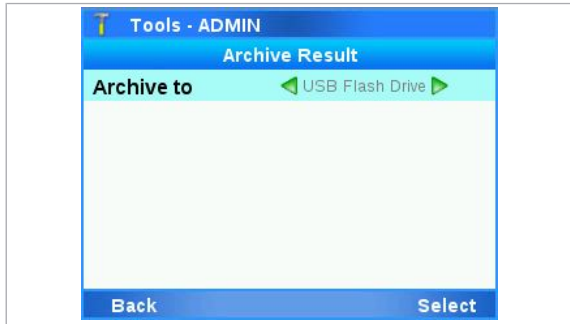
15 To archive the result report in a share location or on a USB flash drive, on the **File** screen, choose the **Archive** item. Choose one of the values for the **Archive to** item, choose the **Select** button, and follow the instructions on the screen:

▪ **USB flash drive**

▪ **Network share {0}** (with {0} = 1 to 3)

▪ **FTP share {0}** (with {0} = 1 to 3)

16 To send the result to the host, choose the **Send** item and follow the instructions on the screen.

Sorting and filtering results

You can sort and/or filter which results are displayed on the **Results** screen.

By default, on the **Results** screen, all results of the last 7 days (corresponding to the **All files** filter and **Last 7 days** filter) are displayed sorted by the concatenated date and run number in descending order (newest to oldest).

If the analyzer is connected to a DMS and patient verification is configured, rows and columns displaying ID data have an **ID** label instead of a **Sample ID** label.

For sorting, the following rules apply:

▪ A white underline as sorting indicator is added to the column header of the column used for sorting.

▪ The sorting order is based on Unicode and case-insensitive.

▪ Sorting by the **Result** column cycles through sorting by the status columns.

▪ If there is more than 1 result for a sorting criterion, the results are sorted further:

– When sorting by the **Date** column, results with the same date are sorted by the concatenated date and run number.

– When sorting by the **Sample ID** column respective **ID** column, results with the same ID are sorted by the concatenated date and run number, e.g., 12345620201126.

– When sorting by the **Assay** column, results from the same assay are sorted by the concatenated date and run number, e.g., 2020-11-29 22222.

– When sorting by the **Result** column, results with the same status are sorted by the concatenated date and run number.

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☑— ☐ Supervisor user role or administrator user role

▶ **To sort and filter results on the Results screen**

1 On the **Main** screen, choose the **Results** item and choose the **Select** button.
  → The **Results** screen is displayed.

2 To sort the results, on the **Results** screen, do the following:
  ▪ To sort by a different column, double-tap inside that column.
  ▪ To toggle between ascending and descending sorting order, double-tap inside the column again.
  ▪ To cycle through sorting by the status columns, double-tap inside the **Result** column repeatedly.
  → A sorting indicator marks the sorting column.

3 To filter the results, on the **Results** screen, choose the **Filter** button.

4 Choose the filter.
  Use the ⬆ and ⬇ navigation buttons to choose a specific filter.
  ▪ **All files**
  ▪ **Sample ID:** or **ID:**
  ▪ **Assay:**
  ▪ **User ID:**
  ▪ **To be sent** (to the host)
  ▪ **Pending approval**

  ⓘ With filter items ending with a colon, you must enter a value, for example an ID or a name.

5 Choose the **Next** button.

6 On the next filter screen, define the time period for which the results should be included.

  ⓘ Use the ⬆ and ⬇ navigation buttons to choose a specific period.
  Last 7 days (results from the last 7 days)
  All (results from any date)
  Today (results from today)
  Last 2 days (results from yesterday and today)
  Last 30 days (results from the last 30 days)
  YYMMDD-YYMMDD (results from the specified period)

7 Choose the **Confirm** button.
  → If 1-500 results match the filter criteria, the filtered results are displayed on the **Results** screen.

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➔ If no result or too many results (>500) match the filter criteria, a message is displayed. To return to the filter screen, choose the **Filter** button.

Setup

6 Setup

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6 Setup

About setting up the analyzer

Setup tasks are performed from the **Settings** screen.

Settings - ADMIN
System
Printers
Connections
Share locations
User management
Scheduled tasks
Main   Print   Select
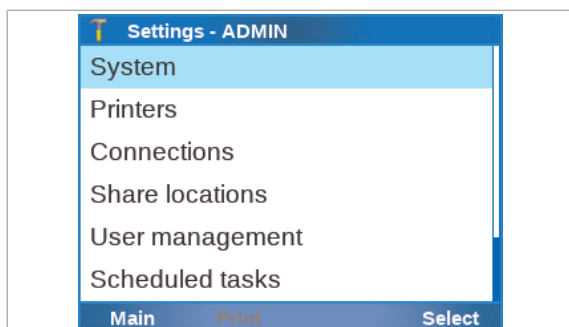
⌖ With administrator user role, you can perform all setup tasks. With supervisor user role, you can perform the setup tasks except for the network definitions.

⌖ All saved data is retained on the analyzer even if it is not connected to the mains.

Installing and updating assays

You install assays typically when Roche deploys new assays or when a new version of an assay becomes available.

To be able to use a new or updated assay, perform the following steps:

1. Install the assay script in one of the following ways:

   – From a USB flash drive provided by your Roche representative

   – From the remote service:
     cobas® **infinity** edge smart
     Axeda

   – From a local source (for new assays only)

2. Add the assay tube lot.

   With an update, this step is not always required. If assay tube lot validation is required, a message informs you.

3. Allow users to perform runs using the new assay (i.e., changing the user information).

After installing an assay, you can print the assay installation report as long as no assay tube lot is added for the assay.

🔆	Do not disconnect the power supply from the analyzer while installing or updating an assay.

In this section

6 Setup

Installing or updating an assay from the USB flash drive

You can install or update an assay from the USB flash drive provided by your Roche representative.

After an assay update, the version of the updated assay may not be compatible with the assay version used to validate the assay tube lots that are in use. In this case only, a message is displayed and you have to revalidate the assay tube lots before you can use them again.

☐ New or updated assay script provided by your Roche representative on USB flash drive

☐ Administrator user role

▸ **To install or update an assay from the USB flash drive**

1 While on the **Main** screen, insert the USB flash drive at the rear of the analyzer.

2 On the message dialog box, choose the **Confirm** button.
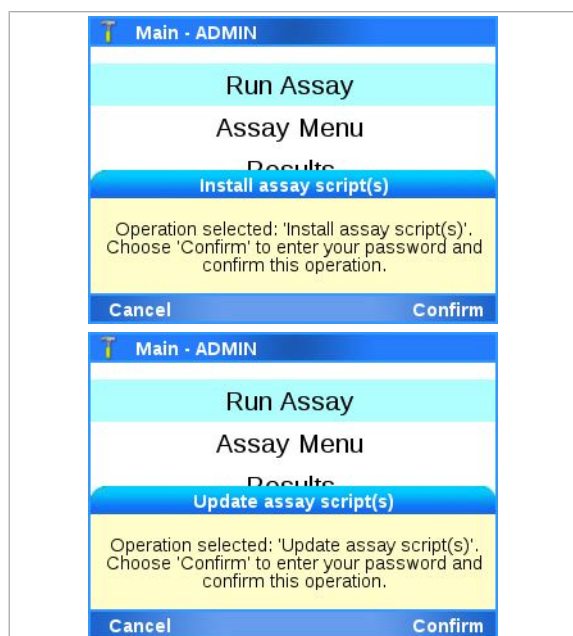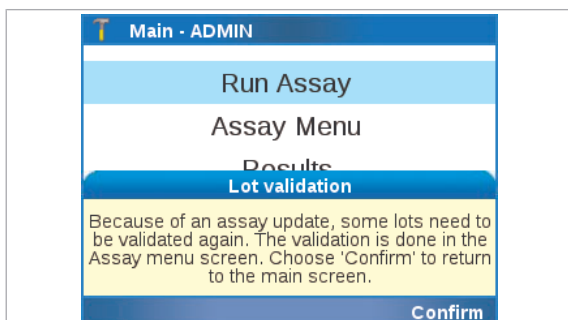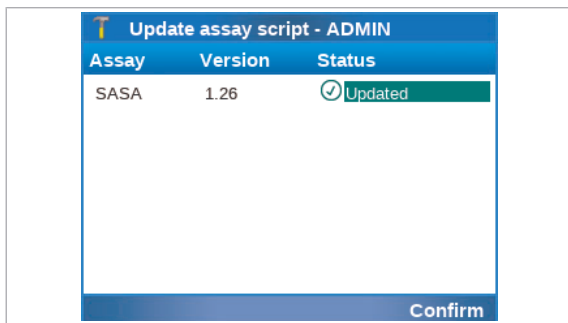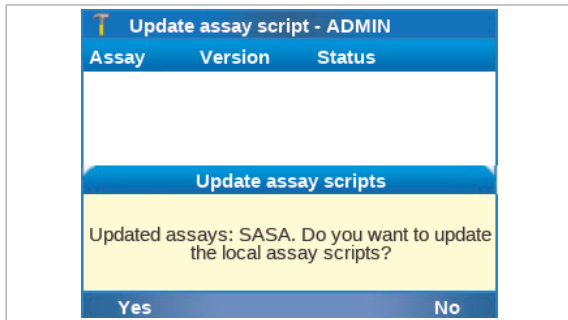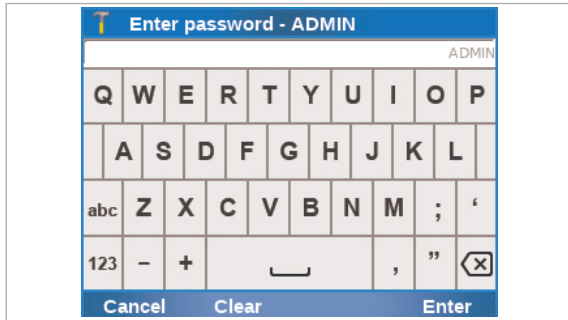
3 Enter your password and choose the **Enter** button.

4 Choose the **Yes** button to confirm that you want to install or update the listed assays.

  ➔ A progress screen is displayed. All available assays or updates are installed.

5 Follow the dialog box: **Remove the USB flash drive. Wait 5 seconds. Then choose 'Confirm' to continue.**

  ➔ The script installation or update completes. This process can take several minutes.

6 Do one of the following:

  ▪ When a successful script installation or update is displayed in the **Status** column, choose the **Confirm** button.

  ▪ When an unsuccessful script installation or update is displayed in the **Status** column, choose the **Confirm** button to return to the **Main** screen. Repeat steps **1** to **5**.

  ℹ The assay script version is displayed in the **Version** column.

7 After an assay update, if assay tube lot validation is required again, a message is displayed. Choose the **Confirm** button to return to the **Main** screen.

8 After an assay installation, you must do the following before users can run the assay:

  ▪ Add an assay tube lot as described in Adding an assay tube lot (124).

  ▪ Add the assay to the users' allowed assays as described in Changing user information (152).

9 You may have to register the assay manually.

  ℹ If the analyzer is connected to the remote service, the analyzer automatically tries to register the assay. You must only register the assay manually if automatic registration fails.

⌗ **Related topics**

  ▪ Installing or updating an assay from the remote service (117)

  ▪ Adding an assay tube lot (124)

Installing or updating an assay from the remote service

You can install or update an assay from the remote service.

Before installing or updating an assay using this method, you must configure access to the remote service.

⇥▤ Remote service configuration (222)

When installing or updating an assay, the analyzer behavior depends on the used remote service and its configuration.
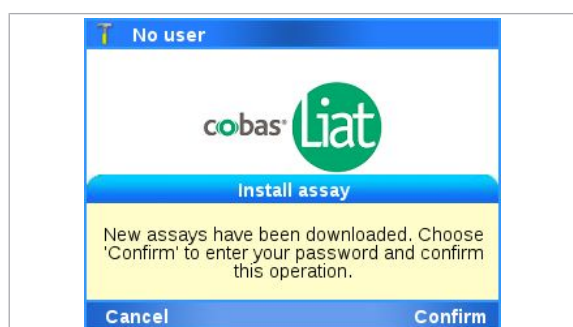
When you use Axeda as the remote service, the following applies:

▪ When a new assay or an assay update becomes available, a message is displayed on the analyzer screen during logon.

▪ If you are logged on with user user role, a message is displayed asking you to contact your supervisor or system administrator.

When you use **cobas®** **infinity** edge smart as the remote service, the analyzer behavior depends on the configuration of **cobas®** **infinity** edge smart. The following applies:

▪ The assay or assay update is automatically installed in the background without user intervention when the analyzer is in status standby.

▪ Alternatively, a message is displayed and you can accept or reject the installation (same behavior as with Axeda).

After an assay update, the version of the updated assay may not be compatible with the assay version used to validate the assay tube lots that are in use. In this case only, you have to revalidate the assay tube lots.

☐ The connection to the remote service has been configured.

☐ Supervisor user role or administrator user role for installation
Administrator user role for update
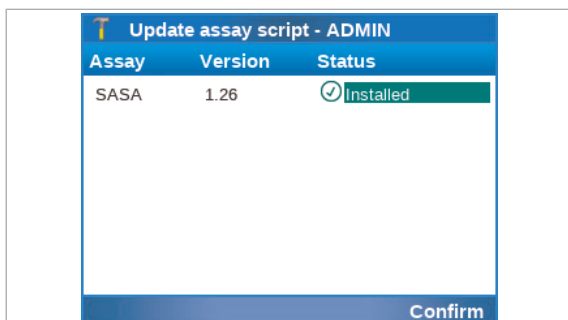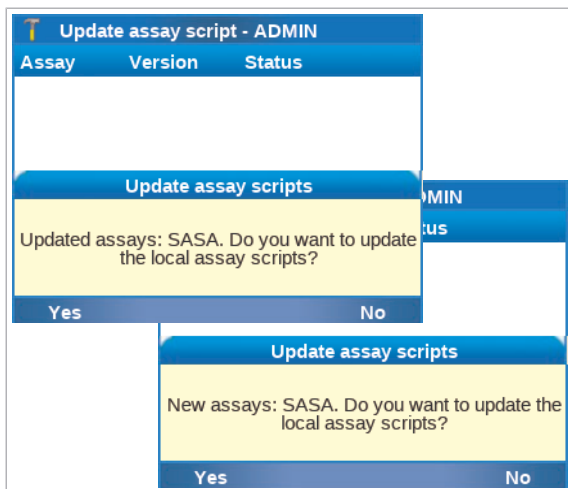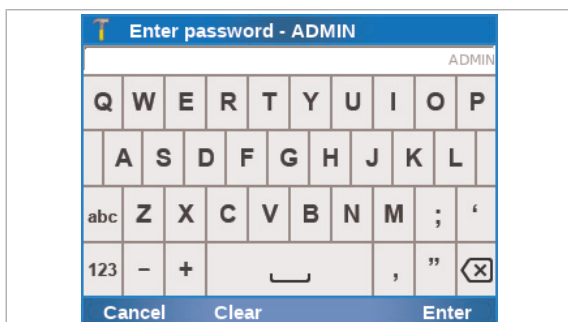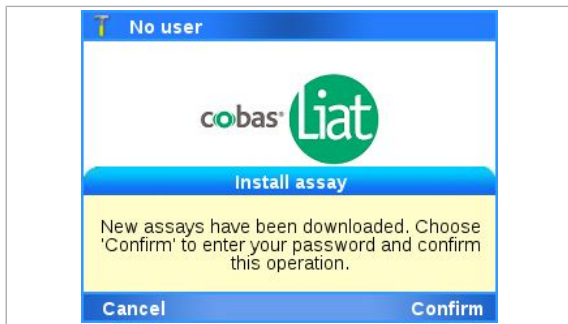
To install or update an assay from the remote service

1 When a new assay or an update to an assay is available, a message is displayed on the analyzer screen during logon.

2 On the message dialog box, choose the **Confirm** button.

3 Enter your password and choose the **Enter** button.

4 On the message dialog box, choose the **Yes** button.
  ➔ A progress screen is displayed.

5 When a successful script installation or update is displayed in the **Status** column, choose the **Confirm** button.

  ⓘ The assay script version is displayed in the **Version** column.

6 Setup
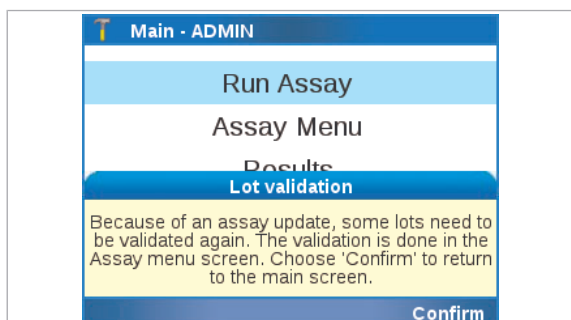
6 After an assay update, if assay tube lot validation is required again, a message is displayed. Choose the **Confirm** button to return to the **Main** screen.

7 After an assay installation, you must do the following before users can run the assay:

- Add an assay tube lot as described in Adding an assay tube lot (124).

- Add the assay to the users' allowed assays as described in Changing user information (152).

8 You may have to register the assay manually.

ⓘ If the analyzer is connected to the remote service, the analyzer automatically tries to register the assay. You must only register the assay manually if automatic registration fails.

Related topics

- Adding an assay tube lot (124)

- Registering assays (121)

Installing an assay from a local source

You can install an assay from a USB flash drive, a network share, or an FTP share.

Before you can install the assay from a local source, you must store the assay script in the correct location.

Share locations configuration (253)

☐ To install an assay from a USB flash drive:
Assay script saved in the root folder of a USB flash drive

☐ To install an assay from a network share or FTP share:
Share location configured correctly
Assay script saved in the root folder of the share location

☐ Administrator user role or supervisor user role

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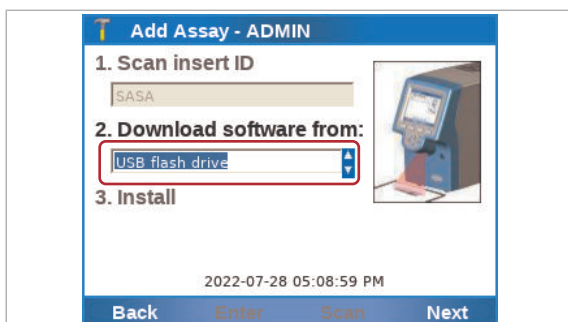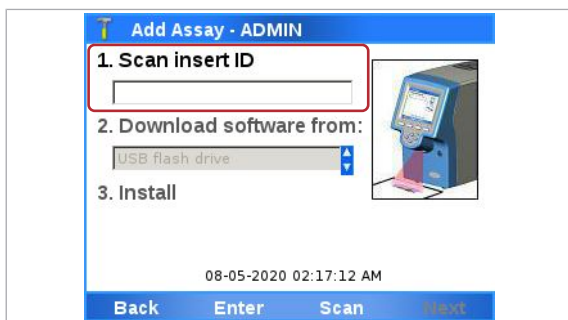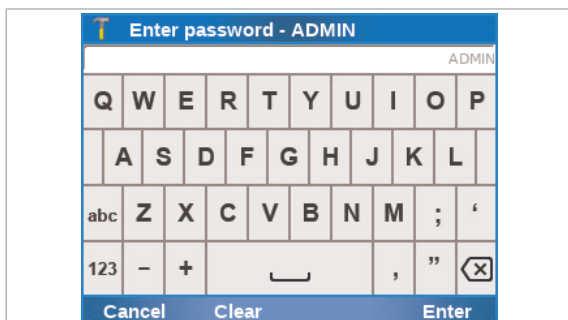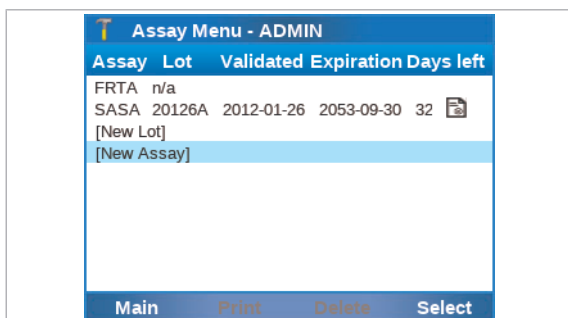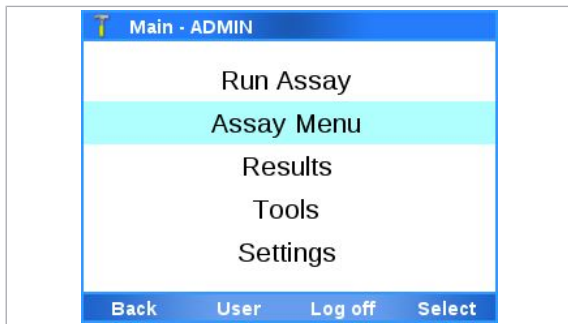
▶ **To install an assay from a local source**

1 On the **Main** screen, choose the **Assay Menu** item and choose the **Select** button.
→ All currently installed assays are listed.

2 Choose the **[New Assay]** item.
ⓘ You may have to scroll down to display this item.

3 Enter your password and choose the **Enter** button.

4 Choose the **Scan** button.

5 Place the barcode from the assay package insert or the Instructions for Use under the barcode reader.
→ The **2. Download software from:** field becomes available.

6 Define where to download the software from:
▪ Choose the **USB flash drive** value, if you install from a USB flash drive.
▪ If you have defined a different share location, choose the appropriate value.

7 Ensure the *signed ZIP file* of the assay to be installed is saved in the root folder of the download location (USB flash drive or share location).
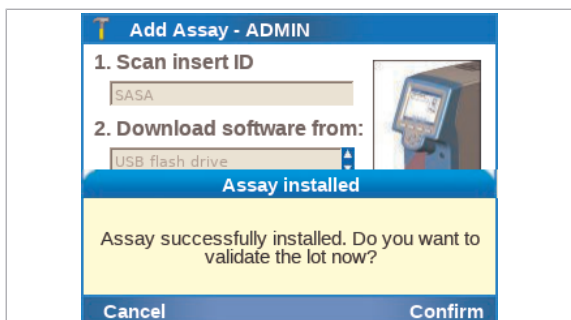
8 If you use a USB flash drive, insert the USB flash drive at the rear of the analyzer.

9 Choose the **Next** button.

10 If you installed from a USB flash drive, follow the dialog box: **Remove the USB flash drive. Wait 5 seconds. Then choose 'Confirm' to continue.**

11 Decide whether you want to validate an assay tube lot (add an assay tube lot) now or later:

- ▪ To validate an assay tube lot now, choose the **Confirm** button.
- ▪ To continue without validating an assay tube lot now, choose the **Cancel** button.

12 You may have to register the assay manually.

ⓘ If the analyzer is connected to the remote service, the analyzer automatically tries to register the assay. You must only register the assay manually if automatic registration fails.

▸▤ **Related topics**

- ▪ Adding an assay tube lot (124)
- ▪ Registering assays (121)
- ▪ System settings (133)
- ▪ Network configuration (219)

Registering assays

Newly installed and updated assays must be registered within 30 days.

You can use the unregistered assays during the registration period. Once this period has expired, the assay can no longer be used for testing until the activation has been completed.

-ᗺ̣́- If the analyzer is connected to the remote service, the analyzer automatically tries to register the assay. If this automatic registration fails, a message is displayed and a user must register the assay manually.

☐ Administrator user role
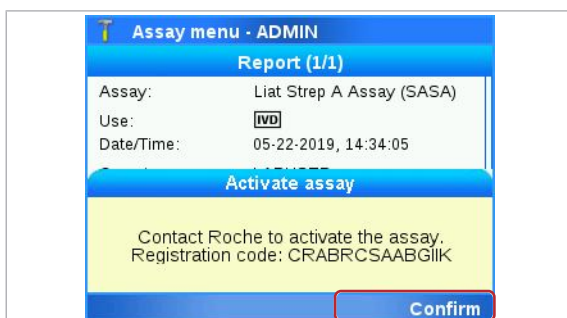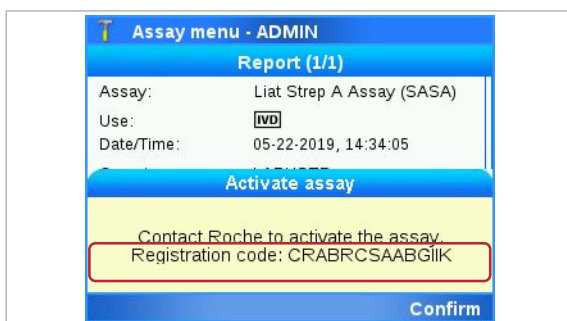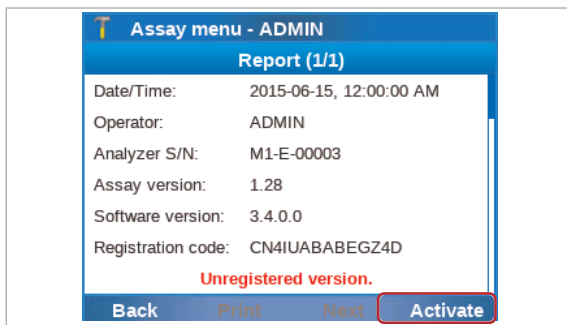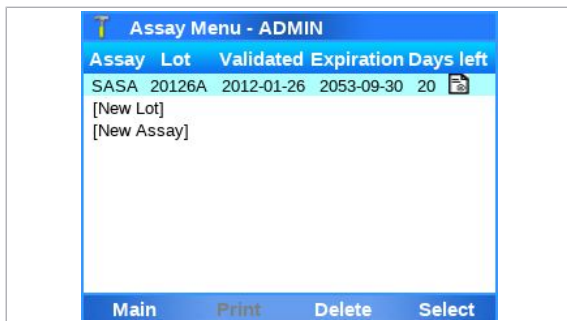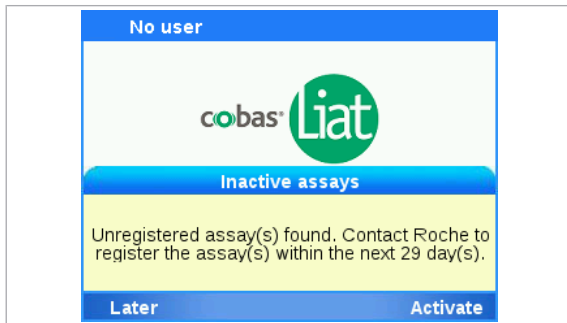
▶ **To register an assay manually**

1 Start the registration process.

• If a message is displayed, choose the **Activate** button.

• If no message is displayed, on the **Main** screen, choose the **Assay Menu** item.

ⓘ If the analyzer is connected to the remote service, the analyzer attempts to register the assay automatically. You must only register the assay manually if automatic registration fails.

2 Choose the assay that needs registering and choose the **Select** button.

ⓘ Unregistered assays are marked with a number and the icon in the **Days left** column. If no number is displayed, the registration period has expired.

3 On the **Report** screen, choose the **Activate** button.

4 From the message dialog box, note the registration code.

5 Call your Roche representative and provide the registration code.

ⓘ You may be able to register assays via a dedicated internet site. Contact your Roche representative for more information.

6 The Roche representative issues an activation code.

7 On the message dialog box, choose the **Confirm** button.
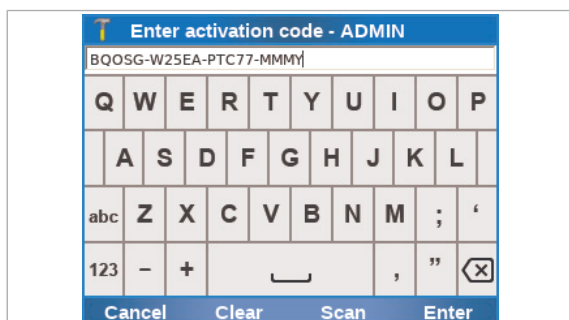
8 Enter or scan the activation code and choose the **Enter** button.

9 On the message dialog box, choose the **Confirm** button.

10 Optionally, to print the assay installation report, choose the **Print** button.

   ⓘ The assay installation report is available as long as no assay tube lot is added for the assay.

Printing the assay installation report

After installing an assay, you can print the assay installation report.

The assay installation report is only available as long as no assay tube lot is added for the assay.

▶ **To print the assay installation report**

1 On the **Main** screen, choose the **Assay Menu** item and choose the **Select** button.

   ➔ All currently installed assays are listed.
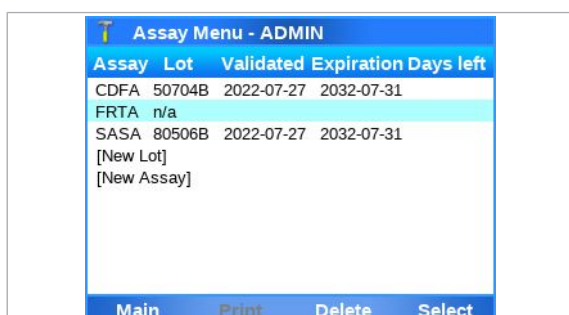
2 Choose an assay without any added assay tube lots and choose the **Select** button.

3 Choose the **Print** button.

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Adding an assay tube lot

Assay tube lots have a certain shelf life. Each new assay tube lot has to be added on the analyzer and is validated by running a negative and positive control.

Adding an assay tube lot includes the following activities:

1. Scanning the new lot data

2. Performing QC (validating the assay tube lot)

-⚬- Enabled patient verification does not affect the runs for validating assay tube lots.

⯈▤ About patient verification (247)

Sharing assay tube lots

Instead of adding and validating the same assay tube lot on several analyzers, you can share assay tube lots between analyzers in the following ways:

▪ By exporting and importing the assay tube lots.

▪ By enabling the share lot folder.

▪ By connecting the analyzers to a DMS and enabling the exchange of lots.

-⚬- If you share assay tube lots via a DMS, you cannot use another way to share assay tube lots between analyzers at the same time.

⯈▤ For more information about exporting assay tube lots, refer to To export assay tube lots (198).

⯈▤ For more information about importing assay tube lots, refer to To import assay tube lots (198).

⯈▤ For more information about using the share lot folder, refer to Using the share lot folder (255).

⯈▤ For more information about configuring the share lot folder, refer to Configuring the share lot folder (255).

⯈▤ For information on the connection to a DMS, refer to Connecting the analyzer to a host system (239).

📅 ▪ Before using the first assay tube of a new lot.

▪ When revalidation of an assay tube lot is necessary.

🧰 ☐ Assay tube from the new lot

☐ Package insert or Instructions for Use of the assay tube lot for the specific assay

☐ Transfer pipette

☐ Quality control kit for the specific assay

☑▤ ☐ Assay installed

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▶ **To add an assay tube lot**
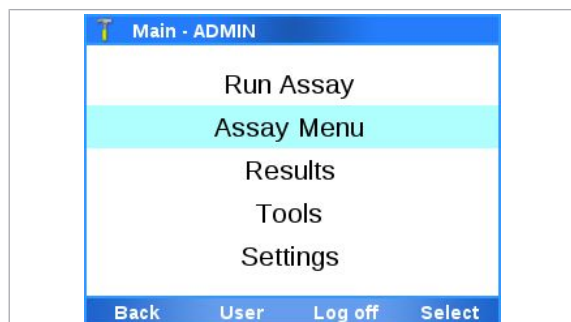
1 On the **Main** screen, choose the **Assay Menu** item and choose the **Select** button.
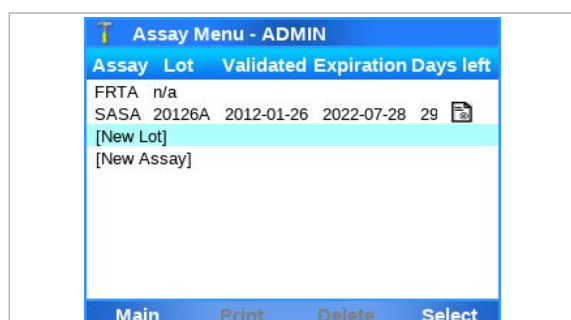
2 Choose the **[New Lot]** item and choose the **Select** button.
- **Assay**: 4-letter name of the installed assays
- **Lot**: Validated assay tube lot numbers
- **Validated**: Date of validation
- **Expiration**: Date the lot is set to expire
- **Days left**: Days left for activation of the assay
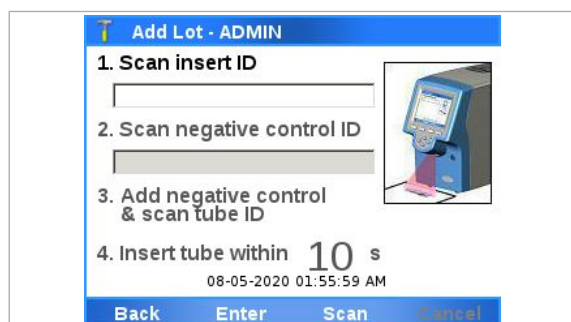
3 Obtain the package insert or the Instructions for Use from the new lot. Choose the **Scan** button. Scan the package insert barcode on the first page of the package insert or the Instructions for Use of the lot you want to add.

4 You may have to confirm that you have read the package insert.

5 Choose the **Scan** button and place the barcode of the negative control under the barcode reader.
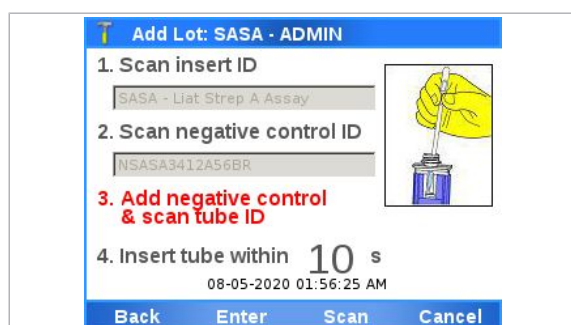
6 Follow the instructions in the assay tube package insert or the Instructions for Use on how to add the negative control sample to an assay tube from this lot.

7 Dispose of all used transfer pipettes in accordance with the disposal policy of your institution and according to local regulations.

8 Choose the **Scan** button.

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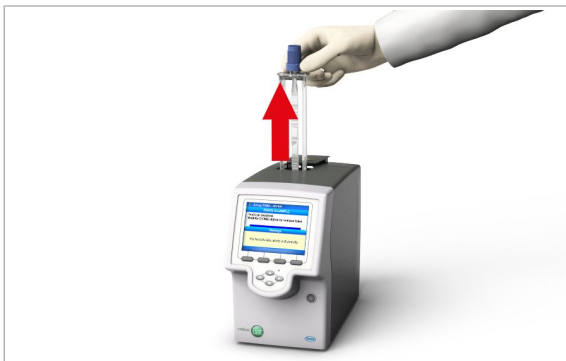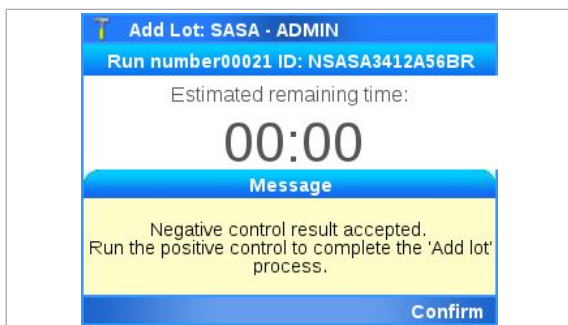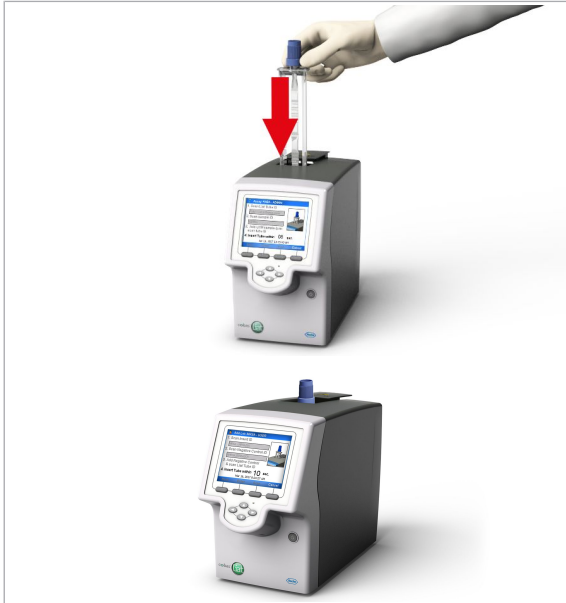
9 Place the prepared assay tube under the barcode reader.

10 Within the time limit for inserting assay tubes, insert the prepared assay tube in the analyzer.
  → Processing starts automatically.

11 Wait for a message to inform you that the negative control result has been accepted. Choose the **Confirm** button to confirm the message.

  ⓘ If the negative control was not completed successfully, refer to the package insert or the Instructions for Use of the assay for further information, and repeat the negative control.

12 When asked to do so, remove the assay tube from the analyzer. Dispose of the assay tube in accordance with the disposal policy of your institution and according to local regulations.

13 Wait until the information in the title bar stops flashing, then choose the **Back** button.

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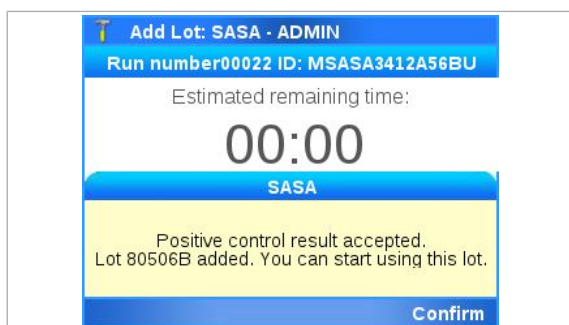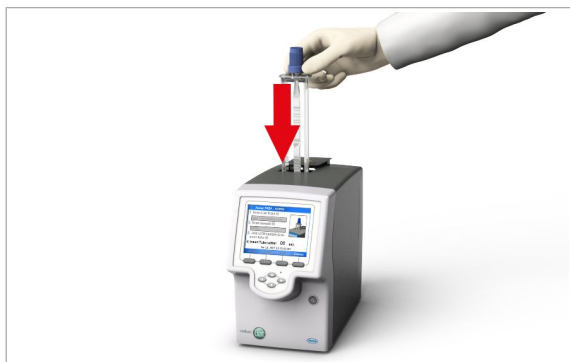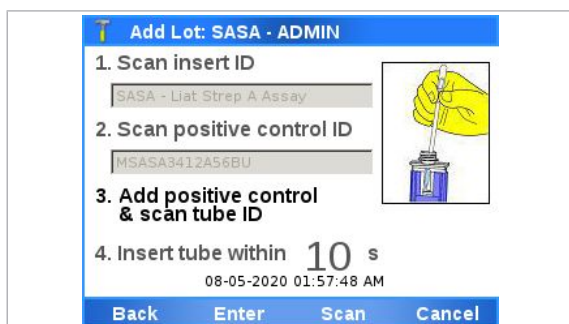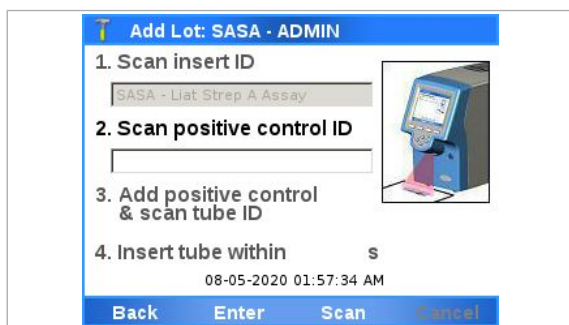
14 Choose the **Scan** button and place the barcode of the positive control under the barcode reader.

