cobas u 601 urine analyzer

Operator's Manual Version 2.5
Software Version 2.3

Document information

Manual version	Software version	Revision date	Change description
1.0.0	1.0	December 2013	First publication
1.0.1	2.0	May 2014	Linguistic and minor content adjustments
1.0.1	2.1	January 2015	Software upgrade. No content changes in operator's manual.
2.0.0	2.2	July 2015	• Illustrations were adapted to latest hardware and software. • New: Optional input connection unit. • New: Optional connection to external water supply. • Improved result presentation. • New: Emergency stop feature • New: Definition of notification periods. • Changes to range tables and cross-check rule configuration. • New: Definition of color ranges for COL. • Various improvements in configuration features. • New: Procedure for adjusting probe action to different tubes and racks.
2.1.0	2.2.3	July 2016	• Improved working with **Sample sequence number** mode. • Improved handling of invalid SG results. • Definition of STAT racks.
2.2	2.3	March 2018	• New version (2) of control unit. • Windows 10 operating system. • Upgraded test strip transport system.
2.3 (English only)	2.3	May 2019	• Effect of intrinsic color of the urine to specific gravity and clarity. • Information on strip tray and transporter IDs removed. • Required volumes of wash solution adapted.
2.4	2.3	March 2020	• New layout. • Linguistic and minor content adjustments.
2.5	2.3	November 2020	• IVDR compliance.

Revision history

Edition notice

This publication is intended for operators and administrators of the **cobas u** 601 urine 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 **Operator's Manual** and the **Online Help** contain all information about the product, including the following:

- Routine operation
- Maintenance
- Safety
- Troubleshooting information
- A software reference
- Configuration information
- Background information

The **Operator's Manual** and the **Online Help** contain important safety information. You must read them before operating the instrument.

The **Quick Reference Guide** provides you with an overview of routine tasks.

⚠ General attention

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

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

⚠ Incident reporting

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

Training

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

Images

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

Warranty

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

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

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

Copyright

Trademarks

The following trademarks are acknowledged:

Feedback

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

Approvals

The **cobas u** 601 urine analyzer meets the requirements laid down in:

- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.
- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

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

The following marks demonstrate compliance:

For *in vitro* diagnostic use.

Complies with the provisions of the applicable EU regulations.

Eurasian Conformity. Demonstrates that the product meets the Eurasian Economic Union (EAEU)'s regulations and standards for customs clearance and trading.

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

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

Contact address

Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany
Made in Hungary

Roche affiliates

A list of all Roche affiliates can be found at:

www.roche.com/about/business/roche_worldwide.htm

eLabDoc

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

www.dialog.roche.com

For more information, contact your local affiliate or Roche Service representative.

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Intended use

The **cobas u** 601 urine analyzer is a fully automated urinalysis system intended for the in vitro quantitative, qualitative or semi-quantitative determination of urine analytes, including pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, and erythrocytes, as well as specific gravity, color, and clarity.

These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders.
This system is intended to be used by trained operators in clinical laboratories.

How to use this manual

Keep this Operator's Manual in a safe place to ensure that it is not damaged and remains available for use.

This Operator's Manual should be easily accessible at all times.

Throughout this documentation, images of screens are included for illustration purposes. They are not necessarily identical with what you see on your analyzer.

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

Content overview

The documentation is divided into the following parts:

- *Part A — System Description:* The system description provides information on the safe operation of the system, on its hardware and software, and an overview of how it is used.
- *Part B — Operation:* The operation part describes how to perform the various tasks that are required when analyzing samples.
- *Part C — Maintenance:* The maintenance part provides information on how to ensure continuous problem-free operation of the system.
- *Part D — Troubleshooting:* The troubleshooting part provides assistance on how to deal with exceptional situations.
- *Part E — Glossary*: The glossary explains key terms used in the user interface and in this documentation.
- *Part F — Index:* The index provides a quick way to information, it consists of an alphabetical list of key words that lead to the relevant information within this documentation.

Symbols and abbreviations

Visual cues are used to help locate and interpret information quickly. This section explains the conventions used for this purpose.

Product names

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

Product name	Descriptor
cobas u 601 urine analyzer	Test strip analyzer

Product names

Symbols used in this publication

The following symbols are used:

Symbol	Explanation
•	List item.
	Cross-reference to another topic.
	Tip. Extra information on correct use or useful hints.
	Extra information within a task.
→	Result of an action within a task.
	Materials that are required for a task.
	Prerequisites of a task.
	Figure. Used in figure titles and cross-references to figures.
	Table. Used in table titles and cross-references to tables.

Symbols used in this publication

Symbol	Comment
	Safety alert.
	Electrical and electronic equipment marked with this symbol are covered by the European directive WEEE.
	Label on the water container for external water supply indicating monthly cleaning.

Symbols used for easy recognition of information

Symbols used on product

The following symbols are used:

Symbol	Explanation
	Catalogue number.
	Global Trade Item Number.
	Serial number.
	Date of manufacture.
	Manufacturer.
	Indicates that the equipment is suitable for alternating current only; to identify relevant terminals.
	For *in vitro* diagnostic use.
	Unique device identifier.
	Complies with the provisions of the applicable EU regulations.
	Please consult instructions for use.
	Issued by Underwriters Laboratories, Inc. (UL) for Canada and the US.
	Eurasian Conformity.

Symbols used on product

Symbol	Explanation
Equipment de Laboratoire / Laboratory Equipment	'Laboratory Equipment' is the product identifier as shown on the type plate.
	Temperature limit
	Humidity limit

Symbols used on product

Abbreviations

The following abbreviations are used:

Abbreviation	Explanation
ANSI	American National Standards Institute
BIL	Bilirubin
CLA	Clarity
COL	Color
CSA	Canadian Standards Association
EC	European Community
EN	European standard
ERY	Erythrocytes and hemoglobin
ESD	Electrostatic discharge
GLU	Glucose
IEC	International Electrical Commission
IVD	In vitro diagnostic
IVDR	In vitro diagnostics regulation
KET	Ketones
LEU	Leukocytes
LAS	Laboratory automation system
LIS	Laboratory information system
n/a	Not applicable
NIT	Nitrite
PRO	Protein
QC	Quality control
RD	Roche Diagnostics
RF	Radio frequency
RFID	Radio frequency identification
SG	Specific gravity
STAT	Short turn around time
UBG	Urobilinogen
UL	Underwriters Laboratories Inc.

Abbreviations

Abbreviation	Explanation
UPS	Uninterrupted power supply
VAC	Volt alternating current
WEEE	Waste Electrical and Electronic Equipment

Abbreviations

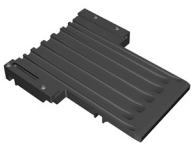
List of available accessories and consumables

Below are lists of globally available accessories and consumables. For ordering information, contact your local sales representative.

Accessories

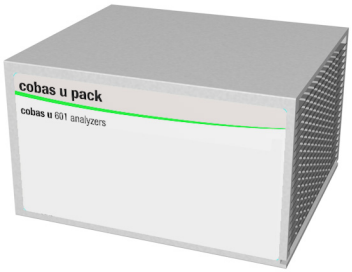
Image of product	Product name Catalog number
Tables	
	cobas 6500 Table REF 07524811001
	Table Cobas Integra 400 plus REF 03310264001
	PC Table (D) REF 04590457001
Racks and rack trays	
	RD Standard rack 0001-0050 REF 11902997001
	Std-rack 0051-0100 REF 11903004001
	Std-rack 0101-0150 REF 11903012001
	Std-rack 0151-0200 REF 11903039001
	Std-rack Control Q001-Q010 white REF 12025574001
	Std-rack, Wash W999 green (2 pcs) REF 12025728001
	Rack Tray, 75 pos, collapsible, RDA REF 05099986001

Available accessories

Image of product	Product name Catalog number
Liquid containers	
	Water Container REF 06390528001
	Water Container (External Water Supply) REF 07524803001
	Liquid Waste Container REF 06390536001
	Kit External Water Supply REF 07564490001
Sample handling	
	Sample probe cobas u 601 REF 07127162001
Test strip handling	
	Test strip tray V2 REF 09109170001
	Test strip transporter V2 REF 09109161001

Available accessories

Consumables

Image of product	Product name
	**cobas u** pack REF 06334601001
	cobas u calibration strip REF 06390579001
	Waste Box Carton REF 06390544001

Available consumables

What is new in publication version 2.2

New control unit version

The control unit was replaced with a new version (version 2).

Windows 10 operating system

The internal PC uses the Windows 10 operating system.

Upgraded test strip tray and transporter

The test strip tray and test strip transporter were enhanced.

Replacing of reference plate

The reference plate can only be replaced by a Roche Service representative.

What is new in publication version 2.1.0

Illustrations and screenshots

Illustrations and screenshots were adapted to reflect the latest hardware and software.

Optional components

Colored labels for Roche 5-position racks are now available.

Optional components (120)

Working with Sample sequence number mode

The procedure for working with **Sample sequence number** mode has been improved.

Defining the sample sequence number ranges (162)

Rerunning tests when working with Sample sequence number mode (191)

STAT and routine results are marked when working with Sample sequence number mode

If you work with **Sample sequence number** mode, sample IDs for routine test results are marked with an “N” preceding the sample sequence number, and “E” for STAT test results.

Validating results (178)

Invalid SG results

You can now search for invalid SG results and edit them manually.

Managing invalid SG results (182)

Working with Sample sequence number mode

The information on defining the validation method has been adapted.

Defining the validation method (254)

STAT racks

You can now define dedicated STAT racks.

To define a STAT rack (280)

What is new in publication version 2.0.0

Illustrations and screenshots

Illustrations and screenshots were adapted to reflect the latest hardware and software.

Automatic rack feed, input connection unit

You can optionally connect the analyzer to a laboratory automation system by replacing the input buffer with an input connection unit. This allows automatic rack feed to the analyzer.

Input connection unit (82)

Operation with input connection unit (170)

To load a priority rack when working with an LAS (173)

To perform a QC measurement when working with an LAS (230)

To clean the inlet water filter (external water supply) (320)

To loosen the floats in the water container for external water supply (322)

External water supply

You can optionally connect the analyzer to an external laboratory water supply system. When using this feature, the liquid waste is drained off directly to the laboratory liquid waste system.

- Water container for external water supply (90)
- Liquid waste with external water supply (92)
- To clean the inlet water filter (external water supply) (320)
- To loosen the floats in the water container for external water supply (322)

Technical specifications

Some values were adjusted.

- External conditions
- Power requirements
- Water quality
- Wash solution
- Cleaning solution

- Technical specifications (115)

Safety information

Input connection unit

Information on the proper use of the following items was added:

- Input connection unit (82)
- Water container for external water supply (90)
- Racks (85)
- To adjust the probe action (282)
- Safety labels on the equipment (40)

Overview work area

- The categorizing of the task list has been improved.
- An emergency stop button (**E. Stop**) was added. Use this function if, for some reason, all activities on the analyzer must be stopped immediately or if the analyzer is stuck in either the **Operating** or **Init** status.
- When working with a laboratory automation system, the **Priority rack** button is available on the **Overview** work area.

- Emergency stop (313)
- To load a priority rack when working with an LAS (173)

Result presentation

- To assist people with color vision deficits, in addition to the colors hatching is displayed.
- New symbols and data alarms were introduced to provide more information about the status of the result.

Color coding (144)

Checking the status of processing (173)

Validating results (178)

To review QC results (237)

QC charts

The QC charts function has been improved.

Working with QC charts (139)

Printing and exporting information

The feature was adapted and applied consistently.

Some changes:

- Screenshots are no longer part of the problem report, instead, you can save them separately.

Printing and exporting information, generating reports (242)

Emergency stop

An emergency stop feature has been introduced for situations when all activities on the analyzer must be stopped immediately or if the analyzer is stuck in either the **Operating** or **Init** status.

Emergency stop (313)

Replacing the reference plate

The description of how to replace the reference plate was adjusted.

Warning intervals

You can now define how long before the event a warning is issued for expiry of materials and maintenance actions.

Defining when notifications should be generated (272)

QC materials

The conditions for making changes to QC materials have changed.

To change QC material data (233)

To make test parameter related changes (234)

To include or exclude tests from the QC measurements (235)

Defining QC materials using the RFID reader

The procedure for defining QC materials using the RFID reader was adapted.

To define a new QC material by reading the RFID tag (232)

Report definition

The items have been regrouped and complemented.

Defining the look, content, and handling of reports (274)

Range tables and cross-check rules

The procedures for defining range tables and cross-check rules were simplified.

Defining range tables (258)

Defining cross-check rules (255)

Color ranges for COL

You can now adjust the color ranges for COL to achieve full correspondence with the actual color.

Defining the ranges for the colors of COL (265)

Importing system settings

You can now import system settings that were generated using software versions other than the current one.

Importing and exporting system settings (277)

Adjusting the probe action

To enable the use of different racks and tubes, a function is now provided to adjust the probe action to the changed dimensions.

To adjust the probe action (282)

System description

Safety

In this chapter you find information about the safe operation of the equipment.

In this chapter 1

Safety classification

This section explains how precautionary information is presented in this manual.

The safety precautions and important user notes are classified according to the ANSI Z535.6 Standard. Familiarize yourself with the following meanings and icons:

⚠ Generic hazard statements

The safety alert symbol by itself without a signal word is used to promote awareness to hazards which are generic or to direct the reader to safety information provided elsewhere in the document.

These symbols and signal words are used for specific hazards:

⚠ WARNING

Warning

- Indicates a hazardous situation which, if not avoided, could result in death or serious injury.

⚠ CAUTION

Caution

- Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

NOTICE

Notice

- Indicates a hazardous situation which, if not avoided, could result in damage to equipment.

Important information that is not safety relevant is indicated by the following symbol:

Tip

Indicates additional information on correct use or useful tips.

Safety precautions

⚠ Generic hazard statements

Particular attention must be paid to the following safety precautions. If these safety precautions are ignored, the operator may suffer serious or fatal injury. Each precaution is important.

In this section

Operator qualification

Insufficient knowledge and skills

Operators are required to have a sound knowledge of relevant guidelines and standards as well as the information and procedures contained in the Operator's Manual.

- Do not carry out operation and maintenance unless you have been trained by Roche. Carefully follow the procedures specified in the Operator's Manual for the operation and maintenance of the analyzer. Leave maintenance, installation or service that is not described in the Operator's Manual to trained Roche Service representatives. Follow Good Laboratory Practices especially when working with biohazardous material.

Safe and proper use of the analyzer

In this section

Personal safety

Personal injury and infection due to sharps, rough edges, and/or moving parts

- Good Laboratory Practice can reduce the risk of injury.
- Be aware of your laboratory environment, well-prepared, and follow the instructions for use.
- Some areas of the instrument may have sharps, rough edges, and/or moving parts.
  Wear personal protective equipment to minimize the risk of injury from bodily contact with such parts, especially in less accessible areas, or while cleaning the instrument.
- Your personal protective equipment should be appropriate to the degree and type of potential hazard, e.g. suitable lab gloves, eye protection, lab coat, and footwear.

Personal protective equipment

Risk of injury due to missing personal protective equipment

- Be sure to wear appropriate protective equipment, including, but not limited to, eye protection with side shields, fluid resistant lab coat, and approved lab gloves. Wear a face shield if there is a chance of splash or splatter.

Accuracy and precision of measured results

Incorrect measuring results

An incorrect measuring result may lead to an error in diagnosis, therefore posing danger to the patient.

- For proper use of the instrument, measure QC samples and monitor the instrument during operation. Do not use consumables that have exceeded their expiry date, otherwise inaccurate data may be obtained. For diagnostic purposes always assess the results in conjunction with the patient's medical history, clinical examination, and other findings.

Installation

Performing installation

- Installation must be performed by personnel authorized and trained by Roche only.

Environmental conditions

Unsuitable environmental conditions

Operation outside the specified environmental conditions may lead to incorrect results or malfunction of the instrument.

- Use the instrument indoors only and avoid heat and humidity.
- Always comply with your local laboratory regulations.
- Perform maintenance according to the specified intervals and when instructed to do so by the system software to maintain the required environmental conditions for the analyzer.
- Ensure that the analyzer's ventilation openings remain unobstructed at all times.
- Keep the Operator's Manual in a safe place to ensure that it is not damaged and remains available for use. It must be easily accessible at all times.

Technical specifications (115)

Approved parts

Use of non-approved parts

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

- Only use parts and devices approved by Roche.

Third-party software

Installation of third-party software

Installation of any third-party software that is not approved by Roche may result in incorrect behavior of the analyzer.

- All Roche approved software must be installed by personnel authorized and trained by Roche.

Miscellaneous safety precautions

Power interruption

A power failure or momentary drop in voltage may damage the analyzer or lead to data loss. Perform regular backups of measurement results. Roche recommends to operate the analyzer with an uninterruptible power supply. Do not switch off power while the PC accesses the hard disk or an external storage device.

Analyzer unused for an extended period of time

If the analyzer is not used for an extended period of time, the power switch must be set to the off position. Observe the onboard stability values for test strips.

Relocation and transportation

Do not attempt to relocate or transport the analyzer. Leave relocation and transport to personnel trained or authorized by Roche.

Disposal of the equipment (45)

Safety summary

This safety summary contains the most important and general warning, caution, and notice messages. Additionally, you will find specific safety information at the beginning of chapters and with procedures.

In this section

Warning messages

⚠ List of warning messages

- Before operating the analyzer, read the warning messages contained in this summary carefully. Failure to observe them may result in death or serious injury.

In this section

Electrical safety

Electrical shock by electronic equipment

Removing the covers of electronic equipment can cause electric shock, as there are high voltage parts inside.

- Do not attempt to work in any electronic compartment.
- Do not remove any cover of the analyzer other than those specified in this Operator's Manual.
- Installation, service, and repair must only be performed by personnel authorized and trained by Roche.
- Observe the safety labels on the equipment.

Biohazardous materials

Infection by samples and associated materials

Contact with samples containing material of human origin may result in infection. All materials and mechanical components associated with samples of human origin are potentially biohazardous.

- Follow Good Laboratory Practices, especially when working with biohazardous material.
- Keep the cover closed and in place during operation.
- Be sure to wear appropriate protective equipment, including, but not limited to, eye protection with side shields, fluid resistant lab coat, and approved lab gloves.
- Wear a face shield if there is a chance of splash or splatter.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If sample or liquid waste comes into contact with your skin, wash it off immediately with soap and water and apply disinfectant. Consult a physician.

Infection by injury due to sharp objects

- When wiping probes, use several layers of tissue and wipe from the top down.
- Be careful to not puncture yourself.
- Be sure to wear appropriate protective equipment, for example gloves. Take extra care when working with lab gloves; these can easily be pierced or cut, which can lead to infection.

Waste

Infection by liquid waste

Contact with liquid waste may result in infection. All materials and mechanical components associated with the waste systems are potentially biohazardous.

- Be sure to wear protective equipment. Take extra care when working with lab gloves; these can easily be pierced or cut, which can lead to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If liquid waste comes into contact with your skin, wash it off immediately with water and apply disinfectant. Consult a physician.
- Observe the safety labels on the equipment.

Contamination of the environment by liquid and solid waste

The waste of the analyzer is potentially biohazardous and must be treated in accordance with the relevant laws and regulations.

- When disposing of any waste, do so in accordance with the appropriate local regulations.
- Any substances contained in QC materials and other working materials, which are legally regulated for environmental protection, must be disposed of in accordance with the relevant water discharge facility regulations. For the legal regulations on water discharge, please contact the suppliers of the materials.

Barcode readers

Barcode readers using LED technology with very low output power are used to scan the barcodes on samples and racks.

Loss of sight

The intense light of the LEDs may damage your eyes.

- Do not stare into the LEDs.

Foam, bubbles or films on sample

Incorrect results due to incorrect sample volume

Foam, bubbles or films on a sample or inside a sample container may cause pipetting volume shortage and lead to deterioration in measurement accuracy.

- When loading samples or QC materials on the instrument, ensure that they do not contain foam, bubbles or films.

About the protection of personal data and software security

The General Data Protection Regulation (GDPR) is a regulation in EU law on data protection and privacy for all citizens of the European Union (EU) and the European Economic Area (EEA). The regulation also covers the processing of personal data outside the EU and EEA.

If this regulation or any other privacy protection regulation is applicable for your country, observe the following safety messages to prevent data breaches and to meet the GDPR:

Access control

Unauthorized access may lead to data breaches.

- Implement physical access controls to ensure that only authorized personnel operate the system at all times.
- Assign a personal, unique user ID to each user for system access.
- Assign access rights to each user only as high as required for the tasks of the user.
- Delete user IDs from the system for users who no longer work on the system.

Corrupt data due to a disclosed password

The security of the system and its data depends on the password-protected access. If an unauthorized person discovers your user ID and password, they could compromise this security.

- Always enter your password unobserved.
- Do not write down your password anywhere, including in a contact form, in the address book, or in a file on the computer.
- Do not disclose your password to anyone. Roche will never ask you for your password.
- If you ever disclose your password to anyone, change it immediately afterwards.
- Contact your local Roche affiliate if you think your account has been compromised.

Network security

Malicious software and hacker attacks may impair IT security. The laboratory is responsible for the IT security of their IT infrastructure.

- To protect and separate Roche systems from other laboratory infrastructure, the Roche-provided firewall must be used.
- Secure all devices and services used in the lab infrastructure against malicious software and unauthorized access.
- Secure the network environment to be resilient against traffic redirection and eavesdropping.

Data entry and data transfer

Writing patient sensitive information in comment fields can violate protection laws for protected health information.

- Do not write any patient sensitive information into comment fields.
- Do not download patient identifiers from any host system (e.g., LIS, middleware, or HIS) onto the system.
  Data transfer using any host protocol is not encrypted; data is transferred as plain text and readable with IT tools like sniffer.

Secure data storage

Unauthorized access to data backups and archive files can violate data protection laws.

- Any data backup or data archive that has been exported from the instrument must be physically stored in a secured location.
- Ensure only authorized persons may access the secure data storage. This includes the data transfer to remote storage locations and disaster recovery.
- Data backups must not be taken from the secure data storage. Do not take external storage devices outside the lab environment.

Cybersecurity and privacy awareness

Insufficiently informed employees can endanger security.

- Perform regular cybersecurity and privacy awareness trainings for staff handling personal data. Instruct staff how to handle data in a compliant way and according to the privacy principles as mandated by customer regulations.
- Check your instrument for suspicious activity and report any suspected compromise to your local Roche representative immediately.
- Update to the latest software versions provided by Roche as soon as possible.
- Exercise care when using external storage devices.
  Do not connect to the system any external storage device that you use on public or home computers.
  Failure to do so may result in data loss and render the instrument unusable.

Use of storage devices

Wrong handling of external storage devices may result in data loss or system malfunction.

- Only insert or remove an external storage device after the data export is finished.
- At any one time only one external storage device can be in use. Before inserting an external storage device into a USB port, check that no other external storage device is connected.

Computer viruses

If you detect an unexpected operation or program/data damage, the PC may be infected with a computer virus.

- To avoid virus infections, scan removable storage media by an antivirus program before using them on the system.
- Never use a program or external storage device that is suspected of containing a virus.
- If you think your PC is infected with a computer virus, call your local Roche Service representative. Your local Roche Service representative will check your system for proper functionality.

Data backup

Data may get lost due to hard disk failures or damages.

- Back up your data (measurement results and system parameters) at regular intervals.
- Use the backup function periodically to store relevant data on an external storage device.
- Make a backup copy if you have changed any system parameters.

Non-approved third-party software

Installation of any third-party software that is not approved by Roche Diagnostics may result in incorrect behavior by the system.

- Do not copy or install any software or software patches on the system unless it is part of the system software or your Roche Service representative advises it.

Caution messages

⚠ List of caution messages

- Before operating, read the caution messages contained in this summary carefully. Failure to observe them may result in minor or moderate injury.

In this section

Mechanical safety

Personal injury due to contact with moving parts

- Keep the main cover closed and in place while the analyzer is operating.
- During operation and maintenance, proceed according to the instructions contained in the Operator's Manual.
- Observe the safety labels on the equipment.

Safety labels on the equipment (40)

Working solutions

Skin inflammation or injury caused by working solutions

Direct contact with cleaning solutions or other working solutions may cause skin irritation, inflammation, or burns.

- If a cleaning solution or other working solution comes into contact with your skin, wash it off immediately with water and apply disinfectant. Consult a physician.

Insoluble contaminants in samples

Incorrect results and interruption of analysis due to contaminated samples

Insoluble contaminants in samples and bubbles or films inside a sample container may cause clogging or pipetting volume shortage and lead to a deterioration in measurement accuracy.

- Ensure that samples contain no insoluble contaminants such as fibrin or dust.

Influence of vibrations

Incorrect results due to vibrations or knocking the analyzer

Strong vibrations or knocking the instrument may influence the positioning of the measuring devices and lead to false results.

Strong vibrations or knocking the instrument may lead a rack being moved to the rack entry position, which may lead to incorrect sample identification.

- Ensure that no vibrations influence the surface the analyzer stands on and take care not to knock the analyzer while processing tests.

Excessive ambient humidity

Incorrect results due to high ambient humidity

Excessive ambient humidity may influence the chemical reactions of test strips and lead to incorrect results.

- Always operate the analyzer in environmental conditions defined in the technical specifications.
- Do not store test strip cassettes in their protective packaging once the latter was opened.
- After removing them from their protective packaging, always load the test strip cassettes in the test strip cassette compartment within the time defined in their Instructions for Use.

Malfunction due to interfering electromagnetic fields

Malfunction of analyzer and incorrect results due to interfering electromagnetic fields

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

- The electromagnetic environment should be evaluated prior to operation of the device.
- Do not operate this analyzer in close proximity to sources of strong electromagnetic fields (for example unshielded intentional RF sources), as these may interfere with the proper operation.

Fatigue due to long hours of operation

Fatigue due to long hours of operation

Looking at the monitor screen over an extended period of time may lead to eye strain or body fatigue.

- Avoid spending long periods looking at the monitor screen.

Notices

⚠ List of notices

- Before operating, read the notices contained in this summary carefully. Failure to observe them may result in damage to equipment.

In this section

Moving parts

Damage to the analyzer due to contact with moving parts

Contact with moving parts may bend the sample probe or damage some other component. If the analyzer detects a collision, an alarm is issued and operation stops immediately.

- Keep all covers closed and in place during operation.
- Do not touch any parts of the analyzer other than those specified. Keep away from moving parts during operation.

Fuses

Damage to the analyzer due to improper use

- Should one of the fuses blow, do not attempt to operate the analyzer before contacting your Roche Service representative.

Spillage

Malfunction due to spilled liquid

Any liquid spilled on the analyzer may result in malfunction or damage.

- Do not place samples or any other liquid on the surface of the analyzer.
- If liquid does spill on the analyzer, wipe it up immediately and apply disinfectant. Be sure to wear protective equipment.

Excessive ambient humidity

Malfunction due to high ambient humidity

Excessive ambient humidity may cause condensation inside the analyzer and lead to short-circuiting in electrical components.

- Always operate the analyzer in environmental conditions defined in the technical specifications.

Influence of vibrations

Analyzer malfunction due to sample spillage

Strong vibrations or knocking the instrument may lead to spillage of sample, which may lead to malfunction of the analyzer.

- Ensure that no vibrations influence the surface the analyzer stands on and take care not to knock the analyzer while processing tests.

Safety labels on the equipment

Warning labels have been placed on the analyzer to draw your attention to areas of potential hazard. The labels and their definitions are listed below according to their location on the instrument.

The safety labels on the analyzer comply with the following standards: ANSI Z535, IEC 61010-1, IEC 60417, or ISO 7000.

If the labels are damaged, they must be replaced by a Roche Service representative. For replacement labels, contact your local Roche Service representative.

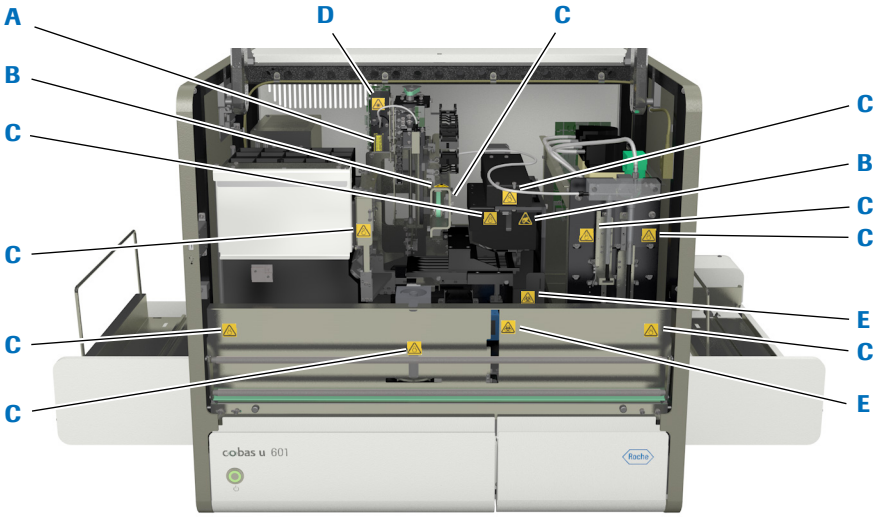
In this section

Analyzer views

In this section

Front view

Safety labels on the test strip analyzer (front view)



Safety labels on the test strip analyzer (front view)

A

Laser light source (Class 1)
This label indicates that a laser light source is integrated in the measuring cell, but there is no danger of coming into contact with laser light. Do not alter the measuring cell.
This label indicates that the measuring cell as a unit conforms to IEC 60825-1:2007 on laser products, and that there is a danger of Class 3R laser radiation if the measuring cell is opened.

B

ESD sensitivity
This label indicates a part that is electromagnetically sensitive.
Do not operate this analyzer in close proximity to sources of strong electromagnetic fields (for example unshielded intentional RF sources), as these may interfere with the proper operation.

C

Moving parts
This label indicates that there is a danger of moving parts within the vicinity of this label. Keep hands away from moving parts.

D

Laser light source (Class 1)
This label indicates that a laser transmitter is integrated in the measuring cell, but there is no danger of coming into contact with laser light. Do not alter the photometer unit.

E

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.

Back view

Safety labels at the rear of the test strip analyzer

Safety labels at the rear of the test strip analyzer (control unit version 1)

Safety labels at the rear of the test strip analyzer (control unit version 2)

A

Warning
This label indicates that there are hazardous situations arising within the vicinity of this label, which may result in death or serious injury. Refer to the Operator's Manual for instructions on safe operation.

Solid waste compartment

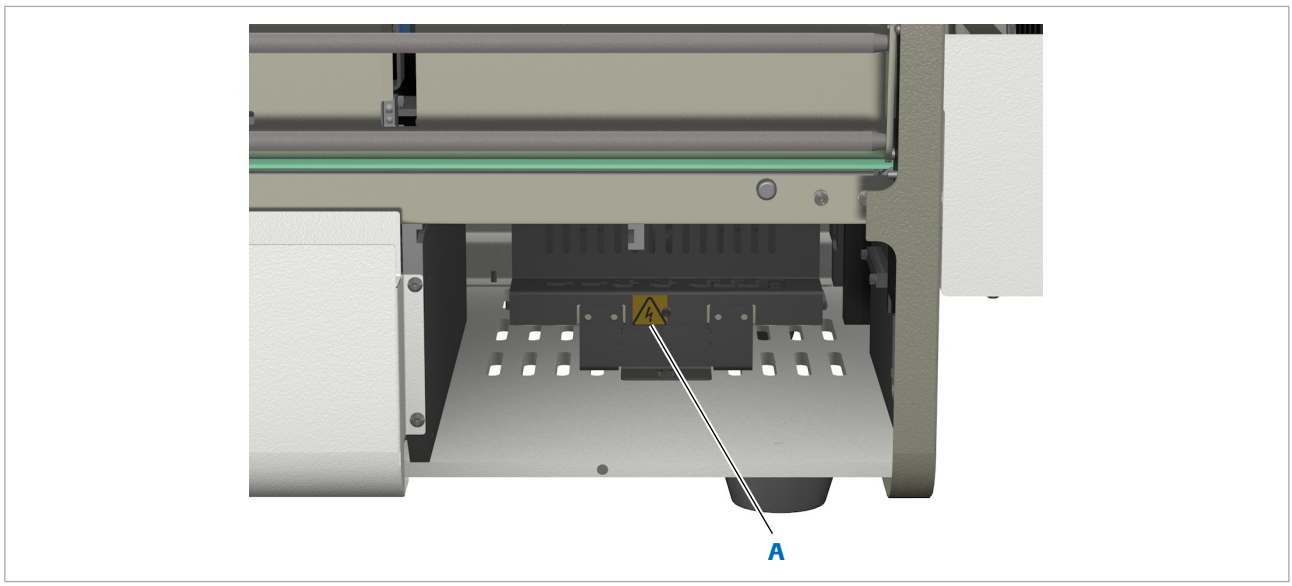
Safety labels on the test strip analyzer (waste drawer)

Safety labels on the test strip analyzer (waste drawer)

A 

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.

Safety labels on the test strip analyzer (waste drawer removed)



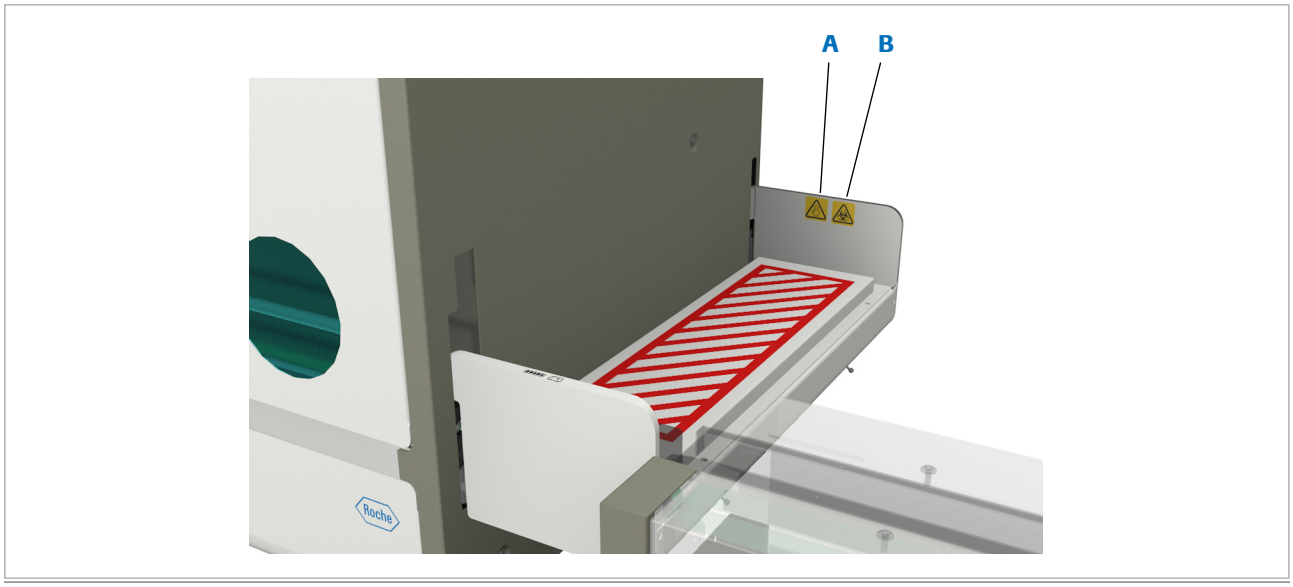
Safety labels on the test strip analyzer (waste drawer removed)

A 

Electrical warning
Contact with electrical components can cause an electric shock. This label indicates that there is a danger of coming into contact with electrical components, when gaining access to parts of the system marked with this label. Refer to the Operator's Manual for instructions on safe operation.

Input connection unit

Safety labels on the input connection unit



Safety labels on the input connection unit

A 

Moving parts
This label indicates that there is a danger of moving parts within the vicinity of this label. Keep hands away from moving parts.

B 

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.

Disposal of the equipment

Disposal of control unit components

Components of your control unit (such as the computer, monitor, keyboard) which are marked with this symbol are covered by the European Directive on *Waste Electrical and Electronic Equipment* (WEEE, 2002/96/EC).

- These items must be disposed of via designated collection facilities appointed by government or local authorities.
- For more information about disposal of your old product, please contact your city office, waste hazardal service or your Roche Service representative.
- Constraint:
  It is left to the responsible laboratory organization to determine whether control unit components are contaminated or not. If contaminated, treat them in the same way as the analyzer.

Contamination of the environment by biohazardous materials

The instrument must be treated as biologically contaminated hazardous waste.

- Final disposal must be organized in a way that does not endanger the personnel responsible for the disposal of the instrument.
- As a rule, such equipment must be sterile before it is passed for final disposal. For more information contact your Roche Service representative.

Disposal of the equipment

Introduction

In this chapter, you find general information on the urine analysis system and an overview of its operation.

In this chapter

2

General description

In this section

Overview

The **cobas u** 601 urine analyzer (called *test strip analyzer* in this documentation) is a fully automated urine analysis system intended for in vitro qualitative or semi-quantitative determination of urine analytes.

It can process up to 240 tests per hour and urine can be tested for the following characteristics and analytes:

Test	Test characteristics
ERY	Erythrocytes and hemoglobin
LEU	Leukocytes
NIT	Nitrite
KET	Ketones
GLU	Glucose
PRO	Protein
UBG	Urobilinogen
BIL	Bilirubin
pH	
COL	Color
CLA	Clarity
SG	Specific gravity

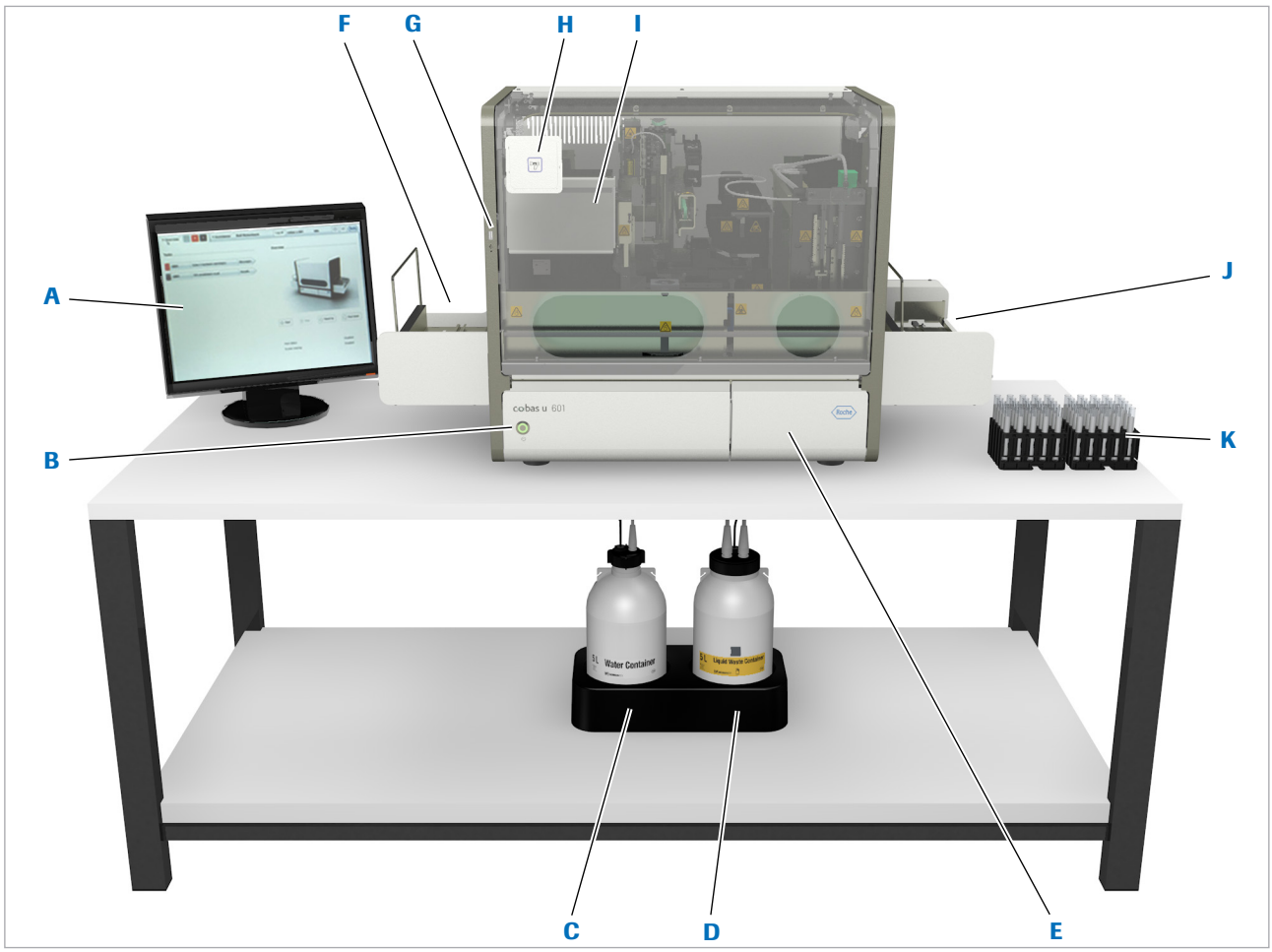
Parameters measured by the test strip analyzer

Operation

During routine operation, operator intervention is reduced to loading and unloading samples and to validating results. (You can set up the system to automatically validate results that passed a series of internal checks.) You may need to perform some routine maintenance such as replenishing consumables, cleaning up spillages, and performing wash actions of the fluid system. You are informed when these actions are due and supported by interactive online guidance (wizards); you simply follow the online instructions. The same applies to function checks and calibration and QC tasks. All you normally need to do for these tasks is to prepare the tubes and place the dedicated items on the analyzer when you are prompted to do so.

Introducing the analyzer

The following illustration shows the complete test strip analyzer.

