cobas® Liat® system
Operator's Manual
Version 7.2

Software Version 3.1

Roche

cobas®

Life needs answers

Publication information

Edition notice

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

The contents of this document, including all graphics and photographs, are the property of Roche. No part of this document may be reproduced or transmitted in any form or by any means, electronic or mechanical, for any purpose, without the express written permission of Roche.

Every effort has been made to ensure that the information is correct at the time of publishing. Not all functionality described in this manual may be available to all users. Roche Diagnostics reserves the right to change this publication as necessary and without notice as part of ongoing product development. Such changes may not immediately be reflected in this document.

Screenshots

Any screenshots in this publication are added exclusively for the purpose of illustration. Configurable and variable data such as parameters, results, path names etc. visible therein must not be used for laboratory purposes.

Intended use

This document is intended for the US market only.
Caution: Federal law restricts this device to sale by or on the order of a physician.

Copyright

©2014 - 2017, Roche Diagnostics. All right reserved.

Trademarks

The following trademarks are acknowledged.

COBAS, LIAT and LIFE NEEDS ANSWERS are trademarks of Roche.

All other product names and trademarks are the property of their respective owners.

Feedback

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

Roche Diagnostics Corporation
Engineering Operations Department
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457
USA

Document availability

This document is available on the Roche Diagnostics USA website at https://usdiagnostics.roche.com.

Warranty for the instrument

Roche warrants the instrument against defects in materials and workmanship (except for consumable items and lamps) for a period of one year (90 days in the case of parts in direct contact with reagents). Roche, at its option, either replaces or repairs free of charge, on an f.o.b. Indianapolis, Indiana basis, all instruments and parts which prove to be defective and are subject to such warranty.

Field-installed options, modifications, and used equipment carry a ninety (90) day parts and labor warranty. Any component part(s) and labor necessary to complete a repair are guaranteed for thirty (30) days. Some replacement components, such as printers, monitors, etc., may carry a longer warranty.

This warranty does not apply to instruments not installed by a Roche Field Service Representative/Field Application Specialist (or authorized agent of Roche) and/or not used according to instructions or damaged by accident, alteration, misuse, tampering, and/or abuse.

We warrant that the services provided under a Roche Warranty or Service Agreement are free from defects in workmanship for a period of thirty (30) days from the date of service.

Warranty for the reagent

Roche warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label.

WE HEREBY DISCLAIM ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO THE EQUIPMENT, REAGENTS AND SERVICES PROVIDED, EXCEPT THE LIMITED WARRANTY SET FORTH ABOVE. WE ARE NOT LIABLE FOR ANY INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, INCLUDING BUT NOT LIMITED TO, LOST PROFITS OR REVENUES, LOSS OF THE USE OF THE CAPITAL, COST OF SUBSTITUTE EQUIPMENT, REAGENTS, FACILITIES OR SERVICES AND/OR DOWN-TIME COSTS RESULTING FROM OR ARISING IN CONNECTION WITH THE PERFORMANCE, DELAY IN PERFORMANCE OR NONPERFORMANCE OF ANY TERM OR CONDITION OF A ROCHE WARRANTY OR SERVICE AGREEMENT OR FROM THE USE OR MISUSE OF THE INSTRUMENT (OR ANY SUBSTITUTE THEREFORE) OR REAGENTS OR ANY MATERIALS OR WORKMANSHIP DELIVERED HEREUNDER, EVEN IF WE HAVE BEEN ADVISED, KNEW OR SHOULD HAVE KNOWN OF THE POSSIBILITY OF SUCH DAMAGES. YOUR EXCLUSIVE REMEDY WITH RESPECT TO OUR WARRANTY OF ANY EQUIPMENT, REAGENTS OR PARTS SHALL BE REPAIR OR REPLACEMENT OF THE DEFECTIVE ITEM(S), AT OUR OPTION. AS YOUR EXCLUSIVE REMEDY FOR ANY SERVICE PERFORMED UNDER THIS LIMITED WARRANTY WE SHALL RE-PERFORM ANY SERVICE WHICH WAS DEFECTIVE.

Contact Support and/or Service Representatives

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.

Chemistry, Immunology, Automation & Urinalysis products   **1-800-428-2336**

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 the appropriate Customer Support Center number.

Customer Training

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 Customer and Business Support Center.

Roche Customer and Business Support Center number   **1-800-428-5030**

Contacting Sales Representatives

If you wish to contact your sales representative, he or she may be reached by calling Customer and Business Support Center or by leaving a message on their voice mail.

Roche Customer and Business Support Center number   **1-800-428-5076**

Voice mail   **1-800-845-7355**
Entering the appropriate mailbox number or press # to spell the name.

Customer Communications

As the need arises, you shall 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 https://usdiagnostics.roche.com and select **Documentation**.

Bulletins

Bulletins (Reagent, Software, or Analyzer) are printed on Roche Diagnostics letterhead. Bulletins contain information that is vital to the performance of your system. Bulletin information should be communicated internally to all analyzer operators. Bulletins should be kept 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).

Contacting Commercial Education

The documentation you receive to operate your system, prepare and/or utilize reagents, is created by several departments within Roche. The Commercial Education department produces most of the training documentation you receive here in Indianapolis, or at your on-site training.

To contact Commercial Education
- send an email to Indianapolis.TechPub@roche.com

Provide your name and account number when contacting us. We will get back to you, or fill your request, as soon as possible.

If you have any questions on documentation that is not of a training nature, contact the appropriate Customer Support Center as designated in the **Contact Support and/or Service Representative section**.

To Change Mailing Addresses or Contact Names

There are several ways to change your mailing address or the contact name for your account. You may send an email, leave a message or go to https://usdiagnostics.roche.com

Please 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.techpub@roche.com

https://usdiagnostics.roche.com Contact > Contact Change Form.

cobas® Liat® System

Operator's Manual
Version 7.2

Software version 3.1

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	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. ▸⧉ What is new in publication version 7.2 (12)

⊞ Revision history

Edition notice

This publication is intended for operators 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 **Operator's Manual** 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® **Cleaning Tool Guide** is intended as an instruction for using the **cobas**® Liat® Cleaning Tool with the **cobas**® Liat® Analyzer.

The **cobas**® Liat® **Advanced Tools Key Guide** is intended as an instruction for performing a variety of functions, including backing up data and syncing assay lots between **cobas**® Liat® Analyzers.

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

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

⚠ **General attention**

To avoid incorrect results, ensure that you are familiar with the instructions and safety information.
- Pay particular attention to all safety notices.
- Always follow the instructions in this publication.
- Do not use the software in a way that is not described in this publication.
- Store all publications in a safe and easily retrievable place.

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

Warranty Any customer modification to the 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.

Copyright © 2014‑2017, Roche Molecular Systems, Inc.

Trademarks The following trademarks are acknowledged:

COBAS and LIAT are trademarks of Roche.

All other product names and trademarks are the property of their respective owners.

Patents	See *http://www.roche-diagnostics.us/patents*
Support	If you have any further questions, please contact your Roche representative with the system information collected as described in the Troubleshooting chapter in the **cobas**® Liat® System Operator's Manual.
Approvals	The **cobas**® Liat® Analyzer meets the requirements laid down in:

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

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: |

IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE

CE	Complies with the provisions of the applicable EU directives.

TÜVRheinland C US	Issued by TÜV Rheinland for Canada and the US.

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

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

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

Contact addresses

Roche Molecular Systems, Inc.
1080 US Highway 202 South
Branchburg, NJ 08876
USA

EC REP

Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany

6

Table of contents

8

Preface

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.

Symbols and abbreviations

Product names

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

Product name	Descriptor
cobas® Liat® Analyzer	analyzer
cobas® Liat® Assay Tube	assay tube
cobas® Liat® Cleaning Tool	cleaning tool
cobas® Liat® Advanced Tools Key	advanced tools key
cobas® Liat® Quality Control Kit	quality control kit

⊞ Product names

Symbols used in the publication

Symbol	Explanation
•	List item
▸▤	Related topics containing further information
☼	Tip. Extra information on correct use or useful hints.
▸	Start of a task
❶	Extra information within a task
➔	Result of an action within a task.
▦	Frequency of a task.
◗	Duration of a task.
▤	Materials that are required for a task.
▦	Prerequisites of a task.
▸▤	Topic. Used in cross-references to topics.

⊞ Symbols used in the publication

Symbol	Explanation
▶	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.
√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
GTIN	Global Trade Item Number.
%	Humidity limits.
⇈	Keep upright.
⚱	Fragile handle with care.
☂	Keep dry.
☀	Keep away from sunlight.
0kg	Stacking limit by mass.
⊠1	Stacking limit by number.
♲	Recyclable.
ℹ	Consult operating instructions.

⊞ Symbols used on product

Abbreviations   The following abbreviations are used.

Abbreviation	Definition
AD	Amplification and detection
ANSI	American National Standards Institute

⊞ Abbreviations

Abbreviation	Definition
CFR	Code of Federal Regulations
CISPR	Comité International Spécial des Perturbations Radioélectriques (International Special Committee on Radio Interference)
CSA	Canadian Standards Association
DML	Device messaging layer
DMS	Data management system
EC	European Community
EN	European standard
FTP	File transfer protocol
HIS	Hospital information system
HL7	Health Level Seven
IEC	International Electrical Commission
IP	Internet provider
IVD	In vitro diagnostic
LAN	Local area network
LIS	Laboratory information system
n/a	not applicable
NA	Not available
NAT	Nucleic acid test
PCR	Polymerase chain reaction
POCT	Point of care testing
RF	Radio frequency
QC	Quality Control
SD	Standard deviation
SL	Shared lot
SNTP	Standard network time protocol
UPS	Uninterruptible power supply
URI	Uniform resource identifier
WEEE	Waste Electrical and Electronic Equipment
WLAN	Wireless LAN
WPA2	Wireless protected access 2

⊞ Abbreviations

What is new in publication version 7.2

Printing

The procedure how to install a USB printer was extended. A procedure how to install a network printer was added. Information about color printing was added.

▸ Installing the analyzer (17)

▸ System settings (79)

Audit trail

Information about the audit trail feature was added.

▸ About the audit trail (23)

Logon procedures

The procedure how to log on was reworked to cover the different authentication modes. The procedure how to change your password was reworked. A procedure how to assign or change your badge barcode was added.

▸ Logging on (29)

▸ Changing your password (31)

▸ Assigning or changing your badge barcode (34)

Inspection of printed barcode labels

Recommendations for inspection of printed barcode labels were added.

▸ Scanning barcodes (37)

User management

Requirements for user IDs and passwords were added. The procedures how to define a new user and how to change user information were reworked to cover the new features (e.g., locking users, assigning badge barcodes, change password at first logon).

▸ Managing users (90)

Reviewing results

The procedures how to review results were reworked.

▸ Reviewing results (53)

Export and delete results

The former functions for moving results and deleting results were combined to one function for exporting and deleting results. The corresponding procedures were combined and reworked.

▸ Exporting and deleting results (57)

Sharing assay tube lots

Information about ways to share assay tube lots between different analyzers was added.

▸ Sharing assay tube lots (70)

Authentication modes

Information about the supported authentication modes was added.

▸ About authentication modes (80)

DMS connectivity	Information about the data exchange with a DMS was added. A procedure how to connect the analyzer to a DMS was added. Information how to disconnect the analyzer from a host was added.

▸▣ Connections to a host system (85)

Data migration	Information about the impact of the software update on the user information was added.

▸▣ About migration of user information (97)

Error codes	The error codes were differentiated between software, hardware/firmware, and assay codes. The list of error messages was extended.

▸▣ List of error messages (111)

Troubleshooting	Troubleshooting procedures were reworked and added.

▸▣ Troubleshooting (111)

Other environmental conditions	Information about other environmental conditions was added.

▸▣ Other environmental conditions (131)

Caution statements	Caution statements about the risks of power interruption, contamination of the cleaning tool, and data security were added.

▸▣ Installing the analyzer (17)

▸▣ Cleaning spillages or leakages from an assay tube (110)

▸▣ Generating a backup for troubleshooting purposes (124)

Changed user interface	The user interface was changed with software version 3.1. Screenshots and text were updated to reflect the changes.

Safety instructions

Safety classification

The safety precautions and important user notes are classified according to the ANSI. 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. To avoid possible injury or death, comply with all safety messages that follow this symbol.

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.

Safety summary

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

⚠ **WARNING**

Insufficient knowledge and skills

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

▸ Only trained personnel may operate the **cobas**® Liat® Analyzer. Operators must have received and read the comprehensive instructions for the use, quality control, and care of the **cobas**® Liat® Analyzer.

⚠ WARNING

Infectious materials

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

▶ Use lab gloves.

▶ Use a new disposable 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 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 a laser barcode reader.

▶ Do not remove covers from barcode readers.

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

▶ Perform only the procedures described in operating instructions. Performing unauthorized procedures may result in exposure to hazardous radiation.
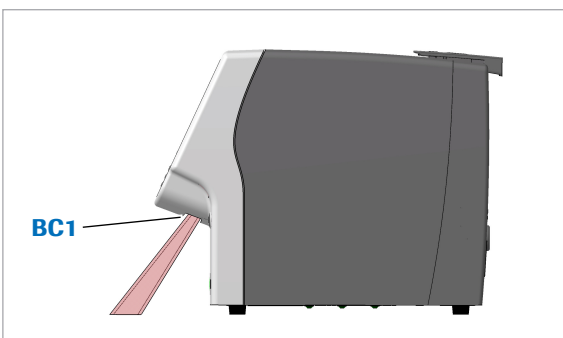
Barcode reader beam localization	Wave length	Pulse duration	Max. output	Remark
BC1	650 nm	720 µs	1.0 mW	Class 2 laser IEC 60825-1 CFR 21 Part 1040.10

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

Electromagnetic interference

⚠ **CAUTION**

Malfunction of system and incorrect results due to interfering electromagnetic fields

This system is designed and tested to CISPR 11 Class A standard. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

▸ The electromagnetic environment should be evaluated prior to operation of the device.

▸ Do not operate this system in close proximity to sources of strong electromagnetic fields (for example unshielded intentional RF sources), as they may interfere with proper operations.

Class A equipment is suitable for all 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).

This instrument has been designed and tested to IEC 61326-2-6 and complies with the emission and immunity requirements.

This system is designed and tested to CISPR 11 Class A standard. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

Disposal

The analyzer must be disposed of in accordance with relevant local regulations and in coordination with your local authorities, as appropriate. Please note that the analyzer may potentially be infectious. It should therefore be decontaminated before disposal.

Labels on the analyzer

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 Practices for working with biohazardous materials

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

Installation

Installing the analyzer

Place the analyzer on a suitable level surface and connect it to the mains 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.

⚠ **CAUTION**

Incorrect results or malfunctions due to incorrect installation

Performing installation actions other than those mentioned in this documentation may lead to malfunction and incorrect results.

▸ Do not carry out any installation actions that are not described in this documentation or for which you were not appropriately trained.

⚠ **CAUTION**

Injury by tripping over cables

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

▸ Position the analyzer as close to the wall 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
☐ Universal Power Supply
☐ Power cable
☐ Touch screen stylus
☐ User ID Card Kit
☐ Administrator password card
☐ **cobas**® Liat® Advanced Tools Key
☐ **cobas**® Liat® Cleaning Tool Kit
☐ **cobas**® Liat® Analyzer Quick Start Guide

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

-ᵜ- Retain the shipping container and packaging materials in the event that the analyzer needs to be returned to Roche for service.

☐ **cobas**® Liat® Analyzer
☐ Power supply
☐ Power cables
☐ Ethernet data cable, if you intend to connect the analyzer to a data network
☐ USB cable, if you intend to connect the analyzer to a USB printer

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

▶ **To install the analyzer**

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

> ❶ Allow at least 10 cm (4 inches) of space at the rear of the analyzer for airflow. Ensure vents 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 outlet to avoid creating a trip hazard with the power cable.

2 Connect the power supply with the analyzer.

> ❶ Only use voltage of 100–240 V AC, 50-60 Hz.

3 Connect the power supply to a properly grounded mains outlet.
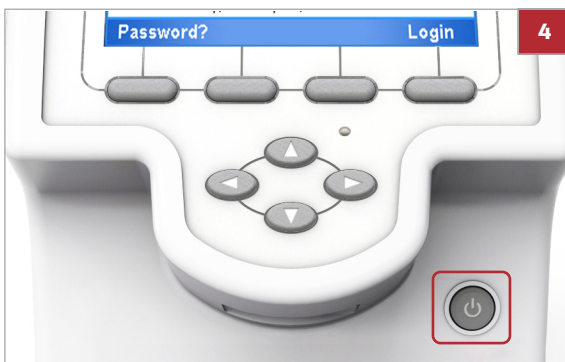
4 Press and release the power button to power on the analyzer.
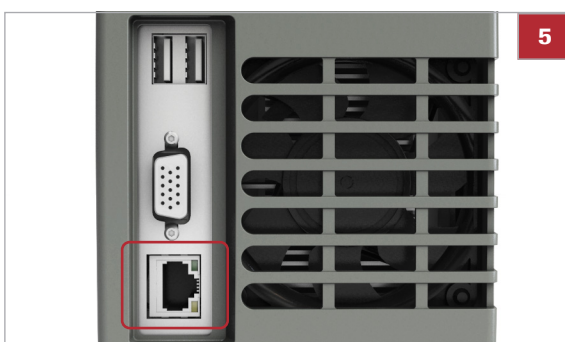
5 Connect the analyzer to the local data network, if required.

> ❶ Use a standard Ethernet data cable and connect to an appropriate wall connector or switch.

6 Log on to the analyzer.

> ❶ When you use a default user account for the first time, you must change the password at logon.
> When you log on to the analyzer for the first time and you intend to connect a USB printer, make sure this USB printer is **not** connected.
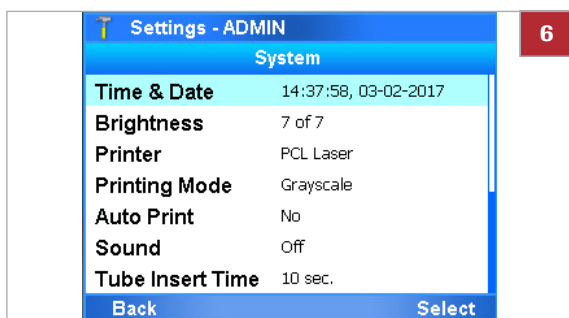
▶ **To install a USB printer**

1 When you start the analyzer for the first time, make sure the USB printer is **not** connected.

2 Log on to the analyzer.
❶ You need Supervisor or Administrator access role.

3 Connect the printer to the analyzer.
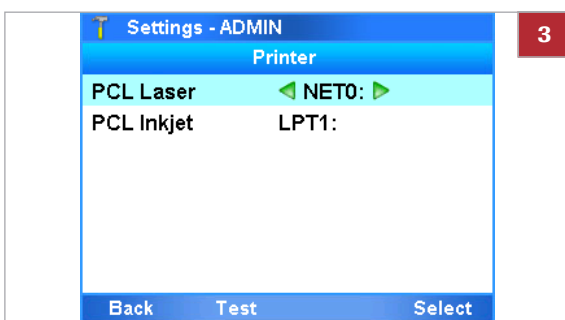
4 Choose **Main > Settings > System > Printer**.

5 Choose the printer type and connection:
- For a laser printer, choose the **PCL Laser** item and choose the **LPT1:** option.
- For an inkjet printer, choose the **PCL Inkjet** item and choose the **LPT1:** option.

6 Choose the **Select** button. Choose the **Printing Mode** item:
- For a grayscale printer, keep the default **Grayscale** option.
- For a color printer, choose the **Color** option.

▶ To install a network printer
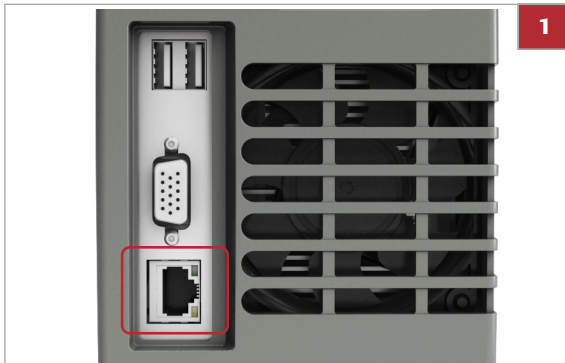
1 Connect the analyzer to the local data network.
  ❶ Use a standard Ethernet data cable and connect to an appropriate wall connector or switch.

2 Choose **Main > Settings > System > Printer**.
  ❶ You need Supervisor or Administrator access role.

3 Choose the printer type and connection:
  ▪ For a laser printer, choose the **PCL Laser** item and choose the **NET0:** option.
  ▪ For an inkjet printer, choose the **PCL Inkjet** item and choose the **NET0:** option.

4 Choose the **Select** button.

5 Enter **Server Name**, **Share Name**, **User Name**, and **Password** settings.
  ❶ For information about the settings for the print server, contact your network administrator.
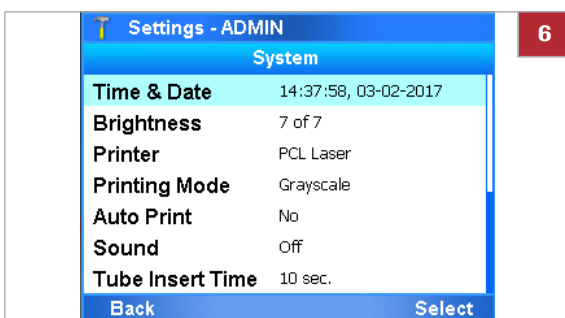
6 Choose the **Printing Mode** item:
  ▪ For a grayscale printer, keep the default **Grayscale** option.
  ▪ For a color printer, choose the **Color** option.

7 Return to the **Main** menu.
  ❶ If you do not return to the **Main** menu, settings will be lost at the next restart of the analyzer.

Related topics

- Logging on (29)
- Changing your password (31)
- System settings (79)

About the analyzer

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 on-board computer analyzes the collected data and outputs an interpreted result.

In a typical assay, a raw 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 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.

-`Q`- 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 standard supplies table in this publication.

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.
Running assays	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.

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

About the audit trail	The system logs each user action that triggers a system change in an audit trail entry together with user information and time stamp.

You can export the audit trail using the advanced tools key.

⊡ For information on exporting the audit trail, refer to the **cobas**® Liat® Advanced Tools Key Guide.

⊡ **Related topics**

- Setting up the analyzer (60)
- Installing or updating assays from a USB key (62)
- Installing or updating an assay from the Roche remote service platform (64)
- Installing an assay from a local source (66)
- Adding an assay tube lot (70)

Overview of the analyzer operating elements
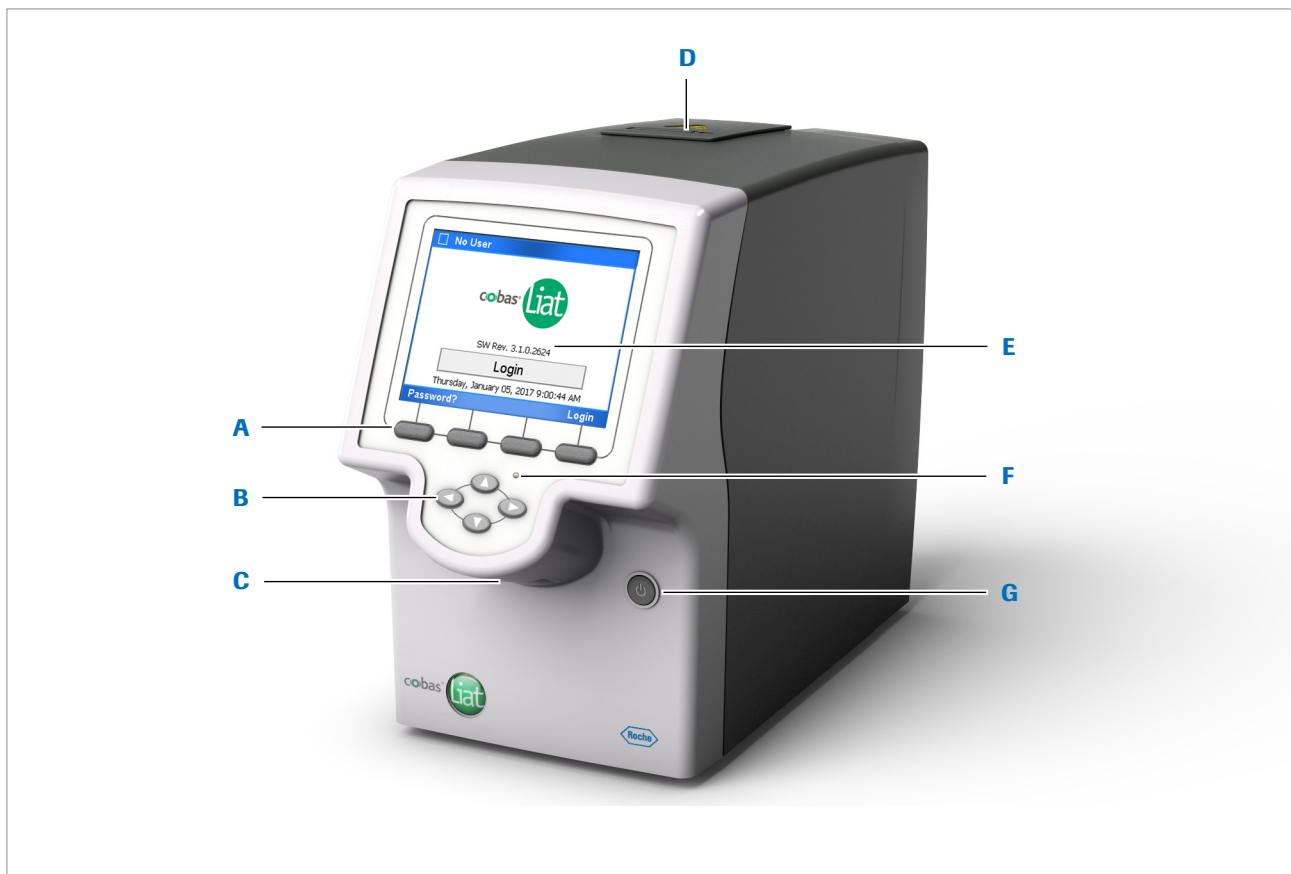
A	Function buttons	**D**	Tube entry door	**G**	Power button
B	Navigation buttons	**E**	Touch screen		
C	Barcode reader	**F**	Power indicator light		

▣ 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 touching 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 menus, position the cursors, and toggle selections.
Barcode reader	The barcode reader aims the scanning beam down in front of the analyzer. Choosing the **Scan** button 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.

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

Touch screen	You touch the items on the screen with your finger (also when wearing lab gloves), or the stylus included with the analyzer.
Power button	Switch on and switch off the analyzer.

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 assay menu by installing assay scripts. You need Supervisor or Administrator access role to install an assay script.

The currently installed assays are listed on the **Assay Menu** panel.

▸▤ **Related topics**

- Installing an assay from a local source (66)
- Adding an assay tube lot (70)
- Running an assay (46)

Overview of the touch screen

To operate the touch screen, use your finger (even when wearing lab 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
B Subtitle bar
C Touch screen buttons
D Function buttons
E Navigation buttons
F Scroll bar

▭ Overview of touch screen.

☼ To choose an item, either touch it directly or use the corresponding function button.

Title bar   Displays

▪ User access role icon:

 User

 Supervisor

 Administrator

▪ Current main menu or assay name, including indication whether the share lot function is enabled (SL).

▪ User ID

Note that user IDs shown in screenshots in this publication are for illustration purposes only.

▪ Possibly alert icon:

 Warning

 Service

▪ In case of a configured DMS or HL7 connection, connectivity monitor icon:

So far, there has been no connection or there was an error during the last connection.

Last connection was successful.

Connection currently transmitting.

To display information on the meaning of an icon, touch it.

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 cursors, and toggle selections.