15 Follow the instructions in the assay tube package insert or the Instructions for Use on how to add the positive control sample to an assay tube from this lot.

16 Dispose of all used transfer pipettes in accordance with the disposal policy of your institution and according to local regulations.

17 Choose the **Scan** button.

18 Place the prepared assay tube under the barcode reader.

19 Within the time limit for inserting assay tubes, insert the prepared assay tube in the analyzer.
   → Processing starts automatically.

20 Wait for a message to inform you that the positive control result has been accepted. Choose the **Confirm** button to confirm the message.

   ❶ If the positive control was not completed successfully, refer to the package insert or the Instructions for Use of the assay for further information, and repeat the positive control.

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21 When asked to do so, remove the assay tube from the analyzer. Dispose of the assay tube in accordance with the disposal policy of your institution and according to local regulations.

22 Wait until the information in the title bar stops flashing, then choose the **Back** button.

23 Check the entry for the new assay tube lot.

Deleting assay tube lots

If you delete the assay tube lot, you cannot run the associated assay anymore, unless there is another validated assay tube lot for this assay or the deleted assay tube lot is added and revalidated again.

It is recommended to archive assay tube lots before deletion.

▸🗐 Archiving assay tube lots (188)

—————————————————————

💡 If assay tube lots are exchanged with a DMS, you cannot delete assay tube lots on the analyzer.

▸🗐 About data exchange with a DMS (243)

—————————————————————

☐ Supervisor user role or administrator user role

▶ **To delete an assay tube lot**

1 On the **Main** screen, choose the **Assay Menu** item and choose the **Select** button.
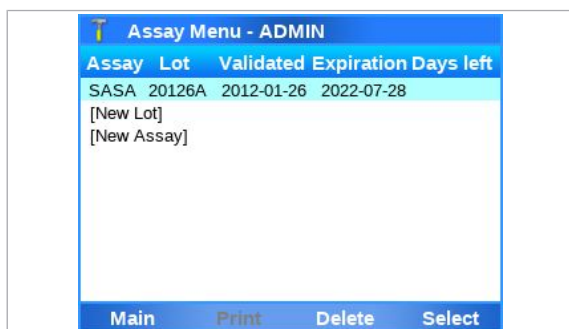
2 Choose the assay tube lot entry.

3 Choose the **Delete** button.
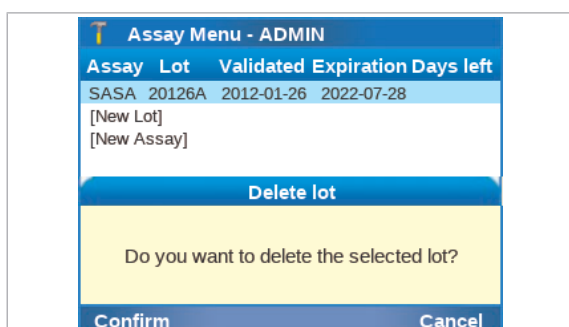
4 On the confirmation message dialog box, choose the **Confirm** button.
 → The lot entry **n/a** on the **Assay Menu** screen indicates that there are no validated lots for this assay.

Uninstalling assays

Uninstalling an assay removes the assay script from the analyzer.

□ Administrator user role

▶ **To uninstall an assay**

1 On the **Main** screen, choose the **Assay Menu** item and choose the **Select** button.

2 Choose the assay entry.

 ⓘ If there are validated assay tube lots for the assay, there may be several entries for this assay.

3 If there are assay tube lots for the assay you want to uninstall, delete them all first:
 ▪ Choose the assay tube lot entry.
 ▪ Choose the **Delete** button.

 ⓘ When all assay tube lots are deleted, there is only one entry left for the assay and the value in the **Lot** column is **n/a**.

4 Choose the **Delete** button.

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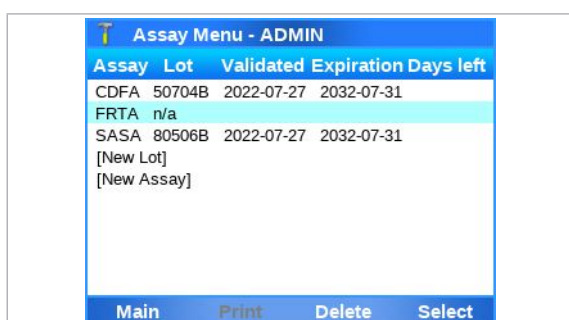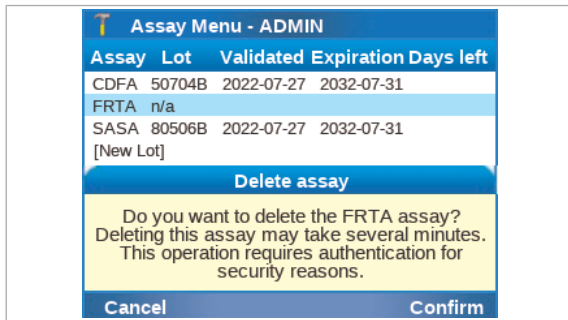
5 On the confirmation message dialog box, choose the **Confirm** button.

6 Enter your password and choose the **Enter** button.

Related topics

- Deleting assay tube lots (128)

Viewing and printing assay tube lot information

You can view and print the details of all added assay tube lots.

If the assay tube lot was imported, shared, or synchronized, only information of the assay script is displayed on the analyzer. You can view and print control test results of an assay tube lot only on the analyzer where the assay tube lot was added and validated.

▶ **To view and print assay tube lots**

1 On the **Main** screen, choose the **Assay Menu** item and choose the **Select** button.

2 To print the list of installed assays and assay tube lots, choose the **Print** button.
→ The list of installed assays and assay tube lots is sent to the printer.

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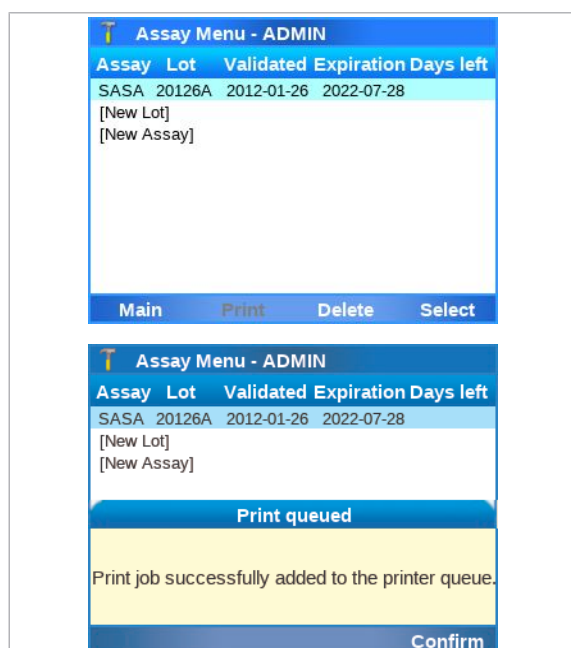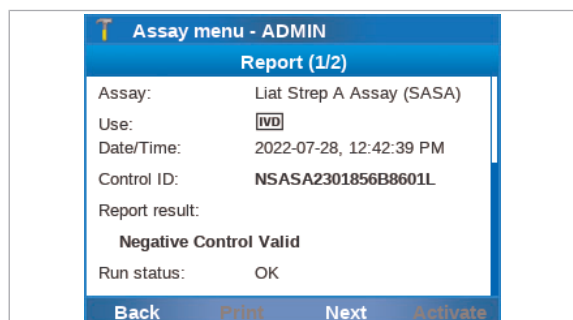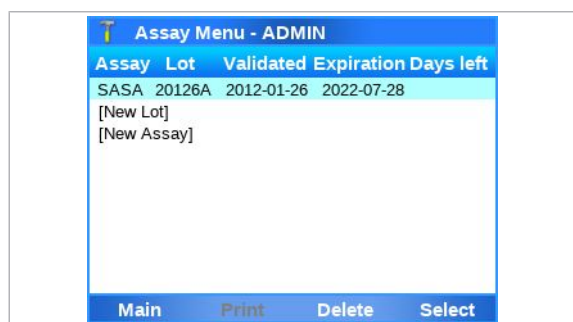
▶ **To view and print control test results of a lot**

1 On the **Main** screen, choose the **Assay Menu** item and choose the **Select** button.

2 Choose the assay tube lot you are interested in and choose the **Select** button.

3 On the report screen for the control, do either of the following:

- ▪ To print the results, choose the **Print** button.
- ▪ To display the report screen of other controls, choose the **Next** button.

ⓘ You can view and print control test results of an assay tube lot only on the analyzer where the assay tube lot was added and validated.

4 To return to the assay tube lot list, choose the **Back** button.

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Defining system settings

Define the general operating environment.

In this section

System settings (133)

Changing system language (136)

About logon modes (137)

Configuring barcode settings (138)

Configuring the log level (140)

Data collection (142)

Configuring automatic release of results (146)

System settings

To define the general operating environment, enter the required information choosing **Settings > System**.

To edit the system settings, you need supervisor user role or administrator user role.

💡	For your records, you can print the system settings and the user settings using the **Print** button.

System item	Configuration item	Comment
Date and time	**Date and time**	Displays the date and time in the currently set formats.
		Choose to set a different date and time.

⊞ System configuration items

System item	Configuration item	Comment
	Format	Choose the format for how the date and time are displayed on the analyzer (dd = day, mm = month, yyyy = year): **Date format** values: ▪ yyyy-mm-dd ▪ mm-dd-yyyy ▪ dd.mm.yyyy ▪ dd/mm/yyyy ▪ dd-mm-yyyy **Time format** values: ▪ 12 hours ▪ 24 hours
	SNTP	If the analyzer is connected to an SNTP server, date and time are updated automatically: ▪ To connect the analyzer to an SNTP server, choose the **Server** item, enter the server information, and choose the **Save** button. ▪ To temporarily disable the automatic updates but keep the server information, choose the **SNTP** item and set it to the **Disabled** value. ▪ To enable the automatic updates again, choose the **SNTP** item and set it to the **Enabled** value. ▪ To permanently disconnect the analyzer from the SNTP server, choose the **Server** item, delete the server information, and choose the **Confirm** button. Do not manually change the time and date when SNTP is enabled.
	Server	IP address or DNS name of the SNTP server from which time and date are obtained. This server can be any workstation in the network or any remote SNTP server. -☼- The analyzer adjusts the date and time to the last known values if the connection to the SNTP server fails.
	Time zone	Choose the time zone where your analyzer is located. Make any changes to the time zone before changing the time, as a change to the time zone will cause the time to be updated. If the configured time zone supports Daylight Saving Time, the time on the analyzer is adjusted automatically.
Brightness		Screen brightness. Choose a value between 0 (darkest) to 7 (brightest).
Sound	**Initialization**, **Barcode scan**, **Tube insert**, **Run finished**, **Touch screen**, **Key clicks**	Choose the **Off** value to turn off the acoustic signal for the chosen event. Choose any of the available signal types to define that an acoustic signal should be sounded at the end of the chosen event.

⊞ System configuration items

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System item	Configuration item	Comment
	Volume	Choose a value between 0 (off) to 5 (loudest).
		The volume setting applies to all acoustic signals.
Tube insert time	1-20 seconds	Maximum time in seconds allowed for inserting the assay tube after scanning its barcode.
		Defining a short time ensures that the inserted assay tube is the same that was just scanned, and it reduces the likelihood of contamination of the reaction chamber.
Name of analyzer	Up to 15 alphanumeric characters.	By default, the analyzer serial number.
Language		Choose the language of the user interface.
		Default language is English.
		⯈▤ Changing system language (136)
Auto lock time	1-1440 minutes	Time in minutes after which the auto lock function is activated.
		Default time is 3 minutes.
		🔅 To prevent unauthorized access, it is recommended to set a short auto lock time, e.g., by keeping the default value of 3 minutes.
Auto restart time	**Hours**, **Minutes**	Set the time for the automatic daily restart of the analyzer.
		Default time: 3 AM
		🔅 To ensure that the automatic daily restart of the analyzer does not interfere with any ongoing activity (e.g., assay runs, scheduled tasks, etc.), schedule the daily restart for a time when the analyzer is not frequently used.
		⯈▤ About auto monitoring (262)
Logon mode > Logon mode	**User ID and password**, **Barcode and password**, or **Barcode**	Choose the logon mode for logging on to the analyzer.
		⯈▤ About logon modes (137)
		🔅 Consider the level of security provided by the different logon modes.
Barcode settings	**Codabar**, **Code 39**, **Code 93**, **Code 128**, **EAN-8**, **EAN-13**, **GS1 DataBar**, **Interleaved 2 of 5**	Enable/disable and customize the supported barcode standards.
		By default, all barcode standards except interleaved 2 of 5 are enabled.
		Code 128 is the barcode standard for system barcode labels (e.g., on assay tubes) and cannot be disabled.
		⯈▤ Configuring barcode settings (138)
		⯈▤ Barcode specifications (300)

▦ System configuration items

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System item	Configuration item	Comment
Log level	**Normal** or **Verbose**	Enable or disable the verbose logging. By default, verbose logging is disabled (default **Normal** value) and the analyzer only logs errors, warnings, and informations in the log files. If requested by your Roche representative for troubleshooting purposes, enable verbose logging (**Verbose** value) to include additional information for troubleshooting and messages in the log files. ▸▤ Configuring the log level (140)
Data collection	**Enabled** or **Disabled**	Enable or disable data collection on the analyzer. By default, data collection is disabled. Additionally, data collection is automatically disabled whenever a new data collector or a new version of a data collector is installed on the analyzer. You can only enable data collection if at least 1 data collector is installed on the analyzer. ▸▤ Data collection (142)
Result settings > Auto release	**Yes** or **No**	Enable or disable the automatic release of results. If automatic release is disabled (default **No** value), a user with administrator or supervisor user role must approve (release or reject) results manually. ▸▤ Configuring automatic release of results (146)
Default settings		Choosing the **Select** button resets all values defined from the **Settings** screen to the factory values, except for the **Date and time** value, the **Name of analyzer** value, and the **Language** value.

⊞   System configuration items

Changing system language

You can change the language of the user interface.

The language setting determines the language of the user interface for all users of the analyzer. It is not possible to set an individual user language.

The language setting also determines the sorting order in the **Results** screen and in the **User** screen.

The following languages are available:
- Czech
- Danish
- German
- English
- Spanish
- French
- Italian

- Hungarian
- Dutch
- Norwegian (Bokmål)
- Polish
- Portuguese
- Swedish

☐ Administrator user role or supervisor user role.

▶ **To change system language**
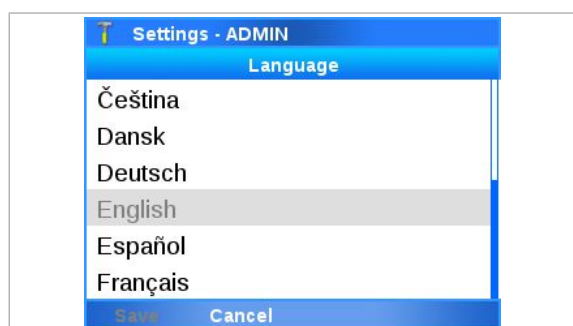
1 On the **Main** screen, choose **Settings > System > Language**.

→ All available system languages are listed.

2 To choose a language, use the ⬆ and ⬇ navigation buttons. On the message dialog box, choose the **Confirm** button.

ⓘ The currently set system language is unavailable.

3 On the message dialog box, choose the **Log off** button.

→ The changed system language is applied at next logon.

About logon modes

The logon mode determines the logon method.

You can choose between the following logon modes:

- **User ID and password**:

  To log on to the analyzer, you must enter your user ID and password. Instead of manually entering your user ID, you can scan a corresponding user ID barcode (a barcode representing your user ID, e.g., the barcodes on the cards provided with the user ID card kit).

- **Barcode and password**:

  To log on to the analyzer, you must scan your assigned badge barcode and enter your password.

- **Barcode**:

  To log on to the analyzer, you must scan your assigned badge barcode only.

  This logon mode provides the lowest level of security.

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-ໍ- Independent of the set logon mode, you can always log on with your user ID and password.

The first user that logs on after starting or restarting the analyzer must always log on with user ID and password, regardless of the logon mode set on the analyzer.

The first user that logs on after starting or restarting the analyze must enter their user ID manually. It is not possible to scan a user ID barcode.

⊡ **Related topics**

- Logging on (72)
- Managing users (148)

Configuring barcode settings

You can enable/disable and customize the supported barcode standards.

By default, all barcode standards except interleaved 2 of 5 are enabled.

Code 128 is the barcode standard for system barcode labels (e.g., on assay tubes) and cannot be configured.

-ໍ- Changing barcode settings may take some time. Wait until the analyzer is responsive again.

About barcode settings You can configure the following barcode settings:

Barcode standard	Min. length [characters]	Max. length [characters]	Values	Customization item	Values
Codabar	5	55	▪ **Enabled**[(a)] ▪ **Disabled**	**Start/Stop char.**	▪ **Omit transmission**[(a)] ▪ **Transmit**
Code 39	2	55	▪ **Enabled**[(a)] ▪ **Disabled**	**Checksum**	▪ **Enabled**[(a)] ▪ **Disabled**
Code 93	4	55	▪ **Enabled**[(a)] ▪ **Disabled**	n/a	n/a

(a)   Default value

(b)   Fixed length including check digit

(c)   Checksum digit calculation algorithm: Uniform Symbology Specification (USS)

(d)   Default value: 10

⊞ Barcode settings configuration

Barcode standard	Min. length [characters]	Max. length [characters]	Values	Customization item	Values
Code 128	1	55	▪ System barcode standard ▪ Not configurable		
EAN-8	8[b]	8[b]	▪ Enabled[a] ▪ Disabled	n/a	n/a
EAN-13	13[b]	13[b]	▪ Enabled[a] ▪ Disabled	n/a	n/a
GS1 DataBar	14[b] (16 with prefix 01)	14[b] (16 with prefix 01)	▪ Enabled[a] ▪ Disabled	n/a	n/a
Interleaved 2 of 5	2	26	▪ Enabled ▪ Disabled[a]	Checksum[c]	▪ Enabled[a] ▪ Disabled
				Fixed length	▪ One discrete length[a] ▪ Disabled
				Barcode length	▪ 2-26[d] (in increments of 2)

(a)   Default value

(b)   Fixed length including check digit

(c)   Checksum digit calculation algorithm: Uniform Symbology Specification (USS)

(d)   Default value: 10

⊞ Barcode settings configuration

The risk of an undetected barcode reading error increases in the following situations:

▪ When using the barcode standard code 39 with checksum disabled.

▪ When using the barcode standard interleaved 2 of 5 with checksum and/or fixed length disabled.

To avoid barcode scanning errors when using the barcode standard code 39, it is recommended to have checksum enabled.

To avoid barcode scanning errors when using the barcode standard interleaved 2 of 5, it is recommended to have checksum and fixed length enabled.

☐ Administrator user role or supervisor user role

▸ **To configure barcode settings**

1   On the **Main** screen, choose **Settings > System > Barcode settings**. Choose the **Select** button.

→ The **Barcode settings** screen is displayed listing all supported barcode standards.

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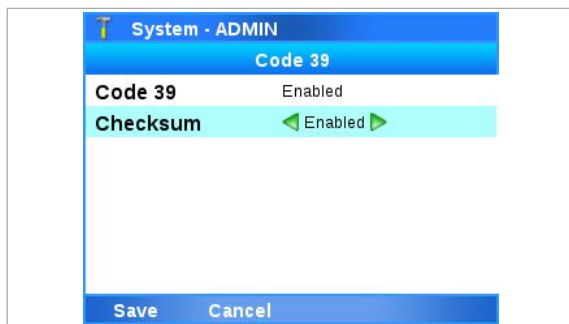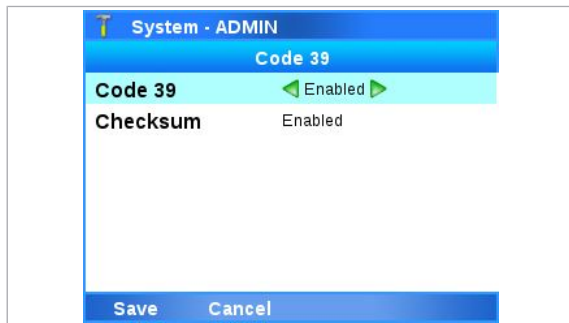
2 To choose a barcode standard, use the ⬆ and ⬇ navigation buttons. Choose the **Select** button.

➔ The barcode settings of the chosen barcode standard are displayed.
If supported, the barcode settings include customization items.

3 To enable/disable a barcode standard, use the Left ◀ and Right ▶ navigation buttons and choose the desired value.

▪ To enable the **Interleaved 2 of 5** barcode standard, on the confirmation message, choose the **Yes** button.

4 To customize a barcode standard, use the ⬆ and ⬇ navigation buttons and choose the customization item (e.g., the **Checksum** item).

5 Use the Left ◀ and Right ▶ navigation buttons and choose the desired value.

▪ To customize the **Interleaved 2 of 5** barcode standard, on the confirmation messages, choose the **Yes** button.

6 Choose the **Save** button. Wait until the analyzer applies the changed barcode settings and is responsive again.

ⓘ Changing barcode settings may take a short time to apply.

▸ **Related topics**

▪ Barcode specifications (300)

▪ Scanning barcodes (83)

Configuring the log level

If requested by your Roche representative for troubleshooting purposes, configure the log level for verbose logging to include additional information for troubleshooting and messages in the log files.

About logging on the analyzer

By default, verbose logging is disabled and the analyzer only logs errors, warnings, and informations in the log files.

If verbose logging is enabled, the analyzer additionally logs additional information for troubleshooting, and sent and received messages in the log files.

The log files are included in problem reports (depending on the content configured for problem reports).

-ᗭ̣- To prevent a potential reduction of the lifetime of the analyzer, configure verbose logging only if requested by your Roche representative.
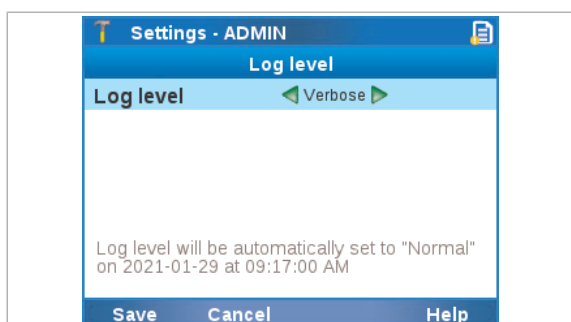
If verbose logging is enabled, the 📄 icon is displayed in the title bar and the remaining time of verbose logging is displayed on the **Log level** screen.

Verbose logging is automatically disabled again after 48 hours or if the date and time is changed on the analyzer.

▢ Administrator user role or supervisor user role

▶ **To enable verbose logging**

1 On the **Main** screen, choose **Settings > System > Log level**. Choose the **Select** button.
  ➜ The **Log level** screen is displayed.

2 Optionally, to display a description of the log levels, do the following:
  ▪ Choose the **Help** button.
  ▪ To return to the **Log level** screen, choose the **Confirm** button.

3 To enable verbose logging and include additional information for troubleshooting in the log files, choose the **Log level** item and change it to the **Verbose** value.

4 Choose the **Save** button.

5 On the message dialog box, choose the **Confirm** button.
  ➜ The analyzer logs additional information for troubleshooting for the next 48 hours.
  ➜ The 📄 icon is displayed in the title bar.
  ➜ On the **Log level** screen, the remaining time of verbose logging is displayed.
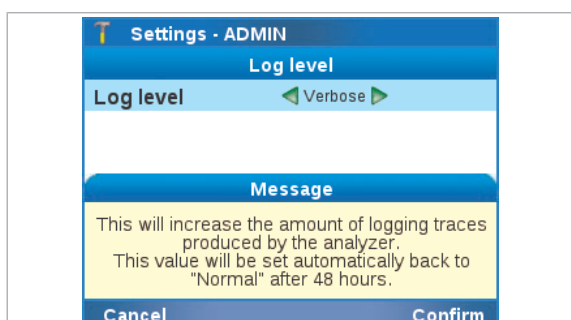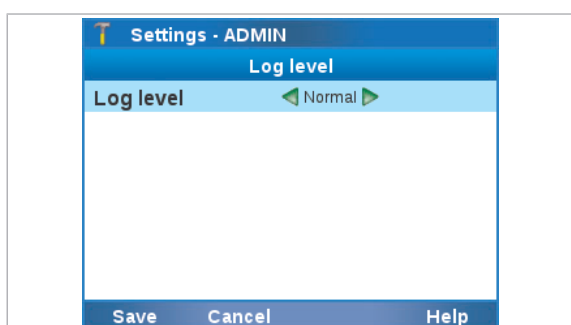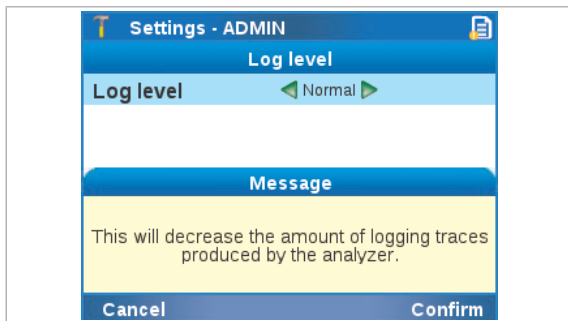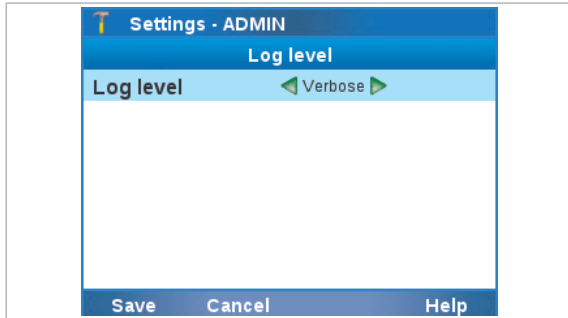
6 Setup

Data collection

▶ **To disable verbose logging**

1 On the **Main** screen, choose **Settings > System > Log level**. Choose the **Select** button.

→ The **Log level** screen is displayed.

2 Optionally, to display a description of the log levels, do the following:

▪ Choose the **Help** button.

▪ To return to the **Log level** screen, choose the **Confirm** button.

3 To disable verbose logging and exclude additional information for troubleshooting from the log files, choose the **Log level** item and change it to the **Normal** value.

4 Choose the **Save** button.

5 On the message dialog box, choose the **Confirm** button.

→ The analyzer stops logging additional information for troubleshooting.

⊟ **Related topics**

▪ Problem reports (205)

Data collection provides information for Roche about analyzer use and issues.

⭘ By default, data collection is disabled on the analyzer.

For data collection to be executed, an administrator or a supervisor has to enable data collection on the analyzer.

In this section

About data collection (142)

Configuring data collection (144)

About data collection

To gather statistical information and to facilitate product care, the analyzer software contains a data collection function.

The following applies:

- **Data collection** is the global function of information gathering on the analyzer. By default, data collection is disabled.
- **Data collectors** are individual plug-ins that are installed on the analyzer and collect their designated data. Roche deploys an individual data collector for each specific data collection purpose.
- **Collected data packages** are the files that are created by the data collectors from their collected data and are transferred to Roche.

-ᗧ- Data collection requires that the analyzer is connected to the remote service.

About installation of data collectors
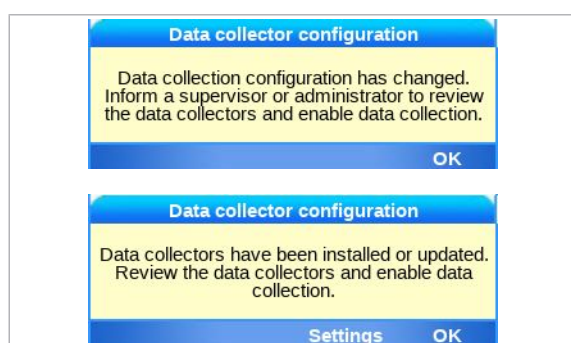
Data collectors are solely deployed via the remote service and installed automatically on the analyzer during initialization. A corresponding message is displayed on the **Log on** screen.

Whenever a new data collector or a new version of a data collector is installed on the analyzer, data collection is disabled automatically. For data collection to be executed again, an administrator or a supervisor has to enable data collection again.

Data collection can only be enabled if at least 1 data collector is installed on the analyzer.

About details on data collectors

A list of the installed data collectors is available on the analyzer.

Additionally, the following detailed information is available for each data collector that is installed on the analyzer:

Detailed information	Description
Name	The name of the data collector that is displayed on the analyzer.
Summary	A short description of the kind of data that is collected.
Version	The current version of the data collector.

⊞ Details on data collectors

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Detailed information	Description
Last execution date	The last time the data collector collected a data package and transferred it to Roche.
	If no data package has ever been collected and transferred, **n/a** is displayed.
Installation date	The date the data collector was installed on the analyzer.
Collects PHI	Information if the collected data packages contain patient information.
	Possible values: **No**, **Yes**
Frequency	How often a data package is collected and transferred to Roche.

▦   Details on data collectors

▸▤ To view details about a data collector (145)

About collected data packages

If the execution of a data collector is due (as defined by its frequency), the data collector is triggered at the next shutdown or restart of the analyzer and collects its designated data.

The collected data is then automatically transferred as collected data package to the remote service.

Collected data packages are password-protected. Therefore, only Roche can open collected data packages and access the content.

Configuring data collection

You can view details about data collectors, delete data collectors, and enable or disable data collection.

Alternatively, if the analyzer is connected to a DMS, it can receive the data collection settings from the DMS as part of the device configuration.

🔆   You cannot enable or disable individual data collectors. If you want to prevent the execution of a specific data collector, you must delete the data collector.

▯ At least 1 data collector installed on the analyzer

▯ Administrator user role or supervisor user role

▸ To view details about a data collector

1 From the **Main** screen, choose **Settings > System > Data collection**. Choose the **Select** button.
  - → The **Data collection** screen is displayed.
  - → All installed data collectors are displayed.

2 From the list of installed data collectors, choose a data collector and choose the **View** button.
  - → Detailed information about the data collector is displayed.
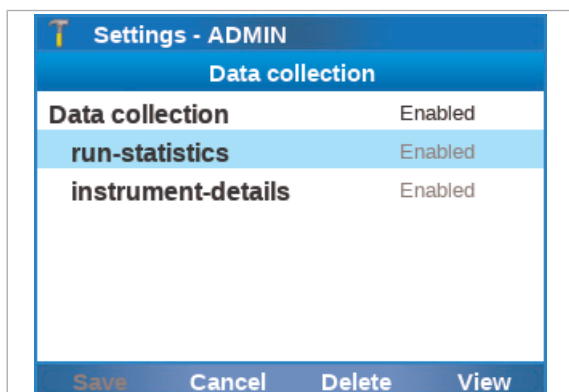
▸ To delete a data collector

1 From the **Main** screen, choose **Settings > System > Data collection**. Choose the **Select** button.
  - → The **Data collection** screen is displayed.
  - → All installed data collectors are displayed.

2 From the list of installed data collectors, choose the data collector and choose the **Delete** button.

3 On the message dialog box, choose the **Confirm** button.

4 On the success message dialog box, choose the **Confirm** button.
  - → The data collector is deleted from the analyzer.

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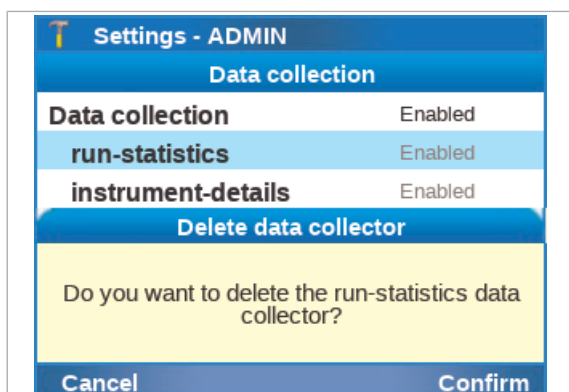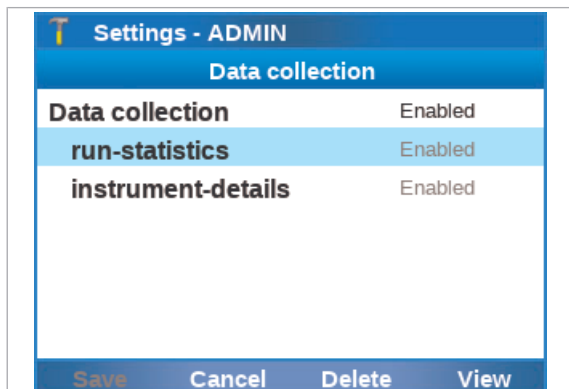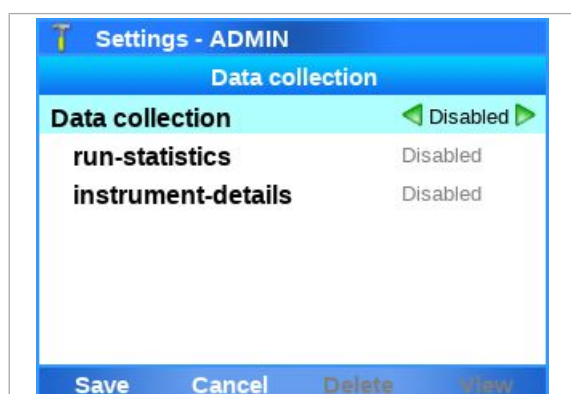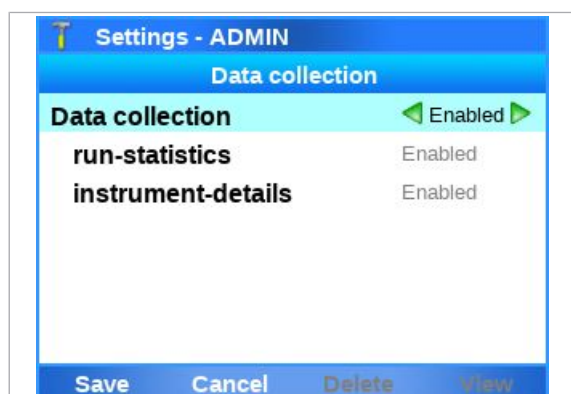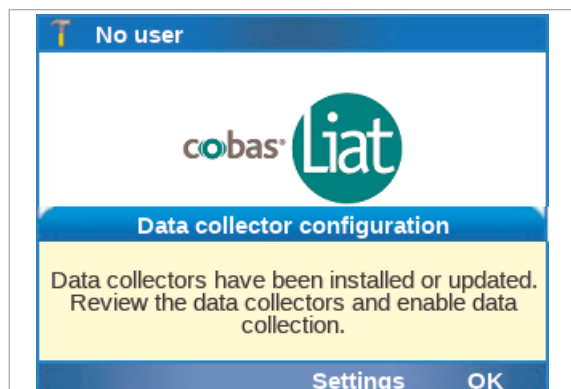
▶ **To enable data collection**

1 Do one of the following:
- On the message dialog box that is displayed after installation of a data collector, choose the **Settings** button.
- Alternatively, from the **Main** screen, choose **Settings > System > Data collection**. Choose the **Select** button.
→ The **Data collection** screen is displayed.

2 Choose the **Data collection** item and change it to the **Enabled** value.

3 Choose the **Save** button.
→ Data collection is enabled.
→ All installed data collectors are enabled.

▶ **To disable data collection**

1 From the **Main** screen, choose **Settings > System > Data collection**. Choose the **Select** button.
→ The **Data collection** screen is displayed.
→ All installed data collectors are displayed.

2 Choose the **Data collection** item and change it to the **Disabled** value.

3 Choose the **Save** button.
→ Data collection is disabled.
→ All installed data collectors are disabled.

Configuring automatic release of results

You can configure the analyzer to release results automatically.

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If automatic release is enabled, results are automatically released at the end of a run. The system is logged as approver of the results.

If automatic release is enabled and the analyzer is connected to a host, results are automatically released and sent to the host at the end of a run (because released results are always automatically sent). In this case, review of results is not done on the analyzer.

If automatic release is disabled when you configure the analyzer for host connection, you are asked if you want to enable automatic release of results. If confirmed, automatic release of results is enabled in the system settings.

⯈ Connecting to a host system (236)

☐ Administrator user role or supervisor user role

⯈ **To configure automatic release of results**

1   On the **Main** screen, choose **Settings > System > Result settings**. Choose the **Select** button.
    → The **Result** screen is displayed.

2   Choose the **Auto release** item and do one of the following:
    ▪ To enable automatic release of results, choose the **Yes** value.
    ▪ To disable automatic release of results, choose the **No** value.

3   Choose the **Save** button.
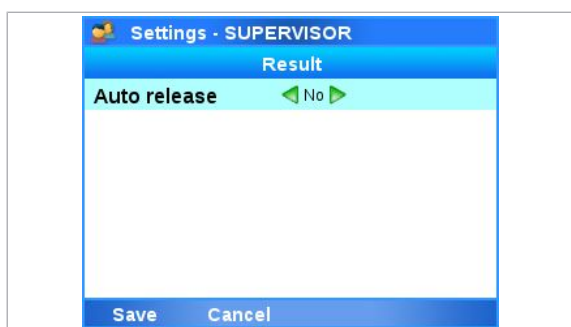
Managing users

You can create users, change user information, and delete complete user accounts.

Make sure that each user has their own user account on the analyzer. Do not use shared user accounts.

-ᕯ̣- If the analyzer exchanges user data with a DMS, user management is disabled on the analyzer.

Instead of managing users separately on several analyzers, you can export the users from one analyzer and import them on a different analyzer.

In this section

Overview of user account user roles

The user role defines which actions a user can perform on the analyzer.

Icon	User role	Permitted actions
	User	Run authorized assays and view assay tube lots. Add assay tube lots. Change own password and badge barcode.
	Supervisor	As user, plus: review results, manage users (with user role supervisor or user), set up the analyzer (except network settings), configure data collection, manage assay tube lots, install assays, schedule tasks, archive and delete data, export data, import assay tube lots, back up analyzer, manage problem reports, clean USB flash drives.

▦ User roles

Icon	User role	Permitted actions
	Administrator	As supervisor, plus: network configuration settings, manage all users, update assays and software, register assays and software, import settings and users, restore analyzer.

⊞ User roles

-🔅- When the analyzer is delivered to the customer, default user accounts are provided.

-🔅- The user IDs shown in screenshots in this publication are for illustration purposes only. The user ID does not necessarily reflect the user's user role.

About user IDs and passwords

On the analyzer, user IDs and passwords are restricted in length and/or allowed characters.

For user IDs, the following rules apply:

▪ The user ID is case insensitive.

▪ The length of a user ID must be 1-20 characters.
To avoid cut-off user IDs in the title bar, it is recommended to define short user IDs.

▪ The user ID must not contain unsupported characters.

For passwords, the following rules apply:

▪ For passwords, alphanumeric characters, symbols, and/or spaces are allowed.

▪ The length of a password must be 4-20 characters.

About user management on a DMS If the analyzer exchanges user data with a DMS, the following rules apply additionally:

▪ Passwords defined on the analyzer must comply with the password rules on the DMS.
For the password rules on the DMS, contact your DMS administrator.

▪ User IDs defined on the DMS must not contain characters that are not supported on the analyzer.

▪ Passwords defined on the DMS must only consist of ASCII Printable Characters (33-126) without #96 (grave accent `).