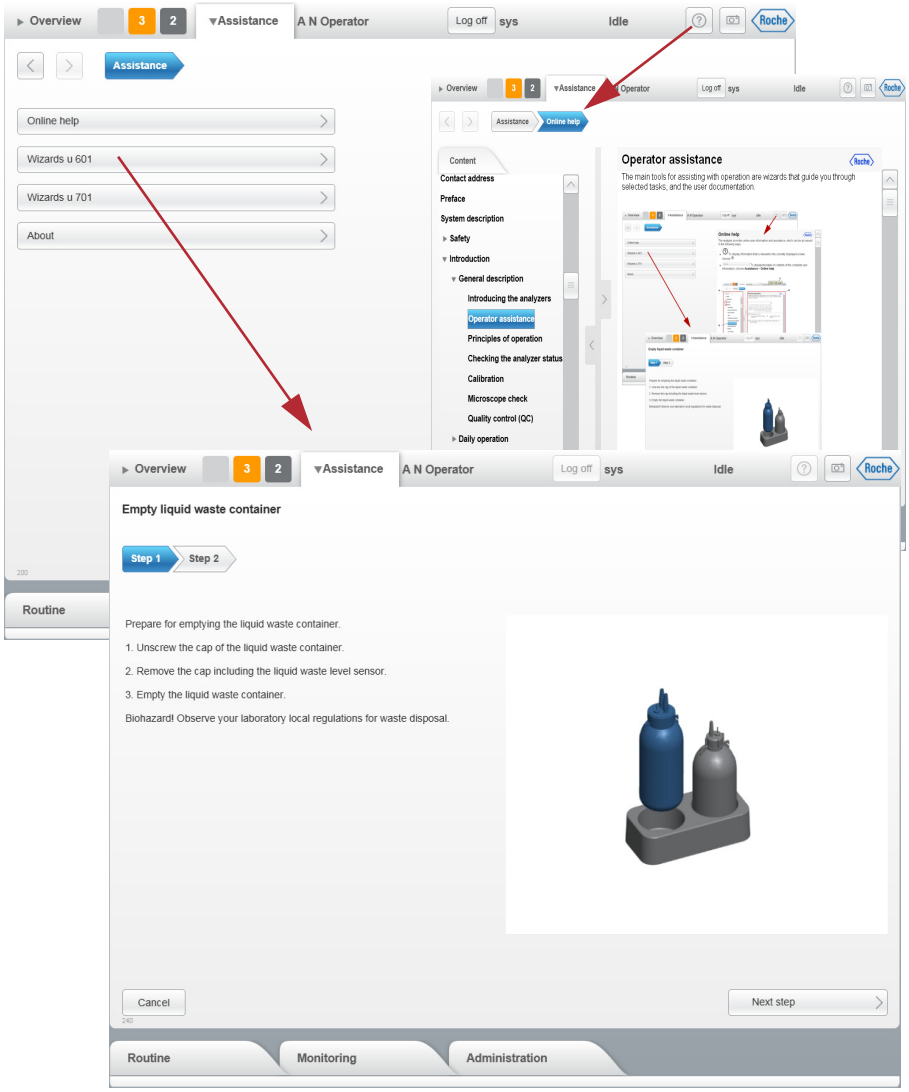


A Touch screen
B On/off switch
C Water container
D Liquid waste container
E Solid waste container
F Output buffer
G USB port
H RFID reader for QC materials
I Test strip cassette compartment
J Input buffer
K Sample racks

Main hardware elements

Operator assistance

The main tools for assisting with operation are wizards that guide you through selected tasks, and the user documentation.



Assistance tab

Related topics

- Wizards (141)
- Online help (145)

Principles of operation

The analyzer is designed to operate with rack and sample barcodes, but you can use the system without sample barcodes. Rack barcodes are used to identify the various rack types; dedicated racks are used for performing patient tests, QC tests, and wash actions of the fluid system. This allows a high degree of automation, whereby the tests and activities start automatically when you load the corresponding rack.

With patient tests, if you work with a laboratory information system (LIS), the order is downloaded as soon as a sample barcode is read, if you do not work with a LIS the analyzer automatically generates the orders during measurement.

Optionally, you can connect the analyzer to a laboratory automation system (LAS), which allows automatic feed of sample racks.

Performing a test consists of the following activities and tasks:

1. The operator places the samples on a rack, loads the rack on a rack tray and then places the rack tray on the input buffer.
2. The rack is automatically moved to the rack conveyor.
3. The rack and sample tube barcodes are read.

   If you work with a laboratory information system (LIS), the order is downloaded as soon as a sample barcode is read, if you do not work with a LIS the analyzer automatically generates the order.
4. The sample tube (on its rack) is transported to the sampling position.
5. The sample is mixed inside the sample tube.

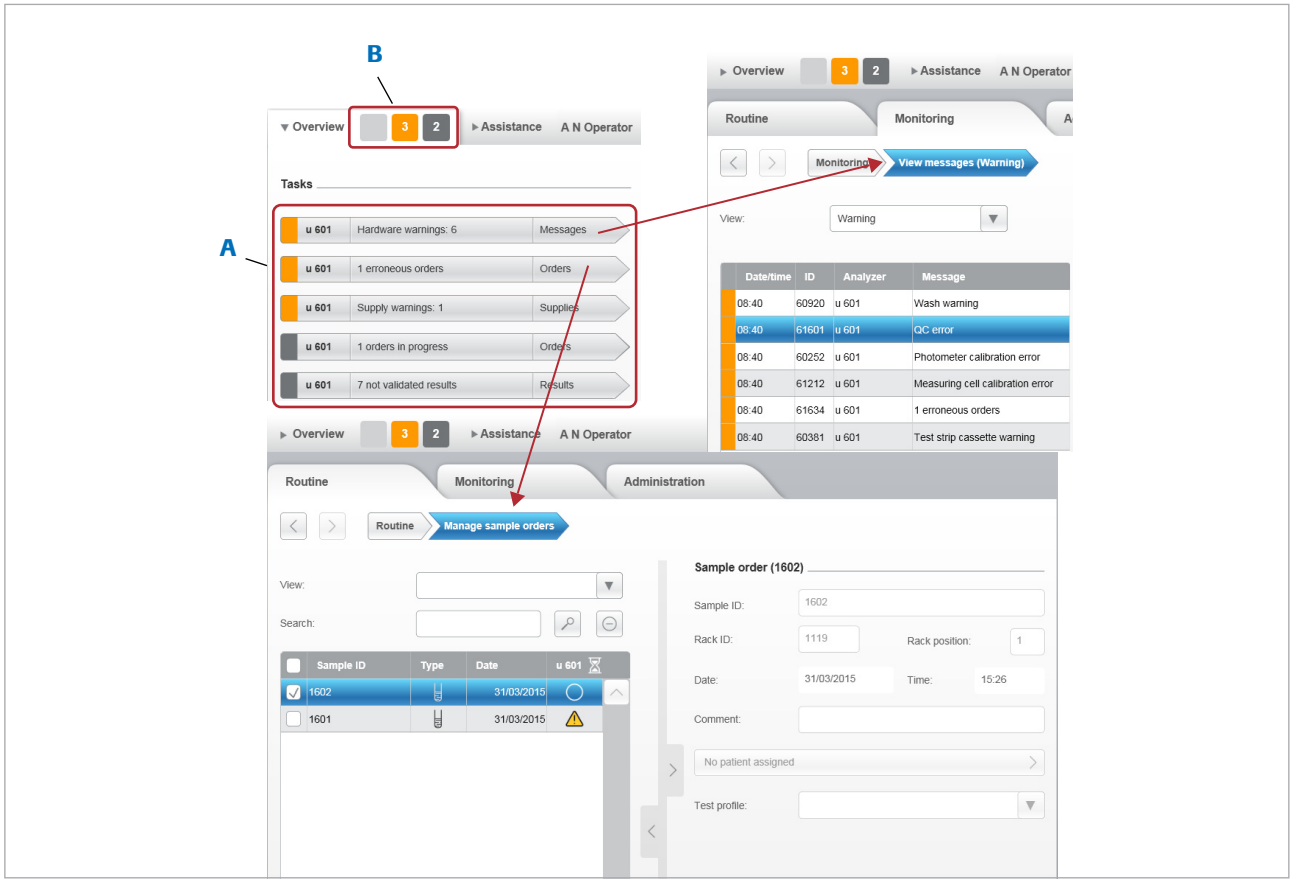
   This is done by aspirating and dispensing sample.
6. Sample is aspirated into the fluid system.(1)
7. Clarity and specific gravity are established in the measuring cell (except when working with a **reduced** test profile).
8. A test strip is removed from the test strip cassette and placed on the pipetting position on the test strip tray.
9. The exact amounts of urine are pipetted onto the test pads on the test strip.

   The probe is washed after the pipetting action to avoid carryover.
10. The test strip is moved along the test strip tray in regular intervals, resulting in an incubation time of 60 seconds.
11. When the test strip reaches the measurement position the reflectance of each test pad is photometrically measured.
12. The test strip is discarded into the solid waste container.
13. In the **Routine** work area, the results are displayed and can be validated either manually or automatically.
14. When all sample tubes of the rack are processed, the rack is moved to the rack tray on the output buffer, from where the operator can remove it.

(1) The minimal sample volume required depends on the test profile. See Minimal sample volumes (dependent on test profile) (118)

Checking the analyzer status

The main tools for checking the status of the analyzer are the task indicator (B) and the task list (A).



Task indicator and task list

Task indicator

The task indicator provides a rough overview of the current analyzer status. The color of the buttons represents the urgency of the tasks and the number in the button tells you how many tasks there are of this urgency. A task can comprise several messages.

The following table explains the meaning of the colors.

Color	Meaning
Red	The task requires immediate operator intervention. Operation may have stopped. When such a task is generated, an acoustic signal is sounded as well, unless this function is turned off.
Orange	The task requires early operator intervention, operation may otherwise stop.
Gray	Ongoing tasks. If operator intervention is required, perform it.
Light gray	There are no tasks. No operator intervention is required.

Color coding for messages

Task list

The task list contains the task buttons. Choosing such a button either leads to a list of all messages of the category or to a panel that contains information and functions related to the issue mentioned in the task button (supplies, orders, results).

The messages and tasks that are represented by the buttons are grouped first by their analyzer, then by their thematic category (messages, supplies, orders, results) and then their priority.

Calibration

In order to ensure proper functioning of the photometer unit, a calibration needs to be performed every 4 weeks. It consists of measuring the pads of a dedicated calibration strip and of the built-in reference plate.

In order to ensure proper functioning of the measuring cell, the clarity and specific gravity of system water is periodically measured as part of the normal measurement procedure. Calibration of the measuring cell should be performed every 4 weeks or as part of troubleshooting.

When a calibration becomes due a message is added to the message list. You can continue performing tests, but the results will be marked with **C** in the ⚑ column.

▸ Calibrating the photometer unit (225)
Calibrating the measuring cell (227)

Quality control (QC)

Quality control (QC) measurements ensure the proper functioning of the analyzer. A QC material for which the results are known is measured and the results are then compared against the defined ranges for these known results. When the lot of the QC material expires or the QC test has failed a message is added to the message list. Test are still performed but the test results are marked with **Q** in the ⚑ column.

You generally perform QC tasks when instructed to do so. Performing a QC measurement consists of preparing a dedicated QC rack with the appropriate materials and placing it on the analyzer; the tests are then performed automatically.

Daily operation

In this section

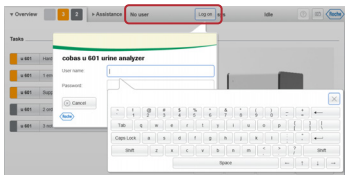
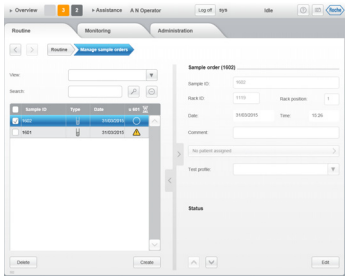
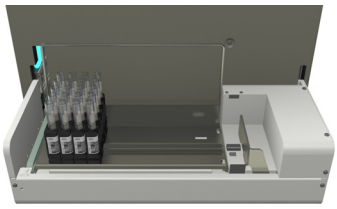
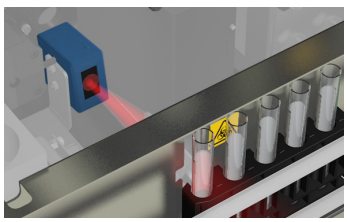
Overview

Daily operation consists of the following phases:

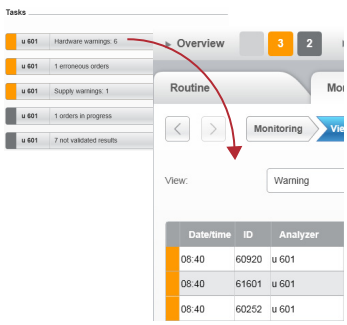
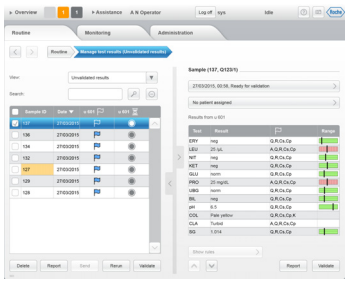
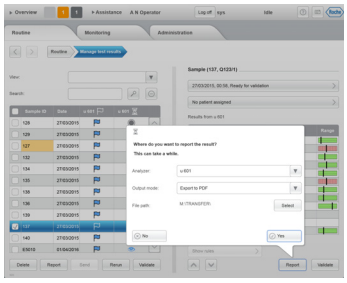
1. Preparing the system
   - Ensure that all consumables are available, the water container is full, and the liquid waste container is empty.
   - Address the issues of all red or orange entries in the task list.
2. Performing tests and ongoing maintenance
   - Load the samples.
   - Clean up spills, replenish consumables as needed.
   - Validate the results.
   - Print results and save as PDF files as required.
   - Unload the samples.
3. Keeping the data safe
   - Archive the results according to your laboratory procedures.
4. Keeping the analyzer clean
   - Empty the liquid and solid waste containers.
   - Perform the daily wash action and shut down the system.
   - Clean the input and output buffers.
   - Clean the rack conveyors.
   - Clean the test strip tray, test strip transporter, and the test strip pipetting area.
   - Clean the probe bend detector.
   - Remove spills and soiling from the analyzer housing.

Short guide to a typical work session

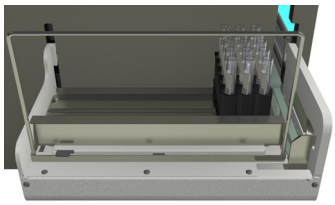
The following table lists the major operator tasks when performing routine tests.

Step	Task		Procedure
1	Starting the analyzer		1. Ensure that all covers are closed. 2. Power on the analyzer. 3. Wait until the **Overview** work area is displayed. This may take a few minutes.
2	Logging on		1. On the **Overview** work area, choose the **Log on** button. A dialog box is displayed. 2. Enter your user name and password. 3. Choose the **Log on** button. Your name is now displayed in the global information area.
3	Preparing the analyzer		1. On the **Overview** work area, check the task indicator. Address any red and orange items. 2. Check the water container.(1) If it is not full, start the appropriate wizard and fill it. 3. Check the liquid waste container.(1) If it is not empty, start the appropriate wizard and empty it. 4. Check the test strip cassette. If it is nearly empty, ensure that there is a new one available for when the old one needs to be replaced. (1) If you work with external water supply, this step is not required.
4	Defining orders		The orders are defined automatically when the rack and tubes have passed the barcode reader.
5	Loading the samples and racks		• Ensure that the sample barcodes point towards that long side of the rack where the rack barcode is affixed. • Ensure that the rack barcodes point outwards and towards the back of the analyzer when placed on the input buffer. The analyzer detects the presence of the rack tray or of individual racks in the priority and single rack slots and moves a rack onto the rack conveyor. (If you work with an input connection unit, you do not need to load racks manually, it is done automatically.)
6	Start testing		Testing starts automatically.

Short guide for performing tests

Step	Task		Procedure
7	Monitoring the analyzer		1. On the **Overview** work area, check the task indicator and the task list. Address all red or orange items in the task list. 2. Choose a task button. If the message list is displayed, choose a message, check the details, and follow the on-screen instructions. If another panel is displayed, for example the supplies panel, perform the appropriate task, usually a wizard is available. Red: Issues that require immediate operator intervention. Orange: Issues that require early operator intervention, operation may otherwise stop. Gray: Messages that inform about the status of ongoing tasks. If operator intervention is required, perform it. Light gray: There are no issues of the associated severity. 7 The number in a button tells you how many messages of this severity there are.
8	Validating the results		1. Choose **Routine > Manage test results**, if required. 2. Select a result in the list and check for data alarms and the range graphics. Green: negative Yellow: positive (low pathological) Red: positive (pathological) If you work with patient demographics you can assign a patient to each result. Choose the **No patient assigned** button. 3. Choose the **Validate** or **Rerun** button as required. You can set up the analyzer to automatically accept all results or to exclude results from automatic validation if they have certain data alarms associated with them. You can also choose to validate all results manually.
9	Printing or exporting selected or all results		To print selected or all results, choose **Routine > Manage test results**. 1. In the result list, select the check box of all results that you want to print or save to a PDF file. 2. Choose the **Report** button. 3. Choose whether to print the results or save them to a file. 4. Choose the **Yes** button.

Short guide for performing tests

Step	Task		Procedure
10	Printing or exporting the results of selected patients		To print the results of selected patients, choose **Routine > Manage patients**. 1. In the patient list, select the check box of all patients whose results you want to print or save to a PDF file. 2. Choose the **Report** button. 3. Choose whether to print the results or save them to a file. 4. Define which results you want to print. 5. Choose the **Yes** button.
11	Clearing the output buffer		1. Remove the rack tray and replace it with an empty one.
12	Performing end of shift maintenance and shutting down the analyzer	 	If the next shift does not follow immediately after, perform the following tasks: 1. Archive the results according to your laboratory procedures, if required. 2. Empty the liquid and solid waste containers. 3. Perform the daily wash action and shut down the system. 4. Clean the input and output buffers. 5. Clean the rack conveyors. 6. Clean the test strip tray, test strip transporter, and the test strip pipetting area. 7. Clean the probe bend detector. 8. Remove spills and soiling from the analyzer housing.

Short guide for performing tests

Result handling

In this section

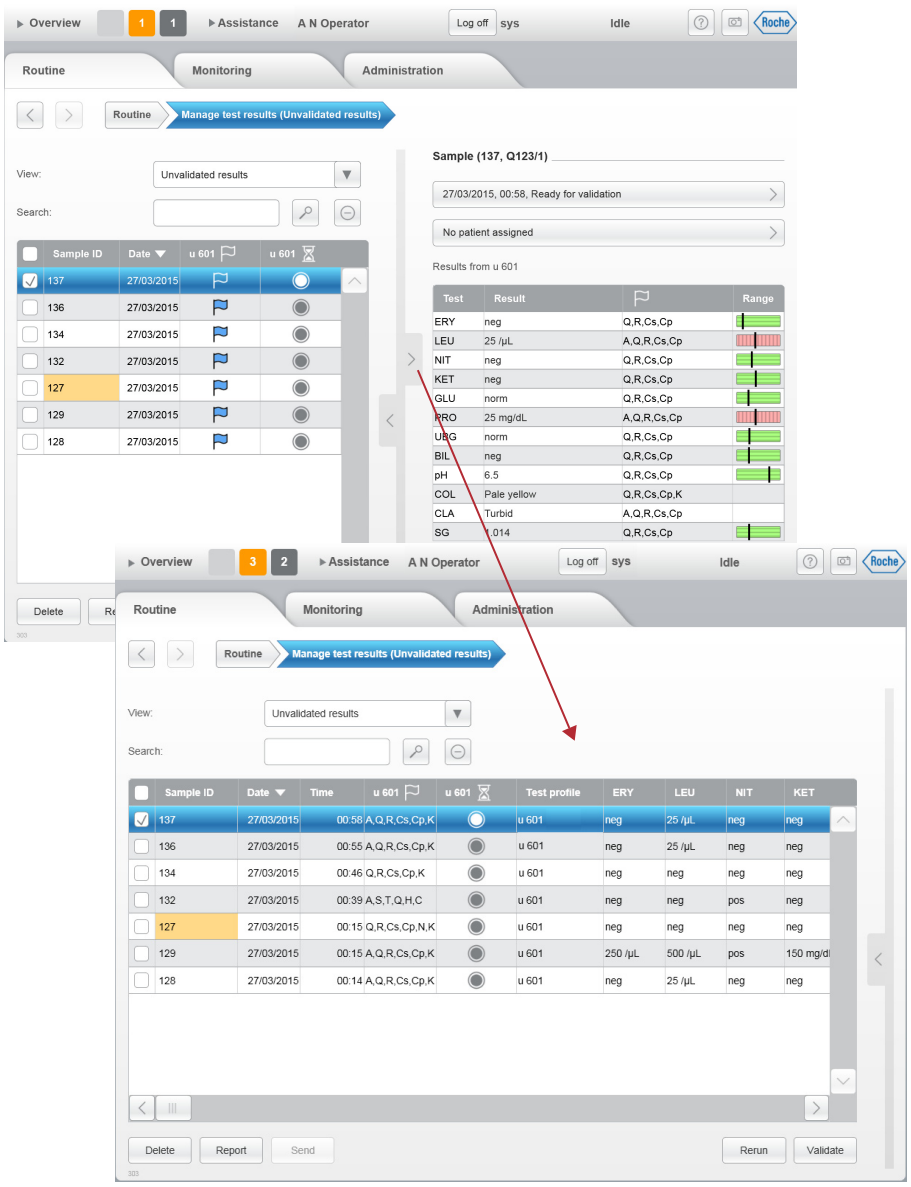
Overview

You can set up the analyzer to automatically validate all results or to exclude results from automatic validation if they have certain data alarms associated with them. You can also choose to validate all results manually.

Details of results can be displayed and studied.

Viewing results

Results are displayed in a dedicated panel, and both full-screen and split-screen displays are available. Exactly which results are displayed can be defined with the help of views; for example you can display only results that have not been validated yet. You can also search for specific results or a group of results by entering part of the sample ID in the **Search** field.



Result display

Validating results

Value ranges and limits are used to determine whether a result is positive or negative and whether to trigger data alarms and actions such performing additional tests. If these ranges and values are exceeded data alarms are generated and the results are marked accordingly; these indications help you identify critical results and point to possible actions that need to be taken.

The analyzer provides several aids for validating results:

- You can set up the analyzer to automatically accept all results or to exclude results from automatic validation if they have certain data alarms associated with them. You can also choose to validate all results manually.

For information on setting up the analyzer, see Defining the validation method (254).

If you work with a laboratory information system, validated results are sent automatically to the host computer.

- In the result list, results that have a data alarm associated with them are marked with in the column.
- If you work with **Sample sequence number** mode, the sample IDs for routine test results are marked with an “N” preceding the sample sequence number, and “E” for STAT test results.
- In the result details, the results are color coded to indicate whether the values are normal (green), low pathological (yellow) or pathological (red).
- You can print the results and save them in PDF format.
- You can export the results in CSV format and process them on an external computer.

Printing and exporting results

You can print selected results or save them to a file in PDF format. You can also export the results in the character separated values (CSV) data format for reporting purposes or for processing in a spreadsheet program.

The analyzer can be connected to a network or directly to a printer.

End of shift

If the next shift does not follow immediately after, Roche recommends to perform the following tasks:

1. Archive the results according to your laboratory procedures.
2. Empty the liquid and solid waste containers.
3. Perform the daily wash action and shut down the system.
4. Clean the input and output buffers.
5. Clean the rack conveyors.
6. Clean the test strip tray, test strip transporter, and the test strip pipetting area.
7. Clean the probe bend detector.
8. Remove spills and soiling from the analyzer housing.

Maintenance

For routine operation, all maintenance actions can be performed using wizards, which are sets of interactive step-by-step instructions. You are informed by a message in the message list when a maintenance action is due, choosing such a message leads to detailed information and to the appropriate wizard.

Hardware

In this chapter, the hardware elements are introduced that the operator might need to handle during daily operation or maintenance.

In this chapter

3

Safety

⚠ Read and understand the information in the Safety chapter

The following safety messages are particularly relevant:

- Warning messages:
  Electrical safety (30)
  Biohazardous materials (31)
- Caution messages:
  Mechanical safety (36)
- Notice messages:
  Excessive ambient humidity (39)
  Spillage (39)

⚠ CAUTION

Personal injury and damage to the analyzer due to improper handling

Touching the probe with bare fingers may leave residues on its surface and consequently influence the accuracy of the results.

The analyzer is quite heavy. Attempting to move it without the appropriate resources, tools and techniques may lead to personal injury and to damage to the analyzer by dropping it from some height.

- Do not attempt to lift the analyzer by yourself.
- To move the analyzer, always use the resources, tools and techniques in accordance with the regulations that apply to you locally.

NOTICE

Malfunction due to inappropriate placing of the analyzer

Placing the analyzer on an uneven or slanting surface may impair its proper functioning.

Placing the analyzer on a surface that cannot be reached comfortably by all operating personnel may lead to incorrect operation of the analyzer.

- Place the analyzer on an even surface with a maximum tilt as defined in:
  - Allowed tilt (117)
- Adjust the height of the surface so all operating personnel can comfortably open and close the main cover.

NOTICE

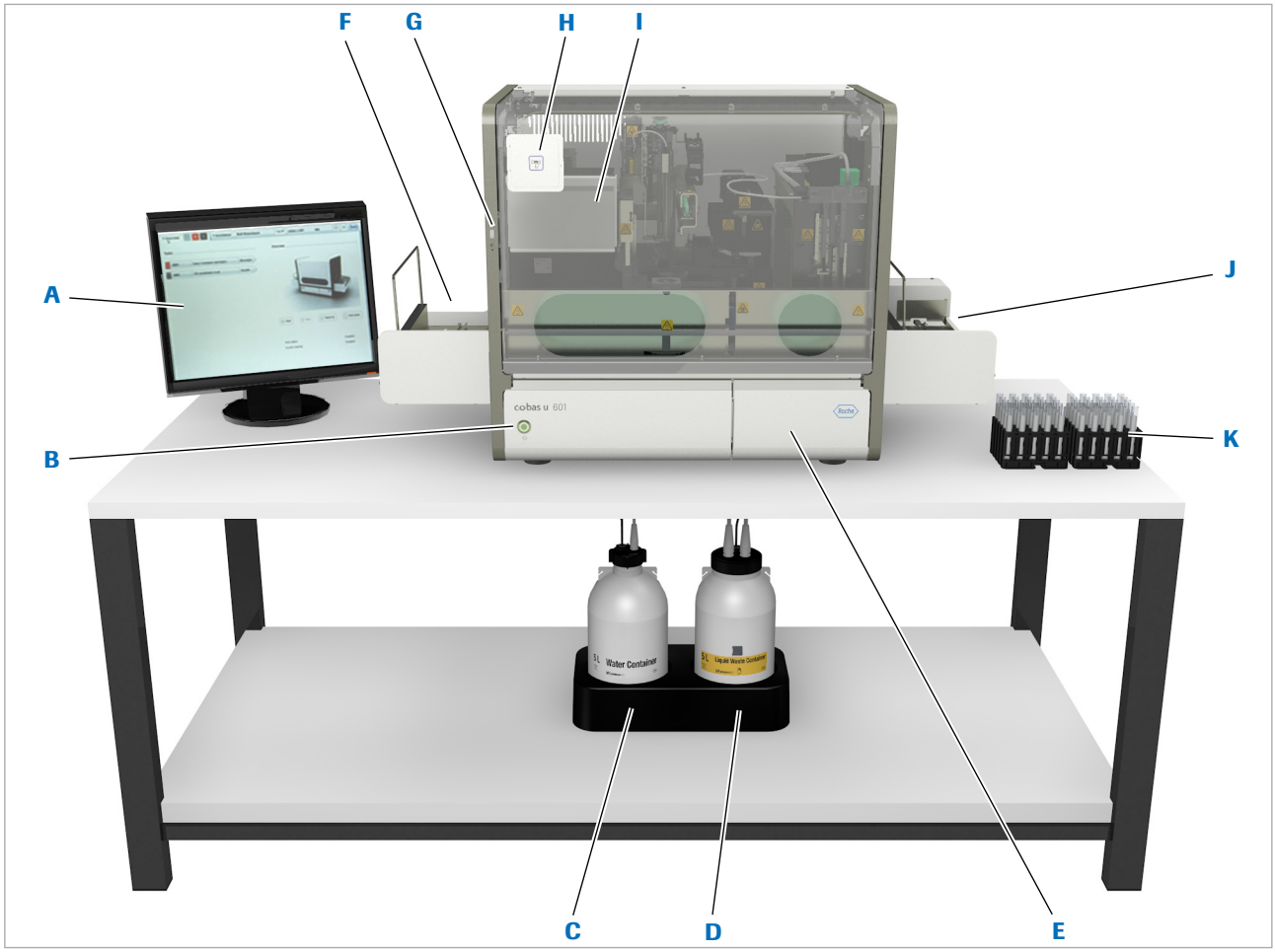
Malfunction due to incompatible monitor drivers

For proper functioning of the monitor, the appropriate drivers must be installed.

- Do not replace the monitor yourself. If it needs replacing, contact your Roche Service representative.

Main components

The following illustration highlights the main components.



A Touch screen
B On/off switch
C Water container
D Liquid waste container
E Solid waste container
F Output buffer
G USB port
H RFID reader for QC materials
I Test strip cassette compartment
J Input buffer
K Sample racks

Main hardware elements

Covers

All covers must be kept closed during processing. They should only be opened when instructed to do so by on-screen instructions or as part of maintenance and troubleshooting activities.

⚠ WARNING

Personal injury due to contact with moving parts

- Keep the main cover closed and in place while the analyzer is operating.
- During operation and maintenance, proceed according to the instructions contained in the Operator's Manual.
- Observe the safety labels on the equipment.

⚠ CAUTION

Personal injury due to incorrect handling of the main cover

If the main cover is not fully opened, it may fall back to its closed position and possibly trap your fingers in the process.

- Always open the main cover fully to its upright position.
- When closing the main cover, be sure not to position your hands or fingers on the side frame of the analyzer.

⚠ CAUTION

Loss of data and sample due to opening covers or drawers

Opening the main cover during operation interrupts the power supply to all units, processing stops immediately and no status information can be stored. Incomplete tests and other activities will have to be redone.

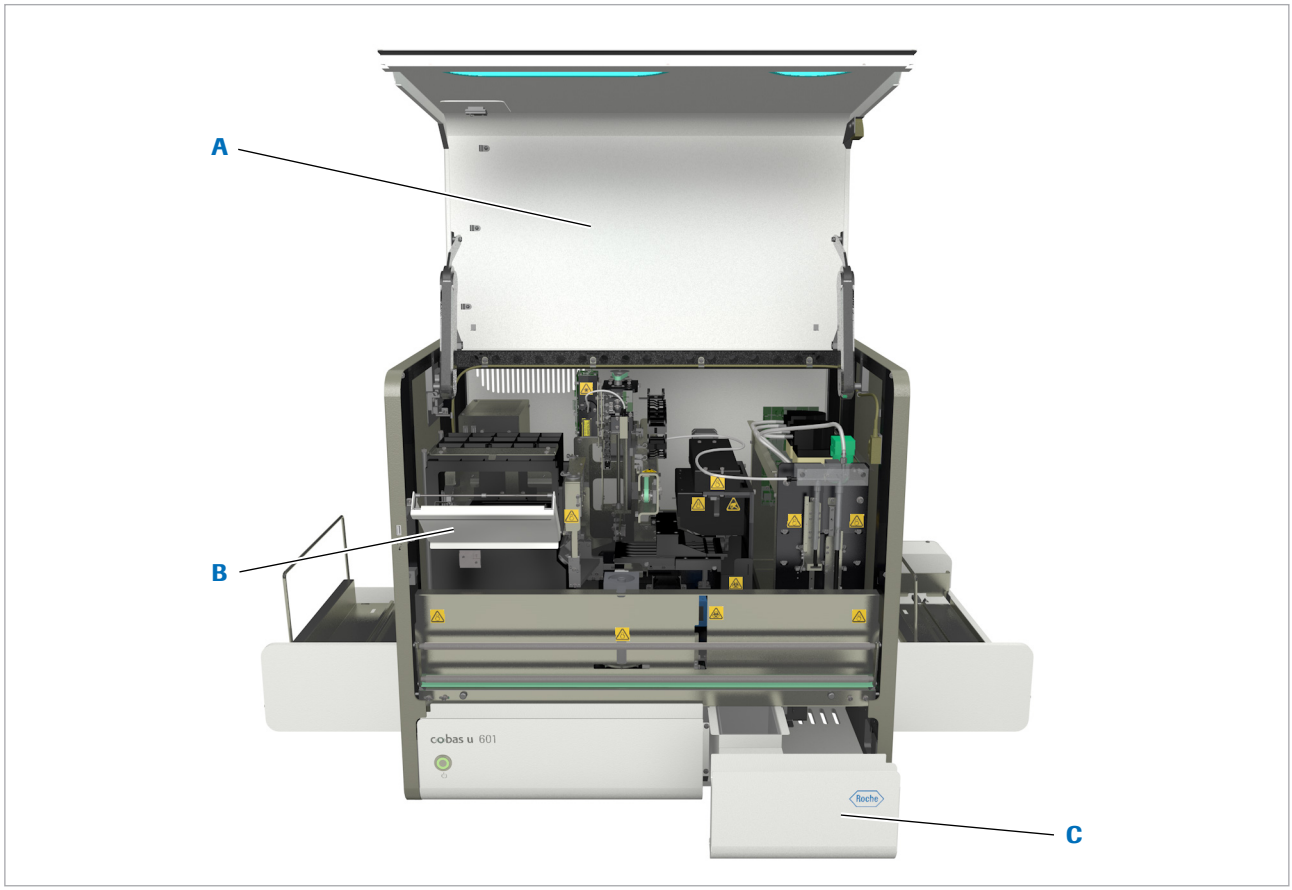
Opening a waste drawer interrupts the current measuring activities. No results are generated for the tests that have been started.

- Do not open any cover while the analyzer is performing some activity. Only do so in an emergency.

  For information on how to recover from such a situation, see the following topics:

  When you have accidentally pulled the waste drawer during operation (315)

  Recovering from an irregular stop (312)



A Main cover
B Cassette compartment door
C Waste drawer

Covers

Connectors

In this section

About connectors

At the rear of the analyzer, there are connectors for mains electricity, liquids, and data.

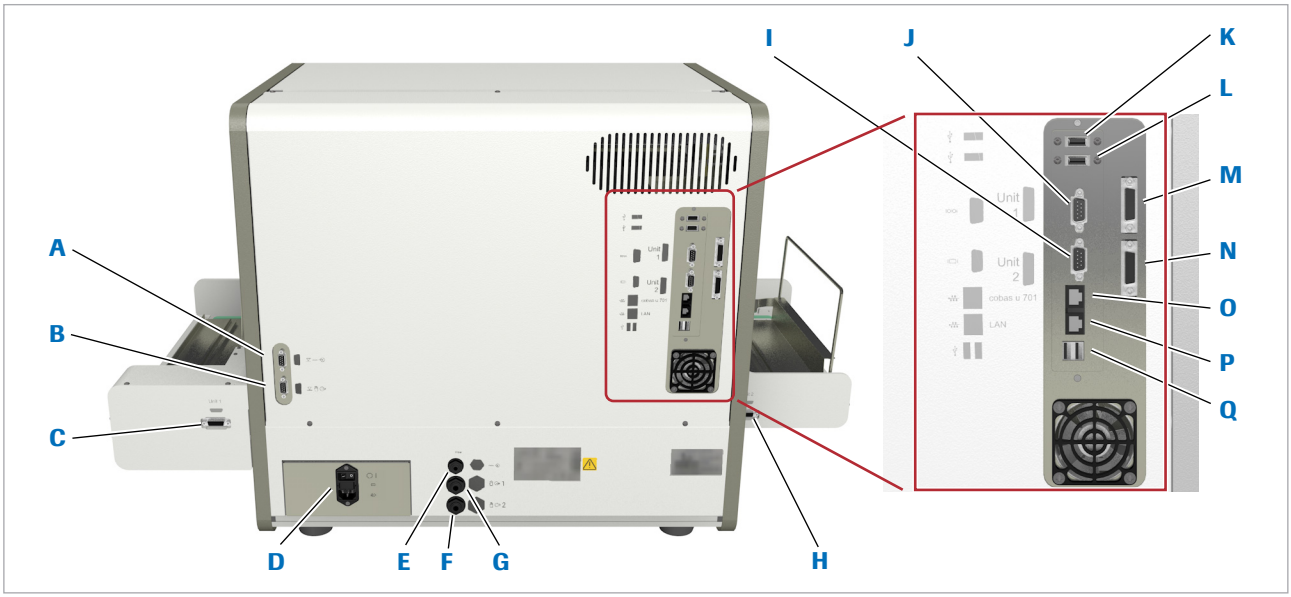
The fittings of the external liquid connectors differ to prevent mix-up.

⚠ CAUTION

Damage to the analyzer due to connecting inappropriate devices

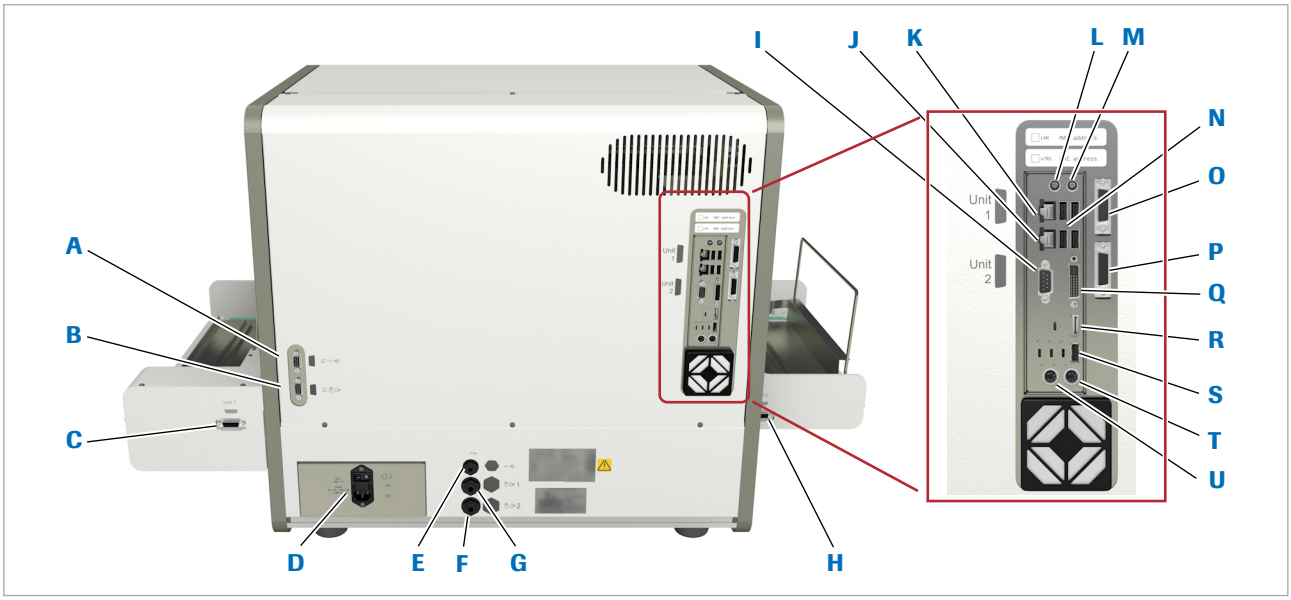
Connecting external devices that are not intended to be used with the analyzer may damage the analyzer or impair its functioning.

- Only connect external devices to the analyzer that are intended to be used with the analyzer and mentioned in the Operator's Manual.



A Water level sensor connector
B Liquid waste level sensor connector
C Input buffer connector to serial connector M
D Mains connector with power switch and fuse
E System water inlet
F Liquid waste safety outlet
G Liquid waste outlet
H Output buffer connector to serial connector N
I Monitor connector (VGA)
J Not in use
K USB port to touch screen
L USB port to mouse, keyboard, printer
M Serial connector to input buffer connector C
N Serial connector to output buffer connector H
O LAN port to microscopy analyzer
P LAN port to LIS or network printer
Q USB port to mouse, keyboard, printer

Connectors on the test strip analyzer (control unit version 1)



A Water level sensor connector
B Liquid waste level sensor connector
C Input buffer connector to serial connector O
D Mains connector with power switch and fuse
E System water inlet
F Liquid waste safety outlet
G Liquid waste outlet
H Output buffer connector to serial connector P
I Not in use
J LAN port to microscopy analyzer
K LAN port to LIS or network printer
L Not in use
M Not in use
N USB ports to touch screen, mouse, keyboard, printer
O Serial connector to input buffer connector C
P Serial connector to output buffer connector H
Q Monitor connector (DVI)
R Not in use
S USB port to touch screen, mouse, keyboard, printer
T Not in use
U Not in use

Connectors on the test strip analyzer (control unit version 2)

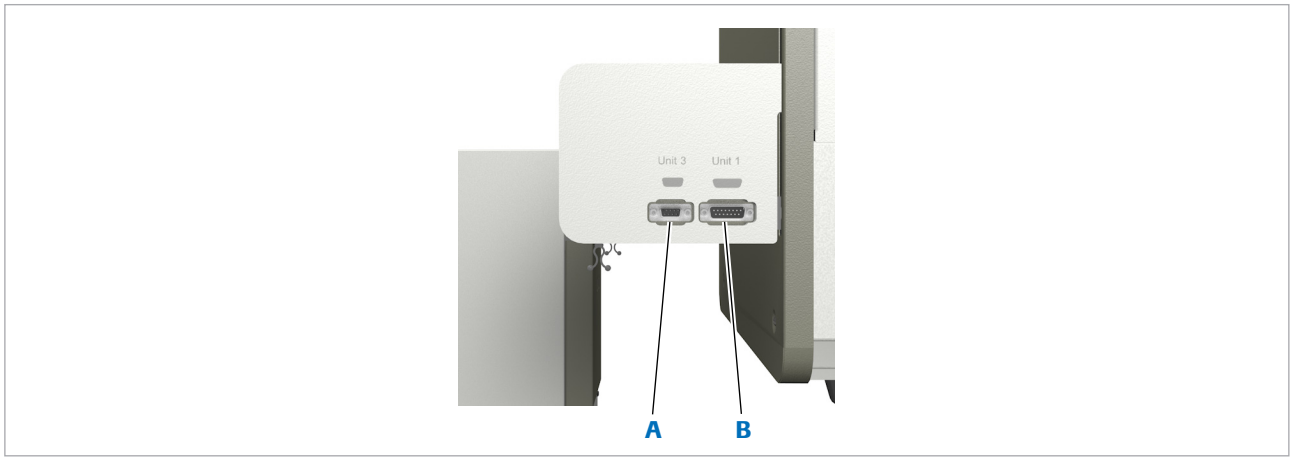
NOTICE

Operating complications due to simultaneous use of virtual keyboard and external keyboard

The system is designed to be operated using the touch screen, but you can use the supplied external keyboard instead.