Common user actions

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
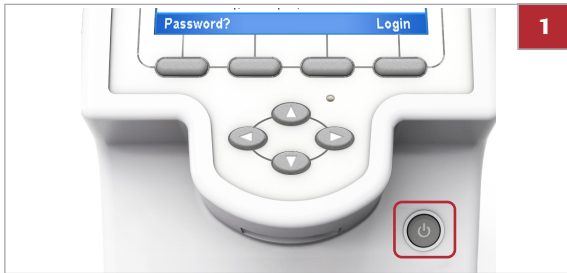
▶ **To start the analyzer**

1 Press the power button.

   ❶ 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 login panel is displayed.

   ❶ Initialization may take several minutes.

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. A badge barcode can be any barcode that complies with the system standards.

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

☀ Independent of the authentication 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 (37).

⮞▤ Scanning barcodes (37)

⮞▤ About authentication modes (80)
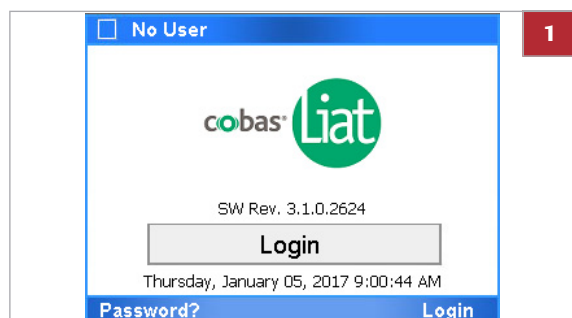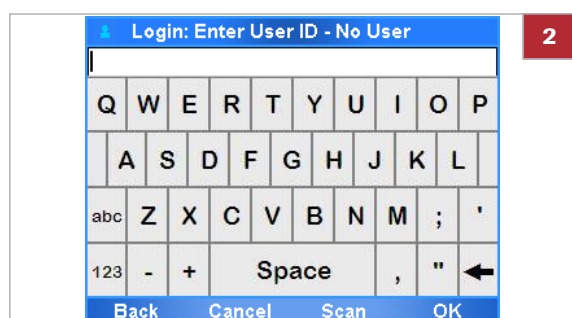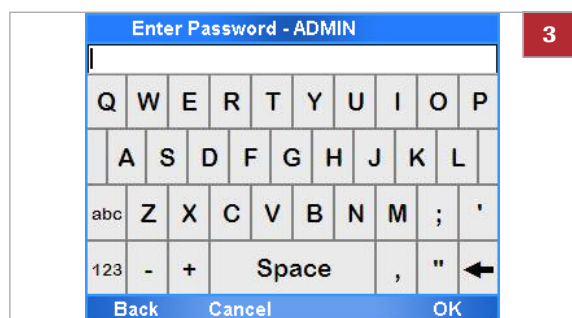
▸ **To log on with user ID**

1 On the login panel, choose the **Login** button.

[1]

2 To enter your user ID, do one of the following:
- ▪ Enter your user ID manually and choose the **OK** button.
- ▪ Place your user ID barcode parallel to the analyzer directly beneath the barcode reader. Choose the **Scan** button.

[2]

3 Enter your password and choose the **OK** button.
➔ In the title bar of the **Main** menu, your access role and user ID are indicated.

[3]

▸ **To log on with badge barcode**

1 On the login panel, choose the **Login** button.
❶ If a badge barcode authentication mode is set on the analyzer, the barcode reader is enabled automatically.
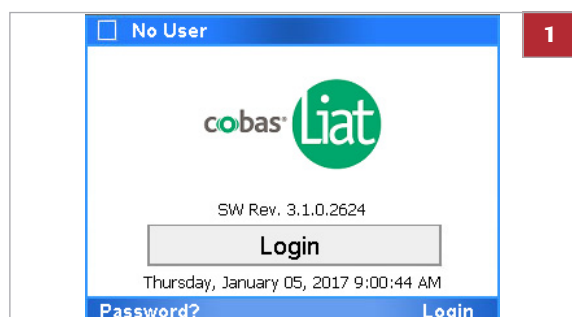
[1]
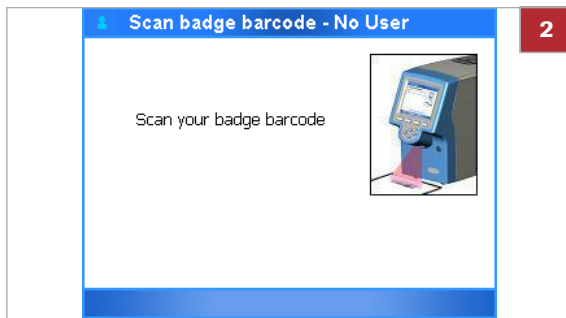
2 Scan your badge barcode.
- ❶ If you want to log on with your user ID instead, wait until the time to scan your badge barcode runs out. On the message dialog box, choose the **Manual** button.
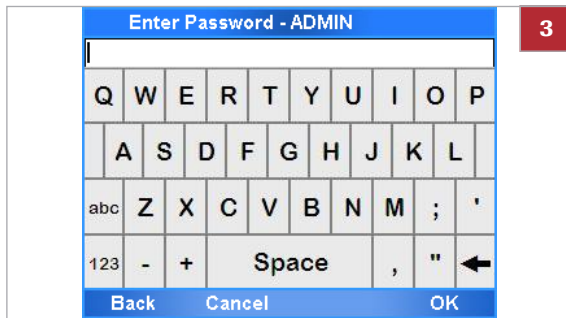
3 If required, enter your password and choose the **OK** button.
- → In the title bar of the **Main** menu, your user ID and access role are indicated.

⟩▤ **Related topics**

- Scanning barcodes (37)
- About authentication modes (80)

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 (86)

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 ▶ (33)

⟩▤ About user IDs and passwords (91)

⟩▤ Resetting the lost default administrator password (125)

Changing the password of another user

Users with Supervisor or Administrator access role can do the following:

▪ Change the password of another user up to their own access role.

▪ Request a password change at next logon for another user up to their own access role.

These changes work the same way as changing any other item of a user information.

▸▤ Changing user information (94)

▶ **To change your password at anytime**

1 Choose **Settings > User**.
❶ If you are logged on with User access role, only your own user account is listed.

2 Choose the **Info** button.
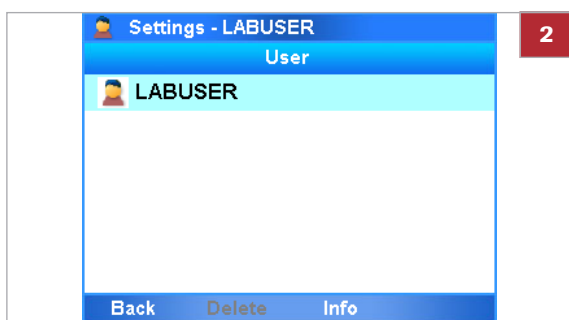

3 Choose the **Password** item.
❶ If you are logged on with User access role, you have access to the **Password** item and the **Badge Barcode** item only.
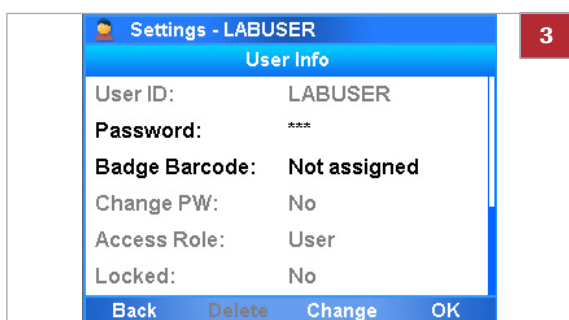
4 Enter your current password and choose the **OK** button.
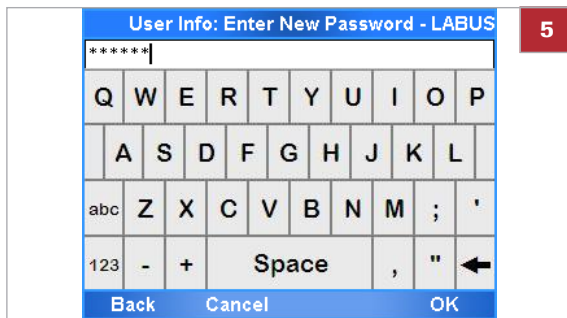
5 Enter your new password and choose the **OK** button.

   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 **OK** button.

   ➔ Your password is changed.

▸ To change your password at logon
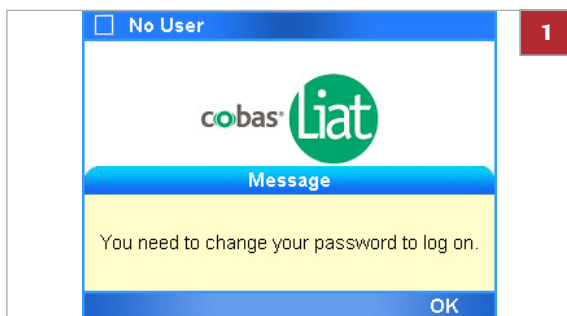
1 When prompted to change your password, choose the **OK** button.

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

   ❶ For passwords, you can use alphanumeric characters, symbols and/or spaces. Passwords are restricted in length to 4–20 characters.

3 To confirm your new password, enter the password again and choose the **OK** 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 (86)

Changing the badge barcode of another user

Users with Supervisor or Administrator access role can assign or change the badge barcodes of other users up to their own access role.

Assigning or changing the badge barcodes of another user works the same way as changing any other item of a user information.

▸ Changing user information (94)

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

1 Choose **Settings > User**.

❶ If you are logged on with User access role, only your own user account is listed.
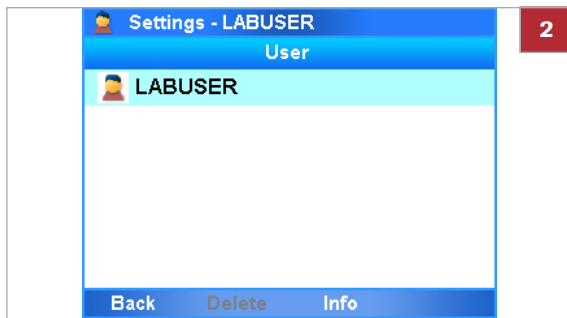
2 Choose the **Info** button.
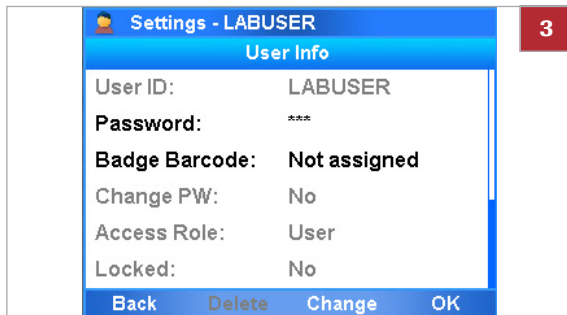
3 Choose the **Badge Barcode** item and choose the **Change** button.

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

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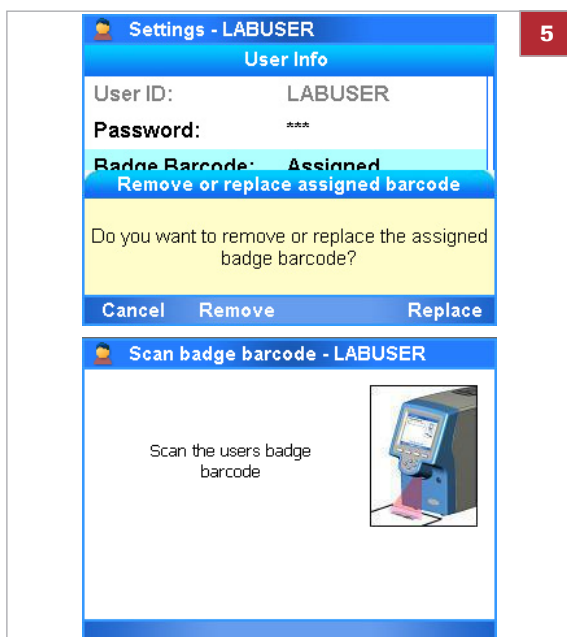
5 To change your badge barcode, do one of the following:
- To remove an assigned badge barcode, choose the **Remove** button.
- To replace your badge barcode, choose the **Replace** button. Scan your badge barcode twice.

›▦ **Related topics**
- Scanning barcodes (37)

Selecting items on the screen
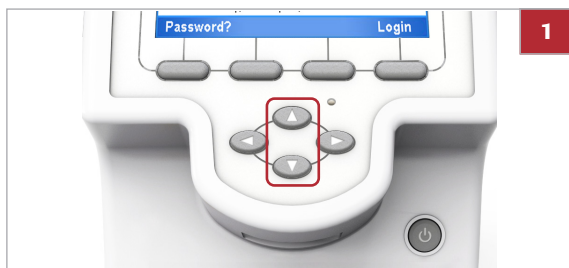
To select an item using the buttons

1 Use the ⊕ and ⊖ navigation buttons to select the desired item.

> ❶ Alternatively, you can touch the item on the screen.
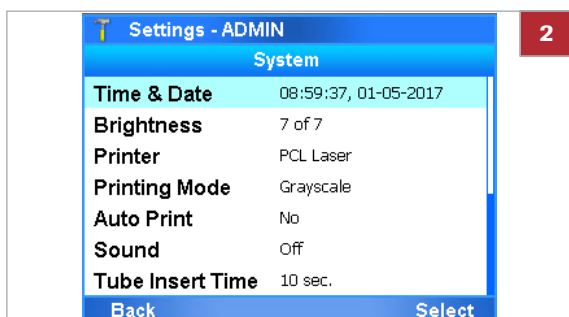
2 Choose the **Select** button.

> → This may lead to detailed information on the selected item or to a new panel. It may also confirm an action.

Selecting predefined values

Some items can take one of several predefined values.

Values that can be chosen are framed by green arrows, when selected.

To select a predefined value
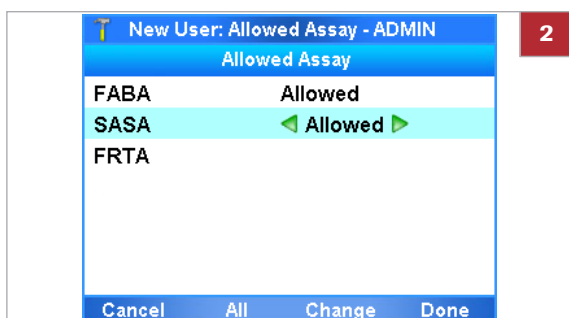
1 Select the item you want to change.

2 Use the Left ◁ and Right ▷ navigation buttons to select the desired value.

> ❶ The value that can be chosen is displayed between green arrows, for example ◁ **Allowed** ▷ .

3 Choose the **Change** button.

**4** Choose the **Done** or **OK** button, whichever is available.

Entering text and numbers

Depending on the situation, either the alphanumeric or the numeric keyboard is displayed.
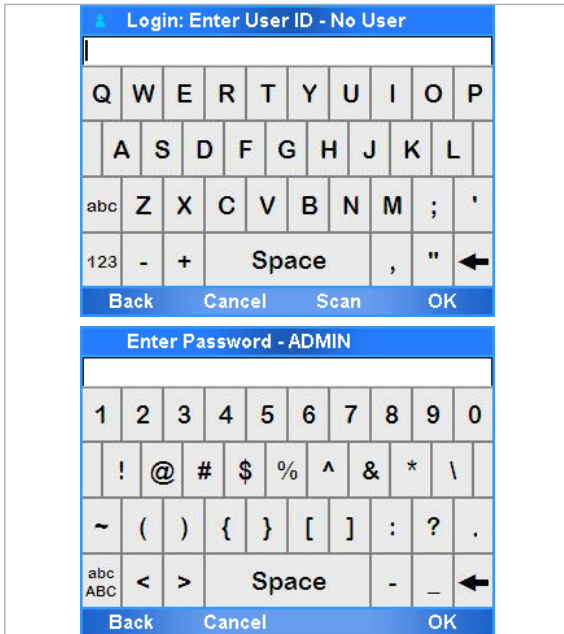
Key	Function
ABC	Enter capital letters.
abc	Enter lower case letters.
123	Switch to number/symbol entry.
abc ABC	Switch to letter entry.
←	Delete the character to the left of the cursor.

⊞ Selected keys on the alphanumeric keyboard

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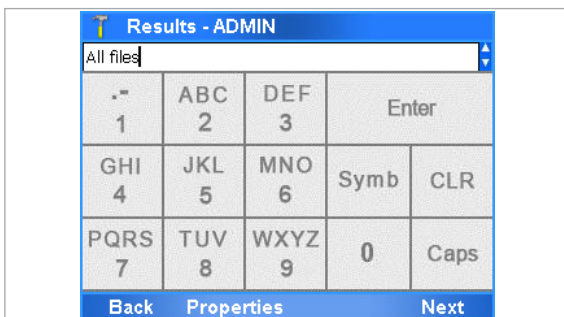
Key	Function
CLR	Delete the character to the left of the cursor.
Caps	Switch to letter entry.
Symb	Switch to symbol entry.
Enter	Confirm the entry and close the numeric keyboard.

⊞ Selected keys on the numeric keyboard

To confirm the entry, choose the **Enter** button of the **Next** button.

Scanning barcodes

You use the barcode reader for scanning assay tube, sample, package insert, control, user ID, 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.

The sample ID barcode must comply with one of the following standards:

- Code 39
- Code 93
- Code 128
- Codabar
- GS1 Databar-14

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 even not if body oil, disinfection or other fluids are used, watch out for wrinkles.

All specimen 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.

▶ **To scan an assay tube barcode**

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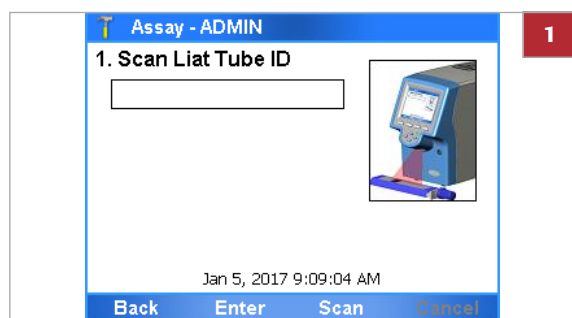
2 NOTICE Placing the barcode inappropriately may lead to reading errors or malfunction.

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

3 If for some reason, 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.

About locking the analyzer

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

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

▣ Walk-by panel.

The auto-lock function locks the analyzer 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 a value between 1–10 minutes. The default value is 3 minutes.

You lock the analyzer manually by choosing the user icon in the top left corner of a panel.

🔆 Locking the analyzer manually is not possible when a message box is displayed or when a process is running (e.g. running an assay).

Unlocking the analyzer   When your account is locked, unlock it by entering your password or by scanning your badge barcode. You are returned to the panel in which you were working when the analyzer locked.

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.

Auto-lock and assay runs   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 analyzer manually until the assay run is finished.
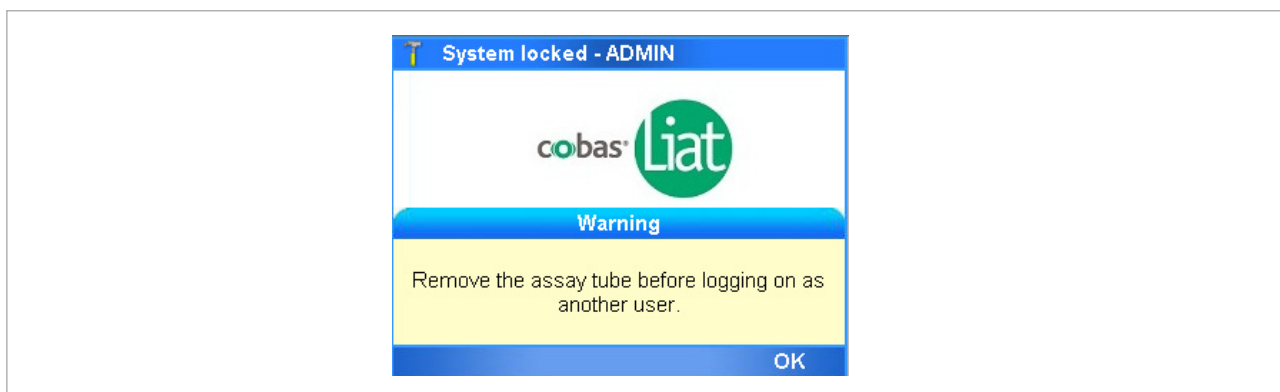
A message is displayed when the assay tube can be removed from the analyzer. The auto-lock function starts again at this point.
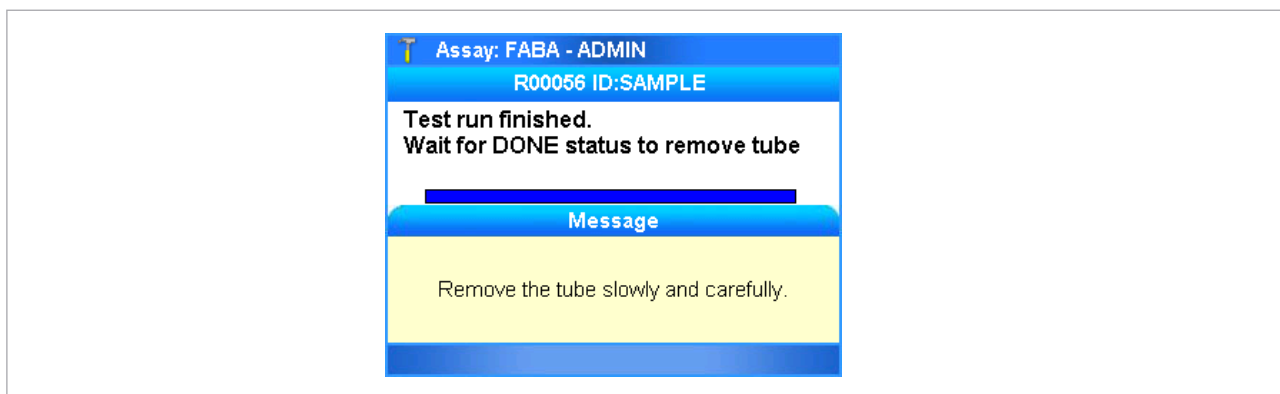

▣ Remove the assay tube.

If the assay tube remains in the analyzer for longer than the auto-lock time, the analyzer locks and the walk-by panel is displayed.

To log on and use the analyzer when a tube is inserted, you must first remove the assay tube.

▣ Remove the assay tube and log on.

A red flashing message at the top of the panel 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.
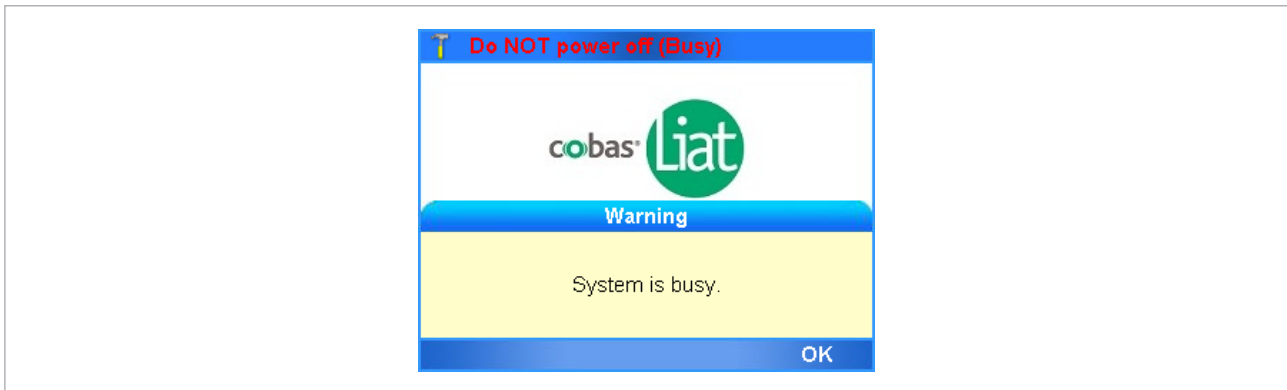
▣ System is busy while assay run finishes.

Clear the message and log on.
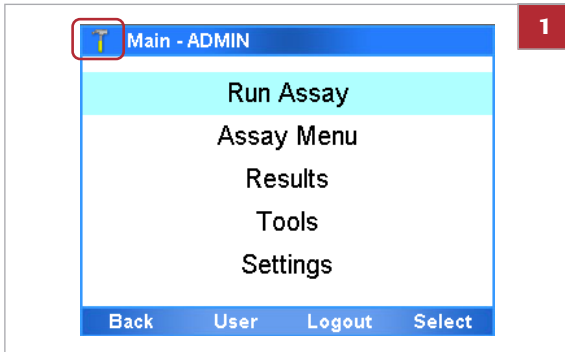
▸▤ **Related topics**

- Locking the analyzer manually (41)
- System settings (79)
- Unlocking the analyzer (42)
- Logging on (29)
- Running an assay (46)

Locking the analyzer manually

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

You can lock the analyzer manually at any time with the following exceptions:

- When a message box is displayed.
- When a process is running (e.g. an assay run).

▶ **To lock the analyzer manually**

1 In the top left corner of the panel, choose the user icon.
→ The walk-by panel is displayed.

⏲ **Related topics**
▪ Unlocking the analyzer (42)

Unlocking the analyzer

The walk-by panel is displayed when the analyzer is locked.

If you were logged on when the analyzer locked, you must unlock it to continue working.

If another user was logged on when the analyzer locked, you must log on to use it.

The procedures are explained in this task.

⏲ To unlock the analyzer by entering your password ▶ (42)

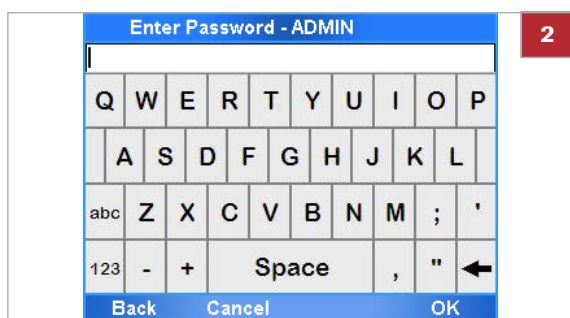⏲ To unlock the analyzer by logging on as another user ▶ (43)

☐ The walk-by panel is displayed.

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

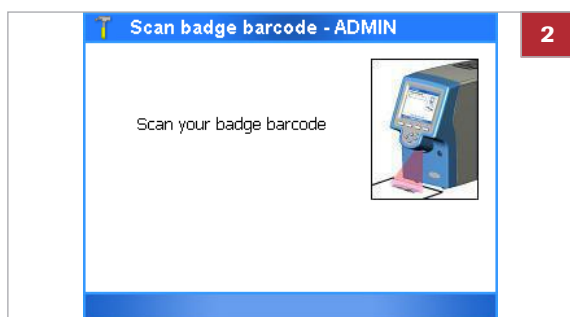**1** On the walk-by panel, choose the **Unlock** button.

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

▸ **To unlock the analyzer by scanning your badge barcode**

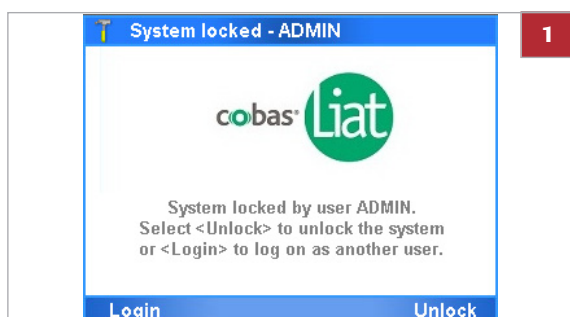**1** On the walk-by panel, choose the **Unlock** button.
  ❶ If the **Barcode & Password** authentication mode or the **Barcode** authentication mode is set on the analyzer, the barcode reader is enabled automatically.
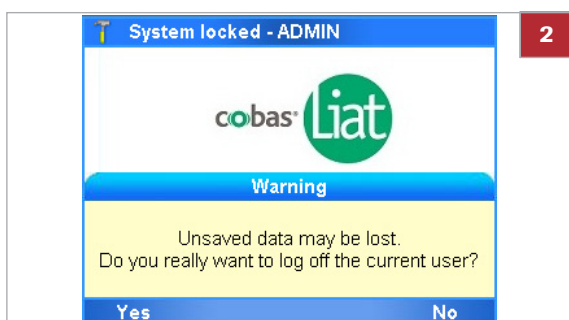
2 Scan your badge barcode.
  → You are returned to the panel in which you were working when the analyzer locked.