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Creating users

User accounts control access to the analyzer and determine which functions the user can perform on the analyzer, including the assays the user can perform.

If your user role is supervisor, you can create users of the user and supervisor user role.

If your user role is administrator, you can manage users of the administrator, supervisor, and user user role.

NOTICE!

Risk of data loss

If the password for the default administrator account ADMIN is lost and you have no alternative way to change the password, you must reset the analyzer before you can use the account again. The reset deletes user accounts, passwords, sample IDs, patient IDs, order IDs, visit IDs, and results from the analyzer.

‣ It is recommended to create another administrator account immediately after analyzer installation.

☐ Supervisor user role or administrator user role
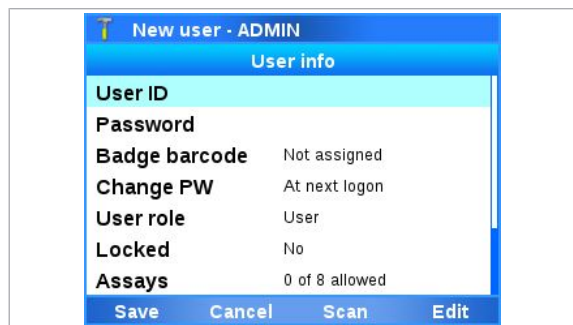
‣ To create a user

1 To display the **User** screen, do one of the following:

  ▪ On the **Main** screen, choose the **User** button.

  ▪ Choose **Settings > User management**.

  ➜ The **User** screen lists all defined users. The icon preceding the user ID indicates the user's user role.

2 Choose the **Create** button.

3 Choose the **User ID** item and do the following:

  ▪ Choose the **Edit** button. Enter the user ID and choose the **Apply** button.

  ▪ Alternatively, choose the **Scan** button. Scan the user ID barcode.

  ⓘ To avoid cut-off user IDs in the title bar, it is recommended to define short user IDs.

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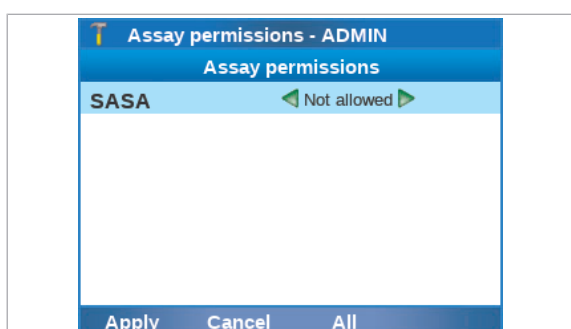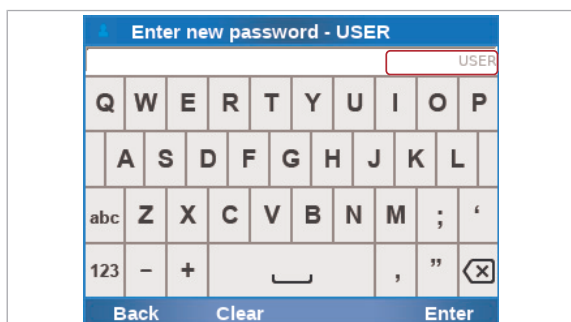
4 Choose the **Password** item. Enter the password and choose the **Apply** button. To confirm the password, enter the password again and choose the **Apply** button.

ⓘ The corresponding user account is displayed in the password field.

5 If the analyzer is configured for a badge barcode logon mode, assign and scan the badge barcode:

▪ In the **User info** screen, choose the **Badge barcode** item. Choose the **Edit** button.

▪ Scan the badge barcode twice.

ⓘ New users cannot assign their badge barcodes at logon. This is only possible when a user is logged on.

6 Optionally, change the following default values:

▪ Choose the **Change PW** item and choose the **No** value.

▪ Choose the **User role** item and choose the **Edit** button. Choose a user role and choose the **Apply** button.

▪ Choose the **Locked** item and choose the **Yes** value.

ⓘ By default, new users must change their passwords on first logon, are created with user role user, and are not locked.
Locked users cannot log on to the analyzer.

7 To define which assays the user can run, do the following:

▪ Choose the **Assays** item and choose the **Edit** button.

▪ On the **Assay permissions** screen, choose the assay you want the user to be able to run. Change it to the **Allowed** value.

▪ To enable the user to run all assays installed on the analyzer, choose the **All** button.

▪ To disable the user to run an assay, choose the assay and change it to the **Not allowed** value.

▪ Choose the **Apply** button.

ⓘ By default, new users cannot run any assay.

8 Optionally, choose the **User name** item, the **Department** item, and/or the **Contact** item. Choose the **Edit** button. Enter the information and choose the **Apply** button.

6 Setup

9 On the **User info** screen, choose the **Save** button to create the user.

ⓘ A new user that must change the password at logon cannot be the first user to log on after starting or restarting the analyzer. At first, a user without a request to change the password must log on and log off again.

Changing user information

User accounts control access to the analyzer and determine which functions you can perform on the analyzer, including the assays the user can perform.

If your user role is user, you can change your own password and badge barcode.

If your user role is supervisor, you can change user information of the user and supervisor user role.

If your user role is administrator, you can change user information of the user roles: administrator, supervisor, and user.

About locking user accounts

To prevent a user from logging on, lock the user account. To allow access to the analyzer again, unlock the user account.

Locking and unlocking user accounts is part of changing the user information. You cannot lock your own account.

> 💡 You cannot lock the default administrator account.

☐ Available for user roles: user, supervisor and administrator

▶ **To change user information**
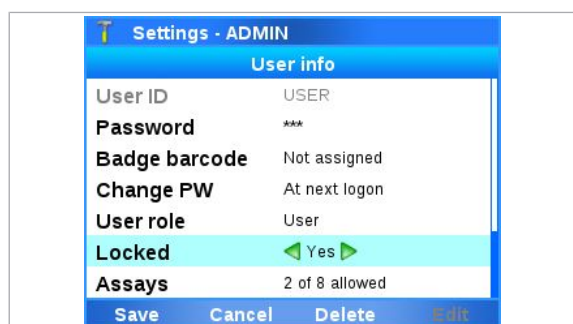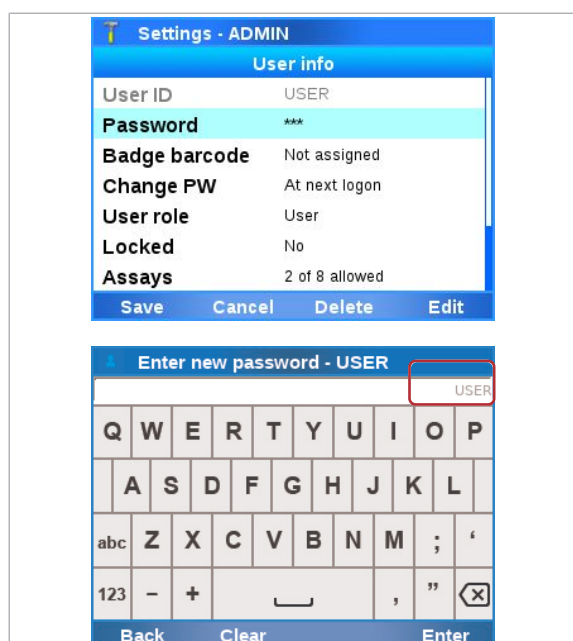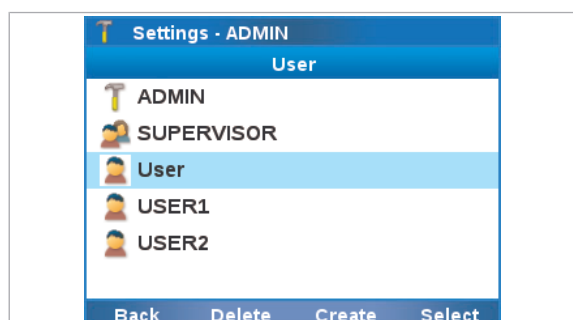
1 To display the **User** screen, do one of the following:

- On the **Main** screen, choose the **User** button.
- Choose **Settings > User management**.

2 Choose a user entry.

  ⓘ If you are logged on with administrator user role or supervisor user role, all currently defined users of the same user role or lower are listed.
If you are logged on with user user role, your own user account is listed only.
The icon preceding the user ID indicates the user's user role.

3 To change the password of a user, do the following:

- Choose the **Password** item and choose the **Edit** button.
- Enter your own password (i.e., the password of the changing user) and choose the **Enter** button.
- Enter the password of the user to be changed and choose the **Apply** button. To confirm the password, enter the password again and choose the **Apply** button.

  ⓘ The corresponding user account is displayed in the password field.

4 To lock a user, choose the **Locked** item. Choose the **Yes** value.

  ⓘ Locked users cannot log on to the analyzer.
To unlock a user, change the **Locked** item to the **No** value.

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VV-07723-04
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6 Setup

5 To change a user detail, choose the item and enter the information. If required, choose the **Apply** button.

ⓘ If you set the **Change PW** item to the **At next logon** value, the user must change the password when logging on the next time.
A user that must change the password at next logon cannot be the first user to log on after starting or restarting the analyzer. At first, a user without a request to change the password must log on and log off again.

6 Choose the **Save** button.

▸ **Related topics**

- Creating users (150)
- Changing your password (74)

Deleting a user

User accounts control access to the analyzer and determine which functions you can perform on the analyzer, including the assays the user can perform.

If your user role is administrator or supervisor, you can delete users of your own level and below.

You cannot delete the default administrator account ADMIN. This does not apply to all other user accounts with administrator user role.

-☼- Deleting a user does not affect results.

☐ Supervisor user role or administrator user role

▸ **To delete a user**

1 To display the **User** screen, do one of the following:

- On the **Main** screen, choose the **User** button.
- Choose **Settings > User management**.
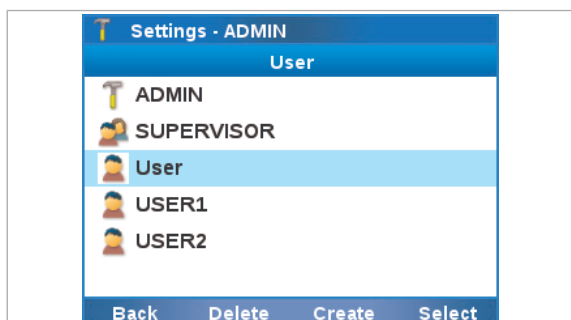
2   Choose a user entry.

   ⓘ If you are logged on with administrator user role or supervisor user role, you can delete users of your own level and below.

3   Choose the **Delete** button.

4   On the message dialog box, choose the **Delete** button to confirm the deletion.

Printer setup

About printer setup

The analyzer can print to connected USB printers and/or shared network printers.

Printer setup comprises the following actions:

1. Connect a printer to the analyzer.

2. Configure the printer for report and/or result printing.

A thermal printer for result printing, and a laser or inkjet printer for report printing can be configured on the analyzer at the same time.

Do not connect a printer to the analyzer via both USB and network. Printing via USB may not work correctly if the analyzer and the printer are additionally connected to the same network.

About laser and inkjet printers

A laser or inkjet printer can be configured for result printing and report printing. You can then print the following on a laser or inkjet printer:

- If configured for result printing:
  - Sample results
  - Control results
  - Assay tube lot validation results
  - Run status information

- If configured for report printing:
  - Installed assays and assay tube lots, and assay details
  - System settings
  - User settings
  - Event log

Reports and results printed on an inkjet printer can be damaged by moisture or liquid. It is therefore recommended to use a laser printer.

To connect a laser printer or inkjet printer, the printer must at least support PCL4.

> For a list of recommended printers, contact your Roche representative.

The printer drivers for the supported laser printers and inkjet printers are part of the analyzer software. Other printers are not recommended to be used.

If you connect a non-supported laser printer or inkjet printer, the printout may not be as intended (misaligned, missing symbols, etc.).

About thermal printers A thermal printer can be configured for result printing only. You can then print the following on a thermal printer:
- Sample results
- Control results
- Assay tube lot validation results

Results printed on a thermal printer can be damaged by exposure to heat, light, or liquid. It is therefore not recommended to rely on the printouts from a **thermal** printer.

If you use a thermal printer, only the following thermal printers and print media are supported and can be connected:

Thermal printer	Print medium	Paper width	Paper length
Brother QL-820NWB	Die-cut labels DK-11202[a]	62 mm	100 mm
Citizen CT-S281L[b]	-	58 mm	Endless
Martel MCP 1860X	-	58 mm	100 mm

(a)   The paper samples (DK-1201, DK-22251) that are delivered with the printer are not compatible with the analyzer.

(b)   Only the printer model with a USB port is supported.

⊞ Supported thermal printers

The printer drivers of the supported thermal printers are part of the analyzer software.

- To connect a thermal printer (161)

- **Related topics**

  - Printers (302)

Printer connection items

The connection items in the **Printers** screen determine the connection to the printers.

→ **Settings > Printers**

Most printer connection items are configured automatically when the analyzer detects the available printers and cannot be changed.
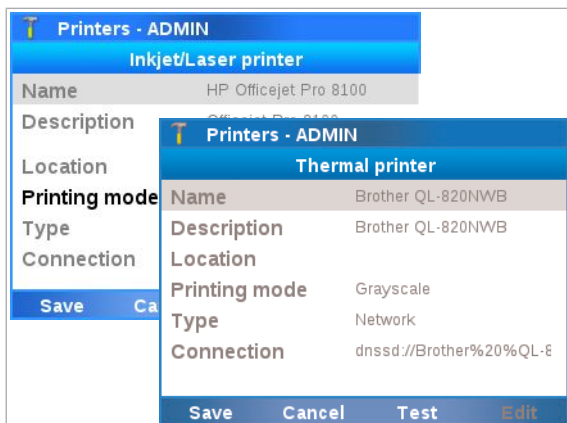
Connection item	Comment
Name	Name of the detected printer (if available).
Description	Description of the detected printer (if available).
Location	Physical location of the detected printer (if available).
Printing mode	The analyzer does not support color printing. Therefore, you can always keep the default **Grayscale** value.
Type	Connection type of the detected printer: ▪ **USB** ▪ **Network**
Connection	Address of the detected printer. For network printers, the address starts with the network protocol.

⊞ Printer connection items

Connecting a printer

You must connect a printer to the analyzer before you can configure it for report printing and/or result printing.

-ᣛ- Automatic detection of shared network printers may be limited by your local network infrastructure and configuration. If a shared network printer is not detected, contact your local network administrator.

Do not connect a printer to the analyzer via both USB and network. Printing via USB may not work correctly if the analyzer and the printer are additionally connected to the same network.

☐ USB cable (for USB printer)
☐ Standard Ethernet data cable (for shared network printer if the analyzer is not yet connected to the local data network)

☐ Supervisor user role or administrator user role
☐ Optionally: user name and password for the user-specific account on the printer or print server

▶ **To connect a supported laser printer or inkjet printer**

1 To connect a USB printer, use a USB cable and connect the USB printer to a USB port of the analyzer.

2 To connect a shared network printer, do the following if the analyzer is not yet connected to the local data network:
   ▪ Use a standard Ethernet data cable and connect the Ethernet port of the analyzer to an appropriate wall connector or switch.
   ▪ By default, the analyzer tries to connect to a DHCP server in your network to configure its network settings automatically.
   ▪ If the network settings are not configured automatically, configure the network settings manually as described in Network configuration (219).

6 Setup

3 From the **Main** screen, choose **Settings > Printers > Configured**. Choose the **Select** button.

4 Choose the **Inkjet/Laser** item and choose the **Detect** button. Wait until the list of available printers is displayed.

    ⓘ Non-supported printers may be detected, but it is not recommended to use them.

5 Optionally, to make sure that all available printers are detected, choose the **Refresh** button.

    ⓘ Automatic detection of shared network printers may be limited by your local network infrastructure and configuration. If a shared network printer is not detected, contact your local network administrator.

6 Choose the laser printer or inkjet printer from the list and choose the **Select** button.

7 To print a test page, choose the **Test** button. Wait until a message is displayed that the test page was sent to the printer successfully. Choose the **Confirm** button.

8 Check that the test page was printed and that the content of the test page is correct.

    ⓘ If you use a non-supported printer, the format of the printed output may be misaligned and/or incomplete (e.g., the IVD symbol may be missing).

9 If the test page was printed successfully, on the **Inkjet/Laser printer** screen, choose the **Save** button.

    ➔ The laser printer or inkjet printer is connected to the analyzer.

    ➔ On the **Printers** screen, the printer name is displayed.

    ➔ On the **Inkjet/Laser printers** screen, the printer name is marked with a ⊘ icon.

    ➔ The laser printer or inkjet printer can be configured for report printing and/or result printing.

6 Setup

▶ To connect a thermal printer

1 To connect a USB printer, use a USB cable and connect the USB printer to a USB port of the analyzer.

2 To connect a shared network printer, do the following if the analyzer is not yet connected to the local data network:

- ▪ Use a standard Ethernet data cable and connect the Ethernet port of the analyzer to an appropriate wall connector or switch.
- ▪ By default, the analyzer tries to connect to a DHCP server in your network to configure its network settings automatically.
- ▪ If the network settings are not configured automatically, configure the network settings manually as described in Network configuration (219).

3 From the **Main** screen, choose **Settings > Printers > Configured**. Choose the **Select** button.

4 Choose the **Thermal** item and choose the **Detect** button. Wait until the list of available printers is displayed.

🛈 You cannot connect non-supported thermal printers.

6 Setup
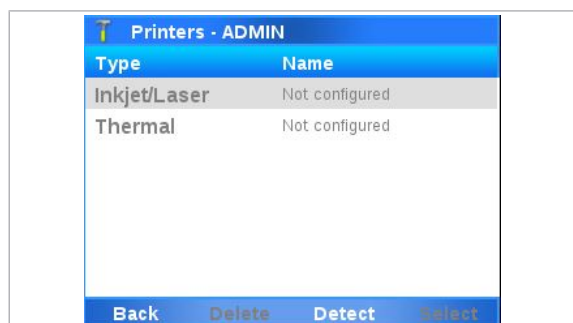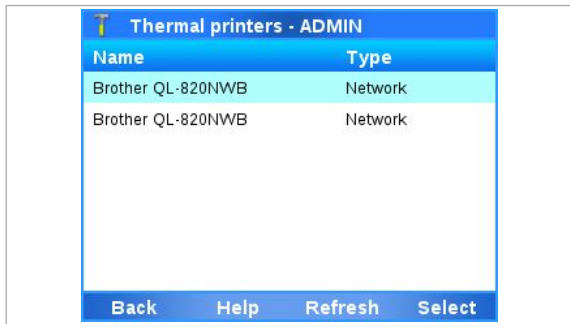
5 Optionally, to display a list of the supported printers, choose the **Help** button. Choose the **Confirm** button.

6 Optionally, to make sure that all available printers are detected, choose the **Refresh** button.

   ⓘ Automatic detection of shared network printers may be limited by your local network infrastructure and configuration. If a shared network printer is not detected, contact your local network administrator.

7 Choose the thermal printer from the list and choose the **Select** button.

8 To print a test page, choose the **Test** button. Wait until a message is displayed that the test page was sent to the printer successfully. Choose the **Confirm** button.

9 Check that the test page was printed and that the content of the test page is correct.

10 If the test page was printed successfully, on the **Thermal printer** screen, choose the **Save** button.

   → The thermal printer is connected to the analyzer.

   → On the **Printers** screen, the printer name is displayed.

   → On the **Thermal printers** screen, the printer name is marked with a ✓ icon.

   → The thermal printer can be configured for result printing.

▶ **To connect a non-supported laser printer or inkjet printer**

1 To connect a USB printer, use a USB cable and connect the USB printer to a USB port of the analyzer.

2 To connect a shared network printer, do the following if the analyzer is not yet connected to the local data network:

- ▪ Use a standard Ethernet data cable and connect the Ethernet port of the analyzer to an appropriate wall connector or switch.
- ▪ By default, the analyzer tries to connect to a DHCP server in your network to configure its network settings automatically.
- ▪ If the network settings are not configured automatically, configure the network settings manually as described in Network configuration (219).

3 From the **Main** screen, choose **Settings > Printers > Configured**. Choose the **Select** button.

4 Choose the **Inkjet/Laser** item and choose the **Detect** button. Wait until the list of available printers is displayed.

5 Optionally, to make sure that all available printers are detected, choose the **Refresh** button.

   ⓘ Automatic detection of shared network printers may be limited by your local network infrastructure and configuration. If a shared network printer is not detected, contact your local network administrator.

6 Choose the non-supported laser printer or inkjet printer from the list and choose the **Select** button.
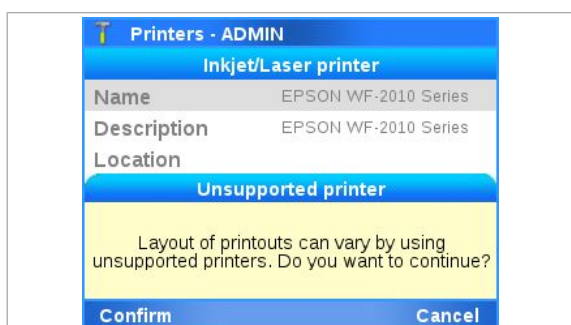
7 On the message dialog box, choose the **Confirm** button.

   → The analyzer checks the compatibility of the printer drivers with the non-supported printer.

6 Setup
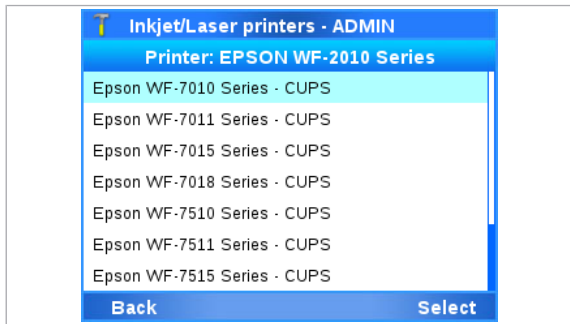
8 Wait until a list of printer drivers is displayed. Choose a printer driver from the list and choose the **Select** button.

9 To print a test page, choose the **Test** button. Wait until a message is displayed that the test page was sent to the printer successfully. Choose the **Confirm** button.

- ⓘ Always print a test page when connecting a non-supported printer.

10 Check that the test page was printed and that the content of the test page is correct.

- ⓘ If you use a non-supported printer, the format of the printed output may be misaligned and/or incomplete (e.g., the IVD symbol may be missing).

11 If the test page was printed successfully, on the **Inkjet/Laser printer** screen, choose the **Save** button.

- ➔ The laser printer or inkjet printer is connected to the analyzer.
- ➔ On the **Printers** screen, the printer name is displayed.
- ➔ On the **Inkjet/Laser printers** screen, the printer name is marked with a ✓ icon.
- ➔ The laser printer or inkjet printer can be configured for report printing and/or result printing.

▸▤ **Related topics**

- ▪ Printer connection items (158)

Configuring report printing

If you want to print reports from the analyzer, you must configure a connected laser printer or inkjet printer for report printing.

You cannot configure a thermal printer for report printing.

☑▭ ☐ Laser printer or inkjet printer connected to the analyzer

▸▤ To connect a supported laser printer or inkjet printer (159)

▶ **To configure report printing**

1 Choose **Settings > Printers**.

2 Optionally, to display the names of the printers connected to the analyzer, choose the **Configured** item. To return to the **Printers** screen, choose the **Back** button.

3 On the **Printers** screen, choose **Report printing > Printer**. Choose a value for report printing:
- To enable report printing, choose the **Inkjet/ Laser** value.
- To disable report printing, choose the **Not configured** value.
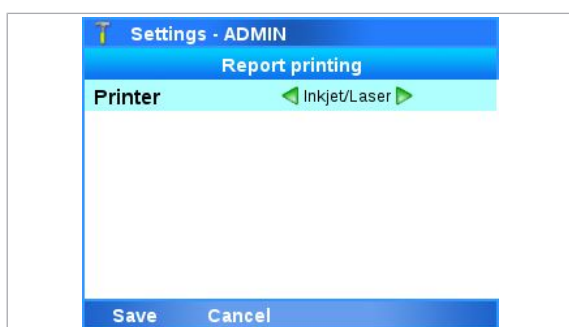
4 Choose the **Save** button.
➔ The connected laser printer or inkjet printer is configured for report printing.
➔ On the **Printers** screen, the **Inkjet/Laser** value is displayed for the **Report printing** item.
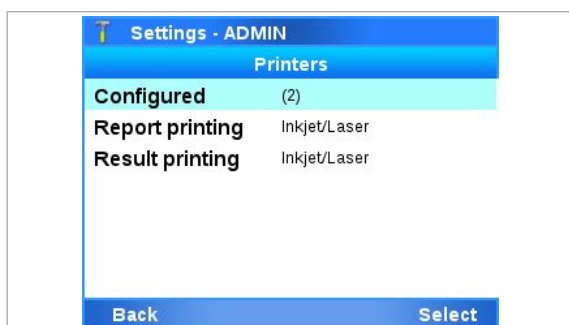
Configuring result printing

If you want to print results from the analyzer, you must configure a connected laser printer, inkjet printer, or thermal printer for result printing.

6 Setup

For result printing, you can either configure the same laser printer or inkjet printer as for report printing, or you can configure a thermal printer.

🖳 ☐ Laser printer, inkjet printer, and/or thermal printer connected to the analyzer

📄 To connect a supported laser printer or inkjet printer (159)

📄 To connect a thermal printer (161)

▶ **To configure result printing**

1 Choose **Settings > Printers**.
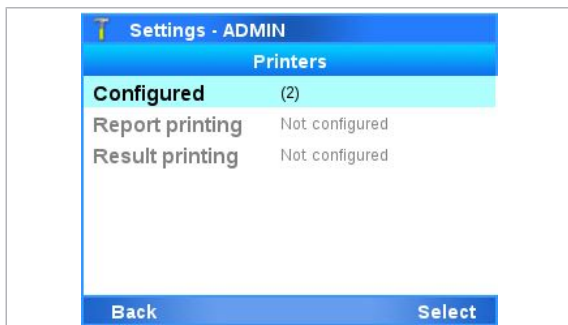
2 Optionally, to display the names of the printers connected to the analyzer, choose the **Configured** item. To return to the **Printers** screen, choose the **Back** button.

3 On the **Printers** screen, choose **Result printing > Auto print**. Choose a value for automatic printing of results:
- To print results automatically as soon as assay processing is finished, choose the **Yes** value.
- To disable automatic printing of results, choose the **No** value.

4 Choose the **Printer** item and choose a value for result printing and the default printer for it:
- To enable result printing on the thermal printer, choose the **Thermal** value.
- To enable result printing on the laser printer or inkjet printer, choose the **Inkjet/Laser** value.
- To disable result printing, choose the **Not configured** value.

5 Choose the **Manual print** item and choose a value for manual printing of results:
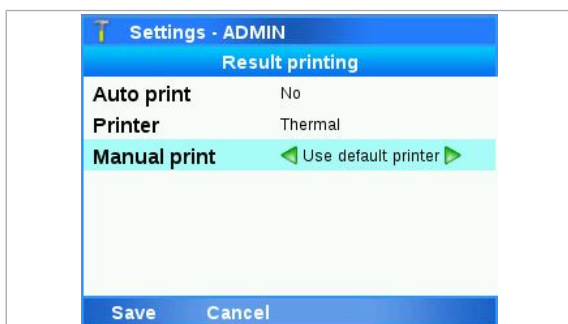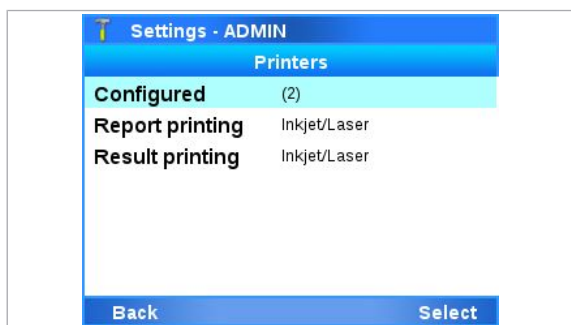
- ▪ To print results manually on the default printer configured in step **4**, choose the **Use default printer** value.
- ▪ To print results manually on the laser printer or inkjet printer, choose the **Inkjet/Laser printer** value.
- ▪ To print results manually on the thermal printer, choose the **Thermal printer** value.
- ▪ To choose the printer each time when printing results manually, choose the **Custom** value.

6 Choose the **Save** button.
- → The connected laser printer, inkjet printer, or thermal printer is configured for report printing.
- → On the **Printers** screen, the **Inkjet/Laser** value or the **Thermal** value is displayed for the **Result printing** item.

Updating the software

As part of further product development, Roche may issue updates to the analyzer software remotely or via USB flash drive provided by your Roche representative.

When updating the software, always follow the instructions that are displayed on the screen because the specific steps may differ depending on the installed software version. For example, you may be prompted to export and delete results and/or to calibrate the screen.

-`☀`- If you are logged on with user user role or supervisor user role and a message is displayed informing you that a software update is available, contact your system administrator.

To update the analyzer software remotely, you must configure access to the remote service.

If you use **cobas® infinity** edge smart as the remote service, software updates may be automatically installed in the background without user intervention when the analyzer is in status standby.

▸▤ Remote service configuration (222)

🧰 ☐ For update from the USB flash drive:
USB flash drive provided by your Roche representative that contains the update to the analyzer software

☐ Administrator user role

▸ **To update the software from the remote service**

1 CAUTION! Do not disconnect the power supply from the analyzer while updating software.

When a software update is available, a message is displayed on the analyzer screen.

2 On the message dialog box, choose the **Continue** button.

➔ If the analyzer detects insufficient storage space on the analyzer, a message is displayed. Free up storage space by archiving and deleting audit trails and/or results, or by deleting assay tube lots.
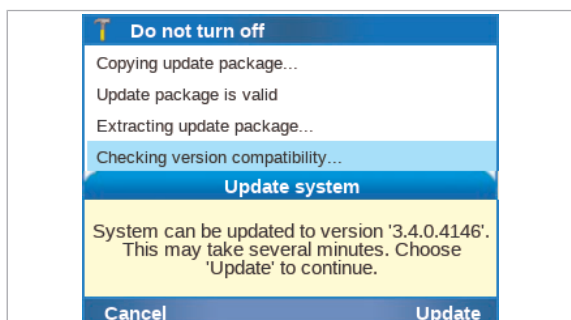
3 When a message is displayed that the analyzer can be updated, choose the **Update** button.

→ A progress screen is displayed.

4 Wait until the update is complete.

ⓘ The update of the analyzer software may take time (up to 60 minutes).

5 Log on to the analyzer.

ⓘ The analyzer attempts to register the software automatically.

6 If automatic registration fails, you must register the software manually.

7 To check the version of the updated software, choose **Settings > About the system > Versions** from the **Main** screen.

▶ **To update the software from the USB flash drive**

1 CAUTION! Do not disconnect the power supply from the analyzer while updating software.

While on the **Main** screen, insert the USB flash drive at the rear of the analyzer.
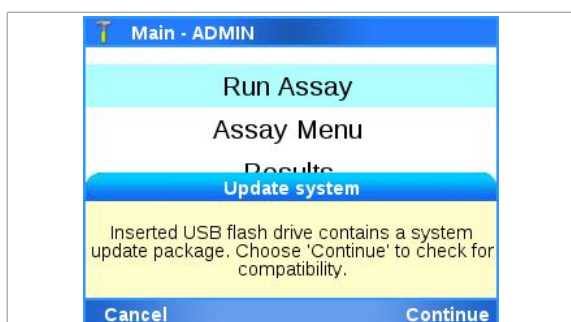
2 On the message dialog box, choose the **Continue** button.

→ If the analyzer detects insufficient storage space on the analyzer, a message is displayed. Free up storage space by archiving and deleting audit trails and/or results, or by deleting assay tube lots.

3 Follow the dialog box: **Remove the USB flash drive. Wait 5 seconds. Then choose 'Close'.**
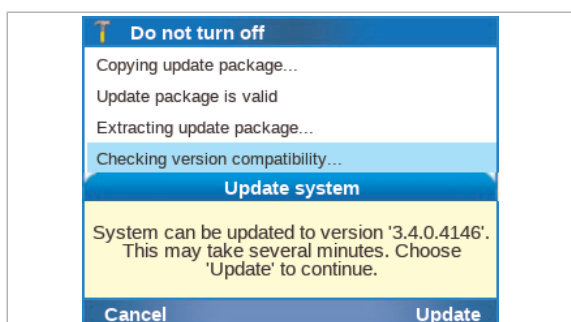
4 When a message is displayed that the analyzer can be updated, choose the **Update** button.

→ A progress screen is displayed.

5 Wait until the update is complete.

ⓘ The update of the analyzer software may take time (up to 60 minutes).

6 Log on to the analyzer.

ⓘ The analyzer attempts to register the software automatically.

7 If automatic registration fails, you must register the software manually.

8 To check the version of the updated software, choose **Settings > About the system > Versions** from the **Main** screen.

⊟ **Related topics**

▪ Registering the software (171)

▪ Deleting assay tube lots (128)

Registering the software

Updated software must be registered within 30 days.

You can use the unregistered software during the registration period, but once this period has expired, the analyzer is locked for testing.

⚬ If the analyzer is connected to the remote service, the analyzer automatically tries to register the software. If this automatic registration fails, a message is displayed and a user must register the software manually.

☐ Administrator user role

▶ **To register the software manually**

1 Start the registration process.
   ▪ If a message is displayed, choose the **Activate** button.
   ▪ If no message is displayed, from the **Main** screen, choose **Settings > System information**.
   ❶ If the analyzer is connected to the remote service, the analyzer attempts to register the software automatically. You must only register the software manually if automatic registration fails.

2 From the **System information** screen, note the registration code.

3 Call your Roche Support and provide the registration code.
   ❶ You may be able to register the software via a dedicated internet site. Contact your Roche representative for more information.

4 The Roche Support issues an activation code.

5 On the **System information** screen, choose the **Activate** button.

6 Setup
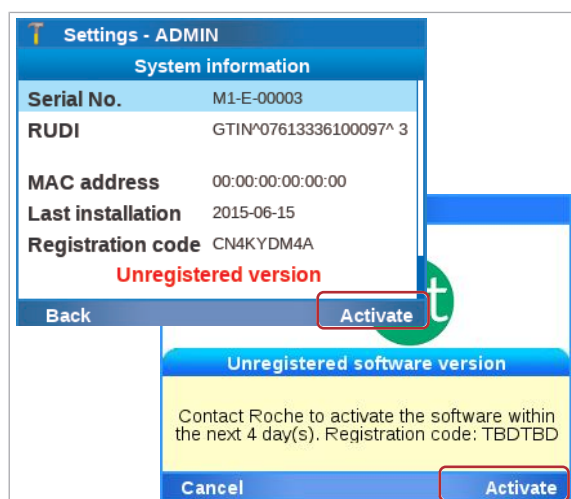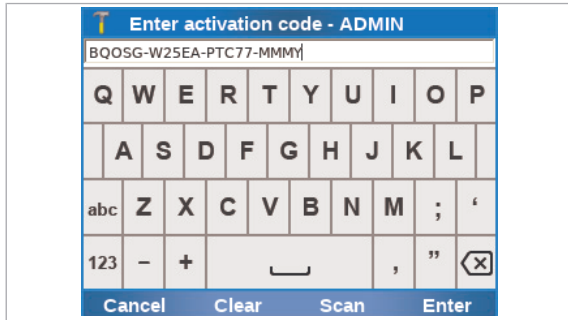
6 Enter or scan the activation code and choose the **Enter** button.

7 When a message indicating successful software activation is displayed, choose the **Confirm** button.

6 Setup

Viewing system information

For troubleshooting reasons, it may be necessary to check versions and IDs of the installed system elements.

In this section
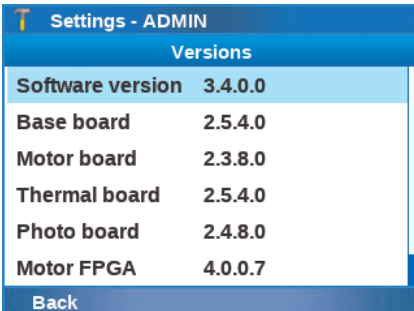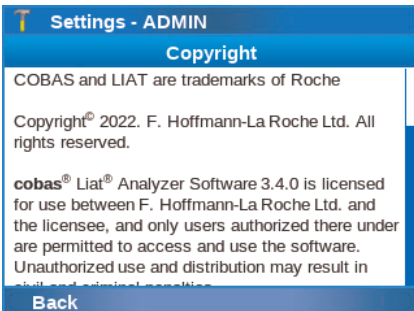
Viewing information about the analyzer (173)

Viewing system information (174)
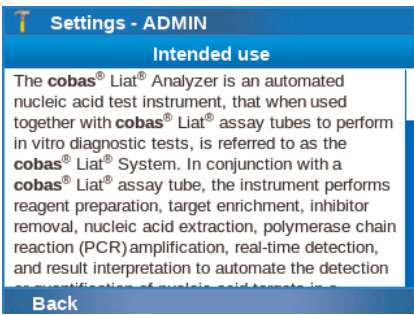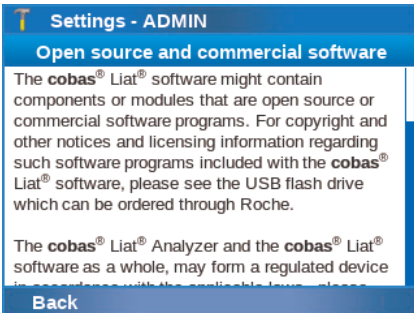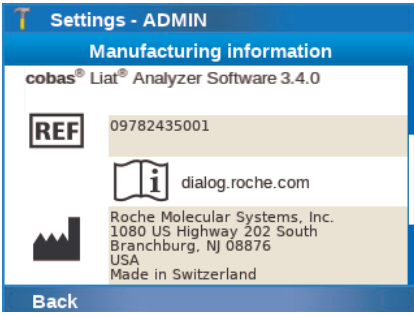
Viewing information about the analyzer

For troubleshooting or other reasons, you may be asked to provide information about the analyzer and installed software.

To access information about the analyzer, choose **Settings > About the system**. Choose an item on the screen and choose the **Select** button.

Screen items	Comment	
Versions	For troubleshooting, you may be asked to check the installed versions. Screenshots in this publication are for illustration purposes only.	**Settings - ADMIN** **Versions** Software version 3.4.0.0 Base board 2.5.4.0 Motor board 2.3.8.0 Thermal board 2.5.4.0 Photo board 2.4.8.0 Motor FPGA 4.0.0.7 **Back**
Copyright	Copyright information, including trademark information.	**Settings - ADMIN** **Copyright** COBAS and LIAT are trademarks of Roche Copyright© 2022. F. Hoffmann-La Roche Ltd. All rights reserved. **cobas**® Liat® Analyzer Software 3.4.0 is licensed for use between F. Hoffmann-La Roche Ltd. and the licensee, and only users authorized there under are permitted to access and use the software. Unauthorized use and distribution may result in civil and criminal penalties **Back**

⊞ **About the system** screen items

6 Setup

Screen items	Comment	
Intended use	The intended use.	
Open source	Information about open source and commercial software.	
Manufacturing information	Manufacturing-related information about the analyzer.	

⊞ **About the system** screen items

Viewing system information

When installing or updating the software or for troubleshooting reasons, you may have to know the serial number of your analyzer and its installation or activation dates. Choose **Settings > System information** to show this information.