Setting up the instrument to work with the virtual keyboard and at the same time connecting the external keyboard may lead to operating complications.

- Only work with either the virtual keyboard or the external keyboard.



A Connection line

B Analyzer

Connectors on the input connection unit

Liquid connectors

In this section

About liquid connectors

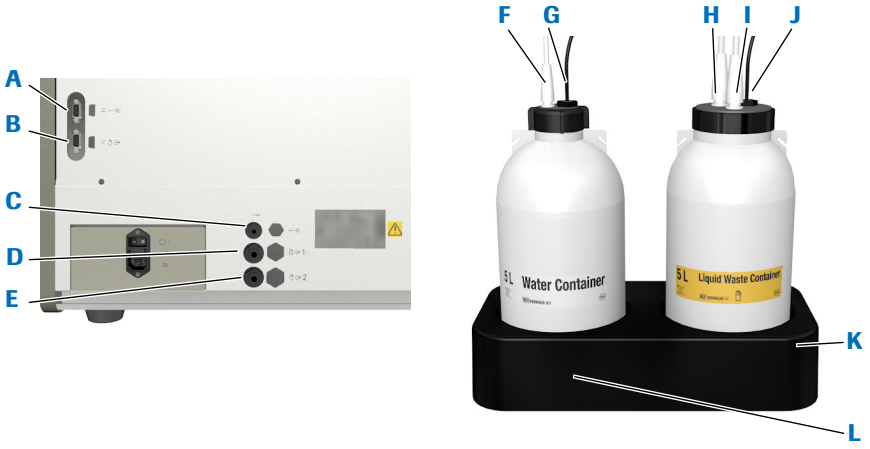
The external liquid connectors must be properly fixed before you power on the analyzer.

⚠ CAUTION

Incorrect results due to air in the tubing

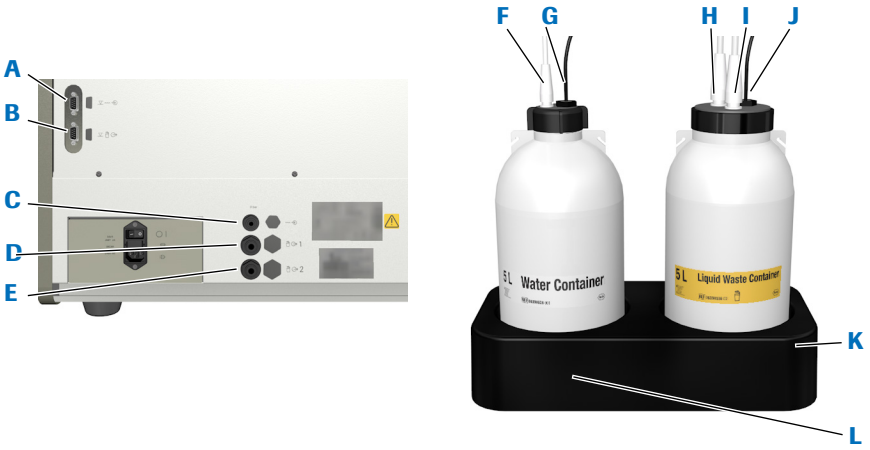
If liquid connectors are not properly connected, air may enter the tubing and consequently incorrect amounts of liquid may be aspirated and dispensed, which can lead to incorrect results.

- Be sure to screw on all liquid connectors properly, place the connectors square on when connecting them.



A Water level sensor connector
B Liquid waste level sensor connector
C System water inlet
D Liquid waste outlet
E Liquid waste safety outlet
F Tubing for system water
G Water level sensor connection
H Tubing for liquid waste
I Tubing to liquid waste safety outlet
J Liquid waste level sensor connection
K Liquid waste container
L Water container

Liquid connectors (control unit version 1)



A Water level sensor connector
B Liquid waste level sensor connector
C System water inlet
D Liquid waste outlet
E Liquid waste safety outlet
F Tubing for system water
G Water level sensor connection
H Tubing for liquid waste
I Tubing to liquid waste safety outlet
J Liquid waste level sensor connection
K Liquid waste container
L Water container

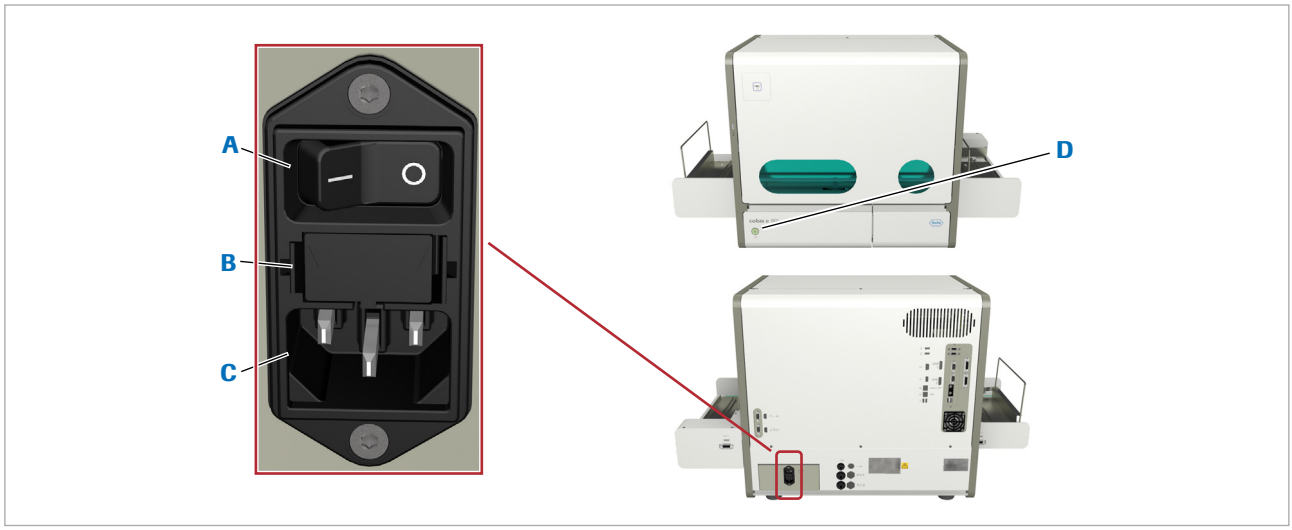
Liquid connectors (control unit version 2)

With external water supply

With external water supply, the laboratory water supply is connected to the 5 L water container, which itself is connected to the analyzer in the same way as a standard water container. (The two liquid waste outlets on the analyzer are connected directly to the laboratory waste system.)

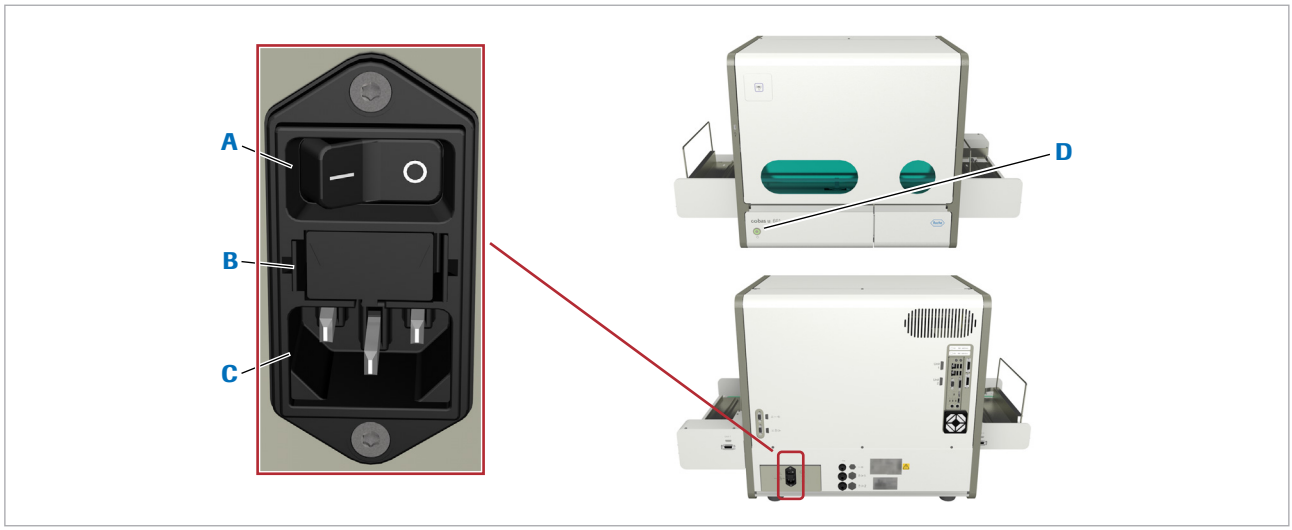
Power switches

The analyzer automatically adjusts to 100 to 240 V and 50 to 60 Hz mains electricity.



A Power switch
B Fuse compartment
C Mains connector
D On/off switch

Power switches (control unit version 1)



A Power switch
B Fuse compartment
C Mains connector
D On/off switch

Power switches (control unit version 2)

Pressing the on/off switch for several seconds shuts down the whole analyzer.

⚠ CAUTION

Loss of data and sample due to turning off the analyzer using the on/off switch

Pressing the on/off switch for several seconds stops all processing and shuts down the internal PC. No status information can be stored. Incomplete tests and other activities will have to be redone.

- Do not use the on/off switch to turn off the analyzer except in an emergency, e.g. when the screen is “frozen” and analyzer does not react to any user action on-screen or otherwise.

  For information on recovering from such an emergency situation, see To recover from a forced shutdown (313).

⚠ CAUTION

Loss of data and sample and damage to equipment due to switching off power

Switching off the power using the power switch stops all processing and no status information can be stored. Incomplete tests and other activities will have to be redone. Equipment may be damaged.

- Do not switch off power during operation.
- Ensure that the mains cables are placed safely away from areas where personnel might pass through.
- Roche recommends using an uninterruptible power supply.

  Uninterruptible power supply (UPS) (117)

  For information on recovering from such an emergency situation, see To recover from a power outage (316).

Input and output buffers

The input and output buffers are positioned at the side of the analyzer. They remain uncovered for easy access.

⚠ CAUTION

Personal injury due to contact with moving parts

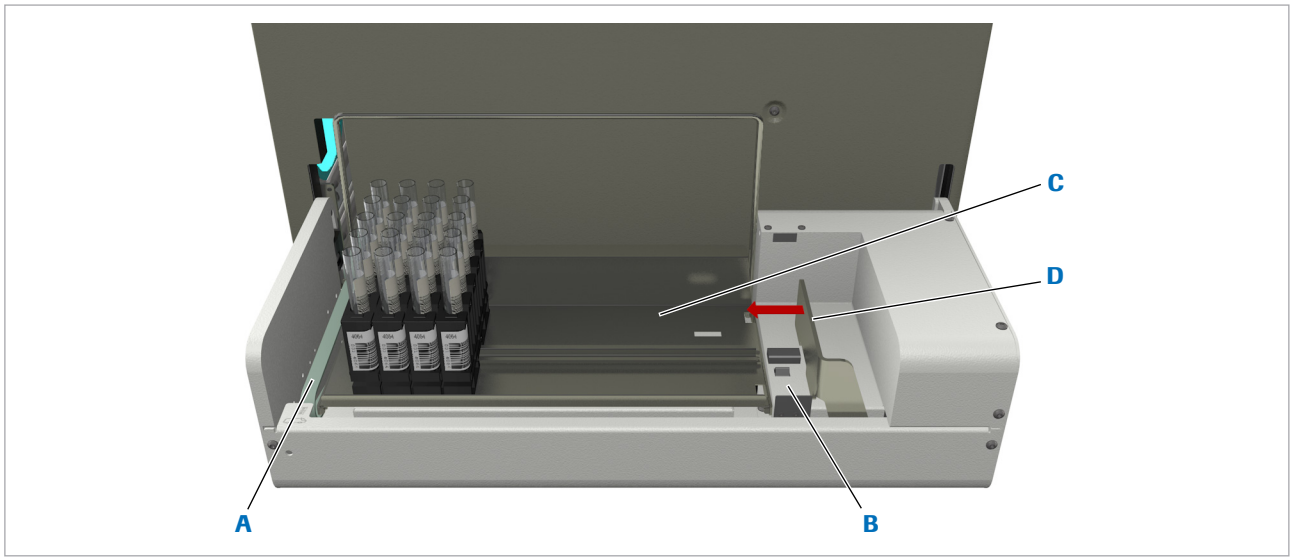
Racks are moved automatically on the input and output buffers by the rack pusher. If you place your hands or fingers on a buffer while racks are moved you may get your fingers caught.

- Do not place your hands on the input or output buffer or the racks while the analyzer moves racks.
- Do not load racks while the analyzer moves racks on the input buffer.
- Do not unload racks while the analyzer moves racks on the output buffer.

In this section

Input buffer

The space is divided into the area for the input rack tray with up to 15 racks, the single rack slot and the priority rack slot.

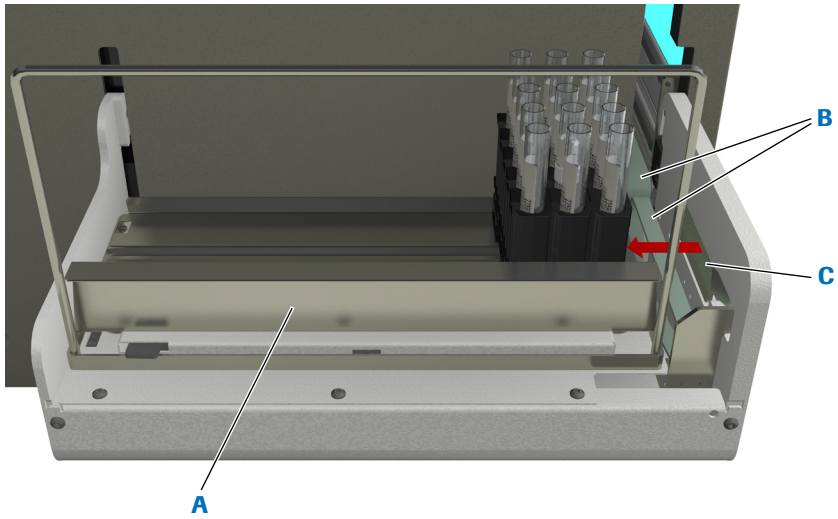


A Priority rack slot
B Single rack slot
C Rack tray
D Rack pusher

Input buffer

Output buffer

There is space for up to 15 racks on the output rack tray. A message is generated in the message list when the output rack tray is full. No new racks can be processed when the rack is full.



A Rack tray
B Rack conveyor
C Rack pusher

Output buffer

Input connection unit

For automated rack input, you can link the test strip analyzer to a laboratory automation system (LAS).

This is done with the help of an input connection unit, which itself is connected to an external connection line as part of an LAS. The input connection unit, in conjunction with the LAS and LIS, automatically feeds racks to the analyzer.

The input connection unit and connection line must be installed by a Roche Service representative.

⚠ CAUTION

Incorrect results and damage to the analyzer due to use of non-recommended type of rack

Using racks that do not conform to the established dimensions may lead to malfunction or pipetting errors and consequently to incorrect results.

Racks with unsuitable colors may lead to barcode reading errors.

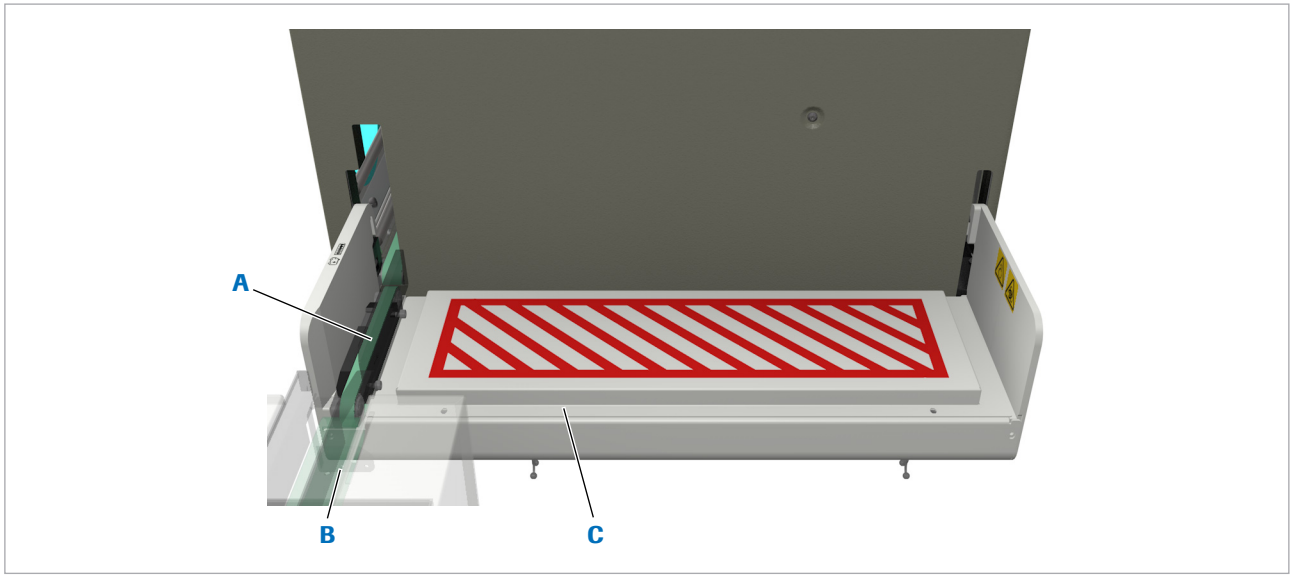
- Only use racks defined in the following table:

  Supported tube types for allowed rack types (84)

NOTICE

Malfunction due to placing items on the ICU

- Do not place anything on the ICU.
- Always make sure that the rack conveyor belt of the input connection unit is unobstructed.



A Rack conveyor belt of the input connection unit

B Connection line

C Input connection unit

Input connection unit

The rack conveyor belt of the input connection unit automatically passes on the racks to the analyzer when it is ready to perform the tests. This belt also serves as the input location for STAT racks, wash racks, and QC racks.

To load a priority rack when working with an LAS (173)

To perform a QC measurement when working with an LAS (230)

To wash the fluid system when working with an LAS (204)

Tubes, racks, and rack trays

This section introduces the containers for handling samples.

In this section

Tubes

The following table lists the supported tube types for the allowed rack types.

Rack type	Round bottom tube			Conical bottom tube		False bottom tube	
	ø 13 mm	ø 16 mm	ø 13-16 mm	ø 13 mm	ø 16 mm	ø 13 mm	ø 16 mm
Standard RD 5 rack (gray)	✓	✓	✓	x	✓	✓	✓
RD 5 wash rack (green)	✓	✓	✓	x	✓	x	x
RD 5 QC rack (white)	✓	✓	✓	x	✓	✓	✓
URISYS rack (yellow)	x	✓	x	x	✓	x	x

Supported tube types for allowed rack types

The tube length can be between 65 mm and 115 mm.

For identification purposes, tubes should have a barcode label attached, but you can process non-barcoded tubes.

The same rack/tube type combination must be used for urine and QC materials, but you can use a different combination for the wash rack.

Tubes must be loaded on racks to be processed by the analyzer.

Which tubes and racks are being used is defined by a Roche Service representative, typically during initial installation.

⚠ CAUTION

Malfunction or incorrect results due to using inappropriate tubes

The analyzer has been designed and tested for the use of specific types of tubes.

Using tubes that do not conform to the specified dimensions and that are not defined for this analyzer may lead to malfunction or pipetting errors and consequently to incorrect results.

- Only use the tubes defined for this analyzer.

Racks

The analyzer is designed to handle the racks defined in the following table:

Tubes (84)

A rack can hold up to 5 tubes of 13 to 16 mm diameter and 65 to 115 mm length. Racks can be loaded on the analyzer either individually or on a rack tray, which holds up to 15 racks. For identification purposes, racks must have a barcode label attached. This ID identifies a rack either as a sample rack for routine tests, sample rack for STAT tests, QC rack, or as a wash rack, and the corresponding actions are started automatically as soon as such a rack is identified.

The barcode label of the rack must always face towards the rear of the analyzer when loaded on the input buffer.

⚠ CAUTION

Malfunction or incorrect results due to using inappropriate racks

Using racks that do not conform to the established dimensions may lead to malfunction or pipetting errors and consequently to incorrect results.

- Only use racks defined in the following table:

  Tubes (84)

⚠ CAUTION

Malfunction or incorrect results due to using inappropriate rack rubber disks

Using rack rubber disks that differ in height from the original ones may lead to malfunction or pipetting errors and consequently to incorrect results.

- Do not replace individual rack rubber disks, if one is damaged, replace the whole rack.

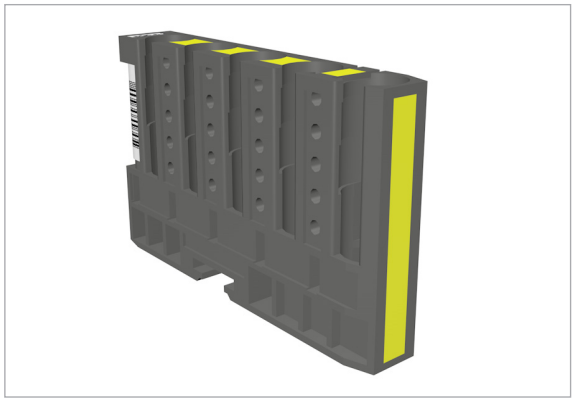
A Sample barcode
B Rack ID
C Rack barcode
D Rack rubber disk
E Racks on a rack tray that is placed on the input buffer

Roche 5-position rack

Roche recommends using racks with rack rubber disks.

Sample rack All racks that are not specifically defined as STAT racks, wash racks, or QC racks are treated as sample racks.

STAT rack The STAT rack is a dedicated sample rack for performing STAT tests.



To visually distinguish STAT racks from routine sample racks, Roche recommends to mark them with dedicated colored labels for Roche 5-position racks.

Optional components (120)

Wash rack

The wash rack is a dedicated rack for performing the daily wash maintenance action. It contains the required wash solution.

For information on how to define a wash rack and how to assign it to the analyzer, see Managing racks (280).

QC rack

The QC rack is a dedicated rack for performing QC measurements. It contains the required QC materials at predefined positions on the rack.

For information on how to define a QC rack and how to assign it to the analyzer, see Managing racks (280).

Rack IDs

The software is able to manage the following human readable rack IDs.

Sample rack IDs	0001-9999
QC rack IDs	Q001-Q999
Wash rack IDs	W001-W999

Rack trays

A rack tray can hold up to 15 racks. Generally, racks are loaded onto rack trays for loading on and unloading from the analyzer. For processing single racks there is a priority rack slot and a single rack slot.

You can load one rack tray on the input buffer and one on the output buffer. The analyzer monitors the fill level of the output buffer and whether there is a rack tray or individual racks on the input buffer.

NOTICE

Malfunction due to damaged rack tray

A rack tray that is dented or bent or damaged in any other way may impede the locking mechanism.

- Be sure to use undamaged rack trays only.

NOTICE

Malfunction due to unsupported rack trays

Using unsupported rack trays can cause the analyzer to block or the sensor to malfunction.

- Only use supported rack trays.

Liquid containers

The water containers and the liquid waste containers are positioned under the table on which the analyzer is placed. Their fill levels are monitored and messages in the message list inform you when certain levels have been reached or when a container is full or empty.

In this section

Water container

A Water tubing
B Float assembly rod
C Floats
D Inlet water filter

The white water containers hold up to 5 L of water.

The fill level is monitored and messages in the message list inform you when the level is getting low and when the container is empty.

Use water of the quality defined in:

Water quality (118)

Water container for external water supply

The white water container for external water supply holds up to 5 L of water. It serves as an intermediary water reservoir between the laboratory water supply and the analyzer. It is continually and automatically replenished.

⚠ CAUTION

Incorrect results due to incorrect water pressure in the external water supply

Working with incorrect water pressure may lead to hardware malfunction and consequently insufficient or irregular water supply to the analyzer and possibly air bubbles in the fluid system.

- The water pressure at the water inlet on the water container must not exceed 4 bar.
- Use water of the specified quality:

  Water quality (118)

⚠ CAUTION

Contamination due to deposits of algae and bacteria

In the inside of the bottle where it is exposed to air, deposits of algae and bacteria may build up over time.

- Clean the water container once a month.

  To clean the water container for external water supply (292)

⚠ CAUTION

Overfilling of the water container when the analyzer is switched off

When the analyzer is switched off, the water level sensors do not work and consequently cannot warn the operator if the water container accidentally becomes too full.

- Turn off the external water supply when you switch off the analyzer.

A Water level sensor connection

B Tubing to system water inlet on the analyzer

C Tubing to laboratory water supply

D Float valve

E Float ball

F Float

G Inlet water filter

The fill level is monitored and messages in the message list inform you when for some reason the water level cannot automatically be kept at the required level.

Liquid waste container

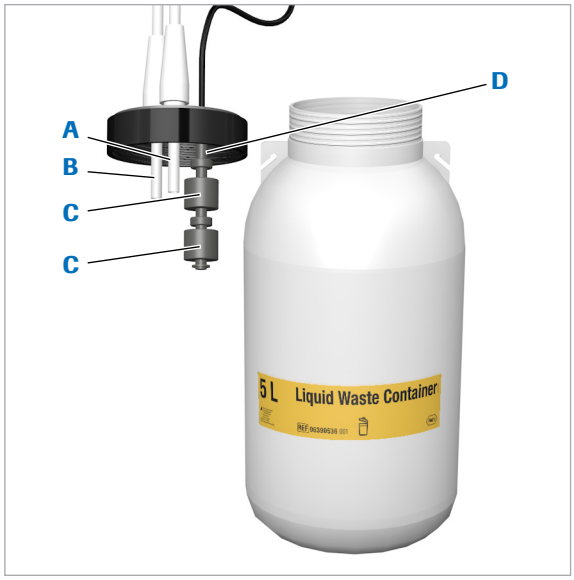
The yellow liquid waste container holds up to 5 L of waste. Treat the waste as potentially biohazardous material.

⚠ CAUTION

Infection by liquid waste

Contact with liquid waste may result in infection. All materials and mechanical components associated with the waste systems are potentially biohazardous.

- Be sure to wear protective equipment. Take extra care when working with lab gloves; these can easily be pierced or cut, which can lead to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If liquid waste comes into contact with your skin, wash it off immediately with water and apply disinfectant. Consult a physician.
- Observe the safety labels on the equipment.



A Waste tubing
B Tubing to liquid waste safety outlet
C Floats
D Float assembly rod

The fill level is monitored and messages in the message list inform you when the level is getting high and when the container is full.

In this section

Liquid waste with external water supply

When working with external water supply, the liquid waste is led directly to the laboratory waste system.

⚠ CAUTION

Spilling and infection by liquid waste

If you work with external water supply, the waste outlets are directly connected to the laboratory waste system, and no liquid waste container is required. Connecting the liquid waste container could lead to overflow of the liquid waste container, because the liquid level sensors are disabled.

- Never install the liquid waste container if you work with external water supply.

⚠ CAUTION

Incorrect results due to inefficient wash actions

Insufficient flow in either the pumped or the gravitational liquid waste connection may lead to backflow, which can lead to decreased efficiency of the wash actions and consequently to carryover.

- The liquid waste connectors at the laboratory waste system must be lower than the ones on the analyzer. The gradient must be at least 3%.

Solid waste container

The solid waste container is designed to hold at least as many test strips as are contained in a full test strip cassette. There is a disposable Waste Box Carton that must be installed properly. The analyzer monitors whether the drawer is closed properly. The fill level is monitored using counters. When a certain fill level is reached a message is added to the message list.

For information on defining the fill levels, see To define the warning limits (266).

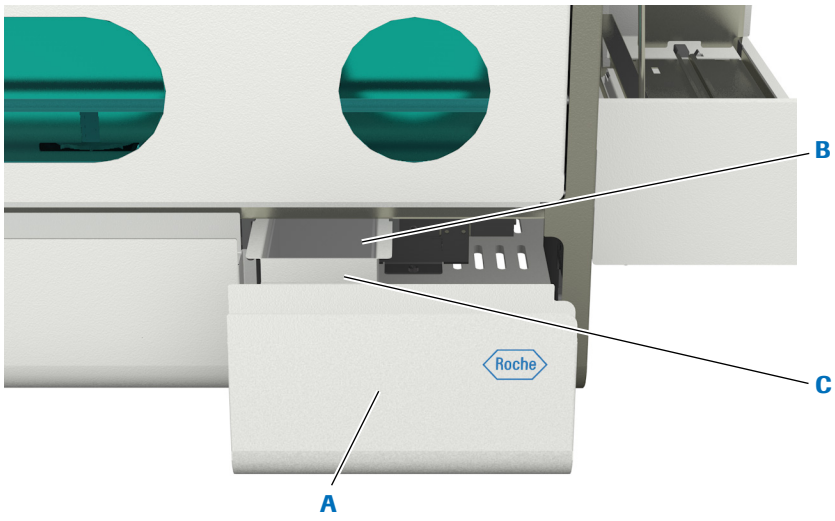
NOTICE

Analyzer damage due to overfilled solid waste container

If the solid waste container is full, test strips may get stuck in the waste chute or the test strip tray and the may interfere with the measuring mechanism.

- Be sure to empty the solid waste container when you are alerted by a message in the task list.
- Roche recommends emptying the solid waste container whenever you load a new test strip cassette.

The system automatically assumes that the solid waste container is empty at the end of the **Empty solid waste container** maintenance action.



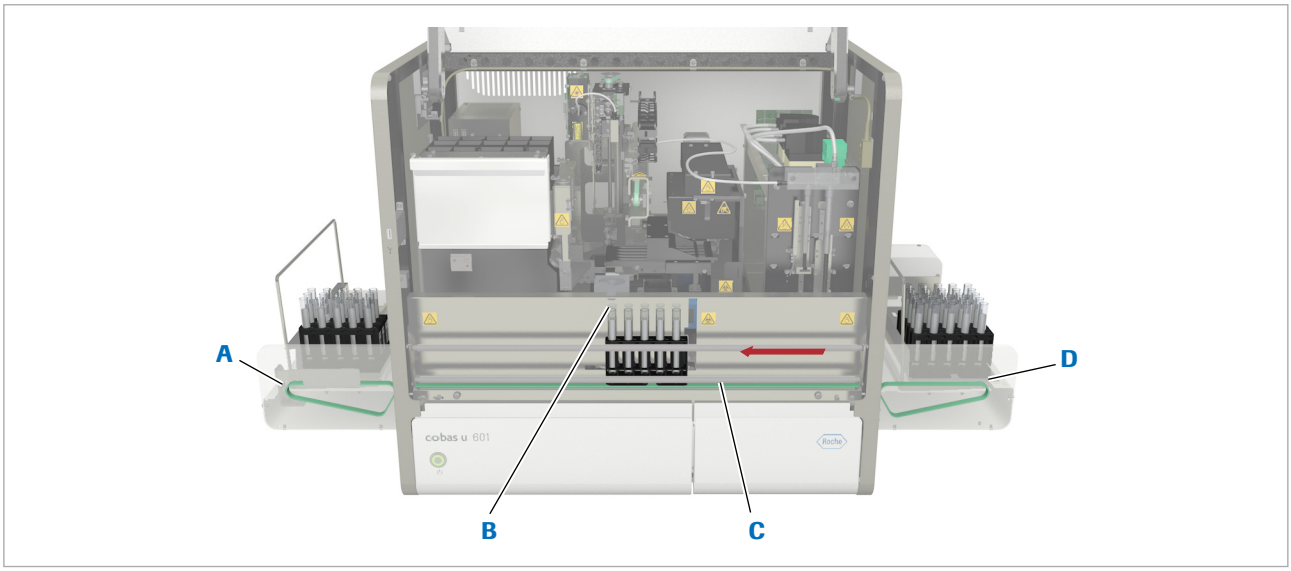
A Waste drawer
B Waste Box Carton
C Solid waste container

Solid waste container

Rack transport unit

The rack conveyor picks up the racks at the input buffer and transports them to the sampling position. When all tubes are processed the rack is transported to the output buffer.

If you work with an input connection unit, the racks are picked up from the rack conveyor belt of the input connection unit.



A Output buffer rack conveyor
B Sampling position
C Rack conveyor
D Input buffer rack conveyor

Rack transport unit

Rack handling consists of the following steps:

1. The operator loads the rack on the input buffer, either on the rack tray, the single rack slot or the priority rack slot.
2. The rack pusher moves the rack, if required, to the priority rack slot, which also serves as the feed to the rack conveyor.
3. The rack conveyor moves the rack to the sampling position.

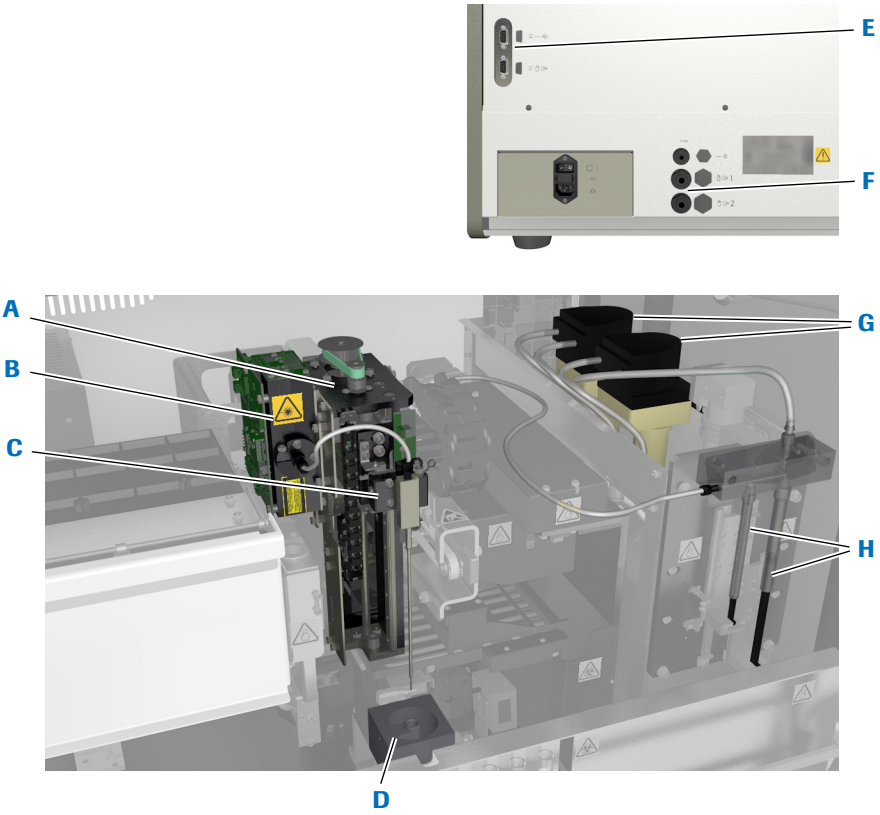
   All samples on the rack are pipetted.
4. When all tubes on the rack are processed, the rack conveyor moves the rack to the rack exit position on the output buffer.
5. The rack pusher moves the rack onto the rack tray on the output buffer.
6. The operator removes the rack, either by itself or by removing the rack tray.

Fluid system

In this section

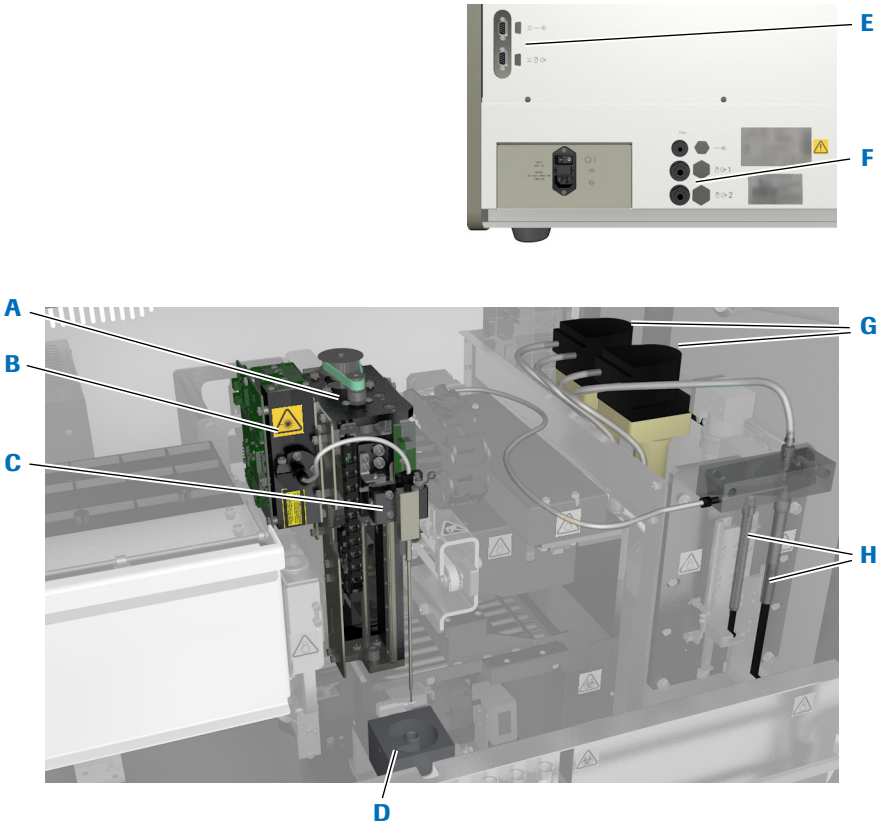
About the fluid system

The fluid system consists of all the valves, pumps, tubing, syringes, fluid sensors, water and waste containers, the probe, the measuring cell, and the rinse station. The fluid system transports all fluids around the instrument, including urine, system water, and waste. The fluid system also delivers the correct amounts of urine to the test strips.



A Transfer head
B Measuring cell
C Pipetting unit with probe
D Rinse station
E Water level sensor connector and liquid waste level sensor connector at the back of the analyzer
F External liquid connectors at the back of the analyzer
G Peristaltic pumps
H Syringes

Fluid system of the test strip analyzer (control unit version 1)



A Transfer head

B Measuring cell

C Pipetting unit with probe

D Rinse station

E Water level sensor connector and liquid waste level sensor connector at the back of the analyzer

F External liquid connectors at the back of the analyzer

G Peristaltic pumps

H Syringes

Fluid system of the test strip analyzer (control unit version 2)

Pipetting unit

The pipetting unit moves the probe to the appropriate positions for aspirating and dispensing liquid. It is equipped with liquid detection and probe crash prevention mechanisms.

Pipetting unit (97)

Probe

The probe is rinsed internally and externally with water after each pipetting action. It has a flat tip, which is required for liquid level and tube bottom detection.

If the probe is damaged it can be replaced.

For details on replacing the probe, see Issues with the probe (296).

⚠ WARNING

Incorrect results due to touching the probe

Touching the probe with bare fingers may leave residues on its surface and consequently influence the accuracy of the results.

- Do not touch the probe except for maintenance as described on screen or in this documentation.

Rinse station

The rinse station serves to clean the probe after each pipetting action to prevent carryover between samples.

Rinse station (99)

Fluid system

The fluid system with its syringes and pumps controls the aspiration and dispensing of sample. It also controls the supply of system water and wash solution. The probe is rinsed with system water after every pipetting action to prevent carryover between samples.

External liquid connectors

There is a water and two waste connections, one of them being a safety outlet for cases when the tubing of the main connection is blocked.

You can connect the liquid waste to the waste system of your facility. Ensure that the facility installation is lower than the connector on the analyzer (gravity driven).

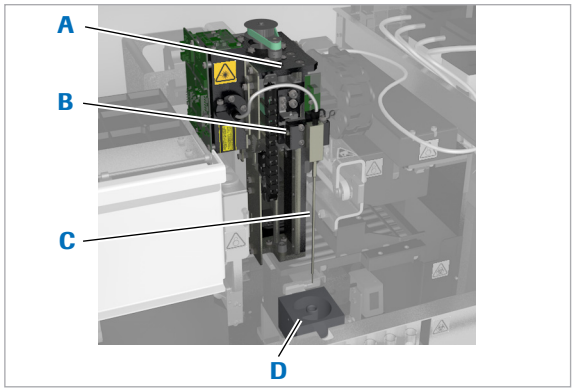
The external liquid containers must be properly connected before you power on the analyzer.

Liquid connectors (75)

Pipetting unit

In this section

About the pipetting unit

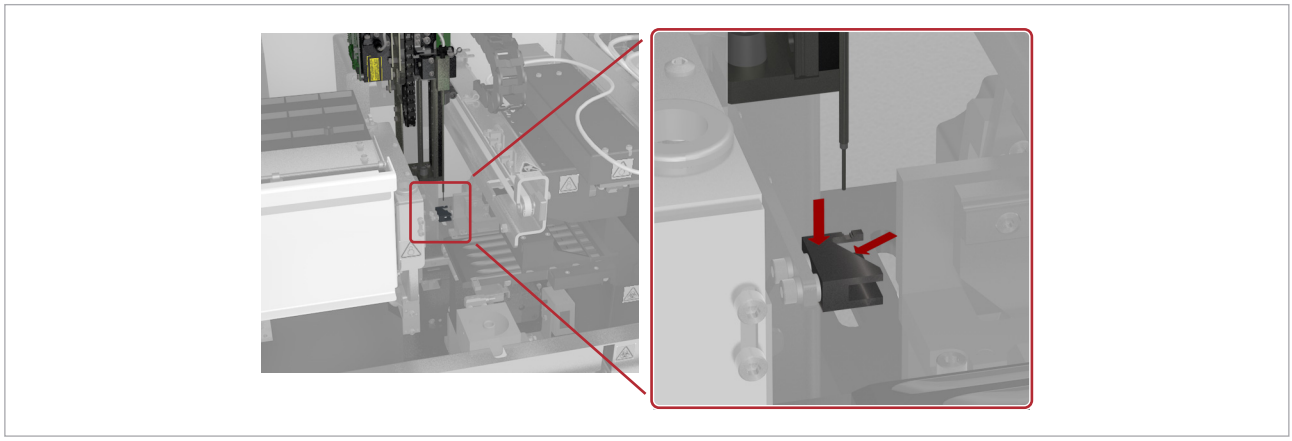


A Transfer head
B Probe release button
C Probe
D Rinse station

The pipetting unit moves the probe to the appropriate positions for aspirating and dispensing liquid. Mixing of the sample liquid is done by aspirating and dispensing liquid inside the sample tube. The pipetting unit is equipped with liquid level detection and probe crash prevention mechanisms. If there is insufficient liquid in the tube the sample is not pipetted, the order is marked with ⚠ in the orders list and a message is added to the message list.