▸ **To unlock the analyzer by logging on as another user**

1 On the walk-by panel, choose the **Login** button.
  → A warning message is displayed.

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

   ❶ Choosing the **No** button, returns you to the walk-by panel.

3 Follow the normal logon procedure (⯈🗐 29).

🗐 Related topics

▪ About locking the analyzer (39)
▪ Locking the analyzer manually (41)

Switching off the analyzer

Switching off the analyzer shuts down the software and turns off the power.

> ⚠ **CAUTION**
>
> **Loss of power**
>
> ▶ Do not turn power off while the analyzer is running an assay.
> ▶ In the event of power loss 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 "Please remove the tube slowly and carefully" is displayed.

☐ There is no activity on the analyzer.

▶ **To switch off the analyzer**

1 Press and hold the power button until both the power indicator light and the touch screen turn dark.

Performing a run

Safety ⌑ Make sure you are familiar with the safety instructions in Safety instructions (14).

⚠ **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.

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 and sample ID 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.
    - If you must enter the sample ID manually, do not use spaces.
- Inserting the assay tube into the analyzer.
- The analyzer performs the required assay steps and reports the test results.

-ᅌᅩ- 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.

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

-ᅌᅩ- 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.
‣▤ About locking the analyzer (39)

☐ Assay tube
☐ Disposable pipette supplied with the assay tube
☐ Sample ID barcode

▶ To run an assay

1 Tear open the foil packaging of the assay tube.
   ❶ 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 protective sleeve until you insert the assay tube in the analyzer.

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

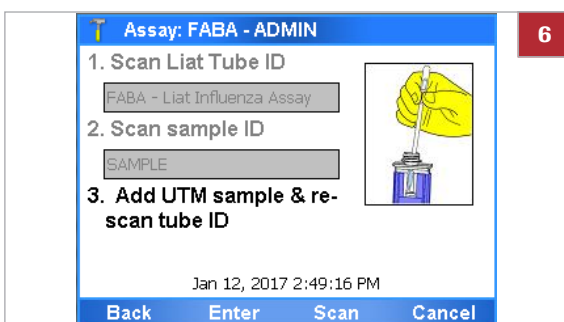3 On the **Main** menu, select the **Run Assay** option and choose the **Select** button.
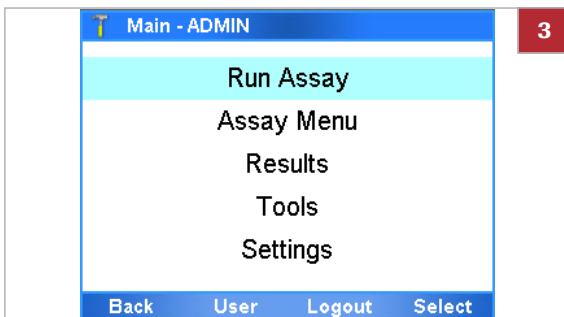
4 Choose the **Scan** button.
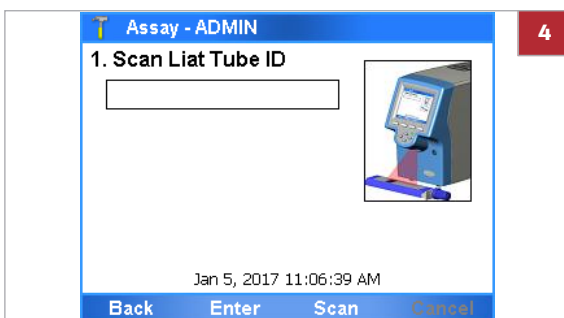
5 Scan the assay tube barcode.
   ❶ Do not remove the assay tube sleeve.

6 Choose the **Scan** button again and then scan the sample ID barcode.
   ❶ If necessary, you can enter the sample ID manually. No spaces should be used when you enter the values.

7 Transfer the correct type of sample:
- Use the sample type indicated on the screen.
- Decap the assay tube.
- Transfer sample into the assay tube.
- Recap the assay tube.
- ❶ 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.

8 Dispose of all used disposable pipettes in accordance with the disposal policy of your institution.


9 Choose the **Scan** button and 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.


10 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.
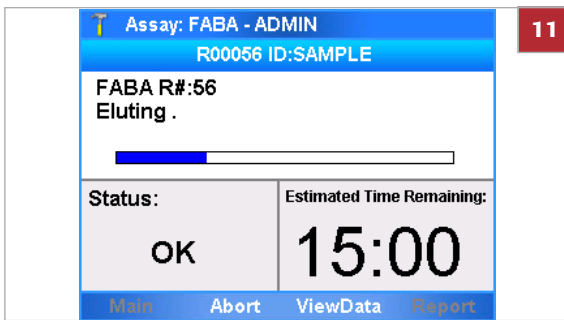
11 Check the progress, if required.

❶ In the subtitle bar, a run number (for example "R00056") and the sample ID are displayed. Choose the **ViewData** button to view messages or to display the growth curve. To abort the assay run, choose the **Abort** button.
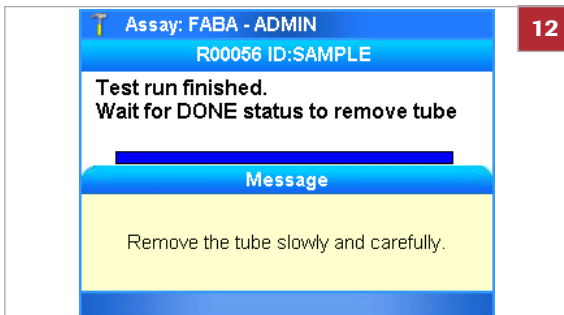
12 When the assay run is complete, the tube entry door opens. A message asks you to remove the assay tube. Remove the assay tube and dispose of it in accordance with the disposal policy of your institution.

➔ If configured, results will be sent to a host automatically.
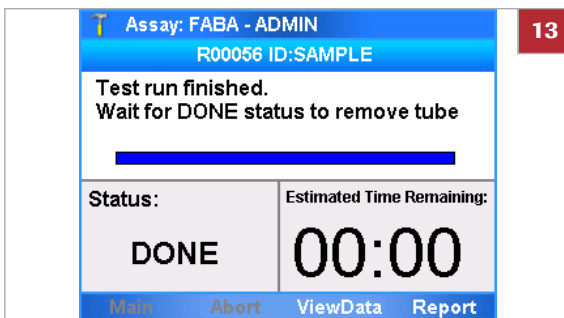
13 Do one of the following:

▪ To review the results, choose the **Report** button.

▪ To return to the **Main** menu – and for example to start another assay – choose the **Main** button.

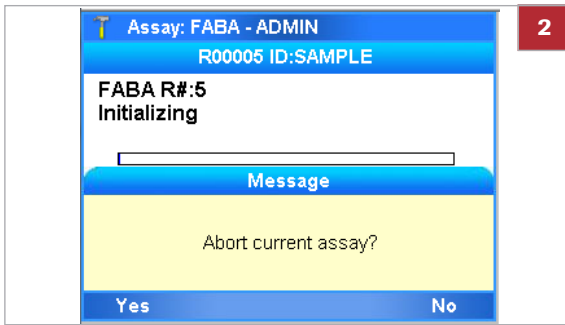▪ To view the growth curve or messages, choose the **ViewData** button.

▸▤ Related topics

▪ Reviewing results (53)

▪ About assays (25)

▪ Scanning barcodes (37)

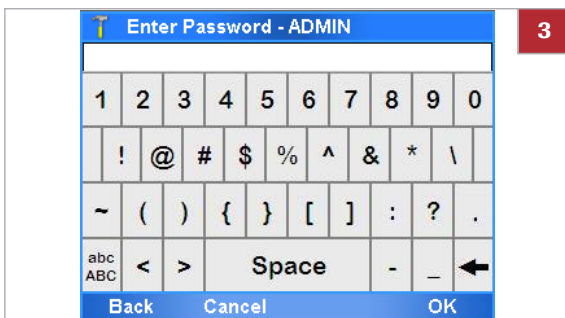▪ Aborting an assay run (49)

Aborting an assay run

▸ To abort an assay run

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

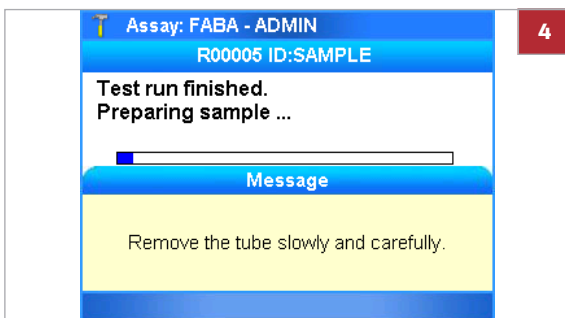**2** On the confirmation message, choose the **Yes** button.

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

❶ You can choose the **Back** button to return to the previous panel.

➔ The analyzer stops assay processing.

➔ The analyzer writes a result report.

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.

6 Do one of the following:
- To view the result report, choose the **Report** button.
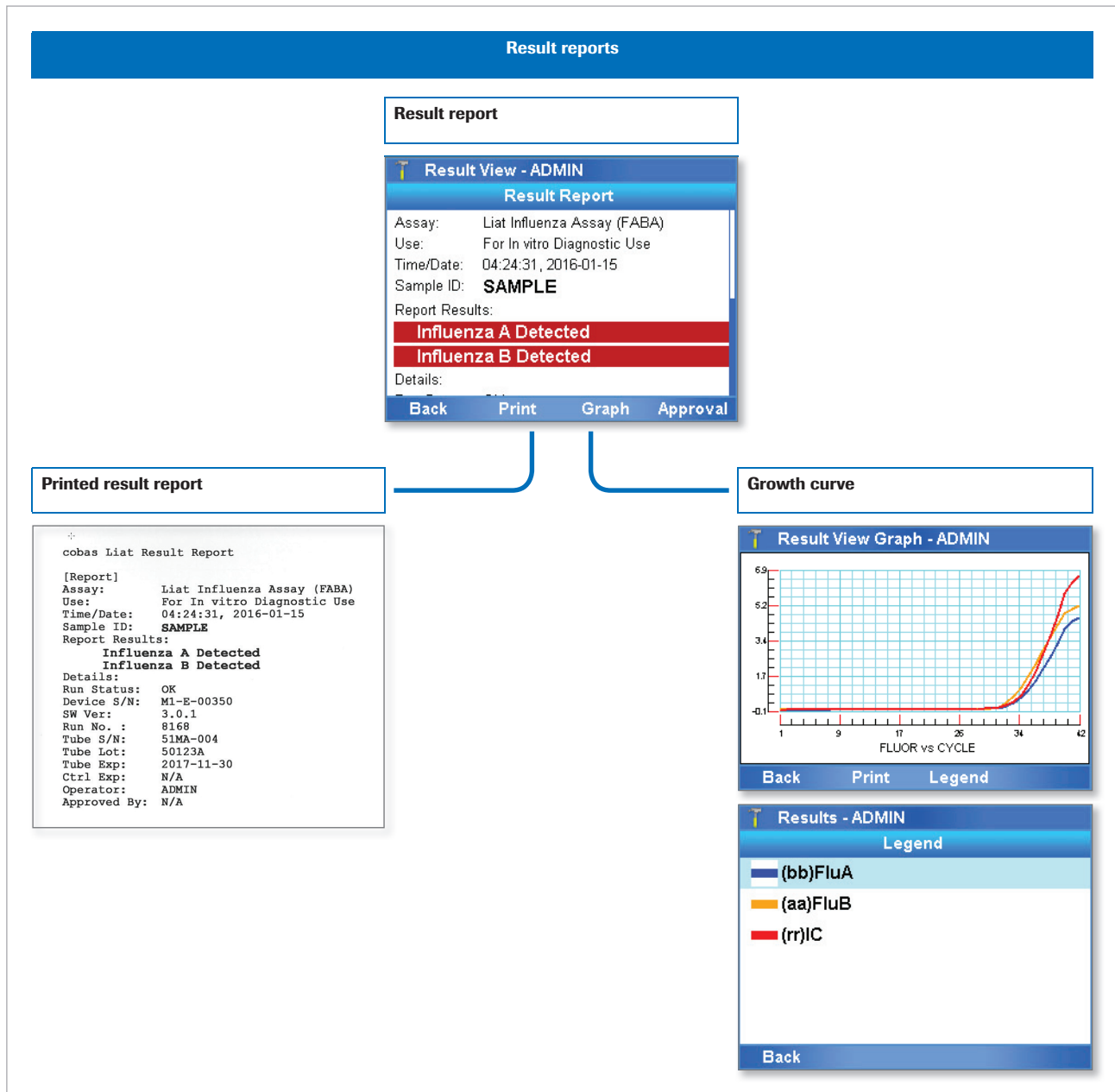- To return to the **Main** panel, choose the **Main** button.

Result handling

About results

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

Result reports

Result report

Result View - ADMIN
Result Report
Assay: Liat Influenza Assay (FABA)
Use: For In vitro Diagnostic Use
Time/Date: 04:24:31, 2016-01-15
Sample ID: **SAMPLE**
Report Results:
Influenza A Detected
Influenza B Detected
Details:
Back   Print   Graph   Approval

Printed result report

```
cobas Liat Result Report

[Report]
Assay:        Liat Influenza Assay (FABA)
Use:          For In vitro Diagnostic Use
Time/Date:    04:24:31, 2016-01-15
Sample ID:    SAMPLE
Report Results:
      Influenza A Detected
      Influenza B Detected
Details:
Run Status:   OK
Device S/N:   M1-E-00350
SW Ver:       3.0.1
Run No. :     8168
Tube S/N:     51MA-004
Tube Lot:     50123A
Tube Exp:     2017-11-30
Ctrl Exp:     N/A
Operator:     ADMIN
Approved By:  N/A
```

Growth curve

Result View Graph - ADMIN

FLUOR vs CYCLE

Back   Print   Legend

Results - ADMIN
Legend
(bb)FluA
(aa)FluB
(rr)IC

Back

☼ If a run has the run status "Warning" (on the message panel and in the result report), but the run did not abort, the result of this run is still valid.

Reviewing results

Users with Supervisor or Administrator access role can accept or reject results.

You typically review results as part of assay processing. Alternatively, you can select results on the **Results** panel and review them.
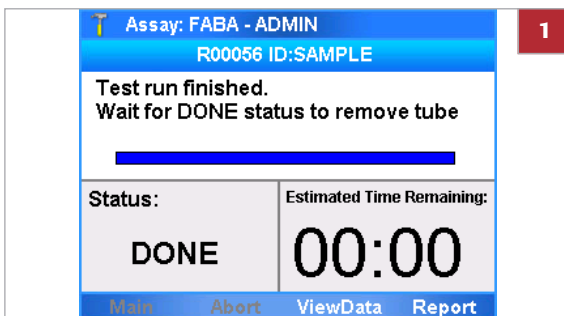
💡 If the analyzer is set up to send results automatically to a host system, reviewing is not done on the analyzer.

▸📄 About data exchange with a DMS (86)

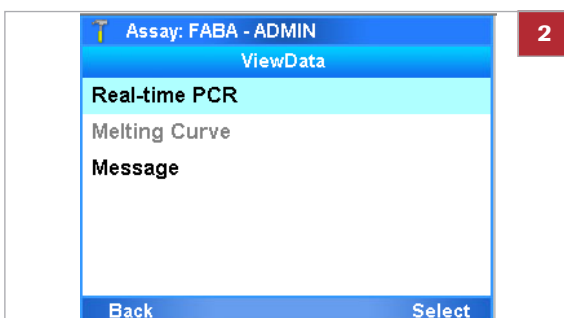☐ Logged on with Supervisor or Administrator access role.

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

1 From the assay status panel, you can do the following:
   - Display the growth curve (see step **2**).
   - Display and print run status information (see step **3**).
   - Review and print the result report (see steps **4** to **9**).
   ❶ You can perform these actions when the assay run is complete.

2 To display the growth curve, on the assay status panel, choose the **ViewData** button. Choose the **Real-time PCR** option.
   ❶ From the graph panel, you can print the graph. You can zoom into an area of the graph by dragging a finger, or the stylus, across the area into which you want to zoom. To zoom out, touch the screen and from the drop-down list that displays do one of the following. Either, choose the **Zoom Out** option to zoom out incrementally, or the **Zoom Normal** option to the original magnification.
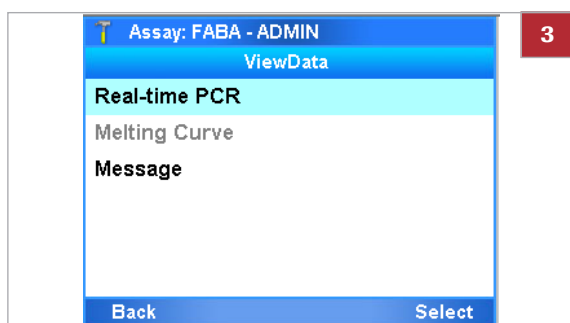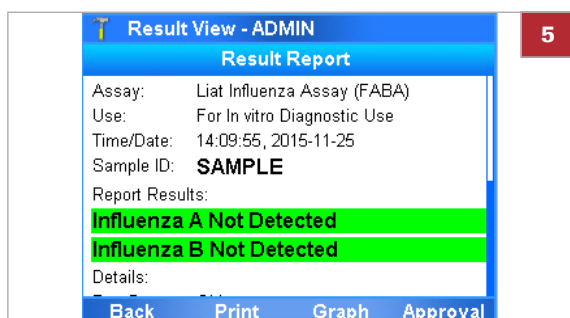
3 To display run status information, on the assay status screen, choose the **ViewData** button. Choose the **Message** option.

- ❶ From the message panel, you can print the messages.
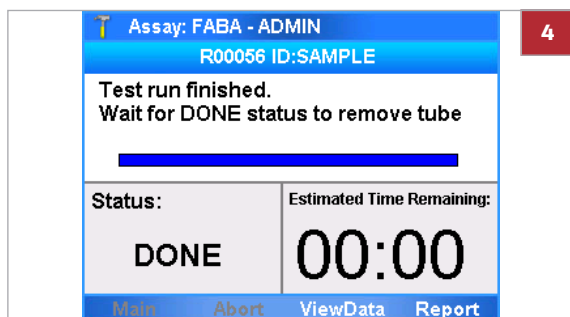
**4** To view the result report, on the assay status panel, choose the **Report** button.

5 On the **Result Report** panel, 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** panel, you can do the following:

- ▪ Approve or reject the result (see steps **7** to **8**).
- ▪ Print the result report (see step **9**).

7 To approve or reject the result, on the **Result Report** panel, choose the **Approval** button.
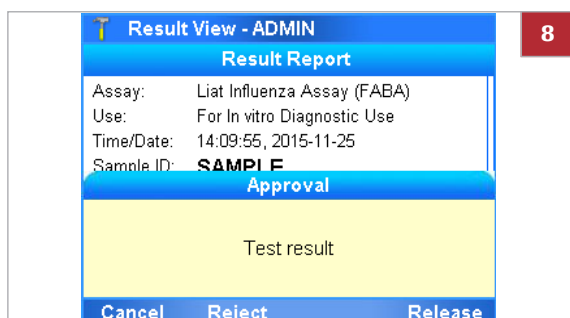
8 On the **Approval** message, choose the **Release** button to accept the result or the **Reject** button to reject it.

- ➜ On the result report, your user ID is added to the **Approved By** line.
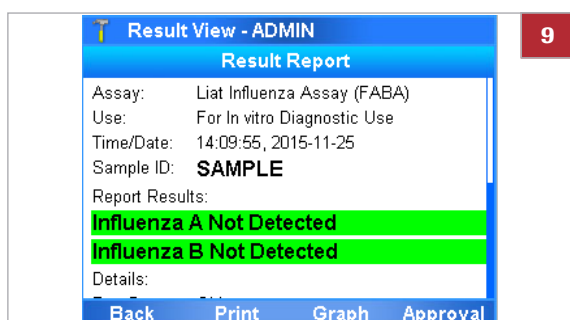
9 To print the result report, on the **Result Report** panel, choose the **Print** button.

- ❶ If the analyzer is set up to print the results automatically or to send the results automatically to an information system or a POCT1-A interface, this step is not required.

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

1 On the **Main** menu, select the **Results** option and choose the **Select** button.

➜ A panel is displayed for selecting specific results.
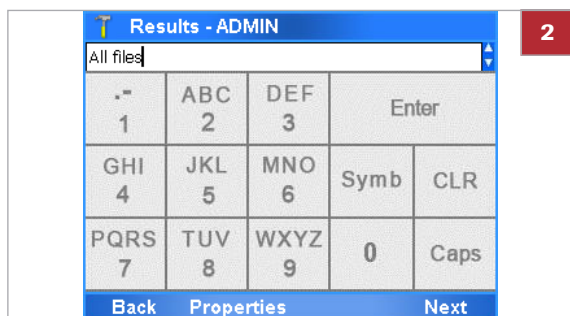
2 Select the filter.
Use the ⬆ and ⬇ navigation buttons to select a specific filter.

- **All files**
- **Sample ID**
- **Assay**
- **User ID**
- **Calib**
- **Unreleased**
- **Needs Approval**
- **Export and delete results**

❶ With filter options ending with a colon, you need to enter a value, for example an ID or name.
Choose the **Properties** button to display the total number of result reports, the space used so far (**Flat File**), and the remaining space available.

3 Choose the **Next** button.
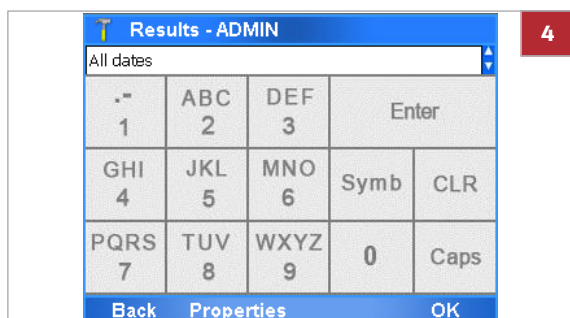
4 On the next filter panel, define the time period for which the results should be included.

❶ Use the ⬆ and ⬇ navigation buttons to select a specific period.
This week
All dates
Today
Last 2 days
Last month
MMDDYY-MMDDYY (you need to enter the two dates)

5 Choose the **OK** button.
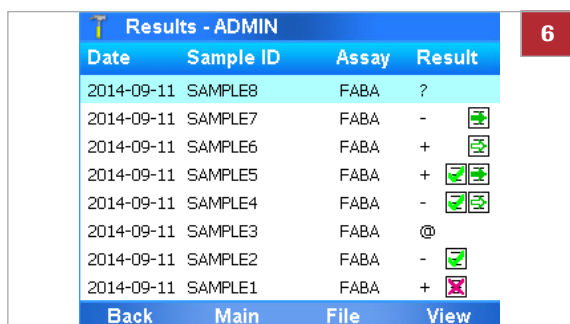
6 On the **Results** panel, select the desired result entry.

❶ **+** Positive
– Negative
? Indeterminate
! Invalid
@ Aborted
✅ Approved
❌ Rejected
🔲 Sent, but not yet confirmed by host
➡ Sent to host successfully
Double-touch a column header to sort the table according to this criterion.
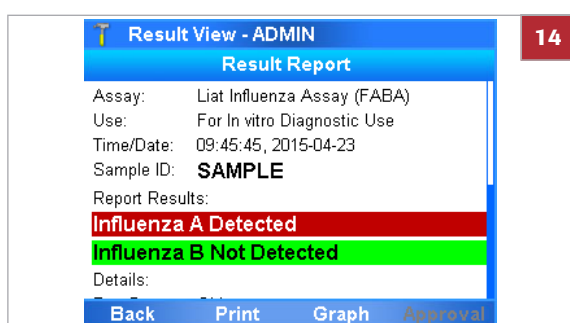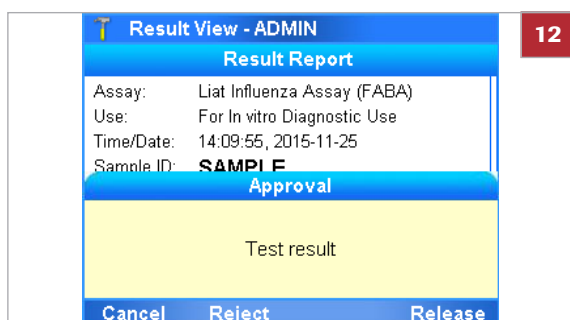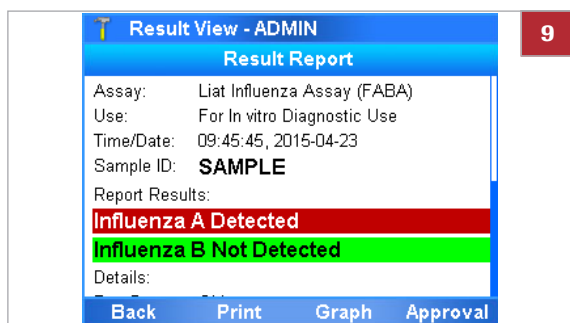
7 From the **Results** panel, you can do the following:
- Review and print the result report (see steps **8** to **14**).
- Save the result in a specific location or send the result to a host (see steps **15** to **17**).

8 To review the result report, on the **Results** panel, choose the **View** button.


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

10 From the **Result Report** panel, you can do the following:
- Approve or reject the result (see steps **11** to **13**).
- Print the result report (see step **14**)

11 To approve or reject the result, on the **Result Report** panel, choose the **Approval** button.

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

13 On the confirmation message, choose the **Yes** button.
➜ On the result report, your user ID is added to the **Approved By** line.

14 To print the result report, on the **Result Report** panel, choose the **Print** button.
❶ If the analyzer is set up to print the results automatically or to send the results automatically to an information system or a POCT1-A interface, this step is not required.
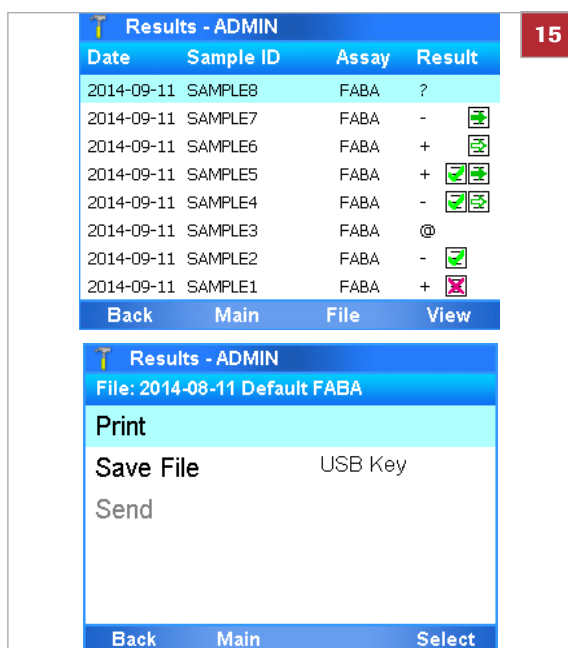
15 To save the result report or to send it to a host, on the **Results** panel, choose the **File** button. From the **File** panel, you can do the following:

- Save the report in a specific location (see step **16**).
- Send the report to a host (see step **17**).

16 To save the report in a specific location, on the **File** panel, choose the **Save File** option. Choose one of the options and follow the instructions on the screen:

- **USB Key**
- **Share Folder**
- **Service FTP**
- **LAN FTP**

17 To send the result to a HIS, LIS, or a POCT1-A interface, choose the **Send** option and follow the instructions on the screen.