Version and ID item	Comment
Serial No.	Defined by Roche.
	The serial number of the analyzer can also be found on the product label at the back or on the bottom of the analyzer.
RUDI	Roche unique device identifier that identifies the analyzer for the remote service.
MAC address	Network interface card defined by manufacturer of main board.
Last installation	Date of last software installation/update.

⊞ System elements

Version and ID item	Comment
Registration code	Software registration code needed for software activation. (This information is only displayed if the currently installed software has not been activated.)
Activation date	Date when the software was activated.
Total results	Total number of sample and control results. (Results from tube lot validation are not included.)
Available space	Storage space available on the analyzer.

⊞ System elements

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Advanced Tools functions

7 Advanced Tools functions

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About the Advanced Tools

The Advanced Tools offer functions for archiving and exchanging data, creating problem reports, locking and unlocking the analyzer, and cleaning USB flash drives.
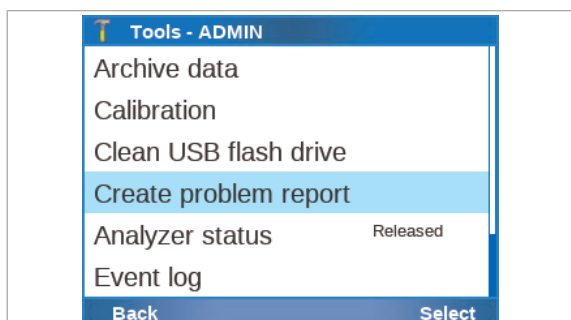
-☼- The Advanced Tools are only used to transfer and to allow storing of medical data, with no intended use of analyzing or interpreting clinical results.

To perform a function from the Advanced Tools, the analyzer must be in status ready.

For the Advanced Tools, do not connect more than 1 USB flash drive to the analyzer at the same time.

About compatibility Only import and export settings, and use the backup and restore functions between analyzers that have the same software version installed. For example, the backup and restore between analyzers with different software versions does not work due to different system settings between the two software versions.

▸🗐 **Related topics**

- ▪ Archiving data (180)
- ▪ Exchanging data (195)
- ▪ Problem reports (205)
- ▪ Cleaning a USB flash drive (215)

Archiving data

The Advanced Tools offer functions for archiving data.

In this section

About archiving

Archiving allows you to store the data away from the analyzer and to free up storage space on the analyzer.

Roche recommends to archive all data regularly.

To ensure analyzer performance, manually archive and delete data regularly, at least once a month. Alternatively, schedule automatic archiving.

Archived data is only deleted from the analyzer if archiving was successful.

You need supervisor user role or administrator user role for archiving.

⚠ CAUTION!

Data security

Archived data is stored as plain text files and so their content is accessible to unauthorized persons.

‣ Ensure that you store archive files safely and securely so that they are not accessible by unauthorized persons.

‣ To ensure data privacy if a USB flash drive is lost that contains archive files, it is recommended to use a lockable USB flash drive that you must unlock before use.

If archiving fails, check the connections and the archiving location, e.g., the network share. Try again to archive manually and/or wait for the next scheduled execution of automatic archiving. If archiving still fails, contact your Roche representative.

About content of archive files

Archive files contain the following data:
▪ For results:
  – Patient results
  – QC results
  – Assay tube lot validation results
  – Result report PDFs
  – Ct values for detected target results
▪ For audit trails:
  – Audit trail entries
▪ For assay tube lots:
  – Assay tube lot information
  – Assay tube lot report PDFs

When you archive and delete results (manually or automatically), a problem report is automatically created with the same archiving criterion and contained in the archive file.

About archiving locations

To archive, the analyzer must be connected to an archiving location for the archive.

You can save archives to the following archiving locations:
▪ Share location (network share or FTP share)
▪ USB flash drive (for manual archiving only)

The archives are saved in the root folder of the archiving location.

Only connect a USB flash drive to the analyzer if the analyzer is in status ready. Do not connect more than 1 USB flash drive to the analyzer at the same time.

You cannot configure a USB flash drive as archiving location for automatic archiving.

▸▤ About analyzer status (55)

▸▤ Configuring network shares (257)

▸▤ Configuring FTP shares (258)

7 Advanced Tools functions

About archive file format and naming

Results are archived as a CSV file. The CSV file and the result report PDFs are compressed and exported as a single ZIP file.
The result archive files are named as follows:
ResultArchive_Serial#_YYYYMMDD_hhmmss.csv
ResultArchive_Serial#_YYYYMMDD_hhmmss.zip

Audit trails are archived as a CSV file. The CSV file is compressed and exported as a ZIP file.
The audit trails archive files are named as follows:
AuditTrailArchive_Serial#_YYYYMMDD_hhmmss.csv
AuditTrailArchive_Serial#_YYYYMMDD_hhmmss.zip

Assay tube lots are archived, compressed and exported as a ZIP file.
The assay tube lots archive files are named as follows:
AssayLotArchive_Serial#_YYYYMMDD_hhmmss.zip

With:

- Serial# = Serial number of the analyzer
- YYYY = Four-digit year number
- MM = Two-digit month number with leading zero
- DD = Two-digit day number with leading zero
- hh = Two-digit hour number with leading zero in 24 h format
- mm = Two-digit minute number with leading zero
- ss = Two-digit second number with leading zero
- The time for the file name is the timestamp (local time) when the archive file is created (ISO 8601 format).

If you archive to a share location (network share or FTP share), an MD5 file is saved together with the archive ZIP file. The MD5 file contains the MD5 checksum of the ZIP file. To verify the integrity of the ZIP file, you can use any MD5 checker tool.

Archiving results manually

Archive results to store them away from the analyzer.

If you archive results, they remain on the analyzer.

If you archive and delete results, they are deleted from the analyzer. Choose this option to free up storage space on the analyzer.

▸▤ Viewing system information (174)

You can also archive the result report directly from the **Results** screen.

‣▤ To review results from the Results screen (106)

🕐 Depending on number of results

☑☰
- ☐ Supervisor user role or administrator user role
- ☐ Analyzer in status ready
- ☐ Access to an archiving location:
  Share location (network share or FTP share)
  USB flash drive

‣▤ About analyzer status (55)

‣▤ Configuring network shares (257)

‣▤ Configuring FTP shares (258)

▸ To archive results manually

1 Optionally, to archive to a USB flash drive, insert the USB flash drive at the rear of the analyzer.

> ❶ Only connect a USB flash drive to the analyzer if the analyzer is in status ready.
> Do not connect more than 1 USB flash drive to the analyzer at the same time.

2 From the **Main** screen, choose **Tools > Archive data > Archive results**. Choose the **Select** button.

3 Choose the archiving criterion:
- ▪ **Older than 365 days** (default)
- ▪ **Older than 180 days**
- ▪ **Older than 90 days**
- ▪ **Older than 60 days**
- ▪ **Older than 30 days**
- ▪ **Older than 7 days**
- ▪ **All results**

7 Advanced Tools functions

4   Choose the archiving location:
  - **Network share {0}** (with {0} = 1 to 3)
  - **FTP share {0}** (with {0} = 1 to 3)
  - **USB flash drive**

  ℹ Accessible storage locations are displayed in black font.
     The network shares and the FTP shares are displayed with the names configured in **Settings > Share locations**.

5   Choose the **Select** button.

  ℹ You cannot perform any other action on the analyzer until archiving is finished.

6   Wait until a message is displayed that the results were archived successfully. Choose the **Confirm** button.

  → The archived results remain on the analyzer.

7   Optionally, if you archived to a USB flash drive, remove the USB flash drive from the analyzer.

▸ **To archive and delete results manually**

1   Optionally, to archive to a USB flash drive, insert the USB flash drive at the rear of the analyzer.

  ℹ Only connect a USB flash drive to the analyzer if the analyzer is in status ready.
     Do not connect more than 1 USB flash drive to the analyzer at the same time.

2   From the **Main** screen, choose **Tools > Archive data > Archive and delete results**. Choose the **Select** button.

3   Enter your password and choose the **Enter** button.

7 Advanced Tools functions

4 Choose the archiving criterion:
- **Older than 365 days** (default)
- **Older than 180 days**
- **Older than 90 days**
- **Older than 60 days**
- **Older than 30 days**
- **Older than 7 days**
- **All results**

5 Choose the archiving location:
- **Network share {0}** (with {0} = 1 to 3)
- **FTP share {0}** (with {0} = 1 to 3)
- **USB flash drive**

ⓘ Accessible storage locations are displayed in black font.
The network shares and the FTP shares are displayed with the names configured in **Settings > Share locations**.

6 Choose the **Select** button.

ⓘ You cannot perform any other action on the analyzer until archiving is finished.

7 Wait until a message is displayed that the results were archived successfully. Choose the **Confirm** button.

➔ The archived results are deleted from the analyzer.

8 Optionally, if you archived to a USB flash drive, remove the USB flash drive from the analyzer.

Archiving audit trails manually

Archive audit trails to store them away from the analyzer.

If you archive audit trails, they remain on the analyzer.

If you archive and delete audit trails, they are deleted from the analyzer. Choose this option to free up storage space on the analyzer.

▸▤ Viewing system information (174)

◑ Depending on number of audit trails

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7 Advanced Tools functions

☑ □ Supervisor user role or administrator user role

□ Analyzer in status ready

□ Access to an archiving location:
Share location (network share or FTP share)
USB flash drive

⯈▤ About analyzer status (55)

⯈▤ Configuring network shares (257)

⯈▤ Configuring FTP shares (258)

▸ **To archive audit trails manually**

1 Optionally, to archive to a USB flash drive, insert the USB flash drive at the rear of the analyzer.

   ⓘ Only connect a USB flash drive to the analyzer if the analyzer is in status ready.
Do not connect more than 1 USB flash drive to the analyzer at the same time.

2 From the **Main** screen, choose **Tools > Archive data > Archive audit trails**. Choose the **Select** button.
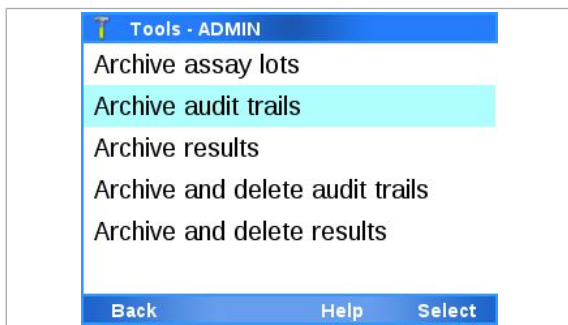
> **Tools - ADMIN**
> Archive assay lots
> Archive audit trails
> Archive results
> Archive and delete audit trails
> Archive and delete results
>
> Back   Help   Select

3 Choose the archiving location:
- ▪ **Network share {0}** (with {0} = 1 to 3)
- ▪ **FTP share {0}** (with {0} = 1 to 3)
- ▪ **USB flash drive**

   ⓘ Accessible storage locations are displayed in black font.
The network shares and the FTP shares are displayed with the names configured in **Settings > Share locations**.

> **Tools - ADMIN**
> **Archive audit trails**
> Archive to   ◀ USB flash drive ▶
>
> Back   Help   Select

4 Choose the **Select** button.

   ⓘ You cannot perform any other action on the analyzer until archiving is finished.

5 Wait until a message is displayed that the audit trails were archived successfully. Choose the **Confirm** button.

   → The archived audit trails remain on the analyzer.

6 Optionally, if you archived to a USB flash drive, remove the USB flash drive from the analyzer.

7 Advanced Tools functions

▶ **To archive and delete audit trails manually**

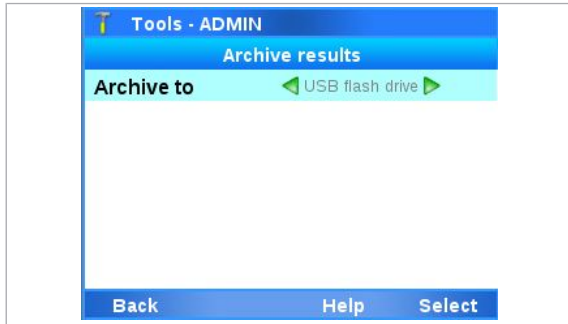**1** Optionally, to archive to a USB flash drive, insert the USB flash drive at the rear of the analyzer.

> ⓘ Only connect a USB flash drive to the analyzer if the analyzer is in status ready.
> Do not connect more than 1 USB flash drive to the analyzer at the same time.

2 From the **Main** screen, choose **Tools > Archive data > Archive and delete audit trails**. Choose the **Select** button.
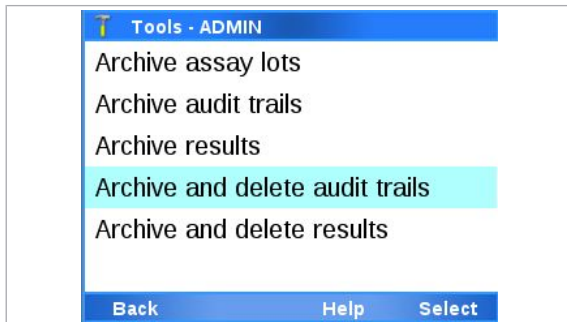
3 Enter your password and choose the **Enter** button.

4 Choose the archiving location:
- **Network share {0}** (with {0} = 1 to 3)
- **FTP share {0}** (with {0} = 1 to 3)
- **USB flash drive**

> ⓘ Accessible storage locations are displayed in black font.
> The network shares and the FTP shares are displayed with the names configured in **Settings > Share locations**.

5 Choose the **Select** button.

> ⓘ You cannot perform any other action on the analyzer until archiving is finished.

6 Wait until a message is displayed that the audit trails were archived successfully. Choose the **Confirm** button.

> ➜ The archived audit trails are deleted from the analyzer.

7 Optionally, if you archived to a USB flash drive, remove the USB flash drive from the analyzer.

7 Advanced Tools functions

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Archiving assay tube lots

Archive assay tube lots to store them away from the analyzer.

If the analyzer is connected to a share lot folder, the assay tube lots are archived from the share lot folder.

Archiving assay lots will fail if share lots is configured but not properly connected.

Archived assay tube lots remain on the analyzer or in the share lot folder.

🕐 Depending on number of assay tube lots

☐ Supervisor user role or administrator user role
☐ Analyzer in status ready
☐ Access to an archiving location:
Share location (network share or FTP share)
USB flash drive

▸ To archive assay tube lots

1 Optionally, to archive to a USB flash drive, insert the USB flash drive at the rear of the analyzer.

ℹ Only connect a USB flash drive to the analyzer if the analyzer is in status ready.
Do not connect more than 1 USB flash drive to the analyzer at the same time.

2 From the **Main** screen, choose **Tools > Archive data > Archive assay lots**. Choose the **Select** button.
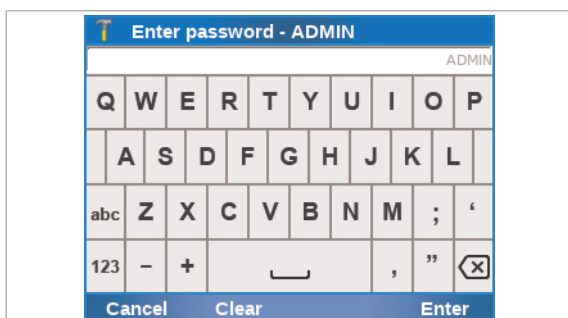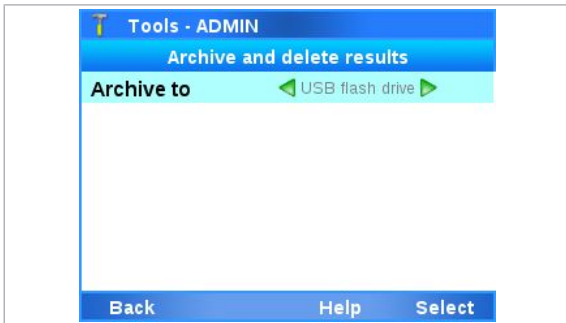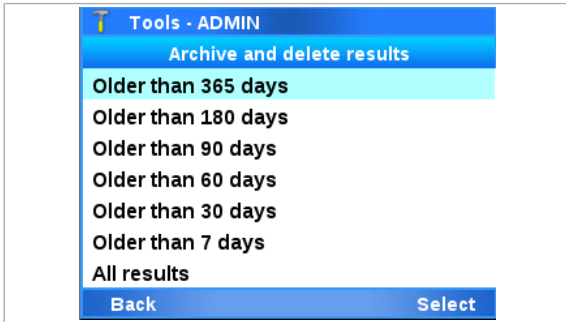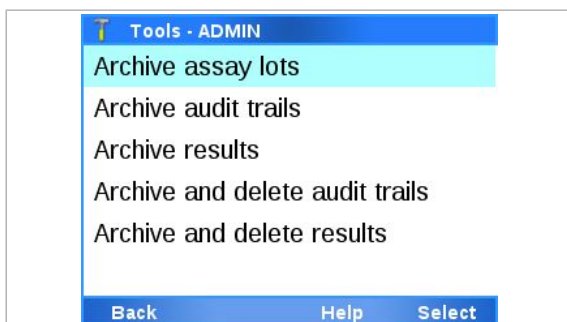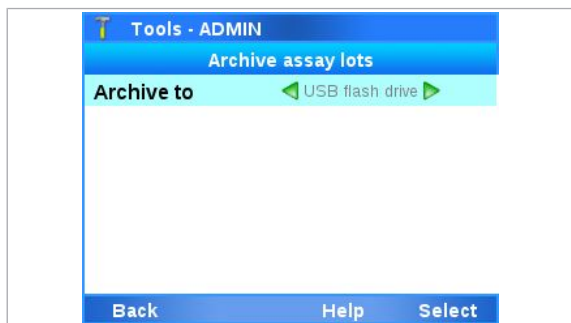
7 Advanced Tools functions

3 Choose the archiving location:

- **Network share {0}** (with {0} = 1 to 3)
- **FTP share {0}** (with {0} = 1 to 3)
- **USB flash drive**

ℹ Accessible storage locations are displayed in black font.
The network shares and the FTP shares are displayed with the names configured in **Settings > Share locations**.

4 Choose the **Select** button.

ℹ You cannot perform any other action on the analyzer until archiving is finished.

5 Wait until a message is displayed that the assay tube lots were archived successfully. Choose the **Confirm** button.

➔ The archived assay tube lots remain on the analyzer or in the share lot folder.

6 Optionally, if you archived to a USB flash drive, remove the USB flash drive from the analyzer.

Scheduling automatic archiving and deletion of results

To maintain analyzer performance without manual intervention, schedule the automatic archiving and deletion of results.

If you archive and delete results, they are deleted from the analyzer.

For automatic archiving and deletion of results, you can configure an archiving criterion that determines which results are archived. The archiving criterion applies to the automatically created archive only. For manual archiving, you choose the archiving criterion independently.

As archiving may take some time and you cannot perform any other action meanwhile, schedule the automatic archiving and deletion of results for a time when the analyzer is not frequently used.

7 Advanced Tools functions

-ᗢ- Do not schedule the different automatic tasks for the same time:

- ▪ Daily restart
- ▪ Archive and delete results
- ▪ Archive and reduce audit trails
- ▪ Problem report

Additionally, observe the restrictions for the scheduled tasks.

⦿ About restrictions for scheduled tasks (64)

⦿ About scheduled tasks (64)

☐ Supervisor user role or administrator user role
☐ Access to a share location (network share or FTP share) as archiving location

⦿ Configuring network shares (257)

⦿ Configuring FTP shares (258)

▶ **To configure the archiving criterion**

1 From the **Main** screen, choose **Settings > Scheduled tasks > Archive and delete results > Content**. Choose the **Select** button.
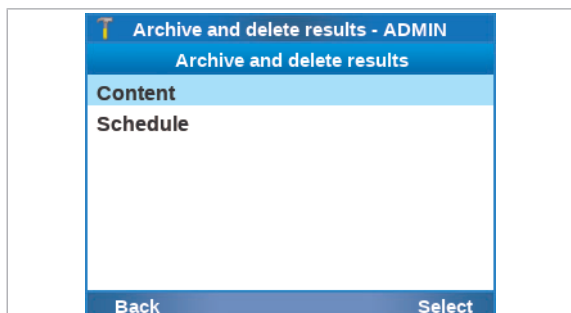
2 Choose the archiving criterion:
- ▪ **Older than 365 days** (default)
- ▪ **Older than 180 days**
- ▪ **Older than 90 days**
- ▪ **Older than 60 days**
- ▪ **Older than 30 days**
- ▪ **Older than 7 days**
- ▪ **All results**

3 Choose the **Save** button.

ⓘ The configured archiving criterion applies to automatic archiving only.
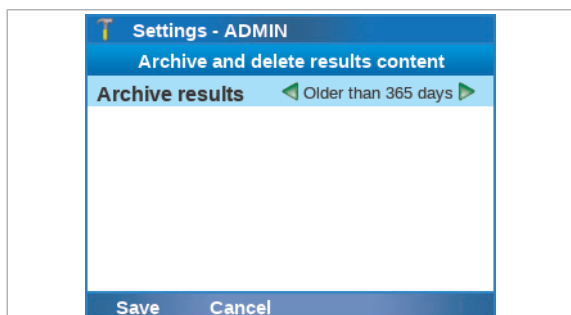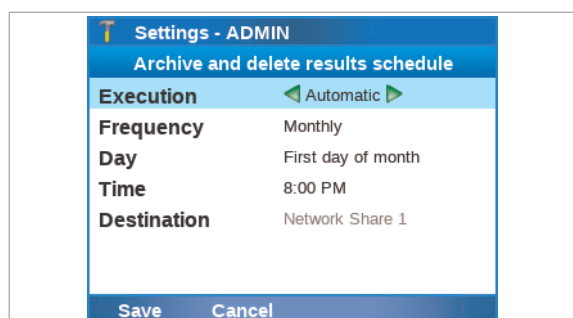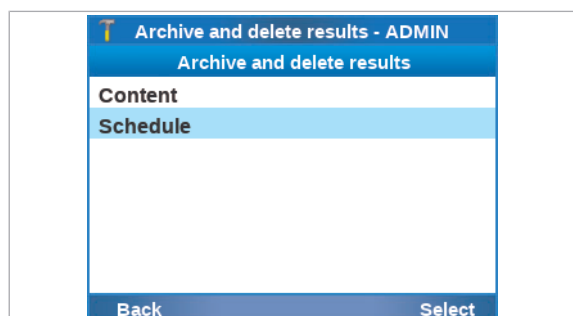
7 Advanced Tools functions

▶ To schedule automatic archiving and deletion of results

1 From the **Main** screen, choose **Settings > Scheduled tasks > Archive and delete results > Schedule**. Choose the **Select** button.

2 Choose the **Execution** item and choose the **Automatic** value.

ⓘ Keep the default **On demand** value for manual archiving only.

3 Choose the frequency, day, and time of automatic archiving and deletion of results.

ⓘ By default, the automatic archiving and deletion of results is executed monthly on the first day of the month at 8:00 p.m.
Do not schedule different automatic tasks for the same time.

4 Choose the **Destination** item and set the archiving location:

- **Network share {0}** (with {0} = 1 to 3)
- **FTP share {0}** (with {0} = 1 to 3)

ⓘ Accessible network shares and FTP shares are displayed in black font.
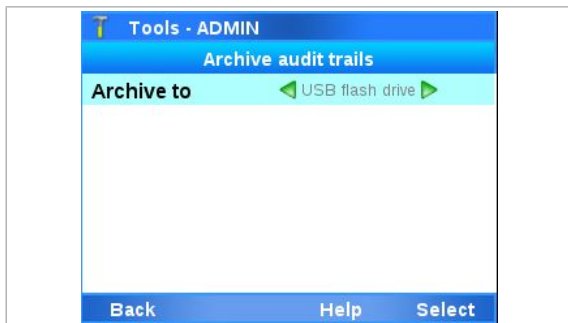The network shares and the FTP shares are displayed with the names configured in **Settings > Share locations**.

5 Choose the **Save** button.

→ Results are archived and deleted at the scheduled time.
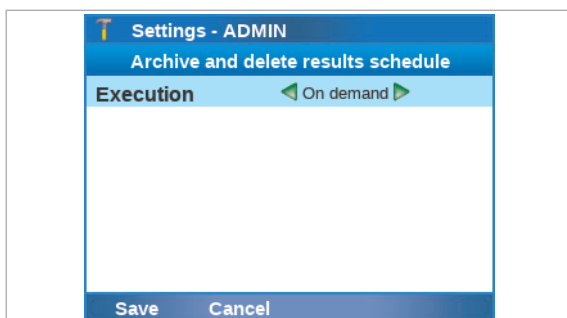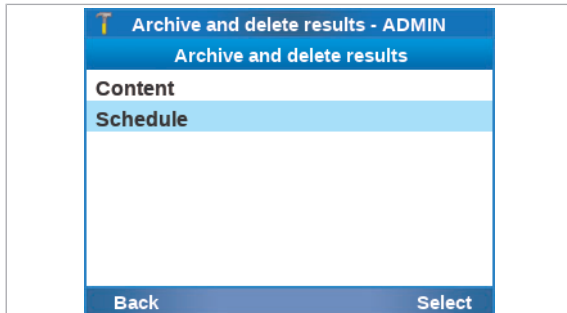
→ The archive file is saved in the configured archiving location.

> **To stop automatic archiving and deletion of results**

1 From the **Main** screen, choose **Settings > Scheduled tasks > Archive and delete results > Schedule**. Choose the **Select** button.

2 Choose the **Execution** item and choose the **On demand** value.

3 Choose the **Save** button.

→ The scheduled archiving and deletion of results is stopped.

Scheduling automatic archiving and reduction of audit trails

To maintain analyzer performance without manual intervention, schedule the automatic archiving and reduction of audit trails.

If you archive and reduce audit trails automatically, all audit trails are archived but they are only partially deleted from the analyzer. The following audit trails are kept on the analyzer:

- The last 7 days of audit trails that are caused by managing users (on **Settings > User management**)
- The latest 10000 audit trails that are caused by other actions

To delete **all** audit trails from the analyzer, use the manual **Archive and delete audit trails** function from the **Tools** menu.

As archiving may take some time and you cannot perform any other action meanwhile, schedule the automatic archiving and reduction of audit trails for a time when the analyzer is not frequently used.

7 Advanced Tools functions

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🔆 Do not schedule the different automatic tasks for the same time:

- Daily restart
- Archive and delete results
- Archive and reduce audit trails
- Problem report

Additionally, observe the restrictions for the scheduled tasks.

▸▣ About restrictions for scheduled tasks (64)

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▸▣ About scheduled tasks (64)

☑▤ ☐ Supervisor user role or administrator user role
☐ Access to a share location (network share or FTP share) as archiving location

▸▣ Configuring network shares (257)

▸▣ Configuring FTP shares (258)

▸ **To schedule automatic archiving and reduction of audit trails**

1 From the **Main** screen, choose **Settings > Scheduled tasks > Archive and reduce audit trails > Schedule**. Choose the **Select** button.
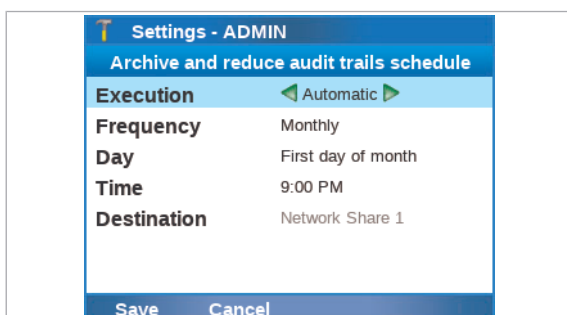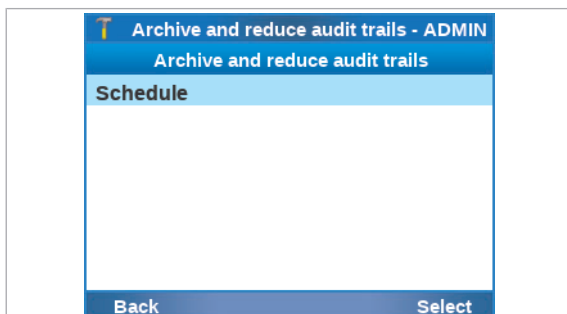
2 Choose the **Execution** item and choose the **Automatic** value.

ℹ Keep the default **On demand** value for manual archiving only.

3 Choose the frequency, day, and time of automatic archiving and reduction of audit trails.

ℹ By default, the automatic archiving and reduction of audit trails is executed monthly on the first day of the month at 9:00 p.m.
Do not schedule different automatic tasks for the same time.

4 Choose the **Destination** item and set the archiving location:
- **Network share {0}** (with {0} = 1 to 3)
- **FTP share {0}** (with {0} = 1 to 3)
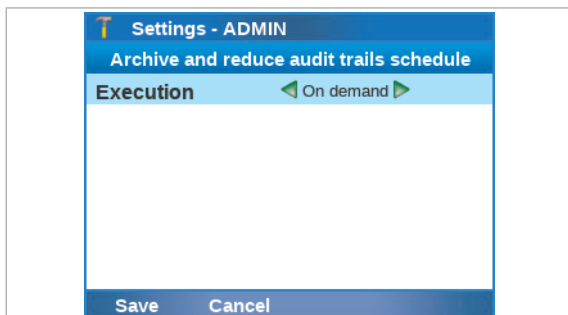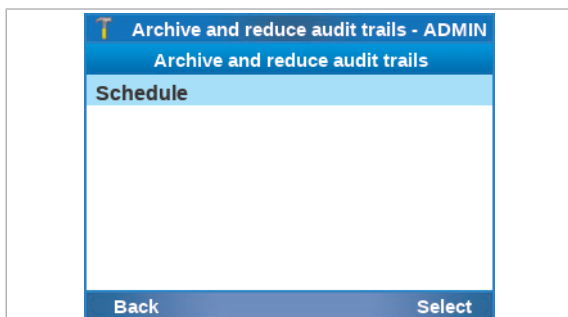
ⓘ Accessible network shares and FTP shares are displayed in black font.
The network shares and the FTP shares are displayed with the names configured in **Settings > Share locations**.

5 Choose the **Save** button.

→ The audit trails are archived and reduced at the scheduled time.

→ The archive file is saved in the configured archiving location.

▶ **To stop automatic archiving and reduction of audit trails**

1 From the **Main** screen, choose **Settings > Scheduled tasks > Archive and reduce audit trails > Schedule**. Choose the **Select** button.

2 Choose the **Execution** item and choose the **On demand** value.

3 Choose the **Save** button.

→ The scheduled archiving and reduction of audit trails is stopped.

Exchanging data

The Advanced Tools offer functions for exchanging data.

In this section

About exchanging data

Exchanging data allows you to synchronize assay tube lots, settings, and/or users between different analyzers, or to restore the data on the same analyzer.

Exchanging data consists of the following steps:

1. Export data from analyzer

2. Import data on same or different analyzer

Backing up an analyzer combines the export of assay tube lots, settings, and users, and additionally includes the used assay tubes.

Exchanging data is only possible using a USB flash drive.

Only connect a USB flash drive to the analyzer if the analyzer is in status ready. Do not connect more than 1 USB flash drive to the analyzer at the same time.

It is recommended to clean the USB flash drive before you export data to it.

▸🖹 About analyzer status (55)

▸🖹 Cleaning a USB flash drive (215)

-ᗅ- If the analyzer is connected with a DMS and data synchronization is enabled, the Advanced Tools to import settings, to import users, and to restore the analyzer are disabled.

About content of export files Export files contain the following data:

▪ For assay tube lots:

- – Shareable assay tube lot information

- – Signature

▪ For settings:

- – System settings

- – Printer settings

- – Share location configuration

- – Network settings

- – Host connections settings

▪ For users:

- – User ID

- – Password (secured)

- – User role

- – Assay permissions

- – Badge barcode (secured)

- – Lock status

- – Change password

- – User name

- – Department

- – Contact

▪ For analyzer backup:

- – Assay tube lots

- – Settings

- – Users

- – Used assay tubes

About export file formats and naming

Assay tube lots are exported as a ZIP file.
The assay tube lot export file is named as follows:
AssayLotExport.zip
If there is already an export file on the USB flash drive, you can merge or replace the data on the USB flash drive. For assay tube lots, only 1 export file can be present on the USB flash drive.

Settings are compiled as an XML file. The XML file is compressed and exported as a ZIP file.
The settings export files are named as follows:
LiatSettings_Serial#_YYYYMMDD_hhmmss.xml
LiatSettings_Serial#_YYYYMMDD_hhmmss.zip

Users are compiled as a CSV file. The CSV file is compressed and exported as a ZIP file.
The user export files are named as follows:
Users_Serial#_YYYYMMDD_hhmmss.csv
Users_Serial#_YYYYMMDD_hhmmss.zip

An **analyzer backup** is exported as a ZIP file.
The backup export file is named as follows:
InstrumentBackup_Serial#_YYYYMMDD_hhmmss.zip

With:
▪ Serial# = Serial number of the analyzer
▪ YYYY = Four-digit year number
▪ MM = Two-digit month number with leading zero
▪ DD = Two-digit day number with leading zero
▪ hh = Two-digit hour number with leading zero in 24 h format
▪ mm = Two-digit minute number with leading zero
▪ ss = Two-digit second number with leading zero
▪ The time for the file name is the timestamp (local time) when the export file is created (ISO 8601 format).

The export files are saved in the root folder of the USB flash drive.

The analyzer checks the data integrity of the export files during import. If the check fails, the data is not imported.

Exporting and importing assay tube lots

To restore or to synchronize assay tube lots, export the assay tube lots from an analyzer and then import them on the same or a different analyzer.

The following rules apply to the export and import of assay tube lots:
▪ Only validated assay tube lots are exported and can be imported.
▪ You can merge or replace the assay tube lots during export and import.
▪ Assay tube lots are not imported if the corresponding assay is not installed on the analyzer.
▪ If the analyzer is connected to a share lot folder, the assay tube lots are exported from the share lot folder and imported to the share lot folder.
▪ Exporting and importing assay lots will fail if share lots is configured but not properly connected.

☐ USB flash drive

☐ Supervisor user role or administrator user role
☐ Analyzer in status ready

▸🗐 About analyzer status (55)
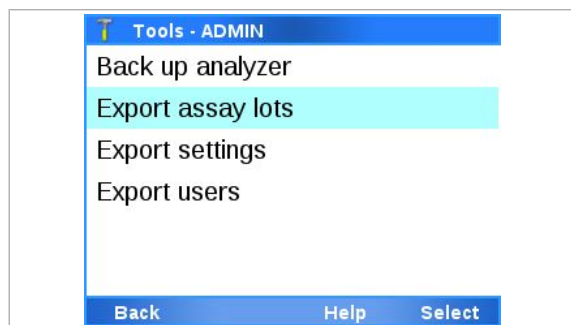
▶ **To export assay tube lots**

1 Insert a USB flash drive at the rear of the analyzer.

ⓘ Only connect a USB flash drive to the analyzer if the analyzer is in status ready.
Do not connect more than 1 USB flash drive to the analyzer at the same time.

2 Optionally, clean the USB flash drive as described in Cleaning a USB flash drive (215).

3 From the **Main** screen, choose **Tools > Export data > Export assay lots**. Choose the **Select** button.

ⓘ You cannot perform any other action on the analyzer until the export is finished.

4 Optionally, if there is already an export file present on the USB flash drive, do one of the following:
- ▪ To replace the export file, choose the **Replace** button.
- ▪ To merge the export file, choose the **Merge** button.

5 Wait until a message is displayed that the assay tube lots were exported successfully. Choose the **Confirm** button.

→ If the analyzer is not configured to use a share lot folder, the assay tube lots that are stored locally on the analyzer are exported.

→ If the analyzer is configured to use a share lot folder, the assay tube lots from the share lot folder are exported.

6 Remove the USB flash drive from the analyzer.

▶ **To import assay tube lots**

1 Insert the USB flash drive that contains the export file at the rear of the analyzer.

ⓘ Only connect a USB flash drive to the analyzer if the analyzer is in status ready.
Do not connect more than 1 USB flash drive to the analyzer at the same time.

2 From the **Main** screen, choose **Tools > Import data > Import assay lots**. Choose the **Select** button.

ⓘ You cannot perform any other action on the analyzer until the import is finished.

3 Enter your password and choose the **Enter** button.
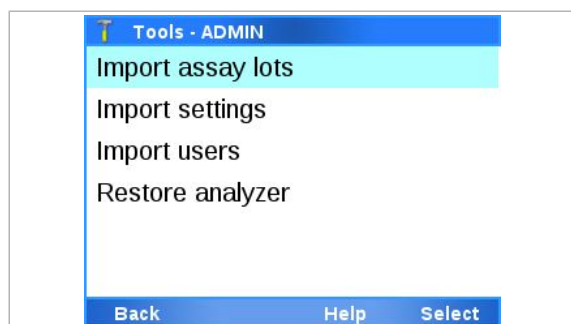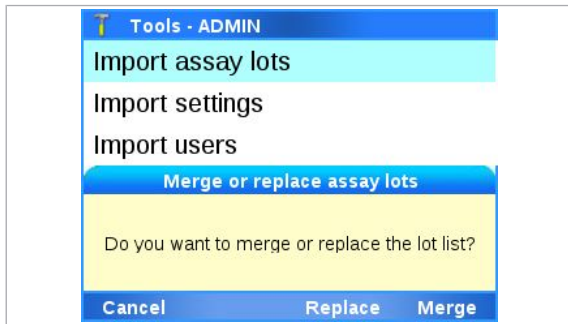
4 Choose the import option:
- ▪ To keep the existing assay tube lots and to add any non-existing ones, choose the **Merge** button.
- ▪ To replace any existing assay tube lots, choose the **Replace** button.

5 Wait until a message is displayed that the assay tube lots were imported successfully. Choose the **Confirm** button.
- → If the analyzer is not configured to use a share lot folder, the assay tube lots are stored locally on the analyzer.
- → If the analyzer is configured to use a share lot folder, the assay tube lots are stored on the share lot folder.

6 Remove the USB flash drive from the analyzer.

Exporting and importing settings

To restore or to synchronize settings, export the settings from an analyzer and then import them on the same or a different analyzer.

The following rules apply to the export and import of settings:
- ▪ If more than 1 export file is present on the USB flash drive, the latest export file is imported after confirmation by the user.
- ▪ Importing settings overwrites the existing exportable settings on the analyzer.
- ▪ Only export and import settings between analyzers that have the same software version installed.
- ▪ If the analyzer exchanges settings with a DMS, the import of settings is disabled on the analyzer.

□ USB flash drive

□ To export settings:
Supervisor user role or administrator user role
□ To import settings:
Administrator user role
□ Analyzer in status ready

▸ About analyzer status (55)

▸ To export settings

1 Insert a USB flash drive at the rear of the analyzer.
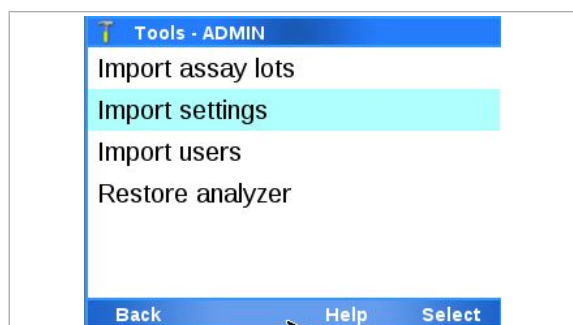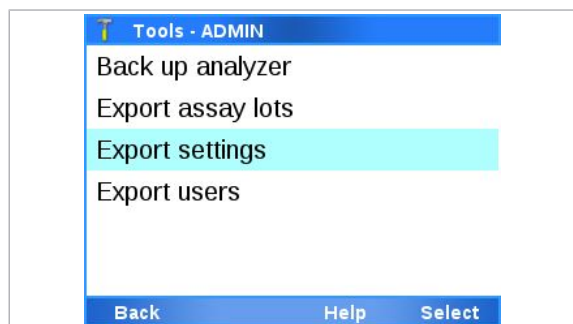
ⓘ Only connect a USB flash drive to the analyzer if the analyzer is in status ready.
Do not connect more than 1 USB flash drive to the analyzer at the same time.