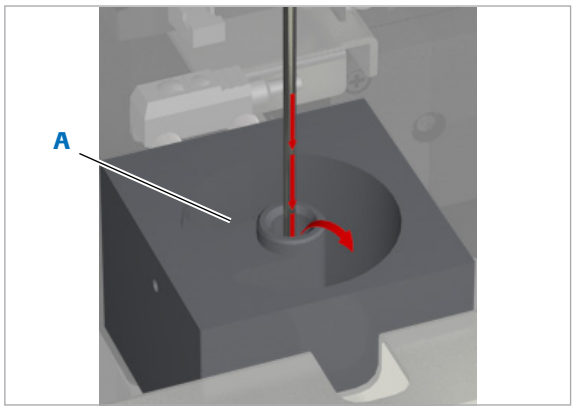
Probe calibration

During initialization of the analyzer the probe positioning is automatically calibrated and its position adjusted. This is done by moving the probe in the horizontal and vertical plane along a reference block.



Probe bend detector on the test strip analyzer

Rinse station



A Probe chamber

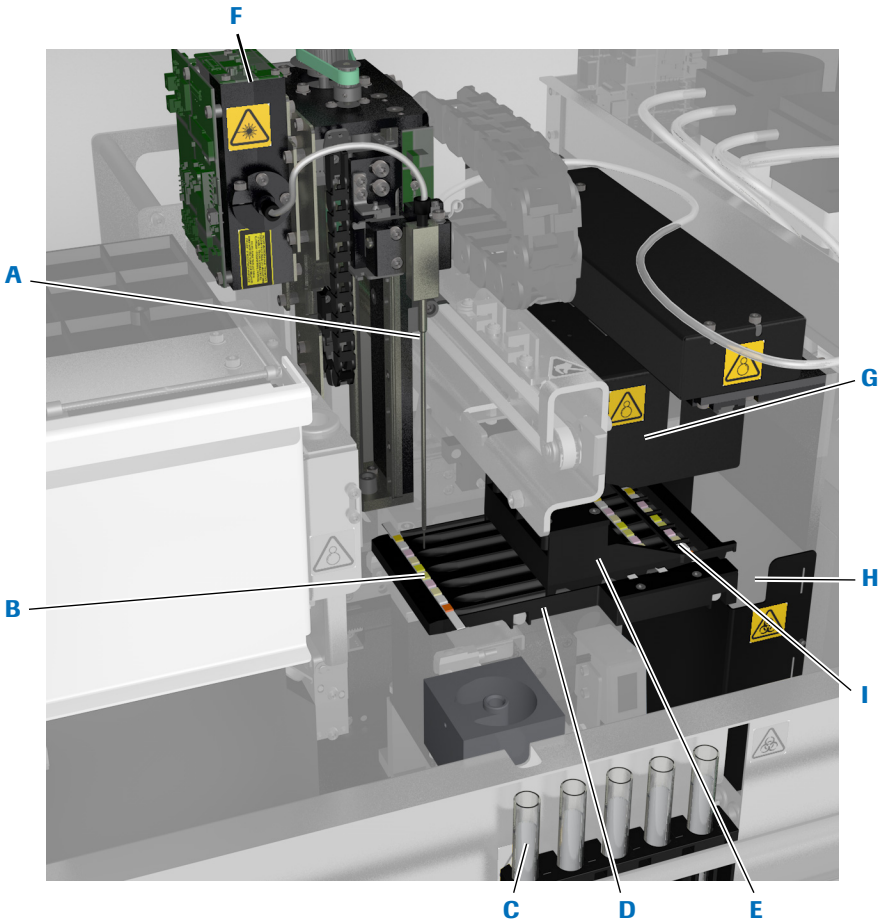
The probe is rinsed after each pipetting. It is lowered in the probe chamber of the rinse station and then water is pumped through the probe to wash it in and outside.

During the **Daily wash** maintenance action, wash solution is dispensed into the probe chamber of the rinse station several times. With the last of these actions, the wash solution remains in the chamber, the probe aspirates wash solution from the tube and with solution inside is lowered into the probe chamber, where it remains for a certain time. The last step is to wash the probe and the rinse station with water.

Sample handling

Before urine is pipetted, it is mixed to ensure even distribution of particles. This process is performed by aspirating and dispensing urine in the sample tube on the sampling position.

The probe aspirates urine, which is then passed through the tubing to the measuring cell, where clarity and specific gravity are measured. Then, the predefined amount of urine is pipetted on each test pad on the test strip. The test strip is then moved along the test strip tray in regular intervals. By the time it reaches the measurement position an incubation time of 60 seconds has elapsed. When measuring is complete, the test strip is discarded into the solid waste container.



A Probe
B Test strip on pipetting position
C Sample on sampling position
D Test strip tray
E Test strip transporter
F Measuring cell
G Photometer
H Waste chute
I Test strip on measurement position

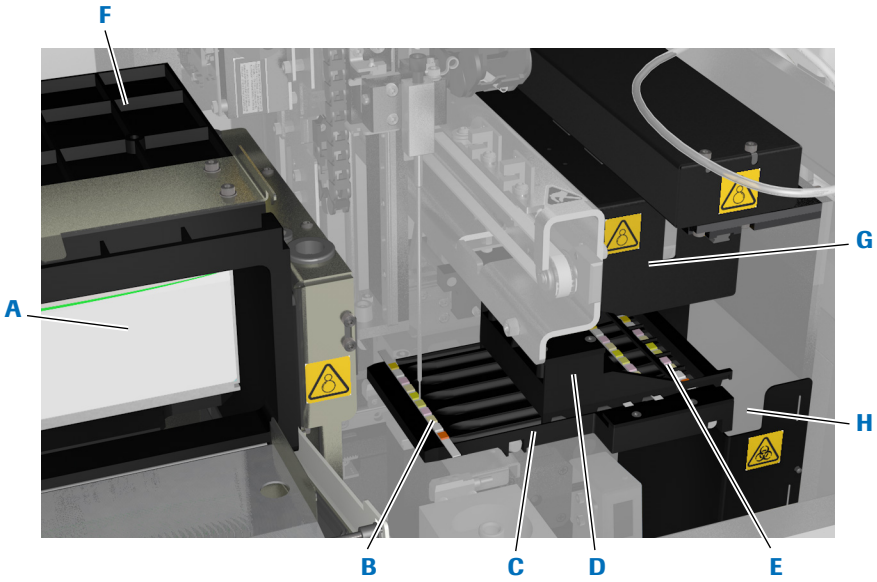
Sample stages on the test strip analyzer

Test strip handling

In this section

About test strip handling

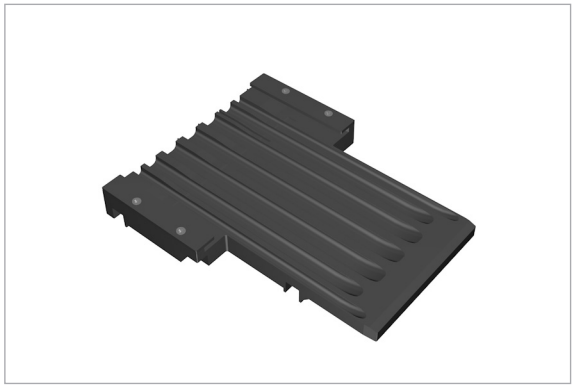
Test strips are supplied in bespoke cassettes (**cobas u** pack), which are loaded into the test strip cassette compartment on the analyzer. For each new test, a test strip is removed from the test strip cassette and placed on the pipetting position on the test strip tray. After pipetting, the test strip is moved along the test strip tray in regular intervals, resulting in an incubation time of 60 seconds. When the test strip reaches the measurement position, reflectance photometric measurements are performed for each test pad on the test strip. The measuring process can last up to 5.5 s for a whole test strip. When measuring is complete, the test strip is removed from the test strip tray and discarded into the solid waste container.



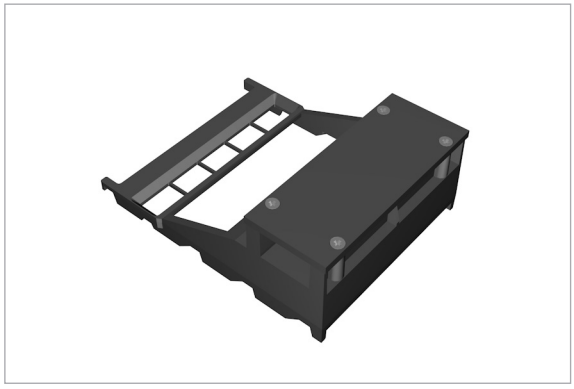
A Test strip cassette
B Pipetting position
C Test strip tray
D Test strip transporter
E Measurement position
F Test strip cassette compartment
G Photometer
H Waste chute

Hardware involved in test strip handling

Test strip tray (version 1)



Test strip transporter (version 1)



⚠ WARNING

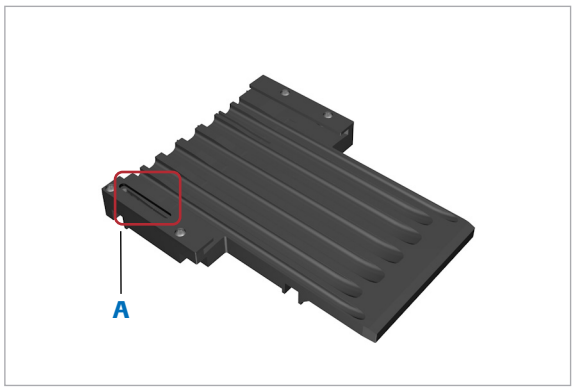
Malfunction, pipetting errors and incorrect results due to using test strip tray and transporter (version 1) on different instruments

The test strip tray and transporter (version 1) are guaranteed to work properly with the instrument they are delivered with. (The test strip tray and transporter (version 1) are specifically calibrated to the instrument they are installed on.)

Using a test tray and transporter (version 1) on a different instrument may lead to malfunction, pipetting errors and possibly to incorrect results.

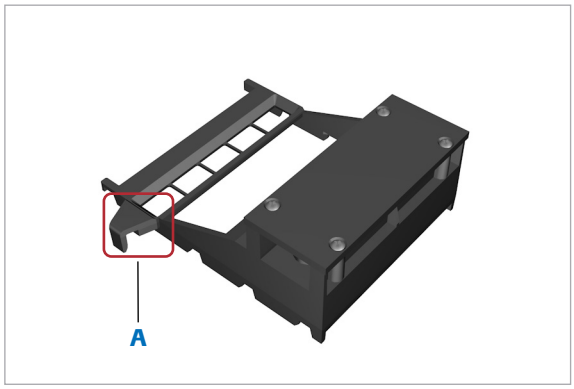
- Do not use the test strip tray or transporter (version 1) other than on the instrument they were originally delivered with.

Test strip tray (version 2)



A Groove

Test strip transporter (version 2)

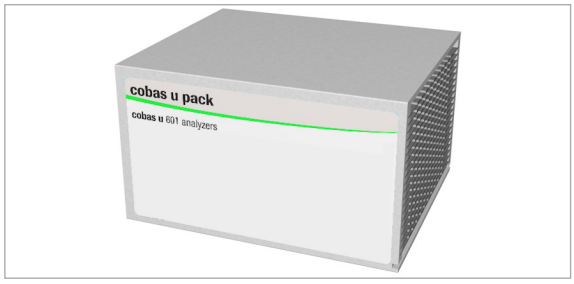


A Hook

The test strip tray and transporter (version 2) are interchangeable and guaranteed to work properly with instruments designed for version 2.

The test strip tray (version 2) is identifiable by a groove and the test strip transporter (version 2) is identifiable by a hook.

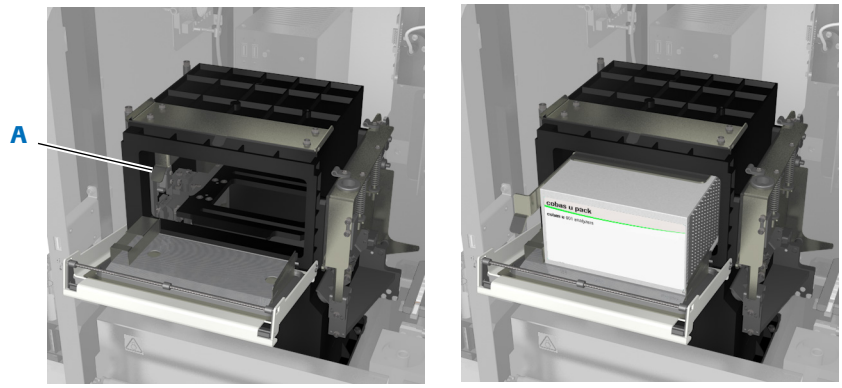
Test strip cassette



The test strip cassette holds 400 test strips in 20 rows of 20 test strips each. It is supplied in airtight packaging. Each cassette is identified by a unique ID contained in the radio frequency identification (RFID) tag. This tag also contains important information such as the onboard stability, expiry date, lot number and the current number of available test strips.

Test strip cassette compartment

The test strip cassette compartment holds one test strip cassette. It is airtight and designed in a manner that the inside temperature remains in the range of 18 to 32°C (64 to 90°F) and that the water absorption of the desiccant in the inserted test strip cassette is kept to a minimum (reflected in the onboard stability value of the cassette).



A Test strip cassette release lever

Test strip cassette compartment

NOTICE

Diminished test strip stability due to excessive ambient humidity

Excessive ambient humidity will limit the effectiveness of the desiccant in the test strip cassette and may render the test strips unsuitable for use.

- Use the analyzer only in the environmental conditions defined in:

  Environmental conditions (116)

- Open this compartment only for replacing the test strip cassette.

⚠ CAUTION

Incorrect results due to excessive ambient humidity

Excessive ambient humidity will limit the effectiveness of the desiccant in the test strip cassette and consequently may influence the test pad constituents in a manner that incorrect results are generated.

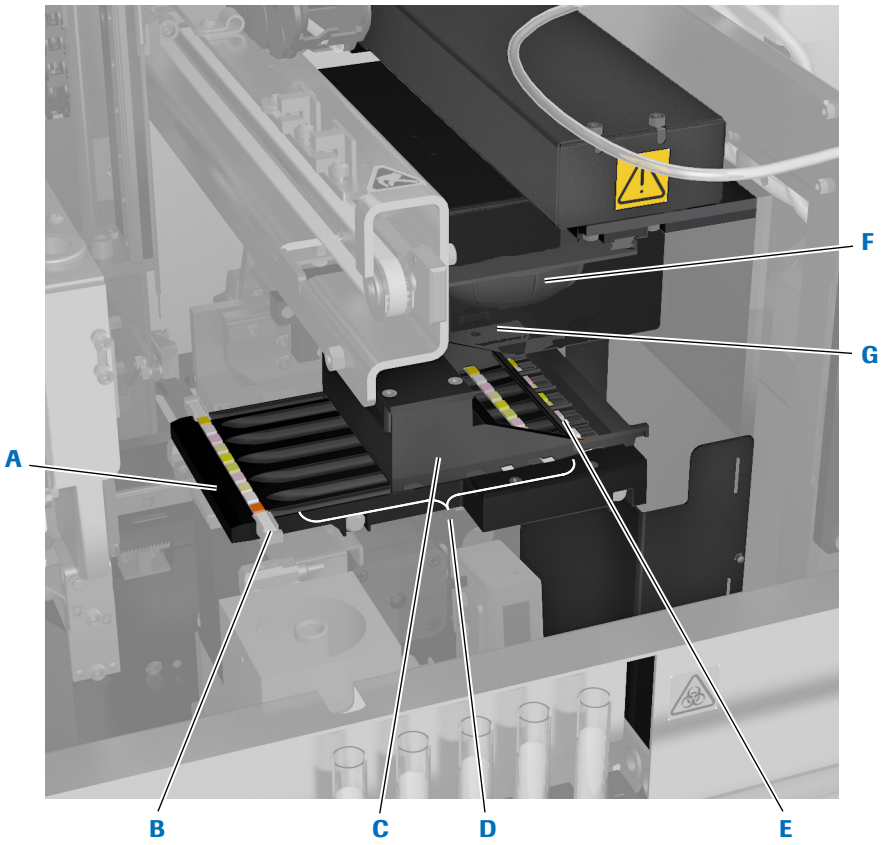
- Use the analyzer only in the environmental conditions defined in:

  Environmental conditions (116)

- Always load the test strip cassette immediately after removing it from its airtight packaging. Follow the instructions defined in the **cobas u** pack Method Sheet.

Test strip processing

The test strip tray holds the test strips during pipetting, incubation, and measuring.



A Test strip tray
B Pipetting position
C Test strip transporter
D Incubation positions
E Measurement position
F Photometer
G Reference plate (hidden)

Test strip tray

When pipetting is complete, the test strip is moved one position along the test strip tray (to the first incubation position). All test strips on the test strip tray are moved one position towards the measurement position in regular intervals. By the time they reach the measurement position an incubation time of 60 seconds has elapsed.

The reference plate is measured with each test strip measurement and the results are taken into account when calculating the test results.

Do not touch or soil the reference plate.

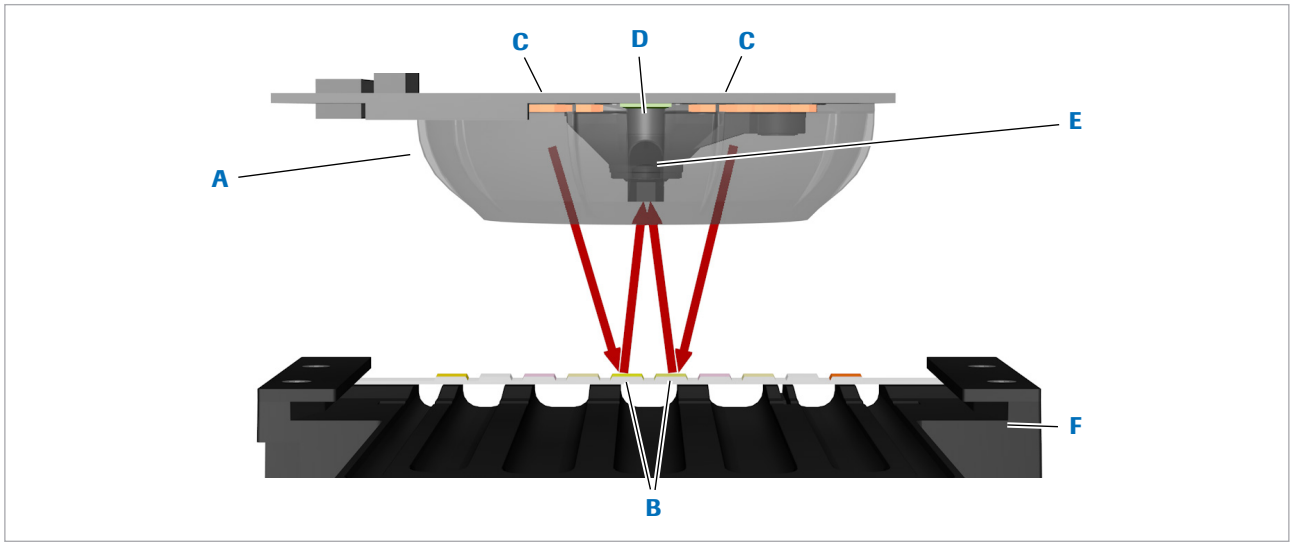
Reflectance photometric measuring

In this section

About reflectance photometric measuring

The photometer performs reflectance photometric measurements on each pad on a test strip, measuring two pads at a time. Measuring a whole test strip takes up to 5.5 seconds.

The photometer contains LEDs of four different wavelengths (465, 525, 560, and 615 nm). The LEDs are arranged in groups in a circular array to achieve optimal illumination, each group consisting of one LED of each light quality.



A Movable photometer
B Test strip pads in measurement positions
C LED ring
D Image sensor
E Optical lens
F Test strip tray

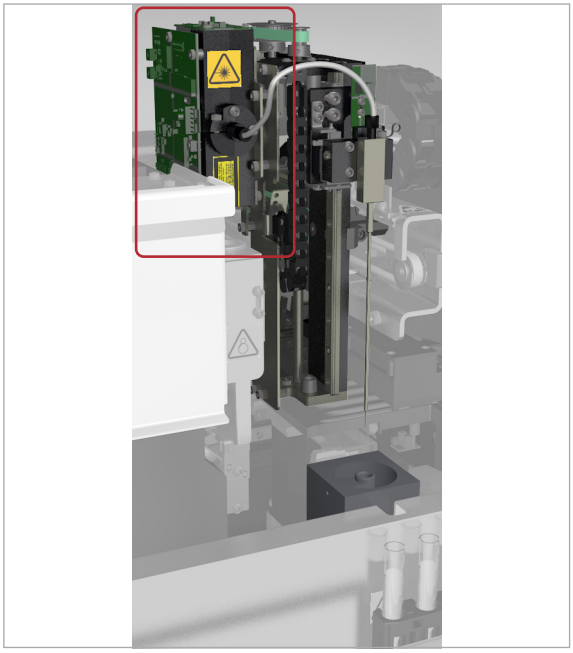
Schematic of photometer

The light that is emitted by the LEDs is reflected by the test pad surfaces with an intensity that is dependent on the color of the test pad. An optical lens projects an image of the test pad onto an image sensor. These images are then processed by the software and presented as results. The intensity of the reaction color of the test pad is detected by measuring the percentage of light reflected from the surface of the test pad. The larger the color change on the test pad, the larger the change in reflectance gets. The reflectance value therefore corresponds to the concentration of the analyte in the sample.

Compensation measurement

Intrinsic coloring of the urine influences the reflectance value and may lead to false results. For this reason, a white reagent-free compensation pad is measured to establish a correction algorithm. When calculating the measurement results of the test pads, this algorithm is used to compensate for the intrinsic urine coloring.

Measuring cell



The measuring cell establishes the specific gravity and clarity of the sample. Sample is passed through a transparent tube in the measuring cell, where a refractometer determines the specific gravity and the turbidimeter determines the clarity. Specific gravity and clarity are not affected by the intrinsic color of the urine.

The specific gravity is the ratio of the density of analyte to the density of water at a specified temperature.

Clarity is either clear, light turbid or turbid.

Both the refractometric and turbidimetric determinations are temperature dependent. Therefore, the temperature of the liquids is monitored, it must remain between 15°C (59°F) and 32°C (89.6°F).

Barcode reader

Barcode readers using LED technology with very low output power are used to scan the barcodes on samples and racks.

⚠ WARNING

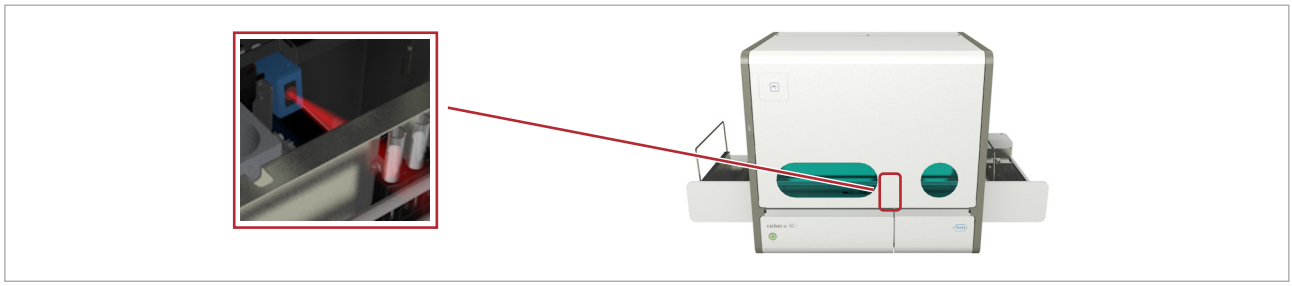
Loss of sight

The intense light of the LEDs may damage your eyes.

- Do not stare into the LEDs.

The following barcode formats are supported:

- Codabar (NW7)
- Code 39
- ITF (interleaved 2 of 5 barcode)
- Code 128

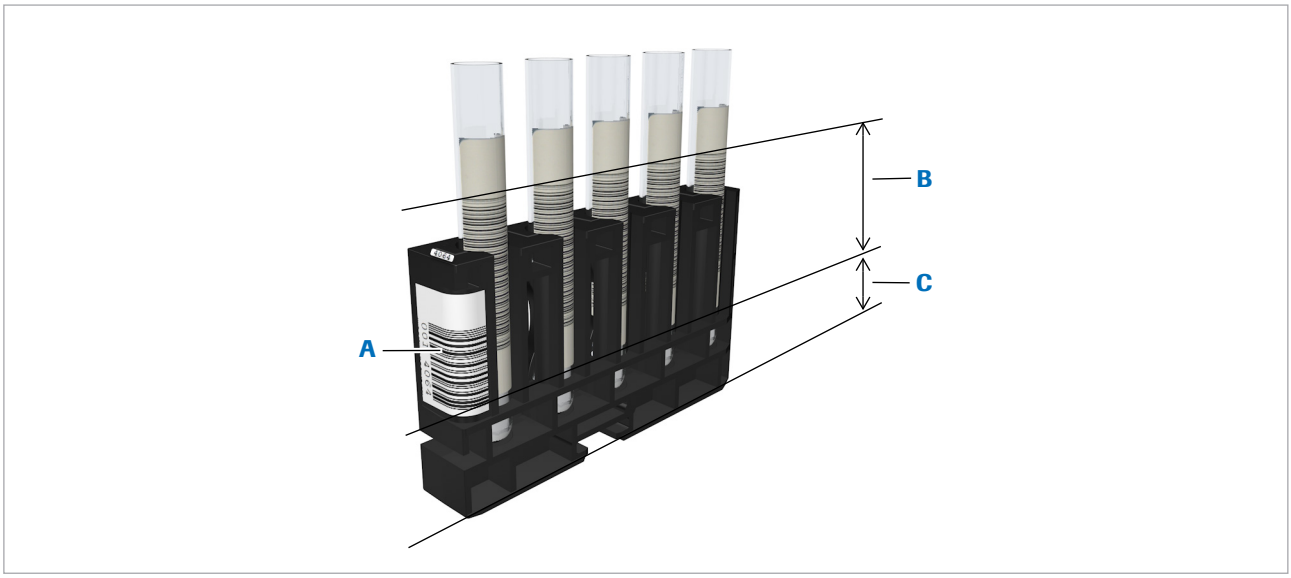


Barcode reader

Barcodes

Barcodes are used on racks and sample tubes. The minimum resolution of a barcode line is 0.2 mm and the maximum barcode length is 72 mm. The barcode must be at least 35 mm away from the bottom of the rack.

For more information about barcode specification, contact your Roche Service representative.



A Barcode line resolution min. 0.2 mm

B Barcode length max. 72 mm

C Distance from rack bottom min. 35 mm

Tubes on rack, both barcoded

The sample barcode can contain the sample ID and a checksum. The rack barcode contains the rack ID.

⚠ WARNING

Unidentified samples due to undetected reading errors

Barcode reading errors could potentially go undetected if a checksum is not used, which could lead to sample mismatch.

- Always work with the checksum feature on.
- Use only barcode labels of a good print quality.

Radio frequency identification

Roche consumables are equipped with radio frequency identification (RFID) tags. With cassettes the tag is automatically read when they are installed, and certain information is written to the tag every time a cassette is used and when it is removed, e.g. the number of items left in the cassette. There is also an RFID reader for identifying QC materials from outside the analyzer housing.

Always use test strip cassettes with RFID tags.

A RFID reader for QC materials

B RFID reader for test strip cassette

RFID readers

The following table lists the consumables that are equipped with RFID tags and the information items contained in the tags.

When identifying QC materials with RFID tags, present the tag to the reader at a distance of between 1 and 25 mm (0.04–1 in).

	Consumable item	Information items contained in the RFID tag
	**cobas u** pack	• Lot number • Expiry date • Load date • Onboard stability • Number of test strips left
	QC material	• QC level • Target ranges • Lot number • Expiry date

RFID tag information

Technical specifications

Technical specifications may change without notice

Every effort has been made to ensure that all the information contained in these specifications is correct at the time of publication. However, Roche reserves the right to make any changes necessary without notice as part of ongoing product development.

In this section

List of technical specifications

In this section

Storage conditions

Temperature range	5 to 40°C (41 to 104°F)
Relative humidity	75% at 30°C (86°F), non condensing
Altitude and pressure	Max. 2000 m (6561 feet) above sea level, 80-106 kPa

Storage conditions

Environmental conditions

Ambient room temperature	18 to 32°C (64.4 to 90°F)
Relative humidity	30%-80%, non condensing
Altitude and pressure	Max. 2000 m (6561 feet) above sea level, 80-106 kPa
Pollution	Degree 2 (EN 61010-1)
Ambient light influence	Up to 2 kLux of artificial direct light Up to 20 kLux of direct light (solar radiation)
Minimum ambient light	500 Lux of ambient light

Environmental conditions

Physical dimensions

Width (with buffers)	107.9 cm (42.48 in)
Width (with output buffer and input connection unit)	104.5 cm (41.12 in)
Width (without buffers)	68.7 cm (27.05 in)
Depth	53.2 cm (20.94 in)
Height	64.4 cm (25.35 in)
Weight (with buffers)	92.7 kg (207.5 lb)
Width (with output buffer and input connection unit)	89.4 kg (197.1 lb)
Weight (without buffers)	80.5 kg (177.47 lb)

Physical dimensions

Effective footprint

The effective footprint represents the analyzer footprint plus the user and service access requirements.

Width	107.9 cm (42.48 in)
Depth	130.0 cm (51.18 in)

Effective footprint

Allowed tilt

Incline < 3°

Allowed tilt

Power requirements

Line voltage	100 to 240 VAC
Line voltage variation	± 10%
Line frequency	50 to 60 Hz
Line frequency variation	± 5%
Current	Max. 3 A
Power consumption (control unit version 1)	Max. 160 VA, typical 140 VA
Power consumption (control unit version 2)	Max. 160 VA, typical 140 VA
Effective power consumption	See the name plate on the analyzer.
Line fuse	2 x T8AL
Insulation coordination	Installation category II (EN/IEC 61010-1)

Power requirements

Uninterruptible power supply (UPS)

Output power capacity	1500 VA
Battery runtime	Min. 5 min

Uninterruptible power supply (UPS)

Heat output

Heat dissipation	Control unit version 1: 115 W Control unit version 2: 115 W
Thermal load	Control unit version 1: 393 Btu/h (412 kJ/h) Control unit version 2: 393 Btu/h (412 kJ/h)

Heat output

Noise level

cobas u 601 urine analyzer	62 dB

Noise level

Measurement principles

Reflectance photometry
Refractometry
Turbidimetry

Measurement principles

Interfaces

USB1.1/2.0	Connection to external storage devices
USB1.1/2.0	Connection to peripherals
RJ45	Connection to network

Interfaces

Throughput

Test strip analysis	240 samples per hour

Throughput

Minimal sample volumes (dependent on test profile)

Test strip	2.0 mL
Test strip reduced volume (no measuring cell measurements)	1.5 mL

Minimal sample volumes (dependent on test profile)

Water quality

Type II/IF (according to CLSI C3-A4 guidelines) (Conductivity: 1µS/cm; 25°C) Water temperature between 18 and 32°C.

Water quality

Wash solution

Recommended solution for performing the daily wash action:	1.2% - 4% Na-hypochlorite solution

Wash solution

Roche recommends to use a concentration near the lower value (1.2%) of the recommended range, and no higher than 2%. Higher concentrations do not enhance the cleaning efficacy. Solutions with higher concentrations can be diluted with water.

Cleaning solutions

Recommended solutions for manually cleaning the instrument:	• Isopropyl alcohol, 70% • Ethanol, 70% • Mikrozid® (EtOH/Propanol)

Cleaning solutions

Waste handling

Solid waste container for test strips	Capacity: 400 test strips Inside dimensions: (W x D x H): 8.34 cm x 13.34 cm x 11.82 cm (3.28 in x 5.25 in x 4.65 in)
Liquid waste container	Capacity: 5 L Dimensions: (diameter x H): 16.2 cm x 32.5 cm (6.38 in x 12.80 in)
Water container	Capacity: 5 L Dimensions: (diameter x H): 16.2 cm x 33.5 cm (6.38 in x 13.19 in)
Water container for external water supply	Capacity: 5 L Dimensions: (diameter x H): 16.2 cm x 32.5 cm (6.38 in x 12.80 in)

Waste handling

Display

Touch screen	19 inch (1280 x 1024 pixels)

Display

Keyboard

Standard US QWERTY layout	Only use supplied keyboard.

Keyboard

Mouse

Only use supplied mouse.

Mouse

Standard supplies

The analyzer has been tested for the following Roche supplies:

- **cobas u** pack
- **cobas u** calibration strip

Optional components

The following optional components are available:

- **cobas®** 6500 installation kit for LAS
- Colored labels for Roche 5-position racks:
  - Label for Std-rack, color yellow
  - Label for Std-rack, color light blue
  - Label for Std-rack, color dark blue
  - Label for Std-rack, color light green
  - Label for Std-rack, color orange
  - Label for Std-rack, color pink
  - Label for Std-rack, color brown

Concentration ranges (International)

The following table lists the international concentration ranges for the **cobas u** 601 urine analyzer.

Test parameter	Range		
	Conventional	SI	Arbitrary
PH	5 6 6.5 7 8 9	5 6 6.5 7 8 9	5 6 6.5 7 8 9
LEU	neg 25/µL 100/µL 500/µL	neg 25/µL 100/µL 500/µL	neg 1+ 2+ 3+
NIT	neg pos	neg pos	neg pos
PRO	neg 25 mg/dL 75 mg/dL 150 mg/dL 500 mg/dL	neg 0.25 g/L 0.75 g/L 1.5 g/L 5 g/L	neg 1+ 2+ 3+ 4+
GLU	norm 50 mg/dL 100 mg/dL 300 mg/dL 1000 mg/dL	norm 3 mmol/L 6 mmol/L 17 mmol/L 56 mmol/L	neg 1+ 2+ 3+ 4+
KET	neg 5 mg/dL 15 mg/dL 50 mg/dL 150 mg/dL	neg 0.5 mmol/L 1.5 mmol/L 5 mmol/L 15 mmol/L	neg 1+ 2+ 3+ 4+
UBG	norm 1 mg/dL 4 mg/dL 8 mg/dL 12 mg/dL	norm 17 µmol/L 68 µmol/L 135 µmol/L 203 µmol/L	neg 1+ 2+ 3+ 4+
BIL	neg 1 mg/dL 3 mg/dL 6 mg/dL	neg 17 µmol/L 50 µmol/L 100 µmol/L	neg 1+ 2+ 3+
ERY	neg 10/µL 25/µL 50/µL 150/µL 250/µL	neg 10/µL 25/µL 50/µL 150/µL 250/µL	neg 1+ 2+ 3+ 4+ 5+
COL	p. yel. yellow amber brown orange red green other	p. yel. yellow amber brown orange red green other	p. yel. yellow amber brown orange red green other

International concentration ranges for the **cobas u** 601 urine analyzer

Software

In this chapter, the major software elements are introduced and you find information on how to best work with the user interface.

In this chapter

4

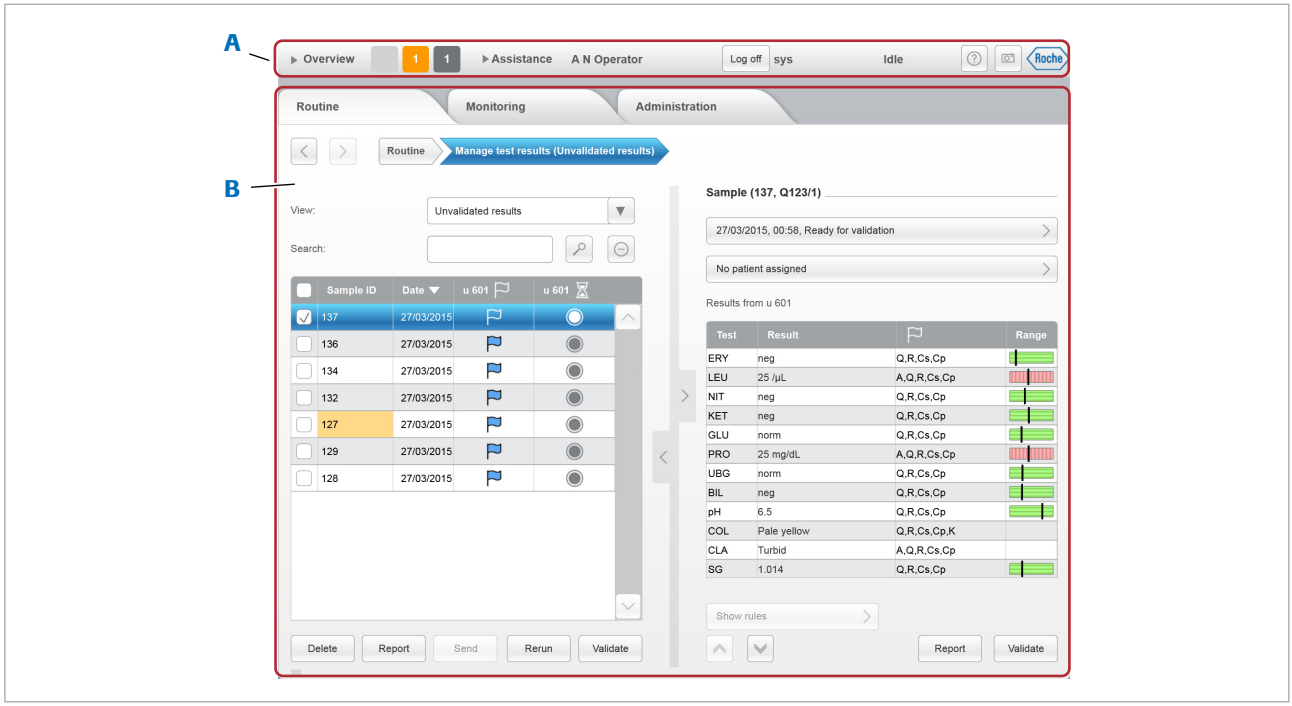
Introduction

Throughout this documentation, images of screens are included for illustration purposes. They are not necessarily identical with what you see on your analyzer.

The user interface is designed to make the operation of the analyzer easy and intuitive. Its logical and visual structure and its color coding help you identify and perform the necessary tasks. It is designed to be operated from the touch screen, but you can instead connect the supplied keyboard and mouse.

Key screen elements

A screen is divided into a global information area at the top and the work area beneath.



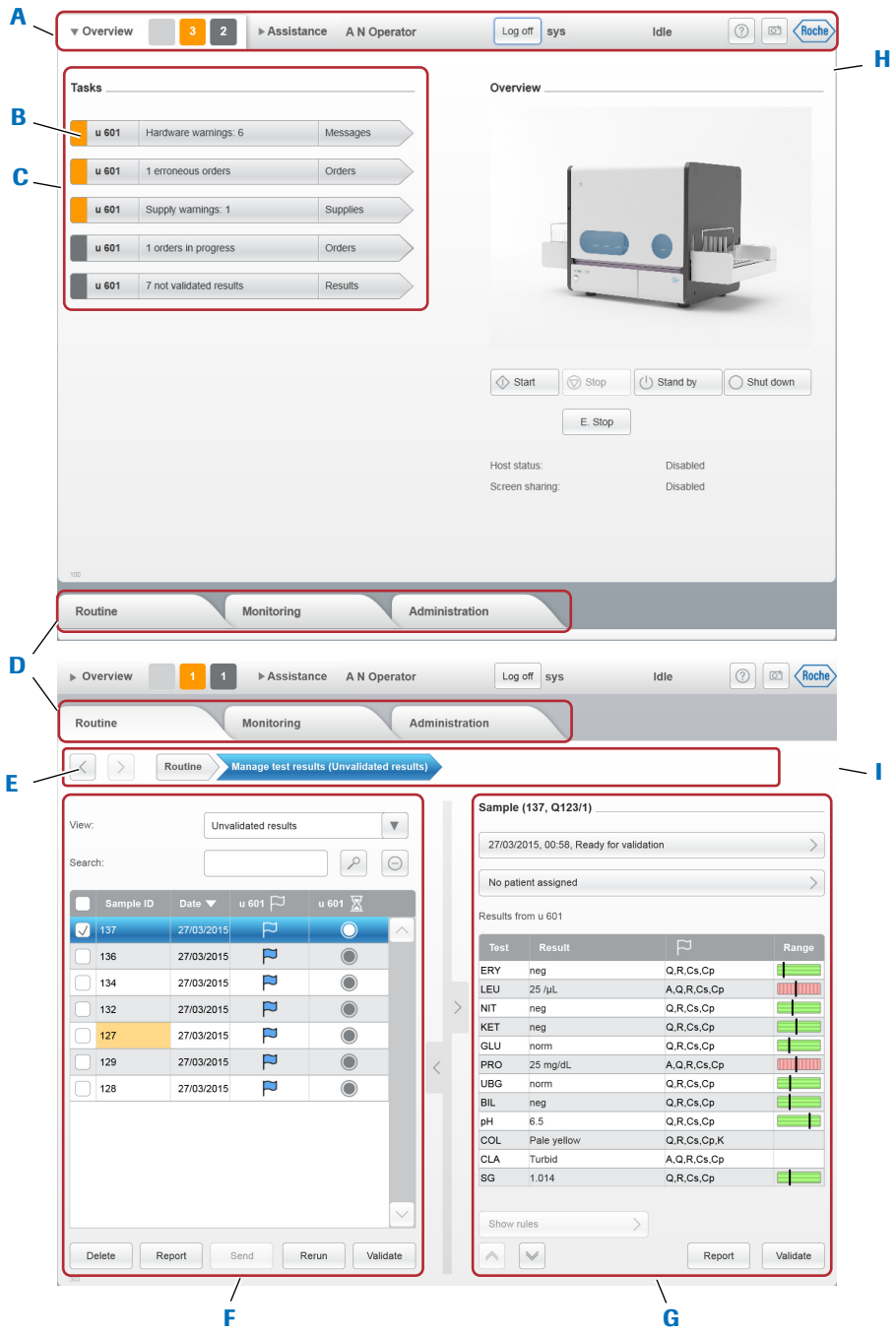
A Global information area

B Work area

Basic screen structure

The global information area contains permanently available elements.