Exporting and deleting results

You can only delete a result after exporting it to a different location. Once you have deleted a result, you can no longer retrieve it from the analyzer.

Roche recommends to regularly back up all results. You can use the advanced tools key for this purpose.

⚠ **CAUTION**

Data security

Results backed up by the advanced tools key are stored as *plain text* files and so their content is accessible to unauthorized persons.

▸ Ensure that you store backed up results safely and securely so that they are not accessible by unauthorized persons.

▸ For information on backing up results, refer to the **cobas**® Liat® Advanced Tools Key Guide.

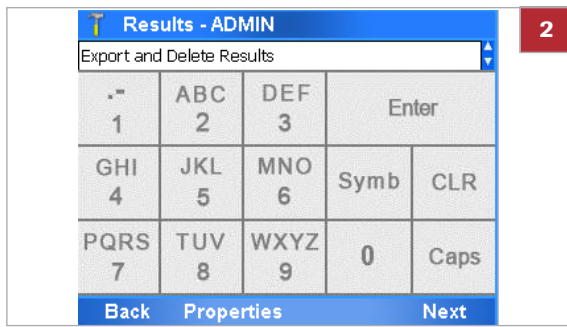☐ Logged on with Supervisor or Administrator access role.
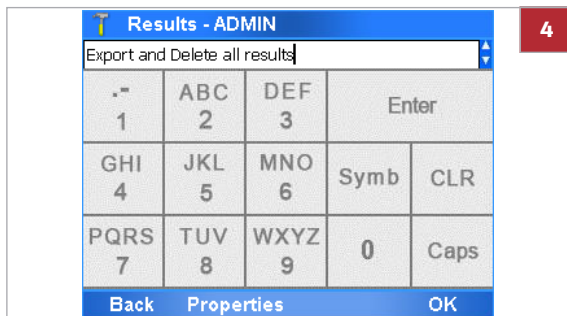
▸ **To export and delete a result**

1 On the **Main** menu, select the **Results** option and choose the **Select** button.

➔ A panel is displayed for selecting specific results.

2 Use the ⬆ and ⬇ navigation buttons to select the **Export and Delete Results** option.

3 Choose the **Next** button.

4 On the next filter panel, define the kind of results you want to delete.
Use the ⬆ and ⬇ navigation buttons to select a specific criterion.

- **Export and Delete all results**
- **Export and Delete results over 7 days old**
- **Export and Delete results over 30 days old**
- **Export and Delete results over 60 days old**
- **Export and Delete results over 90 days old**
- **Export and Delete results over 180 days old**
- **Export and Delete results over 365 days old**
- **Export and Delete results before MMDDYY**
  You must enter the required date, for example "103115" to delete all results older than October 31, 2015.

5 Choose the **OK** button.

6 Choose the export location:

- **USB Key**
- **Share Folder**
- **Service FTP**
- **LAN FTP**

7 Choose the **Select** button.
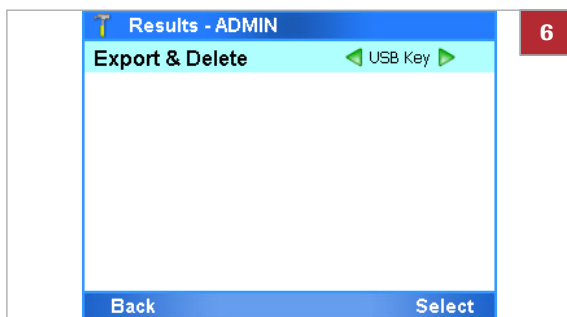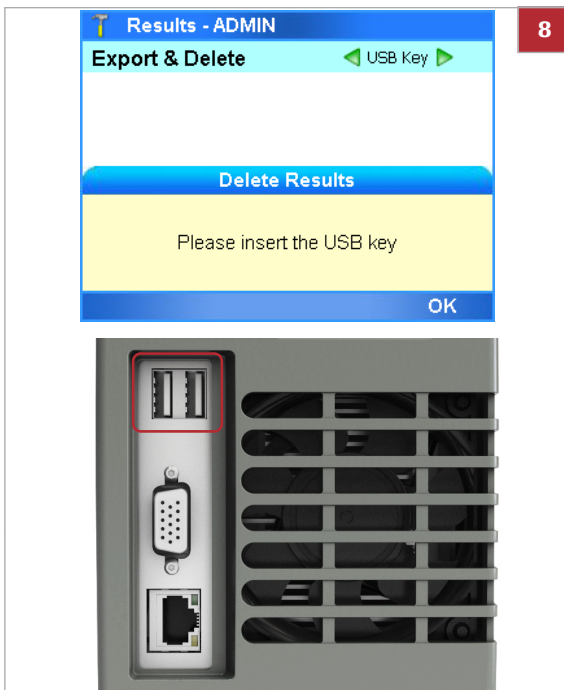
8   If you use a USB key, insert the USB key at the rear of the analyzer. Choose the **OK** button.

9   On the message dialog box, choose the **Yes** button to confirm that this is the correct criterion and that you want to export and delete all results that meet this criterion.

10 Wait for the operation to complete and choose the **OK** button to return to the **Main** menu.

Related topics

- Network definitions (81)
- Network resources (81)

Setting up the analyzer
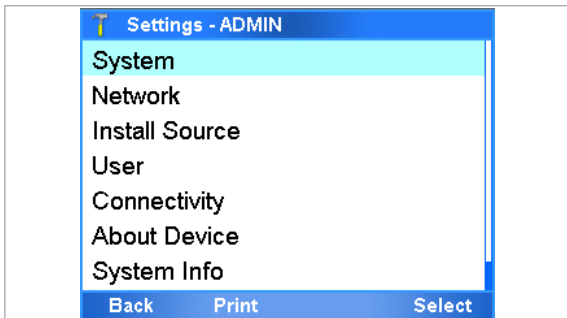
Setup tasks are performed from the **Settings** panel.

-ᗐ- With Administrator access role, you can perform all setup tasks, with Supervisor access role, you can perform the setup tasks with the exception of the Network definitions.

-ᗐ- Result and setup data are retained on the analyzer even if it is not connected to a mains power supply.

In this section

Defining values

You define values by entering text or by selecting a predefined value.

▸ **To enter text**

1 Use the ⬛ and ⬛ navigation buttons to select the configuration item.

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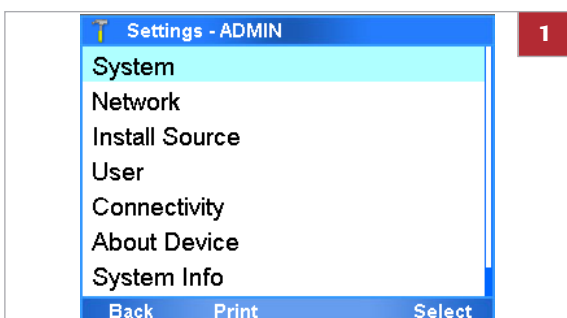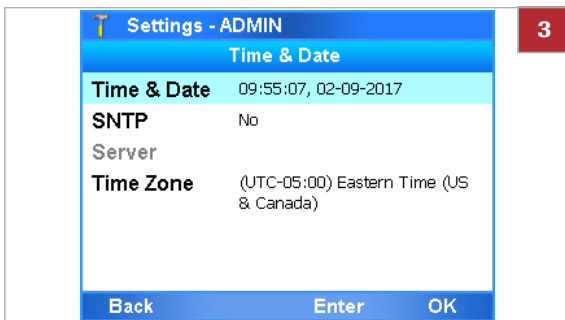
3 Use the ⬆ and ⬇ navigation buttons to select the specific item that you want to define, and choose the appropriate button, typically **Enter**.

➔ The alphanumeric keyboard or the numeric keyboard is displayed.

4 Enter the value and to confirm choose the **OK** button.

➔ The panel is displayed again where you have made the last item selection.

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

▶ **To select a predefined value**

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

❶ Items with predefined values are framed by green arrows.
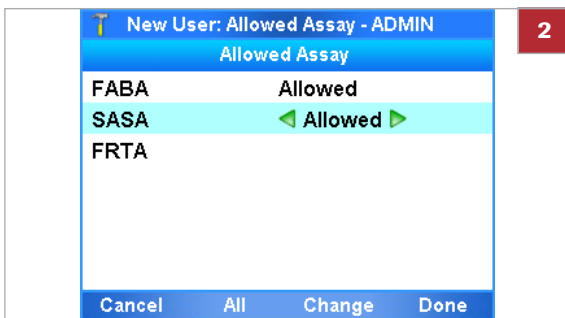
2 Use the Left ◀ and Right ▶ navigation buttons to select the desired value.

3 Choose the **Change** button.
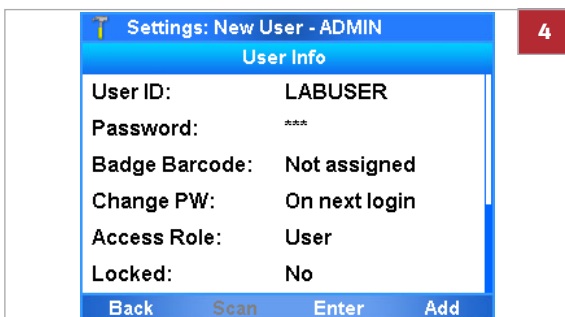
4 To save the setting, choose the **Enter** or **OK** button, whichever is available.

Installing and updating assays
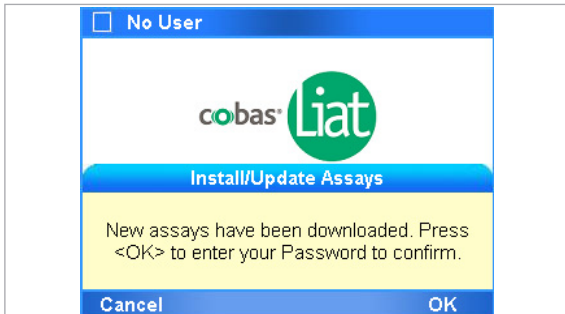
Before you can perform an assay, the assay must be installed.

If the analyzer is set up to install and update from the Roche remote service platform, a message is displayed when a new assay or an update to an installed assay is available.

To use a new assay, the following steps need to be performed:

1. Installing the assay script
2. Adding the assay tube lot
3. Allowing users to perform runs using the new assay (i.e., changing the user information)

> 💡 Do not disconnect the mains power supply to the analyzer while installing or updating an assay.

In this section

Installing or updating assays from a USB key

Before you can perform an assay you must install it. You update an assay when changes are available for this assay.

> 💡 It is recommended to use the USB key as the preferred method for installing and updating assays.
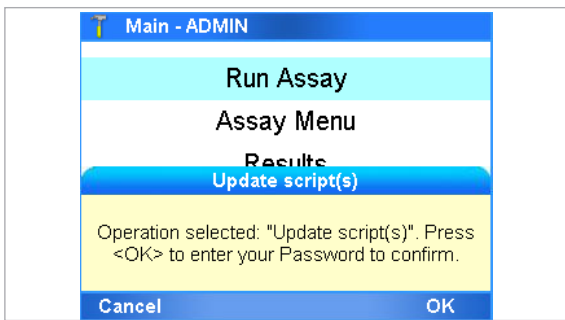
If you are logged on with User or Supervisor access role, a message is displayed asking you to inform your system administrator.

After an assay update, you may need to revalidate the assay lots that are in use.

☐ Logged on with Administrator access role.

▶ **To install or update an assay from a USB key**
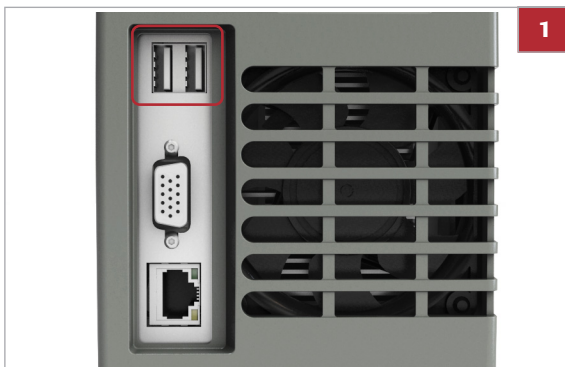
1 While on the **Main** menu, insert the USB key at the rear of the analyzer.
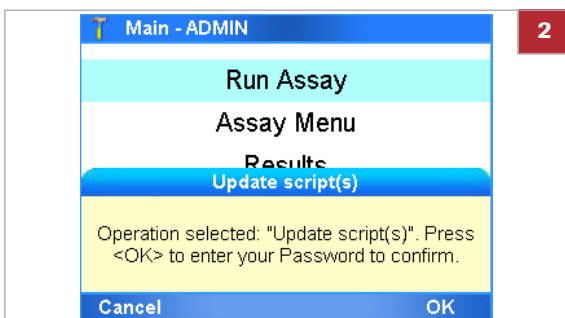
2 On the message dialog box, choose the **OK** button.
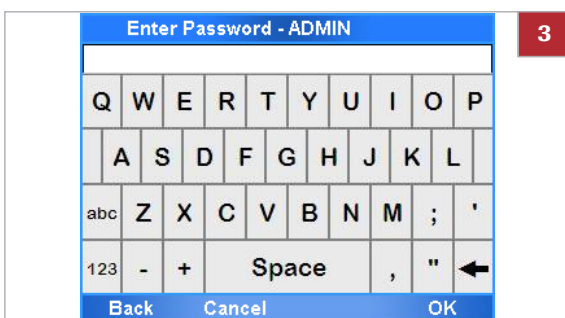
3 Enter your password and choose the **OK** button.
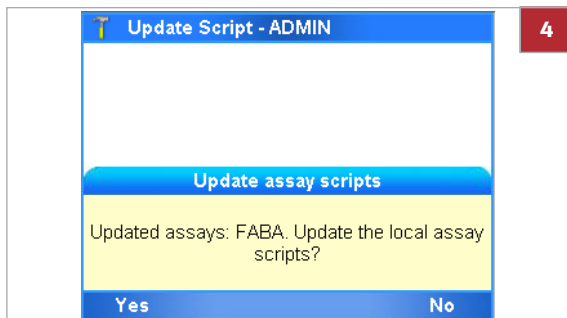
4 Choose the **Yes** button to confirm that you want to install or update the listed assays.

→ A progress panel is displayed. All available assays or updates are installed.

5 Follow the dialog box: "*Please remove the USB drive, wait 5 seconds and hit <OK> to continue.*"

→ The script installation or update completes. This process can take several minutes.
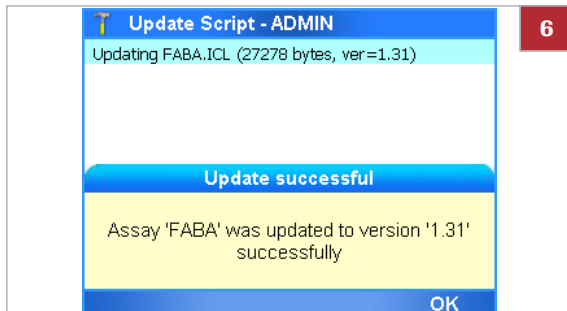
6 Do one of the following:

▪ When a message indicating a successful installation or update is displayed, choose the **OK** button to confirm.
You can check the new assay in the **Assay Menu** panel.
You can check the updated assay script version by choosing **Settings > Versions**.

▪ When a message indicating an unsuccessful update is displayed, choose the **OK** button to return to the **Main** menu.
You should repeat steps **1** to **5**.
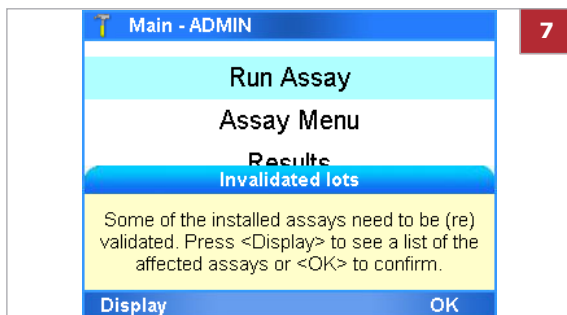
7 If assay revalidation is required, a message is displayed.

▪ Choose the **Display** button to display a list of assays that need to be revalidated.

▪ Choose the **OK** button to return to the **Main** menu.

8 You may need to register the assay manually.

⊟ Related topics

▪ Installing or updating an assay from the Roche remote service platform (64)
▪ Adding an assay tube lot (70)
▪ Registering assays (68)

Installing or updating an assay from the Roche remote service platform

Before you can perform an assay you must install it. You can install it from the Roche remote service platform.

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 access role, a message is displayed asking you to inform your supervisor or system administrator.
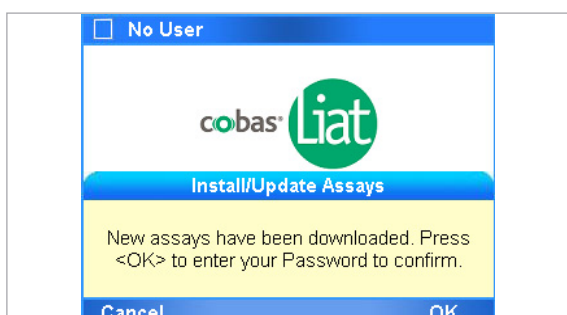
To be able to use a new or updated assay, the following steps need to be executed:

1. Installing or updating the assay
2. Validating the assay tube lot

   With an update, this step is not always required, a message would inform you if validation was required.

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

☐ Your IT infrastructure is set up to allow communication with Roche remote service (IP: 62.209.44.11)

☐ Logged on with Supervisor or Administrator access role for installation, with Administrator for update.

☐ The analyzer is connected to the internet.

▶ **To install or update an assay from the Roche remote service platform**

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 **OK** button.
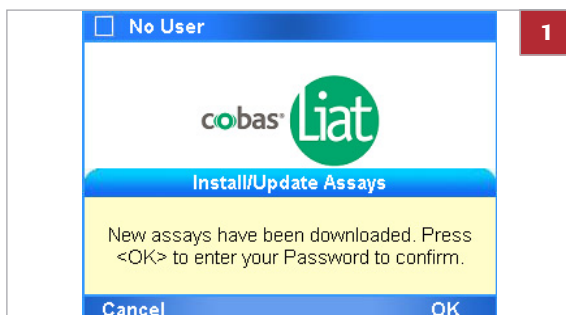
3 Enter your password and choose the **OK** button.
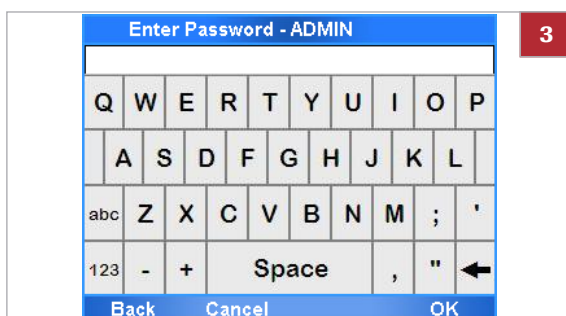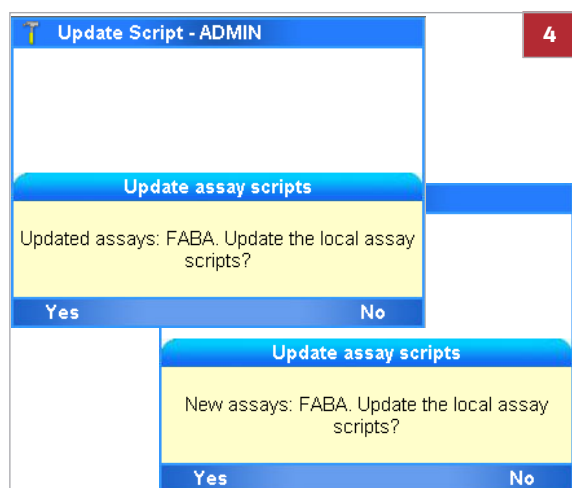
4 On the message dialog box, choose the **Yes** button.
➔ A progress panel is displayed.
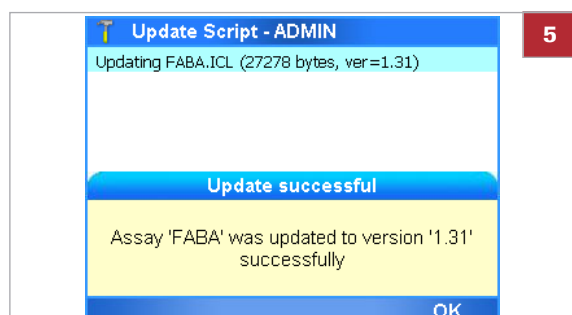
5 When the installation is complete, a message is displayed. Choose the **OK** button.
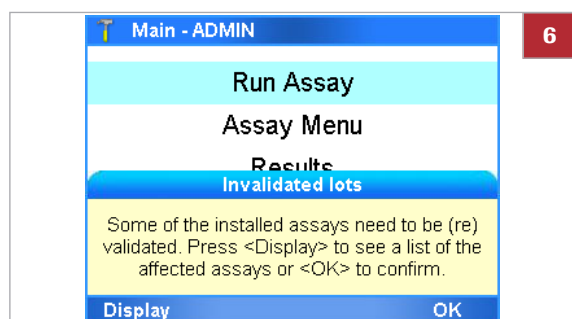
6 If assay validation is required, a message is displayed.
▪ Choose the **Display** button to display a list of assays that need to be validated.
▪ Choose the **OK** button to return to the **Main** menu.

7 You may need to register the assay manually.

▸ **Related topics**
▪ Adding an assay tube lot (70)
▪ Registering assays (68)

Installing an assay from a local source

You can install an assay from a USB key, an FTP server, or a share folder in your network.

You would typically want to do this when Roche deploys new assays.

▸ Defining network resources (82)

☐ If you install from a network server, make sure the assay script is stored in the appropriate location and the network settings are configured correctly.

☐ Logged on with Administrator or Supervisor access role.

▶ **To install an assay from a local source**
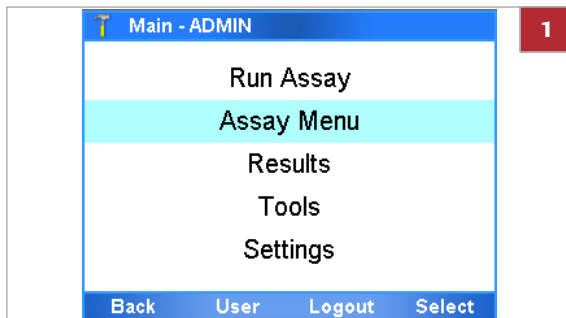
1 On the **Main** menu, select the **Assay Menu** option and choose the **Select** button.

→ All currently installed assays are listed.
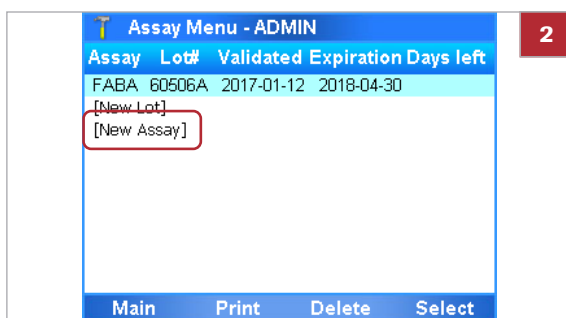
2 Choose the **[New Assay]** option.

❶ You may have to scroll down to display this option.
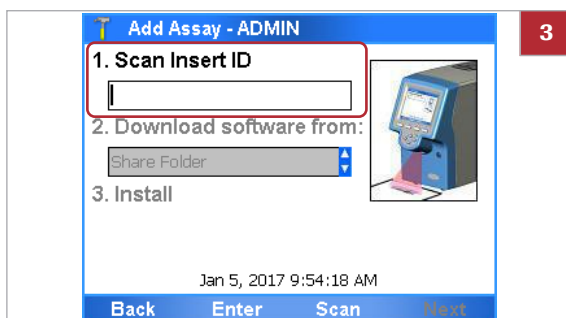
3 Choose **Scan**.

4 Within the time limit for inserting tubes, place the barcode from the assay package insert or the instructions for use under the barcode reader.

→ The **Download software from:** field becomes available.
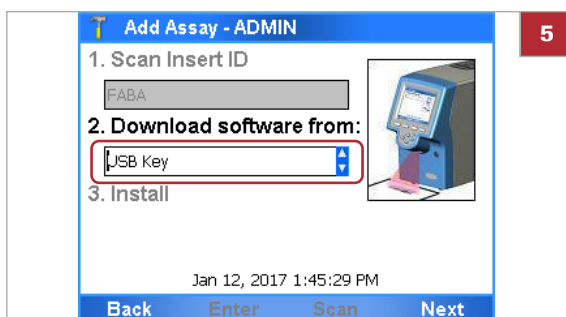
5 Define where to download the software from.

▪ Select **USB Key** if you install from a USB key.

▪ If you have defined a different install source setting, choose the appropriate option.

6 If you use a USB key, ensure the *signed ZIP file* of the assay to be installed is in the root folder of USB key.
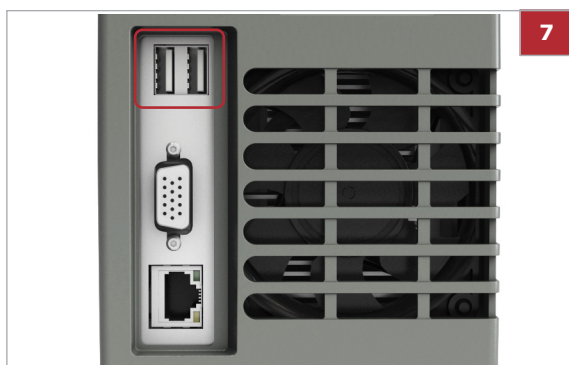
7 If you use a USB key, insert the USB key at the rear of the analyzer.

8 Choose the **Next** button.

9 If you installed from a USB key, remove the USB key from the rear of the analyzer when asked to do so.
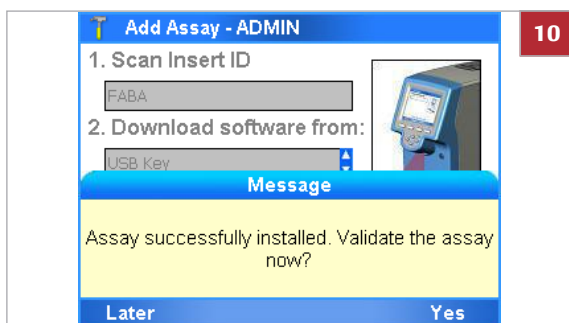
10 Decide whether you want to validate (add an assay tube lot) this assay now or later.

11 You may need to register the assay manually.

Related topics

- Adding an assay tube lot (70)
- Registering assays (68)
- System settings (79)
- Defining network resources (82)

Registering assays

New and updated assays must be registered within 30 days.

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

If the analyzer is connected to the Roche remote service platform, the analyzer automatically tries to register. If this fails, a message is displayed and a user must register the assay manually.