2 Optionally, clean the USB flash drive as described in Cleaning a USB flash drive (215).

3 From the **Main** screen, choose **Tools > Export data > Export settings**. Choose the **Select** button.

ⓘ You cannot perform any other action on the analyzer until the export is finished.

4 Wait until a message is displayed that the settings were exported successfully. Choose the **Confirm** button.

5 Remove the USB flash drive from the analyzer.

▸ **To import settings**

1 Insert the USB flash drive that contains the export file at the rear of the analyzer.

ⓘ Only connect a USB flash drive to the analyzer if the analyzer is in status ready.
Do not connect more than 1 USB flash drive to the analyzer at the same time.

2 From the **Main** screen, choose **Tools > Import data > Import settings**. Choose the **Select** button.

ⓘ You cannot perform any other action on the analyzer until the import is finished.

3 Enter your password and choose the **Enter** button.

4 Optionally, to import the latest export file if more than 1 export file is present on the USB flash drive, choose the **Confirm** button.

5 Wait until a message is displayed that the settings were imported successfully. Choose the **Restart** button.

➔ The analyzer is restarted.

➔ The imported settings are applied to the analyzer.

6 Remove the USB flash drive from the analyzer.

Exporting and importing users

To restore or to synchronize user accounts, export the users from an analyzer and then import them on the same or a different analyzer.

The following rules apply to the export and import of users:

7 Advanced Tools functions

▪ If more than 1 export file is present on the USB flash drive, the latest export file is imported after confirmation by the user.

▪ The default administrator account ADMIN is neither exported nor imported.

▪ Importing users deletes all existing users on the analyzer except the currently logged on user and the default administrator account ADMIN.

▪ If the analyzer exchanges user data with a DMS, the import of users is disabled on the analyzer.

□ USB flash drive

□ To export users:
Supervisor user role or administrator user role

□ To import users:
Administrator user role

□ Analyzer in status ready

⊡ About analyzer status (55)

▶ **To export users**

1 Insert a USB flash drive at the rear of the analyzer.

   ❶ Only connect a USB flash drive to the analyzer if the analyzer is in status ready.
   Do not connect more than 1 USB flash drive to the analyzer at the same time.

2 Optionally, clean the USB flash drive as described in Cleaning a USB flash drive (215).

3 From the **Main** screen, choose **Tools > Export data > Export users**. Choose the **Select** button.

   ❶ You cannot perform any other action on the analyzer until the export is finished.

4 Wait until a message is displayed that the users were exported successfully. Choose the **Confirm** button.

5 Remove the USB flash drive from the analyzer.

▶ **To import users**

1 Insert the USB flash drive that contains the export file at the rear of the analyzer.

   ❶ Only connect a USB flash drive to the analyzer if the analyzer is in status ready.
   Do not connect more than 1 USB flash drive to the analyzer at the same time.

7 Advanced Tools functions
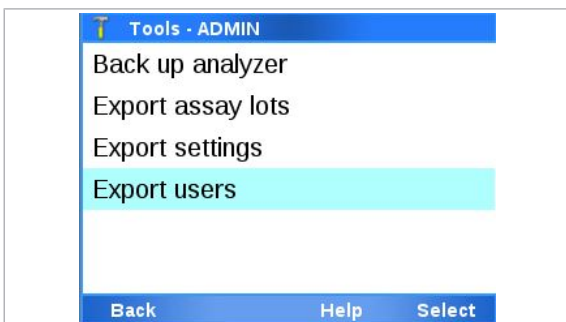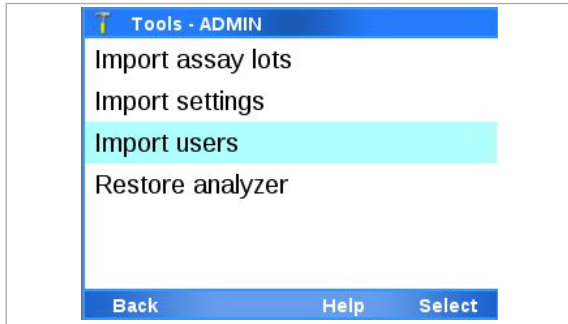
2 From the **Main** screen, choose **Tools > Import data > Import users**. Choose the **Select** button.

ⓘ You cannot perform any other action on the analyzer until the import is finished.

3 Enter your password and choose the **Enter** button.

4 Optionally, to import the latest export file if more than 1 export file is present on the USB flash drive, choose the **Confirm** button.

5 Wait until a message is displayed that the users were imported successfully. Choose the **Confirm** button.

➔ All users previously existing on the analyzer are deleted, except the currently logged on user and the default administrator account ADMIN.

➔ All imported users are added to the analyzer.

6 Remove the USB flash drive from the analyzer.

Backing up and restoring an analyzer

You can back up the analyzer and restore the backup on the same or a different analyzer.

The following rules apply to the backup and restore of analyzers:

▪ Backing up an analyzer combines the export of assay tube lots, settings, and users, and additionally includes the used assay tubes.

▪ If more than 1 export file is present on the USB flash drive, the latest export file is imported after confirmation by the user.

▪ All assay tube lots, settings, users, and used assay tubes on the restored analyzer are overwritten with the content of the export file.

▪ Assay tube lots are not imported during the restore if the corresponding assay is not installed on the analyzer.

▪ Only use the backup and restore functions between analyzers that have the same software version installed.

▪ If the analyzer exchanges settings and/or users with a DMS, the restore of the analyzer is disabled on the analyzer.

🧰 ☐ USB flash drive

☑▤ ☐ To back up an analyzer:
Supervisor user role or administrator user role

☐ To restore an analyzer:
Administrator user role

☐ Analyzer in status ready

▸▤ About analyzer status (55)

▸ To back up an analyzer

1 Insert a USB flash drive at the rear of the analyzer.

> ❶ Only connect a USB flash drive to the analyzer if the analyzer is in status ready.
> Do not connect more than 1 USB flash drive to the analyzer at the same time.

2 Optionally, clean the USB flash drive as described in Cleaning a USB flash drive (215).

3 From the **Main** screen, choose **Tools > Export data > Back up analyzer**. Choose the **Select** button.

> ❶ You cannot perform any other action on the analyzer until the backup is finished.

4 Wait until a message is displayed that the analyzer was backed up successfully.

5 Remove the USB flash drive from the analyzer.
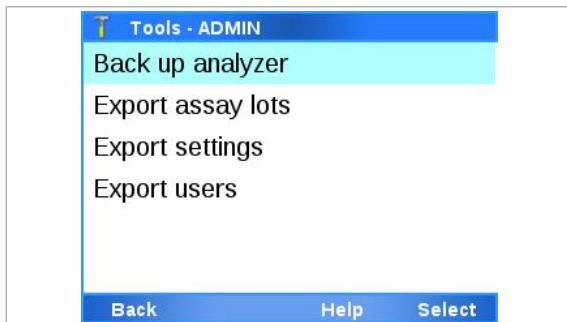
▸ To restore an analyzer

1 Insert the USB flash drive that contains the backup file at the rear of the analyzer.

> ❶ Only connect a USB flash drive to the analyzer if the analyzer is in status ready.
> Do not connect more than 1 USB flash drive to the analyzer at the same time.

2 From the **Main** screen, choose **Tools > Import data > Restore analyzer**. Choose the **Select** button.

> ❶ You cannot perform any other action on the analyzer until the backup is finished.

3 Enter your password and choose the **Enter** button.

4 Optionally, to import the latest export file if more than 1 export file is present on the USB flash drive, choose the **Confirm** button.

5 Wait until a message is displayed that the analyzer was restored successfully. Choose the **Restart** button.

→ The analyzer is restarted.

→ All assay tube lots, settings, users, and used assay tubes are overwritten on the analyzer.

7 Advanced Tools functions
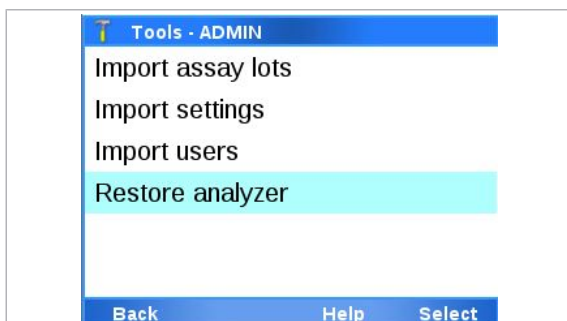
6 Remove the USB flash drive from the analyzer.

Problem reports

The Advanced Tools offer functions for problem reports.

In this section

About problem reports

If you encounter a problem Roche recommends generating a problem report that you can send to your Roche representative.

Roche reviews your problem reports upon your request only.

You need supervisor user role or administrator user role to configure, to schedule, and to create problem reports.

If problem report creation fails, check the connections and the storage location, e.g., the network share. Try again to create a problem report manually and/or wait for the next scheduled execution of the automatic problem report. If it still fails, contact your Roche representative.

About problem reports content

Problem reports contain relevant data required by Roche to perform diagnostics.

Problem reports always contain the following data:
- System configuration
- System logs
- Settings
- Event logs
- Audit trail
- QC results
- Assay tube lot information
- Assay tube lot validation results
- Free and used storage space on the analyzer
- Data synchronization details (if connected to DMS)

Optionally, problem reports can contain the following additional data:

▪ Communication logs
▪ Users (except passwords)
▪ Run logs (filtered by data range)
▪ Sample results (filtered by data range)
▪ Sample IDs (only if sample results are included)

To facilitate diagnostics, it is recommended to include the optional content in problem reports and consider the appropriate data range.

About problem reports storage locations

To create a problem report, the analyzer must be connected to a storage location for the problem report.

You can save problem reports to the following storage locations:
▪ Remote service
▪ Share location (network share or FTP share)
▪ USB flash drive (manually created problem reports only)

The problem reports are saved in the root folder of the share locations or the USB flash drive.

Only connect a USB flash drive to the analyzer if the analyzer is in status ready. Do not connect more than 1 USB flash drive to the analyzer at the same time.

About problem reports file format, naming, and encryption

When a **problem report** is created, all contained data is compressed and saved as a single ZIP file.
The problem report files are named as follows:
ProblemReport_Serial#_YYYYMMDD_hhmmss_ [ABCDEF].zip

With:
▪ Serial# = Serial number of the analyzer
▪ YYYY = Four-digit year number
▪ MM = Two-digit month number with leading zero
▪ DD = Two-digit day number with leading zero
▪ hh = Two-digit hour number with leading zero in 24 h format
▪ mm = Two-digit minute number with leading zero
▪ ss = Two-digit second number with leading zero

7 Advanced Tools functions

- [ABCDEF] = indication if optional data is included or excluded (see below)
- The time for the file name is the timestamp (local time) when the file is created (ISO 8601 format).

The values of the placeholders ABCDEF in the file name indicate if the optional data is included or excluded in the problem report. The possible values of the placeholders correspond to the options available in the software when configuring problem report content:

Placeholder	Denotes	Values	Explanation
A	Communication logs	C	Included
		-	Excluded
B	Users	U	Included
		-	Excluded
C	Data range	D	Last 24 hours
		W	Last 7 days
		M	Last 30 days
		A	All
D	Run logs	L	Included
		-	Excluded
E	Sample results	S	Included
		-	Excluded
F	Sample IDs	I	Included
		-	Excluded

⊞ Placeholders in problem report files names

The problem report ZIP file is encrypted. Therefore, only Roche can open problem reports and access the content.

However, you can still check the content of a problem report by its file name only, without decrypting it. Examples:

- **[C–W–SI]**

  – Included:
  Communication logs
  Sample results of the last 7 days
  Sample IDs

  – Excluded:
  Users
  Run logs

- **[-UALS–]**

  – Included:
  Users
  All run logs
  All sample results

– Excluded:
Communication logs
Users
Sample IDs

About problem reports creation

If the analyzer is not in status busy, you can create a problem report manually at any time.

Additionally, you can schedule automatic problem report creation. If the analyzer is in ready status at the scheduled time, it notifies the user about the upcoming problem report creation. If the user does not cancel the action within 30 s of the notification, the analyzer proceeds to create the problem report automatically.

When you archive and delete results (manually or automatically), a problem report is automatically created with the same archiving criterion and contained in the archive file.

You cannot perform any other action on the analyzer until the problem report is finished.

‣▤ About analyzer status (55)

‣▤ About scheduled tasks (64)

‣▤ Creating problem reports manually (210)

‣▤ Scheduling automatic problem reports (211)

‣▤ **Related topics**

▪ Configuring the log level (140)

Configuring problem reports content

You can include or exclude the optional additional content in problem reports and set the data range filter.

By default, the communication logs, the run logs, and the sample results are included in problem reports.

The content configuration and data range filter apply to problem reports created both manually and automatically.

-ϙ́- To facilitate diagnostics, it is recommended to include the optional content in problem reports and consider the appropriate data range.

▯ Supervisor user role or administrator user role

▶ To configure problem reports content
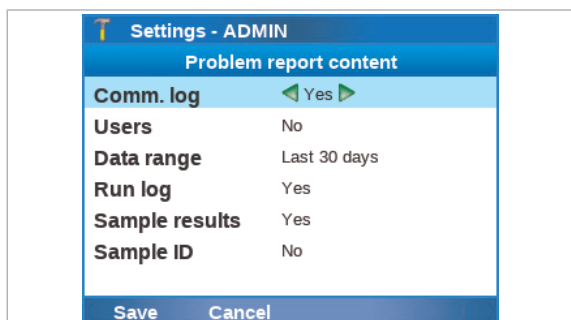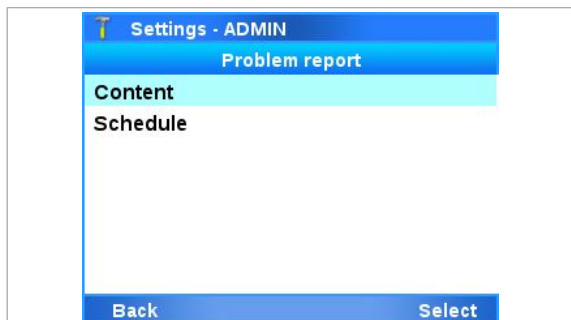
1 From the **Main** screen, choose **Settings > Scheduled tasks > Problem report > Content**. Choose the **Select** button.

2 To include the communication logs, choose the **Comm. log** item and choose the **Yes** value.

> ❶ It is recommended to include the communication logs.

3 To include the users, choose the **Users** item and choose the **Yes** value.

> ❶ It is recommended to include the users.

4 Choose the **Data range** item and choose a value:
> ▪ **All**
> ▪ **Last 30 days** (default)
> ▪ **Last 7 days**
> ▪ **Last 24 hours**

> ❶ The chosen value applies to the run logs and the sample results (if included).
> It is recommended to consider the appropriate data range.

5 To include the run logs, choose the **Run log** item and choose the **Yes** value.

> ❶ It is recommended to include the run logs.

6 To include the sample results, choose the **Sample results** item and choose the **Yes** value.

7 If results are included, to include the sample IDs, choose the **Sample ID** item and choose the **Yes** value.

8 Choose the **Save** button.
> ➜ The content configuration applies to problem reports created both manually and automatically.

⮡ **Related topics**

▪ Configuring the log level (140)

Creating problem reports manually

Create a problem report manually when you encounter a problem.

Even if automatic problem reports are scheduled on the analyzer, you can still create a problem report manually at any time.

Manually created problem reports contain the optional content as configured. However, you can overrule the configured data range for included results.

▸▤ About problem reports content (205)

▸▤ Configuring problem reports content (208)

Depending on problem report content (e.g., number of included results)

☐ Supervisor user role or administrator user role
☐ Access to a storage location for the problem report:
   Remote service
   Share location (network share or FTP share)
   USB flash drive

▸▤ Remote service configuration (222)

▸▤ Configuring network shares (257)

▸▤ Configuring FTP shares (258)

▸ To create a problem report manually

1 Optionally, to save the problem report to a USB flash drive, insert the USB flash drive at the rear of the analyzer.

   ❶ Only connect a USB flash drive to the analyzer, if the analyzer is in status ready.
   Do not connect more than 1 USB flash drive to the analyzer at the same time.

2 From the **Main** screen, choose **Tools > Create problem report**. Choose the **Select** button.

7 Advanced Tools functions

Tools - ADMIN
Include results
Last 24 hours
Last 7 days
Last 30 days
All

Back   Select

Tools - ADMIN
Create problem report
Archive to   ◄ USB flash drive ►

Back   Select
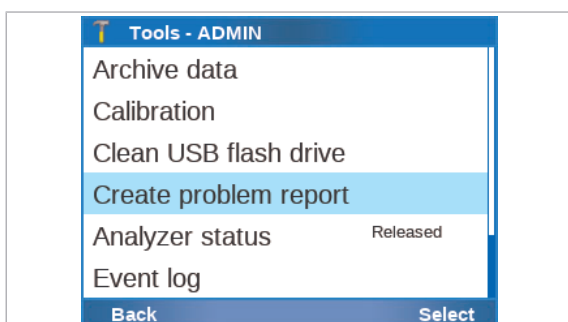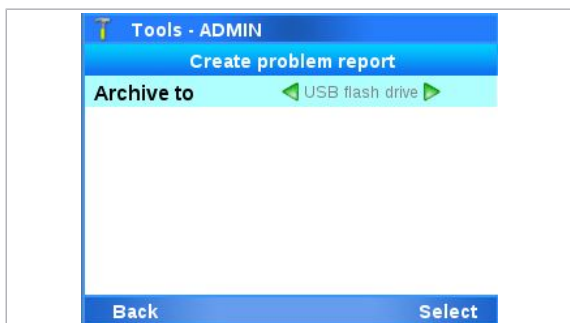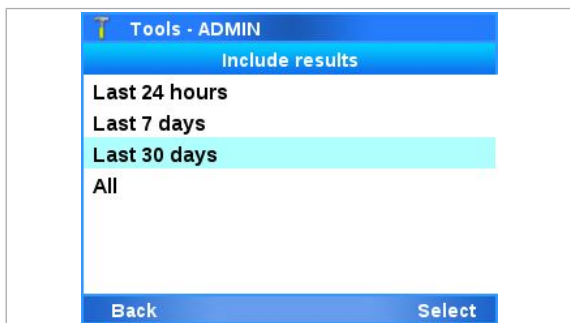
3 If prompted, choose the data range for included results:
- **Last 24 hours**
- **Last 7 days**
- **Last 30 days**
- **All**

  ❶ The configured data range is preselected as value here.

4 Set the storage location for the problem report:
- **Remote service**
- **Network share {0}** (with {0} = 1 to 3)
- **FTP share {0}** (with {0} = 1 to 3)
- **USB flash drive**

  ❶ Accessible storage locations are displayed in black font.
  The network shares and the FTP shares are displayed with the names configured in **Settings > Share locations**.

5 Choose the **Select** button.

  ❶ You cannot perform any other actions on the analyzer until the problem report is finished.

6 Wait until a message is displayed that the problem report was created successfully. Choose the **Confirm** button.

7 Optionally, if you saved the problem report to a USB flash drive, remove the USB flash drive from the analyzer.

▸ **Related topics**
- Configuring the log level (140)

Scheduling automatic problem reports

To ensure you have a recent problem report if you encounter problems, schedule automatic problem reports.

You cannot save automatic problem reports to a USB flash drive.

Automatic problem reports contain the optional content as configured.

▸ About problem reports content (205)

▸ Configuring problem reports content (208)

As creating a problem report may take some time and you cannot perform any other action meanwhile, schedule the automatic problem reports for a time when the analyzer is not frequently used.

> Do not schedule the different automatic tasks for the same time:
> - Daily restart
> - Archive and delete results
> - Archive and reduce audit trails
> - Problem report
>
> Additionally, observe the restrictions for the scheduled tasks.
>
> About restrictions for scheduled tasks (64)

About scheduled tasks (64)

☐ Supervisor user role or administrator user role
☐ Access to a storage location for the problem report:
Remote service
Share location (network share or FTP share)

Remote service configuration (222)

Configuring network shares (257)

▶ **To schedule automatic problem reports**

1 From the **Main** screen, choose **Settings > Scheduled tasks > Problem report > Schedule**. Choose the **Select** button.

2 Choose the **Creation** item and choose the **Automatic** value.

> ⓘ Keep the default **On demand** value for manual creation of problem reports only.

3 Choose the frequency, day, and time of automatic problem report creation.

> ⓘ By default, automatic problem reports are created monthly on the first day of the month at 4:00 p.m. Do not schedule different automatic tasks for the same time.
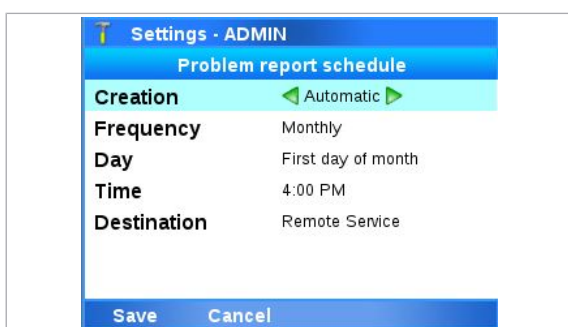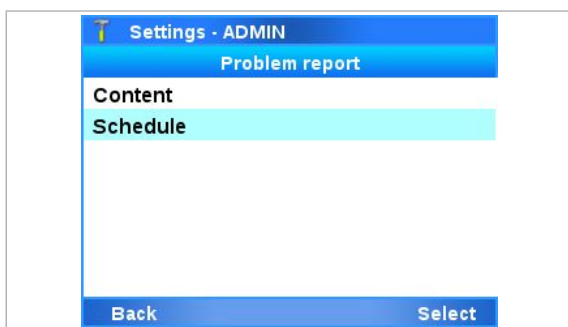
4 Choose the **Destination** item and set the storage location of the problem reports:

- ▪ **Remote service**
- ▪ **Network share {0}** (with {0} = 1 to 3)
- ▪ **FTP share {0}** (with {0} = 1 to 3)

ⓘ Accessible storage locations are displayed in black font.
The network shares and the FTP shares are displayed with the names configured in **Settings > Share locations**.

5 Choose the **Save** button.

→ Problem reports are created at the scheduled time and stored in the configured storage location.

▶ **To stop automatic problem report creation**

1 From the **Main** screen, choose **Settings > Scheduled tasks > Problem report > Schedule**. Choose the **Select** button.

2 Choose the **Creation** item and choose the **On demand** value.

3 Choose the **Save** button.

→ The scheduled creation of problem reports is stopped.
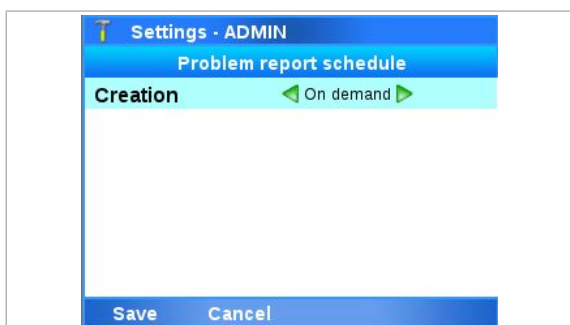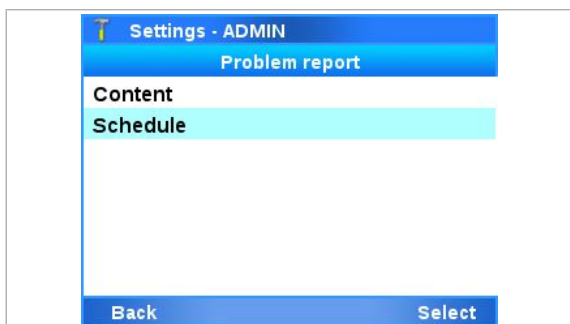
▸🗐 **Related topics**

- ▪ Configuring the log level (140)

7 Advanced Tools functions

Locking and unlocking the analyzer

The **Analyzer status** option allows you to lock and to unlock the analyzer manually.

If the analyzer is in status locked, you cannot perform any runs on the analyzer.

About locking the analyzer (67)

☐ Administrator or supervisor user role

▶ To lock the analyzer manually

1 From the **Main** screen, choose **Tools > Analyzer status**. Choose the **Select** button.
→ The **Analyzer status** screen is displayed.

2 Use the Left ◁ and Right ▷ navigation buttons to choose the **Locked out** value.

3 Choose the **Save** button.
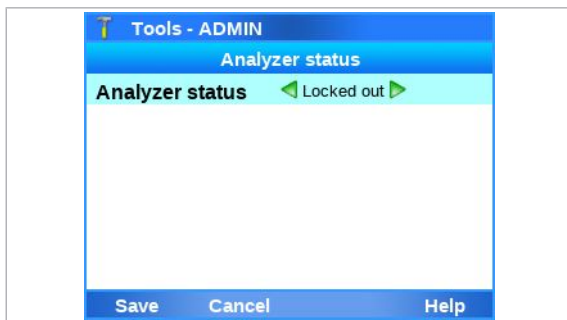
4 On the message dialog box, choose the **Confirm** button.
→ The analyzer is locked.
→ Only users with supervisor user role or administrator user role can log on to the analyzer.
→ You cannot perform runs on the analyzer.
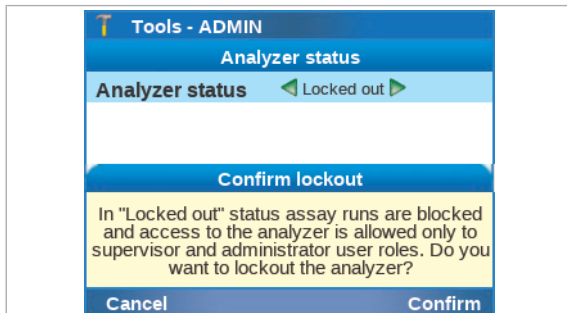
▶ To unlock the analyzer manually

1 From the **Main** screen, choose **Tools > Analyzer status**. Choose the **Select** button.
→ The **Analyzer status** screen is displayed.

2 Use the Left ◁ and Right ▷ navigation buttons to choose the **Released** value.

3 Choose the **Save** button.
→ The analyzer is unlocked.
→ All users can log on to the analyzer.
→ You can perform runs on the analyzer.

7 Advanced Tools functions

Cleaning a USB flash drive

The Advanced Tools offer a function for cleaning USB flash drives.

Cleaning a USB flash drive deletes all files on the USB flash drive.

Only connect a USB flash drive to the analyzer if the analyzer is in status ready.

You need supervisor user role or administrator user role to clean a USB flash drive.

⯈▤ About analyzer status (55)

▭ USB flash drive

▭ Supervisor user role or administrator user role
▭ Analyzer in status ready

⯈▤ About analyzer status (55)

▸ To clean a USB flash drive

1 Insert a USB flash drive at the rear of the analyzer.

> ⓘ Only connect a USB flash drive to the analyzer if the analyzer is in status ready.
> Do not connect more than 1 USB flash drive to the analyzer at the same time.

2 From the **Main** screen, choose **Tools > Clean USB flash drive**. Choose the **Select** button.

3 Enter your password and choose the **Enter** button.

4 To clean the USB flash drive, choose the **Confirm** button.

5 Wait until a message is displayed that the USB flash drive was cleaned successfully. Choose the **Confirm** button.

➜ All files are deleted from the USB flash drive.

6 Remove the USB flash drive from the analyzer.

7 Advanced Tools functions
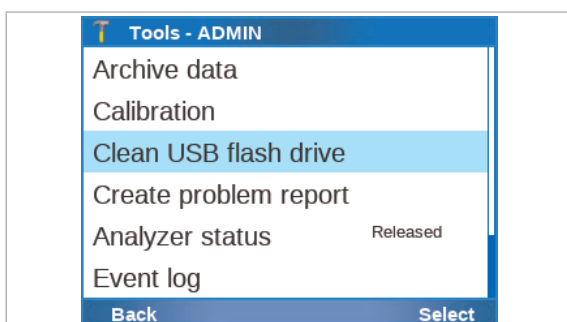
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Connectivity

8 Connectivity

Network configuration

In this section

About network configuration

You can connect the analyzer to a 10/100 Ethernet network.

When connected to the network, by default the analyzer tries to connect to a DHCP server in your network to configure its network settings automatically. A DHCP server automatically assigns an IP address and other network settings to the analyzer. If a DHCP server is not available, you can configure the analyzer network settings manually.

The analyzer incorporates an embedded firewall that denies all inbound network connections by default. This firewall cannot be configured. The firewall allows the necessary connections automatically when a new connectivity item is enabled.

> ☼ The analyzer is not ping-able.

> ⚠ **CAUTION!**
>
> **Breach of confidentiality and privacy**
>
> Unprotected network connections may allow access by unauthorized persons and confidential personal information may be obtained.
>
> ▶ When connecting the analyzer to a network, make sure that the connection is secure and monitored for security breaches.
>
> ▶ If parts of your network, which the analyzer uses to exchange data, are connected by WLAN, secure the WLAN with WPA2 encryption.

8 Connectivity

Network configuration items

The configuration items in the **Network** screen determine the connection to the network.

➜ **Settings > Connections > Network**

For IP addresses, the analyzer interprets numbers with a zero prefix as octal, and numbers with a 0x prefix as hexadecimal.

Settings - ADMIN	
Network	
DHCP	◀ Yes ▶
IP address	10.138.206.63
Subnet mask	255.255.255.0
Gateway	10.138.206.1
DNS server	10.138.206.6
Save Cancel	Edit
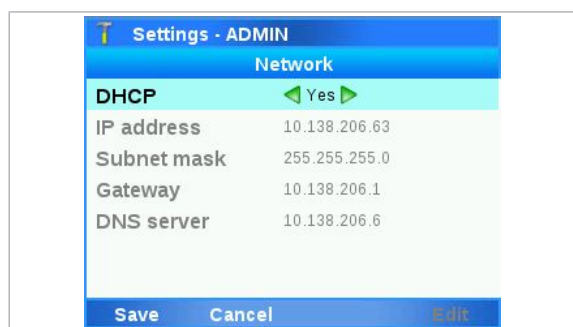
Network item	Configuration value	Comment
DHCP	**Yes**	If you choose the **Yes** value, the network definitions are automatically obtained from your DHCP server.
	No	If you choose the **No** value, you can choose the other configuration items and enter the appropriate values.
IP address		Define the IP address of the analyzer.
Subnet mask		Define the used subnet mask.
Gateway		Define the IP address of the gateway server.
DNS server		Define the IP address of the DNS server.

⊞ Network configuration items

Connecting to the network

The analyzer configures its network settings automatically using a DHCP server. You can also configure network settings manually.

☐ Using a network cable, connect the analyzer network port to the appropriate network socket.

☐ Administrator user role

▸ **To connect to the network**

1 Choose **Settings > Connections > Network**. Choose the **Select** button.

2 To configure network settings using a DHCP server, choose the **Yes** value.

3 To configure the network settings manually, choose the **No** value. Enter the IP address and subnet mask information of the analyzer.

    ⓘ The analyzer interprets numbers with a zero prefix as octal, and numbers with a 0x prefix as hexadecimal.

4 Enter the Gateway and DNS information.

5 Choose the **Save** button.

▸⊟ **Related topics**

- Network configuration items (220)

8 Connectivity

Remote service configuration

You can connect the analyzer to a remote service using an internet connection.

The following options are available as remote service:

- Axeda (default)
- **cobas® infinity** edge smart

Currently, you can choose either option. However, **cobas® infinity** edge smart will become the only available option with future software releases.

In this section

Configuration of Axeda as remote service

You can connect the analyzer to Axeda as the remote service via the internet.

> Currently, you can choose between Axeda and **cobas® infinity** edge smart to connect the analyzer to the remote service. However, **cobas® infinity** edge smart will become the only available option with future software releases.
>

When you use Axeda as the remote service, you can automatically:

- Update the analyzer software.
- Install and update assay scripts.
- Register and activate the analyzer software and assay scripts.
- Install and update data collectors.
- Store collected data packages.
- Store problem reports.

When connected, the analyzer checks the remote service frequently for updates.

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When a new software or assay script is available, the analyzer downloads this update in the background. When the update is ready to be installed, you can accept or reject the update.

When a new data collector is available, the analyzer downloads this update in the background and installs it automatically during initialization.

About connecting to Axeda

The analyzer automatically connects to Axeda, if the following conditions are satisfied:

- Axeda is configured as the remote service on the analyzer.
- The analyzer is connected to the network and the internet.
- The firewall of your network is configured to allow communication with:
    - Host: remoteservice.roche.com
    - IP: 62.209.44.11
    - Port: 443
    - Protocol: TCP / SSL

To disconnect the analyzer from Axeda, configure the firewall of your network to block the communication.

▸▤ **Related topics**

Configuration of cobas® infinity edge smart as remote service

cobas® infinity edge smart is available as remote service.

In this section

8 Connectivity

About cobas® infinity edge smart as remote service

You can connect the analyzer to **cobas® infinity** edge smart as the remote service via the internet.

-ᄋ- Currently, you can choose between Axeda and **cobas® infinity** edge smart to connect the analyzer to the remote service. However, **cobas® infinity** edge smart will become the only available option with future software releases.

If connected, the analyzer automatically contacts **cobas® infinity** edge smart every 10 minutes (periodic inquiry). If applicable, the analyzer then performs the following workflows in the background:

▪ Registration with **cobas® infinity** edge smart

▪ Software download from **cobas® infinity** edge smart to the analyzer:

– Updated analyzer software

– New and updated assay scripts

– New and updated data collectors

▪ Data upload from the analyzer to **cobas® infinity** edge smart:

– Registration and activation of the analyzer software and assay scripts

– Storing of collected data packages

– Storing of problem reports

When a software download is ready to be installed, the analyzer behavior depends on the configuration of **cobas® infinity** edge smart:

▪ You are informed on the analyzer about the update, and can accept or reject it.

▪ Alternatively, the update is automatically installed in the background without user intervention when the analyzer is in status standby.

▪ Data collectors are always automatically installed on the analyzer during initialization.

About the registration workflow

The analyzer registers with **cobas® infinity** edge smart in the following situations.

▪ When you connect the analyzer to **cobas® infinity** edge smart for the first time.

▪ Whenever the installation of a software update or an assay script is finished.

▪ Whenever you delete an assay from the analyzer.

During this registration workflow, the analyzer transfers the software version, and the installed assays and their versions to **cobas®** **infinity** edge smart.

Registration happens in the background and is displayed on the **Status** screen of the **cobas®** **infinity** edge smart connection.

‣ Checking the status of the **cobas®** **infinity** edge smart connection (230)

About connecting to cobas® infinity edge smart

To connect the analyzer to **cobas®** **infinity** edge smart, you must configure the connection on the analyzer.

Once you have configured **cobas®** **infinity** edge smart, you can only go back to Axeda by resetting the system settings to the default values. This resets all values defined from the **Settings** screen to the factory values, except for the **Date and time** value, the **Name of analyzer** value, and the **Language** value.

‣ Configuration items for **cobas®** **infinity** edge smart (225)

‣ Connecting the analyzer to **cobas®** **infinity** edge smart (227)

‣ **Related topics**

- Installing or updating an assay from the remote service (117)
- Updating the software (168)

Configuration items for cobas® infinity edge smart

When you change to **cobas®** **infinity** edge smart as the remote service, the configuration items that are specific for **cobas®** **infinity** edge smart are displayed on the **Remote service** screen.

➔ **Settings > Connections > Remote service > System > infinity edge**
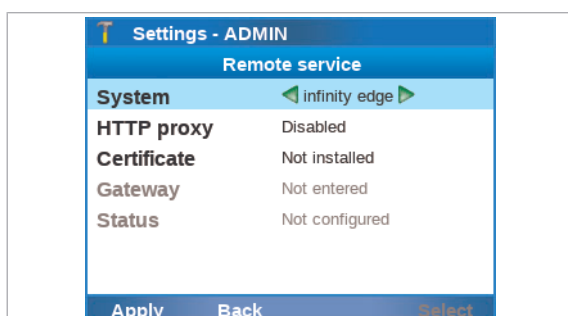
The following applies to the configuration items:
- The order of the configuration items reflects the consecutive steps to connect the analyzer. A configuration item will only become available when the previous configuration steps have been completed.

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▪ To display a screen where you can enter the required information for each configuration item, choose the configuration item (except Status item).

▪ The displayed value for a configuration item (except Status item) indicates the status of that configuration step, for example, Not installed.

▪ The displayed value for the Status item indicates the overall status of the connection, for example, Configured.

▸▤ Connecting the analyzer to cobas® infinity edge smart (227)

infinity edge configuration items		Comment
Certificate		Indicates if the required certificate is installed on the analyzer. Possible values are:
		▪ Not installed
		▪ Installed
		Choose to display the Remote certificate screen for installing the certificate.
		The analyzer-specific certificate is used to encrypt any communication between the analyzer and cobas® infinity edge smart.
		Certificates are issued by Roche and installed when you connect the analyzer to cobas® infinity edge smart.
		New and repaired analyzers are delivered with a pre-installed certificate.
		If a PIN is required for subsequent certificate requests, contact your Roche representative and provide the RUDI of the analyzer.
Gateway		Indicates if the gateway details are entered. Possible values are:
		▪ Not entered
		▪ Entered
		Choose to display the infinity edge gateway screen for entering the gateway details and viewing the customer details (if available).
		Contact your local cobas® infinity edge smart administrator or your local network administrator for the gateway details (server, port).
Gateway > Gateway details	Server	Name or IP address of the cobas® infinity edge smart gateway server.
	Port	Port of cobas® infinity edge smart.
	Timeout	Connection timeout (in seconds) for the communication with cobas® infinity edge smart.
		To prevent a long waiting time in case of connection problems, it is recommended to use the shortest timeout that is compatible with your network performance.
Gateway > Customer details		If the analyzer is connected to a DMS, the customer information is displayed that is received from the DMS (read only).
		Alternatively, the customer information can be imported from other analyzers.

⊞ infinity edge configuration items

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infinity edge configuration items	Comment
Status	Indicates if the connection to **cobas®** **infinity** edge smart is established. Possible values are: ▪ **Not configured** ▪ **Configured** ▪ **Registering...** ▪ **Registered** ▪ **Error** ▪ **Internal error** Choose to check the status details for the connection. ▸▣ Checking the status of the **cobas®** **infinity** edge smart connection (230)

🎛 **infinity edge** configuration items

▸▣ **Related topics**

- Installing or updating an assay from the remote service (117)
- Updating the software (168)

Connecting the analyzer to cobas® infinity edge smart

You can connect the analyzer to **cobas®** **infinity** edge smart as the remote service.

Connecting to **cobas®** **infinity** edge smart comprises the following steps on the **Remote service** screen of the analyzer:

1. Configure **cobas®** **infinity** edge smart as the remote service.

2. If required, configure the proxy server.

3. If required, install the certificate.

4. Configure the gateway details.

The required steps are reflected by the order of the configuration items on the **Remote service** screen. A configuration item will only become available when the previous configuration steps have been completed.