The work areas consist of tabs and panels, each of which containing thematically related information. They can contain buttons, wizards that guide you through tasks, information items such as lists and tables, graphics elements such as symbols representing hardware elements, input fields, as well as navigation and display aids. The following figure illustrates the various parts.



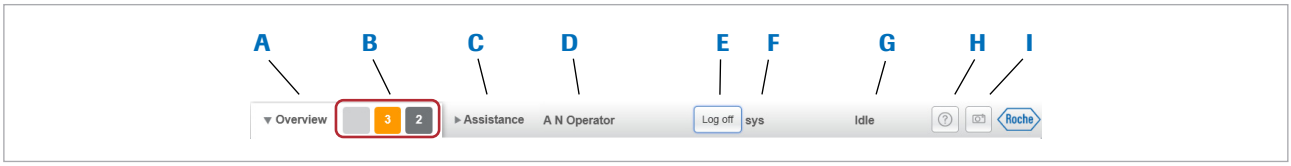
A Global information area
B Task button
C Task list
D Tabs representing work areas
E Navigation bar with back and forward buttons and navigation path
F Main panel
G Detail panel
H **Overview** work area
I **Routine** tab in split-screen mode display (two panels)

Key screen elements

The following sections explain the various elements in more detail.

Global information area

Contains permanently available elements.



A **Overview** work area
B Task indicator
C **Assistance** button
D Name of the user who is currently logged on
E Button for logging on and off
F System name
G System status
H Online help button
I Screenshot button

Global information area

Task indicator

The task indicator provides a rough overview of the current analyzer status. The color of the buttons represents the urgency of the tasks and the number in the button tells you how many tasks there are of this urgency. A task can comprise several messages.

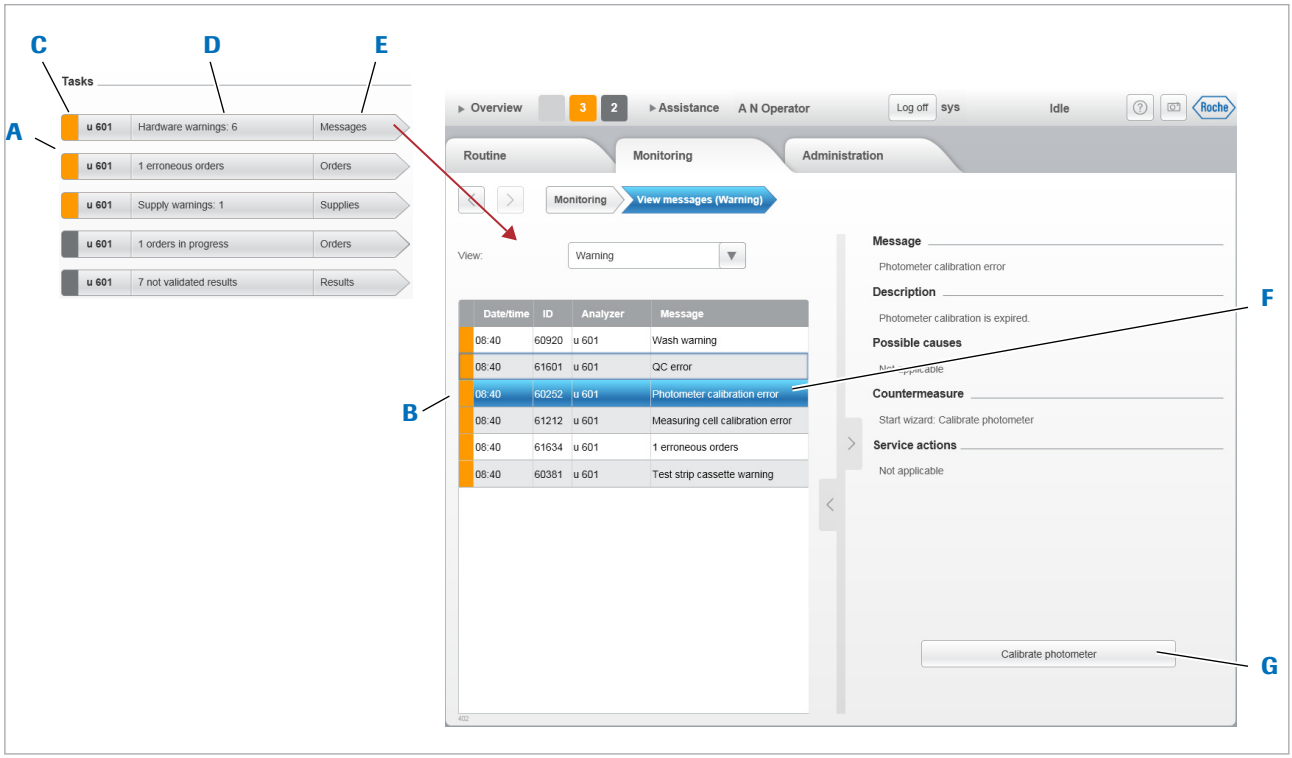
The following table explains the meaning of the colors.

Color	Meaning
Red	The task requires immediate operator intervention. Operation may have stopped. When such a task is generated, an acoustic signal is sounded as well, unless this function is turned off.
Orange	The task requires early operator intervention, operation may otherwise stop. When such a task is generated, an acoustic signal is sounded as well, unless this function is turned off.
Gray	Ongoing task. If operator intervention is required, perform it.
Light gray	There are no tasks. No operator intervention is required.

Color coding for messages

Task list, message list, and buttons

Use the task buttons to display a list of all messages of a given category and severity (message list). Choose a message to display details of the message. These could for example contain a button for starting a wizard that guides you through the various steps of dealing with the issue.



A Task buttons

B Message list

C Color code for severity

D Thematic group, summary of underlying issues

E Tab or panel where the issue can be addressed

F Message that can be selected and which leads to detailed information

G Wizard button

Example of using task buttons and message lists

Tabs

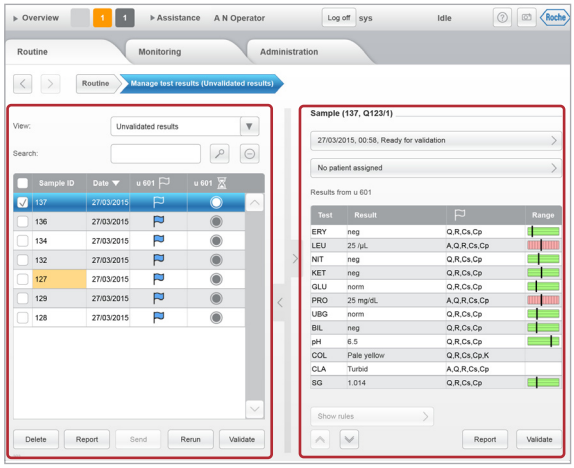
Tabs group information and tasks of the work areas such as performing tests and result handling, maintenance actions, or defining the analyzer work environment.

Tabs (133)

Navigation bar

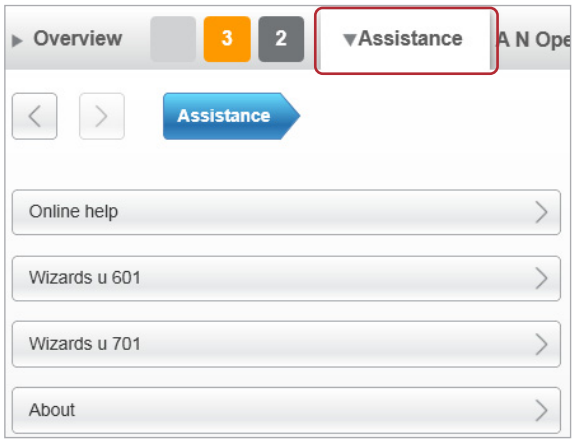
The navigation bar helps you move between the various panels. A "history" function registers which panels have been displayed so far, use the back and forward buttons to display the previous or next panel within this history. The navigation path tells you how to navigate to the current panel (the blue element denotes the current panel). You can choose any of the path elements to display the corresponding panel.

Main panel, detail panel



Information is often displayed in two panels, the information in panel on the right (detail panel) contains detailed information of an item selected in the panel on the left (main panel).

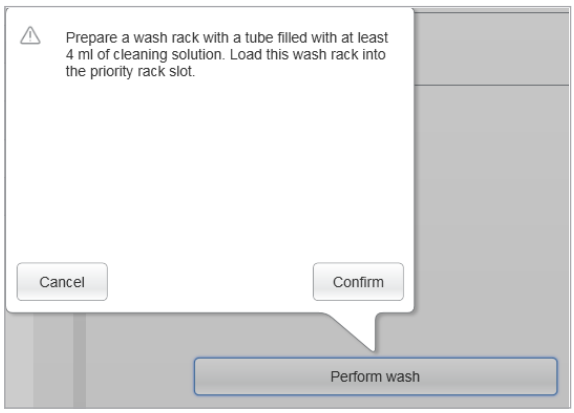
Assistance



Choose the **Assistance** tab to access operation aids such as wizards and user documentation.

For details on the Assistance work area, see Wizards (141) and Online help (145).

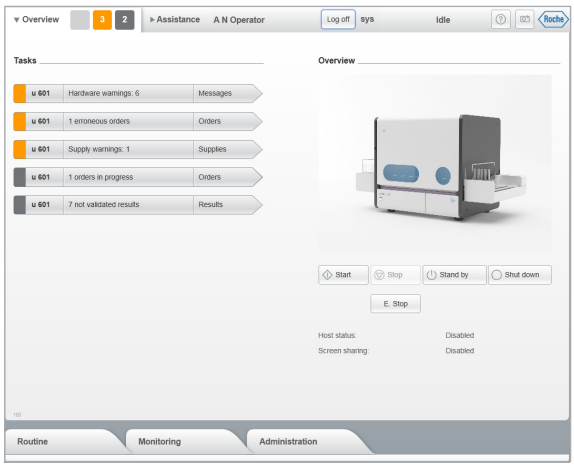
Callouts



Callouts are a kind of work areas that are displayed on top of the current panel, for example for displaying messages, entering information, or confirming an action.

Key work areas

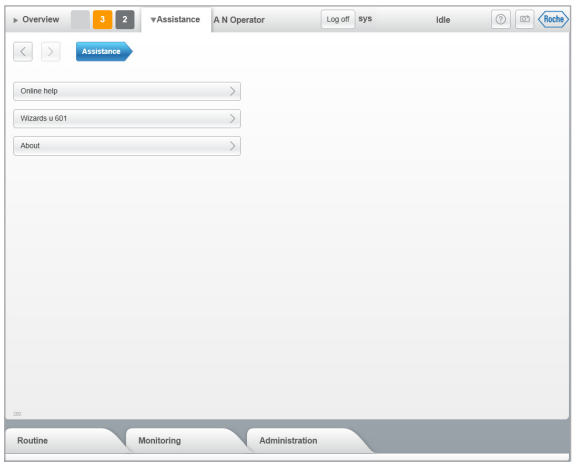
Related tasks are grouped in separate work areas.



The **Overview** work area is displayed when you start the analyzer. It contains general status information of the analyzer and lists the user actions that are due to ensure the proper functioning of the analyzer and the smooth progress of tasks and actions. Its main elements are:

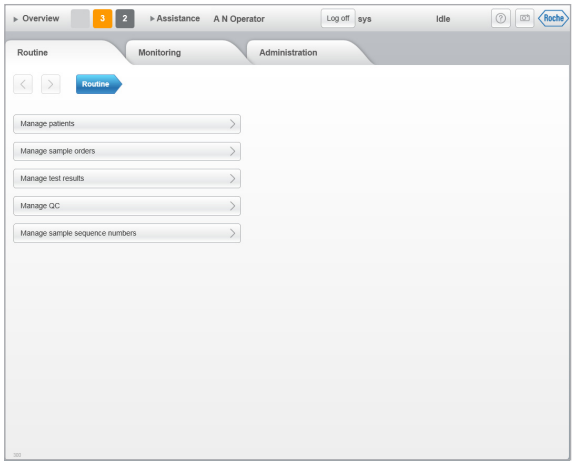
- The **Tasks** panel contains the task list and the task buttons, which lead to the relevant panels for addressing the issues they concern.
- The **Overview** panel provides access to a graphic overview of the analyzer hardware components. You can choose these elements if some intervention is required, and callouts provide the required functions.

- If you work with **Sample sequence number** mode, the sample sequence number that will be used next is also displayed below the **Overview** panel, both for routine samples and for STAT samples.



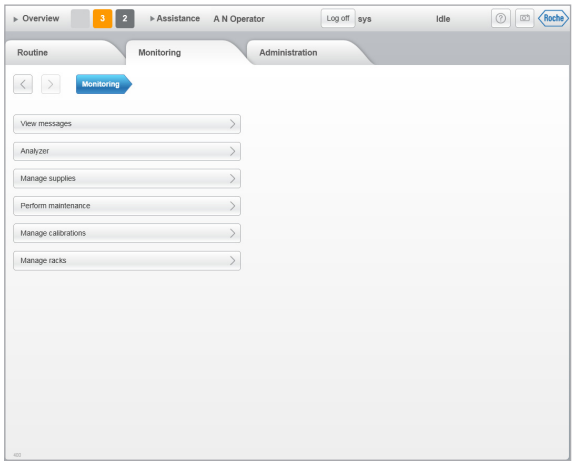
The **Assistance** work area provides operation aids such as:

- User documentation
- Wizards that guide you through selected tasks
- Legal notice



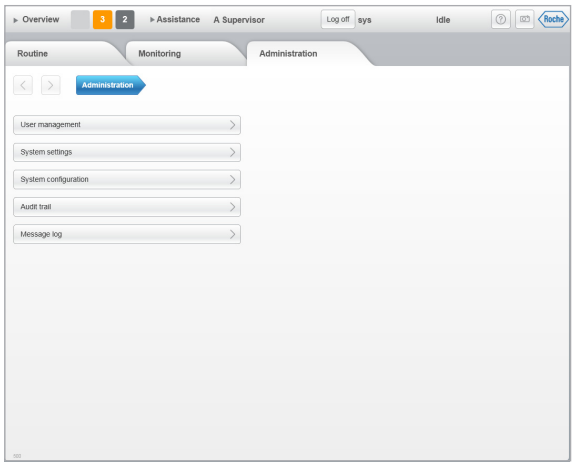
The **Routine** tab encompasses all activities directly related to performing tests and handling results.

- Patient management
- Order definition and handling
- Result viewing, validation, and reporting
- QC materials and QC result handling
- Manage sample sequence numbers (if you work with **Sample sequence number** mode)



The **Monitoring** tab encompasses the activities related to ensuring the trouble-free operation of the analyzer:

- Dealing with messages and related tasks
- Checking the hardware status and performing hardware related tasks
- Performing consumables related tasks
- Performing maintenance actions
- Performing calibration measurements
- Managing racks and rack IDs

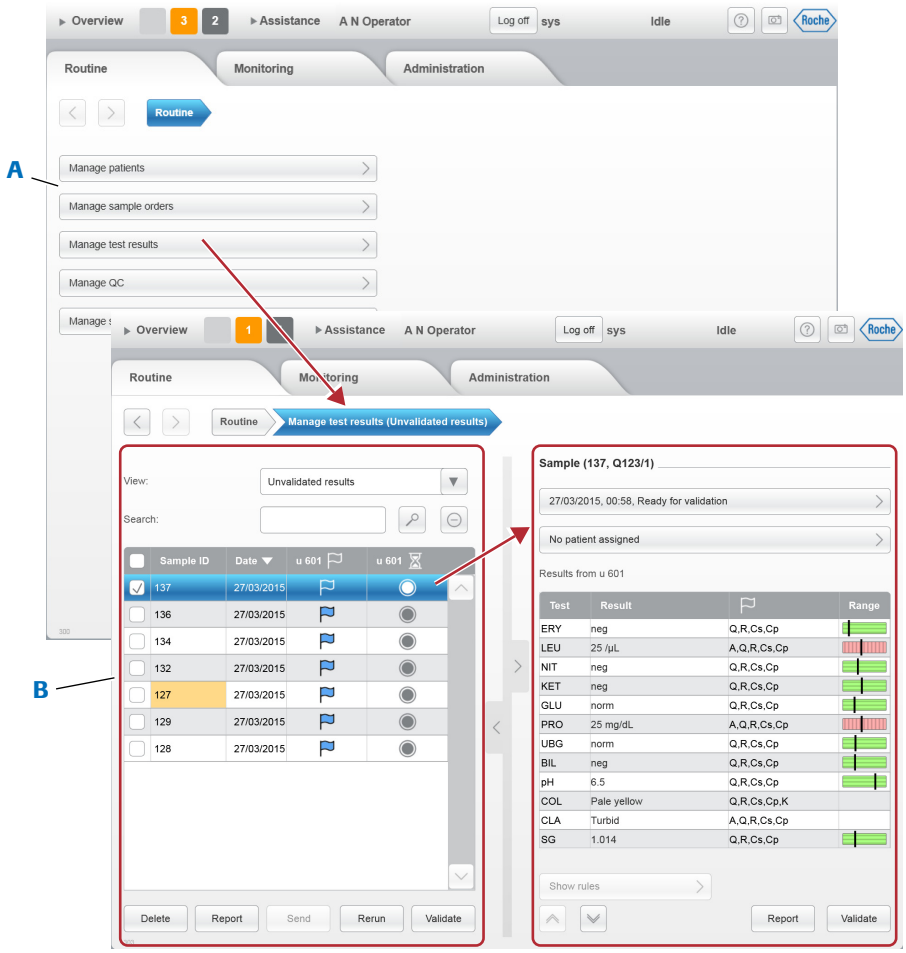


The **Administration** tab provides the functions required for setting up and maintaining the analyzer's operating environment.

- Defining and managing users
- Defining the characteristics for result display, measurements, QC, and tests
- Configuring the analyzer environment
- Displaying the audit trail
- Displaying the message log

Tabs

When choosing a tab, a list is displayed with the buttons for the items dealt with in this work area (A). Choosing one of these buttons displays two panels next to each other (B); the panel on the left (the main panel) usually contains a list whose elements can be selected. It may also contain buttons for starting tasks and features for preselecting the type of information that should be contained in the list. The panel on the right (the detail panel) contains information related to the item selected in the left panel, and it may also contain buttons.



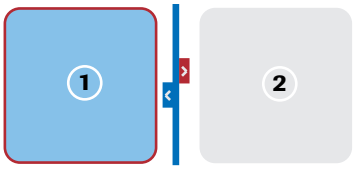
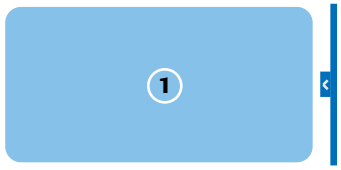
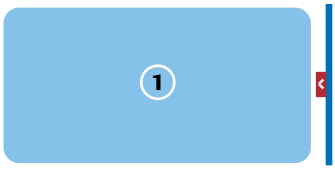
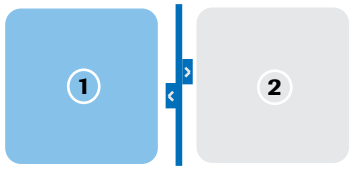
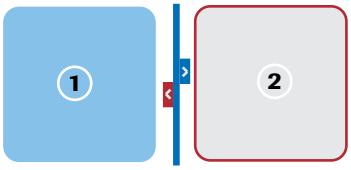
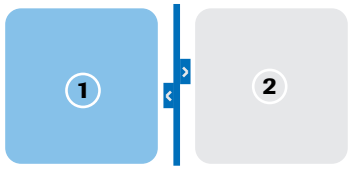
Main elements in a tab

Display modes

Another feature of some tabs is the fact that they can be displayed in either full-screen or split-screen mode.

In split-screen mode, two panels are displayed next to each other, whereby the information contained in the detail panel on the right depends what is selected in the main panel on the left. In full-screen mode one panel covers the whole width of the screen.

Use the panel splitter to switch between the two display modes. Its function depends on its relative position to the panel. The following table illustrates how it works:

Position relative to panel	Resulting panel(s)
	
	
	
	

Functions of the display-mode buttons (panel splitters)

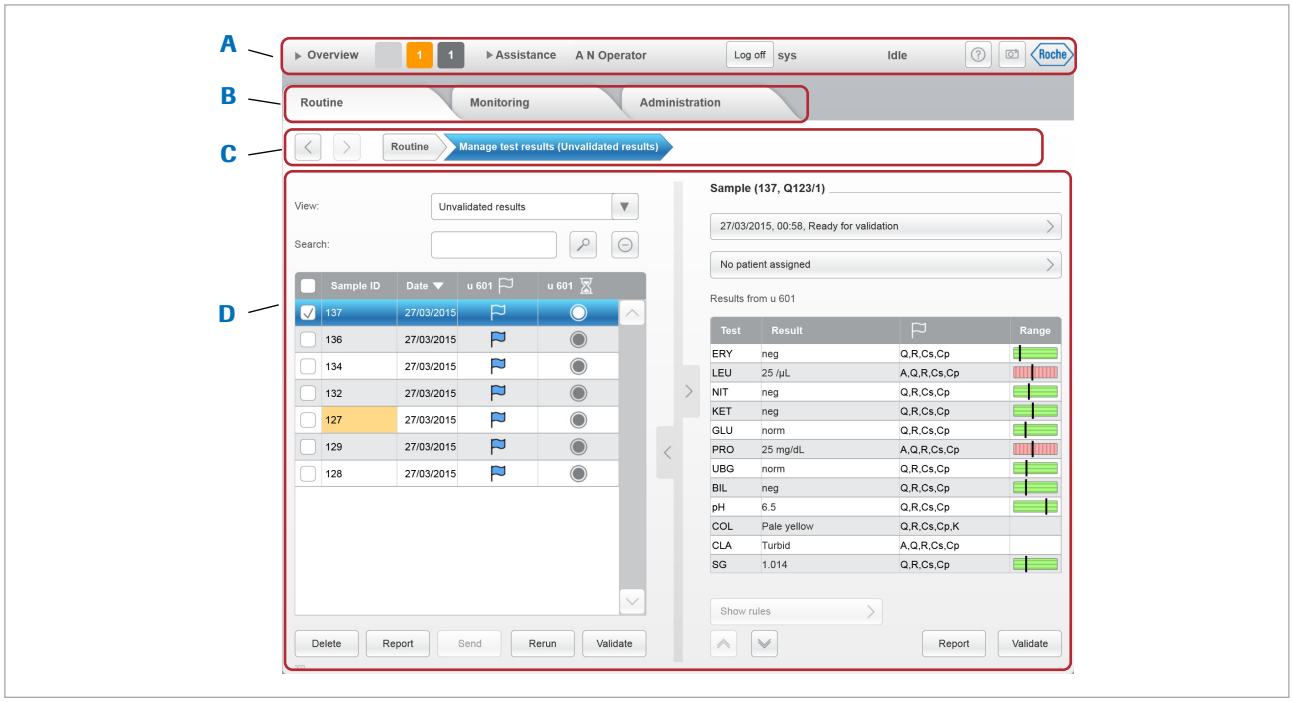
Displaying information

In this section

About displaying information

There are several features that help you access panels and their functions:

- The global information area contains permanently available information and control elements
- The navigation bar contains buttons for displaying panels that were displayed before (back, forward) and shows how you can navigate to the current panel (navigation path).
- Tabs and panels can contain lists and tables, buttons, and graphic elements to access further information.



A Global information area
B Tabs
C Navigation bar
D Panels

Features for accessing information and functions

Working with lists (tables)

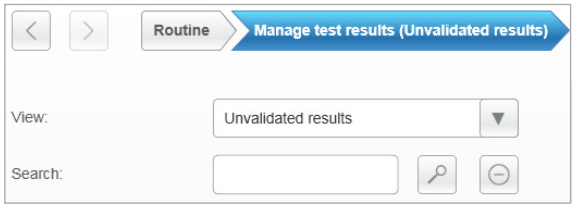
In this section

About sorting lists

You can sort lists by choosing a column head.

The sort order is marked by △ for ascending and ▽ for descending order.

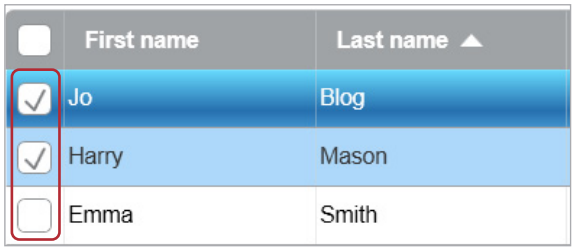
About filtering table information



In some tables you can choose what kind of items are contained. You do so by either selecting one of the predefined filters from drop-down lists or by entering in the **Search** field the first part of the items you are looking for and then choosing the 🔍 button; for example, if you enter 7, all items beginning with 7 are displayed.

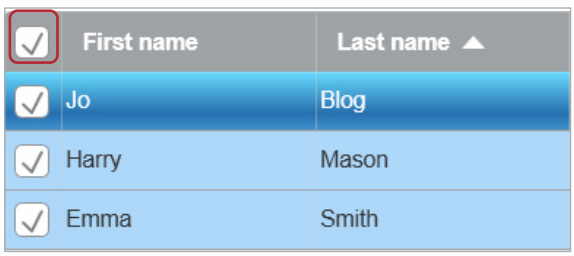
Press the ⊖ button to cancel the search.

About selecting table items



You can select items by selecting the check box to the left of the item.

Selected items are colored blue.



You can select all items in the table by selecting the check box to the left of the table headers.

Entering information

Normally the virtual keyboard is displayed whenever you need to enter information. (The system is designed to be operated using the touch screen, but you can use the supplied external keyboard and mouse instead. If you do so ensure that the virtual keyboard is not displayed (**Administration > Basic configuration 2**)).

A Close the keyboard callout

B Go to the next input field or to the next tab

Keyboard on the touch screen

Keyboard layout

The virtual keyboard layout corresponds to the US English QWERTY keyboard layout. This cannot be changed.

Entry fields with compulsory information are marked with an asterisk and colored yellow.

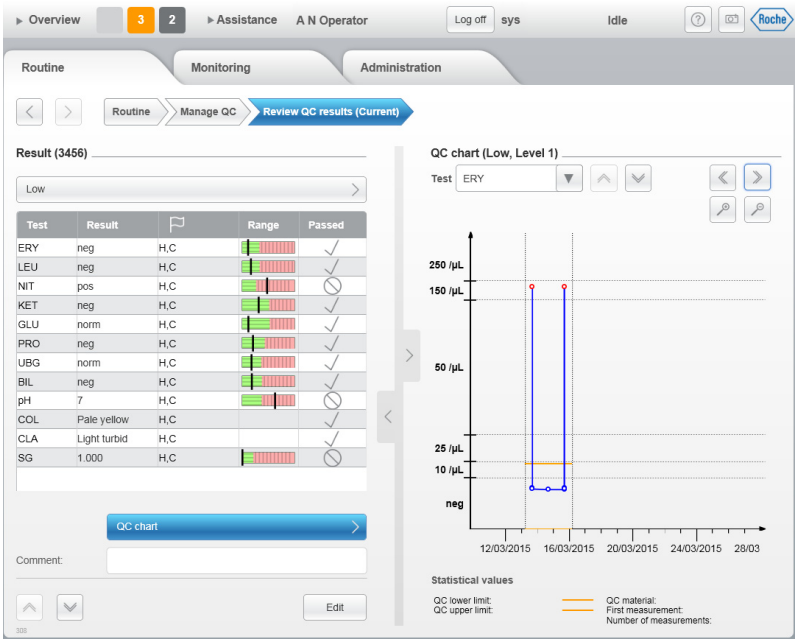
Compulsory entry fields

The validity of the information you enter is continuously checked. As long as the value is not valid the entry field shows a red border (A). When the entry is valid, the field has its normal active display (B).

Validity checking of text entries

Working with QC charts

The QC chart allows you to review QC results over a period of time.



Choose this button to move back the displayed time interval by one month.
To continuously move back the displayed time interval, keep the button pressed.

Use this button to move forward the displayed time interval by one month.
To continuously move forward the displayed time interval, keep the button pressed.

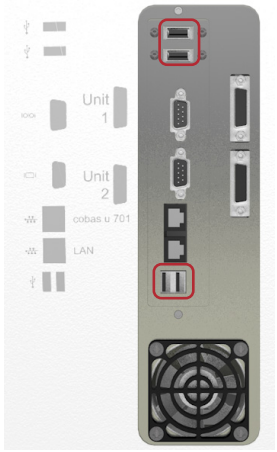
Use this button to double the size of the displayed items, i.e. to increase the scale.
You can increase the scale four times.

Use this button to half the size of the displayed items, i.e. to decrease the scale.
You can decrease the scale until normal view is displayed (100%).

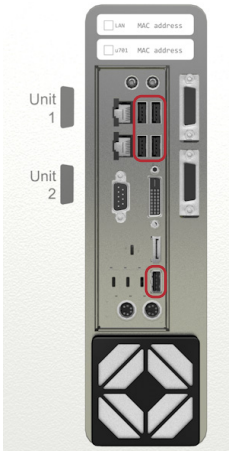
External keyboard and mouse

You can connect the supplied external standard US English keyboard and the mouse to the analyzer using any of the USB ports.

The system is designed to be operated using the touch screen, but you can use the supplied external keyboard and the mouse instead. If you do so ensure that the virtual keyboard is not displayed (**Administration > Basic configuration 2**).



USB ports (control unit version 1)



USB ports (control unit version 2)

When working with a host system, non-ASCII characters are converted to spaces. Therefore, if you work with a host system, only use standard ASCII characters.

Wizards

In this section

About wizards

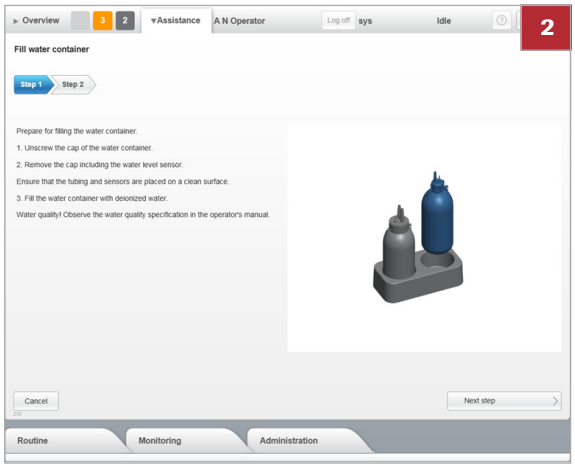
A wizard is an interactive set of step-by-step instructions for performing a certain task. The instructions that are currently displayed depend on checks the analyzer performs continuously and on user input, for example a confirmation that a certain step has been completed or on entering data.

You start wizards by choosing their buttons. All wizards are listed in **Assistance > Wizards**. Wizards are also available for example when you follow up a message in the message list; they guide you through the actions required to deal with the issue mentioned in the message.

Examples

In this section

Example: Starting a wizard

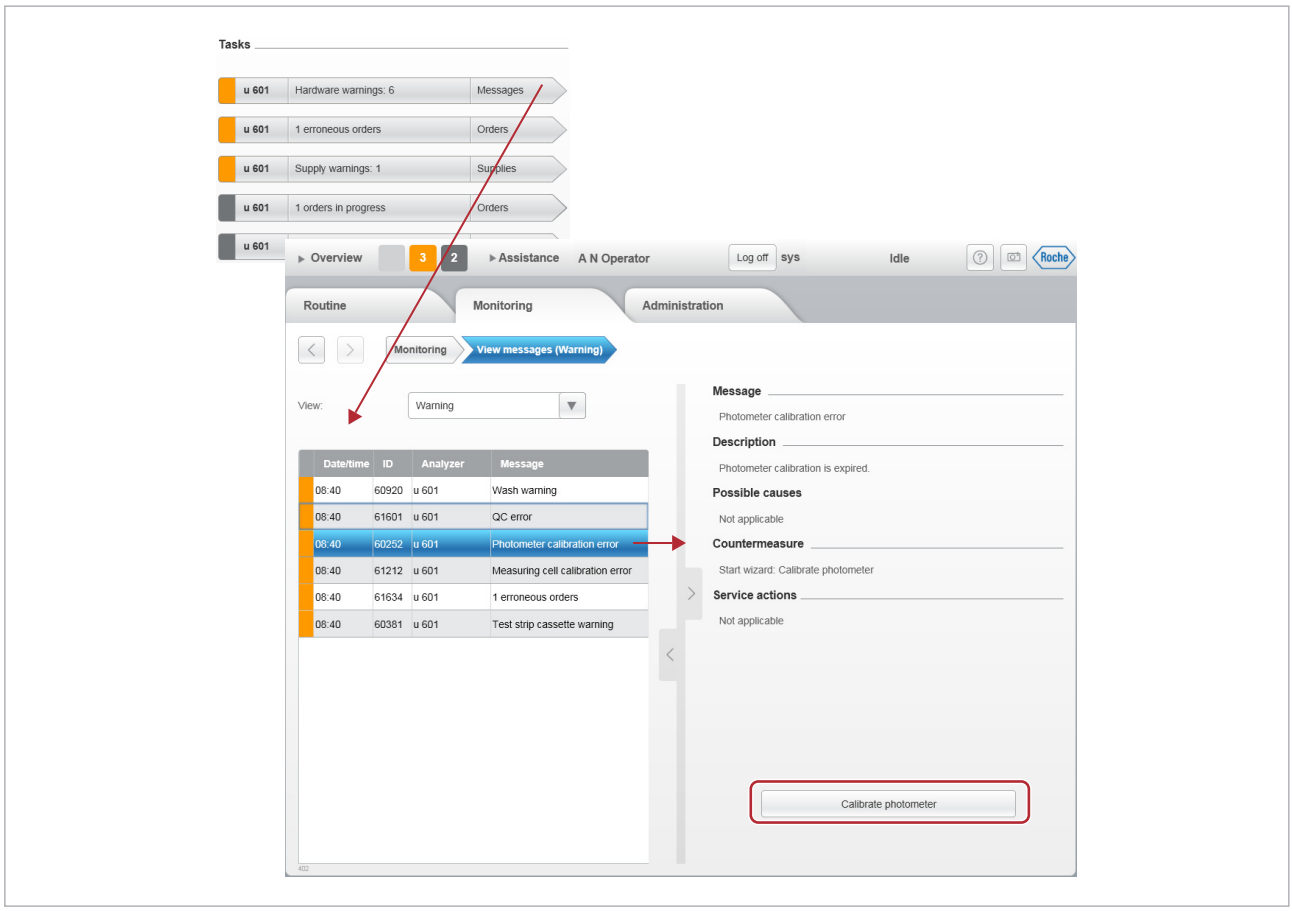


To start a wizard

1 Choose **Assistance > Wizards u 601**.

2 Choose the button for the task you want to perform, for example for filling the water container.

Example: Using a wizard for performing a task that is due



Choosing an element from the list in the main panel

To use a wizard for performing a task that is due

1 Choose the **Overview** work area.

2 Choose a red or orange task button that leads either to the message list or the **Supplies** panel.

3 Choose an element from the list in the main panel.

4 In the detail panel, choose the button for the wizard.

Color coding

The color of buttons and other display items inform you about the status of the display item or the item it represents.

Color	Meaning
Light gray	You cannot currently select this element.
Gray	For information purposes. No operator intervention is required.
Orange	Your intervention is required to ensure continuous operation.
Red	Your immediate intervention is required. Operation may have stopped.
Yellow	This field must contain content (compulsory information).
Blue	This item is selected for display.
Light blue	Multiple items are selected.

General color concept for user interface elements

In result related displays, the colors indicate the degree of pathology of the result. To assist people with color vision deficits, result related elements additionally display hatching.

Color	Result range
Green	Normal.
Yellow	Low pathological.
Red	Pathological.

Color concept for degree of pathology in results

In result related displays for the SG parameter, the background color indicates a measurement error.

Color	Meaning
Yellow	For this sample, the SG parameter could not be measured in the measuring cell.
– Red	No result could be generated by the measuring cell for the SG parameter. (Instead of a result, "–" is displayed.)

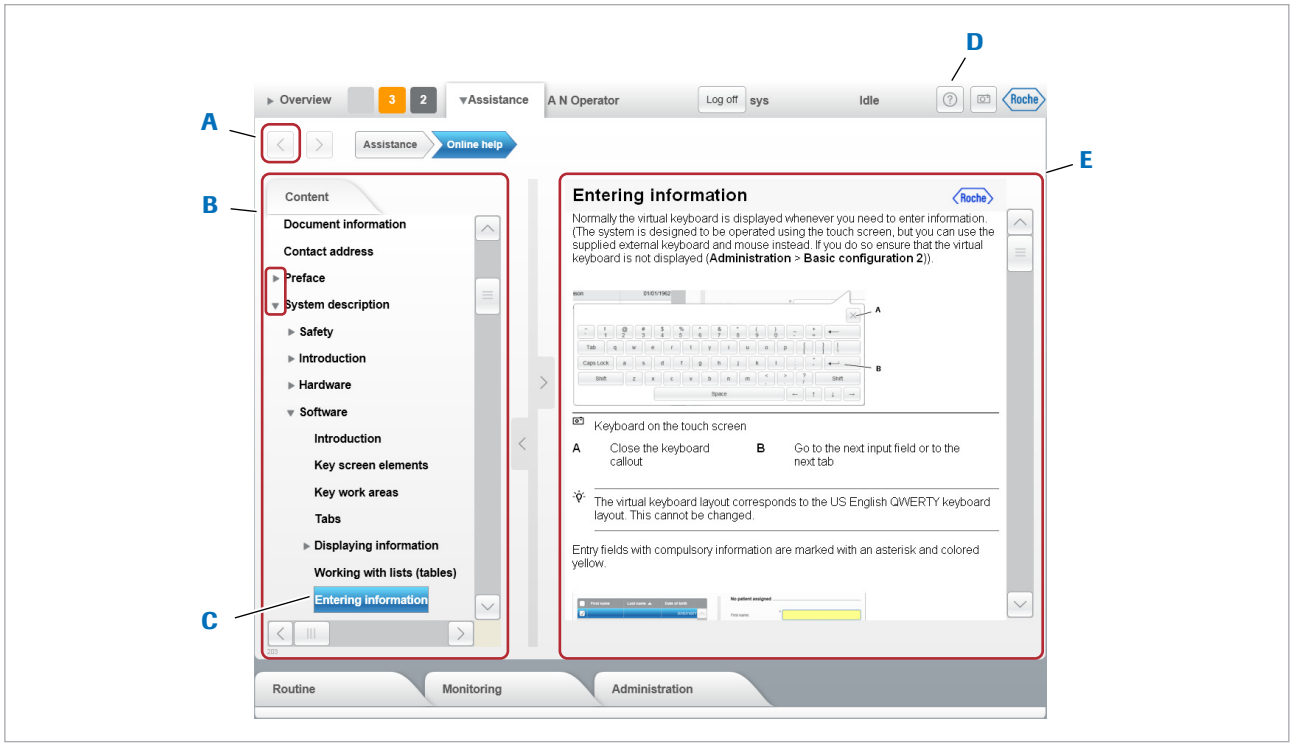
Color concept for severity of measurement errors in the measuring cell

Online help

The analyzer provides online user information and assistance, which can be accessed in the following ways:

- To display information that is relevant to the currently displayed screen, choose ⓘ.

- To display the table of contents of the complete user information, choose **Assistance > Online help**.



A Button for closing online help
B Table of contents
C Selected section
D Help button
E Display area for content

Online help page

Choose ▶ to display the titles of the subtopics.

Choose ▼ to hide (collapse) the titles of the subtopics.

Choose ◀ to close the online help and return to the screen from where you started it.

Note that the ◁ function does not work if you started the online help from the **Overview** work area; instead, to close the online help, choose the **Overview** tab.

Operation

Operation

In this chapter, you find instructions on how to perform the daily operation tasks.

In this chapter 5

Safety

⚠ Read and understand the information in the Safety chapter

The following safety messages are particularly relevant:

Warning messages:

- Biohazardous materials (31)
- Waste (31)

Caution messages:

- Mechanical safety (36)
- Working solutions (36)
- Influence of vibrations (37)

Notice messages:

- Spillage (39)
- Excessive ambient humidity (39)

⚠ CAUTION

Incorrect results due to extreme ambient temperatures

High ambient temperatures may cause sample evaporation during incubation of the test strip, which may lead to incorrect results.

Low ambient temperatures may slow the chemical reactions on the test strips, which may lead to incorrect results.

- Always operate the analyzer in the specified ambient conditions:
  - Environmental conditions (116)

⚠ CAUTION

Incorrect results due to contaminated samples

Solid particles in the sample may influence the functioning of the fluid system, which may lead to incorrect pipetting volumes and consequently to incorrect results.

Food and drink particles in the sample may influence the reaction on the test strip.

- Store and transport samples in a manner that prevents contamination with foreign substances.
- Do not store or consume food and drink in the vicinity of the analyzer.

⚠ CAUTION

Incorrect results due to carryover of samples

Hands that are contaminated with urine can transfer urine to the touch screen monitor or mouse, from where it may be transferred to samples, leading to carryover.

- Avoid getting into contact with urine.
- If you get into contact with urine, either dispose of the lab gloves immediately or clean them using one of the recommended cleaning solutions.

⚠ CAUTION

Incorrect results due to foamy and contaminated samples

Foam in samples may lead to incorrect amounts of liquid being aspirated and dispensed, which can lead to incorrect results.

Insoluble contaminants in samples may cause clogging or pipetting volume shortage and lead to deterioration in measurement accuracy.

- Ensure that samples are clear of foam and insoluble contaminants such as fibrin or dust.

⚠ CAUTION

Loss of data and analyzer damage due to disconnection of mains power

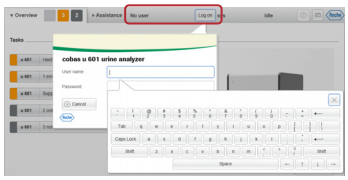
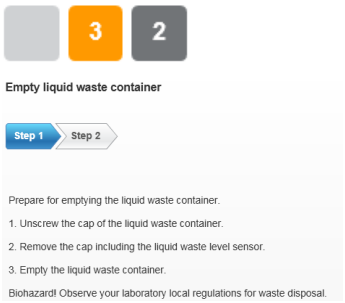
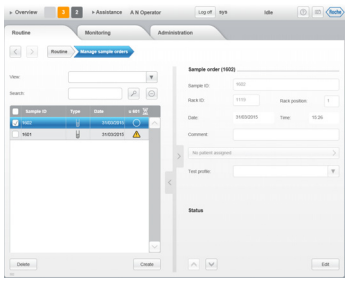
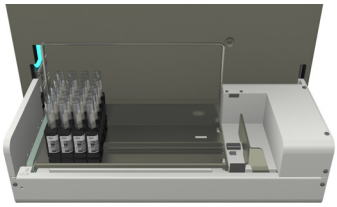
Disconnecting the mains cable while the analyzer is processing may lead to loss of data and hardware damage.