☐ Logged on with Administrator access 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, in the **Main** menu, choose the **Assay Menu** option.
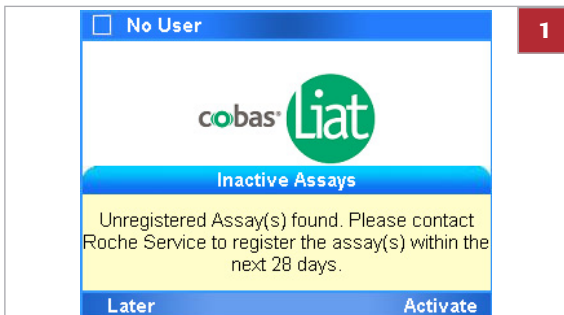
2 Select the assay that needs registering and choose the **Select** button.
- ❶ Unregistered assays are marked with a number in the **Days left** column.
  A red icon 🗎 at the end of an entry indicates that the registration period has expired.
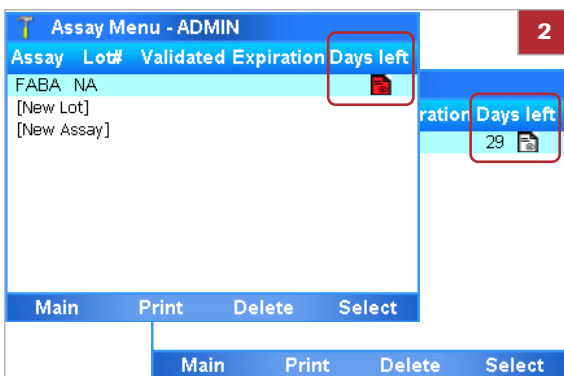
3 On the **Report** panel, choose the **Activate** button.
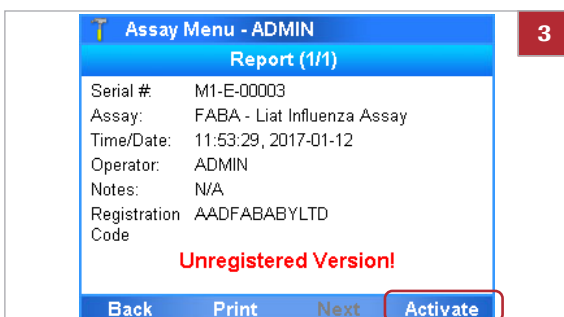
4 From the message dialog box, note the registration code.

5 Call your Roche representative and provide the registration code.

6 The Roche representative issues an activation code.
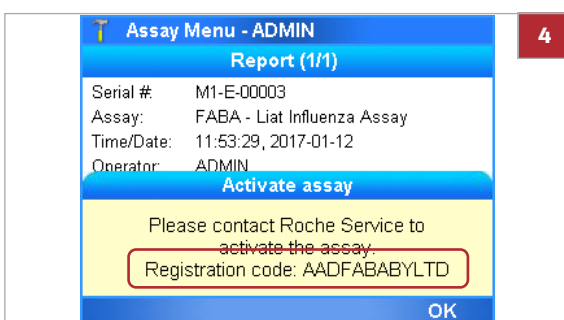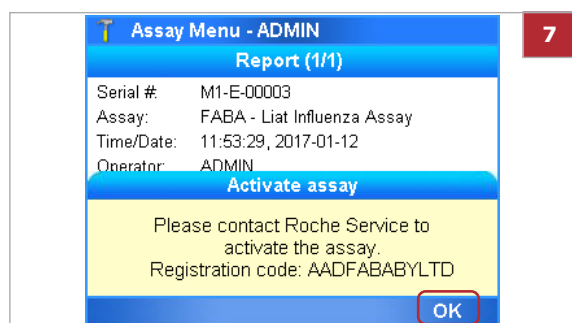
7 On the message dialog box, choose the **OK** button.
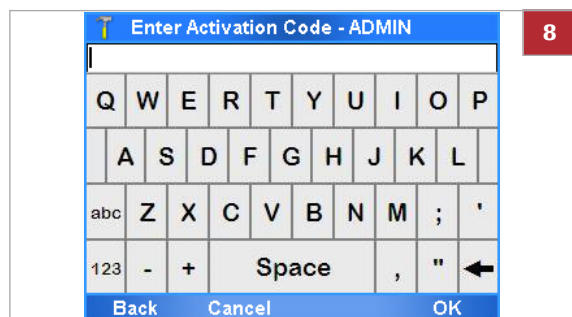
8 Enter the activation code and choose the **OK** button.
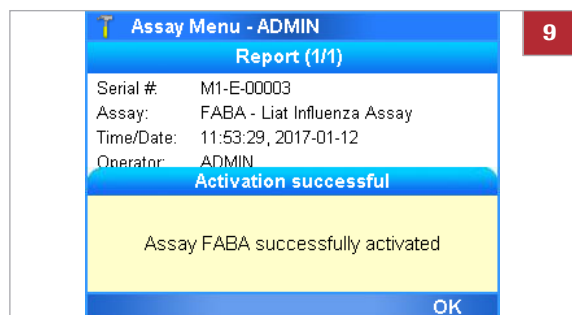
9 On the message dialog box, choose the **OK** button.

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)

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 synchronizing the assay tube lots using the advanced tools key.
- By using the share lot function over the share lot folder.
- By connecting the analyzers to a DMS and enabling the exchange of lots.

-ᄋ- Do not use different ways to share assay tube lots at the same time.

‣▤ For information on the advanced tools key, see the **cobas**® Liat® Advanced Tools Key Guide.

‣▤ For information on using the share lot function, refer to Defining network resources (82)

‣▤ For information on the connection to a DMS, refer to Defining settings for host systems (85)

- ▪ 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 instruction for use of the assay tube lot for the specific assay
- □ Disposable pipette

- □ Assay installed

▶ To add a new assay tube lot

1 On the **Main** menu, select the **Assay Menu** option and choose the **Select** button.
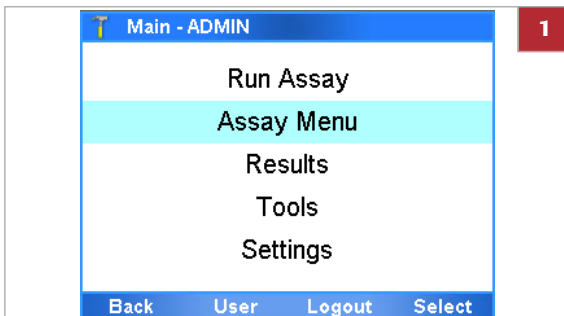
2 Select the **[New Lot]** option and choose the **Select** button.
- ▪ Assay: 4-letter name of the installed assays
- ▪ Lot#: Validated assay tube lot numbers
- ▪ Validated: Date of validation
- ▪ Expiration: Date the lot is set to expire
- ▪ Days left: Days left for activation of the assay
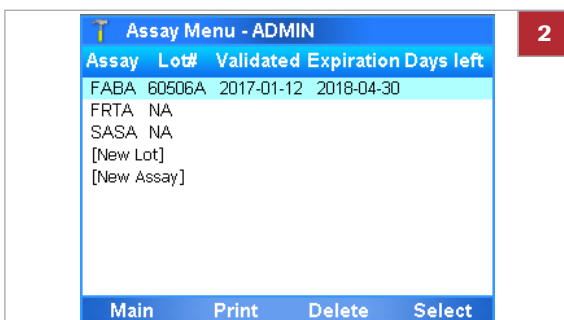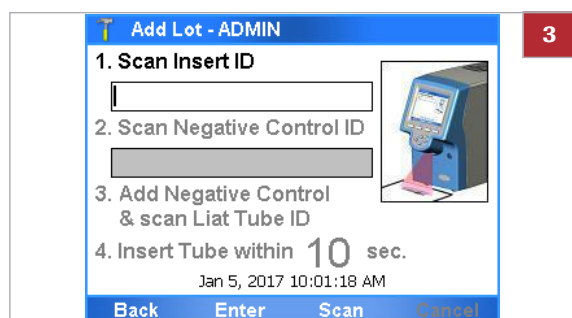
3 Obtain the package insert or the instructions for use from the new lot. Choose the **Scan** button and scan the package insert barcode on the first page of the package insert or the instructions for use of the lot you want to add.

4 You may need to confirm that you have read the package insert.
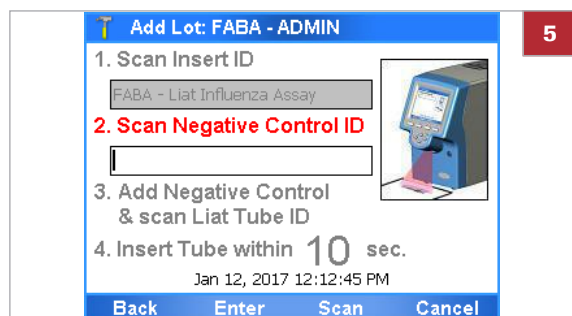
5 Choose the **Scan** button and place the barcode of the negative control under the barcode reader.
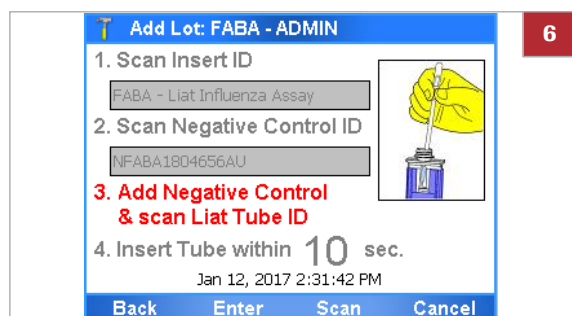
6 Follow the instructions in the assay tube package insert or the instructions for use on how to add the negative control sample to an assay tube from this lot.

7 Dispose of all used disposable pipettes in accordance with the disposal policy of your institution.

8 Choose the **Scan** button.
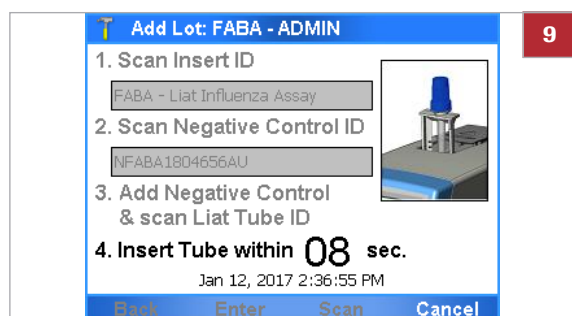
9 Place the prepared assay tube under the barcode reader.

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 **OK** button to confirm the message.

❶ If the QC was not completed successfully, repeat the measurement of the negative control.

12 When asked to do so, remove the assay tube from the analyzer and dispose of it in accordance with the disposal policy of your institution.
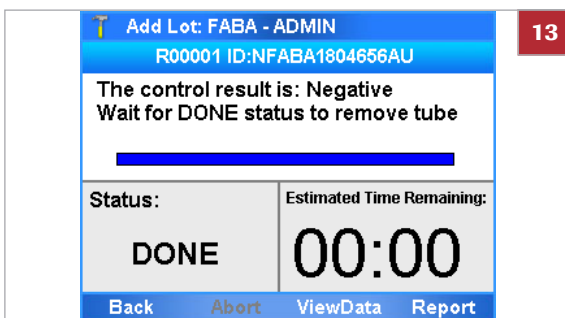
13 Wait until the information in the title bar stops flashing, then choose the **Back** button.

14 Choose the **Scan** button and place the barcode of the positive control under the barcode reader.
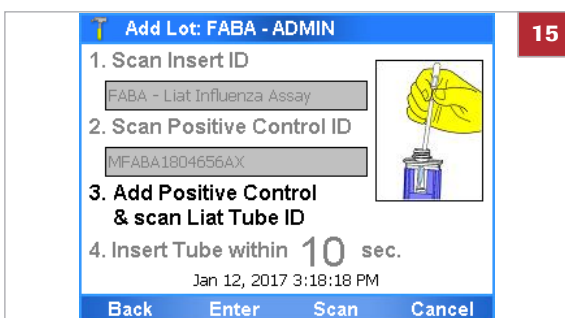
15 Follow the instructions in the assay tube package insert or the instructions for use on how to add the positive control sample to an assay tube from this lot.

16 Dispose of all used disposable pipettes in accordance with the disposal policy of your institution.
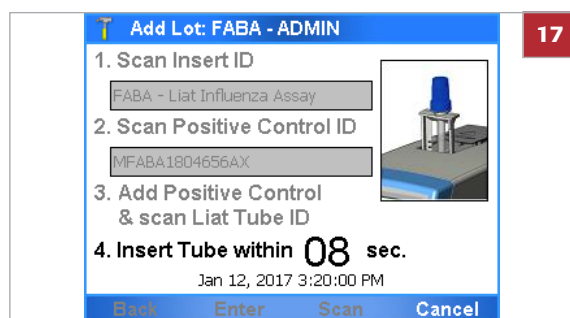
17 Choose the **Scan** button.

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 **OK** button to confirm the message.
ℹ If the QC was not completed successfully, repeat the measurement of the positive control.
Check the Instructions for Use of the control for further information.

21 When asked to do so, remove the assay tube from the analyzer and dispose of it in accordance with the disposal policy of your institution.
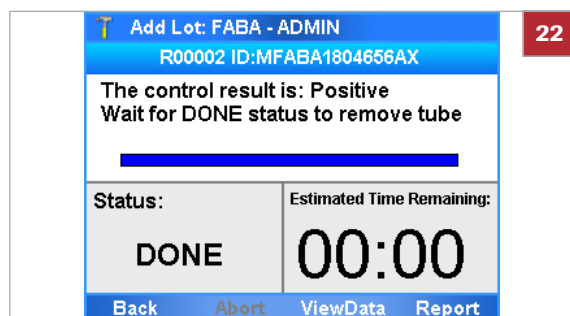
22 Wait until the information in the title bar stops flashing, then choose the **Back** button.
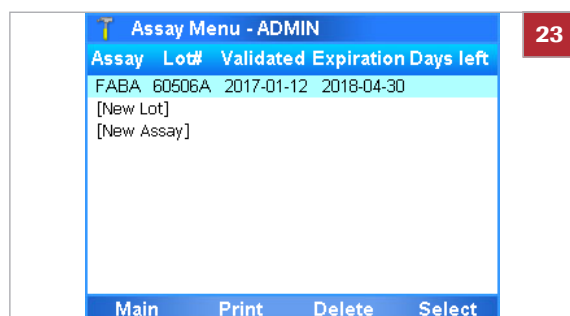
23 Check the entry for the new assay tube lot.

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.

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

▸▣ About data exchange with a DMS (86)

☐ Logged on with Supervisor or Administrator access role

▸ **To delete an assay tube lot**

1 On the **Main** menu, select **Assay Menu** and choose the **Select** button.

2 Select the assay tube lot entry.

3 Choose the **Delete** button.

4 On the confirmation message dialog box, choose the **OK** button.
  → The lot entry **NA** on the **Assay Menu** panel indicates that there are no validated lots for this assay.
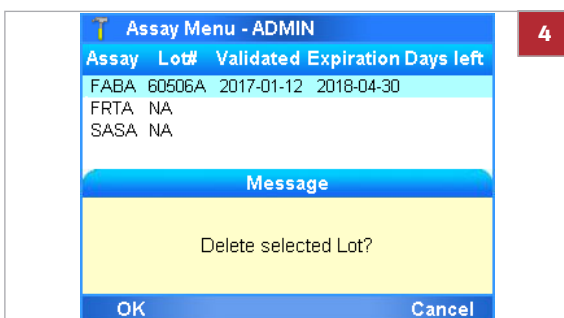
Uninstalling assays

Uninstalling an assay removes the assay script from the analyzer.

-�- Roche does not recommend to uninstall assays.

☐ Logged on with Administrator access role.

▶ **To uninstall an assay**

1 On the **Main** menu, select **Assay Menu** and choose the **Select** button.

2 Select the assay entry.
   ❶ 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.
   ▪ Select the assay tube lot entry.
   ▪ Choose the **Delete** button.
   ❶ When all assay tube lots are deleted, there is only one entry left for the assay and the value in the **Lot#** column is **NA**.

4 Choose the **Delete** button.

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

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

▶ **Related topics**
▪ Deleting assay tube lots (74)
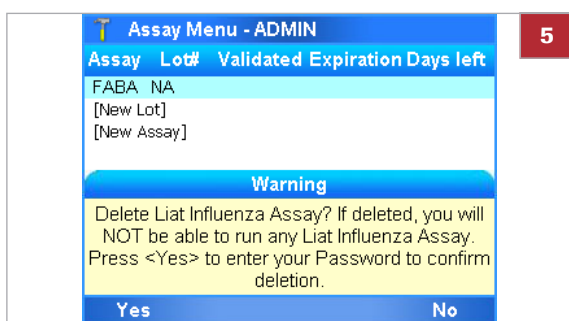
Viewing and printing assay tube lot information

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

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

1 On the **Main** menu, select the **Assay Menu** option and choose the **Select** button.
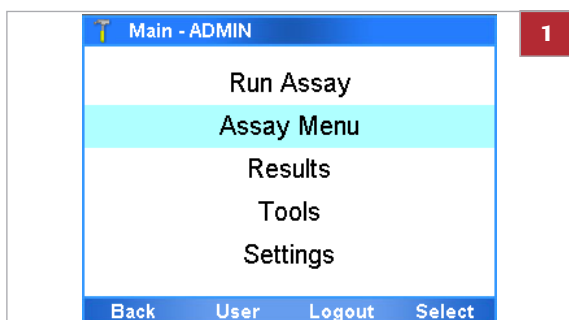
2 To print the list of installed assays and assay lots, choose the **Print** button.

→ The list of installed assays and assay lots is sent to the printer.
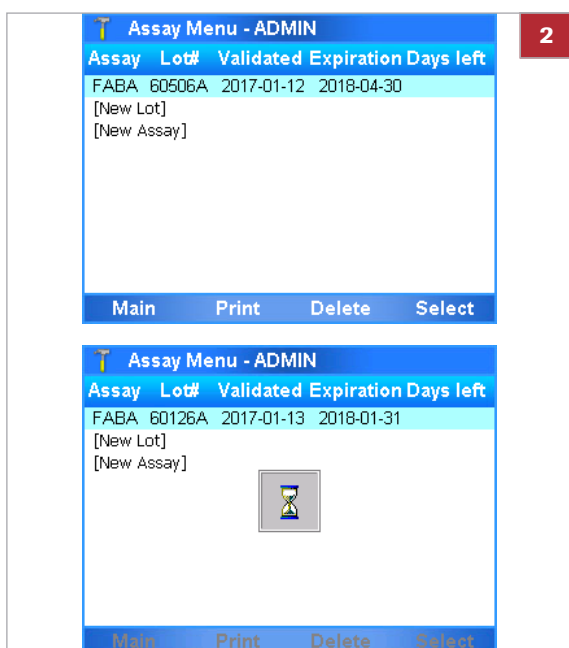
▶ **To view and print control test results of a lot**

1 On the **Main** menu, select the **Assay Menu** option and choose the **Select** button.

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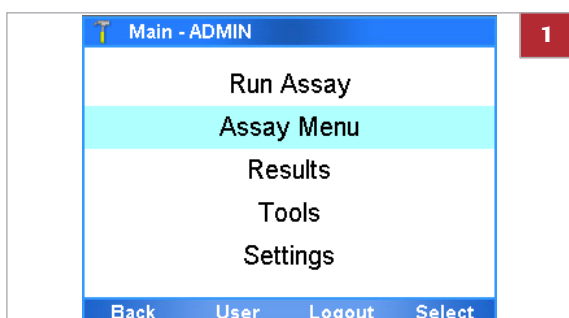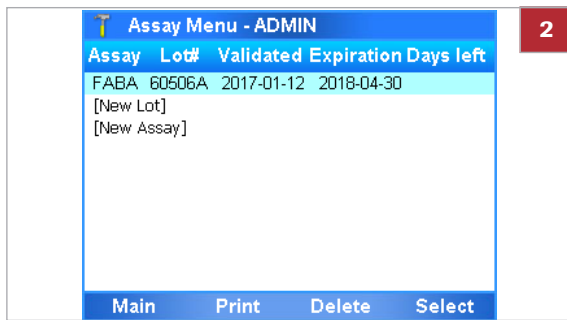
2 Select the assay tube lot you are interested in and choose the **Select** button.

3
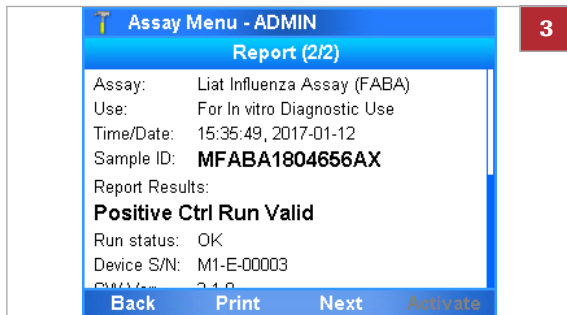
3 On the report panel for the control, do either of the following:
- To print the results, choose the **Print** button.
- To display the report panel of other controls, choose the **Next** button.
(Choose the **Previous** button to display the previous report panel again.)

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

Defining system settings

Define the general operating environment.

In this section

System settings (79)

About authentication modes (80)

System settings

To define the general operating environment, enter the required information.

➜ **Settings > System**

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

System item	Configuration item	Comment
Time & Date	Time & Date	Time format: hh:mm:ss Date format: mm-dd-yyyy
	SNTP	Choose **Yes** to have date and time automatically updated from a server. If you choose **Yes**, you need to define the server. Do not manually change the time and date when SNTP is on.
	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.
Brightness		Screen brightness. 1 = darkest, 7 = brightest.
Printer		Use a standard PCL compatible printer. (PCL 3 GUI is not supported.)
	LPT1	Choose for a USB printer. No further configuration is required.

	NET0	Choose for a network printer.
		Choose the **Select** button and then enter the required printer information:
		• **Server Name**
		  Name of the print server.
		• **Share Name**
		  Name of the share.
		• **User Name**
		  User name of the analyzer specific account on the print server.
		• **Password**
		  Password of the analyzer specific account on the print server.

Printing Mode		Keep the default **Grayscale**, if a grayscale printer is connected. Choose **Color**, if a color printer is connected.
Auto Print		Choose **Yes** to automatically print the results as soon as assay processing is finished.
Sound	Initialization, Barcode Scan, Tube Insert, Assay Aborted, Touch Screen, Key Clicks	Choose **Off** to turn off the acoustic signal for the selected event. Choose any of the available signal types to define that an acoustic signal should be sounded at the end of the selected event.
	Volume	Choose a value between 0 (off) to 5 (loudest). The volume setting applies to all acoustic signals.
Tube Insert Time	Value between 1 and 20 seconds	Maximum time in seconds allowed for inserting the assay tube after scanning its barcode. Defining a short time ensures that the assay tube is inserted that was just scanned, and it reduces the likelihood of contamination of the reaction chamber.

⊞ System configuration items

System item	Configuration item	Comment
Name of Machine	Up to 15 alphanumeric characters.	By default, this is the analyzer serial number.
Tilt Sensing	Enable	If the analyzer is tilted by ten or more degrees, the current assay is stopped. Roche recommends to have this feature enabled.
Language		You cannot currently choose this option.
Auto-Lock Time	Value between 1 and 10 minutes.	Time in minutes after which the auto-lock function is activated. Default time is 3 minutes.
Default Settings		Choosing the **Select** button resets all values defined from the **Settings** panel to the factory values, with the exception of the **Time & Date** and **Name of Machine** values.
Authentication	**User ID & Password**, **Barcode & Password**, or **Barcode**	Choose the authentication mode for logging on to the analyzer. -ᗌ- Consider the level of security provided by the different authentication modes.

⊞ System configuration items

About authentication modes

The authentication mode determines the logon method.

You can choose between the following authentication modes:

- **User ID & Password**:

  To logon 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).

- **Barcode & Password**:

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

- **Barcode**:

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

  This authentication mode provides the lowest level of security.

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

📑 **Related topics**

- Logging on (29)
- Managing users (90)

Network definitions

Define the network environment.

➜ **Settings > Network**

⚠ **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 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, make sure to use WPA2 encryption.

You can connect the analyzer to a 10/100 Ethernet network.

-ᗡ̣- •The Liat is not ping-able.

• For detailed information on how to set up communication between the analyzer and a host system, contact your Roche representative.

Network item	Configuration item	Comment
DHCP	Yes	When choosing Yes, the network definitions are automatically obtained from your DHCP server.
	No	When choosing No, you can select the other configuration items and enter the appropriate values.
IP Address		Define the IP address.
Subnet Mask		Define the subnet mask.
Gateway		Define the IP address of the gateway server.
DNS Server		Define the name of the DNS server.

⊞ Network configuration items

Network resources

You can define network resources for installing and updating assays, and for sharing assay tube lots. These resources can also be used for backing up results.

In this section

Defining network resources (82)

Using the share lot function (83)

Defining network resources

To define the network resources, enter the required information.

➜ **Settings > Install Source**

Before you can define network resources, obtain the following information:

☐ Share name (full path if you intend to use FTP)
☐ Server name (IP address if you intend to use FTP)
☐ User name and password for the specific account

You can define one of the following options.
(Note that you can only use IP addresses for FTP servers. Share servers use IP addresses and host names).

Network resource item	Configuration item	Comment
Share Folder		Used for installing new assays and saving results.
	Server Name	URI of the Share folder server.
	Share Name	Name of the share.
	User Name	User name of the analyzer specific account on server.
	Password	Password of the analyzer specific account on server.
Service FTP		Used for installing new assays and saving results.
	Server IP	IP address of the Service FTP server.
	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.
LAN FTP		Used for installing new assays and saving results.
	Server IP	IP address of the LAN FTP server.
	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.
Share Lot Folder		Used for sharing assay tube lots.
		☀ Instead of adding the same assay tube lot on several analyzers, use share lots.
	Server name	URI of the Share Lot server.
	Share Name	Name of the share.
	User Name	User name of the analyzer specific account on server.
	Password	Password of the analyzer specific account on server.
	Use Share Lot	• To enable the share lot function, choose the **Yes** option. • To disable the share lot function again, choose the **No** option.

▦ Network resource configuration items

-ʘ- With some items, the **Sample** button is available when they are selected. Choosing **Sample** displays a valid example for the value you should enter.

-ʘ- If you are using Windows Server 2008 or above for Share Lot or network printing, do the following:

- Choose the **Group policy editor** option, and then choose **Local Computer Policy > Computer Configuration > Windows Settings > Security Settings > Local Policies > Security Options**.

- Choose the **Network security: LAN Manager authentication level** option and set the value to **Send LM & NTLM. Use NTLMv2 session security if negotiated**.

- Ensure that the share lot folder is configured to allow read and write privileges for the appropriate user account.

Using the share lot function

The share lot function allows you to share assay tube lots between analyzers.

Depending on your setup, you can use one of the following ways to share assay tube lots:

- The advanced tools key
- The share lot function
- The exchange of lots with a DMS

-ʘ- Do not use different ways to share assay tube lots at the same time.

▸▤ Sharing assay tube lots (70)

☑☰ ☐ Logged on with Administrator access role.
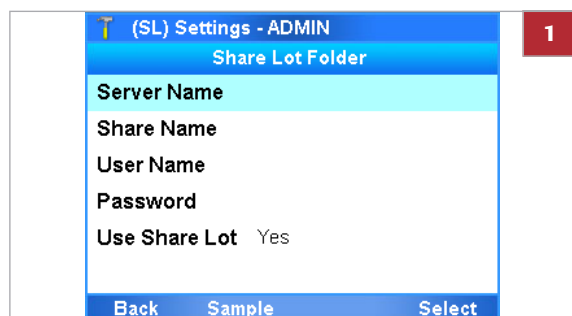
▶ **To enable the share lot function**

1 Choose **Settings > Install Source > Share Lot Folder**.
- Choose the **Server Name**, **Share Name**, **User Name**, and **Password** items and enter the required information.
- Choose the **Use Share Lot** item and choose the **Yes** option.

2 Restart the analyzer. Log on with Administrator access role.
➔ In the title bar, **(SL)** is displayed next to the **Main** menu.

3 Choose **Settings > Install Source > Share Lot Folder** and review the installed assays and available assay tube lots.

▶ **To disable the share lot function**
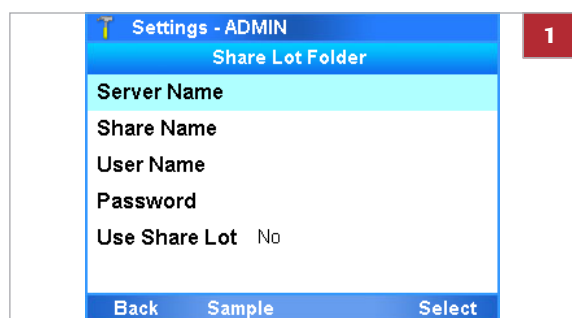
1 Choose **Settings > Install Source > Share Lot Folder**. Choose the **Use Share Lot** item and choose the **No** option.