▸▣ Configuration items for **cobas®** **infinity** edge smart (225)

8 Connectivity

Once you have configured **cobas® infinity** edge smart, you can only go back to Axeda by resetting the system settings to the default values. This resets all values defined from the **Settings** screen to the factory values, except for the **Date and time** value, the **Name of analyzer** value, and the **Language** value.

⯈ System settings (133)

Time required for registering in **cobas® infinity** edge smart:
up to 10 minutes

☐ Analyzer connected to the internet

☐ Certificate issued for the analyzer

☐ Details for the **cobas® infinity** edge smart gateway (server, port)

☐ Supervisor user role or administrator user role

⯈ **To connect to cobas® infinity edge smart as remote service**

1 From the **Main** screen, choose **Settings > Connections > Remote service**. Choose the **Select** button.

2 Choose the **System** item and change it to the **infinity edge** value.

3 To confirm, choose the **edge** button.

4 If required, choose the **HTTP proxy** item and configure the proxy server as described in Configuring a proxy server (234).

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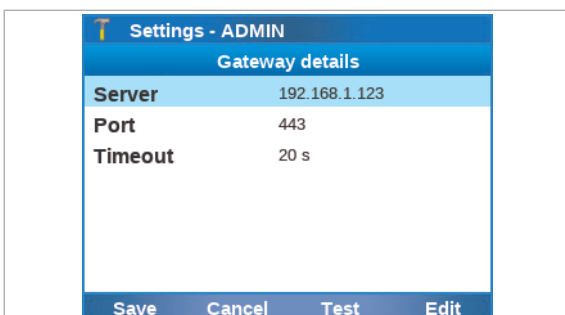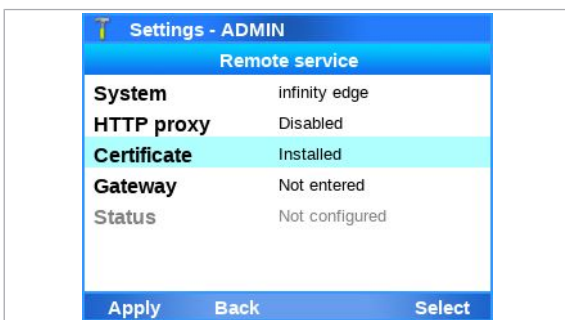
5 If the **Not installed** value is displayed for the **Certificate** item, do the following to request and install the certificate:

- ▪ Choose the **Certificate** item and choose the **Select** button.
- ▪ On the **Remote certificate** screen, choose the **Request** button.
- ▪ Wait until the certificate information is displayed.
- ▪ Choose the **Back** button.

🛈 New and repaired analyzers are delivered with a pre-installed certificate.
If a PIN is required for subsequent certificate requests, contact your Roche representative and provide the RUDI of the analyzer.

➔ The **Installed** value is displayed for the **Certificate** item.

6 Choose the **Gateway** item and choose the **Select** button.

7 Choose the **Gateway details** item and choose the **Select** button.

8 Choose the following items, choose the **Edit** button, and enter the gateway details:

- ▪ **Server**
- ▪ **Port**
- ▪ **Timeout**

9 To test the entered gateway details, do the following:

- ▪ Choose the **Test** button.
- ▪ Choose the **Confirm** button.

10 Choose the **Save** button.

11 Choose the **Back** button.

➔ On the **Remote service** screen, the **Entered** value is displayed for the **Gateway** item and the **Configured** value for the **Status** item.
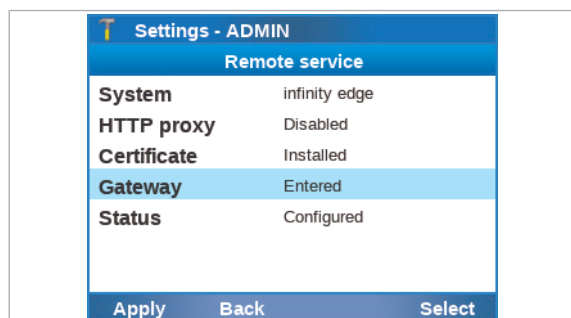
12 Choose the **Apply** button.
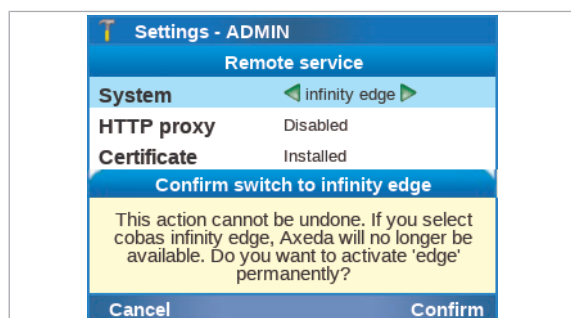
13 Choose the **Confirm** button.

   ⓘ If you confirm the connection to **cobas® infinity** edge smart here, you can only change back to Axeda by resetting the system settings to the default values.

14 Wait until the **Registered** value is displayed for the **Status** item.

   → The analyzer is connected to **cobas® infinity** edge smart as remote service.

▸▤ **Related topics**

- Installing or updating an assay from the remote service (117)
- Updating the software (168)

Checking the status of the cobas® infinity edge smart connection

If the analyzer is connected to **cobas® infinity** edge smart as the remote service, you can check the details of the connection status.

The following table lists the information that is displayed on the **Status** screen:

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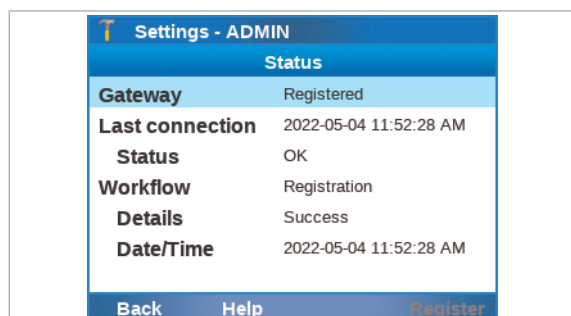
Status information item	Comment
Gateway	Indicates the configuration status of the connection to **cobas® infinity** edge smart. Possible values: ▪ **Configured** ▪ **Registering...** ▪ **Registered**
Last connection	Indicates the date and time, and the status of the last connection to **cobas® infinity** edge smart. Possible values for the **Status** item: ▪ **OK** ▪ **Communication error** Generally, the status of the last period inquiry is listed here.
Workflow	Indicates the type, status, and date and time of the last workflow with **cobas® infinity** edge smart. The last periodic inquiry is not listed here as workflow, but in the **Last connection** item. Possible values of the **Workflow** item: ▪ **Registration** ▪ **SW download** ▪ **Data upload** Possible values of the **Details** item: ▪ **Success** ▪ **Workflow error** ▪ **HTTP error** ▪ **Communication error**

⊞ Status information items for **cobas® infinity** edge smart connection

☐ Analyzer connected to **cobas® infinity** edge smart

☐ Supervisor user role or administrator user role

▸ **To check the cobas® infinity edge smart connection status**

1 From the **Main** screen, choose **Settings > Connections > Remote service**. Choose the **Select** button.

2 Choose the **Status** item and choose the **Select** button.

→ The **Status** screen displays information about the gateway status, the last connection, and the last workflow.

3 If there is a connection or workflow error, force a registration workflow to **cobas® infinity** edge smart as described in .

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Forcing a registration workflow to cobas® infinity edge smart

If the analyzer is connected to **cobas® infinity** edge smart as the remote service and there is a connection or workflow error, force the analyzer to perform a registration workflow to **cobas® infinity** edge smart.

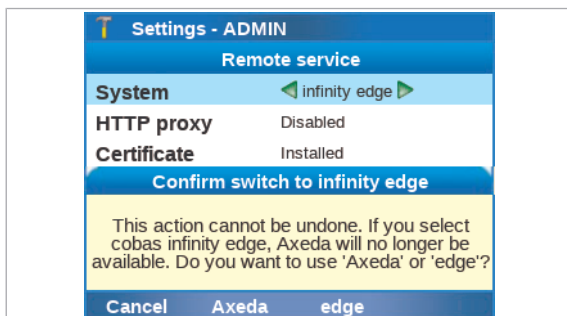🕐   Time required for registering in **cobas® infinity** edge smart:
up to 10 minutes

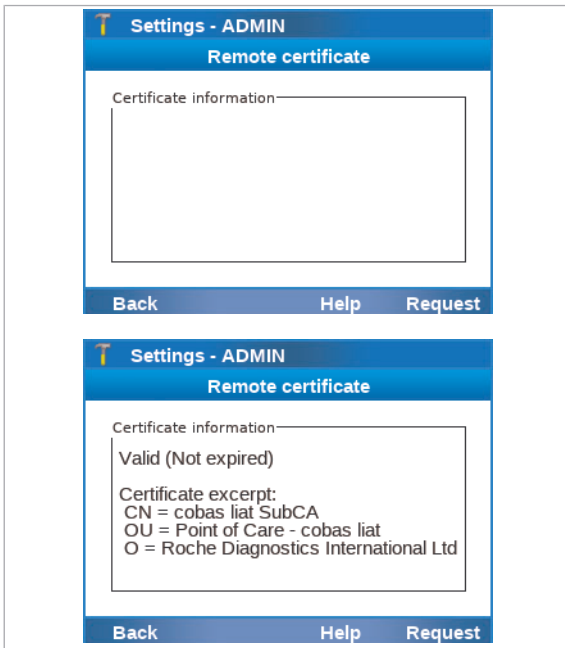🗒   ☐ Supervisor user role or administrator user role
☐ Error displayed on **Status** screen

▸ **To force a registration workflow to the cobas® infinity edge smart**

1   From the **Main** screen, choose **Settings > Connections > Remote service**. Choose the **Select** button.

2   Choose the **Status** item and choose the **Select** button.

→   The **Status** screen displays information about the gateway status, the last connection, and the last workflow.

3   Choose the **Register** button.

4   Choose the **Confirm** button.

→   The analyzer registers again with **cobas® infinity** edge smart.
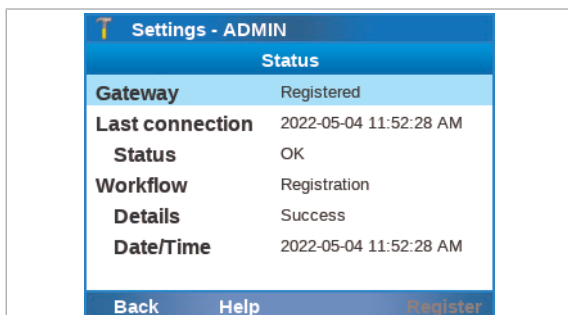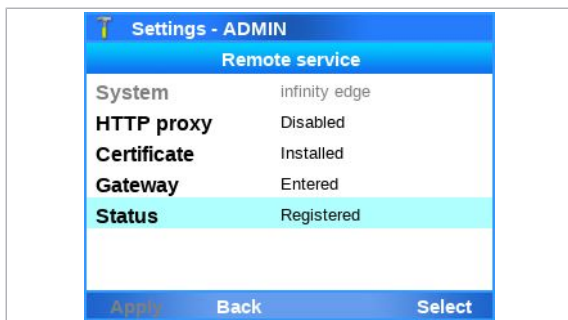
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Proxy server configuration

In this section

Configuration items for proxy server

If the internet access for the analyzer (for its connection to a remote service) is managed via a proxy server, the configuration items in the **Remote service** screen determine the connection to the proxy server.

➔ **Settings > Connections > Remote service > HTTP proxy**
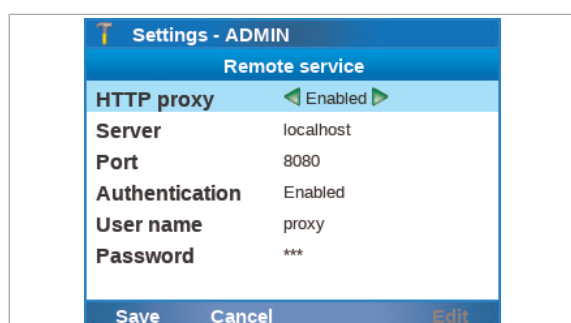
The proxy settings only apply to the analyzer's connection to a remote service via internet. The proxy settings do not apply to any other connections (e.g., network, host, share locations).

In case of Axeda, all traffic between the analyzer and the remote service is directed through the configured proxy server.

In case of **cobas® infinity** edge smart, only the certificate-related traffic is directed through the configured proxy server. All other traffic is not directed through the configured proxy server.

Contact your local network administrator for the proxy-specific settings.

-ᗑ- As a security measure, use a dedicated account on your proxy server for the analyzer.

HTTP proxy configuration item	Comment
HTTP proxy	Enable for access to the remote service if a proxy server handles the internet access. Disabled by default.
Server	Host name or IP address of the proxy server. Examples: ▪ proxy-server.mylab.com ▪ 192.168.1.33

⊞ **HTTP proxy** configuration items

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HTTP proxy configuration item	Comment
Port	Port of the proxy server.
Authentication	Enable for mandatory user authentication for connection to the proxy server.
	If you enable authentication for the proxy server, the **User name** item and the **Password** item are mandatory.
User name	User name of the analyzer-specific account on the server that is providing authentication.
Password	Password of the analyzer-specific account on the server that is providing authentication.

⊞ **HTTP proxy** configuration items

About data exchange via proxy server

If Axeda is configured as the remote service, all data is exchanged between the analyzer and Axeda via the proxy server.

If **cobas® infinity** edge smart is configured as the remote service, only the analyzer's certificate requests and responses are exchanged via the proxy server. All other data is exchanged directly between the analyzer and **cobas® infinity** edge smart.

▸ **Related topics**
- Installing or updating an assay from the remote service (117)
- Updating the software (168)

Configuring a proxy server

If the internet access for the analyzer (for its connection to a remote service) is managed via a proxy server, you must configure the proxy server on the analyzer.

Contact your local network administrator for the proxy-specific settings.

☀ The configured proxy server is only for the connection of the analyzer to a remote service via internet.

☐ Analyzer connected to the network
☐ Server-specific settings
☐ Optional: user name and password of the analyzer-specific account on the server
☐ Supervisor user role or administrator user role

8 Connectivity

▶ To enable a proxy server on the analyzer

1 From the **Main** screen, choose **Settings > Connections > Remote service**. Choose the **Select** button.

2 Choose the **HTTP proxy** item and change it to the **Enabled** value.

3 Choose the **Server** item and the **Port** item and enter the settings for the proxy server.

  ⓘ Contact your local network administrator for the server-specific settings.

4 Optionally, if user authentication is required for connection to the proxy server, do the following:

  ▪ Choose the **Authentication** item and change it to the **Enabled** value.

  ▪ Choose the **User name** item and the **Password** item and enter the required information.

5 Choose the **Save** button.

▶ To disable a proxy server on the analyzer

1 From the **Main** screen, choose **Settings > Connections > Remote service**. Choose the **Select** button.

2 Choose the **HTTP proxy** item and change it to the **Disabled** value.

3 Choose the **Save** button.

⯈🗐 **Related topics**

  ▪ Installing or updating an assay from the remote service (117)

  ▪ Updating the software (168)

  ▪ Configuration items for proxy server (233)

8 Connectivity

Connecting to a host system

About host connections

You can connect the analyzer to a host.

The analyzer can connect to hosts using the following 2 protocols:

- DML: It is used to connect to DMS.
  This communication supports the transfer of:
  - Analyzer status
  - Analyzer settings
  - Users
  - Patient information (if patient verification is enabled)
  - Results (valid and invalid)
  - Ct values for detected target results
  - Information about aborted runs
  - QC data
  - Validated lots
  - Errors, warnings and information messages
- HL7: It is used to connect to LIS, HIS, or CIS.
  Using this protocol, the analyzer can send the following:
  - Results (valid and invalid)
  - Ct values for detected target results
  - Information about aborted runs

8 Connectivity

–   QC data

> ☀ Communication using the DML protocol is also known as the *POC workflow*. Communication using the HL7 protocol is also known as the *Lab workflow*.

Host connections configuration items

With the administrator user role, you can access the **Settings** screen of the analyzer and configure the host connections items.

➔   **Settings > Connections > Host**
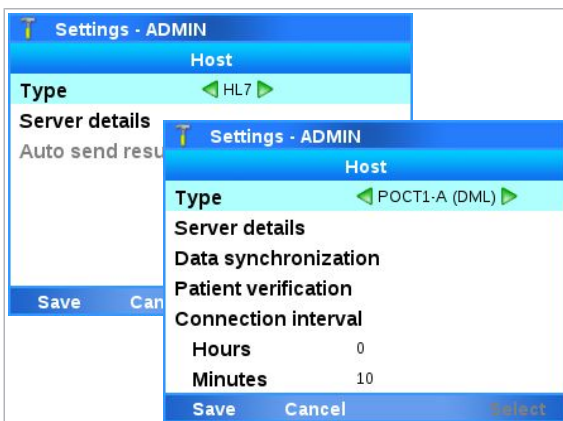
The device initiates all communications. You should choose the items that are relevant for the communication. The following table lists the items required to connect to a DMS or LIS. Most of the connections items are common.

Host configuration item	Applies to	Description
Type	-	Choose:
		▪ **POCT1-A (DML)**. Choose this value to enable the host connection using the DML protocol.
		▪ **HL7**. Choose this value to enable the host connection using the HL7 protocol.
		▪ **None**. Choose this value to disable the host connection.
Server details > Server	DML and HL7	Host IP address (e.g., 192.168.10.69) or the host name (e.g., LISHOST or host.customer.net).
Server details > Port	DML and HL7	Port on which the DML or HL7 application is accessible on the host.
		☀ For information about the host address and port, contact your network administrator.

▦   **Host** connections configuration items

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Host configuration item	Applies to	Description
Server details > Timeout	DML and HL7	Application timeout (in seconds) used by all participants during a conversation.
		If the analyzer is connected to a DMS and patient verification is enabled, the analyzer waits the configured timeout for verification of the scanned ID barcode. To prevent a long waiting time in case of connection problems, it is recommended to use the shortest timeout that is compatible with your network performance.
Server details > TLS encryption	DML and HL7	Defines whether TLS encryption is used for the communication or not.
Server details > Configure secure communication	DML and HL7	When TLS encryption is enabled, the administrator must trust the host certificate on this screen.
Auto send results	HL7	Read-only configuration items (always enabled).
Data synchronization > Auto send	DML	Released results (valid and invalid, including the Ct values for detected target results) are always automatically sent to the host.
		If automatic release of results is enabled on the analyzer, results are automatically released and sent at the end of a run.
		▸ System settings (133)
		-ᗅ- For more information about the **Auto send results** item and the **Auto send** item, consult the **cobas**® Liat® Analyzer Host Interface Manuals.
Data synchronization	DML	Chooses which data topics can be exchanged with a DMS. You can enable or disable the following topics:
		▪ **Users**
		▪ **Assay lots**
		▪ **Device configuration**
		▪ **Log events** (**Information** and **Warnings/Errors**)
Patient verification	DML	Configures patient verification on the analyzer. You can configure the following items:
		▪ **Verification**
		▪ **Verification type**
		▪ **ID mismatch**
		▪ **Displayed data**
		▪ **Manual confirm.**
		▸ Patient verification (247)
Connection interval	DML	Defines the interval (in hours and minutes) for periodically connecting to the DMS, i.e., time between data synchronizations.
		-ᗅ- To keep the analyzer and a connected DMS synchronized, set the connection interval as short as your network performance allows.

⊞ **Host** connections configuration items

8 Connectivity

About security

The analyzer can establish a secure connection with hosts that support the Transport Layer Security (TLS) protocol version 1.2.

With administrator user role, you can access the **Server details** screen (**Settings > Connections > Host**) and enable or disable TLS.

> ☀ TLS is enabled by default, but it is not mandatory.

Earlier versions of TLS than 1.2 are rejected by the analyzer. Before being called TLS, this protocol was known as SSL.

Connecting the analyzer to a host system

The **Type** item in the **Host** screen determines whether the analyzer connects to the host via the DML or HL7 protocol. It is also possible to disable all analyzer communications by setting this item to the **None** value.

Depending on the chosen value, the **Host** screen changes the items available for configuration.

☑ □ Analyzer connected to the network
□ Configuration information for the host system
□ Administrator user role or supervisor user role
□ For a secure connection using TLS:
  Host server supports TLS version 1.2

▶ **To connect the analyzer to a host**

1 Choose **Settings > Connections > Host**. Choose the **Select** button.

2 Choose the **Type** item and do the following:
  ▪ To connect to a DMS, choose the **POCT1-A (DML)** value.
  ▪ To connect to a LIS, choose the **HL7** value.
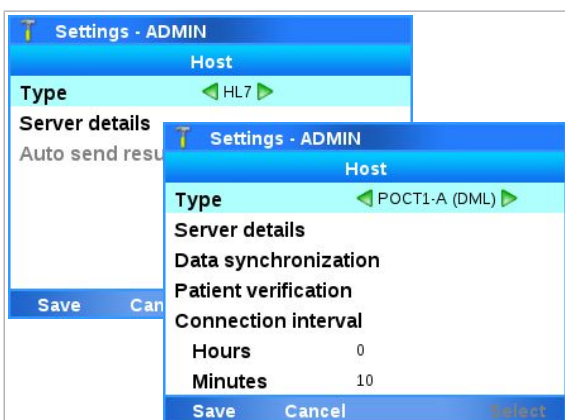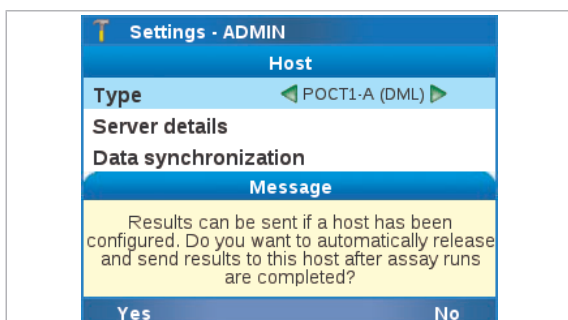
3 Choose the **Server details** item and do the following:

- ▪ Choose the **Server** item. Enter the required information and choose the **Apply** button.
- ▪ Choose the **Port** item. Enter the required information and choose the **Apply** button.
- ▪ Choose the **Timeout** item. Enter the required information and choose the **Apply** button.

4 Optionally, to enable TLS, do the following:

- ▪ For the **TLS encryption** item, keep the default **Yes** value.
- ▪ Choose the **Configure secure communication** item.
- ▪ In the **Secure communication** screen, choose the **Request** button.
- ▪ When the certificate is displayed, choose the **Trust level** item and change it to the **Trusted** value.
- ▪ Choose the **Apply** button.

  ⓘ If no certificate is displayed, the host server does not support the minimal security configuration (TLS version 1.2).
  You only need to trust the server's certificate once for every host. If the certificate or server changes, you must revalidate the certificate trust.

5 Optionally, to disable TLS, choose the **TLS encryption** item and change it to the **No** value.

6 In the **Server details** screen, choose the **Save** button.

  → The analyzer is connected to the host system.

7 Optionally for a DMS connection, in the **Host** screen, configure the **Data synchronization** item, the **Patient verification** item, and the **Connection interval** item.

  ⓘ If the analyzer is connected to a host, released results are always automatically sent to the host.

8 In the **Host** screen, choose the **Save** button.

9 If automatic release of results is disabled in **System > Result settings > Auto release**, a message is displayed. Do one of the following:

- ▪ To enable automatic release of results, choose the **Yes** button.
- ▪ To keep automatic release of results disabled, choose the **No** button.

  ⓘ Only released results are automatically sent to the host.

8 Connectivity

→ If enabled, the setting in **System > Result settings > Auto release** is automatically changed to the **Yes** value.

10 If you connected the analyzer to a DMS and enabled data synchronization, do the following:

- ▪ Log on to the analyzer.
- ▪ Log off from the analyzer again.
- ▪ Wait at least the duration of the connection interval before you log on to the analyzer again.

ⓘ Without this step, the analyzer cannot receive data, e.g., the list of users, from the DMS for the first time.

▸ **To disconnect the analyzer from the host system**

1 Choose **Settings > Connections > Host**. Choose the **Select** button.

2 Choose the **Type** item and choose the **None** value.

3 Choose the **Save** button.

→ The analyzer is disconnected from the host

▸▤ **Related topics**

- ▪ Host connections configuration items (237)
- ▪ Configuring patient verification (251)
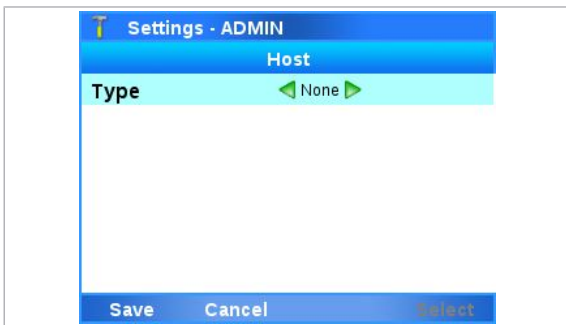
Monitoring host connection

The analyzer provides a way to monitor the connection status in the graphical user interface.

When a connection to a host system is taking place, you can see the following icons in the upper right hand corner of the screen:

Icon	Description
	The connection between the analyzer and the host is configured, but is not currently active.
	There is an active connection between the analyzer and the host, but data is not currently being transferred.
	There is an active connection between the analyzer and the host and data is currently being transferred.

⊞ Connection status icons
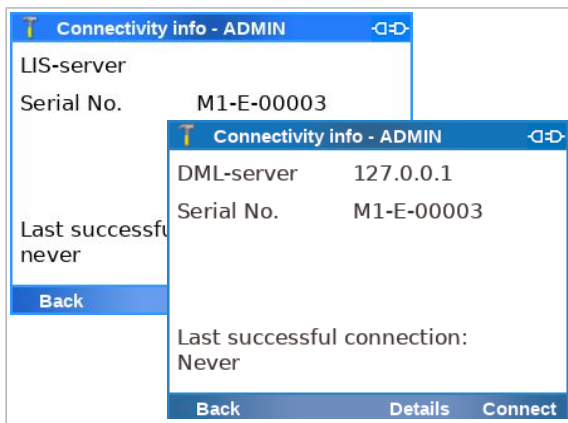
The analyzer does not constantly connect to the host. The connection occurs in the following instances:

- During the configured intervals (when connected to the DMS)
- When transmitting results (when connected to the DMS or LIS)
- When verifying patient information (when connected to the DMS)
- When the analyzer is started (either initially or after the daily restart when connected to the DMS)

To display information about the last connection to the host system, choose the connection status icon in the upper right hand corner of the screen.

If the analyzer is connected to a DMS, you can also force a connection and view the details of the last synchronization via the connection status icon.

- To force a connection to the DMS (242)
- To view details of the last synchronization with a DMS (247)

Forcing a connection to the DMS

You can force a connection to the DMS.

When you force a connection, the data on the analyzer and on the DMS is checked if in sync. If not, the analyzer exchanges data with the DMS depending on analyzer configuration, analyzer status, and the screen that is currently displayed on the analyzer.

- About data exchange with a DMS (243)
- Viewing details of the last synchronization with a DMS (246)

▶ To force a connection to the DMS

1 On the walk-by screen or the **Log on** screen, choose the connection status icon in the upper right hand corner of the screen.

- ℹ️ If you force the connection from another screen, the analyzer will reject data from the DMS if the analyzer and the DMS are not in sync.
- → The **Connectivity info** screen is displayed.

8 Connectivity
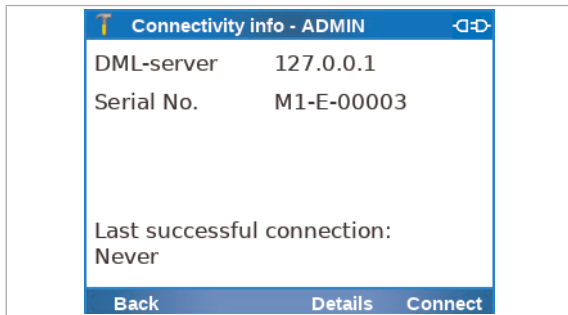
2 Choose the **Connect** button.

→ The analyzer attempts to connect to the DMS. Progress is displayed on the screen.

→ If the connection is successful, the analyzer and the DMS are synchronized depending on analyzer configuration, analyzer status, and the screen that is currently displayed on the analyzer.

Related topics

- Monitoring host connection (241)

About data exchange with a DMS

The connection to a data management system (DMS) and enabled data synchronization influence the functionality of the analyzer.

💡 Connecting to a laboratory information system (LIS) does not change the functionality of the analyzer.
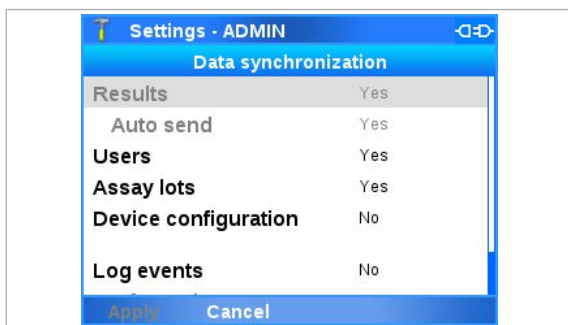
If the analyzer is connected to a DMS and data synchronization is enabled, some functions on the analyzer are overwritten by the DMS and disabled on the analyzer. The following functions are affected:

Function	Change
Automatic locking	Some data received from the DMS (i.e., users, assay tube lots, and device configuration) can only be applied while the analyzer is locked or no user is logged on. While such data is received and applied, you cannot unlock the analyzer.
Results review	If the analyzer releases results automatically, they are directly sent to a DMS or HL7 host. You cannot review results on the analyzer.

▦ Analyzer functions affected by the DMS connection

Function	Change
User management	If the analyzer exchanges user data with a DMS, user management is disabled on the analyzer.
	You cannot delete the default administrator account ADMIN from the analyzer via a DMS. This does not apply to all other user accounts with administrator user role.
	After you installed the analyzer and connected it to a DMS, do the following to enable the analyzer to receive user data for the first time:
	1. Shut down and restart the analyzer.
	2. Log on to the analyzer.
	3. Log off again from the analyzer.
	4. Wait at least the duration of the connection interval before you log on to the analyzer again. Alternatively, force a connection to the DMS.
	⊦▤ Overview of accepted data for different analyzer statuses (245)
	⠃ To enable access to the analyzer, the user IDs and passwords defined on the DMS must comply with the rules that apply on the analyzer. ⊦▤ About user IDs and passwords (149)
Lot management	You can share assay tube lots between analyzers if the exchange of assay tube lots is enabled.
	If assay tube lots are exchanged with the DMS, you cannot delete assay tube lots on the analyzer.
Analyzer settings	If the analyzer accepts system settings from the DMS, the received settings override local settings. Local changes of the settings are only effective as long they are not overwritten from the DMS.
	Network settings cannot be overwritten from the DMS.
Event logs	If configured, the analyzer sends events to the connected DMS.
Changing your password	If the analyzer exchanges user data with a DMS, users can only change their passwords based on a request from the DMS.
	When requested by the DMS, you must change your password at logon.
	In this case, the analyzer expects a password, regardless of the logon mode setting on the analyzer.
	⠃ To prevent logon problems, ensure that the password complies with the rules for passwords on both the analyzer and the DMS. ⊦▤ About user IDs and passwords (149)
Changing your badge barcode	If the analyzer exchanges user data with a DMS, users cannot assign or change their badge barcodes directly on the analyzer.
	⠃ A DMS may not support a separate badge barcode, but a user ID only. In this case, do not configure a logon mode on the analyzer that uses a badge barcode.

⊞ Analyzer functions affected by the DMS connection

About the timing of communications

The analyzer exchanges data with the DMS in the following instances:

- ▪ Periodically, each connection interval.

- ▪ When the status of the analyzer changes.
- ▪ When results are released or sent.
- ▪ After startup of the analyzer.
- ▪ When you force a connection to the DMS on the **Connectivity info** screen.

Exchanging of data may be limited after a restart:

- ▪ It is not possible to exchange results and **Users** until a user has logged on. Results and **Users** may continue to be exchanged after the user logs off.
- ▪ **Assay lots**, **Device configuration**, **Log events** (**Information** and **Warnings/Errors**) can be exchanged before a user has logged on.

⯈🗐 Overview of accepted data for different analyzer statuses (245)

Overview of accepted data for different analyzer statuses

The analyzer accepts or rejects data received from the DMS depending on the analyzer status and displayed screen.

Received data	Analyzer status	Displayed screen	Analyzer action
Device configuration	Standby	**Log on**	Accept
		Walk-by	Accept
	Ready	Any screen other than **Log on** or walk-by, that does not show the progress of an activity (e.g., run assay, software update)	Reject
	Partial lock	Any screen other than **Log on** or walk-by, that does not show the progress of an activity (e.g., run assay, software update)	Reject
	Busy	Any screen other than **Log on** or walk-by, that shows the progress of an activity (e.g., run assay, software update)	Reject
	Locked	**Log on**	Accept
		Walk-by	Accept
		All other screens	Reject
Users	Standby	**Log on**	Reject
		Walk-by	Accept
	Ready	Any screen other than **Log on** or walk-by, that does not show the progress of an activity (e.g., run assay, software update)	Reject
	Partial lock	Any screen other than **Log on** or walk-by, that does not show the progress of an activity (e.g., run assay, software update)	Reject
	Busy	Any screen other than **Log on** or walk-by, that shows the progress of an activity (e.g., run assay, software update)	Reject
	Locked	**Log on**	Reject
		Walk-by	Accept
		All other screens	Reject

⊞ Overview of accepted data for different analyzer statuses
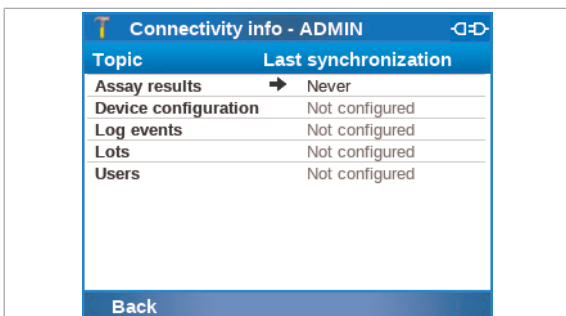
Received data	Analyzer status	Displayed screen	Analyzer action
Assay lots	Standby	**Log on**	Accept
		Walk-by	Accept
	Ready	Any screen other than **Log on** or walk-by, that does not show the progress of an activity (e.g., run assay, software update)	Reject
	Partial lock	Any screen other than **Log on** or walk-by, that does not show the progress of an activity (e.g., run assay, software update)	Reject
	Busy	Any screen other than **Log on** or walk-by, that shows the progress of an activity (e.g., run assay, software update)	Reject
	Locked	**Log on**	Accept
		Walk-by	Accept
		All other screens	Reject

⊞ Overview of accepted data for different analyzer statuses

Viewing details of the last synchronization with a DMS

You can view the details of the last synchronization with the DMS.

The synchronization status of each of the exchanged data topics (users, results, etc.) is displayed:

▪ If a synchronization has not yet occurred, **Never** is displayed.

▪ At a displayed time stamp, the analyzer and the DMS were in sync:

– The analyzer and the DMS were checked to be in sync at the displayed date and time.

– Only if the analyzer and the DMS were found to be out of sync, the data topic was then exchanged at the displayed date and time.

▪ If a data topic is not configured for exchange with the DMS, **Not configured** is displayed.
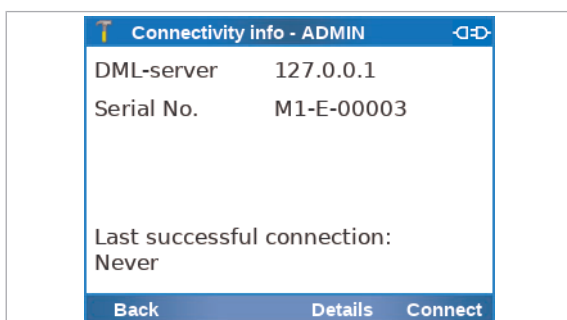
8 Connectivity

▶ To view details of the last synchronization with a DMS

1 Choose the connection status icon in the upper right corner of the screen.

ⓘ The connection status icon is available on each screen.

→ The **Connectivity info** screen is displayed.

2 Choose the **Details** button.

→ Information about the last synchronization is displayed.

▣ **Related topics**

- Monitoring host connection (241)

Patient verification

In this section

About patient verification (247)

Configuration items for patient verification (250)

Configuring patient verification (251)

About patient verification

If the analyzer is connected to a DMS and patient verification is configured, the analyzer sends the scanned IDs to the DMS for verification of the patient information.

8 Connectivity

About running an assay with patient verification
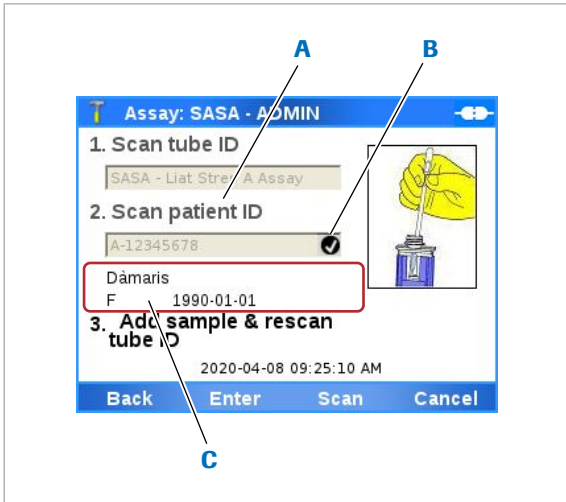
A ID configured as verification type

B Patient verification status

C Displayed patient information (if configured)

Patient verification changes the appearance of the **Assay** screen when running an assay:

- The analyzer prompts you to scan the ID configured as verification type.
- The status of patient verification is indicated by an icon.
- If configured, the patient information is displayed after successful patient verification.
  The patient information is not stored on the analyzer, but temporarily displayed only.

Patient verification does not affect the runs for validating assay tube lots or for additional QC.

If patient verification takes too long (e.g., due to network performance) you can cancel the patient verification. The next step in the assay run then depends on the analyzer configuration and your user role.

- About ID mismatch (249)
- Running an assay (95)

About patient verification status

Patient verification can have the following status, displayed on the **Assay** screen:

Icon	Description
✓	- Patient verification successful.
✕ (yellow)	- Patient verification failed. - Failed patient verification can be overruled. - Assay run can be continued without successful patient verification.
✕ (red)	- Patient verification failed. - Failed patient verification cannot be overruled. - Assay run can only be continued after successful patient verification.

⊞ Patient verification status icons

Failed patient verification is logged in an audit trail entry.

Patient verification can fail for the following reasons:
▪ The entered ID does not exist on the host.
▪ The configured timeout is too short for your network performance.
▪ The connection to the host system is lost.

If patient verification fails even if you enter an existing ID, configure a longer timeout and check the host connection. If the problem persists, contact your local network administrator.

‣🗐 Host connections configuration items (237)

‣🗐 Monitoring host connection (241)

About ID mismatch

The **ID mismatch** configuration item and your user role determine if you can continue the assay run if patient verification fails:
▪ **Run allowed** value:
  You can overrule the failed patient verification and continue with the assay run.
  Overruling a failed patient verification is logged in an audit trail entry.
▪ **Run not allowed** value:
  It depends on your user role if you can continue the assay run:
  – With user user role, you cannot overrule the failed patient verification. You must provide an existing ID to continue the assay run.
  – With supervisor user role or higher, you can overrule the failed patient verification and continue with the assay run.