- Do not disconnect the mains cable while the analyzer has not been shut down properly.

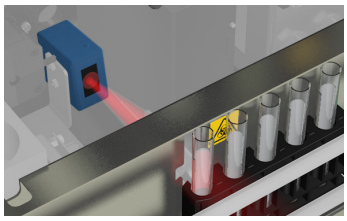
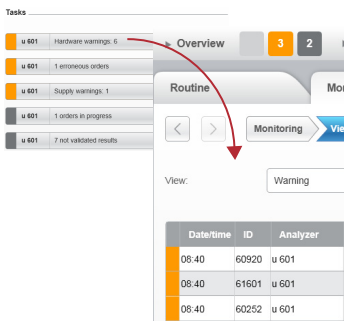
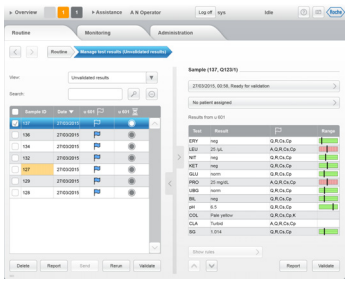
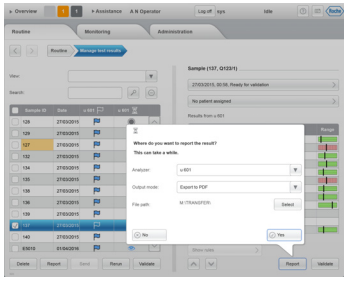
Throughout this documentation, images of screens are included for illustration purposes. They are not necessarily identical with what you see on your analyzer.

Short guide to routine testing

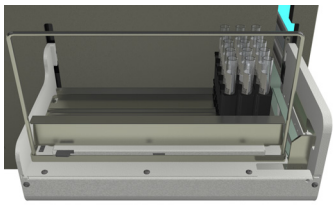
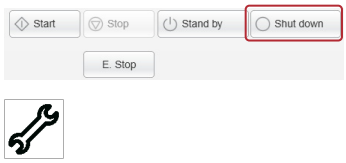
This section provides a short guide to performing routine testing. You can find detailed descriptions of the steps and information on non-routine operating tasks in the subsequent sections.

Step	Task		Procedure
1	Starting the analyzer		1. Ensure that all covers are closed. 2. Power on the analyzer. 3. Wait until the **Overview** work area is displayed. This may take a few minutes.
2	Logging on		1. On the **Overview** work area, choose the **Log on** button. A dialog box is displayed. 2. Enter your user name and password. 3. Choose the **Log on** button. Your name is now displayed in the global information area.
3	Preparing the analyzer		1. On the **Overview** work area, check the task indicator. Address any red and orange items. 2. Check the water container.(1) If it is not full, start the appropriate wizard and fill it. 3. Check the liquid waste container.(1) If it is not empty, start the appropriate wizard and empty it. 4. Check the test strip cassette. If it is nearly empty, ensure that there is a new one available for when the old one needs to be replaced. (1) If you work with external water supply, this step is not required.
4	Defining orders		The orders are defined automatically when the rack and tubes have passed the barcode reader.
5	Loading the samples and racks		• Ensure that the sample barcodes point towards that long side of the rack where the rack barcode is affixed. • Ensure that the rack barcodes point outwards and towards the back of the analyzer when placed on the input buffer. The analyzer detects the presence of the rack tray or of individual racks in the priority and single rack slots and moves a rack onto the rack conveyor. (If you work with an input connection unit, you do not need to load racks manually, it is done automatically.)

Short guide for performing tests

Step	Task		Procedure
6	Start testing		Testing starts automatically.
7	Monitoring the analyzer		1. On the **Overview** work area, check the task indicator and the task list. Address all red or orange items in the task list. 2. Choose a task button. If the message list is displayed, choose a message, check the details, and follow the on-screen instructions. If another panel is displayed, for example the supplies panel, perform the appropriate task, usually a wizard is available. Red: Issues that require immediate operator intervention. Orange: Issues that require early operator intervention, operation may otherwise stop. Gray: Messages that inform about the status of ongoing tasks. If operator intervention is required, perform it. Light gray: There are no issues of the associated severity. 7 The number in a button tells you how many messages of this severity there are.
8	Validating the results		1. Choose **Routine > Manage test results**, if required. 2. Select a result in the list and check for data alarms and the range graphics. Green: negative Yellow: positive (low pathological) Red: positive (pathological) If you work with patient demographics you can assign a patient to each result. Choose the **No patient assigned** button. 3. Choose the **Validate** or **Rerun** button as required. You can set up the analyzer to automatically accept all results or to exclude results from automatic validation if they have certain data alarms associated with them. You can also choose to validate all results manually.
9	Printing or exporting selected or all results		To print selected or all results, choose **Routine > Manage test results**. 1. In the result list, select the check box of all results that you want to print or save to a PDF file. 2. Choose the **Report** button. 3. Choose whether to print the results or save them to a file. 4. Choose the **Yes** button.

Short guide for performing tests

Step	Task		Procedure
10	Printing or exporting the results of selected patients		To print the results of selected patients, choose **Routine > Manage patients**. 1. In the patient list, select the check box of all patients whose results you want to print or save to a PDF file. 2. Choose the **Report** button. 3. Choose whether to print the results or save them to a file. 4. Define which results you want to print. 5. Choose the **Yes** button.
11	Clearing the output buffer		1. Remove the rack tray and replace it with an empty one.
12	Performing end of shift maintenance and shutting down the analyzer		If the next shift does not follow immediately after, perform the following tasks: 1. Archive the results according to your laboratory procedures, if required. 2. Empty the liquid and solid waste containers. 3. Perform the daily wash action and shut down the system. 4. Clean the input and output buffers. 5. Clean the rack conveyors. 6. Clean the test strip tray, test strip transporter, and the test strip pipetting area. 7. Clean the probe bend detector. 8. Remove spills and soiling from the analyzer housing.

Short guide for performing tests

Routine operating tasks

The following sections describe in detail the various tasks you need to perform during routine operation.

In this section

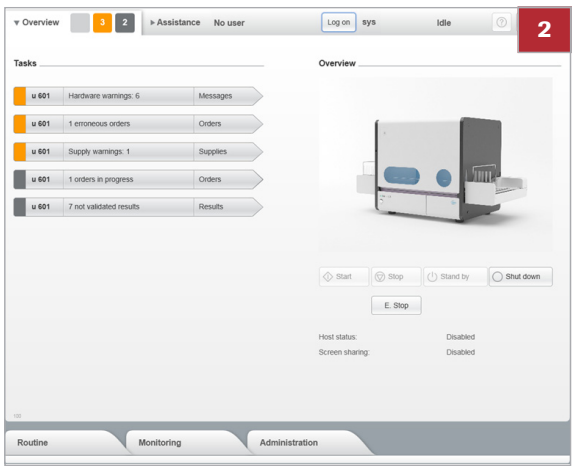
Starting the analyzer

Before you start the analyzer, ensure that the following preconditions are met:

- The analyzer is properly connected to the mains electricity.
- All covers are closed.

To start the analyzer

1 Power on the analyzer.



2 The analyzer software starts automatically. Performing all the initialization and check procedures can take a few minutes. During this process the **Overview** work area is displayed.

Logging on

Results are always associated with the name of the person who operated the analyzer at the time when the test was performed. (This may be a legal requirement for storing results.) Therefore, an operator must be logged on to perform tests.

To log on

1 In the global information area, choose **Log on**.

➔ A dialog box for entering the user name and password is displayed.

2 Enter your user name and password.

Note that both user name and password are case sensitive, this means for example that *O*perator and *o*perator are two different names.

- When you log on for the first time, you may have to change your password. (Whether this is the case depends on how the system is set up.)

Changing the password (240)

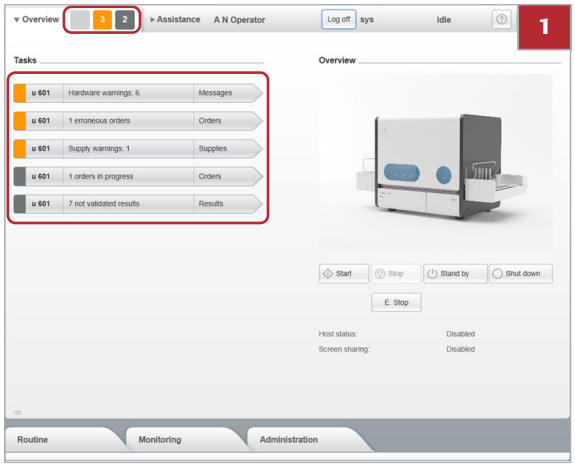
3 Choose the **Log on** button.

➔ Your name is displayed in the global information area.

Preparing the analyzer

The preparation tasks ensure trouble-free uninterrupted processing.

Roche recommends emptying the corresponding waste container whenever you refill supplies.



To prepare the analyzer for test processing

1 On the **Overview** work area, check that there are no red or orange buttons in the task list.

2 Address the issues of all red or orange entries in the task list.

Typical tasks that need doing are emptying waste containers and filling up consumables, and performing QC.

Checking the status of the system (199)

3 CAUTION! Sample mismatch due to pending sample orders
Having pending sample orders in the order list may lead to sample mismatch.
Delete any pending sample orders from the order list before starting the measurement.

On the **Overview work** area, check that there are no pending sample orders in the task list.

- To delete pending sample orders, choose **Routine > Manage sample orders** and delete them from the order list.

4 Choose **Monitoring > Manage supplies**.

5 Check the fill level of the liquid containers (water, liquid waste).

- Choose an entry in the list and check the number of tests that can still be performed.
- To refill the water container, choose **System water > Fill water container**.
- To empty the liquid waste container, choose **Liquid waste > Empty liquid waste container**.

6 CAUTION! Incorrect results due to high ambient humidity
Excessive ambient humidity may influence the chemical reactions of test strips and lead to incorrect results.
Do not store test strip cassettes in their protective packaging once the latter was opened.
After removing them from their protective packaging, always load the test strip cassettes in the test strip cassette compartment within the time defined in the **cobas u** pack Method Sheet.

Choose **Test Strip** and check the number of available tests that can still be performed. Ensure that you have a new test strip cassette available to replace the installed one when it is empty.

7 CAUTION! Loss of results due to resetting the sample sequence number
If you reset the sample sequence number counter, all associated results are deleted.
Only reset the sample sequence number if you do no longer need the results.

If you work with **Sample sequence number** mode, Roche recommends to reset the counter at the beginning of the day:

- Choose **Routine > Manage sample sequence numbers**.
- Choose the **Edit** button.
- In the **Next Sequence No.** area, choose the **Reset** button for both the routine and STAT samples.
  The first number to be used will be the lowest number in the sample sequence number range that is defined.
- Choose the **Save** button.

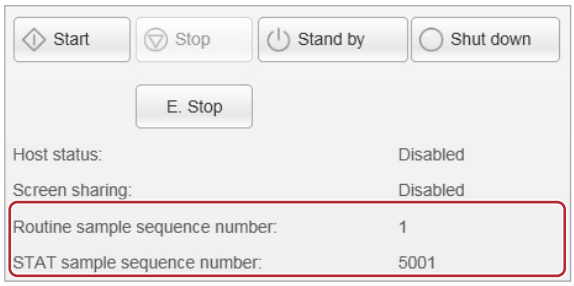
Related topics

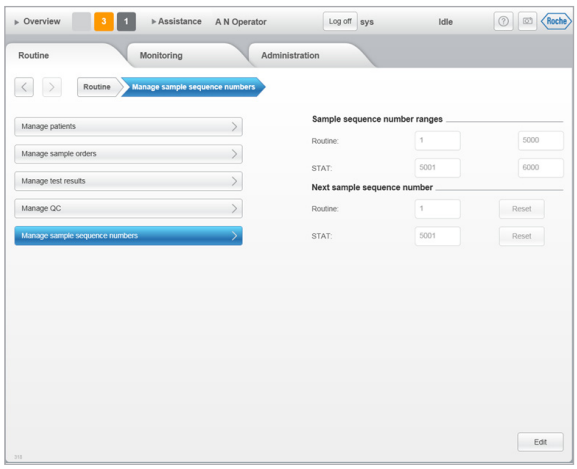
- Defining the sample sequence number ranges (162)

Managing sample sequence numbers

In this section

Defining the sample sequence number ranges





You can either work with barcodes on sample tubes for sample identification or you can use the **Sample sequence number** mode.

The sample sequence number that will be used next is displayed on the **Overview** tab.

To work with **Sample sequence number** mode, the following needs to be set up:

- The analyzer works in **Sample sequence number** mode.

Defining how the sample IDs are generated (258)

- Ranges for sample sequence numbers are defined for routine and STAT samples.

To define the sample sequence number ranges (162)

- The counters for the sample sequence numbers are reset to ensure sufficient available numbers.

To define the sample sequence number ranges

1 Choose **Routine > Manage sample sequence numbers**.

2 Choose the **Edit** button.

3 Enter the lower and upper limits of the sample sequence number range for both the routine and the STAT samples.

ℹ The ranges typically contain enough numbers to cover one day's number of tests.

4 Choose the **Save** button.

Defining the next sample sequence number to be used

The procedure is the same for routine and STAT samples.

To define the next sample sequence number to be used

1 Choose **Routine > Manage sample sequence numbers**.

2 Choose the **Edit** button.

3 To re-start the counter with the lower limit of the range, choose the **Reset** button.
➔ All results are deleted.

4 To use a specific sample sequence number as the next number to use, enter a number from within the defined range.
➔ This number will be the next sample sequence number to be used.

What happens to already used numbers?

If you enter a number lower than the next free sample sequence number, the results of the numbers greater than the one you entered are deleted. For example: The next number would be 150 and you enter 140, the results for numbers 140 to 149 are deleted.

If you enter a number higher than the next free sample sequence number, the numbers between are blocked. For example: The next number would be 150 and you enter 160, numbers 150 to 159 are blocked and cannot be used.

5 Choose the **Save** button.

Defining orders

In this section

Defining orders

The system is designed to operate with rack and sample barcodes. The orders are generated automatically on the basis of the barcode information.

You can also use the analyzer without sample barcodes and use sample sequence numbers for identifying samples.

If you work with a laboratory information system (LIS), the order is downloaded as soon as a sample barcode is read, if you do not work with a LIS the analyzer automatically generates the order.

When working with a host system, non-ASCII characters are converted to spaces. Therefore, if you work with a host system, only use standard ASCII characters.

To define how the sample IDs are generated (258)

When working with Sample sequence number mode

If you work with **Sample sequence number** mode, the number is assigned when the tube is on the measurement position.

⚠ WARNING

Incorrect results due to sample mismatch when working without sample barcodes

When working with **Sample sequence number** mode, it is up to the operating staff to ensure that the sample placement on the racks matches the definitions in the orders.

If the rack number, rack position and sample ID of the order do not agree with the actual racks and positions, the results may not be associated with the correct patient by the medical personnel.

- When working without sample barcodes, be sure to load the samples according to the definitions in the orders.
- Avoid empty positions within the racks. Do not place non-registered samples in any empty rack position.
- When manually assigning rack positions, ensure the position is not already assigned.
- Always follow strictly the rules and regulations for sample preparation and handling that apply to your facility.

To define orders automatically when working with Sample sequence number mode

1 WARNING! Sample mismatch due to inappropriate sample loading
Do not place a routine sample rack on the priority input slot if there are already routine sample racks on the input buffer.

Place the sample tubes on an appropriate rack in the order that agrees with your order sheets.

2 Place the rack on the analyzer.

ⓘ If it is a priority rack, place it on the priority rack slot.

➔ The rack barcode is scanned, the sample sequence number is assigned to each sample when it is on the measuring position, and the orders are automatically defined, using the test profile and validation rules that are currently defined for the analyzer.

Defining an order manually when working with Sample sequence number mode

To define an order manually when working with Sample sequence number mode

1 Choose **Routine > Manage sample orders**.

➔ The samples list is displayed.

2 Choose the **Create** button.

3 Enter the rack ID.

ⓘ You find the 4 digit ID above the rack barcode.

4 Enter the rack position.

5 Enter a comment, if required.

6 If you work with patient demographics choose the **No patient assigned** button to (if necessary define and) assign a patient to the order.

- Select a patient and choose the **Assign** button.
- Choose the **Create** button and fill in the patient demographics, then choose the **Assign** button.

7 Check whether the test profile is correct, if required choose a different profile from the **Test profile** drop-down list.

8 In the detail panel, choose the **Save** button.
➔ The order is now defined.

9 To process the order, place the rack with the sample tube on the correct position on the analyzer.
ℹ If it is a priority rack, place it on the priority rack slot.

Related topics

- Managing patients (196)

Loading racks

In this section

About loading racks

⚠ CAUTION

Personal injury due to contact with moving parts

Racks are moved automatically on the input buffer by the rack pusher. If you place your hands or fingers on the buffer while racks are moved you may get your fingers caught.

- Do not place your hands on the input buffer or the racks while testing is in progress.

NOTICE

Impaired tube content level detection due to metal objects on tubes

Metal objects attached to tubes can impair the functioning of the liquid level detection mechanism.

- Do not attach any materials to tubes other than barcodes.

Stand-alone operation

NOTICE

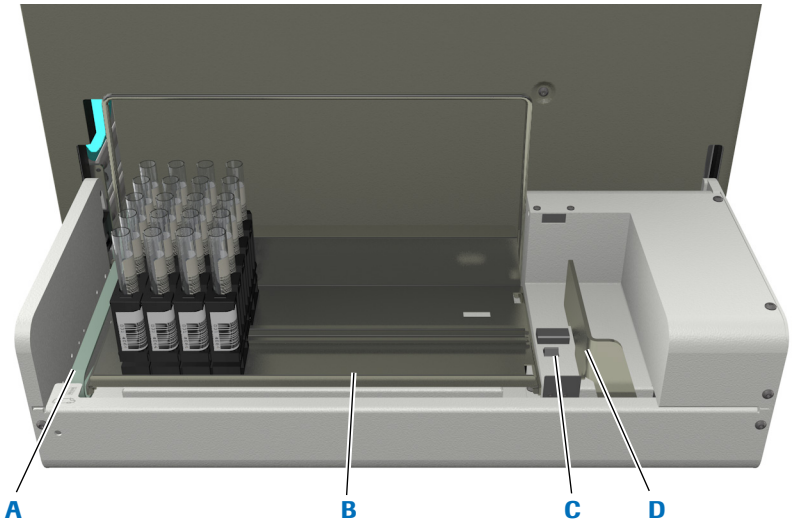
Malfunction and analyzer damage due to obstructions

Placing objects on the rack tray or the input buffer may cause rack jamming and malfunction when moving the racks.

Placing racks or a rack tray on the input buffer when the rack pusher is not in its resting position may cause rack jamming and malfunction.

- Ensure that the rack trays and the input buffer are always free of any foreign objects.
- Do not load racks or rack trays when the rack pusher is not in its resting position.

If you work with an input connection unit, rack loading is done automatically.



A Priority rack slot
B Rack tray
C Single rack slot
D Rack pusher in resting position

Rack loading with input buffer

You have several options for loading racks:

- You can load a rack tray with racks on the buffer (B).
- You can place a single rack on the single rack slot (C).
- You can place a single rack on the priority rack slot (A).

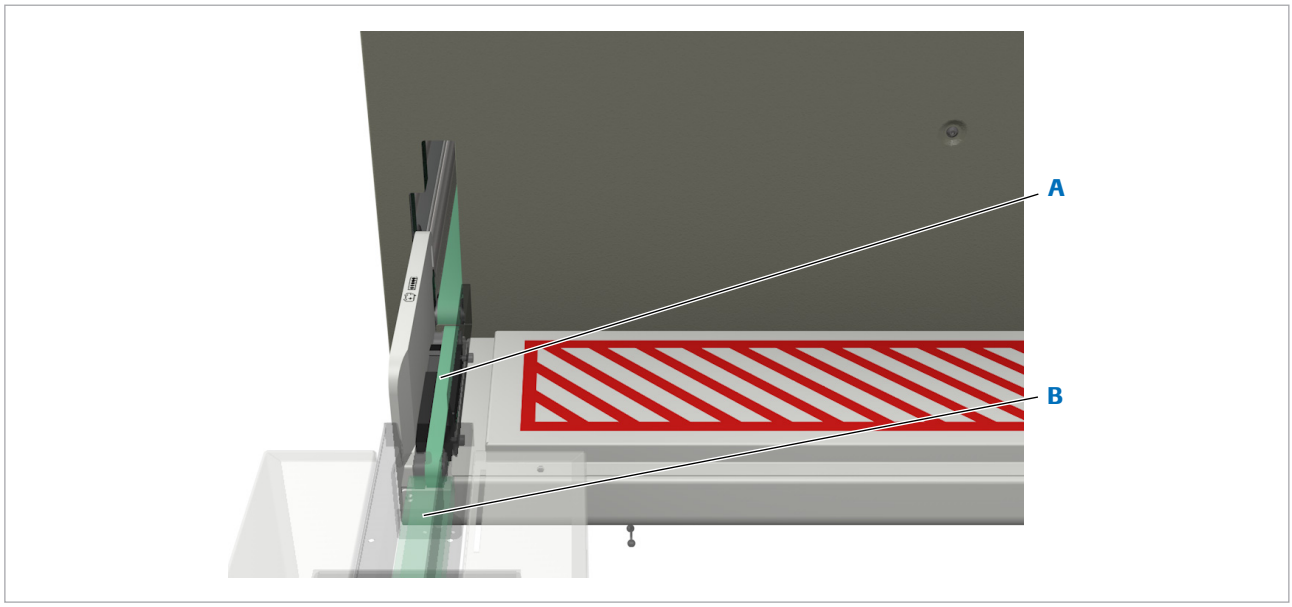
In all cases, the analyzer automatically registers that a rack is present and proceeds to process the rack on the priority rack slot or the one nearest to it.

Ensure that the sample barcodes point towards that long side of the rack where the rack barcode is affixed.

Samples on a rack

Operation with input connection unit

The racks are automatically fed onto the rack conveyor belt of the input connection unit (A) by the rack conveyor belt on the connection line (B).



A Rack conveyor belt of the input connection unit

B Rack conveyor belt of the connection line

Rack loading with an input connection unit

Related topics

- Racks (85)

Priority racks

Any rack that is placed on the priority rack slot is treated as a priority rack.

Ensure that the rack barcode faces you and that sample barcodes point towards that long side of the rack where the rack barcode is affixed.

⚠ WARNING

Incorrect results due to sample mismatch when loading samples on the wrong rack

If you work with **Sample sequence number** mode and place a STAT sample on a routine rack, the next *routine* sample sequence number is assigned to this STAT sample and the sample is processed as a routine sample and not a STAT sample. Equally, if you place a routine sample on a STAT rack, the next *STAT* sample sequence number is assigned to this routine sample and the sample is processed as a STAT sample and not a routine sample.

- Make sure you place every sample on the appropriate rack.

Stand-alone operation

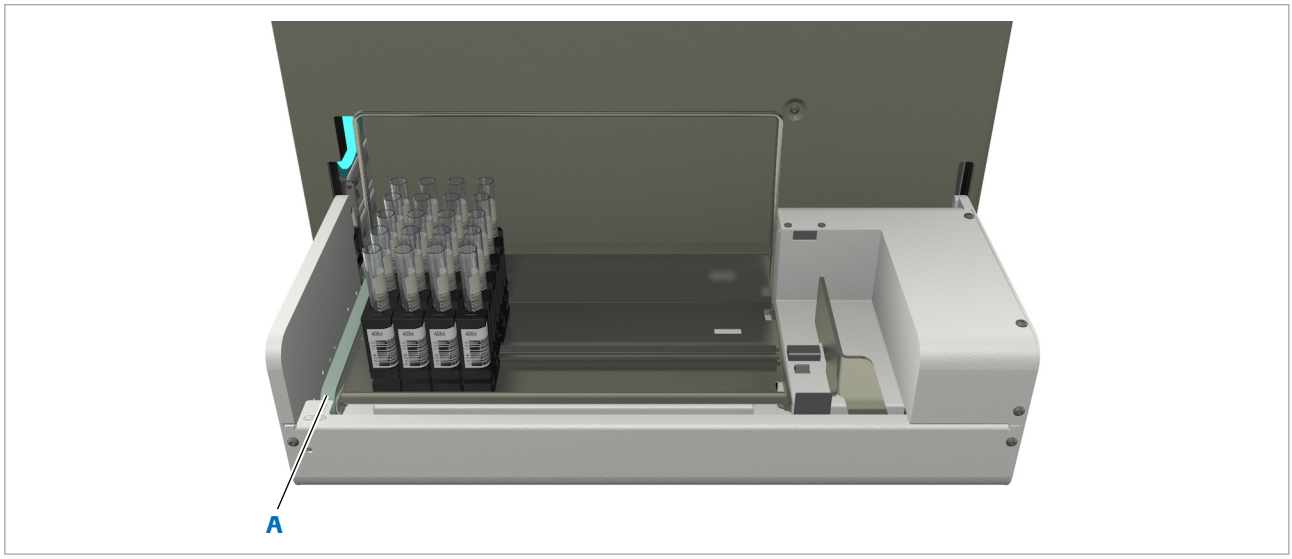
NOTICE

Malfunction and analyzer damage due to inappropriate rack loading

Loading a rack on the priority rack slot while the rack conveyor belt of this slot is moving or when the rack pusher is not in its resting position may cause malfunction of the instrument.

- Do not load a rack on the priority rack slot while the rack conveyor belt is moving.
- Do not load a rack on the priority rack slot if the rack pusher is not in its resting position.

Priority racks are loaded on the priority rack slot (A).



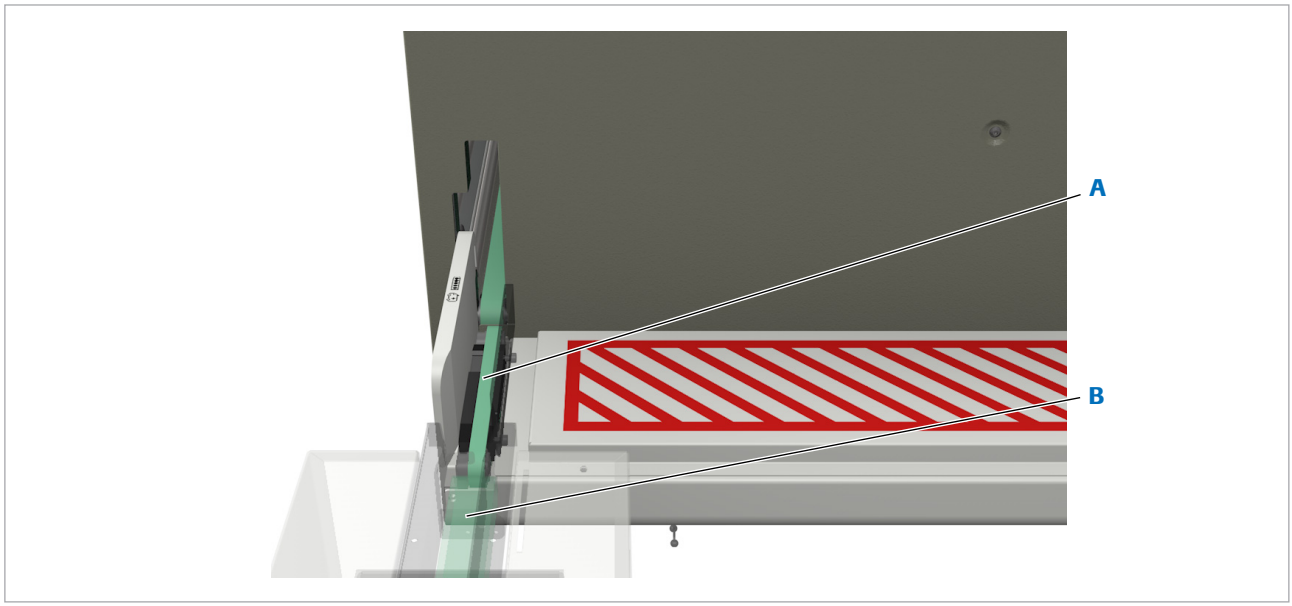
Priority rack slot

Processing of the priority rack starts as soon as all samples of the rack are processed that is currently on the rack conveyor.

Loading a priority rack (172)

Operation with input connection unit

Priority racks are loaded on the rack conveyor belt of the input connection unit (A).



A Rack conveyor belt of the input connection unit

B Rack conveyor belt of the connection line

Rack loading with an input connection unit

To load a priority rack when working with an LAS (173)

Starting the testing process

In this section

Starting sample testing

⚠ CAUTION

Sample mismatch due to pending sample orders

Having pending sample orders in the order list may lead to sample mismatch.

- Delete any pending sample orders from the order list before starting the measurement.

Sample barcode could not be read

If a sample barcode cannot be read, the analyzer automatically defines an order using a generated sample ID and the default test profile. The samples on the rack whose barcodes could be read will be processed as normal.

If you work with a laboratory information system, results of samples whose barcode could not be read are not transmitted to the host computer.

To identify results whose sample barcode could not be read, check the message list and in the result list, check for and for unusual sample IDs.

If you work with **Sample sequence number** mode, the next sample sequence number is assigned to the sample when the tube is on the measuring position.

Non-routine situations (189)

To start sample testing

1 Start sample testing:
   - Place the rack on the input buffer.
   - ➔ Processing starts automatically.

Loading a priority rack

⚠ CAUTION

Personal injury due to contact with moving parts

Racks are moved automatically on the input buffer by the rack pusher. If you place your hands or fingers on the input buffer while racks are moved you may get your fingers caught.

- Do not place your hands on the input buffer or the racks while the analyzer moves racks.
- Do not load racks while the analyzer moves racks on the input buffer.

NOTICE

Malfunction and analyzer damage due to inappropriate rack loading

Loading a rack on the priority rack slot while the rack conveyor belt of this slot is moving or when the rack pusher is not in its resting position may cause malfunction of the instrument.

- Do not load a rack on the priority rack slot while the rack conveyor belt is moving.
- Do not load a rack on the priority rack slot if the rack pusher is not in its resting position.

You can load priority racks any time, as long as the analyzer is not in the process of moving racks on the input buffer.

If you work with **Sample sequence number** mode, the next STAT sample sequence number is assigned to the sample when the tube is on the measuring position, provided you use an assigned STAT rack.

To load a priority rack

1 Place the rack on the priority rack slot. Ensure that the barcodes face towards the back of the analyzer.
➔ Processing starts automatically.

To load a priority rack when working with an LAS

1 On the **Overview** work area, choose the **Priority rack** button.

➔ A callout is displayed, asking you to wait until the current operation is finished.

2 When the message on the callout asks you to do so, place the priority rack on the rack conveyor belt of the input connection unit.

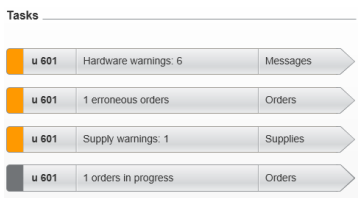
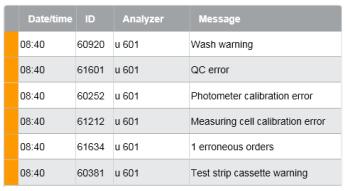
➔ When the rack is placed, the callout disappears and processing starts automatically.

Checking the status of processing

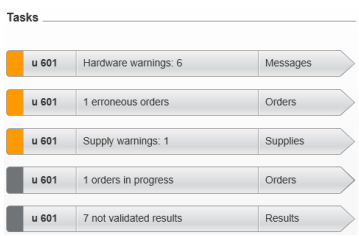
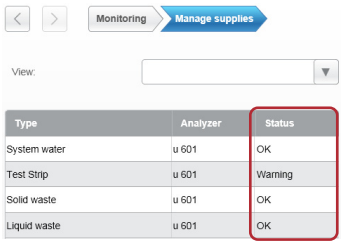
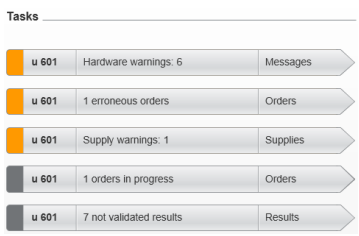
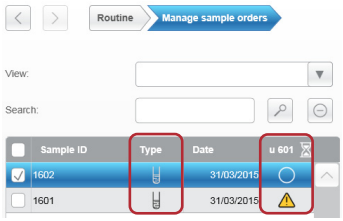
The analyzer constantly monitors the status of its hardware and software components, and it tracks the progress of the testing activities.

The starting point for checking the analyzer status is the task list. The following table provides an overview of the various possibilities that are open to you.

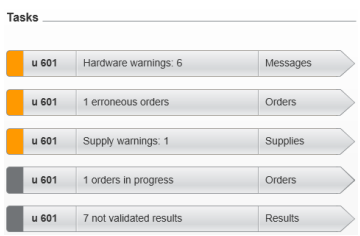
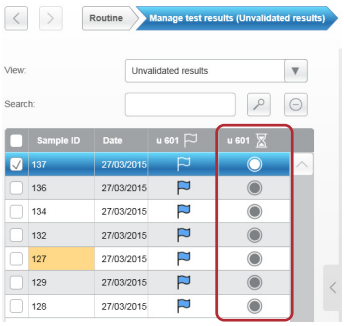
Checking the status of the system (199)

Task list	Tab or panel	Key status elements	
	Message list 	Red	Immediate user intervention is required.
		Orange	Earliest possible user intervention is required.
		Gray	Information about ongoing tasks. If operator intervention is required, perform it.
		Light gray	There are no messages. No operator intervention is required.

Checking the operation status

Task list	Tab or panel	Key status elements	
	Manage supplies 	**Error**	All analyzer activities have stopped. An exceptional hardware situation has occurred, for example a connector is unplugged.
		Alarm	All analyzer activities have stopped. The situation can be resolved by user intervention, for example by refilling some consumable.
		Warning	Operator intervention is required as soon as possible, otherwise processing may stop, for example because the system water level is getting low.
		OK	Everything is fine. No intervention is required.
	Order list 		Pending, measurement has not started yet.
			The order is being processed.
			An error occurred during measurement, no result was generated. (Check the **Status** information in the detail panel. The associated message will give you more detailed information, you may need to rerun the test.)[1][2]
			Order for routine sample testing.
			Order for STAT sample testing.
			Order for QC testing.

Checking the operation status

Task list	Tab or panel	Key status elements
		 The order is being processed.
		 Ready for validation.
		 Validated.
		 Validated and successfully sent to the host computer.
		 An error occurred during measurement, no result was generated. (Check for messages in the message list, you may need to rerun the test.)(1)(2)
		 Result cannot be validated. User intervention is required, check its status.
		Not applicable. No measurement is required on this analyzer.

Tasks

u 601	Hardware warnings: 6	Messages
u 601	1 erroneous orders	Orders
u 601	Supply warnings: 1	Supplies
u 601	1 orders in progress	Orders
u 601	7 not validated results	Results

Result list

Checking the operation status

(1) If more than one erroneous event has occurred that would trigger the error symbol, the associated message describes the event that occurred first.

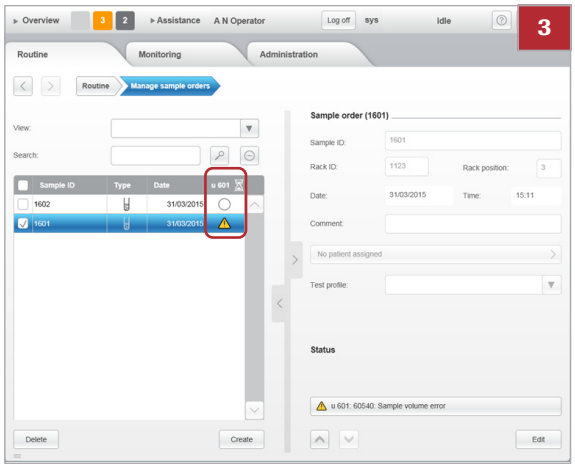
(2) In some cases, an erroneous event has to occur three times before the measurement is stopped. The error symbol is displayed after the first occurrence of such an event.

When all tests of an order have successfully been performed the order is deleted from the orders list.

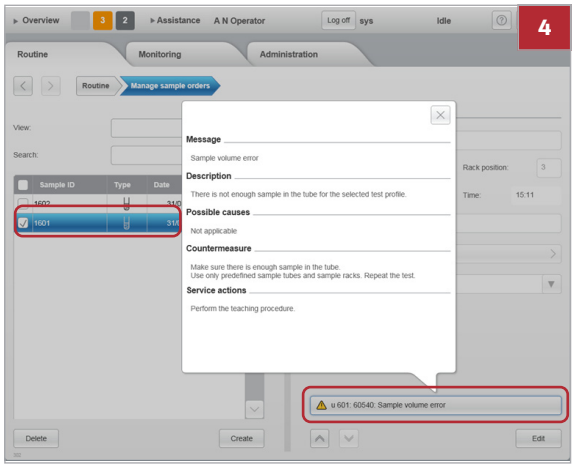
To check the status of order processing

1 Choose **Routine > Manage sample orders**.

2 Choose a view if required or use the search function to find a particular order or group of orders.



3 Display the complete orders list and check the status indicators. (▸ 173)



4 If there are errors:

- Choose the entry in the main panel.
- Choose the **Status** field in the detail panel.

➔ The message details are displayed.

Result handling

⚠ CAUTION

Data loss due to failure of performing regular data backup

The analyzer has limited storage space for results (for up to 10 000 test results, depending on the system setup, and for 300 each for QC, photometer calibration, and measuring cell calibration.

Depending on the analyzer setup, when these limits are reached, the oldest results may automatically be overwritten or testing may stop.

- Periodically back up the database to an external storage device and export the results.

Managing the result storage capacity (292)

In this section

Viewing results

Results are displayed in a dedicated panel, both overview and detail displays are available. Exactly which results are displayed can be defined with the help of views or the text filter.

To view test results

1 Choose **Routine > Manage test results**.

2 To determine which results should be listed, select a view from the drop-down list.

3 To find the results of a certain sample ID or ID range, enter the ID or part of it in the **Search** field and choose .

4 In the main panel, choose the sample whose results you are interested in.
➔ The result is displayed in the detail panel.

5 To view the associated sample information, choose the sample button at the top of the panel.

6 If rules were applied to a result, choose the **Show rules** button to see exactly which.

Validating results

All results need to be validated, the analyzer provides several aids for doing so:

- You can set up the analyzer to automatically accept all results or to exclude results from automatic validation if they have certain data alarms associated with them. You can also choose to validate all results manually.

Defining the validation method (254)

If you work with a laboratory information system, validated results are automatically sent to the host computer.

- In the result list, results that have a data alarm associated with them are marked with in the column.
- If you work with **Sample sequence number** mode, the sample IDs for routine test results are marked with an “N” preceding the sample sequence number, and “E” for STAT test results.
- In the result list, a yellow background in a **Sample ID** field indicates that the SG parameter did not yield a valid result.
- In the result details, the results are color coded to indicate whether the values are normal (green), low pathological (yellow) or pathological (red).
- A red background with a dash in the **SG** result field indicates that the SG parameter did not yield a valid result.
- You can print the results and save them in PDF format.
- You can export the results in CSV format and process them on an external computer.

The examination of the results may lead to further activities.

Rerunning tests (190)

Managing invalid SG results (182)

Generating reports (185)

Non-routine situations (189)

If you work with patient demographics, you need to assign the patients to the results.

Assigning patients (184)

Progress statuses

The order is being processed.

Ready for validation.

Validated.

Validated and successfully sent to host computer.

An error occurred during measurement, no result was generated. (Check for messages in the message list, you may need to rerun the test.)

Result cannot be validated. User intervention is required, check its status.

Data alarms

No data alarm was generated.

! SG result was manually edited.

A Abnormal result.

Cp Calibration. The measuring cell calibration results were no longer valid when the result was generated.

Cs Calibration. The photometer calibration results were no longer valid when the result was generated.

H High temperature. The upper temperature limit has been exceeded.

K The color ranges for the COL parameter were changed.

L Lysed erythrocytes were detected for concentrations ≤50 ERY/µL. (The software cannot reliably identify hemolyzed erythrocytes in concentrations >50 ERY/µL.)

N The SG parameter did not yield a valid result. (If you work with automatic validation and a LIS, the validated results of the other parameters are sent to the host as usual.)

O Parameter is out of range.

P **u 601 reduced** test profile.

Q Invalid QC. QC failed or QC material has expired.

R Test strip cassette onboard stability has expired.

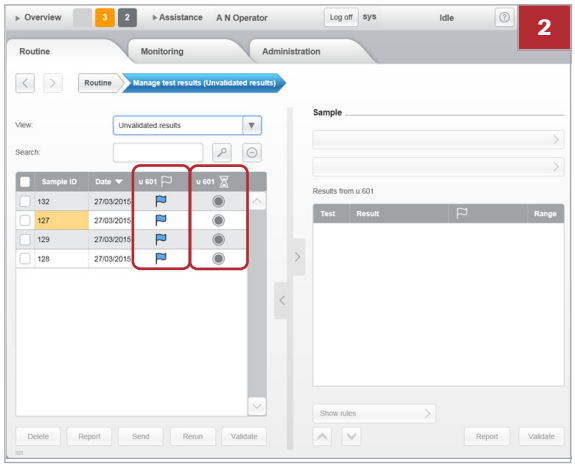
S Sieve result.

T Trace result. Borderline or "soft positive" result.

X A cross-check rule has been triggered.

A Roche Service representative did not cancel a service or troubleshooting function, and it can only be canceled by a Roche Service representative. All results have this data alarm and the validity of these results cannot be guaranteed. (For example, expired materials may have been used).
If you find this data alarm, contact your Roche Service representative immediately.

To validate a result



1 Choose **Routine > Manage test results**.

2 From the **Views** drop-down list, choose **Unvalidated results**.

➔ All results that have not been validate are listed.

➔ If your analyzer is connected to a LIS, all validated results are automatically sent to the host computer and would not be displayed in the result list.

➔ Results for which a data alarm was generated are marked with in the column.