2 Restart the analyzer. Log on with Administrator access role.
➔ In the title bar, **(SL)** is no longer displayed next to the **Main** menu.
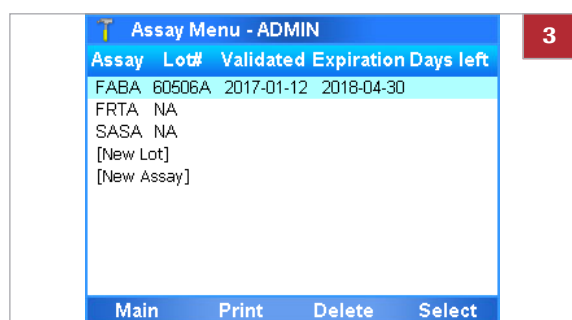
3 Choose the **Assay Menu** option. Review the installed assays and assay tube lots.
❶ You must revalidate assay tube lots that were validated previously while the share lot function was enabled.

Connections to a host system

To set up data exchange, connect the analyzer to a host system.

In this section

Defining settings for host systems

To define the connection to a LIS, HIS, or DMS, enter the required information.

➔ **Settings > Connectivity**

-ᗒ̣̈- For detailed information on how to set up communication between the analyzer and a host system, contact your Roche representative.

HIS/LIS item	Configuration item	Comment
Type	**None**	Choose to set the analyzer to standalone mode.
	POCT1-A (LIS)	Choose to connect to a HIS or LIS.
	POCT1-A (DML)	Choose if you use a POCT1-A DML interface.
Server		Host IP address or the host name (for example "HLSPC"). FQNAME (for example host.customer.net) is not supported.
Port		-ᗒ̣̈- For information about the host address and port, contact your network administrator.
Timeout		Timeout (in seconds) for receiving the acknowledgment from the host.
TLS encryption		Choose **Yes** to secure the communication between the analyzer and the HIS, LIS, or DMS. -ᗒ̣̈- Unsecured communication may result in unauthorized access and misuse. Roche recommends to always enable TLS encryption.
Configure secure communication		Enter the certificate for the TLS encryption.

⊞ Connectivity configuration items

HIS/LIS item	Configuration item	Comment
Auto Send results		Choose to send results automatically to the host computer as soon as they are generated.
		☼ Automatically sent results that were received by the host cannot be resent manually.
Data Synchronization	• **Auto Send** • **Users** • **Assay Lots** • **Device Configuration** • **Log Events**	Choose which data is exchanged with a connected DMS. ☼ Enabled data synchronization affects analyzer functions, e.g. the local deletion of assay tube lots or local user management. ▸ About data exchange with a DMS (86)
Conn. Interval		Time between data synchronizations.

⊞ Connectivity configuration items

About disconnecting an analyzer

To disconnect an analyzer and to set it into standalone mode, choose **Settings > Connectivity > Type** and choose the **None** option.

☼ If you want to reconnect the analyzer later, take note of the settings before disconnecting it.

About data exchange with a DMS

The connection to a data management system (DMS) and enabled data synchronization influences the functionality of the analyzer.
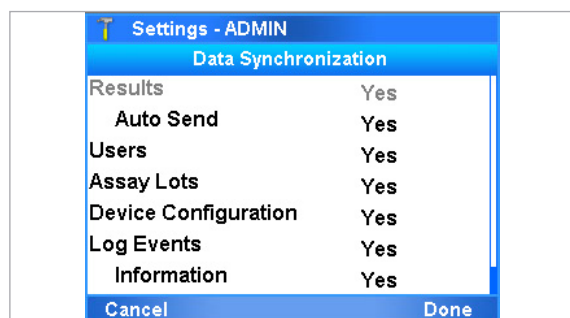
If the analyzer is connected to a DMS and data synchronization is enabled, the following functions of the analyzer are affected:

- Automatic locking
- Results review
- Lot management
- User management
- Changing your password
- Changing your badge barcode
- Analyzer settings / device configuration
- Event logs

Contact your local DMS administrator for tasks that are disabled on the analyzer.

Changes in the DMS are only effective on the analyzer after a completed data synchronization.

About automatic locking	Some data received from the DMS (e.g. user data and assay tube lots) 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.

‣▤ About locking the analyzer (39)

About results review	If the analyzer sends results automatically to a DMS or HL7 host, you cannot review results on the analyzer.

‣▤ Reviewing results (53)

About lot management	You can share assay tube lots between analyzers, if the exchange of lots is enabled.

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

‣▤ Sharing assay tube lots (70)

‣▤ Deleting assay tube lots (74)

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

-👁- To enable access to the analyzer, the user IDs and passwords defined on the DMS must only consist of ASCII Printable Characters (32-126) without #96 (' character).

‣▤ Managing users (90)

About changing your own 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.

-👁- To prevent logon problems, make sure the rules for passwords on the analyzer and the DMS match.

‣▤ Changing your password (31)

About changing your own badge barcode	If the analyzer exchanges user data with a DMS, users cannot assign or change their badge barcodes directly on the analyzer.

‣▤ Assigning or changing your badge barcode (34)

About 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.

➧▤ System settings (79)

About event logs
If configured, the analyzer sends events to the connected DMS.

➧▤ Viewing and printing the event log (124)

Connecting the analyzer to a DMS

To connect the analyzer to a DMS, follow the procedure below.

☐ Logged on with Administrator access role.

▶ **To connect the analyzer to a DMS**

1 Choose **Settings > Connectivity**. Choose the **Type** item and choose the **POCT1-A (DML)** option.
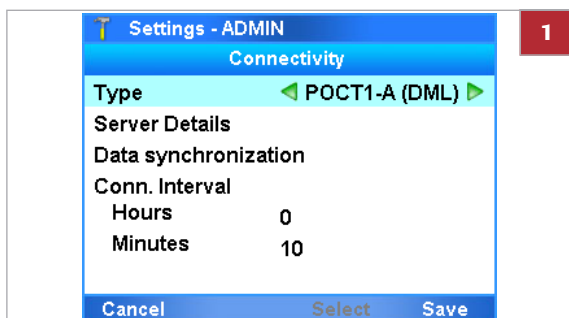
2 Choose the **Server Details** item:
- Enter **Server**, **Port**, and **Timeout** settings.
- Set the **TLS encryption** item to the **Yes** option.
- Configure secure communication.
- ➊ For details, refer to the **cobas**® Liat® Analyzer Host Interface Manual POCT1-A (DML) or contact your Roche representative.

3 To return to the **Connectivity** panel, choose the **Done** button.
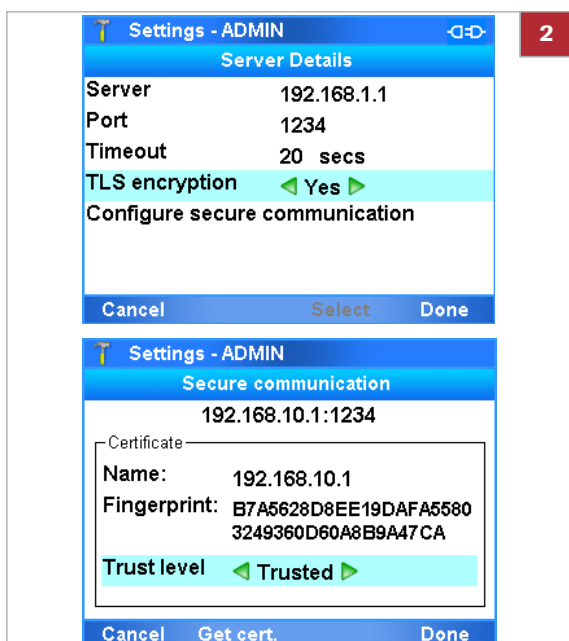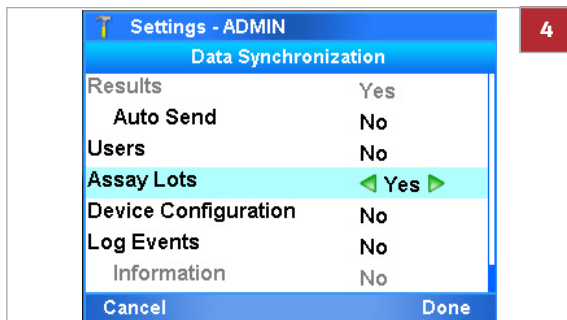
4 Choose the **Data Synchronization** item. If you want the analyzer to exchange data with the DMS, choose the corresponding item and set it to the **Yes** option.

5 To return to the **Connectivity** panel, choose the **Done** button.

6 Choose the **Conn. Interval** option and enter the time between data exchanges. Choose the **Save** button.

7 Restart the analyzer.

Managing users

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

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

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

▸⊟ About data exchange with a DMS (86)

In this section

Overview of user account access roles (90)

About user IDs and passwords (91)

Defining new users (91)

Changing user information (94)

Deleting a user account (95)

Overview of user account access roles

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

Icon	Access role	Permitted actions
	User	Run authorized assays and view assay tube lots. Change own password and badge barcode.
	Supervisor	As user, plus: review results, manage users (with access role Supervisor or User), set up the analyzer (except network settings), manage assay tube lots, install assays.
	Administrator	As Supervisor, plus: network configuration settings, manage all users, update assays and software, register assays and software.

⊞ Access roles

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

-ọ́- Note that the user IDs shown in screenshots in this publication are for illustration purposes only. The user ID does not necessarily reflect the user's access 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 between 1 and 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 any white spaces.

For passwords, the following rules apply:

- For passwords, alphanumeric characters, symbols, and/or spaces are allowed.
- The length of a password must be between 4 and 20 characters.

About user management on a DMS

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

- Make sure the rules for user IDs and passwords on the analyzer and the DMS match.
- User IDs and passwords defined on the DMS must only consist of ASCII Printable Characters (32-126) without #96 (' character).

▸ About data exchange with a DMS (86)

Defining new users

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 access role is Supervisor, you can define users of the User and Supervisor access role.

If your access role is Administrator, you can manage users of the Administrator, Supervisor, and User access role.

☐ Logged on with Supervisor or Administrator access role.
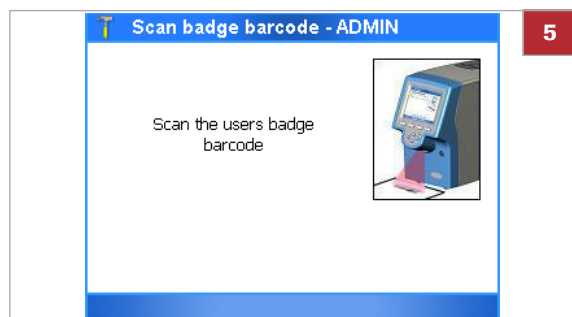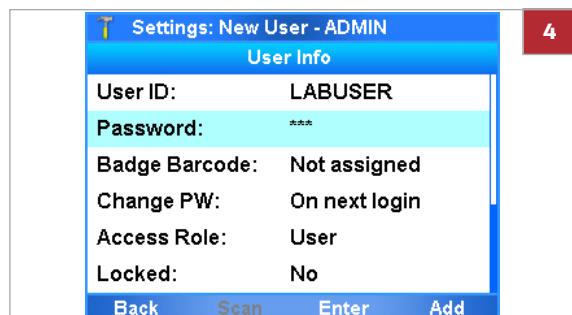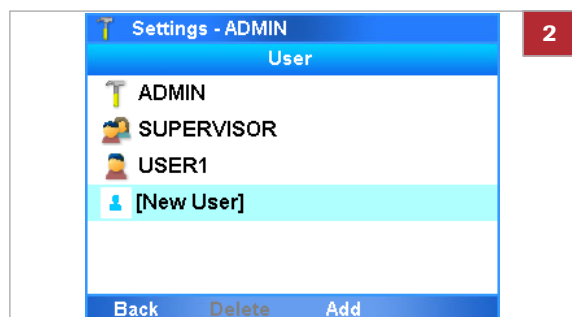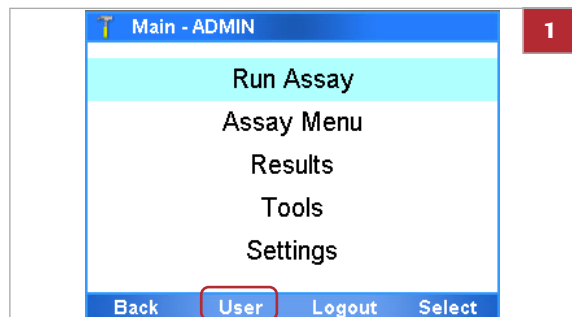
▶ **To define a new user**

1 To display the **User** panel, do one of the following:

▪ On the **Main** menu, choose the **User** button.

▪ Choose **Settings > User**.

➔ The **User** panel lists all defined users. The icon preceding the user ID indicates the user access role.

2 Choose the **[New User]** option.

3 Choose the **Add** button.

4 To define a user detail, select the item and choose the **Enter** button. Then do either of the following:

▪ Enter the information and choose the **OK** button.

▪ Select the option and choose the **Select** button.

❶ To avoid cut-off user IDs in the title bar, it is recommended to define short user IDs.

5 If the analyzer is configured for a badge barcode authentication mode, assign and scan the badge barcode:

▪ In the **User Info** panel, choose the **Badge Barcode** item. Choose the **Enter** button.

▪ Select the **Assigned** option.

▪ Scan the badge barcode twice.

❶ New users cannot assign their badge barcodes at logon. This is only possible when a user is logged on.
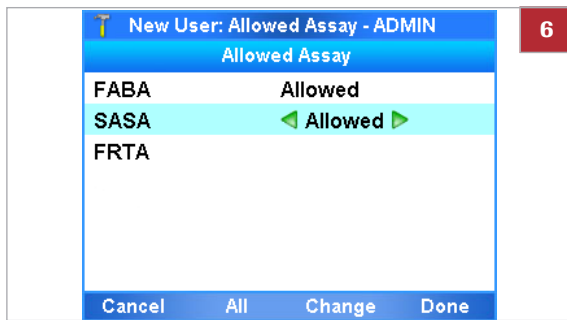
6 To define which assays the user can perform, do the following:

- Select the **Allowed Assay:** option and choose the **Enter** button.
- On the **Allowed Assay** panel, select the assay you want the user to be able to perform. Choose the **All** button if you want to select all listed assays.
- Choose the **Change** button. The values of the selected assays change from blank (not allowed) to **Allowed** or vice versa.
- To keep the changes, choose the **Done** button.
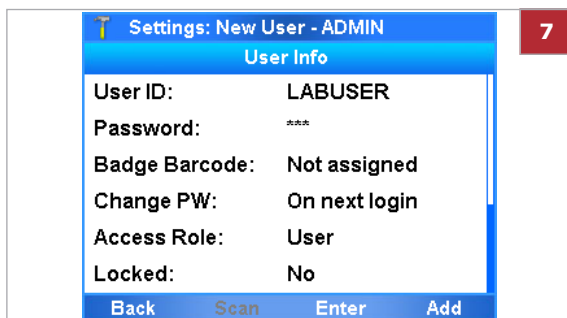
7 On the **User Info** panel, choose the **Add** button to save the definitions.

❶ By default, new users must change their passwords on first logon.

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 access role is User, you can change your own password and badge barcode.

If your access role is Supervisor, you can change user information of the User and Supervisor access role.

If your access role is Administrator, you can change user information of the Administrator, Supervisor, and User access role.

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.

-ʘ- You cannot lock the default Administrator account.

☐ Logged on with User, Supervisor, or Administrator access role.

▸ **To change user information**

1 To display the **User** panel, do one of the following:
- On the **Main** menu, choose the **User** button.
- Choose **Settings > User**.
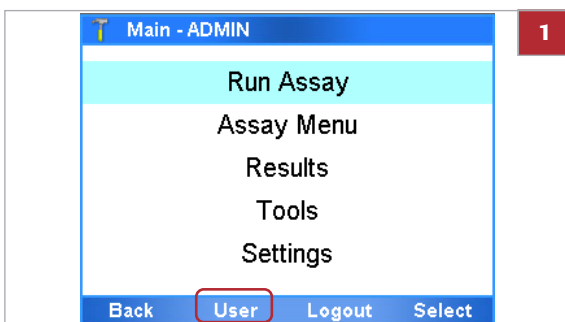
2 Select a user entry.
- ❶ If you are logged on with Administrator or Supervisor access role, all currently defined users of the same access role or lower are listed.
  If you are logged on with User access role, your own user account is listed only.
  The icon preceding the user ID indicates the user access role.
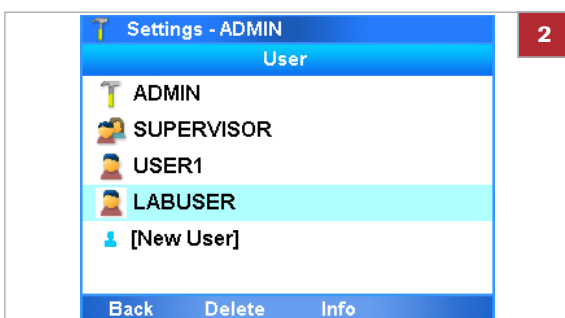
3 Choose the **Info** button.
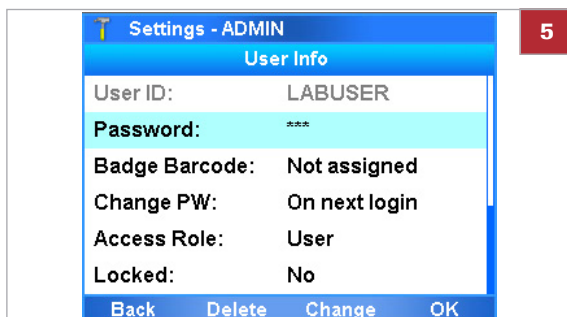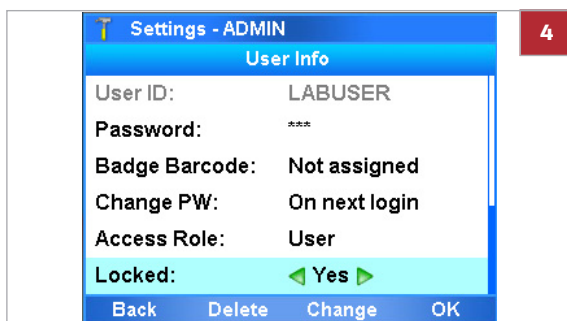
4 To lock a user, select the **Locked** item. Select the **Yes** option and choose the **OK** button.

    ❶ Locked users cannot log on to the analyzer. To unlock a user, change the **Locked** item to the **No** option.

5 To change a user detail, select the item and choose the **Change** button. Then do either of the following:

    ▪ Enter the information and choose the **OK** button.

    ▪ Select the option and choose the **Select** button.

    ❶ If you set the **Change PW item** to the **On next login** option, the user must change the password when logging on the next time.

6 Proceed in the same way as when defining a new user.

⮞🗐 **Related topics**

▪ Defining new users (91)

▪ Changing your password (31)

Deleting a user account

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 access role is Administrator or Supervisor, you can delete users of your own level and below.

🔆 Deleting a user does not affect results.

☐ Logged on with Supervisor or Administrator access role.

▶ **To delete a user account**

1 Choose **Settings > User**.

2 Select the user entry using the ⌃ and ⌄ navigation buttons.

3 Choose the **Delete** button.

4 On the message dialog box, choose the **Yes** button to confirm the deletion.

Updating the software

As part of further product development, Roche may issue updates to the analyzer software remotely or via USB key.

-🔆- If you are logged on with User or Supervisor access role and a message is displayed informing you that a software update is available, inform your system administrator.

About migration of user information

During an upgrade of the analyzer software from version 3.0 to version 3.1, data is migrated. For user information, the following migration rules apply:

- User IDs are no longer case-sensitive. Therefore, if 2 user IDs differ only in capitalization (e.g., user1 and USER1), the newer user account will be deleted. The older user account will be locked.

- If a user ID is longer than 20 characters, the user ID will be truncated and the user account locked.

- If a user ID contains spaces, the spaced are removed and the user account is locked.

- The default Admin account is migrated properly and is not locked.

☐ If you update from the Roche remote service platform, the analyzer must be connected to a network and the internet.
Firewall is set up to allow communication with
Host: remoteservice.roche.com
IP: 62.209.44.11
Port: 443
Protocol: TCP / SSL

☐ Logged on with Administrator security rights.

▶ **To update the software from the Roche remote service platform**

1 CAUTION! Do not disconnect the mains power supply to 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 **Yes** button.
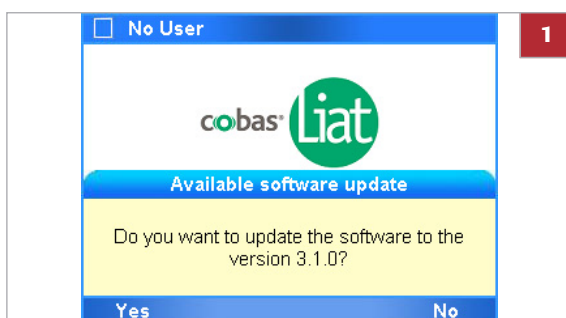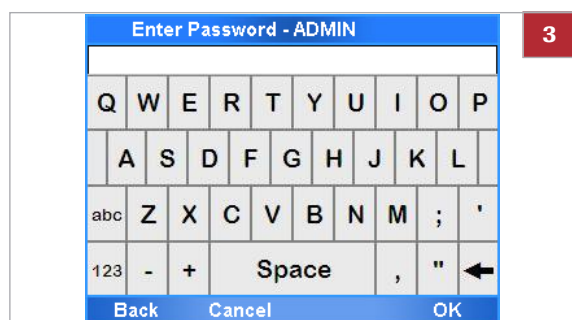
3 Enter your password and then choose the **OK** button.
  → The analyzer checks the available storage space on the analyzer. If there is not enough storage space, a message is displayed and you must make storage space available by deleting either lots or results.
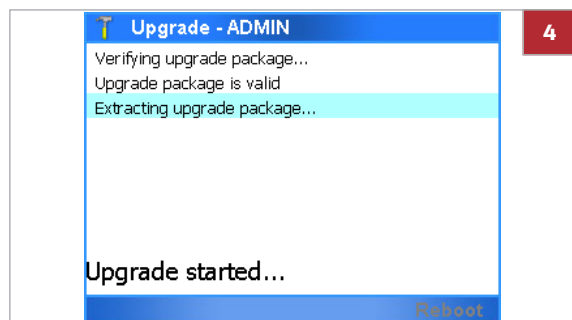
4 On the **Upgrade** panel, when asked to do so, choose the **Reboot** button.
  ❶ After successful restart, the analyzer attempts to register the software automatically.

5 If automatic registration fails, you must register the software manually.

▸ **To update the software from a USB key**

1 CAUTION! Do not disconnect the mains power supply to the analyzer while updating software.

While on the **Main** menu, insert the USB key at the rear of the analyzer.
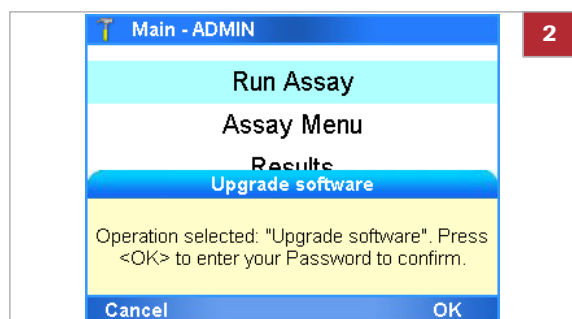
2 On the message dialog box, choose the **OK** button.
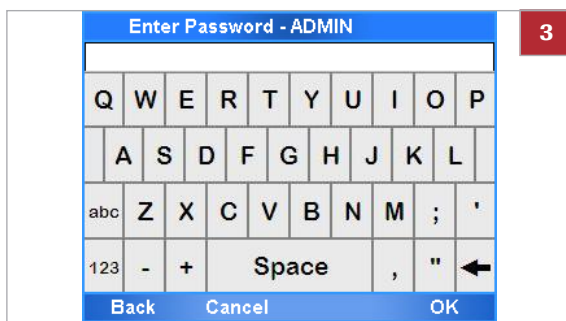
3 Enter your password and choose the **OK** button.

→ The analyzer checks the available storage space on the analyzer. If there is not enough storage space, a message is displayed and you must make storage space available by deleting either lots or results.
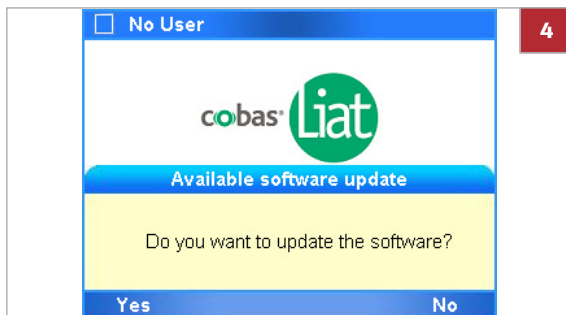
4 On the message dialog box, choose the **Yes** button.

5 Follow the dialog box: "*Please remove the USB drive, wait 5 seconds and hit <OK> to continue.*"

→ The software upgrade completes. This process can take several minutes.
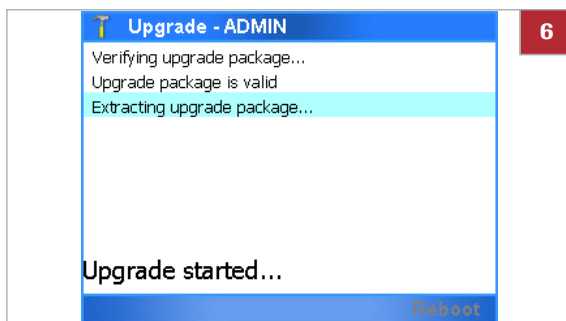
6 Do one of the following:
- When a message indicating a successful upgrade is displayed, choose the **Reboot** button and wait until the analyzer has restarted.
- When a message indicating an unsuccessful upgrade is displayed, choose the **OK** button to return to the **Main** menu.
  Reboot the analyzer and repeat steps **1** to **6**.

7 If a message indicating a config data mismatch is displayed, do the following:
- On the **Init/Get System State Status** dialog box, choose the **OK** button.
- On the **Config Data Mismatch** dialog box, choose the **Yes** button.
- On the **Message** dialog box, choose the **Reboot** button.

8 After successful restart you are prompted to calibrate the screen by following the on-screen instructions.

9 Log on to the analyzer.

❶ The analyzer attempts to register the software automatically.
If automatic registration fails, you must register the software manually.
You can check the version of the updated software by choosing **Main > Settings > Versions**.

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 Roche remote service platform, the analyzer automatically tries to register. If this fails, a message is displayed and a user must register the software manually.

☐ Logged on with Administrator access 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, on the **Main** menu, choose **Settings > System Info**.

2 From the **System Info** panel, note the registration code.

3 Call your Roche Support and provide the registration code.

4 The Roche Support issues an activation code.

5 On the **System Info** panel, choose the **Activate** button.
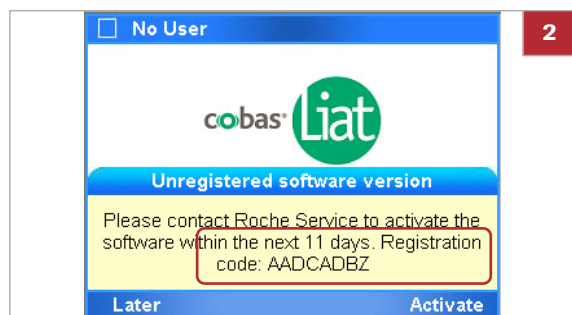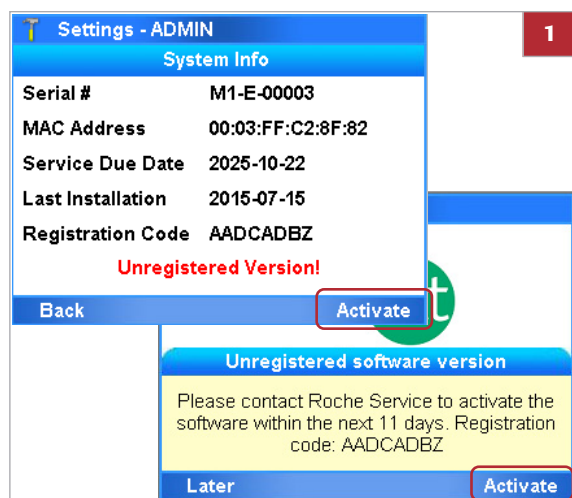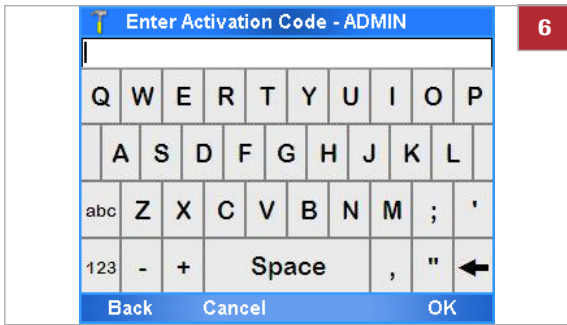
6 Enter the activation code and choose the **OK** button.