About results with patient verification
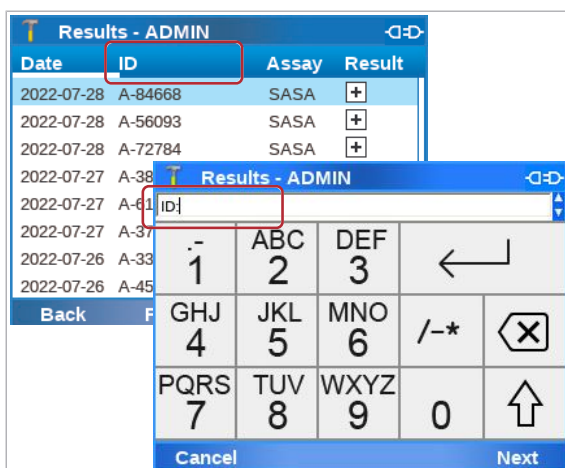
If patient verification is configured, rows and columns displaying ID data have an **ID** label instead of a **Sample ID** label on the **Results** screen and in the result filters.

If patient verification is configured, on the **Result report** screen, both the scanned ID (sample ID, patient ID, order ID, or visit ID) and the received patient ID are displayed.

The scanned ID, the outcome of the patient verification (success, fail), the received patient ID (if patient verification successful), and the action taken by the user if patient verification failed (cancel, retry, overrule patient verification) are part of the results that are transferred to the DMS.

A Scanned ID   **B** Received patient ID

Configuration items for patient verification

The configuration items in the **Patient verification** screen determine the use of patient verification if the analyzer is connected to a DMS.

➔   **Settings > Connections > Host > Patient verification**
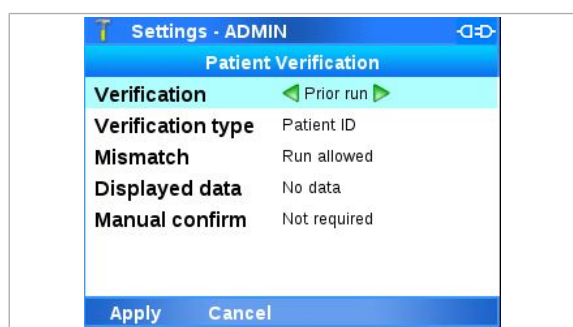
Configuring patient verification is part of the host connections configuration for the DML protocol.

Patient verification item	Configuration item	Comment
Verification	▪ **No verification** ▪ **Prior run**	Choose to enable/disable patient verification.
Verification type	▪ **Patient ID** ▪ **Sample ID** ▪ **Order ID** ▪ **Visit ID**	Choose the type of ID used on samples. When running an assay, on the **Assay** screen, the analyzer prompts you to scan the configured ID barcode. The ID is then verified with the DMS.
ID mismatch	▪ **Run allowed** ▪ **Run not allowed**	Choose if you can continue the assay run if patient verification fails. ⯈▤ About ID mismatch (249)
Displayed data	▪ **No data** ▪ **Name** ▪ **Name, sex, DOB**	Choose the patient information displayed on the analyzer screen after successful patient verification.

⊞   **Patient verification** configuration items

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Patient verification item	Configuration item	Comment
Manual confirm.	▪ **Not required** ▪ **Required**	If manual confirmation is required, you must confirm the patient information received from the DMS before you can continue with the assay run.

⊞ **Patient verification** configuration items

⯈ ▤ Host connections configuration items (237)

⯈ ▤ Configuring patient verification (251)

Configuring patient verification

If the analyzer is connected to a DMS, you can configure patient verification.

If patient verification is configured, the display of information when performing an assay run will be affected.

⯈ ▤ Running an assay (95)

⯈ ▤ Result handling (102)

⯈ ▤ Configuration items for patient verification (250)

☐ Analyzer connected to a host system via DML protocol

☐ Supervisor user role or administrator user role

⯈ To configure patient verification

1 From the **Main** screen, choose **Settings > Connections > Host > Patient verification**. Choose the **Select** button.

2 To enable patient verification, choose the **Verification** item and choose the **Prior run** value.
   → The other patient verification items are displayed and can be changed.

3 To set the type of ID used on samples, choose the **Verification type** item and choose a value:
   ▪ **Sample ID**
   ▪ **Patient ID**
   ▪ **Order ID**
   ▪ **Visit ID**

4 To set the workflow if patient verification fails, choose the **ID mismatch** item and choose a value:
   ▪ **Run allowed**
   ▪ **Run not allowed**

5 To set the patient information displayed on the analyzer screen after successful patient verification, choose the **Displayed data** item and choose a value:
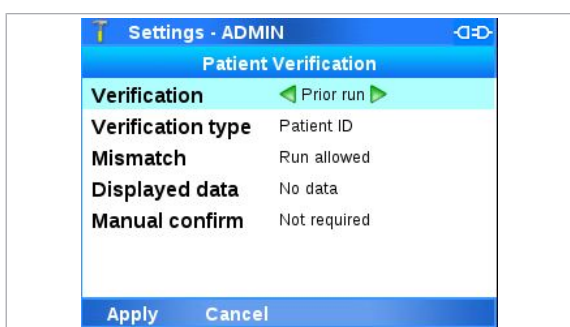
- No data
- Name
- Name, sex, DOB

6 To set the manual confirmation requirement, choose the **Manual confirm.** item and choose a value:

- Not required
- Required

7 Choose the **Apply** button.

8 In the **Host** screen, choose the **Save** button.

Share locations configuration

Share locations are folders on your network, i.e., network resources.

You can define the following share locations on the analyzer:

- 1 share lot folder
- 3 network shares
- 3 FTP shares

> ☀ The network shares use the SMBv2.1 or higher network protocol.

Configure the share lot folder to share the following between analyzers:

- Assay tube lots
- Used assay tubes

The share lot folder is also used as a shared repository for result reports.

Configure the network shares and/or FTP shares for the following tasks:

- Installing new assays
- Archiving data
- Storing problem reports

You need supervisor user role or administrator user role to define share locations.

Before you can define share locations, the analyzer must be connected to the network.

In this section

Configuration items for share locations

The configuration items in the **Share locations** screen configure the access to the share locations.

8 Connectivity
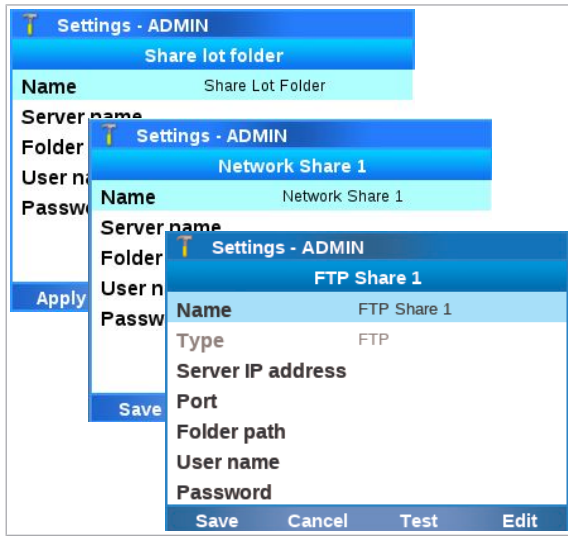
➔ **Settings > Share locations**

Before you can define share locations, obtain the following information:

☐ Folder path for the share location

☐ Server name (IP address if you intend to use FTP)

☐ User name and password for the specific account

> 💡 As a security measure, use a dedicated account on your server for the analyzer.

For the FTP shares, you can only use IP addresses. For the network shares, you can use IP addresses or host names.

You can define the following configuration items for the share locations:

Share location item	Configuration item	Comment
Share lot folder	**Use share lot**	▪ To enable the share lot folder, choose the **Yes** value.
		▪ To disable the share lot folder again, choose the **No** value.
	Name	Name of the share lot folder (not configurable).
	Server name	URI of the share lot server.
		If DNS resolution is not possible, the server name may not work. Try the IP address of the share lot server instead.
	Folder path	Enter the full path using the syntax of the server.
	User name	User name of the analyzer-specific account on server.
	Password	Password of the analyzer-specific account on server.
Network share {0} (with {0} = 1 to 3)	**Name**	Name of the network share.
	Server name	URI of the network share server.
		If DNS resolution is not possible, the server name may not work. Try the IP address of the network share server instead.
	Folder path	Enter the full path using the syntax of the server.
	User name	User name of the analyzer-specific account on server.
	Password	Password of the analyzer-specific account on server.
FTP share {0} (with {0} = 1 to 3)	**Name**	Name of the FTP share.
	Type	FTP or secure FTP.
		Read-only configuration item that is displayed automatically.
	Server IP address	IP address of the FTP server.
	Port	Port on which the FTP share is accessible.
	Folder path	Enter the full path using the syntax of the server.
	User name	User name of the analyzer-specific account on server.
	Password	Password of the analyzer-specific account on server. When you configure a user name for the FTP share, the **Password** item is mandatory.

⊞ Configuration items for share locations

8 Connectivity

Using the share lot folder

The share lot folder makes certain information accessible for all analyzers connected to it.

When configuring the share lot folder, you can share the following information between analyzers connected to the same share lot folder:

▪ Assay tube lots
 If a lot is validated on one analyzer, the lot is available for other analyzers as well and does not need to be validated on several analyzers.

▪ Used tubes
 The share lot folder stores the information about the used tubes. This information is available for other analyzers as well.

The information stored in the share lot folder is included if you archive, export, and/or import assay tube lots using the Advanced Tools from the **Tools** screen.

When using the share lot folder, consider the following information:

▪ You can only share the information that was generated on the analyzer after the share lot folder was enabled. For example, if a lot is validated and you enable the share lot folder afterwards, the lot is not available for the rest of the analyzers connected to the share lot folder.

▪ Lot management using the share lot folder and lot management using a DMS are mutually exclusive.

Share lot folder connection status

If the share lot folder is enabled, the share lot icon in the title bar of the touch screen indicates the connection status:

Icon	Description
LOT	Connected and synchronized
LOT	Disconnected

▦ Connection status of share lot folder

Configuring the share lot folder

Configure the share lot folder to share assay tube lots and used assay tubes.

☐ Analyzer connected to the network.

☐ Server details for the share lot folder.

☐ Supervisor user role or administrator user role.

▶ To configure the share lot folder

1 Before you change the configuration, export the assay tube lots as described in Exporting and importing assay tube lots (197).

2 Choose **Settings > Share locations > Share lot folder**. Choose the **Select** button.

3 Set the **Use share lot** item to the **Yes** value. Choose the **Server details** item.

Settings - ADMIN
Share lot folder
Use share lot   ◀ Yes ▶
Server details   Not configured

Save   Cancel   Select

Settings - ADMIN
Share lot folder
Name   Share Lot Folder
Server name
Folder path
User name
Password

Apply   Cancel   Test   Edit
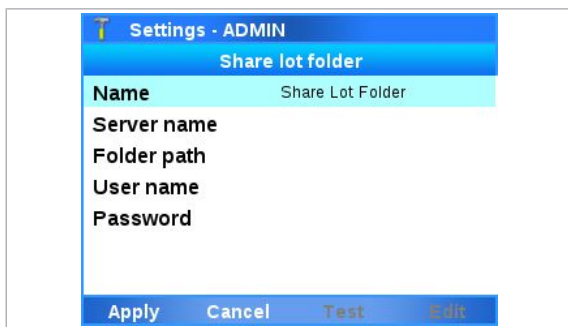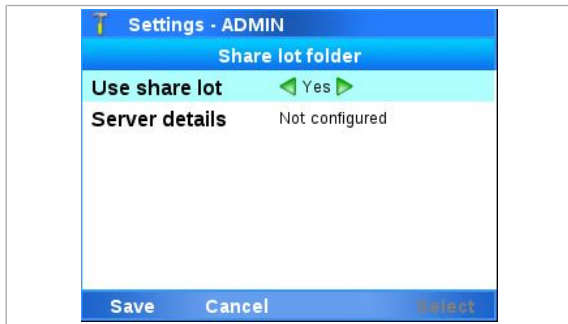
4 For the **Server name** item, **Folder path** item, **User name** item, and **Password** item, do the following:
- Choose the item.
- Enter the server details for the share lot folder.
- Choose the **Apply** button

  ⓘ If the server name does not work, try the IP address of the share lot server.

5 Optionally, to test the connection to the share lot folder, choose the **Test** button.

6 Choose the **Apply** button. Choose the **Save** button.
   ➔ In the title bar, [⚷ LOT] is displayed.

Assay Menu - ADMIN   ⚷ LOT
Assay Lot   Validated Expiration Days left
SASA 20126A 2012-01-26 2053-09-30 0
[New Lot]
[New Assay]

Main   Print   Delete   Select
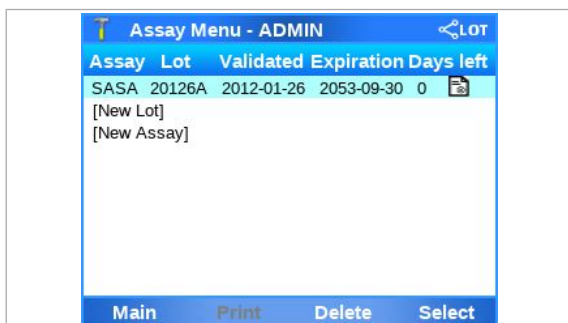
7 On the **Main** screen, choose the **Assay Menu** item and choose the **Select** button. Review the installed assays and available assay tube lots.

8 Import the assay tube lots as described in Exporting and importing assay tube lots (197).

▶ To disable the share lot folder

1 Before you change the configuration, export the assay tube lots as described in Exporting and importing assay tube lots (197).

2 Choose **Settings > Share locations > Share lot folder**. Choose the **Select** button.

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3 Choose the **Use share lot** item and choose the **No** value.

4 Choose the **Save** button.
  → The share lot folder is disabled.
  → In the title bar, ⚹**LOT** is no longer displayed.
  → The server details are kept and the share lot folder can be enabled again without entering the server details again.

5 On the **Main** screen, choose the **Assay Menu** item and choose the **Select** button. Review the installed assays and available assay tube lots.

6 Import the assay tube lots as described in Exporting and importing assay tube lots (197).
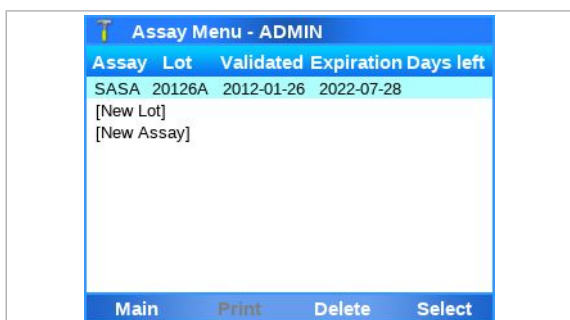
⯈▤ **Related topics**
  ▪ Configuration items for share locations (253)

Configuring network shares

Configure network shares to use them as source location for installing new assays and as storage location for archived data and problem reports.

You can define up to 3 network shares.

☑▤ □ Analyzer connected to the network.
  □ Configuration information for the network shares.
  □ Supervisor user role or administrator user role.

⯈ **To configure a network share**

1 Choose **Settings > Share locations > Network share {0}** (with {0} = 1 to 3). Choose the **Select** button.

2 Optionally, choose the **Name** item and enter a different name for the network share. Choose the **Apply** button.

3 For the **Server name** item, **Folder path** item, **User name** item, and **Password** item, do the following:
  ▪ Choose the item.
  ▪ Enter the information for the network share.
  ▪ Choose the **Apply** button.

8 Connectivity

4 Optionally, to test the connection to the network share, choose the **Test** button.

5 Choose the **Save** button.

≀ **Related topics**

- Configuration items for share locations (253)

Configuring FTP shares

Configure FTP shares to use them as source location for installing new assays, and as storage location for archived data and problem reports.

You can define up to 3 FTP shares.

☐ Analyzer connected to the network.
☐ Configuration information for the FTP shares.
☐ Supervisor user role or administrator user role.

▸ **To configure a FTP share**

1 Choose **Settings > Share locations > FTP share {0}** (with {0} = 1 to 3). Choose the **Select** button.

2 Optionally, choose the **Name** item and enter a different name for the FTP share. Choose the **Apply** button.

3 For the **Server IP address** item, **Port** item, **Folder path** item, **User name** item, and **Password** item, do the following:

- Choose the item.
- Enter the information for the FTP share.
- Choose the **Apply** button.

ℹ When you configure a **User name** for the FTP share, the **Password** item is mandatory. Ensure that the configured user has write permission on the FTP share.

4 Optionally, to test the connection to the FTP share, choose the **Test** button.

ℹ A successful test of the connection only confirms that a configured user can assess the FTP share. It does not test that the configured user has write permission on the FTP share.

5 Choose the **Save** button.

≀ **Related topics**

- Configuration items for share locations (253)

8 Connectivity

Maintenance

9 Maintenance

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Quality control

Internal control   Internal Process Control (IPC) is included in every assay tube. It verifies the adequate processing of the sample.

IPC Ct values are not reported.

▸🗐 Archiving data (180)

Quality control kits   Quality control kits for each **cobas**® Liat® assay are available from Roche. The quality control kits contain positive and negative control sample materials. The process of running positive and negative controls is similar to the process for adding lots.

▸🗐 See Adding an assay tube lot (124) and refer to the **cobas**® Liat® assay package insert or the Instructions for Use for detailed instructions.

NOTICE!

Additional QC testing

Additional QC testing is not required by the manufacturer. Quality control should be run as a patient sample if additional quality control testing is performed at a site. Instructions for running quality control as patient samples are included in the package insert or the Instructions for Use of the assay.

Maintenance

A user is not required to perform any periodic or regular maintenance.

It is recommended to archive and delete results regularly.

In this section

About self-check

The analyzer performs self-diagnostics during startup (initialization) and utilizes an advanced error diagnostics system to monitor the analyzer's performance during an assay.

Under normal operation, the analyzer alerts the user if a malfunction or error is detected.

The analyzer requires no adjustment or calibration by the user.

About auto monitoring

There is an automatic daily restart programmed (at the time configured in the system settings), which helps to maintain the health of your analyzer.

After each daily restart, a message is displayed. The next daily restart (or any scheduled tasks) will only be performed after you have confirmed the message.

To ensure that the automatic daily restart of the analyzer does not interfere with any ongoing activity (e.g., assay runs, scheduled tasks, etc.), schedule the daily restart for a time when the analyzer is not frequently used.

System settings (133)

The analyzer has a built-in auto monitoring system to ensure that it is functioning optimally at all times. During monitoring, you may see informational messages displayed.
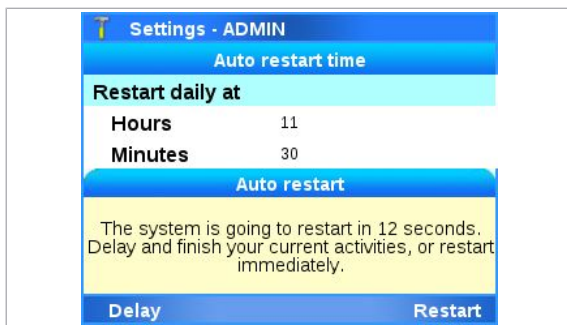
Choose the **Restart** button to start the restart process. Choose the **Delay** button to effect a 60-second delay. After 60 seconds, another notification appears and allows for a final opportunity to delay for an additional 60 seconds before automatically restarting the analyzer. Follow the on-screen instructions, and the analyzer restarts.

Related topics

- System settings (133)

About auto adjustment

The analyzer periodically performs automatic adjustment.
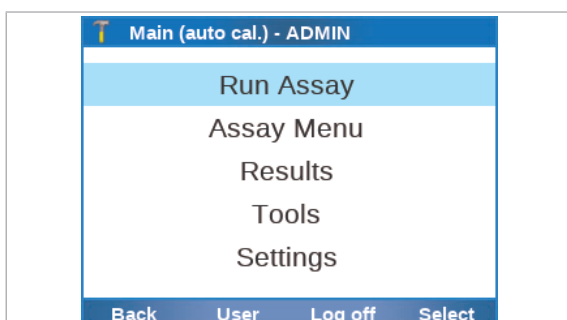
During auto adjustment, **(auto cal.)** is displayed in the title bar. If you choose the **Run Assay** item at this time, the message **Auto calibration in progress. This could take up to a minute.** is displayed. Choose the **Confirm** button to close this message. Wait until **(auto cal.)** is no longer displayed in the title bar.

About service

Contact your local Roche representative if you have questions regarding the analyzer, its service needs, or if you have other questions.

> **⚠ CAUTION!**
>
> **Electrical hazards**
>
> Only a qualified Roche representative can service the analyzer. Disassembling the analyzer could result in electrical hazards.
>
> ▸ Never attempt to repair or adjust the analyzer yourself.
>
> ▸ Contact your local Roche representative if the analyzer fails to operate properly.

Calibrating the touch screen

If you find that the analyzer activates a different item than the one you just tapped, calibrate the touch screen.

☐ Supervisor user role or administrator user role

▸ **To calibrate the touch screen**

1 Choose **Tools > Calibration > Touch screen**.

2 Choose the **Select** button.

3 Follow the instructions on the screen.

4 When calibration is complete, tap the screen to confirm the new settings or wait 30 seconds to discard the change.
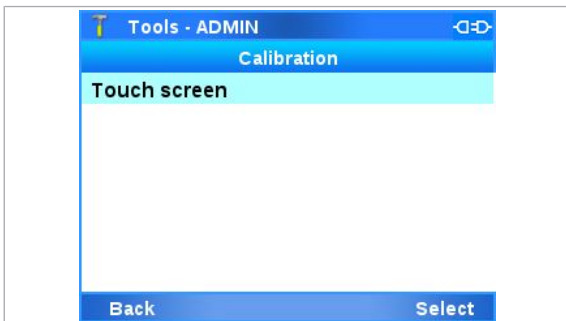
Cleaning the analyzer

▪ Keep the touch screen clean from excessive fingerprints and moisture by gently wiping it with a soft, lint-free cloth.

▪ The exterior of the analyzer and front buttons can also be cleaned using a soft lint-free cloth moistened with either 70% isopropanol or 5-10% bleach solution. If bleach is used, it must be wiped twice using 70% isopropanol to remove all bleach residues.

▪ Do not use isopropanol or bleach to regularly clean the touch screen.

▪ Periodically check the rear vent and bottom of the analyzer for excessive dust or debris.

▪ When prompted by the message "Use cleaning tool" on the screen, use the provided cleaning tool following the instructions included with the cleaning tool kit.

▪ Only clean the window of the barcode reader in case of repeated barcode reading failures. Do not use bleach to clean the window of the barcode reader.

⯈ Cleaning the window of the barcode reader (290)

Safety
⯈ Make sure that you are familiar with the safety instructions in Safety instructions (33).

⚠ CAUTION!

Electric shock

Spraying or applying liquid to the analyzer or the power supply may damage the analyzer or pose an electrical hazard.

▸ Do not spray or apply liquid directly on the analyzer or the power supply.

▸ Do not attempt to clean the interior of analyzer through the vents.

▸ To clean the tube chamber, only use the cleaning tool when prompted by the analyzer.

NOTICE!

Damage to the analyzer due to use of unsuitable cleaning materials

Using unsuitable cleaning materials can damage the touch screen and other surfaces.

▸ Only use the supplied cleaning tool when prompted by the message. Do not attempt to clean the tube chamber of the analyzer with anything other than the cleaning tool kit.

▸ Do not use harsh, abrasive cleaners or wipes.

In this section

Cleaning the outside of the analyzer (265)

Cleaning spillages or leakages from an assay tube (266)

Cleaning the outside of the analyzer

Keeping the analyzer clean prevents contamination and ensures trouble-free operation.

☐ Soft lint-free cloth

☐ For cleaning the front buttons and the exterior of the analyzer only:
70% isopropanol or 5-10% bleach solution

▶ **To clean the touch screen**

1 Wipe the touch screen gently with a soft lint-free cloth.

ⓘ Do not use isopropanol or bleach solution to regularly clean the touch screen.

▶ **To clean the front buttons and the exterior of the analyzer**

1 Moisten a lint-free cloth with either 70% isopropanol or 5-10% bleach solution.

2 Gently wipe the surfaces as required.

3 If you used bleach solution, wipe the affected areas twice with a fresh lint-free cloth moistened with 70% isopropanol to remove all bleach residues.

Cleaning spillages or leakages from an assay tube

In the unlikely event of a spillage or leak of an assay tube, special precautions apply because the tube contains various potentially biohazardous materials and hazardous chemicals.

⚠ **CAUTION!**

Contamination of cleaning tool

Do not use the cleaning tool for biohazardous contamination. The cleaning tool does not decontaminate the analyzer, but becomes contaminated itself.

▶ In case of spillages or leakages from an assay tube follow the procedure given in the User Guide.

9 Maintenance

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▸ **To deal with a leak from an assay tube**

1 Dispose of the assay tube in accordance with the disposal policy of your institution and according to local regulations.

2 If the leak happened inside the analyzer, stop using the analyzer and immediately contact your Roche representative for further instructions.

3 Follow laboratory best practices.
   ▪ Follow Good Laboratory Practice for working with biohazardous materials and hazardous chemicals.
   ▪ Refer to the appropriate assay tube Safety Data Sheet and package insert or the Instructions for Use for assay-specific information.

9 Maintenance

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Troubleshooting

10 Troubleshooting

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About troubleshooting

The analyzer monitors its operation and logs abnormal events. Based on the severity, the analyzer tries to recover or to fix the error while running. If the situation cannot be resolved, the analyzer stops.

In many situations, error messages are displayed on the screen. Read them carefully and follow the instructions provided in them.

Roche support

If you have any questions or problems, contact your Roche representative with the following analyzer information ready:

☐ Analyzer serial number.
You find it on the product label at the back or on the bottom of the analyzer. To display the analyzer serial number in the software, choose **Settings > System information**.

☐ Assay name

☐ Run number
If no run number is available, take note of the date and time when the error occurred.

☐ Error message and code (if displayed)

☐ Maintenance contract number (as applicable)

☐ System diagnostic information, using the **Create problem report** function of the **Tools** screen

▸ Configuring problem reports content (208)

For Roche Support in the U.S., call the following number: 1-800-800-5973.

List of error messages

Error messages are generated in exceptional situations. They describe the issue and provide information on how to resolve the situation.

The messages listed in the table below contain place holders that are replaced with the following information when the message is displayed on the analyzer:

- {0}
  A single digit in a curly bracket is replaced with a specific value, e.g., an alphanumeric value, a run number, a barcode, or a file name.

- Error code: (0x{0:x})
  The place holder (0x{0:x}) is replaced with a software-related, hardware-related, or firmware-related error code. Error codes are displayed in the hexadecimal system, in the range from "0xB01" to "0xBF6".
  If the error persists after the recommended action, take note of the error code and contact your Roche representative.

Message	Recommended action
{0} does not exist. No update is performed.	Contact Roche.
'{0}' is not a valid ID. ID cannot be an assay tube, insert ID, expired, or empty. Try again. Error code: (0x{1:x})	Try again with another sample ID following the guidelines for sample IDs.
{0}: update failed: {1}.	Contact Roche.
0x{0:x}: Service is not up and running:{1}	Restart the analyzer.
0x{0:x}: Unable to determine the status of the service: {1}	Restart the analyzer.
Access denied. Verify that user name and password are correct, and then try again.	Verify that the user name and password are correct, then try again. If the problem persists, contact your local network administrator
Activation code is already expired. Contact Roche to get a new activation code.	Contact Roche and request a new activation code.
Activation code is expired. Contact Roche in order to get a new activation code. Registration code: {0}	Contact Roche and request a new activation code.
Activation code is invalid.	Enter the correct activation code.
Actuators not opened. Try to restart the system.	Restart the analyzer.
An error has occurred while printing. Error code: (0x{0:x})	Ensure that the printer is switched on and connected with the analyzer. Ensure that the printer is ready to print.
An error occurred while reading the barcode. Restart the system. If the problem persists, contact Roche.	Restart the analyzer. If the problem persists, contact Roche.
An old or a corrupted settings file was detected during startup. The settings have to be checked by a supervisor. Error code: (0x{0:x})	Supervisor needs to check the settings on the analyzer.
An unexpected error has occurred and the system must be restarted. If the problem persists, contact Roche.	Restart the analyzer. If the problem persists, contact Roche.

⊞ List of error messages

Message	Recommended action
An unexpected error occurred while checking the storage space. If the error persists, contact Roche.	Restart the analyzer, archive and delete some data to free up internal storage on the analyzer. If the problem persists, contact Roche.
An unknown communication error has occurred. Contact Roche.	Contact Roche.
Analyzer has not been initialized successfully. You cannot perform any assay run.	Restart the analyzer. If the problem persists, contact Roche.
Analyzer temperature: {0:00.00}°C. Shut down the analyzer and wait for some time to allow the temperature to stabilize.	Shut down the analyzer and wait for some time to allow the temperature within the analyzer to stabilize.
Assay run No. {0} started on {1} for sample ID {2} is incomplete. If this assay run has not been repeated, repeat it again. Error code: (0x{3:x})	If this assay run has not been repeated, run it again. Otherwise, contact Roche.
Assay script file {0} does not exist. Error code: (0x{1:x})	Select another assay or contact Roche.
Assay script file {0} is missing. Contact Roche. Error code: (0x{1:x})	Select another assay and contact Roche.
Assay tube does not match the assay/lot in Step 1. Check the assay tube and try again. Error code: (0x{0:x})	Check the assay tube and try again.
Assay tube has already been used. Use a new assay tube.	Use a new assay tube to run an assay.
Assay tube has already been used. Use a new assay tube. Error code: (0x{0:x})	Use a new assay tube.
Badge barcode does not match any known user.	Assign the badge barcode to the corresponding user.
Barcode could not be read. Try again.	Ensure that the barcode is readable. Try again.
Barcode is invalid: {0}. Error code: (0x{1:x})	Ensure that the barcode is readable. Try again.
Barcode is not an assay tube barcode. Error code: (0x{0:x})	Scan the assay tube barcode.
Barcode reader configuration cannot be applied. Restart the system. If the problem persists, contact Roche.	Restart the analyzer. If the error persists, contact Roche.
Barcode settings cannot be saved. Restart the system. If the problem persists, contact Roche.	Try·to·save·the barcode settings again. If the problem persists,·contact·Roche.
Before you can archive data, you need to insert a USB flash drive or configure a share location.	Ensure that you have configured the storage location for the archive correctly. Depending on your configuration, you may have to insert a USB flash drive.
Before you can import data, you need to insert a USB flash drive in the analyzer.	Insert a USB flash drive into the analyzer.
Cannot locate update package.	Contact Roche.
Certificate server cannot be reached. Try again later. If the problem persists, contact Roche.	Try again later. If the problem persists, contact Roche.
Cleaning of the photometer is needed. Shut down the analyzer and follow the instructions from the 'Cleaning Tool Guide'.	Shut down the analyzer and follow the instructions from the Cleaning Tool Guide in order to clean the photometer.
Cleaning up update folder threw an exception:	Contact Roche.
Communication is not possible.	Check the network settings. If the problem persists, contact Roche.
Configuration data do not match. Do you want to synchronize the configuration data?	Confirm to synchronize configuration data.

⊞ List of error messages

Message	Recommended action
Configuration data mismatch has been detected during the last run. Restart the analyzer.	Restart the analyzer.
Configuration data mismatch has been detected during the last run. Restart the analyzer. Error code: (0x{0:x})	Restart the analyzer.
Configured infinity edge gateway is not reachable.	Check the settings for **cobas® infinity** edge smart.
Configured infinity edge gateway is reachable, but a secure connection cannot be checked.	Check the settings for **cobas® infinity** edge smart. If the problem persists, contact Roche.
Configured infinity edge gateway is reachable, but a secure connection cannot be established. There may be an issue with the certificate. If this problem persists, contact Roche.	Contact Roche.
Connection error: Communication is not possible.	Check the host configuration and ensure that the analyzer has access to the internet. If the problem persists, contact your local network administrator.
Connection error: DML protocol timeout	Contact Roche.
Connection error: Expired server certificate	Check the date and time on the analyzer and ensure that the service certificate has not expired. If the problem persists, contact your local network administrator.
Connection error: Network cable unplugged	Ensure a physical network connection and check your network infrastructure. If the problem persists, contact your local network administrator.
Connection error: Server certificate name mismatch	Contact Roche.
Connection error: Server does not respond	Check the host configuration and ensure that the analyzer has access to the internet. If the problem persists, contact your local network administrator.
Connection error: Server not reachable	Check the host configuration and ensure that the analyzer has access to the internet. If the problem persists, contact your local network administrator.
Connection error: Server rejected connection	Check the host configuration and ensure that the analyzer has access to the internet. If the problem persists, contact your local network administrator.
Connection error: Untrusted server certificate	Contact Roche.
Connection not possible. Verify the settings and try again.	Verify the settings and check your network infrastructure. If the problem persists, contact your local network administrator
Contact Roche to check the latest released assay script version in your region or country.	Contact Roche.
Contact your administrator to update your system.	Contact your administrator to update your system.
Copying update files to storage card threw an exception:	Contact Roche.
DML protocol timeout	Check the network settings. If the problem persists, contact Roche.
Ensure that the assay tube is inserted properly. Run was aborted. Error code: (0x{0:x})	Try again. Insert the assay tube correctly.
Error (HTTP {0}) while retrieving the certificate. Contact Roche and provide the RUDI: {1}	Contact Roche.
Error (HTTP {0}) while retrieving the certificate. Contact Roche.	Contact Roche.
Error (HTTP {0}) while retrieving the certificate. Try again later. If the problem persists, contact Roche.	Try again later. If the problem persists, contact Roche.

⊞ List of error messages

10 Troubleshooting

Message	Recommended action
Error connecting to the {0} printer. Ensure that it is connected and turned on. Error code: {1}	Ensure that the printer is connected and turned on.
Error HTTP 407 while retrieving the certificate. There is a problem with the configured HTTP proxy server. Check your credentials and server settings and try again.	Check the proxy server settings and try again.
Error occurred while deleting the data collector {0}. Try again or contact Roche.	Try again. If the problem persists, contact Roche.
Error reading badge barcode.	Ensure that the badge barcode is readable. Try again to scan the badge barcode.
Error reading barcode	Ensure that the barcode settings are correct and the barcode is readable.
Error while installing the retrieved certificate. Contact Roche.	Contact Roche.
Ethernet cable not detected.	Ensure a physical network connection and check your network infrastructure. Connect the ethernet cable. If the problem persists, contact your local network administrator.
Expired server certificate	Check the date and time on the analyzer and ensure that the service certificate has not expired. If the problem persists, contact your local network administrator.
Failed to archive and delete results. Try again and if the problem persists, contact Roche.	Try again to archive and delete the results. If the problem persists, contact Roche.
Failed to archive file. Check the share location settings and try again.	Check the share location settings and try again.
Failed to archive results. Try again and if the problem persists, contact Roche.	Try again to archive the results. If the problem persists, contact Roche.
Failed to back up the analyzer. Try again and if the problem persists, contact Roche.	Try again to backup the analyzer. If the problem persists, contact Roche.
Failed to change password. Try again.	Try again to change the password.
Failed to clean the USB flash drive.	Use another USB flash drive.
Failed to connect to the server. Configure secure communication and try again.	Configure secure communication and try again.
Failed to copy update files.	Archive and delete data to free up some internal storage. Try again. If the error persists, contact Roche.
Failed to delete the assay lot file.	Try again. If the problem persists, contact Roche.
Failed to export assay lots. Try again and if the problem persists, contact Roche.	Try again to export the assay lots. If the problem persists, contact Roche.
Failed to export settings. Try again and if the problem persists, contact Roche.	Try again to export the settings. If the problem persists, contact Roche.
Failed to export the assay lots because the integrity of the file cannot be guaranteed. Try again and if the problem persists, contact Roche.	Try again to export the assay lots. If the problem persists, contact Roche.
Failed to export the audit trail. Try again and if the problem persists, contact Roche.	Try again to export the audit trail. If the problem persists, contact Roche.
Failed to export the problem report. Try again and if the problem persists, contact Roche.	Try again to export the problem report. If the problem persists, contact Roche.
Failed to export users. Try again and if the problem persists, contact Roche.	Try again to export the users. If the problem persists, contact Roche.

⊞ List of error messages

Message	Recommended action
Failed to import the assay lots because the integrity of the import file cannot be guaranteed. Generate a new import file and try again. If the problem persists, contact Roche.	To generate a new file, perform another assay lot export. Then try again to import the assay lots. If the problem persists, contact Roche.
Failed to import the assay lots because there is no file to import on the USB flash drive.	Ensure that the USB flash drive contains an assay lot export file.
Failed to import the assay lots due a problem with the import file.	Import the lots from another lot export file.
Failed to import the settings because the integrity of the import file cannot be guaranteed. Generate a new import file and try again. If the problem persists, contact Roche.	To generate a new file, perform another settings export. Then try again to import the settings. If the problem persists, contact Roche.
Failed to import the settings because there is no file to import on the USB flash drive.	Ensure that the USB flash drive contains a valid settings file.
Failed to import the users because the integrity of the import file cannot be guaranteed. Generate a new import file and try again. If the problem persists, contact Roche.	To generate a new file, perform another user export. Then try again to import the users. If the problem persists, contact Roche.
Failed to import the users because there is no file to import on the USB flash drive.	Ensure that the USB flash drive contains a user export file.
Failed to import users. Try again and if the problem persists, contact Roche.	Try again to import the users. If the problem persists, contact Roche.
Failed to reset the ADMIN password.	Start the process to reset the ADMIN password again.
Failed to restore the analyzer because the integrity of the restore file cannot be guaranteed. Provide a proper restore file and try again. If the problem persists, contact Roche.	Provide another restore file and try again. If the problem persists, contact Roche.
Failed to restore the analyzer. There is no file to import on the USB flash drive.	Insert a USB flash drive that contains a backup file to restore the instrument.
Failed to restore the backup. The imported settings version does not match the current settings version.	System settings are not necessarily compatible across different software versions. The imported system settings are not compatible with this software version. Configure the system settings manually. ⮞ Defining system settings (133)
Failed to restore the backup. Try again and if the problem persists, contact Roche.	Try again to restore the analyzer. If the problem persists, contact Roche.
Failed to send {0} due to a problem with the FTP.	Ensure that the FTP server is accessible and configured correctly.
Failed to send {0} due to a problem with the share folder.	Ensure that the shared folder is accessible and configured correctly.
Failed to send {0} due to a problem with the USB flash drive.	Remove the USB flash drive and use another one.
Failed to send {0}.	Make sure that the selected storage media is available and accessible.
Failed to set SNTP. Error code: (0x{0:x})	Ensure that the settings are correct and check the connection to the SNTP server. If the problem persists, contact your local network administrator.
Failed to set time and date.	Check the time and date settings.
Failed to store the user on the system.	The user name may contain characters that are not allowed. Try another user name. If the problem persists, contact Roche.
Failed to update {0}: {1}	Contact Roche.