➔ In the column, the progress status is indicated.

For more information on progress statuses, see the following section:

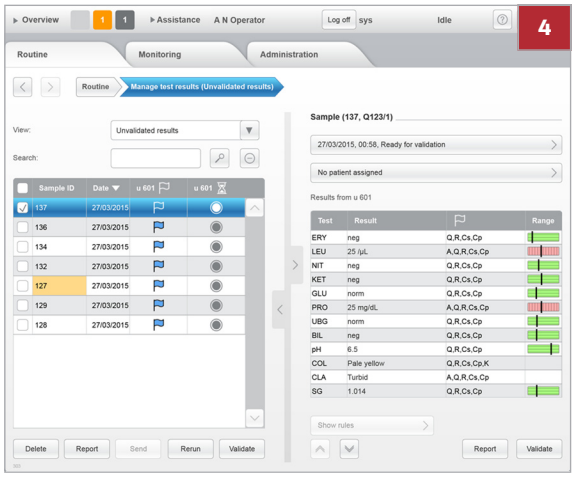
Progress statuses (179)

3 In the result list, check for visual cues and unusual sample IDs.

- indicates that the result cannot be validated. User intervention is required, check its status. The status for these results is **Action required**. See step **5**.
- If you work with **Sample sequence number** mode, the sample IDs for routine test results are marked with an “N” preceding the sample sequence number, and “E” for STAT test results.
- In the result list, a yellow background in a **Sample ID** field indicates that the SG parameter did not yield a valid result.
- A red background with a dash in the **SG** result field indicates that the specific gravity did not yield a valid result.

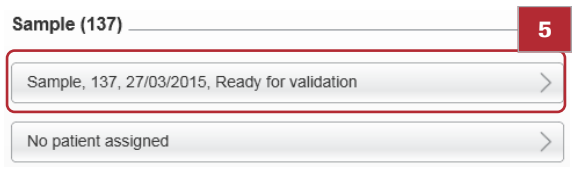
In cases where the sample barcode could not be read, you must define the sample ID as defined in the barcode before you can validate the result.

Adjusting sample information (194)



4 In the main panel, check for entries with a ⚑ symbol and choose one.

ℹ The results are displayed in the detail panel.



5 Observe the status information in the detail panel.

The **Action required** status may have the one of the following reasons:

- The barcode could not be read. You need to enter the correct barcode information manually.
- There already exists an order for this result. Delete the order or rerun the test.

Non-routine situations (189)
Rerunning tests (190)

6 Check for data alarms in the ⚑ column.

For more information on data alarms, see the following section:

Data alarms (179)

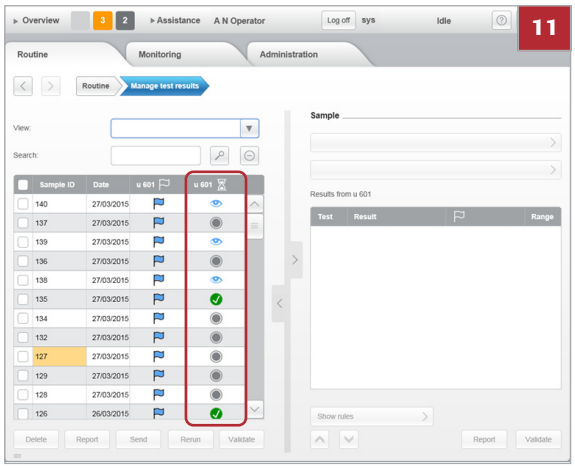
7 Check the **Information** column.

Whether there is an **Information** column depends on the measurement units you work with.

For more information, see:

Defining the units in which results are displayed and reported (253)

8 To add a comment, choose the **Edit** button in the detail panel.



9 When you have entered the comment, choose the **Save** button.

10 If there is an **X** entry in the ⚑ column, a rule was triggered and the **Show rules** button would be available. Choose the **Show rules** button to see which rules were triggered.

11 To validate the result, choose the **Validate** button.
➔ Accepted (validated) results are marked with ✓ in the status column in the result list.

12 To manually send validated results, select them in the results list and choose the **Send** button.

If you work with a laboratory information system, validated results are automatically transmitted to the host computer.

Validated results that were successfully sent to the host computer are marked with the ✓ symbol.

Managing invalid SG results

If the sample is very turbid, no SG results can be generated. In such cases, you can measure SG using a standard refractometer or a dedicated test strip and enter the result manually on the analyzer.

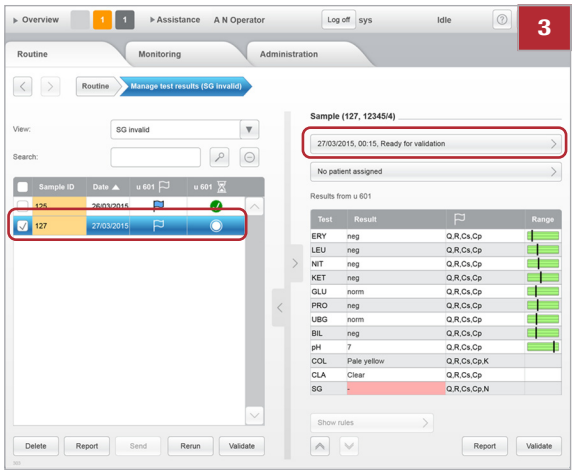
To be able to deal with invalid SG results, the analyzer must be set up not to automatically validate results with invalid SG results. There is a validation rule for this purpose.

Defining the validation method (254)

To identify samples with an invalid SG result

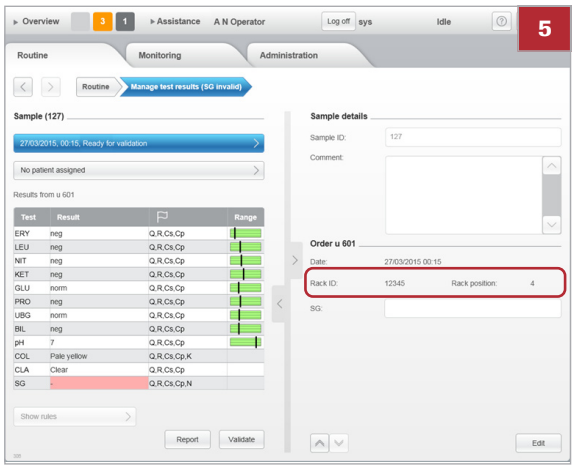
1 On the analyzer, choose **Routine > Manage test results**.

2 Choose the **SG invalid** view.



3 In the main panel, choose the entry of a sample with an invalid SG, it is marked yellow .

4 In the detail panel, choose the sample button at the top of the panel.



5 In the detail panel, note the rack ID and sample position.

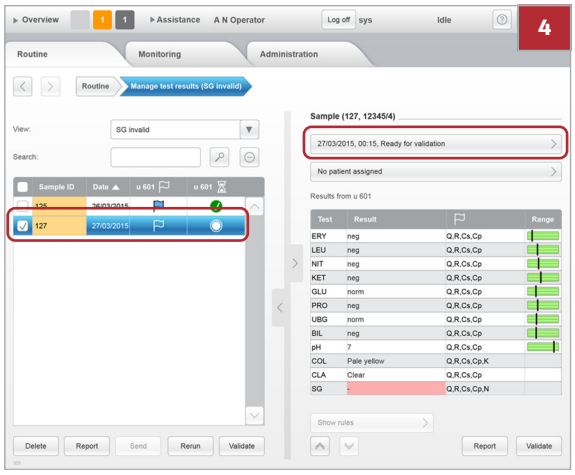
➔ You can now measure SG for this sample manually.

To manually enter the SG result

1 Measure the SG using a refractometer or a dedicated strip.

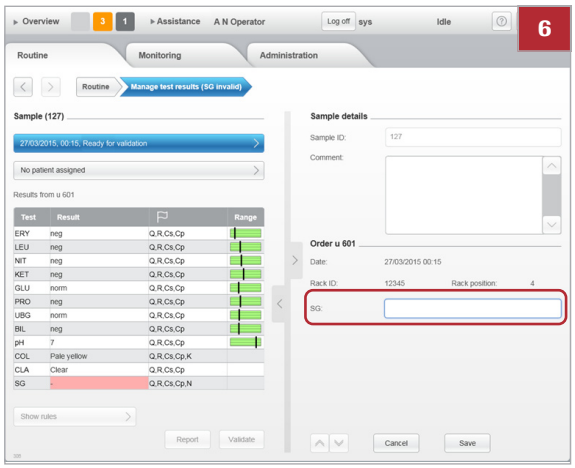
2 On the analyzer, choose **Routine > Manage test results**.

3 Choose the **SG invalid** view.



4 In the main panel, choose the entry of the sample whose SG you just have measured.

5 In the detail panel, choose the sample button at the top of the panel.



6 In the detail panel of the result details screen, choose the **Edit** button.

7 In the **SG** field, enter the result.

ℹ You can enter values in the range of 1.000 to 1.050.

8 Choose the **Save** button.

9 In the main panel of the result details screen, choose the **Validate** button.

Assigning patients

You typically use patient demographics if you want to generate a patient report for the physician.

▸ Managing patients (196)

▸ Generating reports (185)

If the patient data is sent from the host to the analyzer, then the patient data cannot be changed on the analyzer. You can view and delete patient data.

▸ To assign a patient to a result

1 Choose **Routine > Manage test results**.

2 In the result list, choose the result to which you want to assign a patient.

➔ The result details are displayed in the detail panel.

3 In the detail panel, choose the **No patient assigned** button.
   ➔ A list of defined patients is displayed.
   ➔ If there is already a patient assigned and you want to change it, choose the button containing the patient name instead of **No patient assigned**, then proceed as described below.

4 Select the patient by selecting the check box next to its name.
   ⓘ To unassign a patient, clear the check box.

5 Choose the **Assign** button.
   ➔ The result list is displayed again, and the patient is indicated in the detail panel.

Generating reports

You can print selected results or save them to a file in PDF format. You can also export the results in the character separated values (CSV) data format for reporting purposes or for processing in a spreadsheet program.

To export all results (293)

Result report

To print or save to file results of certain samples, you can filter and select results in the result list.

To print results (result report) (186)
To save results to files (result report) (186)

Patient report

To print or save to file results of certain patients, you can select the patients in the patient list and then choose which results of these patients you want to report.

To print results (patient report) (186)
To save results to files (patient report) (187)

The analyzer can be connected to a network or directly to a printer.

Defining the look, content, and handling of reports (274)

To print results (result report)

1 Choose **Routine > Manage test results**.

2 Select the results that you want to print.

Use the **View** or **Search** function if required and select one or several samples.

About filtering table information (136)

3 Choose the **Report** button.
➔ A callout is displayed.

4 From the **Output mode** drop-down list, choose **Print** to print the results on your default printer.

5 Choose the **Yes** button.
➔ The results are printed.

To print results (patient report)

1 Choose **Routine > Manage patients**.

2 Select the patients whose results you want to print.

Select one, several or all check boxes.

About filtering table information (136)

3 Choose the **Report** button.
➔ A callout is displayed.

4 Select one of the **Result selection** options.

5 From the **Output mode** drop-down list, choose **Print** to print the results on your default printer.

6 Choose the **Yes** button.
➔ The results are printed.

To save results to files (result report)

1 Choose **Routine > Manage test results**.

2 Select the results that you want to export.

Use the **View** or **Search** function if required and select one or several samples.

About filtering table information (136)

3 Choose the **Report** button.
➔ A callout is displayed.

4 Using the **Output mode** drop-down list, define where the results should be saved to.
- To save the results in a file in PDF format, choose **Export to PDF**.
- If you want to save the data to a location other than the default location, choose the **Select** button and define the file location. (This can either be a USB storage device connected with the USB port, preferably on the front of the instrument, or a mapped network path.)

For information on the USB port location, see the following illustration:
Main components (69)

5 Choose the **Yes** button.
➔ The results are saved to files.

To save results to files (patient report)

1 Choose **Routine > Manage patients**.

2 Select the patients whose results you want to print.

Select one, several or all check boxes.
About filtering table information (136)

3 Choose the **Report** button.
➔ A callout is displayed.

4 Select one of the **Result selection** options.

5 Using the **Output mode** drop-down list, define where the results should be saved to.
- To save the results in a file in PDF format, choose **Export to PDF**.
- If you want to save the data to a location other than the default location, choose the **Select** button and define the file location. (This can either be a USB storage device connected with the USB port, preferably on the front of the instrument, or a mapped network path.)

For information on the USB port location, see the following illustration:

Main components (69)

6 Choose the **Yes** button.

➔ The results are saved to files.

Non-routine situations

The examination of the results and the messages in the message list may point to one of the following situations.

Situation	Possible tasks	See …
Questionable result	Rerun the test.	Rerunning tests (190)
	Perform maintenance actions as indicated in a message in the message list and then rerun the test.	
Sample barcode could not be read	If a normal result was generated: • Select the result and correct the sample ID before you validate the result.	Adjusting sample information (194)
	If a normal result was generated and you work with a LIS: • Obtain the correct order information from the LIS or someone with access to the LIS. • Select the result, correct the order information and add a comment before you validate the result. Note that such results are only transmitted to the host if the sample and order information agrees with the information of the LIS order.	
	• If the test that was performed does not agree with the one defined in the LIS order, rerun the test.	Rerunning tests (190)
	If a questionable result was generated: • Rerun the test using the **Rerun** function.	Rerunning tests (190)
	If no result was generated: • Adjust the order information and reload the sample. • Make sure you are using a type of rack that is recommended by Roche.	Rerunning tests when working with sample barcodes (190) Adjusting sample information (194) Tubes (84)
Rack barcode could not be read	1. Remove the rack from the output buffer. 2. Check the barcode for soiling, clean it. If you could clean it, reload the rack. 3. If the barcode looks damaged, transfer the tubes to another rack and load the new rack.	

Exceptional processing situations

In this section

Rerunning tests

You would typically rerun a test if no result could be generated or if you want to retest the sample with a different test profile.

To rerun a test that yielded a result you use the **Rerun** function. To rerun a test that did not yield a result, you need to re-define the associated order first.

(If you work with sample barcodes and rerun a test for a sample using the same barcode, the second result overwrites the first result, provided it has not been validated yet.)

In this section

Rerunning tests when working with sample barcodes

You can rerun a test as long as its results have not been validated.

Situation before rerun	What you need to do	What the analyzer does
The test has yielded a result.	• Choose **Routine > Manage test results**.	
	• From the result list, choose the result.	
	• Choose the **Rerun** button.	A callout is displayed
	• In the callout, choose the test profile, then choose the **Create order** button	The new order is added to the orders list.
	• Place the sample tube on a rack, then load the rack.	The test is performed.
The test has *not yielded* a result.	• Check the message in the message list.	A message alerts you of the fact that no result was generated. The order is still on the analyzer.
	• Choose **Routine > Manage sample order**.	
	• In the main panel, choose the order.	
	• In the detail panel, choose the **Edit** button.	
	• Choose the test profile, if required.	
	• Choose the **Save** button.	
	• Place the sample tube on a rack, then load the rack.	The test is performed.

Rerunning tests when working with sample barcodes

Situation before rerun	What you need to do	What the analyzer does
The sample yielded results and the results are already validated	• Make a note of the sample IDs of the samples you want to rerun.	The orders are no longer available in the orders list.
	• Choose **Routine > Manage test results**.	
	• Delete the results of the samples you want to rerun.	
	• Place the sample on the rack, then load the rack.	The test is performed.
	If you want to change the test profile:	
	• Make a note of the sample IDs of the samples you want to rerun.	The orders are no longer available in the orders list.
	• Choose **Routine > Manage sample orders**.	
	• Choose the **Create** button.	
	• Enter the *original sample ID*.	
	• Choose the test profile, if required.	
	• Assign the patient, if required.	
	• Choose the **Save** button.	The new order is created.
	• Place the sample on the rack, then load the rack.	The test is performed.

Rerunning tests when working with sample barcodes

Situation before rerun	What you need to do	What the analyzer does
The sample does not have a barcode label, the test has yielded a result and the result has been validated.	• Make a note of the sample IDs of the samples you want to rerun.	The orders are no longer available in the orders list.
	• Choose **Routine > Manage test results**.	
	• Delete the results of the samples you want to rerun.	
	• Choose **Routine > Manage sample order**.	
	• Choose the **Create** button.	
	• Enter the *original* sample ID.	
	• Enter the rack ID.	
	• Enter the rack position.	
	• Choose the test profile, if required.	
	• Assign a patient, if required.	
	• Choose the **Save** button.	A new order is created.
	• Be sure to place the sample on the rack and position as defined above, then load the rack.	The test is performed.

Rerunning tests when there is no barcode label and there is an already validated result for the test

Rerunning tests when working with Sample sequence number mode

You can rerun a test as long as its results have not been validated.

The following table lists a few typical situations and it illustrates how the analyzer reacts in these situations and what you need to do to rerun a test.

Situation before rerun	What you need to do	What the analyzer does
The test has yielded a result (not validated)	• Choose **Routine > Manage test results**.	
	• Select the result in question. (You can select more than one result.)	
	• Choose the **Rerun** button.	A callout is displayed.
	• In the callout, choose the test profile, then choose the **Create order** button.	A new order is created. (If you selected more than one result, a new order is created for each of them.)
	• Choose **Routine > Manage sample orders**.	
	• Select the order that was just created.	
	• In the detail panel, choose the **Edit** button.	The original sample ID and the current date and time are contained in the form. (You cannot change this ID if you work with **Sample sequence number** mode.)
	• Enter the rack ID.	
	• Enter the rack position.	
	• Assign the patient, if required.	
	• Choose the **Save** button.	The new order is created.
	• Be sure to place the sample on the rack and position as defined above, then load the rack.	The test is performed.
The test *has not* yielded a result	• Choose **Routine > Manage sample orders**.	The order remains in the orders list.
	• In the detail panel, choose the **Edit** button.	The original sample ID and the current date and time are contained in the form. (You cannot change this ID if you work with **Sample sequence number** mode.)
	• Enter the rack ID.	
	• Enter the rack position.	
	• Choose the test profile, if required.	
	• Assign the patient, if required.	
	• Choose the **Save** button.	The new order is created.
	• Be sure to place the sample on the rack and position as defined above, then load the rack.	The test is performed.

Rerunning tests when working with Sample sequence number mode and without sample barcodes

Situation before rerun	What you need to do	What the analyzer does
The sample yielded results and the results are already validated	• Make a note of the sample IDs of the samples you want to rerun.	The orders are no longer available in the orders list.
	• Choose **Routine > Manage test results**.	
	• Delete the results of the samples you want to rerun.	
	• Choose **Routine > Manage sample orders**.	
	• Choose the **Create** button.	
	• Enter the rack ID.	
	• Enter the rack position.	
	• Choose the test profile, if required.	
	• Assign the patient, if required.	
	• Choose the **Save** button.	The new order is created. It gets the next free sequence number, the deleted sequence number cannot be re-used.
	• Be sure to place the sample on the rack and position as defined above, then load the rack.	The test is performed.
The STAT sample was placed on a routine rack	• Choose **Routine > Manage test results**.	
	• Select the sample and choose the **Rerun** button.	
	• Choose **Routine > Manage sample orders**.	
	• Select the order and choose the **Edit** button.	
	• Adjust the rack ID and the rack position.	The STAT rack ID is entered. Order type is set to STAT.
	• Place the rack on the priority rack slot.	The rack barcode is read and the sample is processed.
The routine sample was placed on a STAT rack	• Choose **Routine > Manage test results**.	
	• Select the sample and choose the **Rerun** button.	
	• Select the order and choose the **Edit** button.	
	• Adjust the rack ID and the rack position.	The routine rack ID is entered. Order type is set to routine.
	• Place the rack on the priority rack slot.	The rack barcode is read and the sample is processed.

Rerunning tests when working with Sample sequence number mode and without sample barcodes

Situation before rerun	What you need to do	What the analyzer does
You detect a sample mismatch and need to rectify the situation.	Reset the sample sequence number and run all tests of the rack again.	
	• Choose **Routine > Manage sample sequence numbers**.	
	• Choose the **Edit** button.	
	• As the **Next sequence No.**, enter the lowest sample sequence number that was used for samples on the rack. Enter it in either the **Routine** or **STAT** entry field, as appropriate.	If you enter a number lower than the next free sample sequence number, the results of the numbers greater than the one you entered are deleted. For example: The next free sample sequence number is 150 and you enter 140, the results for numbers 140 to 149 are deleted. If you enter a number higher than the next free sample sequence number, the numbers between are blocked. For example: The next free sample sequence number is 150 and you enter 160, numbers 150 to 159 are blocked and cannot be used.
	• Choose the **Save** button.	
	• Place the tubes in the correct potions on the rack.	
	• Load the rack.	New sample sequence numbers are assigned to the samples and the tests are processed.

Rectifying sample mismatch

Adjusting sample information

You need to adjust the sample information if the sample barcode could not be read and the analyzer generated a default sample ID.

This situation is indicated by the icon in the column of the result list.

To change the sample ID

1 Choose **Routine > Manage test results**.

2 Select the result for which you want to change the sample ID.

3 At the top detail panel, choose the sample button.

4 In the detail panel, choose the **Edit** button.

5 In the **Sample ID** field, enter the new sample ID.

6 Choose the **Save** button.

Managing patients

Patient demographics can be defined separately or when you assign patients. You can assign patients to results and orders, and you can change patient demographics later.

If the patient data is sent from the host to the analyzer, then the patient data cannot be changed on the analyzer. You can view and delete patient data.

Assigning patients (184)

To define a new patient

1 Choose **Routine > Manage patients**.

2 Choose the **Create** button.
➔ In the detail panel the callout for entering information is displayed for the first information item that needs to be defined, i.e. the patient's first name.

3 Enter the first name and choose the Enter key.
➔ The virtual keyboard for entering the last name is displayed.

4 Enter the last name and choose the Enter key.
➔ The calendar for defining the date of birth is displayed.

5 Define the date of birth.
- From the year drop-down list, select the year.
- From the month drop-down list, select the month.
- In the calendar, select the day.
- Close the callout.

6 From the **Gender** drop-down list, choose the gender.

7 If you want to define the patient's physician, select the **Ordering doctor** field and in the virtual keyboard enter the doctor's name, then choose the Enter key.
➔ The callout for entering a comment is displayed.

8 Enter a comment, if required, then choose the Enter key.

9 Choose the **Save** button.

To change patient demographics

1 Choose **Routine > Manage patients**.

2 In the patient list, choose the patient name whose data you want to change.

3 In the detail panel, choose the **Edit** button.
➔ You can now select the fields and change their content.

4 Select a field whose content you want to change.
➔ The virtual keyboard is displayed.
➔ Enter the required information or choose it from lists.

5 Change all fields that need changing in the same way.

6 Choose the **Save** button.

To delete patient demographics

1 Choose **Routine > Manage patients**.

2 In the patient list, choose the patient name whose data you want to delete.

3 Choose the **Delete** button.

4 On the callout, confirm the deletion.
➔ All data relating to this patient are deleted, including its association with results.

Routine maintenance actions

In this section

About routine maintenance actions

The following sections describe how to perform the maintenance actions that you may have to perform during routine testing.

NOTICE

Malfunction due to failure of performing due maintenance actions

Failing to perform maintenance actions that are due may impair the functioning of the analyzer.

- Always perform all maintenance actions as soon as they become due.

NOTICE

Damage to the analyzer due to use of inappropriate cleaning solution

Using inappropriate cleaning solutions may damage the parts you cleaned.

- Only use recommended cleaning solutions.

  Cleaning solutions (119)

- Never use the wash solution for manually cleaning the analyzer.

These are the maintenance actions you routinely need to perform:

- Checking the status of the system (199)
- Washing the fluid system (203)
- Air purge (204)
- Filling the water container (205)
- Emptying the liquid waste container (206)
- Emptying the solid waste container (207)
- Replacing the test strip cassette (208)

Checking the status of the system

The analyzer constantly monitors the status of its hardware and software components, and it tracks the progress of the testing activities. Various sensors and counters allow the monitoring of fill levels and the determination of dates when maintenance actions are due.

To check for tasks that need doing you can use the **Tasks** and **Overview** groups in the **Overview** work area.

Task list in the Overview work area

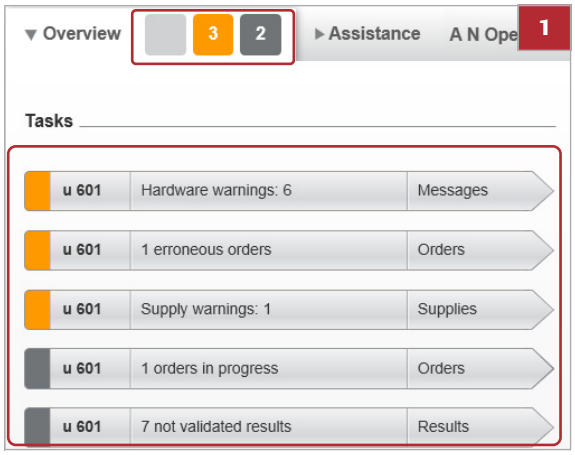
In this section

Checking the status of order processing

To check the status of order processing

1 Follow the instructions in *Checking the status of processing* (173).

Checking for tasks that require intervention

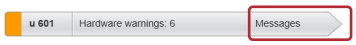


To check for tasks that require intervention

1 Check the task indicator and the task list in the **Overview** work area for red or orange items.

The messages and tasks that are represented by the buttons are grouped first by their analyzer, then by their thematic category (supply, messages, orders, results) and then their priority.

In the rightmost part of a task button, there is indicated which panel will be displayed if you choose it (message list or a panel for managing either the supplies, the orders, or the results).



2 Choose a red or orange task button.

3 Deal with the issues.

- In the message list, choose a red or orange message. In the detail panel a description of the issue is displayed, together with possible causes and remedies. If a wizard is available its button would be displayed as well.
- In the supplies list, choose a task with a status *other than* **OK**. (202)
- In the orders list, make the necessary adjustments. (165)
- In the result list, check for unusual results. (177)

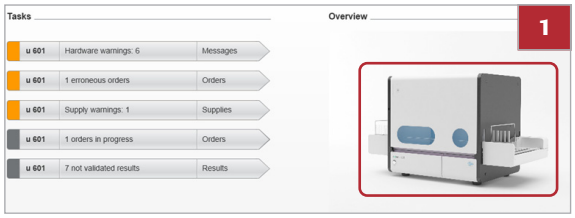
4 Deal with the issues until there is no red or orange task button.

Checking the current hardware status

Color	Meaning
Red	There is at least one issue that requires immediate operator attention. Operation may have stopped.
Orange	There is at least one issue that requires early operator attention. Operation may otherwise stop.
Light gray	There are no current issues. The hardware element works fine.

Color coding for hardware elements

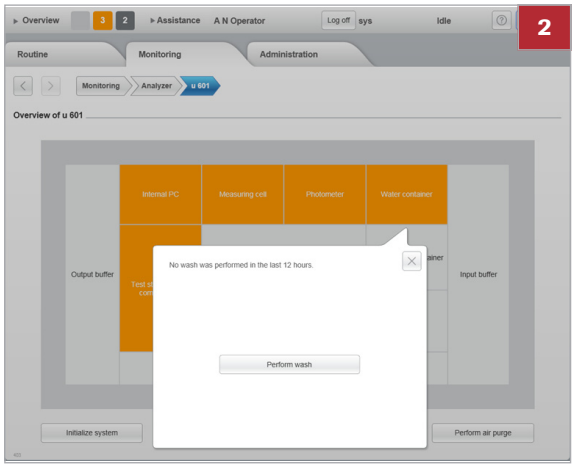
To check the current hardware status



1 In the **Overview** work area, choose the analyzer in the **Overview** illustration.
   - ➔ A schematic representation of key hardware elements is displayed.
   - ➔ The color of the elements represents the severity of the underlying issues.

For more information on element colors, see the following table:

Color coding for hardware elements (201)



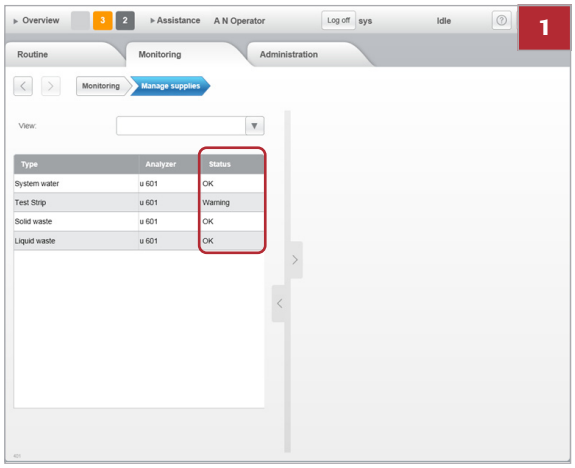
2 In the analyzer overview, choose a colored element.
   - ℹ A callout is displayed containing a description of the issue and possibly a wizard button. The described issue is the one with the highest priority.

3 Address the issues as described on screen.

Checking the status of supplies

Status	Meaning
Error	All analyzer activities have stopped. An exceptional hardware situation has occurred, for example a connector is unplugged.
Alarm	All analyzer activities have stopped. The situation can be resolved by user intervention, for example by refilling some consumable.
Warning	Operator intervention is required as soon as possible, otherwise processing may stop, for example when the system water level gets low.
OK	Everything is fine. No intervention is required.

List of statuses



To check the status of supplies

1 Choose **Monitoring > Manage supplies**.

ℹ In the **Status** column, the status is indicated.

For more information on statuses, see the following table:

List of statuses (202)

2 In the main panel, choose an item.

➔ In the detail panel, information such as fill levels are displayed. If user intervention is required, a wizard button is displayed at the bottom of the detail panel.

3 Choose the wizard button at the bottom of the detail panel to deal with the issue.

Washing the fluid system

The fluid system must be washed daily with wash solution to prevent proteinization and buildup of other pollutants in the probe and the fluid system.

The fluid system is typically washed in the following situations:

- As part of shutting down the system.

Shutting down the analyzer (212)

- When a message in the message list indicates that this action is due.

During the fluid system wash, the analyzer performs the following actions:

1. The rack ID is scanned, the rack is recognized as a wash rack.
2. Wash solution is aspirated.
3. The probe is lowered into the rinse station and solution is pumped into the probe chamber.
4. The solution remains in the tubing, probe, and probe chamber for a predefined amount of time to dissolve any residues.
5. The wash solution is pumped into the liquid waste container.
6. The whole fluid system is rinsed with water.

Wash racks

Be sure to use a defined wash rack. If you use a different rack, the analyzer will treat the wash solution as a normal sample and perform tests on it.

☐ A wash rack is defined.

☐ Wash solution is available.

To define a wash rack (280)

Wash solution (118)

To wash the fluid system

1 Prepare the wash rack.

- Fill a tube with at least 4 mL of wash solution and place it on the wash rack.

2 Place the wash rack on the input buffer, if the wash should be performed immediately, place it on the priority rack slot.

➔ The wash action starts automatically.

3 When the wash is complete, remove the wash rack from the output buffer, dispose of the left-over wash solution according to the relevant local regulations and store the rack in its accustomed place.

To wash the fluid system when working with an LAS

1 Prepare the wash rack.
   - Fill a tube with about 4 mL of wash solution and place it on the wash rack.

2 On the **Overview** work area, choose the **Priority rack** button.
   ➔ A callout is displayed, asking you to wait until the current operation is finished.

3 When the message on the callout asks you to do so, place the prepared wash rack on the rack conveyor belt of the input connection unit.
   ➔ When the rack is placed, the callout disappears and processing starts automatically.

4 When the wash is complete, remove the wash rack from the output buffer, dispose of the left-over wash solution according to the relevant local regulations and store the rack in its accustomed place.

Air purge

Air purge is periodically performed to remove any possible air pockets in the tubing. This is achieved by pumping system water through the whole fluid system. You may also need to perform this action as a result of a message in the message list or as part of troubleshooting.

To define how frequently automatic air purge is performed see Defining the operating environment (268).

Air purge is normally performed automatically, without operator intervention.

To perform air purge

1 Start the air purge maintenance action.
- In the message list, choose the message that indicates that air purge is due, then choose the **Perform air purge** button in the detail panel.
- Choose **Monitoring > Analyzer > u 601**, then choose the **Perform air purge** button.

➔ The maintenance action is started.

2 Wait until the system status changes to **Idle**.

Filling the water container

The fill level is continuously monitored and when the level is getting low, a message is added to the message list. When the water container is empty processing stops and another message is added to the message list and an acoustic signal sounded, if so configured.

Roche recommends emptying the corresponding liquid waste container whenever you refill a water container.

Emptying the liquid waste container (206)

⚠ CAUTION

Incorrect results due to using unsuitable system water

Using unsuitable system water may influence the measured values and lead to incorrect results.

- Always use water of the specified quality:

Water quality (118)

NOTICE

Analyzer damage due to using unsuitable system water

Using unsuitable system water may cause proteinization and buildup of other pollutants in the probe and the fluid system.

- Always use water of the specified quality:

Water quality (118)

⚠ CAUTION

Incorrect results due to not using the wizard

Failing to use the **Fill water container** wizard when refilling water may lead to air bubbles in the fluid system, which may lead to incorrect pipetting and consequently to incorrect results.

- Always use the **Fill water container** wizard when refilling water.

To refill a water container

1 Start the **Fill water container** wizard.
   - In the message list, choose the message that indicates that the water container needs filling, then choose the **Fill water container** button in the detail panel.
   - Choose **Monitoring > Manage supplies > System water**, then choose the **Fill water container** button in the detail panel.

   ➔ The wizard is started.

2 Follow the on-screen instructions.

Emptying the liquid waste container

The analyzer monitors the fill level of the liquid waste containers. When a certain fill level is reached a message is added to the message list. Processing still continues as normal, but you should empty the waste container as soon as possible. When the container is full, processing stops and another message is added to the message list.

To empty a liquid waste container

1 Start the **Empty liquid waste container** wizard.
   - In the message list, choose the message that indicates that the liquid waste container needs emptying, then choose the **Empty liquid waste container** button in the detail panel.
   - Choose **Monitoring > Manage supplies > Liquid waste**, then choose the **Empty liquid waste container** button in the detail panel.

   ⓘ The wizard is started.

2 Follow the on-screen instructions.

Emptying the solid waste container

The analyzer monitors the fill level using counters. When a certain fill level is reached a message is added to the message list. Processing still continues as normal, but you should empty the waste container as soon as possible. When the container is full, processing stops and another message is added to the message list.

NOTICE

Incorrect fill level indication and analyzer damage due to re-insertion of non-empty waste container

Fill level monitoring is performed with the help of a counter. When you confirm that you have emptied the container, the counter is reset to zero.

If the solid waste container is full, test strips may get stuck in the waste chute and interfere with the measuring mechanism.

- Always empty the waste container before you confirm its emptying and placing it on the analyzer again.

NOTICE

Incorrect counters due to not using the wizard

Failing to use the **Empty solid waste container** wizard when emptying the solid waste may lead to incorrect counters and consequently to inaccurate fill level warnings. If the solid waste container is full, test strips may get stuck in the waste chute and interfere with the measuring mechanism.

- Always use the **Empty solid waste container** wizard when emptying the solid waste.

⚠ CAUTION

Personal injury due to touching internal mechanism

If the solid waste container is removed, parts of the rack transport mechanism can be accessed from the opening for the solid waste container. If you insert your hands while the analyzer is processing, you may get your fingers caught in the mechanism.

- Do not touch any internal mechanisms through the opening for the solid waste container.

To empty a solid waste container

1 Start the **Empty solid waste container** wizard.
   - In the message list, choose the message that indicates that the solid waste container needs emptying, then choose the **Empty solid waste container** button in the detail panel.
   - Choose **Monitoring > Manage supplies > Solid waste**, then choose the **Empty solid waste container** button in the detail panel.

   ➔ The wizard is started.

2 Follow the on-screen instructions.

Replacing the test strip cassette

When the number of test strips left in the cassette reaches a certain low level, a message is added to the message list. Processing still continues as normal, but you should get ready a new test strip cassette. When there is no test strip left in the cassette no further pipetting takes place and a further message is added to the message list.

Test strip cassettes are equipped with RFID tags, which contain the following information:

- Lot number
- Expiry date
- Load date
- Onboard stability
- Number of test strips left

Roche recommends emptying the solid waste container whenever you replace a test strip cassette.

Emptying the solid waste container (207)

⚠ CAUTION

Incorrect results due to deteriorated test strip quality

The test strip cassette compartment is designed to maintain a constant low humidity. Exposing the test strip cassette to the general laboratory environment air may lead to rapid water uptake by the pads on the test strips and so change their chemical characteristics, which may lead to incorrect results.

- Always load the test strip cassette within 3 minutes after removing it from its airtight packaging. Follow the instructions given in the Instructions for Use.
- Do not open the test strip cassette compartment unless you are going to replace the test strip cassette.
- Be sure to always close firmly the cassette compartment door.

NOTICE

Test strip handling error due to touching of test strips

Touching test strips may deform them and cause handling problems.

- Do not touch test strips inside the test strip cassette.

NOTICE

Damage to test strips and test strip cassettes due to inappropriate handling

Trying to force the test strip cassette into the test strip cassette compartment may damage the test strips and the test strip cassette.

- Do not force the test strip cassette into the compartment. Be sure to align it properly and follow the instructions given in the wizard.
- Do not shake or drop the test strip cassette.

To replace the test strip cassette

1 Start the **Exchange test strip cassette** wizard.
   - In the message list, choose the message that indicates that the test strip cassette needs replacing, then choose the **Exchange test strip cassette** button in the detail panel.
   - Choose **Monitoring > Manage supplies > Test strip**, then choose the **Exchange test strip cassette** button in the detail panel.

   ➔ The wizard is started.

2 Follow the on-screen instructions.

At the end of the shift

The following sections describe the typical tasks you may want to perform at the end of a work shift.

In this section

Logging off

Only one user can be logged on the analyzer at any time. You can log off any time, even while the analyzer is processing tests.

Relation between the user who is logged on and orders and results

Generally, orders and their results are associated with the operator who is logged on at the time of their generation and processing (for auditing purposes).

- If the operator logs off during processing and nobody else logs on, the assignments remain.
- If the operator logs off during processing and somebody else logs on, the results of the tests that were processing while logging off remain associated with the previous operator, all remaining results will be associated with the operator who just logged on.

Automatic logging off

You can set up the analyzer to automatically log off the current user after a predefined period of time of inactivity on the analyzer.

Defining the operating environment (268)

To log off

1 Choose **Overview > Log off**.

➔ The **Log on** button is displayed in the global information area.

Shutting down the analyzer

⚠ CAUTION

Loss of data due to using the power switch

Switching off the analyzer by pressing the on/off switch or the power switch does not allow for an orderly software shut-down and may lead to loss of data.

- Do not use the on/off switch or the power switch to shut down the analyzer, instead use the **Shut down** button on the **Overview** work area.

⚠ CAUTION

Incorrect results due to using the on/off or the power switch while processing tests

Switching off the analyzer while processing tests does not allow for an orderly software shut-down and may lead to incorrect results and to loss of data.

- Do not use the on/off switch or the power switch while processing is going on.

In this section

Shutting down the analyzer

Status indicator in the global information area

NOTICE

Possible analyzer damage due to using the on/off switch

Using the on/off switch during shutdown may cause hard-disk damage.

- Do not use the on/off switch during shutdown.

To shut down the analyzer

1 Ensure that the analyzer status in the global information area is **Idle**.

2 On the **Overview** work area, choose the **Shut down** button.
➔ A callout is displayed, asking you whether you want to perform the daily wash maintenance action.

3 If you want to perform the wash now, choose the **Yes** button.
➔ A confirmation callout is displayed.

4 To perform the wash, do the following:
- Prepare the wash rack.
- Load the wash rack on the input buffer.
- On the callout, choose the **Confirm** button.

➔ The wash action starts.
➔ When the wash action is complete, the software is shut down and the analyzer is switched off.

5 If you want to perform the wash later, choose the **No** button.
➔ The software is shut down and the analyzer is switched off.

Putting the analyzer into standby

This function sets the analyzer in a state of minimal power consumption.

To put the analyzer into standby

1 Choose **Overview > Stand by**.
➔ The screen goes black.

You can re-activate the analyzer by touching the screen anywhere.

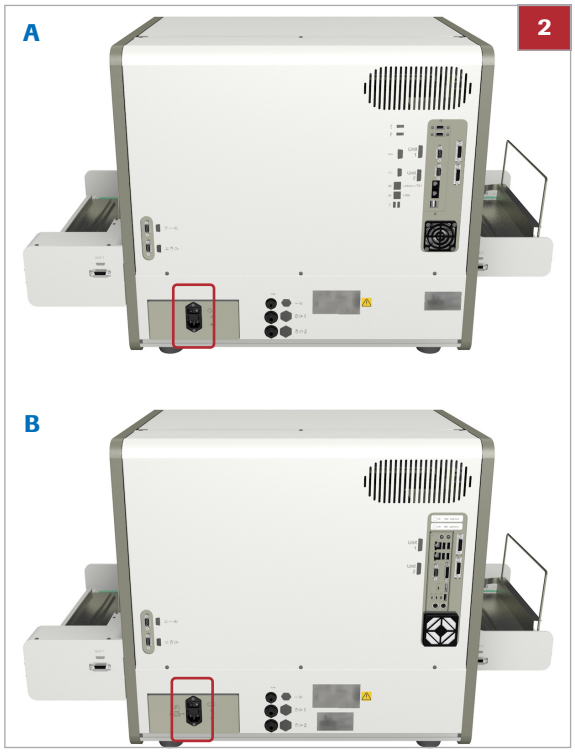
Switching off the power supply

Roche recommends to switch off the power supply if you intend not to use the analyzer for some time or if you want to relocate it.

To switch off the power supply

1 Shut down the analyzer. (212)

2 Put the power switch at the back of the analyzer in the off position ◯.



A Control unit version 1 **B** Control unit version 2

Keeping the analyzer clean

In this section

About keeping the analyzer clean

⚠ CAUTION

Skin inflammation or injury caused by working solutions

Direct contact with cleaning solutions or other working solutions may cause skin irritation, inflammation, or burns.

- If a cleaning solution or other working solution comes into contact with your skin, wash it off immediately with water and apply disinfectant. Consult a physician.

NOTICE

Damage to the analyzer due to use of inappropriate cleaning solution

Using inappropriate cleaning solutions may damage the parts you cleaned.

- Only use recommended cleaning solutions.