7 On the message dialog box, choose the **OK** button.

Viewing software and hardware information

For troubleshooting reasons, it may be necessary to check versions and IDs of the installed hardware and software elements.

In this section
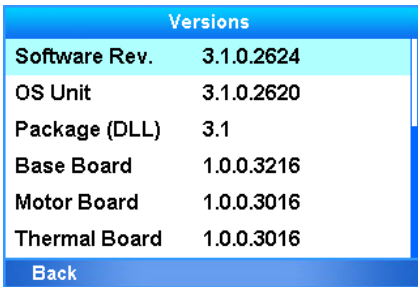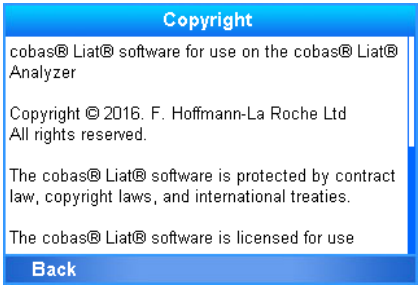
Viewing information about the analyzer and software (102)

Viewing system information (103)
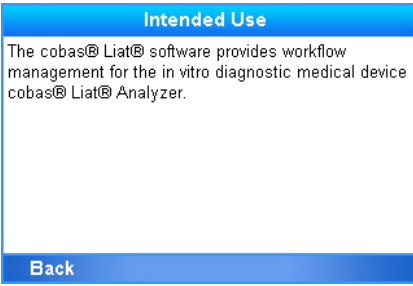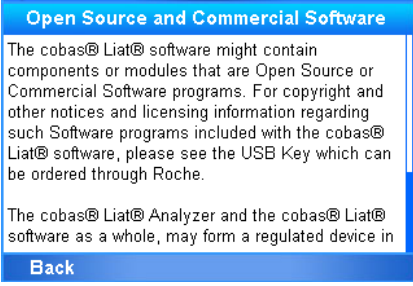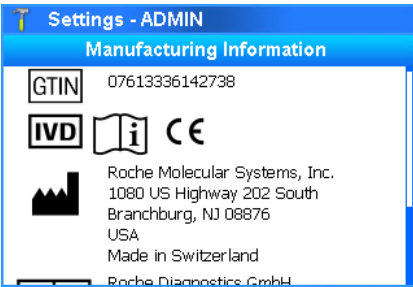
Viewing information about the analyzer and software

For troubleshooting or other reasons, you may be asked to provide information about the analyzer and installed software.

You access information about the analyzer by choosing **Settings > About Device**, and then selecting one of the options on the menu.

Menu options	Comment	
Versions	For troubleshooting, you may be asked to check the versions of the installed software components and assays.	
Copyright	Copyright information about analyzer and software, including trademark information.	

⊞ About Device menu options

Menu options	Comment	
Intended Use	The intended use of the software and the analyzer.	
Open Source	Information about open source and commercial software.	
Manufacturing Information	Manufacturing-related information about the analyzer.	

⊞ About Device menu options

Viewing system information

When installing or updating the software or for troubleshooting reasons, you may need to know the IDs of your analyzer and its installation or activation dates.

➔ **Settings > System Info**

Version and ID item	Comment
Serial #	Defined by Roche.
MAC Address	Network interface card defined by manufacturer of main board.
Service Due Date	Date for service reminder, Roche recommends that the analyzer be returned for service every 5 years.
Last Installation	Date of last software installation/update. yyyy-mm-dd
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.

⊞ System elements

Quality control

Internal control

Internal Process Control (IPC) is included in every assay tube. It verifies the adequate processing of the biological sample. The IPC passes, if sample purification and target amplification meet validated acceptance criteria.

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 that for adding lots.

▸▤ See Adding an assay tube lot (70) 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.

Maintenance and calibration

An operator is not required to perform any maintenance, other than touch screen calibration.

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 operator in the event that a malfunction or error is detected.

The analyzer requires no adjustment or calibration from the operator.

About auto monitoring
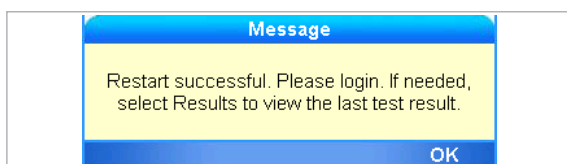
There is an automatic daily restart programmed for 3 AM local time (once your settings have been updated), which helps to maintain the health of your analyzer.

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.
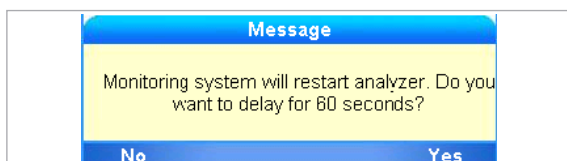
Choose the **No** button to start the restart process. Choose the **Yes** button to effect a 60-second delay. After 60 seconds, another notification will appear and allow for a final opportunity to delay for an additional 60 seconds before automatically restarting the analyzer. Follow the on-screen instructions, and the analyzer will restart.

About auto adjustment
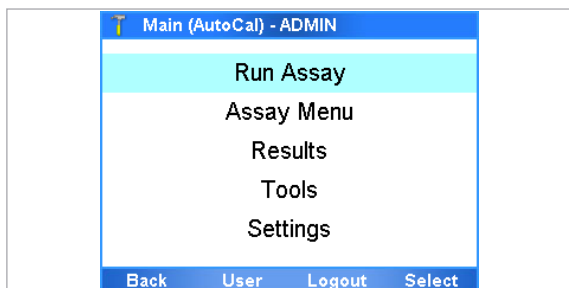
The analyzer periodically performs automatic adjustment. During auto adjustment, **AutoCal** is displayed on the title bar. If you choose the **Run Assay** option at this time, the message "AutoCal started. This could take up to a minute." is displayed. Select the **OK** button to close this message. Wait until **AutoCal** is no longer displayed in title bar.

About service

Please 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 to the one you just touched, calibrate the touch screen.

□ Logged on with Supervisor or Administrator access 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, touch the screen to confirm the new settings or wait 30 seconds to discard the change.
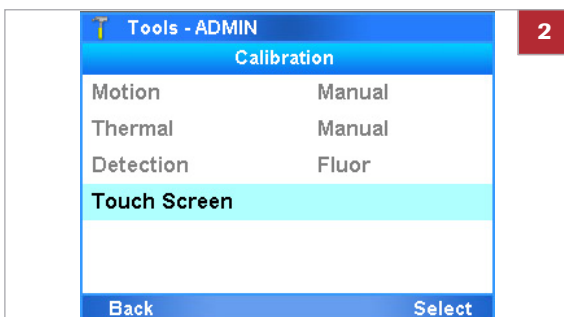
Cleaning the analyzer

- 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.
- 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.

Safety ⌐ Make sure you are familiar with the safety instructions in Safety instructions (14).

⚠ **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 **cobas**® Liat® 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

Keeping the analyzer clean prevents contamination and ensures trouble-free operation.

☐ Soft lint-free cloth

☐ 70% isopropanol or 5-10% bleach solution

▶ To clean the touch screen

1 Wipe the touch screen gently with a soft lint-free cloth.

▶ 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 below.

▸ To deal with a leak from an assay tube

1 Dispose of the assay tube in accordance with the disposal policy of your institution.

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 Practices 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.

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 this on the product label at the back of the analyzer.
☐ Assay name
☐ Run number
☐ Error message and code (if displayed)
☐ Maintenance contract number (as applicable)
☐ System diagnostic information, using the **Diagnostic Backup** function of the advanced tools key

For Roche Support in the U.S., call the following number: 1-800-800-5973.

In this section

List of error messages (111)
Generating a backup for troubleshooting purposes (124)
Viewing and printing the event log (124)
Resetting the lost default administrator password (125)
Cleaning the window of the barcode reader (127)
Resolving a tube entry door error before the start of a run (128)
Resending results manually (128)
Restarting an unresponsive analyzer (129)

List of error messages

Error messages are generated in exceptional situations. They describe the issue and provide information on how to resolve the situation.

Software error codes and error messages

Software error codes for the **cobas**® Liat® Analyzer are displayed in hexadecimal system, in the range from "0xb01" to "0xbff", or numbered as "Error 1" to "Error 10".

Error messages are without codes.

Issues identified by a unique hexadecimal code are often recovered or fixed by the analyzer after restart. For some error codes, additional actions are listed in the following table. If the error persists after these actions, copy the error code and contact Roche Service.

Code	Message	Action
0xb01	Print failed! Please contact the administrator to resolve the problem. Code:(0xb01)	Check the printer settings and connection. For a network printer, contact your local network administrator. If this error continues, call Roche Service.
0xb02	Your clock seems to be incorrect. The barcode indicates the manufacture date YYYY-MM-DD is in the future. Please correct your time. Code:(0xb02)	Adjust the analyzer's date and time so it's accurate. The date format is: year-month-day.
0xb03	Negative Control Result Rejected. Follow QC Kit Insert instructions to prepare NEGATIVE Control sample and try again. Code:(0xb03)	Follow QC Kit insert instructions to prepare negative control and try again.
0xb05	Positive Control Result Rejected. Follow QC Kit Insert instructions to prepare POSITIVE Control sample and try again. Code:(0xb05)	Follow QC Kit insert instructions to prepare positive control and try again.
0xb06	Invalid barcode: [ErrorCode] Code:(0xb06)	See the information on barcode scanning in this publication. Choose **Scan** and try again.
0xb07	This tube does not match the assay/lot in Step 1. Please check the tube and try again. Code:(0xb07)	See the information on running an assay in this publication. The assay tube barcode is scanned twice.
0xb08	Not a tube barcode Code:(0xb08)	Scan the tube barcode.
0xb09	This tube has already been used! You must use a new tube. Code:(0xb09)	An assay tube cannot be reused. Choose **OK** and use a new tube.
0xb0a	Print failed! Please contact the administrator to resolve the problem. Code:(0xb0a)	Check the print settings and cable connections and try again. If this error continues, restart the analyzer. If error still continues, call Roche Service.
0xb0b	LiatLots.xml file is old format or it is corrupted Code:(0xb0b)	Call Roche Service.
0xb0c	Liat Analyzer is not initialized, Add Lot not allowed. Code:(0xb0c)	Call Roche Service.
0xb0d	Negative control process successful, but failed to add lot to list Code:(0xb0d)	Call Roche Service.
0xb0e	Positive control process successful, but failed to add lot to list Code:(0xb0e)	Call Roche Service.
0xb0f	Negative Control Result Rejected. Contact Roche Service or follow QC Kit Insert instructions to prepare NEGATIVE Control sample and try again. Code: (0xb0f)	1. Make sure the QC Kit is not expired. 2. Follow QC Kit insert instructions to prepare negative control and try again. 3. If negative control still fails, call Roche Service.
0xb10	Positive Control Result Rejected. Contact Roche Service or follow QC Kit Insert instructions to prepare POSITIVE Control sample and try again. Code: (0xb10)	1. Make sure the QC Kit is not expired. 2. Follow QC Kit insert instructions to prepare positive control. Make sure the sample was mixed and the time period elapsed, then try again. 3. Call Roche Service.
0xb11	InstalledPackages.xml file is corrupted Code: (0xb11)	Choose **OK** and call Roche Service.

List of error messages

Code	Message	Action
0xb20	More than 500 results found. Use filters to limit your search results. Code:(0xb20)	Use filters to limit your search results or perform export and delete results to reduce the number of results.
0xb21	Graph data file was not found! Code:(0xb21)	Issue with assay result. Call Roche Service.
0xb22	Invalid datapoints in file. Code:(0xb22)	Issue with assay result. Call Roche Service.
0xb23	Graph data file is Invalid/corrupted! Code:(0xb23)	Issue with assay result. Call Roche Service.
0xb24	Unable to update the approval status Code:(0xb24)	Issue with assay result. Call Roche Service.
0xb30	Script file is missing. Call Roche Service: [full path of the script file] Code:(0xb30)	Choose **OK** and try again. If error continues, call Roche Service.
0xb31	\" + sampleIDText + \"" + " is not a valid sample ID. Sample ID cannot be a Liat Tube or Insert barcode or be empty. Please try again. Code:(0xb31)	Choose **OK** and enter or scan the sample ID again.
0xb32	Script has no battery power warning setting. Run not allowed. Code:(0xb32)	Issue with assay script file. Call Roche Service.
0xb33	Incorrect power warning setting, check your script. Code: (0xb33)	Issue with assay script file. Call Roche Service.
0xb34	Invalid Runtime in Script File, Abort! Code:(0xb34)	Choose **OK** and try again. If error continues, call Roche Service.
0xb35	No tube has been inserted! Code:(0xb35)	Ensure you have fully inserted the tube. Choose **OK** and try again. If error continues call Roche Service.
0xb36	Assay aborted. Tube in place was found, but lost after about a second. Code:(0xb36)	Ensure you have fully inserted the tube. Choose **OK** and try again. If error continues call Roche Service.
0xb37	Actuators not opened. Try reboot Code:(0xb37)	Restart the analyzer. If error continues, call Roche Service.
0xb38	Illegal script file selected Code:(0xb38)	Issue with assay run. Call Roche Service.
0xb39	Script Manager is offline Code:(0xb39)	Issue with assay run. Call Roche Service.
0xb3a	Unable to save the result. Code:(0xb3a)	Issue with assay run. Call Roche Service.
0xb3b	The log file is: [LogFileName] You can manually save the file through FTP Code:(0xb3b)	The location of the temporary log file is displayed. Ask a user with Administrator access role to get the file via FTP.
0xb50	No Network connections detected. Please check your network connections. Code:(0xb50)	Check your cable connections, wait a few minutes and attempt to reconnect. Contact your network administrator to ensure network settings are correct. If network is still not detected, call Roche Service.
0xb51	Failed to reload lots from shared folder (Network), check your network connections, re-login to reload the lots. Code:(0xb51)	Check your network settings, cable connections, then restart the analyzer.
0xb52	Volume set failed! Code:(0xb52)	Restart the analyzer. If this error continues, call Roche Service.
0xb61	No barcode scanned! Code:(0xb61)	The barcode reader did not get a scan of the barcode. Choose **OK** and try again.
0xb70	Battery level too low. Plug in AC power and press OK to continue. Code:(0xb70)	Connect the analyzer to the mains power supply and choose **OK** to continue.
0xb71	Motor PCB is not responding. Code:(0xb71)	Restart the analyzer. If this error continues, call Roche Service.
0xb72	Motor PCB has error: [FPGA/Config] Code:(0xb72)	Restart the analyzer. If this error continues, call Roche Service.

⊞ List of error messages

Code	Message	Action
0xb73	Photometer PCB is not responding. Code:(0xb73)	Restart the analyzer. If this error continues, call Roche Service.
0xb74	Photometer PCB has error: [FPGA/Config] Code:(0xb74)	Restart the analyzer. If this error continues, call Roche Service.
0xb75	Thermal PCB is not responding. Code:(0xb75)	Restart the analyzer. If this error continues, call Roche Service.
0xb76	Thermal PCB has error: [FPGA/Config] Code:(0xb76)	Restart the analyzer. If this error continues, call Roche Service.
0xb77	Config data fixed, please reboot. Code:(0xb77)	Restart the analyzer.
0xb78	System was unable to fix the problem, reboot and try again. Code:(0xb78)	Restart the analyzer. If this error continues, call Roche Service.
0xb79 0xb7c	Current Temp={0:00.00}°C is out of operating range. Please shut down and wait for the device to stabilize between 4°C and 40°C Code:([0xb79/0xb7c])	Operating temperature is out of range. Switch off the analyzer. Allow the analyzer to reach suitable temperature before powering on again.
0xb7a	Unable to open actuators. Code:(0xb7a)	Restart the analyzer. If this error continues, call Roche Service.
0xb7b	Unable to move entry. Code:(0xb7b)	Choose **OK** to continue or restart.
0xb7d	You will not be able to run assays. Reboot analyzer or perform maintenance. If error persists, contact Roche Service. Code:(0xb7d)	Insert and remove the cleaning tool several times. Restart the analyzer. If this error continues, call Roche Service.
0xb7e	An old or a corrupted setup/settings file is detected at boot. Please have your supervisor check the settings Code:(0xb7e)	Ask an Administrator to check the settings. If this error continues, call Roche Service.
0xb7f	Internal storage space is running low. Please make more space available. Code:(0xb7f)	Do not run any assays until more storage is made available. Call Roche Service.
0xb80	Problem archiving assays results to [DIRECTORY]:[MESSAGE] Code:(0xb80)	Restart the analyzer. If this error continues, call Roche Service.
0xb81	Problem archiving logs to [DIRECTORY]:[MESSAGE] Code:(0xb81)	Restart the analyzer. If this error continues, call Roche Service.
0xb84	Manually move door to [position] position. Code:(0xb84)	Restart the analyzer. If this error continues, call Roche Service.
0xb85	Unable to connect to Script Manager Code:(0xb85)	Restart the analyzer. If this error continues, call Roche Service.
0xb86	No response from Dualport. Try reboot. Code:(0xb86)	Restart the analyzer. If this error continues, call Roche Service.
0xb87	The application version might not work with the current embedded firmware. Code:(0xb87)	Restart the analyzer. If this error continues, call Roche Service.
0xb88	Motor PCB firmware version expected: [FirmwareVersion] Code:(0xb88)	Restart the analyzer. If this error continues, call Roche Service.
0xb89	Motor PCB firmware version expected: [FirmwareVersion] Code:(0xb89)	Restart the analyzer. If this error continues, call Roche Service.
0xb8a	Motor PCB firmware version expected: [FirmwareVersion] Code:(0xb8a)	Restart the analyzer. If this error continues, call Roche Service.
0xb8c	Missing instrument data. Contact Roche Service. Code:(0xb8c)	Restart the analyzer. If error continues, call Roche Service.
0xba0	Photometer LUT value(s) out of range with config LUT. Reboot to try again. If error persists, Contact Roche Service. Code:(0xba0)	Restart the analyzer. If this error continues, call Roche Service.
0xba1	Photometer Base value(s) out of range with config Base. Reboot to try again. If error persists, Contact Roche Service. Code:(0xba1)	Restart the analyzer. If this error continues, call Roche Service.

List of error messages

Code	Message	Action
0xba2	iled to update current time to External RTC. Code:(0xba2)	Restart the analyzer. If this error continues, call Roche Service.
0xba3	Software upgrade is incomplete. Reboot and try again to complete the upgrade. Code:(0xba3)	Reboot the analyzer. If error continues, call Roche Service.
0xba4	Result summary file is being used by another user and can not be opened. Code:(0xba4)	Choose **OK** to continue. Restart the analyzer and/or the share folder server
0xba5	Run #[RUN_NR] on [Date] for sample ID "[SAMPLE_ID]" incomplete, if assay have not been repeated, please repeat assay again Code:(0xba5)	Check the power cable connection. Restart the analyzer. If this error continues, call Roche Service.
0xba6	Folder [FolderName] could not be accessed Code:(0xba6)	Restart the analyzer. If this error continues, call Roche Service.
0xbaa	Unable to connect to SL folder. Check your log files for further information. Code:(0xbaa)	Check your network settings and connections. Restart and try again.
0xbab	Unable to get a Key. Please try rebooting. Code:(0xbab)	Choose **OK** to continue. Reboot if error continues.
0xbad	Password change FAIL. Please try again. Code: (0xbad)	Password could not be saved. Try again.
0xbaf	Tube could not be added to the list of used tubes. Code(0xbaf)	Check your network connections. Restart and try again.
0xbb0	List of used tubes could not be opened. Code:(0xbb0)	Check your network connections. Restart and try again.
0xbb1	Lots file is being used by another user and can not be open. Code:(0xbb1)	Choose **OK** to continue. Restart the analyzer and/or the share folder server.
0xbb3	Unrecognized Liat Tube ID Code:(0xbb3)	An invalid tube barcode is scanned. Try again. If error continues call Roche Service.
0xbb4	Unrecognized insert ID. Code:(0xbb4)	An invalid package insert barcode is scanned. Try again. If error continues, call Roche Service.
0xbb5	Unrecognized Control ID Code:(0xbb5)	An invalid control barcode is scanned. Try again. If error continues call Roche Service.
0xbb6	Identification number checksum failed Code:(0xbb6)	The checksum on the barcode is invalid. Try again. If error continues, call Roche Service.
0xbb7	Not positive control barcode. Code:(0xbb7)	If this error continues, call Roche Service.
0xbb8	Not negative control barcode. Code:(0xbb8)	If this error continues, call Roche Service.
0xbb9	Barcode is expired! Code:(0xbb9)	The barcode is expired. Ensured today's date is correct. Try again. If error continues, call Roche Service.
0xbba	This lot is expired! Code:(0xbba)	Ensure today's date is correct. Try again. If error continues, call Roche Service.
0xbbb	Duplicate Lot #, already validated. Code:(0xbbb)	The lot has already been added and validated. You can start using this lot.
0xbbc	Error connecting to USB printer. Ensure it is connected and turned on. Code:(0xbbc)	Ensure USB printer is powered on and connected. Try again.
0xbbd	Error connecting to Network printer. Ensure it is connected and turned on. Code:(0xbbd)	Ensure network printer is powered on and connected. Ensure printer settings are correct. Try again.
0xbbe	Invalid printer settings	Ensure printer settings are correct. Try again.
0xbbf	Sound could not be played. Code:(0xbbf)	Choose **OK** to continue. Restart if error continues.
0xbc0	Failed to set SNTP! Code:(0xbc0)	Choose **OK** to continue. Restart if error continues.

⊞ List of error messages

Code	Message	Action
0xbc1	There is no assay/lot list in the device. Code:(0xbc1)	If this error continues, call Roche Service.
0xbc2	File missing: There is no assay/lot list in the USB drive. Code: (0xbc2)	First back up lots before attempting to restore lots.
0xbc3	Last run have detected a Config data problem/mismatch. Reboot to restart device. Code:(0xbc3)	Restart the analyzer. If this error continues, call Roche Service.
0xbc4	Last ReSync have problem. Reboot to restart device. Code:(0xbc4)	Restart the analyzer. If this error continues, call Roche Service.
0xbc5	Last ReCal have problem. Reboot to restart device. Code:(0xbc5)	Restart the analyzer. If this error continues, call Roche Service.
0xbc6 0xbc7 0xbc8 0xbc9	Invalid Reset Code entered, please try again. Code: (0xbc6)	The reset code was invalid. Try again. If it does not work, call Roche Service.
0xbca	The Reset Code you provided has already expired. Please start the Reset ADMIN Password process again. Code:(0Xbca)	Choose **OK** and choose **Password?** on the login panel to start the procedure for resetting the administrator password again.
0xbf0	Send failed. An unknown HL error has occurred. Contact Roche Service. Code:(0xbf0)	There was an issue sending the result to the host, call Roche Service.
0xbf1	Send failed. ACK file from CME not found: [ACKFileName] Contact Roche Service. Code:(0xbf1)	There was an issue sending the result to the host, call Roche Service.
0xbf2 0xbf4 0xbf5	Send failed. Contact Roche Service. Code:(0xbf2)	There was an issue sending the result to the host, call Roche Service.
0xbf3 0xbf6	Send failed. Please check your network/Connectivity connections and settings then try again. Code:(0xbf3)	Check the network and connectivity connection and settings in the Settings Menu and try again.
Error 1	Upgrade failed. IM Upgrade failed. Error code 1. Please contact Roche Service.	Call Roche Service.
Error 10	Upgrade failed. IM Upgrade failed. Error code 10. Please contact Roche Service.	Power down the analyzer and call Roche Service.
	[AssayName] has not been installed. Do you want to install this assay?	This assay has not been installed. Choose **Yes** to go to the **Assay Menu** to add the assay. Choose **No** to abort running the assay.
	[AssayName]: Script file is missing. Call Roche Service.	Choose **OK**. Ensure that the tube barcode is correct and scan it again. Alternatively, manually enter the tube barcode (see the information on barcode reading in this publication). If error continues, call Roche Service.
	[NumberOfRecords] records found. It will take some time to load. Continue?	Choose **Yes** to view the results. You might need to wait for a long time. Choose **No** to cancel viewing the results.
	Activation code is expired. Please contact Roche in order to get a new activation code. Your registration code: [RegistrationCode]	Choose **OK** and call Roche Service.
	Activation code is invalid!	Choose **OK** and call Roche Service.
	Analyzer has not been initialized, Assays can not be performed.	Restart the analyzer. If error continues, call Roche Service.

⊞ List of error messages

Code	Message	Action
	Audit log capacity has reached 100%. No further tests can be performed. Insert Advanced Tools USB and select "Export and Delete audit trail.	Choose **OK** to continue.
	AutoCal in progress. This could take up to a minute.	Choose **OK** to continue. Wait for **(busy)** to disappear and try again.
	AutoCal started. This could take up to a minute.	Choose **OK** to continue. Wait for **(busy)** to disappear and try again.
	Auto-Lock Time value must be between 1 and 10.	Choose **OK** and enter a value between 1 and 10.
	Bad thermal reading. Channel=[SpecificChannelWithError]	Restart the analyzer. If error continues, call Roche Service.
	Badge barcode already assigned.	Choose **Retry** to try again or **Cancel** to cancel.
	Badge barcode is already assigned to another user.	Choose **Retry** to try again or **Cancel** to cancel.
	Badge barcode scan mismatch.	Choose **Retry** to try again or **Cancel** to cancel.
	Barcode could not be read. Try again.	1. Choose **OK** and try again. 2. In case of repeated failure, clean the outside of the barcode reader window. ▸▤ Cleaning the window of the barcode reader (127)
	Battery level too low to run this assay, plug in AC power and try again	Connect the analyzer to the mains power supply to run this assay. Choose **OK** and try again.
	Battery may have insufficient power to run this assay. Do you really want to continue?	It is suggested that you connect the analyzer to the mains power supply to run this assay. Choose **Yes** to run this assay. Choose **No** to cancel.
	Cannot locate upgrade package	Call Roche Service, if you choose **OK**, the analyzer can still be used.
	Changes were not saved and will be lost. Do you really want to exit?	Choose **Yes** to discard the new user information input. Choose **No** to return to the new user info panel.
	Config file could not be reloaded: [ConfigFileName]	Restart the analyzer and if error continues, call Roche Service.
	Contact Roche Service.	Call Roche Service.
	Do you really want to delete the following user: [user id]	Choose **Yes** to delete the user. Choose **No** to reject deleting the user.
	Do you really want to restore default settings?	Choose **Yes** to reset the settings to the default settings. Choose **No** to keep the current setting.
	Enter a valid assay name!	Choose **OK** and try again.
	Enter a valid Calibration	Choose **OK** and try again.
	Enter a valid sample ID!	Choose **OK** and try again.
	Enter a valid User!	Choose **OK** and try again.
	Enter the data range in valid format. Format: MM,DD,YY-MM,DD,YY.	Choose **OK** and try again.
	Enter the data range in valid format. Format: MM,DD,YY.	Choose **OK** and try again.
	Error reading badge barcode.	Choose **OK** and try again.
	Failed to copy upgrade files	Choose **OK** and try again.