⊞ List of error messages

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Message	Recommended action
Folder not found. Verify that the folder path is correct.	Verify the settings and check your network infrastructure. If the problem persists, contact your local network administrator.
Hardware error has occurred. Assay runs cannot be performed until the analyzer has been restarted.	Restart the analyzer.
Hardware error occurred during initialization. Error code: 0x{0:x}	Restart the analyzer. If the error persists, contact Roche.
Hardware error occurred. Shut down the analyzer and try again. If the error persists, contact Roche. Error code: {0}	Shut down the analyzer. Restart the analyzer and try again. If the problem persists, contact Roche.
Hardware error with error code {0} has occurred. Assay runs cannot be performed until the analyzer has been restarted.	Restart the analyzer.
Identification number checksum failed	Ensure that the barcode settings match the used barcode and try again.
Illegal assay script file selected. Error code: (0x{0:x})	Select another assay script or contact Roche.
Instrument certificate might be corrupted. Contact Roche.	Contact Roche.
Internal storage is full. Archive and delete data to free space.	Archive and delete some data to free up internal storage on the analyzer.
Internal storage is low or inaccessible. There may not be enough space available to finish an assay run. Delete some data to free space.	Restart the analyzer, archive and delete some data to free up internal storage on the analyzer. If the problem persists, contact Roche.
Invalid activation code. Try again.	Enter the correct activation code.
Invalid assay tube	Use another assay tube.
Invalid barcode: {0}	Ensure that the barcode settings allow the barcode used to be scanned. Try again to scan the barcode.
Invalid barcode: {0} Error code: (0x{1:x})	Ensure that the barcode settings allow the barcode used to be scanned. Try again to scan the barcode.
Invalid destination selected. The audit trails will not be archived and reduced until the selected destination is properly configured.	Configure the archiving location properly.
Invalid destination selected. The problem report will not be generated until the selected destination is properly configured.	Configure the archiving location properly.
Invalid destination selected. The results will not be archived and deleted until the selected destination is properly configured.	Configure the archiving location properly.
Invalid printer settings. Error code: (0x{0:x})	Check the printer settings and ensure that the printer is connected to the analyzer.
Invalid reset code. Try again.	Enter the correct reset code.
Invalid runtime in assay script file. Operation was aborted.	Try again. If the problem persists, contact Roche.
Invalid runtime in assay script file. Operation was aborted. Error code: (0x{0:x})	Contact Roche.
It is not possible to change the remote service platform. Try again later. If the problem persists, restart and try again. Otherwise, contact Roche.	Try again later. If the problem persists, restart the analyzer and try again. If the problem still persists, contact Roche.
It is not possible to perform an assay run. Restart the software update process. If the error persists, contact Roche.	Restart the software update. If the error persists, contact Roche.

⊞ List of error messages

Message	Recommended action
Liat Analyzer is not initialized, Add Lot not allowed.Code:(0x{0:x})	Restart the analyzer.
List of used assay tubes could not be opened. Error code: (0x{0:x})	Check the network connection to the share lot folder.
Loading of settings failed. Default values have been applied.	The system settings provided cannot be applied. Check and update the system settings manually. ▸▤ Defining system settings (133)
Memory is full. Choose 'Confirm' to restart the analyzer.	Restart the analyzer.
Memory is full. Choose 'Restart' to restart the analyzer now or 'Wait' if you want the system to check again in 60 seconds.	Restart the analyzer.
Message string incorrect from script.	Contact Roche.
Migration of settings failed. Default values have been applied.	The system settings provided cannot be applied. Check and update the system settings manually. ▸▤ Defining system settings (133)
Motion compensation is switched off.	Restart the analyzer. If the error persists, contact Roche.
Motor status: 0x{0:X4}	Restart the analyzer. If the problem persists, contact Roche.
Negative control process successful, but failed to add lot to list. Error code: (0x{0:x})	Contact Roche.
Negative control result rejected. Follow the QC Kit Insert instructions to prepare a negative control sample and try again. Error code: (0x{0:x})	Follow the package insert or Instructions for Use of the quality control kit to prepare a negative control sample and try again.
Negative control result rejected. Follow the QC Kit Insert instructions to prepare a negative control sample and try again. If problem persists, contact Roche. Error code: (0x{0:x})	Follow the package insert or Instructions for Use of the quality control kit to prepare a negative control sample and try again. If the problem persists, contact Roche.
Network cable unplugged	Connect the network cable.
No assay tube has been inserted. Error code: (0x{0:x})	Try again. Insert the assay tube correctly.
No network connections detected. Check your network connections and try again.	Verify the settings and try again. If the error persists, check your network infrastructure.
No patient information found. Use an existing order ID. Choose 'Retry' to try again or 'Overrule' to continue without verification.	Retry or overrule the verification.
No patient information found. Use an existing patient ID. Choose 'Retry' to try again or 'Overrule' to continue without verification.	Retry or overrule the verification.
No patient information found. Use an existing sample ID. Choose 'Retry' to try again or 'Overrule' to continue without verification.	Retry or overrule the verification.
No patient information found. Use an existing visit ID. Choose 'Retry' to try again or 'Overrule' to continue without verification.	Retry or overrule the verification.
No patient information found. Use an existing order ID.	Use an existing order ID.
No patient information found. Use an existing patient ID.	Use an existing patient ID.
No patient information found. Use an existing sample ID.	Use an existing sample ID.
No patient information found. Use an existing visit ID.	Use an existing visit ID.

⊞ List of error messages

10 Troubleshooting

Message	Recommended action
No update files found. The update process will be canceled.	Contact Roche.
No USB flash drive has been detected. Insert the USB flash drive and try again.	Insert a USB flash drive and try again.
Not all actuators are open. Restart the system. Error code: (0x{0:x})	Restart the analyzer.
Not enough storage space available for the software update.	Archive and delete some data in order to free up some internal storage. Retry the software update.
Not enough storage space available for the update. The updated process will be canceled.	Archive and delete some data in order to free up some internal storage. Retry the software update.
Patient could not be verified due to a technical problem. Choose 'Retry' to try again or 'Overrule' to continue without verification.	Retry or overrule the verification.
Patient could not be verified due to a technical problem.	Check the network connection. If the problem persists, contact Roche.
Photometer baseline is out of range. Restart the analyzer and try again. If the error persists, contact Roche. Error code: (0x{0:x})	Restart·the·analyzer·and·try·again.·If·the·error·persists,·contact Roche
Photometer LUT value(s) are out of range. Restart the analyzer and try again. If the error persists, contact Roche. Error code: (0x{0:x})	Restart·the·analyzer·and·try·again.·If·the·error·persists,·contact Roche
Photometer status: 0x{0:X4}	Restart the analyzer. If the problem persists, contact Roche.
Positive control process was successful, but failed to add lot to list. Error code: (0x{0:x})	Contact Roche.
Positive control result rejected. Follow the QC Kit Insert instructions to prepare a positive control sample and try again. Error code: (0x{0:x})	Follow the package insert or Instructions for Use of the quality control kit to prepare a positive control sample and try again.
Positive control result rejected. Follow the QC Kit Insert instructions to prepare a positive control sample and try again. If problem persists, contact Roche. Error code: (0x{0:x})	Follow the package insert or Instructions for Use of the quality control kit to prepare a positive control sample and try again. If the problem persists, contact Roche.
Print job could not be added to the configured printer queue. Check the printer, make sure that there is a connection to the printer, or restart the analyzer.	Check the printer connection.
Problem detected during the last recalibration. Restart the analyzer.	Restart the analyzer.
Problem detected during the last recalibration. Restart the analyzer. Error code: (0x{0:x})	Restart the analyzer.
Problem detected during the last resynchronization. Restart the analyzer.	Restart the analyzer.
Problem detected during the last resynchronization. Restart the analyzer. Error code: (0x{0:x})	Restart the analyzer.
Retrieved certificate is not valid and cannot be installed. Contact Roche and provide the RUDI: {0}	Contact Roche.
Sample ID exceeds maximum length (Characters: {0})	Use a shorter sample ID.
Sending of result failed. {0} Error code: (0x{1:x})	Contact Roche.
Server certificate name mismatch	Contact Roche.
Server does not respond	Check the host configuration and ensure that the analyzer has access to the internet. If the problem persists, contact your local network administrator.

⊞ List of error messages

10 Troubleshooting

Message	Recommended action
Server not found. Verify the server name and try again.	Verify the server name for the network share and try again.
Server not reachable	Check the network settings.
Server rejected connection	Check the network settings on the analyzer and on the server. If the problem persists, contact Roche.
Settings could not be imported. The imported settings version does not match the current settings version.	System settings are not necessarily compatible across different software versions. The imported system settings are not compatible with this software version. Configure the system settings manually. ▸▤ Defining system settings (133)
Software update is incomplete. Restart the system and try again to complete the update.	Restart the analyzer and try again to complete the update.
Software update is incomplete. Restart the system and try again to complete the update. Error code: (0x{0:x})	Restart the system and try again to complete the update.
System date is incorrect. The barcode indicates that the manufacture date is in the future: '{0:yyyy-MM-dd}'. Correct the date and try again. Error code: (0x{1:x})	Set the correct date, time, and time zone on the analyzer. Try again.
System time is not correct. Correct the time and restart the process.	Set the correct date, time, and time zone on the analyzer. Try again.
The analyzer name was changed, but the new name cannot be set as a network host name. Try again with a different name or restart the analyzer.	Restart the analyzer. If the problem persists, configure another network host name.
The archive file cannot be verified. There might be a problem with the USB flash drive.	Check the USB flash drive. Try again with a different USB flash drive.
The audit trail is full. No further assay runs can be performed. Contact your administrator immediately.	Contact your administrator immediately. The administrator must archive and delete some data from the analyzer to free up internal storage.
The barcode contains invalid characters. Follow the recommendations in the User Guide.	Only use supported characters in barcodes. Remove invalid characters.
The certificate cannot be retrieved with the given PIN ({0}). Check the PIN and try again. If the problem persists, contact Roche.	Try again. If the problem persists, contact Roche.
The certificate returned by the server has a wrong host name.	Ensure that the server certificate bears the correct host name. If the problem persists, contact your local network administrator.
The certificate returned by the server has expired.	Check the date and time on the analyzer and ensure that the service certificate has not expired. If the problem persists, contact your local network administrator.
The connection to the USB flash drive has been interrupted. Reinsert the USB flash drive to restart the update.	Reinsert the USB flash drive and try again.
The export file cannot be verified. There might be a problem with the USB flash drive.	Try again with a different USB flash drive.
The grace period for this assay has expired. Contact Roche to activate the assay.	Contact Roche to activate the assay.
The grace period for this assay has expired. Inform an administrator to contact Roche to activate the assay.	Inform an administrator to contact Roche to activate the assay.
The HTTP proxy server cannot be reached. Check the server settings and try again.	Check the server settings and try again.
The instrument certificate is not available. Contact Roche and provide the following ID (RUDI): {0}	Contact Roche.

⊞ List of error messages

Message	Recommended action
The magnet motor initialization failed. Error code: 0x{0:x}	Restart the analyzer. If the problem persists, contact Roche.
The magnet motor initialization failed. Error code: 0x{0:x}	Restart the analyzer. If the problem persists, contact Roche.
The problem report cannot be verified. There might be a problem with the USB flash drive.	Try again with a different USB flash drive.
The remote storage certificate is not installed. Contact Roche.	Contact Roche.
The reset code you provided has already expired. Start the process to reset the ADMIN password again.	Start the process to reset the ADMIN password again.
The sample entry initialization failed. Error code: 0x{0:x}	Shut down the analyzer. Carefully try to move the tube entry door manually. Restart the analyzer. If the problem persists, contact Roche.
The software update package is corrupted. Contact Roche.	Contact Roche.
The system could not find any assay script file.	Contact Roche.
The system is locked out. You cannot log on. Only supervisor and administrator user roles can log on.	Unlock the analyzer.
The system time is not correct. To update the software, first correct the system time.	Set the correct date, time, and time zone on the analyzer. Retry the software update.
The update failed. The system will be restored to the previous version. Contact Roche.	Contact Roche.
The update process threw an exception:	Contact Roche.
The validation of the software update package failed.	Contact Roche.
There is not enough internal storage space to perform an assay update.	Archive and delete some data to free up internal storage on the analyzer. If the error persists, contact Roche.
Thermal status: 0x{0:X4}	Restart the analyzer. If the problem persists, contact Roche.
This server does not support secure connectivity compatible with the analyzer.	Connect to a server that supports TLS.
Tube entry door error. Check the door and try again or choose 'Manual' to operate the door manually.	Operate the tube entry door manually.
Unable to connect to the FTP server. Check the event log for further information.	Ensure that the FTP server configuration is correct. Check your network.
Unable to connect to the share folder.	Ensure that the share folder configuration is correct. Check your network.
Unable to connect to the share lot folder. Check the event log for further information.	Ensure that the share lot folder configuration is correct. Check your network. The analyzer's event file may give you further information about the connection problem.
Unable to update the approval status. Error code: (0x{0:x})	Contact Roche.
Unknown user ID: {0}	Enter a valid user ID.
Unrecognized insert ID.	Scan the correct barcode.
Untrusted server certificate	Contact Roche.
Unzipping the update package threw an exception:	Contact Roche.
Update canceled.	Contact Roche.
Update check failed. Check the documentation and correct your data. Then, try again.	Check the documentation and prepare the analyzer accordingly. Retry the software update. If the problem persists, contact Roche.

⊞ List of error messages

10 Troubleshooting

Message	Recommended action
Update failed.	Contact Roche.
Update files not found.	Contact Roche.
Update folder {0} does not exist.	Contact Roche.
Update to version '{0}' is not possible. Contact Roche for further information.	Contact Roche.
Validation failed	Contact Roche.
Verifying update package threw an exception:	Contact Roche.
Version check fail	Contact Roche.
You are no longer able to run assays. Contact an administrator to activate the software.	Contact your administrator to activate the software.
You are no longer able to run assays. Contact Roche to activate the software. Registration code: {0}	Contact Roche and provide the Registration code.
You can only clean 1 USB flash drive at a time. Remove the additional USB flash drive and retry.	Remove the additional USB flash drive and try again.
You can only use 1 USB flash drive to archive data. Remove the additional USB flash drive and try again.	Remove the additional USB flash drive and try again.
You can only use 1 USB flash drive to install an assay. Remove the additional USB flash drive and try again.	Remove the additional USB flash drive and try again.
You will not be able to run assays. Restart the analyzer. If the error persists, contact Roche. Error code: (0x{0:x})	Restart the analyze. If the error persists, contact Roche.
Your account is locked. You cannot log on.	Contact your administrator to unlock your account.

⊞ List of error messages

Viewing and printing the event log

Certain error messages are recorded in a log file, which you can view and print.

If the event log is too large, only the last 100 entries will be displayed. To obtain the full event log, you must create a problem report.

-̣ỵ̣-   If configured, the analyzer sends events to a
        connected DMS.

        ⸰⃞ About data exchange with a DMS (243)

⸏⃞   ☐ Supervisor user role or administrator user role

▸ **To view and print the event log**

1   Choose **Tools > Event log**. Choose the **Select** button.

2   Optionally, if a message is displayed, choose the **Confirm** button.

    ⓘ Large event logs may take some time to load.

3   To scroll through the event log, do the following:
    ▪ To scroll continuously, use the ⃟ and ⃟ navigation buttons.
    ▪ To scroll by page, use the Left ⃟ and Right ⃟ navigation buttons.

4   To print the event log, choose the **Print** button.

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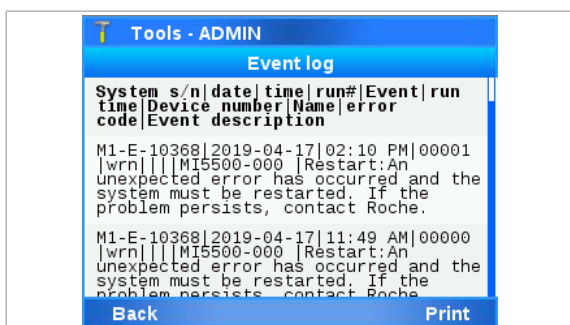
Lost password for the default administrator account ADMIN

If you have lost the password of the default administrator account ADMIN, you must either have a way to change it, or you must reset the analyzer.

In this section

Changing the lost password of the ADMIN account (users managed on the analyzer) (284)

Changing the lost password of the ADMIN account (users managed on a DMS) (285)

Resetting the analyzer (287)

Changing the lost password of the ADMIN account (users managed on the analyzer)

If the analyzer is not connected to a DMS or if the analyzer does not exchange users with a connected DMS, another administrator user account must exist on the analyzer to avoid an analyzer reset.

> -ᗰ̣- It is recommended to create another administrator account immediately after analyzer installation.
>
> 🖹 Creating users (150)

☐ Analyzer is not connected to a DMS or does not exchange users with a connected DMS.

▶ **To change the ADMIN password (user management on the analyzer)**

1 Log on to the analyzer with another administrator user account.

10 Troubleshooting
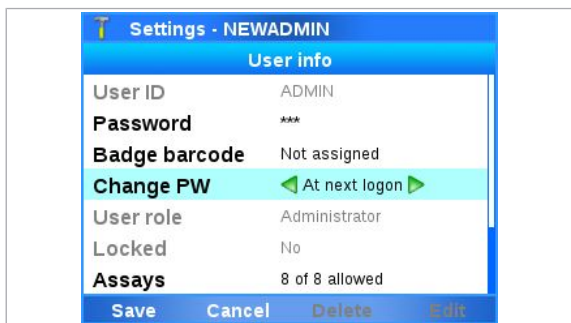
2 Edit the default administrator account ADMIN as described in Changing user information (152):

- Change the password.

- Alternatively, set the **Change PW** item to the **At next logon** value.

- Choose the **Save** button.

3 Log off from the analyzer.

4 Log on to the analyzer with the ADMIN account. If prompted, change the password.

Changing the lost password of the ADMIN account (users managed on a DMS)

If the analyzer is connected to a DMS and exchanges users with the DMS, you can always avoid the analyzer reset, even without an additional administrator account.

☐ Analyzer connected to a DMS.

☐ Analyzer exchanges user data with the DMS, i.e., user management is disabled on the analyzer.

About data exchange with a DMS (243)

▶ **To change the ADMIN password (user management on a DMS)**

1 Create another user with administrator user role on the DMS.

2 Send the list of users from the DMS to the analyzer.

3 Log on to the analyzer with the new administrator account.

4 To disconnect the analyzer from the local data network, disconnect the Ethernet cable from the analyzer.

10 Troubleshooting
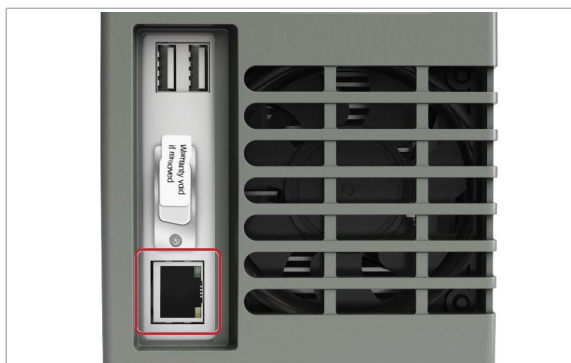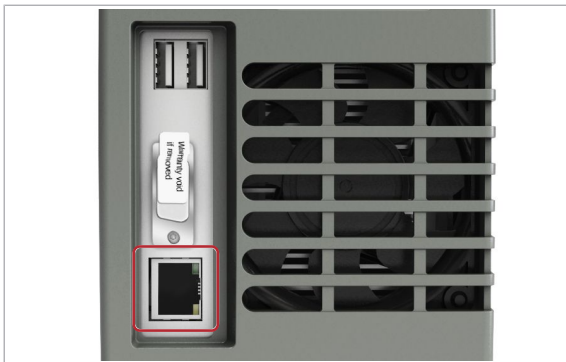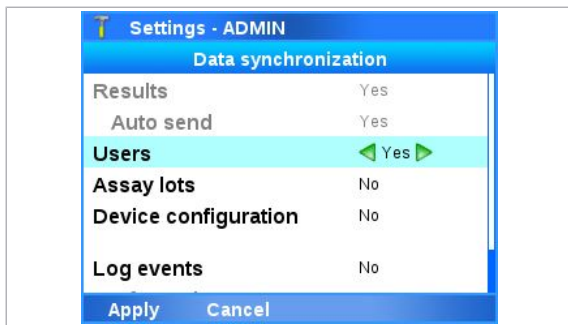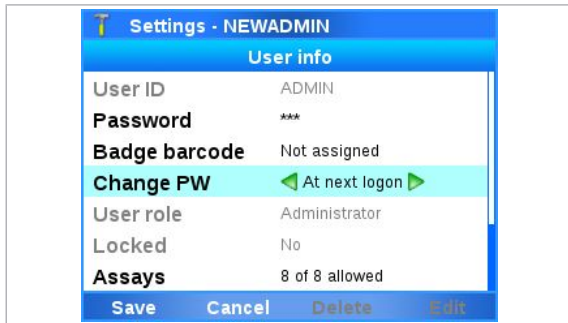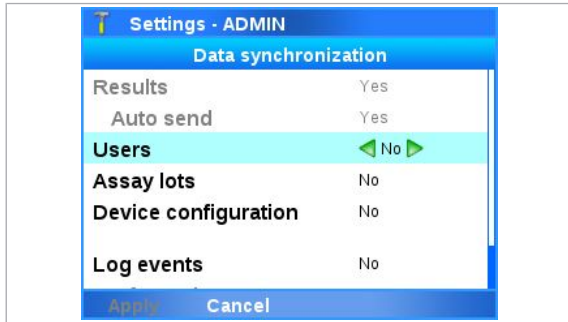
5 Disable the exchange of user data with the DMS:
- Choose **Settings > Connections > Host > Data synchronization**. Choose the **Select** button.
- Choose the **Users** item and change it to the **No** value.
- Choose the **Apply** button.
- On the **Host** screen, choose the **Save** button.
- Navigate back to the **Main** screen.

6 Edit the default administrator account ADMIN as described in Changing user information (152):
- Change the password.
- Alternatively, set the **Change PW** item to the **At next logon** value.
- Choose the **Save** button.
- Navigate back to the **Main** screen.

7 Enable the exchange of user data with the DMS again:
- Choose **Settings > Connections > Host > Data synchronization**. Choose the **Select** button.
- Choose the **Users** item and change it to the **Yes** value.
- Choose the **Apply** button.
- On the **Host** screen, choose the **Save** button.
- Choose the **Apply** button.

8 To connect the analyzer to the local data network again, reconnect the Ethernet cable from the analyzer.

9 Wait at least the duration of the connection interval before you log on with the default administrator account ADMIN. If prompted, change the password.

▶ **To force the change of the ADMIN password (user management on a DMS)**

1 On the DMS, set the **Change PW** item to the **At next logon** value for the default administrator account ADMIN.

2 Send the **full** list of users from the DMS to the analyzer.

   ⓘ Do not send the ADMIN account only. This would delete all other users from the analyzer.

3 Wait until the analyzer has received the user list.

4 Log on with the default administrator account ADMIN. When prompted, change the password.

Resetting the analyzer

If you have lost the password of the default administrator account ADMIN and have no alternative way to change the password, you must apply for an analyzer reset with your Roche representative.

-ᗕᩛᗒ- Before you reset the analyzer, always check if you have a way to change the password of the default administrator account ADMIN instead.

ᐳ🗐 Lost password for the default administrator account ADMIN (284)

Because the password of the default administrator account ADMIN is used to encrypt the sensitive data on the analyzer, the analyzer reset deletes the following data from the analyzer:

- User accounts and passwords except the default user accounts
- Sample IDs, patient IDs, order IDs, and visit IDs
- Results

Other data (e.g., assays, assay tube lots, and system settings) remain on the analyzer.

-ᗕᩛᗒ- To avoid data loss, it is recommended to back up the analyzer before the analyzer reset (using a user account with supervisor user role). Restore the analyzer again after the analyzer reset.

ᐳ🗐 Backing up and restoring an analyzer (202)

☐ Password for the default administrator account ADMIN is lost.

☐ On the analyzer exists no other account with administrator user role.

☐ The analyzer is not connected to a DMS, or the analyzer is connected to a DMS but does not exchange user data with the DMS.

▶ **To reset the analyzer**

1 Optionally, backup the analyzer as follows:
- Log on to the analyzer with supervisor user role.
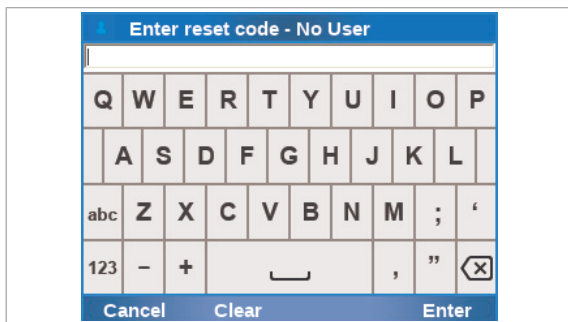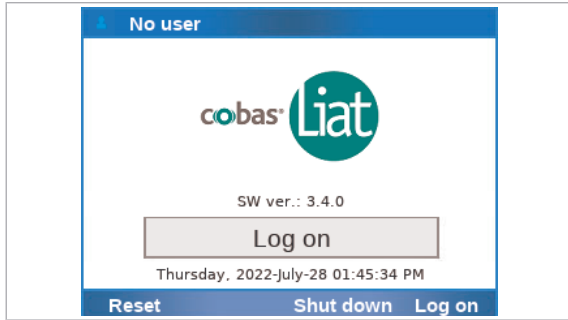
▪ Backup the analyzer as described in Backing up and restoring an analyzer (202).

▪ Log off again.

🛈 If you do not backup and restore the analyzer, you must at least recreate all user accounts except the default user accounts after the analyzer reset.

2 On the **Log on** screen, choose the **Reset** button.

3 On the message dialog box, choose the **Yes** button to confirm that you no longer have access to the administrator password.

→ An eight-digit key is displayed, which is valid for 24 hours.

4 Make a note of the key displayed in the message.

🛈 Do not tap the screen until you have received the reset code.

5 Contact your Roche representative and request an analyzer reset.

🛈 You must provide proof of identity and the eight-digit key that was generated by the analyzer.

6 After successful verification, you receive an eight-digit reset code, which is valid for 24 hours.

7 On the message dialog box, choose the **Confirm** button.

8 To confirm the analyzer reset, choose the **Reset** button.

9 On the **Enter reset code** screen, enter the code provided by your Roche representative.

10 Choose the **Enter** button.

→ If the code is valid, the **Enter password** screen is displayed.

11 Enter a new administrator password.

10 Troubleshooting

12 Choose the **Enter** button.

➔ A success message is displayed.

13 Optionally, restore the analyzer again with the backup file created in step **1**:

▪ Log on to the analyzer with administrator user role.

▪ Restore the analyzer as described in Backing up and restoring an analyzer (202).

Cleaning the window of the barcode reader

Dried residue on the outside of the barcode reader window may cause repeated failure to scan barcodes. Clean the window to ensure trouble-free operation.

> ⚠ **CAUTION!**

Electric shock

▸ Do not spray or apply liquid directly on the analyzer.

> **NOTICE!**

Damage to the analyzer due to use of unsuitable cleaning materials

Using unsuitable cleaning materials can damage the window of the barcode reader.

▸ Do not use harsh, abrasive cleaners (such as bleach) or wipes.

☐ Soft lint-free cloth

☐ 70% isopropanol

☐ Repeated failure to scan barcodes.

▸ **To clean the window of the barcode reader**

1 Shut down the analyzer.

2 Moisten a lint-free cloth with 70% isopropanol.

3 NOTICE! Risk of damage to the window of the barcode reader.
Do not use bleach.

Gently wipe the outside of the barcode reader window.

10 Troubleshooting

Resolving a tube entry door error before the start of a run

If you insert the assay tube just at the end of the tube insert time, a tube entry door error may occur.

☐ Assay tube is inserted in analyzer.

☐ Error message **Tube entry door error. Check the door and try again or choose 'Manual' to operate the door manually.** is displayed.

▶ **To resolve a tube entry door error before the start of a run**

1 Manually remove the assay tube from the analyzer.

2 On the message dialog box, choose the **Manual** button. Choose the **Confirm** button.

3 To run the assay, continue with step **12** of Running an assay (95).

10 Troubleshooting
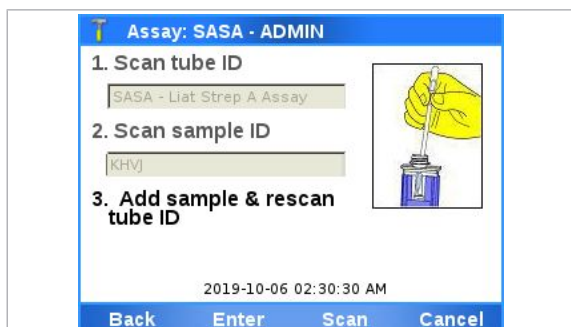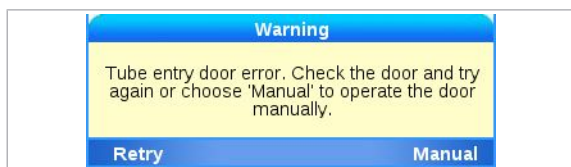
Resending results manually

If the analyzer is configured to release and send results automatically to a host, but the transmission fails, you must resend the results manually.

If the analyzer is connected to the host via the HL7 protocol and the transmission fails, the analyzer tries automatically twice to resend the results. If the transmission still fails, the analyzer displays a result sending error message and you must resend the results manually.

On the **Results** screen, results that need to be resend are marked as follows:

▪ Results that the analyzer could not send, have no icon.

▪ Results that were sent to the host, but not received by the host, have no icon (HL7) or are marked with ![icon] (DMS).

▯ About sending status of results (103)

☐ Automatic sending of results failed.

☐ Supervisor user role or Administrator user role

▸ **To resend results manually**

1 On the **Main** screen, choose the **Results** item.

2 On the **Results** screen, send the results as described in Reviewing results (104).

10 Troubleshooting
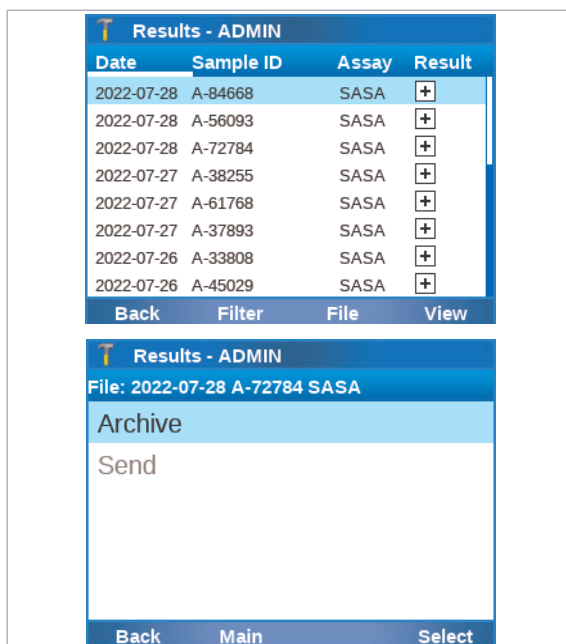
Restarting an unresponsive analyzer

If the analyzer becomes unresponsive and cannot be shut down, power off and restart it.

☀️ Before you restart the analyzer, always try to shut down the analyzer following the shutdown procedure.

⬛ Shutting down the analyzer (88)

☑️ ☐ Analyzer unresponsive
☐ Shutdown of analyzer not working

▸ **To restart an unresponsive analyzer**

1 If the analyzer is unresponsive, press the power button and hold it down for 5–10 seconds until the analyzer powers off.

2 Wait for about 10 seconds.

3 To restart the analyzer, press the power button again.

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10 Troubleshooting

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Specifications

In this chapter   **11**

11 Specifications

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11 Specifications

Technical data

Technical characteristics

The analyzer has the following technical characteristics:

Analyzer	
User interface	Built-in touch screen and keyboard
Internal storage capacity	Approximately 20 000 test results with date and time can be stored on the analyzer (depending on result file size)
Barcode reader	Class 2 Laser Product
Connectivity port	Ethernet, RJ-45, TCP/IP
	2 Universal Serial Bus (USB) (maximum load of 250 mA)
Main connection	Power supply adapter: Input 100-240 V AC / 50-60 Hz
	Output: 15 V DC / 8.6 A
Power consumption	130 W on AC mains power
Safety class	II
Dimensions (L x W x H)	24.1 cm x 11.4 cm x 19.0 cm (9.5 in x 4.5 in x 7.5 in)
Weight	3.76 kg (8.3 lbs)

▦ Technical data

Environmental conditions

For operation, the following environmental conditions must be met:

Analyzer	
Temperature range	+15 °C to +32 °C (59 °F to 90 °F)

▦ Environmental conditions

11 Specifications

Analyzer	
Relative humidity	15% to 80% (non-condensing)
Maximum altitude	2000 m (6500 ft) above sea level

⊞ Environmental conditions

Other environmental conditions	▪ Indoor use only
	▪ Horizontal installation space
	▪ Dust-free environment with adequate ventilation
	▪ No direct sunlight
	▪ No perceptible vibration
	▪ No equipment generating electromagnetic waves in the near vicinity
	▪ No machines discharging ultrahigh frequencies (e.g., electric discharger)

Storage and transport conditions

For storage and transport, the following ambient conditions must be met:

Analyzer	
Temperature range	-20 °C to +60 °C (-4 °F to +140 °F)
Storage relative humidity	10% to 95% (non-condensing)

⊞ Storage and transport conditions

Parts and materials

Parts list (provided)   The package includes the following parts:

Name
cobas® Liat® Analyzer
Power supply
Power cable
Touch screen stylus
User ID card kit
cobas® Liat® Cleaning Tool kit
cobas® Liat® System Short Instructions
cobas® Liat® Analyzer Quick Start Guide
cobas® Liat® Analyzer Cleaning Tool Guide

⊞ Parts list

Required materials (not provided)   The following materials are additionally required:

Image	Name
	cobas® Liat® assay kit
	cobas® Liat® control kit for the assay
	Validated sample collection kit

⊞ Required materials

Read the package insert or the Instructions for Use of the assay for detailed product data and usage limitations.

For ordering information, contact your local Roche representative.

Unsupported characters

The following characters are not supported for sample IDs or user IDs:

- [Space] (ASCII: Space)
- ;
- |
- ^
- &
- \
- ~
- DEL
- [CR] (ASCII: Carriage Return)
- [VT] (ASCII: Vertical Tabulator)
- [FS] (ASCII: Field Separator)
- [NUL] (ASCII: Null)
- [SOH] (ASCII: Start of Heading)
- [STX] (ASCII: Start of Text)
- [ETX] (ASCII: End of Text)
- [EOT] (ASCII: End of Transmission)
- [ENQ] (ASCII: Enquiry)
- [ACK] (ASCII: Acknowledge)
- [BEL] (ASCII: Bell)
- [BS] (ASCII: Backspace)
- [HT] (ASCII: Horizontal Tabulator)
- [LF] (ASCII: Line Feed)

- ▪ [VT](ASCII: Vertical Tabulator)
- ▪ [FF] (ASCII: Form Feed)
- ▪ [CR] (ASCII: Carriage Return)
- ▪ [SO] (ASCII: Shift Out)
- ▪ [SI] (ASCII: Shift In)
- ▪ [DLE] (ASCII: Data Link Escape)
- ▪ [DC1] (ASCII: Device Control 1)
- ▪ [DC2] (ASCII: Device Control 2)
- ▪ [DC3] (ASCII: Device Control 3)
- ▪ [DC4] (ASCII: Device Control 4)
- ▪ [NAK] (ASCII: Negative Acknowledge)
- ▪ [SYN] (ASCII: Synchronous Idle)
- ▪ [ETB] (ASCII: End of Transmission Block)
- ▪ [CAN] (ASCII: Cancel)
- ▪ [EM] (ASCII: End of Medium)
- ▪ [SUB] (ASCII: Substitute)
- ▪ [ESC] (ASCII: Escape)
- ▪ [GS] (ASCII: Group Separator.)
- ▪ [RS] (ASCII: Record Separator)
- ▪ [US] (ASCII: Unit Separator)

-ᗑ- To avoid barcode reading errors, ensure your barcode generation tool uses the following character sets:
- ▪ Standard character set with code 39 barcode standard.
- ▪ Full character set with code 93 barcode standard.
- ▪ Standard ASCII character set with the code 128 barcode standard. Do not use the extended ASCII character set (code 128-255).

Barcode specifications

-ᗑ- To maintain patient confidentiality and privacy standards, do not use protected health information (e.g., patient name, social security number) as the sample ID.

About barcode standards The sample ID barcode must comply with one of the following standards:
- ▪ Code 39
  The barcode must be created using the standard character set.

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- Code 93
  The barcode must be created using the full character set.
- Code 128
  The sample ID barcode must not start with the & character or the = character.
  Do not use the extended ASCII character set (code 128-255).
- Codabar
- GS1 DataBar:
  - Omnidirectional
  - Truncated
  - Stacked
  - Stacked Omnidirectional
  - Limited
- EAN-8
- EAN-13
- Interleaved 2 of 5

▸▤ For a list of not supported characters in user ID barcodes and sample ID barcodes, refer to Unsupported characters (299).

About barcode length

Barcodes (except assay tube barcodes) can have a maximum length of 54 mm (2.125 in), including the left and right quiet zones.

About barcode printing

Roche recommendations for visible inspection of printed barcodes:

- The printing should be of good contrast (dark black on white background).
- The background should be solid white (no transparency, no patterns, no color), non-reflecting material.
- Check for sharp edges and clear lines of the barcode bars (no fringed lines).
- Quiet zone of the barcode must be respected (white space on the left/right of the bars).
- When scratching on the barcodes with the fingers or fingernails, the printing should hold and not smear not even if body oil, disinfection or other fluids are used. Watch out for wrinkles.

All sample barcodes should be printed to achieve ISO/IEC 15416 Grade 2.5-4.0 (formerly ANSI X3, 182-1990 Grade A or B) to ensure reliable barcode reading.

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Printers

Compatible printers (laser, inkjet, or thermal) can be connected to the analyzer either via the USB port or via data network.

The analyzer detects connected printers automatically and adds them to the list of available printers.

A thermal printer for result printing and a laser or inkjet printer for report printing can be configured on the analyzer at the same time.

Reports and results printed on an inkjet printer can be damaged by moisture or liquid. It is therefore recommended to use a laser printer.

Results printed on a thermal printer can be damaged by exposure to heat, light, or liquid. It is therefore not recommended to rely on the printouts from a **thermal** printer.

About supported protocols

Printers can be connected to the analyzer via the following protocols:
▪ Network
▪ IPP (Internet Printing Protocol)
▪ IPPS (secure Internet Printing Protocol)
▪ http (Hypertext Transfer Protocol)
▪ https (secure Hypertext Transfer Protocol)
▪ LPD/Socket (Line Printer Daemon)
▪ Local (for connection via USB port)

▸⊟ **Related topics**

▪ Printer setup (156)

USB devices

The system supports certain connected USB devices.

The following USB devices are supported:
▪ USB flash drive
▪ USB printer
▪ USB hub

Any other USB device is not supported.

Connect a USB device to the analyzer only if the analyzer is in status ready.

▸▤ About analyzer status (55)

About USB flash drives

For USB flash drives, the following limitations apply:

▪ Size: less than 2 TB

▪ Only USB flash drives with MBR (Master Boot Record) are supported
(GPT (GUID Partition Table) is not supported)

▪ Supported file systems:

– fat16 (vfat)

– fat32 (vfat)

– ext2/3/4

– exfat

▪ NTFS (New Technology File System) is not supported.

It is recommended to use a lockable USB flash drive, i.e., a USB flash drive that you must unlock before you insert it in the analyzer.
It is not possible to enter an unlock code for a USB flash drive via the analyzer.

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