▦ List of error messages

Code	Message	Action
	Failed to delete the results. Retry, if problem persists call Roche Service.	Choose **OK** to continue.
	Failed to open NTP0:	Choose **OK** to continue. Restart if error continues.
	Failure to reset database.	Restart the analyzer.
	Failure to reset date.	Restart the analyzer.
	File could not be saved! Check the Install source field and access level!	Check your install source setting and try again.
	File was not found!	Choose **OK** to continue.
	Hard disk drive is full. Archive and delete some data.	Internal storage space is full. You must move or delete files to make more room in order to continue to run assays (move or delete some files).
	Invalid Activation Code. Please try again	Choose **OK** and try again.
	Invalid assay.	Repeat assay. If it still fails, contact Roche Service.
	Invalid barcode:	Choose **OK** and scan again.
	Invalid date/time entered	Choose **OK** and try again.
	Invalid Tube	Ensure that the same assay tube is scanned again.
	Invalid user ID entered: [user name entered]	Incorrect user ID entered or scanned. Choose **OK** and try again.
	Invalid Password	Choose **OK** and try again.
	It's not possible to add more than 500 users.	Choose **OK**, delete unused users and try again.
	Log file [LogFileName] could not be saved. Try again?	Choose **Yes** and try to save again.
	Lot does not exist. Do you want to add this lot?	This lot of assay tubes has not been validated. Choose **Yes** to go to the **Assay Menu** panel to add the lot. Choose **No** to abort running this assay.
	Machine name can not be empty!	Name of the analyzer cannot be empty. Choose **OK** and try again.
	Missing RunTime folder,cannot execute Liat application	Call Roche Service.
	New Lot validation not complete. Do you want to continue the validation?	Choose **Yes** to go to the **Assay Menu** to finish the add lot validation. Choose **No** to abort running the assay.
	No connection to the server can be established. Configure secure communication.	Choose **OK**, check the connectivity settings and try again.
	No Events were logged.	For your information. Choose **OK**.
	No rights to run this type of assay!	Ask your supervisor to add the assay to the **Allow Assay** list in your user profile.
	Out of sync Motor 3.	Check that the tube is inserted all the way.
	Please input: [Server Name/IP address/Share Name/Folder Path/User name/Password!]	Indicated settings are empty. Choose **OK** and enter the specified settings.
	Printing…	Choose **OK**. Wait for print to finish.
	Port value must be between 1 and 65535.	Choose **OK** and try again.
	Remove the assay tube before logging on as another user.	Choose **OK** and remove the assay tube from the analyzer.

⊞ List of error messages

Code	Message	Action
	Remove the tube slowly and carefully. Hit <OK> to continue. (Do NOT pull the tube out forcibly.)	Carefully pull the tube out.
	Remove the USB key in order to continue.	Choose **OK** and remove the USB key from the rear of the analyzer.
	Sample ID exceeds maximum length (60 chars).	Choose **OK** and try again.
	Scanned badge barcode does not match a known user.	Choose **OK** and try again.
	Server does not respond.	Check the connectivity settings and try again.
	Server's certificate expired.	Contact the administrator of your host system.
	Server's certificate name mismatch.	Check the connectivity settings or contact the administrator of your host system.
	Server's certificate untrusted.	Check the connectivity settings and try again.
	SNTP Server cannot be empty	Choose **OK** and try again, or set **SNTP** option to **No**. See the information on the system settings in this publication.
	Some of the provided settings are incorrect. Please refer to the user manual or contact Roche Service.	Choose **OK** to continue.
	System is busy.	Choose **OK**. Wait for **(busy)** to disappear and try again.
	System Reset go back to <Run Assay> screen. Code: [ErrorCode]	Choose **OK** to continue.
	The Activation Code you provided has already expired. Please contact Roche Service to get a new Activation Code.	Choose **OK** and call Roche Service.
	The Assay '[AssayName]' version '[AssayVersion]' is not compatible with the current SW version '[SoftwareVersion]"	Choose **OK**, make sure it is the correct USB key and otherwise call Roche Service.
	The certificate returned by the server has expired.	Contact the administrator of your host system.
	The certificate returned by the server has a wrong host name.	Contact the administrator of your host system.
	The current version ([AssayVersion]) for Assay '[AssayName]' is newer than the detected update ([AssayVersion]). This update will be discarded	Choose **OK**, make sure it is the correct USB key and otherwise call Roche Service.
	The first scanned badge barcode is not identical to the second.	Choose **Retry** to try again or **Cancel** to cancel.
	The grace period for this assay has expired. Please contact Roche Service in order to activate the assay	Choose **Activate** to register and activate your assay(s) or choose **Cancel** to continue.
	The grace period for this assay has expired. Please inform an Administrator to contact Roche Service to activate the assay.	Choose **OK** and inform your Administrator.
	The instrument´s Audit logs have reached 100%. No further tests can be performed. Contact your Administrator immediately.	Choose **OK** to continue.
	The instrument´s Audit logs reached [80/90]%. Contact your Administrator.	Choose **OK** to continue.

⊞ List of error messages

Code	Message	Action
	The instrument´s Audit logs reached [80/90]%. To free up space, insert Advanced Tools USB drive and export audit logs.	Choose **OK** to continue.
	The length of the password must be between 4 and 20 characters.	Choose **OK** and try again.
	The software update package is corrupted. Please contact Roche Service.	Call Roche Service, if you choose **OK**, the analyzer can still be used.
	The system could not find any assay script file on the USB drive	Choose **OK**, make sure it is the correct USB key and otherwise call Roche Service.
	The system does not have enough storage to perform the assay(s) install/update	Internal storage space is full. Move or delete files to free space so you can continue to run assays (move or delete some files).
	The update failed due to unknown reasons. System will be restored. Please contact Roche Service.	Choose **OK** and try again.
	The updated '[AssayVersion]' version for Assay '[AssayName]' does not come from a valid source. This update will be discarded	Choose **OK**, make sure it is the correct USB key and otherwise call Roche Service.
	The upgrade is not compatible with the currently installed version.	Call Roche Service.
	The validation of the software package failed	Call Roche Service, if you choose **OK**, the analyzer can still be used.
	There was an error adding assay '[AssayName]' version '[AssayVersion]'.	Choose **OK** and try again.
	There was an error restoring the assay '[AssayName]' version '[AssayVersion]'. Please, try reinstalling the assay.	Choose **OK** and try again.
	There was an error updating assay '[AssayName]' to version '[AssayVersion]'. The current version will be kept.	Choose **OK** and try again.
	Thermal error. Channel=[ChannelName]	Restart the analyzer. If error continues, call Roche Service.
	This server does not support secure connectivity compatible with the Liat analyzer.	Contact the administrator of your host system.
	Time zone could not be set	Choose **OK** and try again.
	Tube entry door error. Check the door and try again or press manual button to operate the door.	Check the tube entry door for blockage. Retry or manually move the door to the correct positions (i.e., with the tube inserted, carefully open and close the door).
	Tube insert time must be between 1 to 20!	Choose **OK** and try again.
	To restart the analyzer, press the <OK> button. Code: [ErrorCode]	Record the message code and call Roche Service. Choose **OK** to restart.
	Unable to connect to Share Folder.	Choose **OK** to continue. Restart the analyzer and/or the share folder server.
	Unknown error Code: ([ErrorCode])	Record the message. Restart the analyzer. If this error continues, call Roche Service.
	Unknown user ID: [user ID].	Choose **OK** and try again.
	Unregistered Assay(s) found. Please contact Roche Service to register the assay(s) within the next [NumberOfDays] days.	Choose **Activate** to register and activate your assay(s) or choose **Later** to continue.

⊞ List of error messages

Code	Message	Action
	Unregistered Assay(s) found. Please inform an Administrator to get in contact with Roche Service in order to register and activate your assay(s) within the next [NumberOfDays] days.	Choose **OK** and inform your Administrator.
	Unregistered software version. Please contact an Administrator to activate the software within the next [NumberOfDays] days	Choose **OK** and inform your Administrator. Running assays is still possible until the registration period has expired.
	Unregistered software version. Please contact Roche Service to activate the software within the next [NumberOfDays] days. Registration code: [RegistrationCode]	Choose **Activate** to register and activate your software or choose **Later** to continue.
	Unregistered software version. You are no longer able to run assays. Please contact an Administrator to activate the software.	Choose **OK** and inform your Administrator.
	Unregistered software version. You are no longer able to run assays. Please contact Roche Service to activate the software. Registration code: [RegistrationCode]	Choose **Activate** to register and activate your software or choose **Later** to continue.
	Unsaved data may be lost. Do you really want to log off the current user?	Choose **Yes** to log on. Choose **No** to return to the walk-by panel.
	Upgrade check failed. Check the documentation, correct your data, and try again.	Call Roche Service if error continues.
	Upgrade failed. IM Upgrade failed. IMUpgrade did not finish in time. Please contact Roche Service	Call Roche Service.
	Upgrade failed. IM Upgrade failed. IMUpgrade does not exist. Please contact Roche Service.	Call Roche Service.
	Upgrade failed. Missing RunTime folder. Please contact Roche Service.	Call Roche Service.
	Upgrade failed. Something's wrong, \Storage Card\CobasRunTime\ exist. Please contact Roche Service.	Call Roche Service.
	User already exists: Do you want to edit the user?	Choose **Yes** to update/overwrite the existing user's information. Choose **No** to cancel and return to the new user panel.
	User Id and Password can not be empty!	Choose **OK** and try again.
	Year must be between 1980 to 2080	The year entered is not valid. Choose **OK** and try again.
	You do not have the access rights to add this assay.	Ask your supervisor to add the assay to the **Allow Assay** list in your user profile.
	You need to change your password to log on.	Choose **OK** and try again.
	Your system time is not correct. Please correct it first in order to update the software.	Choose **OK** and navigate to the **System Settings** panel. Set the time to the current time and try again to install the software package.

⊞ List of error messages

Hardware-related and firmware-related codes

Hardware-related codes and **firmware-related codes** are generated in case of events related to hardware or module failure during assay runs. These codes appear in the following formats:

- Prefix codes
- Hexadecimal codes

The correlation between these code formats is shown in the following table:

Modules	Prefix	Code range
General	–	0x1 – 0x10
Motor	MO	0x001 – 0x0FF
Thermal	TP	0x101 – 0x1FF
Photometer	PM	0x201 – 0x2FF
Hardware	HW	0x301 – 0x3FF
File Transfer	FT	0x401 – 0x4FF
Miscellaneous	MI	0x501 – 0x5FF
CE / Script	CE	0xA01 – 0xAFF
Unsolicited message	UM	0xF01 – 0xFFF

⊞ Hardware- and firmware-related codes

Prefix codes appear as "XX-YYYYY-YYY". The following rules apply:

- "XX" denotes the affected module (e.g., **MO**).
- The 5th number (XX-YYYY**Y**-YYY) defines the severity of the issue.

🔅 A severity of 4 or less (e.g., MO-0007**1**-000) is a **Warning** that can be self-corrected by the analyzer. No action is necessary. The result generated from the assay run is valid.

🔅 A severity of 5 or greater (e.g., MO-0007**5**-000) is an **Error**, and aborts the assay run. If the issue recurs systematically, contact Roche Service.

Some hardware-related and firmware-related codes are listed in the following table:

Code	Message	Action
0x1	Config file on SD card has error Code:(0x1)	Restart the analyzer. If this error continues, call Roche Service.
0x2	Embedded PCB initialization failed: [Motor/Thermal/Photo] [FPGA/config] Code:(0x2)	Restart the analyzer. If this error continues, call Roche Service.
0x3	Motor Initialization failed (0x3)	Restart the analyzer. If this error continues, call Roche Service.
0x4	[Motor/Thermal/Photo] system serial numbers do not match with the one on SD Card Code:(0x4)	Restart the analyzer. If this error continues, call Roche Service.
0x5	Embedded PCB config data mismatch Code:(0x5)	Restart the analyzer. If this error continues, call Roche Service.
0x6	Thermal Initialization failed Code:(0x6)	Restart the analyzer. If this error continues, call Roche Service.

⊞ Hardware-related and firmware-related codes

Code	Message	Action
0x7	Read all temperature command failed Code:(0x7)	Restart the analyzer. If this error continues, call Roche Service.
0x8	Failed to shutdown thermal Code:(0x8)	Restart the analyzer. If this error continues, call Roche Service.
0xa	Motion calibration LUT failed Code:(0xa)	Restart the analyzer. If this error continues, call Roche Service.
0xb	Config LUT values are invalid (CompOn) Code:(0xb)	Restart the analyzer. If this error continues, call Roche Service.
0xc	Motion calibration call failed Code:(0xc)	Restart the analyzer. If this error continues, call Roche Service.
0xd	Motion calibration value(s) out of range with config LUT Code:(0xd)	Restart the analyzer. If this error continues, call Roche Service.
0xe	Photometer LUT value(s) out of range. Reboot after initialization completes. Contact Roche Service if error persists. Code:(0xe)	Restart the analyzer. If this error continues, call Roche Service.
0xf	Cleaning of photometer is recommended. Shutdown the instrument and use the cleaning tool. Follow instructions from "Cleaning Tool Guide". Code:(0xf)	Use the provided cleaning tool following the instructions included with the cleaning tool kit. Restart the analyzer. If this error continues, call Roche Service.
0x10	Cleaning of photometer is needed. Shutdown the instrument and use the cleaning tool. Follow instructions from "Cleaning Tool Guide". Code:(0x10)	Use the provided cleaning tool following the instructions included with the cleaning tool kit. Restart the analyzer. If this error continues, call Roche Service.
0x503	To restart the analyzer, press the <OK> button. Code:0x503	Call Roche Service. Press OK to reboot.
0x504	To restart the analyzer, press the <OK> button. Code:0x504	Call Roche Service. Press OK to reboot.
0x505	To restart the analyzer, press the <OK> button. Code:0x505	Call Roche Service. Press OK to reboot.
0xF31 0xF32	Assay Aborted Due to Error Code [0xF31/0xF32] Analyzer is not level. Place analyzer on level surface.	Restart the analyzer. If this error continues, call Roche Service.
0xF33	Assay Aborted Due to Error Code 0xF33 Tube in Place Lost.	Restart the analyzer. If this error continues, call Roche Service.
0xF61	Assay Aborted Due to Error Code 0xF61 Bad thermal reading. Channel=[Channel Nr.]	Restart the analyzer. If this error continues, call Roche Service.
0xF62	Assay Aborted Due to Error Code 0xF62 Thermal error. Channel=[Channel Nr.]	Restart the analyzer. If this error continues, call Roche Service.
0xF91	Assay Aborted Due to Error Code 0xF91 [Motor/Thermal/Photometer] config file load failed	Restart the analyzer. If this error continues, call Roche Service.
0xF92	Assay Aborted Due to Error Code 0xF92 [Motor/Thermal/Photometer] external RAM error	Restart the analyzer. If this error continues, call Roche Service.
0xF93	Assay Aborted Due to Error Code 0xF93 [Motor/Thermal/Photometer] serial flash error	Restart the analyzer. If this error continues, call Roche Service.
0xF94	Assay Aborted Due to Error Code 0xF94 Thermal runaway (enable). Channel=[Channel Nr.]	Restart the analyzer. If this error continues, call Roche Service.
0xF95	Assay Aborted Due to Error Code 0xF95 Thermal runaway (disable). Channel=[Channel Nr.]	Restart the analyzer. If this error continues, call Roche Service.

⊞ Hardware-related and firmware-related codes

Assay failure codes and assay pattern codes

Assay failure codes are generated for invalid test results.

Assay pattern codes are generated for abnormal PCR curve patterns. These codes may appear in assay runs which show invalid results.

-ᄋ̣- Assay failure codes and assay pattern codes are assay-specific. Refer to the **cobas**® Liat® Assay package insert or the instructions for use for more information. Contact Roche Service if the failure persists.

Generating a backup for troubleshooting purposes

If you encounter a problem, Roche recommends to generate a backup, which you then can send to your Roche representative.

> ⚠ **CAUTION**

Data security

Data backed up by the advanced tools key is stored as *plain text* files and so their content is accessible to unauthorized persons.

▸ Ensure that you store backed up data safely and securely so that it is not accessible by unauthorized persons.

The diagnostic backup contains all relevant data required to perform diagnostics. Once you have generated this backup using your advanced tools key, you need to prepare it on a Windows computer for transfer.

▸🗐 For information on the advanced tools key, see the **cobas**® Liat® Advanced Tools Key Guide.

Viewing and printing the event log

Certain error messages are recorded in a log file, which you can view and print.

-ᄋ̣- If configured, the analyzer sends events to a connected DMS.

▸🗐 About data exchange with a DMS (86)

☐ Logged on with Supervisor or Administrator access role.

▶ **To view the event log**

1 Choose **Tools > Event Log**.
   ❶ Large event logs might take some time to load.

2 To print the event log, choose the **Print** button.

2

```
Tools - ADMIN
        Event Log
IQM-EventLog
M1-E-12004|2017/02/07|16:12|00000
|wrn||||MI5500-000 |User: "ADMIN" ran Update
Script:FRTA.icl
M1-E-12004|2017/02/07|16:08|00000
|wrn||||MI5500-000 |User: "ADMIN" ran Update
M1-E-12004|2017/02/07|15:55|00000
|wrn||||MI5500-000 |User: "ADMIN" Deleted Liat
Flu/RSV Assay(FRTA.icl file)
M1-E-12004|2017/02/02|02:00|00000
Back                          Print
```
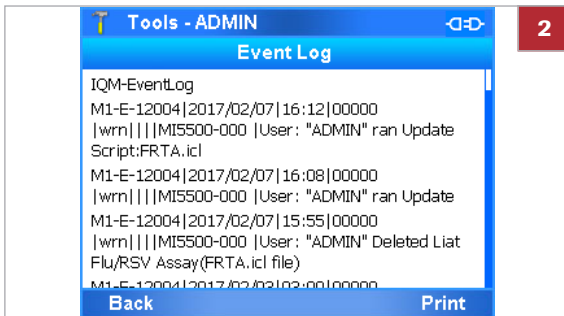
Resetting the lost default administrator password

If you have lost the password of the default administrator account ADMIN, you can apply for a new one with your Roche representative.

☐ Defined account with Administrator access role.

▶ **To reset your default administrator password**

1 On the login panel, choose the **Password?** button.

2 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.

1

```
No User

      cobas liat

      SW Rev. 3.1.0.2624
         Login
 Thursday, January 05, 2017 9:00:44 AM
Password?                     Login
```
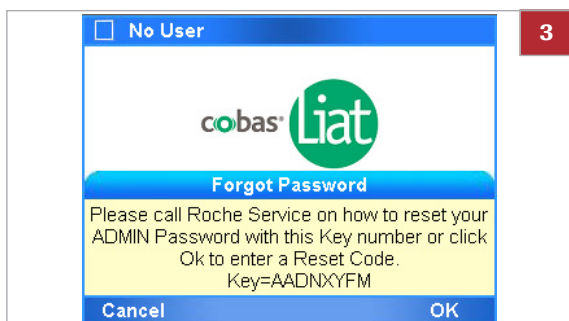
3 Make a note of the key displayed in the message.
- ❶ Do not touch the screen until you have received the reset code.

4 Contact your Roche representative and request a password reset.
- ❶ You need to provide proof of identity and the eight-digit key that was generated by the analyzer.

5 After successful verification, you will receive an eight-digit reset code, which is valid for 24 hours.

6 On the message dialog box, choose **OK**.
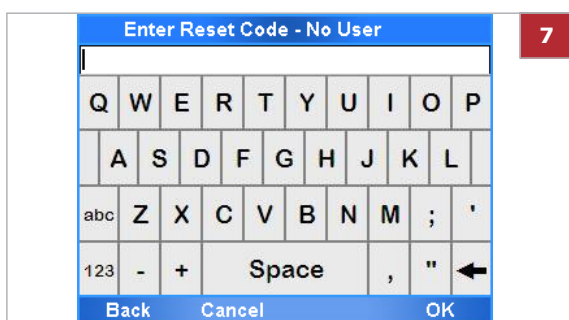
7 On the **Enter Reset Code** panel, enter the code provided by your Roche representative.

8 Choose the **OK** button.
- → If the code is valid, the **Enter Password** panel is displayed.
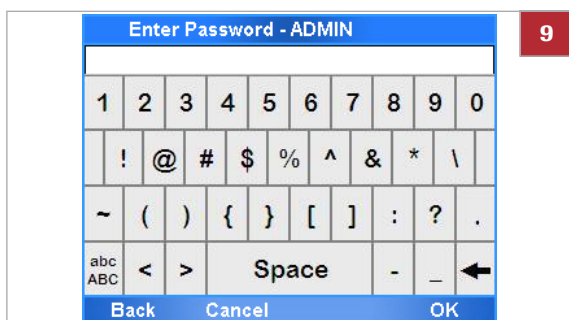
9 Enter a new administrator password.
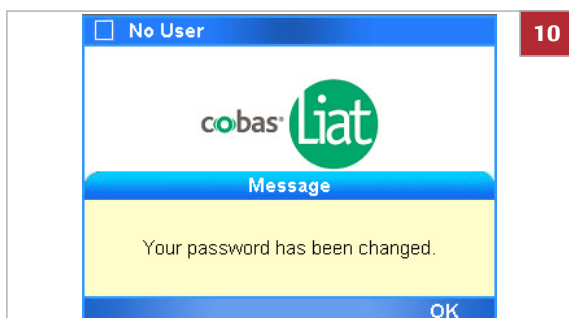
10 Choose the **OK** button.
- → A success message is displayed.

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 scanner.

▸ Do not use harsh, abrasive cleaners or wipes.

☐ Soft lint-free cloth
☐ 70% isopropanol

▪ Repeated failure to scan barcodes.

▸ To clean the window of the barcode reader

1 Switch off the analyzer.

2 Moisten a lint-free cloth with 70% isopropanol.

3 Gently wipe the outside of the barcode reader window.

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 press manual button to operate the door." 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 **OK** button.

3 To run the assay, continue with step **9** of (▸🔲 46).
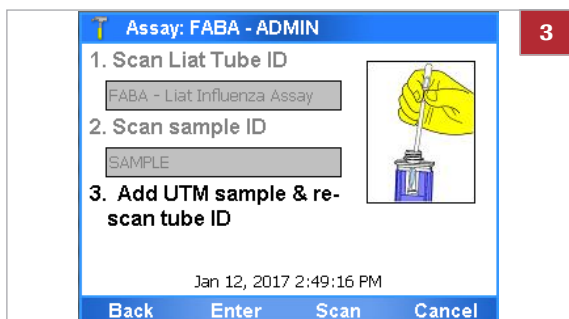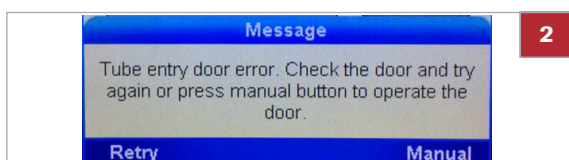
Resending results manually

If the analyzer is configured to send results automatically to a host, but the transmission fails, you have to review the results on the analyzer and resend them manually.

On the **Results** panel, results that were sent to the host, but not received by the host, are marked with 🔲.

☐ Automatic sending of results failed.

☐ Logged on with Supervisor or Administrator access role.

▶ To resend results manually

1 On the main menu, choose the **Results** option.

2 On the **Results** panel, review and send the results as described in (▸🗐 53).
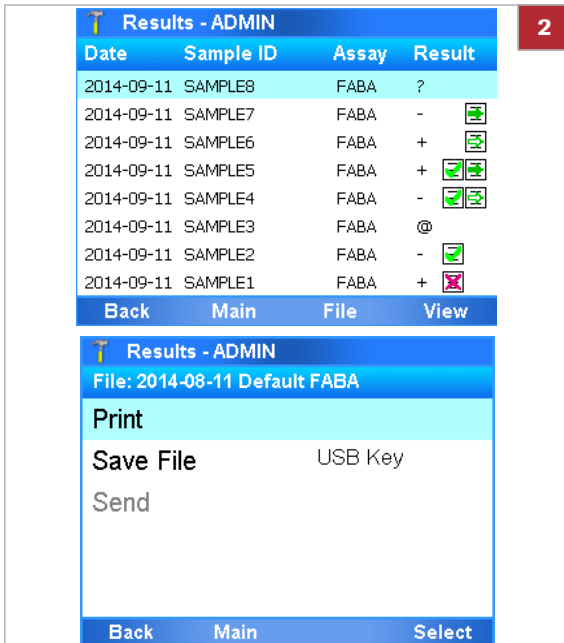
Restarting an unresponsive analyzer

If the analyzer becomes unresponsive, power off and restart it.

☐ Analyzer unresponsive

▶ To restart an unresponsive analyzer

1 If the analyzer is completely 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.

4 Follow the instructions on the screen.

Technical data

To ensure trouble-free operation, ensure that you use the components listed below and that the conditions mentioned in this section are met.

In this section

Technical characteristics

The analyzer has the following technical characteristics:

	Analyzer
User interface	Built-in touch screen & keypad
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 For barcodes, the following standards are supported: Code 39, 93, 128, Codabar, GS1 Databar-14.
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) recommended
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

Standard supplies

For trouble-free operation, use the following standard supplies:

Name
cobas® Liat® Analyzer
cobas® Liat® Advanced Tools Key
Universal Power Supply
Power cable
cobas® Liat® Assay Tube Read the package insert or the instructions for use for detailed product data and usage limitations.
cobas® Liat® Cleaning Tool Kit

⊞ Standard supplies

The assay tubes are specific to each assay. The Roche catalog of assays is constantly expanding. Contact your

Roche representative for a complete list of **cobas**® Liat® assays available for IVD use.

Printer

A standard PCL compatible printer (laser or inkjet) that can be connected either to the USB port or via data network.

-�- PCL 3 GUI is not supported.

Reports printed on an inkjet printer can be damaged by moisture or liquid. It is therefore recommended to use a laser printer.

Index

Logging on, 29
– with badge barcode, 30
– with user ID, 30
Lots
– control results, 77
– information, 77

M

Maintenance, 105
Messages, 111
Monitoring, 105

N

Navigation buttons, 25
Network definitions, 81
Network resources, 81
New in version 7.2, 12
Numbers, entering, 37

O

Operating elements, 24
Overview
– assays, 25
– barcode reader, 25
– results, 52
– touch screen, 26

P

Password
– changing, 31
– changing anytime, 32
– changing at logon, 33
– resetting for Administrator, 125
Passwords
– about, 91
Patents, 4
Performing
– assays, 46
– runs, 45
Power switch, 25
Powering on, 28
Printer
– compatibility, 132
– installing network, 21
– installing USB, 20
Printing
– lot control results, 77
– lot information, 77
Product names, 9

Q

Quality control, 104

R

Reading barcodes, 37
Registering
– assays, 68
– software, 100
Remote service platform, 64
Reports, 52
Resetting Administrator Password, 125
Results
– deleting, 57
– lot controls, 77
– overview, 52
– reviewing, 53
Reviewing results, 53
Revision history, 2
Running assays, 46
Runs, performing, 45

S

Safety
– classification, 14
– disposal, 16
– labels, 16
– summary, 14
Scanning barcodes, 37
Screen
– See Touch screen
Screenshot disclaimer, 3
Selecting items, on screen, 36
Self-checks, 23, 105
Service, 106
Settings
– See Definitions
Setup
– analyzer, 60
– HIS, LIS, DMS connections, 85
– network, 81
– network resources, 82
– system, 79
Share lot function
– disabling, 84
– using, 83
Shutting down analyzer, 44
Software
– installed versions, 102
– registering, 100
– updating, 97
Specifications, 130
Spillages, 110
Starting
– analyzer, 28
Storage conditions, 131

W