  Cleaning solutions (119)

- Never use the wash solution for manually cleaning the analyzer.

NOTICE

Damage to the analyzer due to excessive liquid

Any liquid spilled on the analyzer may result in malfunction or damage.

- Do not spray any liquid on any of the analyzer surfaces.

All the following cleaning tasks are performed with the analyzer shut down and switched off.

To ensure trouble free operation of the system, Roche recommends cleaning the following items and parts:

- Input and output buffer
  - Cleaning the input and output buffers (216)
- Housing
  - Cleaning the analyzer housing (217)
- Rack conveyors
  - Cleaning the rack conveyors (217)
- Rack trays
  - Cleaning the rack trays (218)
- Test strip tray and transporter
  - Cleaning the test strip tray and transporter (221)
- Probe bend detector
  - Cleaning the probe bend detector (224)
- Test strip pipetting area
  - Cleaning the test strip pipetting area (224)

Materials required

- Paper towel
- Lint-free cotton swabs
- Cleaning solution
  - Cleaning solutions (119)

Cleaning the input and output buffers

To clean the input and output buffers

1 Remove all racks and rack trays from the buffers.

2 Wipe all surfaces of the buffers, including the rack conveyors, using a paper towel moistened with cleaning solution.

3 Remove all residual moisture from all surfaces of the buffers, using a dry paper towel.

Cleaning the analyzer housing

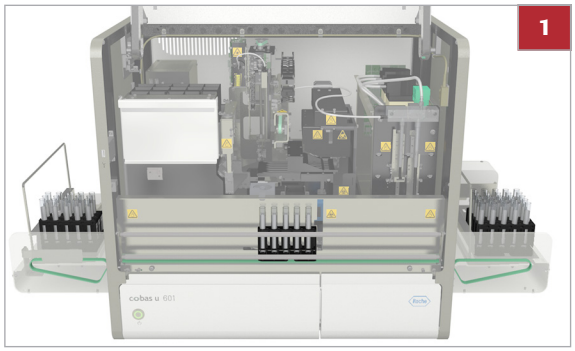
To clean the analyzer housing

1 If there are rack trays on the input and output buffers, remove them and wipe them using a paper towel moistened with cleaning solution, then dry them with a clean paper towel. (216)

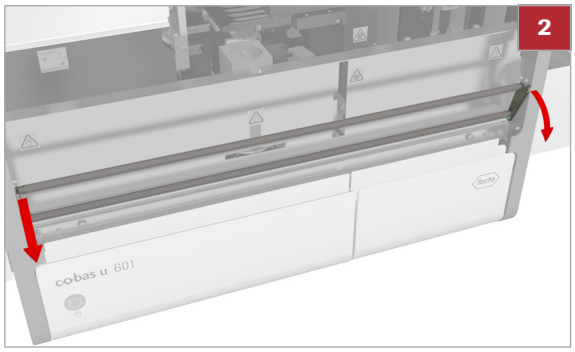
2 Wipe the analyzer housing using a paper towel moistened with cleaning solution, then dry it with a clean paper towel.

Cleaning the rack conveyors

To clean the rack conveyors



1 Wipe the rack conveyors near the input and output buffers using a paper towel moistened with cleaning solution.



2 Fold down the rack transport rail. Hold the rail at both ends and pull it out firmly.

3 Wipe the rack conveyor using a paper towel moistened with cleaning solution.

4 Fold up the rack transport rail. Hold the rail at both ends and push it in firmly.

Cleaning the rack trays

⚠ WARNING

Infection by samples and associated materials

Contact with samples containing material of human origin may result in infection. All materials and mechanical components associated with samples of human origin are potentially biohazardous.

- If any biohazardous material is spilled on the rack tray surface, wipe it up immediately and apply disinfectant.

⚠ WARNING

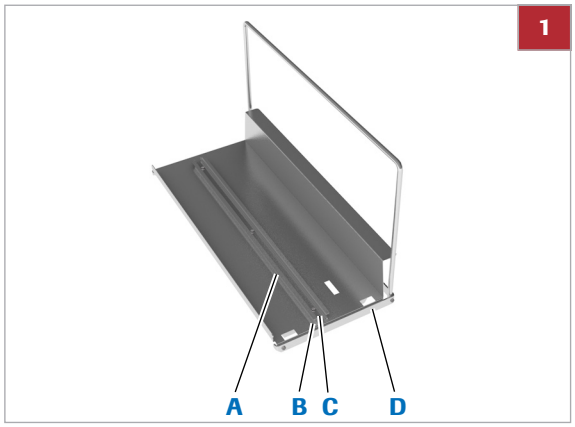
Personal injury and infection due to the edges on the rack tray's center guide rail

The edges on the rack tray's center guide rail may cause personal injury and infection.

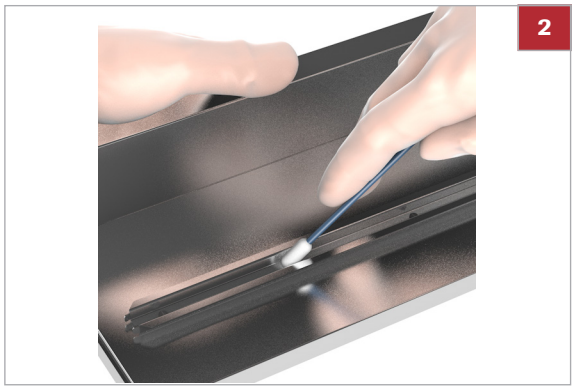
- Avoid contact with all edges, even when wearing lab gloves.
- Wear personal protective equipment such as lab gloves.
- Carefully observe all instructions given in this task.

To clean the rack trays

1 Use personal protective equipment when cleaning the rack tray.

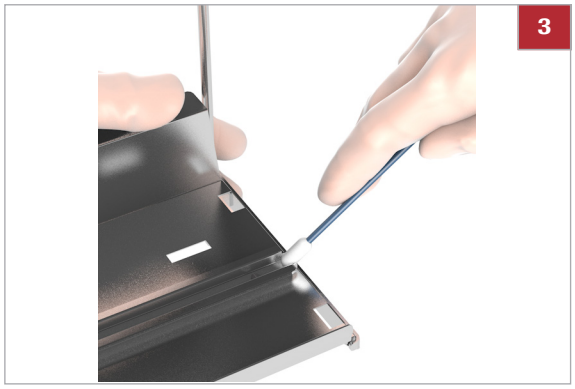


A Rail edge
B Rail grove
C Rail center
D Rack tray



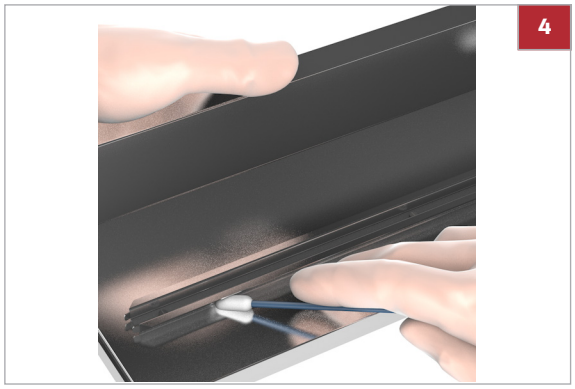
2 Wipe the rail center in both directions with a cotton swab moistened with cleaning solution.

- If there is sticking and crystallized dirt on the rack tray, scrape it with a cotton swab.



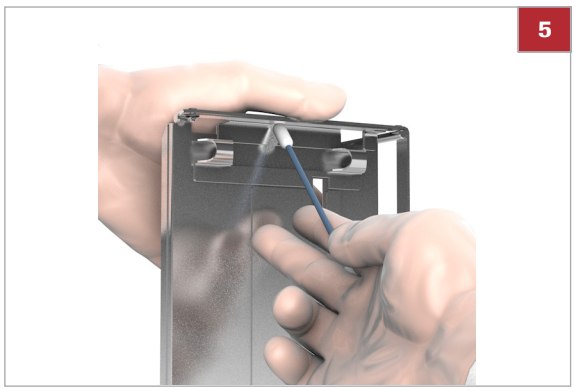
3 Wipe the rail edge in both directions with a cotton swab moistened with cleaning solution.

- If there is sticking and crystallized dirt on the rack tray, scrape it with a cotton swab.



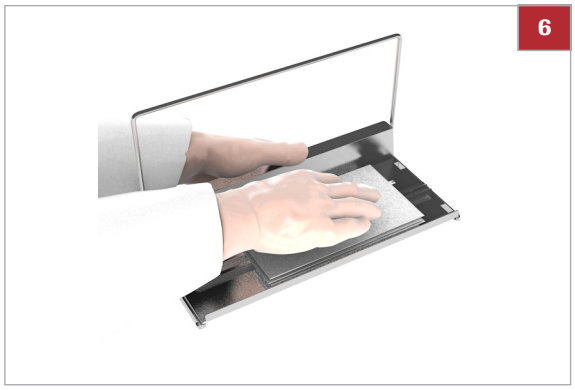
4 Wipe the rail groove in both directions with a cotton swab moistened with cleaning solution.

- If there is sticking and crystallized dirt on the rack tray, scrape it with a cotton swab.



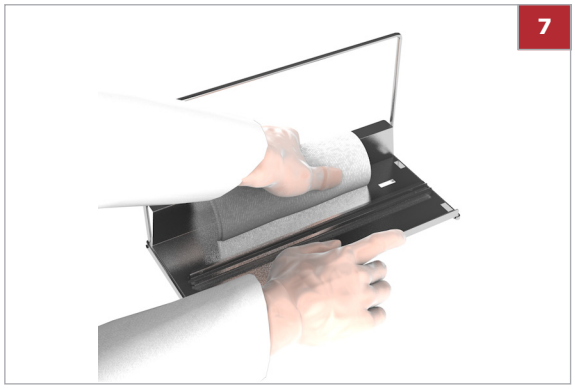
5 Wipe the edges on the bottom of the rack tray in both directions with a cotton swab moistened with cleaning solution.

- If there is sticking and crystallized dirt on the rack tray, scrape it with a cotton swab.



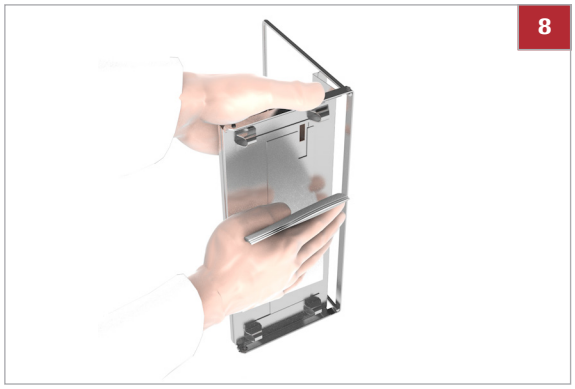
6 Wipe the surface of the rack tray, starting from the center in both directions with an at least 10 mm thick pile of lint-free cloth moistened with cleaning solution.

- Hold the rack tray with one hand, the pile of lint-free cloth with your fingers, and wipe the surface of the rack tray.



7 Wipe the rear surface of the rack tray, starting from the center in both directions with an at least 10 mm thick pile of lint-free cloth moistened with cleaning solution.

- Hold the rack tray with one hand, the pile of lint-free cloth with your fingers, and wipe the surface of the rack tray.



8 Wipe the bottom surface of the rack tray, starting from the center in both directions with an at least 10 mm thick pile of lint-free cloth moistened with cleaning solution.

- Hold the rack tray with one hand, the pile of lint-free cloth with your fingers, and wipe the surface of the rack tray.

9 Visually check the rack trays.

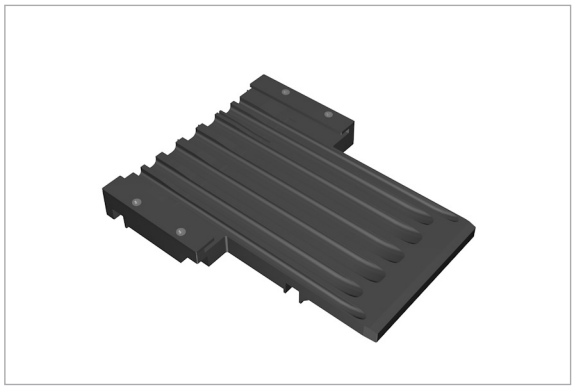
- Make sure that there is no textile remaining on the rack tray.
- Make sure that there are no wet areas on the rack tray.

10 NOTICE Only use supported rack trays.

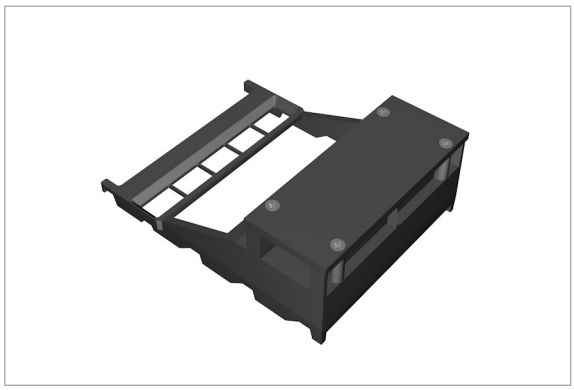
Ensure that the rack tray is supported by the analyzer before using.

Cleaning the test strip tray and transporter

Test strip tray (version 1)



Test strip transporter (version 1)



⚠ WARNING

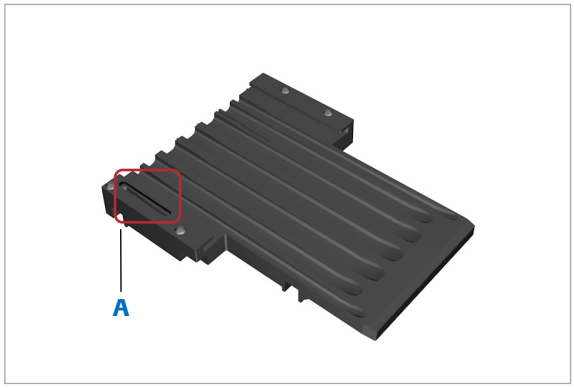
Malfunction, pipetting errors and incorrect results due to using test strip tray and transporter (version 1) on different instruments

The test strip tray and transporter (version 1) are guaranteed to work properly with the instrument they are delivered with. (The test strip tray and transporter (version 1) are specifically calibrated to the instrument they are installed on.)

Using a test tray and transporter (version 1) on a different instrument may lead to malfunction, pipetting errors and possibly to incorrect results.

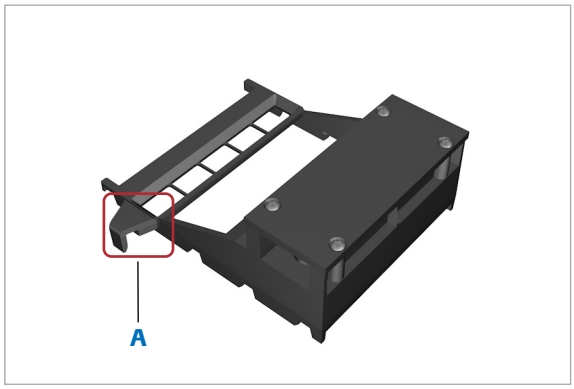
- Do not use the test strip tray or transporter (version 1) other than on the instrument they were originally delivered with.

Test strip tray (version 2)



A Groove

Test strip transporter (version 2)



A Hook

The test strip tray and transporter (version 2) are interchangeable and guaranteed to work properly with instruments designed for version 2.

The test strip tray (version 2) is identifiable by a groove and the test strip transporter (version 2) is identifiable by a hook.

⚠ WARNING

Incorrect results and malfunction due to damaged test strip tray or transporter

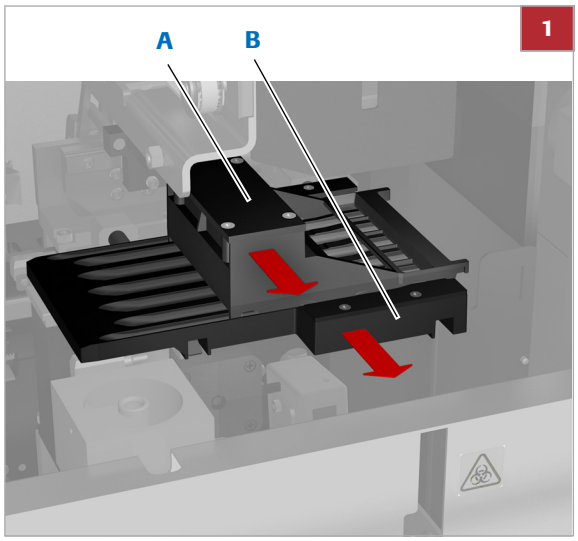
Incorrect handling, for example knocking or dropping, may damage the test strip tray and test strip transporter.

- Handle the test strip tray and transporter with care.
- Make sure you do not drop the test strip tray or transporter and place them gently when putting them down.

The test strip tray and transporter of version 1 can be replaced by version 2 by your Roche Service representative.

You can order the test strip tray and transporter of version 2 as accessories.

To clean the test strip tray and transporter



A Test strip transporter **B** Test strip tray

1 Pull out the test strip transporter (A).

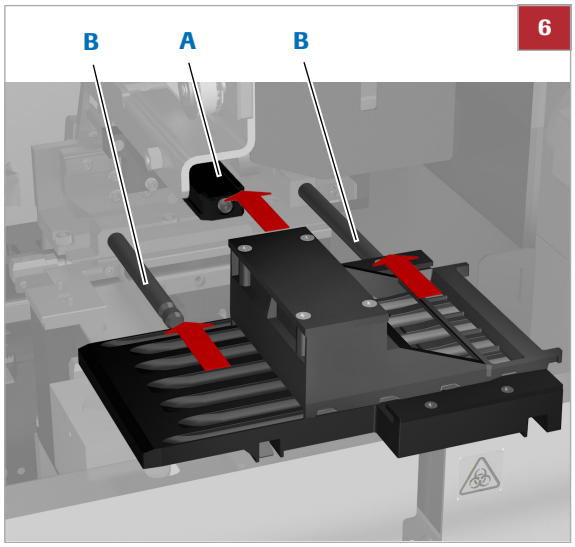
2 Pull out the test strip tray (B).

3 Give the parts a thorough clean by washing them using a commercial household detergent.

4 Wipe the test strip transporter and the test strip tray using a paper trowel moistened with cleaning solution.

5 Dry the test strip transporter and the test strip tray using a dry paper towel.

ℹ Leave the parts to dry completely.

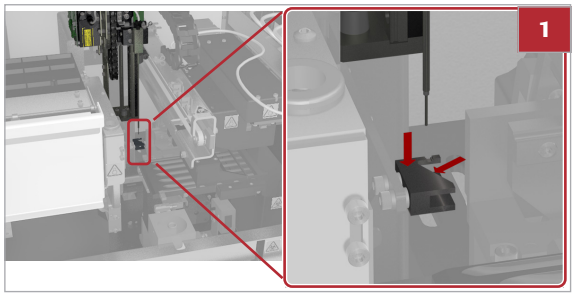


A Support bar for the test strip transporter **B** Support pins for the test strip tray

6 Insert the test strip tray in the two support pins (B) and push it firmly in.

7 Insert the test strip transporter in its support bar (A) and push it firmly in.

Cleaning the probe bend detector

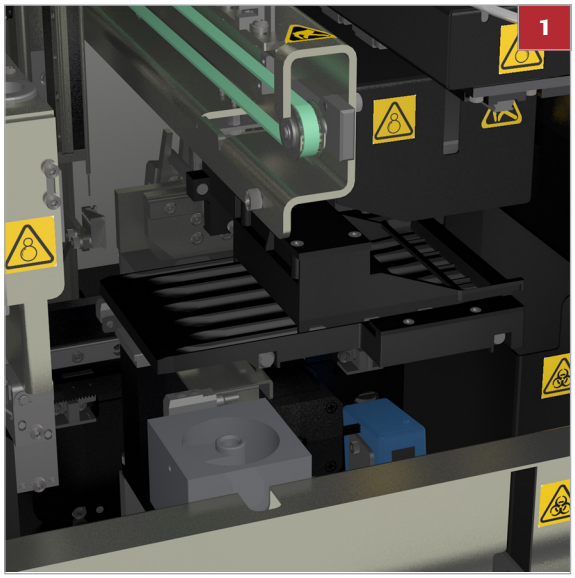


To clean the probe bend detector

1 Wipe the top and the inside of the probe bend detector using a cotton swab moistened with isopropyl alcohol or ethanol.

2 Wipe the top and the inside of the probe bend detector with a dry cotton swab to remove all residual cleaning solution.

Cleaning the test strip pipetting area



To clean the test strip pipetting area

1 Wipe the test strip pipetting area using a paper towel moistened with cleaning solution.

2 Wipe the test strip pipetting area with a dry paper towel to remove all residual cleaning solution.

Calibrating the photometer unit

In order to ensure proper functioning of the photometer unit, a calibration test needs to be performed every 4 weeks. It consists of measuring the pads of a dedicated calibration strip and of the built-in reference plate.

When the calibration becomes due a message is added to the message list. You can continue performing tests, but the results will be marked with **C** in the ⚐ column.

Reference plate

The built-in reference plate is always measured along with each pad on every calibration strip. The relation is established between the reference plate results and the results of each measured pad on the calibration strip. This value must remain within certain ranges, otherwise a message is added to the message list and no valid calibration result can be established.

External target value

Each pad of the calibration strip has its defined reflectance value (supplied with the calibration strip).

Internal target value, correction factor

To actually calibrate the analyzer, a dedicated calibration strip is used, for which the values for each pad are known (external target values). During the calibration process, both the calibration strip pads and the built-in reference plate are measured. Then, for each pad on the calibration strip, the relation between the calibration strip pad results and the built-in plate results is established (internal target value) and compared with the external target values. This results in the correction factor.

Result calculation (reflectance values)

For each test, the reference plate and all the pads on the test strip are measured and for each pad the relation between the results of the reference plate and the test pad is established and then multiplied with the correction factor.

No valid calibration

The system performs plausibility checks for the results. If no valid calibration result can be established, calibration must be repeated, otherwise performing tests is not possible.

▸ For information on how to proceed if calibration is still not successful, see No photometer calibration can be generated (310).

⚠ WARNING

Incorrect results due to biased calibration results

Soiling on calibration strips may influence the calibration results and consequently impair the validity of the test results.

- Do not touch the pads of the calibration strips and avoid placing them on any surface other than the test strip transporter.
- Do not re-use calibration strips. Always use a new calibration strip for each calibration, including repeats.

To calibrate the photometer using the calibration strip

1 Start the **Calibrate photometer** wizard.
   - In the message list, choose the message that indicates that the calibration is due, then choose the **Calibrate photometer** button in the detail panel.
   - Choose **Monitoring > Manage calibrations > Calibrate photometer**, then choose the **Calibrate photometer** button in the main panel.

   ➔ The wizard is started.

2 Follow the on-screen instructions.

Calibrating the measuring cell

In order to ensure proper functioning of the measuring cell, the clarity and specific gravity of system water is periodically measured as part of the normal measurement procedure. Calibration of the measuring cell should be performed every 4 weeks or as part of troubleshooting.

When the calibration becomes due a message is added to the message list. You can continue performing tests, but the results will be marked with **C** in the ⚑ column.

To calibrate the measuring cell

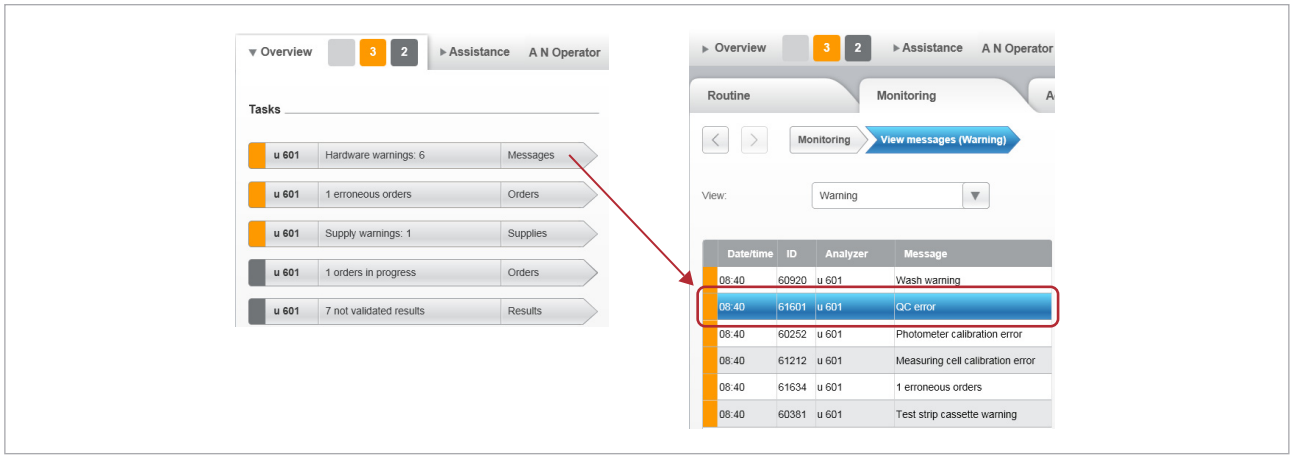
1 Start the **Calibrate measuring cell** wizard.
- In the message list, choose the message that indicates that the calibration is due, then choose the **Calibrate measuring cell** button in the detail panel.
- Choose **Monitoring > Manage calibrations > Calibrate measuring cell**, then choose the **Calibrate measuring cell** button in the main panel.

➔ The calibration is performed.

QC tasks

When the lot of the QC material expires or the QC test has failed a message is added to the message list. Tests are still performed but the test results are marked with **Q** in the ⚑ column.

You generally perform QC tasks when instructed to do so:



Displaying a QC message

To check for tasks that require intervention (200)

In this section

Performing QC measurements

In this section

About performing QC measurements

Perform QC measurements according to your laboratory regulations. When the lot of the QC material expires or the QC test has failed a message is added to the message list. Test are still performed but the test results are marked with **Q** in the ⚑ column.

⚠ CAUTION

Incorrect results due to sample mix-up

Tubes on QC racks are not individually identified. It is assumed that the fluids are valid and placed as defined in the QC rack definitions.

- Be sure to use the QC material that has been defined on the analyzer.
- Be sure to fill the tubes with the prescribed QC materials and place them on the predefined positions.

Preconditions

- There is sufficient QC material in the tubes.
- A QC rack is defined.

Managing racks (280)

If you use QC materials of a new lot, define the new lot first.

Defining QC materials (230)

Preparing the QC rack

To prepare the QC rack

1 Choose **Monitoring > Routine > Manage racks**.

2 Select a defined QC rack.

3 Note which position on the rack must contain which liquid.

4 Place the tubes on the appropriate positions on the rack.

Performing a QC measurement

To perform a QC measurement

1 Prepare the QC rack. (229)

2 Place the prepared QC rack in the priority rack slot.
➔ The rack is recognized as the QC rack, the tests are performed.

3 Check the results for possible data alarms. (235)

4 Remove the QC rack from the output buffer.

Performing a QC measurement when working with an LAS

To perform a QC measurement when working with an LAS

1 Prepare the QC rack. (229)

2 On the **Overview** work area, choose the **Priority rack** button.
➔ A callout is displayed, asking you to wait until the current operation is finished.

3 When the message on the callout asks you to do so, place the prepared QC rack on the rack conveyor belt of the input connection unit.
➔ When the rack is placed, the callout disappears and processing starts automatically.

4 Check the results for possible data alarms. (235)

5 Remove the QC rack from the output buffer.

Defining QC materials

QC materials, including the lot information, can be defined manually or by reading the RFID tag on the material packaging. You can change the data later and you can also exclude tests from being performed during the QC measurements.

There are separate data for each QC level.
Each QC material is, when it is defined, associated with the currently active range table.

- To manually define a new QC material (233)
- To define a new QC material by reading the RFID tag (232)
- To change QC material data (233)
- To include or exclude tests from the QC measurements (235)
- To delete QC materials (235)
- To print QC results or save them to a file (238)

About defining a new QC material by reading the RFID tag

- If the new QC material has more levels than the currently defined maximum number, this maximum number is automatically increased to the number of levels of the new QC material.
- If the number of QC levels of the new QC material is different from that of the current QC material, a yellow message is generated.
- If the number of QC levels is higher than the defined maximum level, there are no current QC results for the highest level and you need to perform QC. Check the yellow messages.
- If the number of QC levels is smaller than the defined maximum level, change the number of QC levels to reflect the number of levels coming from the QC RFID.

- To define the number of QC levels (267)

When reading the RFID tag the following data are read and stored on the analyzer:

- QC level
- Target ranges
- Lot number
- Expiry date

To define a new QC material by reading the RFID tag

1 Choose **Routine > Manage QC > Manage QC materials**.

2 Present the RFID tag of the QC material to the RFID reader at a distance of between 1 and 25 mm (0.04-1 in).

➔ The QC material data are registered and displayed on screen.

If the RFID tag is not valid, an acoustic signal is sounded.

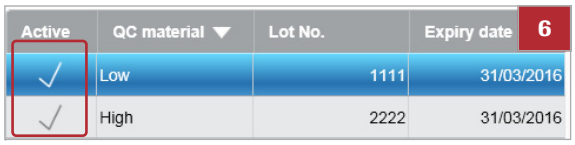
If there is more than one QC level, a material entry is created for each level, and you need to perform the following steps for each of them.

3 In the **QC material** list, choose the new entry, if required.

4 In the **QC material** field, enter the material name.

If the new material is of the same lot as the previous material, make sure to enter the same name. This ensures that the results will be included in the QC chart.

5 Choose the **Save** button.



6 If you want to use the QC material straight away you need to activate it: select the material and choose the **Activate/deactivate** button.

➔ Active materials are marked with ☑ in the **Active** column.

To be able to activate the QC material, a QC material name must have been defined and the system status must be **Idle**.

- Only one lot can be active per QC level.
- Lots that have expired are automatically deactivated.
- To be able to perform a QC measurement, all levels of the QC material must be activated.
- When you try to perform a QC measurement and no QC material is activated, then a yellow message is generated. Check this message.

To manually define a new QC material

1 Choose **Routine > Manage QC > Manage QC materials > Create**.

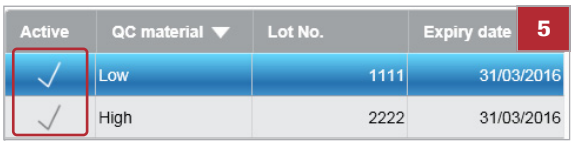
ⓘ To define a material on the basis of an existing one, choose **Routine > Manage QC > Manage QC materials**, select the entry of the existing material and choose the **Copy** button. Then change the values as required.

2 Open the Instructions for Use.

3 Enter the values exactly as defined in the Instructions for Use.

4 Choose the **Save** button.

➔ The material is added to the QC materials list.



5 If you want to use the QC material straight away you need to activate it: select the material and choose the **Activate/deactivate** button.

ⓘ Only one lot can be active per QC level. Lots that have expired are automatically deactivated. Active materials are marked with ☑ in the **Active** column.

Changing QC material data

You can only change QC data of materials that are not currently activated or with which no QC measurements have been performed yet.

To change QC material data

1 Choose **Routine > Manage QC > Manage QC materials**.

2 In the main panel, choose the material you want to change.

3 In the detail panel, choose the **Edit** button.

4 In the detail panel, enter the new values as required.

5 If you want to change test parameter related values, choose the **Manage ranges** button. (▸ 234)

6 Choose the **Save** button.

7 If you want to change the current usage status, choose the **Activate/deactivate** button in the QC materials list.

Making test parameter related changes

You can only change QC data of materials that are not currently activated or with which no QC measurements have been performed yet.

In the QC results list, only those test parameters are displayed that are enabled.

To make test parameter related changes

1 Choose **Routine > Manage QC > Manage QC materials**.

2 In the main panel, choose the material.

3 In the detail panel, choose the **Manage ranges** button.
➔ The **QC material** screen is displayed.

4 Choose the **Edit** button.

5 In the test list, use the drop-down lists to enter the new values as required.

6 Choose the **Save** button.

Including or excluding tests from the QC measurements

You can define which tests are performed with the QC measurements, for example, you can exclude tests for which there are no range values defined for the QC material you use.

You can only change QC data of materials that are not currently activated or with which no QC measurements have been performed yet.

In the QC results list, only those test parameters are displayed that are enabled.

To include or exclude tests from the QC measurements

1 Choose **Routine > Manage QC > Manage QC materials**.

2 In the main panel, choose the material.

3 In the detail panel, choose the **Manage ranges** button.
➔ The **QC material** screen is displayed.

4 Choose the **Edit** button.

5 To enable or disable a parameter, select or clear its **Enabled** box.
ⓘ You must enable a parameter before you can change its limit values.

6 Choose the **Save** button.

Deleting QC materials

You can only delete QC materials that are not currently activated or with which no QC measurements have been performed yet.

To delete QC materials

1 Choose **Routine > Manage QC > Manage QC materials**.

2 In the main panel, choose the material you want to delete.

3 Choose the **Delete** button.

4 In the callout, confirm the deletion.
➔ The QC material is deleted.

Reviewing QC results

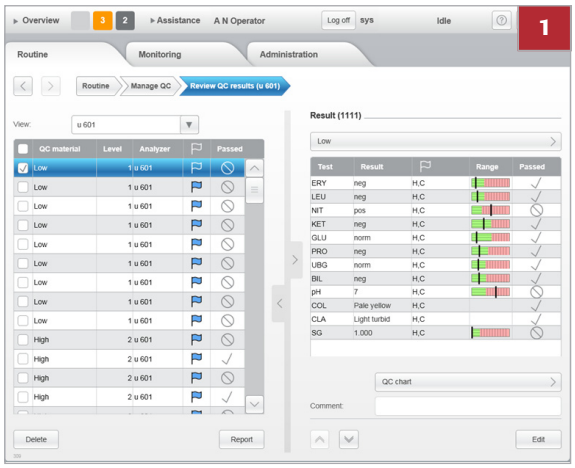
Possible result symbols

✓	Passed

		Not passed
Color coding		
	 Green	The result is within target range.
	 Red	The result is outside target range.
Possible data alarms		
		There are no data alarms.
	Cp	Calibration. The measuring cell calibration results were no longer valid when the result was generated.
	Cs	Calibration. The photometer calibration results were no longer valid when the result was generated.
	H	High temperature. The upper temperature limit has been exceeded.
	L	Lysed erythrocytes were detected for concentrations ≤50 ERY/µL. (The software cannot reliably identify hemolyzed erythrocytes in concentrations >50 ERY/µL.)
	N	The SG parameter did not yield a valid result. (If you work with automatic validation and a LIS, the validated results of the other parameters are sent to the host as usual.)
	O	Parameter is out of range.
	R	Test strip cassette onboard stability has expired.
	#	A Roche Service representative did not cancel a service or troubleshooting function that can only be canceled by a Roche Service representative. (As a result, for example, expired materials may have been used.) All results have this data alarm and the validity of these results cannot be guaranteed. If you encounter this data alarm, contact your Roche Service representative immediately.

You typically delete results if you find you made a mistake in the QC material definition or in performing the QC test, or if you want to exclude results from the QC chart.

You can store up to 300 QC results on the analyzer. When this number is reached, the oldest result is overwritten when the next QC test is performed.



To review QC results

1 Choose **Routine > Manage QC > Review QC results**.

➔ The results are displayed.

2 Select a result. (235)

➔ The details are displayed in the detail panel.

3 To view the results in chart format, choose the **QC chart** button.

For more information, see:

Working with QC charts (139)

4 To add a comment to the result, choose the **Edit** button and enter the text in the **Comment** field.

To delete QC results

1 Choose **Routine > Manage QC > Review QC results**.

2 Select the results you want to delete.

ℹ Select individual check boxes at the beginning of the result entries or select the check box in the table header to select all results in the list.

3 Choose the **Delete** button.

4 In the callout, confirm the deletion.

➔ In the callout, the progress of the deletion process is indicated.

To print QC results or save them to a file

1 Choose **Routine > Manage QC > Review QC results**.

2 In the main panel, select the results you want to print or save to file.

Select one, several or all check boxes.

About filtering table information (136)

3 In the main panel, choose the **Report** button.

➔ A callout is displayed.

4 In the callout, define whether to print or export the data (**Output mode**).

5 In the callout, if you want to save the data to a location other than the default location, choose the **Select** button and define the file location. (This can either be a USB storage device connected with the USB port, preferably on the front of the instrument, or a mapped network path.)

For information on the USB port location, see the following illustration:

Main components (69)

6 In the callout, choose the **Yes** button.

Additional operating tasks

This section describes some tasks that you may need to perform occasionally.

In this section

Stopping and restarting sample processing

Sample processing can be stopped any time. You may want to do so, for example, to perform some routine maintenance actions.

Stopping the sample processing has the following consequences:

- All tests for which orders are defined are completed.
- While testing goes on, the **Stop** status is displayed in the global information area, when the testing activities are complete the **Idle** status is displayed and there are no messages in the message list that refer to ongoing analysis.
- If there are unprocessed samples on the rack, it remains on the conveyor.

Ensure that all covers and drawers are closed.

To interrupt sample processing

1 Choose **Overview > Stop**.

2 Wait until the system status is **Idle**.

To resume sample processing

1 Choose **Overview > Start**.
➔ Testing resumes where it stopped when you used the **Stop** button.

Changing the password

There are two possible password modes: With **Simple password mode** the system administrator (user of the **Supervisor** user group) defines the password and the general user cannot change it. With **Strong password mode**, the system defines the initial password and the user then can change it, in fact, he or she must change the initial password during their first logon, and from then on they must change it every 60 days.

When working with **Simple password mode**, password information is case-sensitive and must contain at least one alphanumeric character. Spaces are allowed.

When working with **Strong password mode**, password information is case-sensitive and must meet the following conditions:

- At least eight characters
- At least one upper case letter
- At least one lower case letter
- At least one digit
- Must not repeat a character more than four times
- Must not contain any part of the user name of more than four characters
- Must not be identical to the previous password

As a user of the **User** user group, you can change the password only if the system works with **Strong password mode**.

To change the password

1 Choose the **Log on** button.
➔ A dialog box is displayed.

2 Enter your user name and password.

3 Choose the **Change password** button.
➔ A dialog box is displayed.

4 Enter your new password and then re-enter it.

5 Choose the **Confirm** button.
➔ If the change was not successful a message is displayed. Read the information carefully and then change the passwords again.

Removing the test strip cassette

In rare circumstances, for example when you want to move a test strip cassette from one analyzer to another or when you intend not to use the analyzer for a long time, you may want to remove the test strip cassette without replacing it with a new one.

When you remove the test strip cassette the number of test strips left and the onboard stability are written to its RFID tag.

⚠ CAUTION

Incorrect results due to deteriorated test strip quality

The test strip cassette compartment is designed to maintain constant low humidity. Exposing the test strip cassette to the general laboratory environment air may lead to rapid water uptake by the pads on the test strips and so change their chemical characteristics, which may lead to incorrect results.

- Always reload the test strip cassette immediately after removing it from an analyzer.

NOTICE

Test strip handling error due to manual touching of test strips

Touching test strips may deform them and cause handling problems.

- Do not touch test strips inside the test strip cassette.

To remove the test strip cassette

1 Choose **Monitoring > Manage supplies > Test strip**, then choose the **Exchange test strip cassette** button in the detail panel.

➔ The wizard is started.

2 Follow the on-screen instructions.

3 In step 5, instead of inserting a new test strip cassette, choose the **Continue without test strip cassette loaded** button.

4 Follow the on-screen instructions.

Printing and exporting information, generating reports

You can print and export critical information to files. The process usually involves the steps described in the following section:

To print or export information (243)

The following table lists which data can be printed and exported, and it provides information on the various options that are available.

Type of information	Navigation path	Callout items	Comment on callout item
Any listed below	**... > Report**	**Output mode**(1)	**Print**: Print on the default printer. **Export to PDF**: Save the information in PDF format to the default file location.
		File path(1)	Available with **Export to PDF Output mode**. If you want to save the data to a location other than the default location, choose the **Select** button and define the file location. (This can either be a USB storage device connected with the USB port, preferably on the front of the instrument, or a mapped network path.) **Axeda** is intended for direct upload to Roche Service. Do not use this destination unless instructed to do so by your Roche Service representative.
Selected results (result report) To print results (result report) (186) To save results to files (result report) (186)	**Routine > Manage test results**	**Analyzer**	Available if you work with **cobas**® 6500 urine analyzer series.
		Output mode	**Export images only**: Available if your system includes a microscopy analyzer. Save each image in a file. (You cannot print images directly on a printer. You need to save them as files first and then use a graphics tool to print them.)
Results of a patient (patient report) To print results (patient report) (186) To save results to files (patient report) (187)	**Routine > Manage patients**	**Analyzer**	Available if you work with **cobas**® 6500 urine analyzer series.
		Result selection	Define which results of this patient should be printed or saved to files.
		Output mode	**Export images only**: Available if your system includes a microscopy analyzer. Save each image in a file. (You cannot print images directly on a printer. You need to save them as files first and then use a graphics tool to print them.)
QC results To print QC results or save them to a file (238)	**Routine > Manage QC > Review QC results**		
Photometer calibration results	**Monitoring > Manage calibrations > Calibrate photometer**		

Printing and exporting information, generating reports

Type of information	Navigation path	Callout items	Comment on callout item
Measuring cell calibration results	**Monitoring > Manage calibrations > Check measuring cell**		
Problem report ▸ To create a problem report (309)	**Monitoring > Perform maintenance > Create problem report**	**Include failsafe photometer images**	Save the photometer images that were taken when an error was detected to a separate password protected file. These images are intended for Roche Service representatives only.
Screenshots	**Monitoring > Perform maintenance > Export screen shots**		Save the last 100 screenshots that were generated using the print screen function to a location that is accessible by the user.
System settings and configuration ▸ To generate a report of the system settings (279)	**Administration > System configuration > Import or export system settings > Report system settings**	**Analyzer**	Available if you work with **cobas®** 6500 urine analyzer series.
Cross-check rule definitions	**Administration > System settings > Measurement settings > Cross-check rules**	**Analyzer**	Available if you work with **cobas®** 6500 urine analyzer series.
Limit definitions	**Administration > System settings > Measurement settings > u 601 > Limit configuration**		The report includes the limits for trace, abnormal, and sieve of all parameters.
Range table definitions	**Administration > System settings > Measurement settings > u 601 > Range table configuration**		
Range table activities	**Administration > System settings > Measurement settings > u 601 > Range table configuration > History**		List of all actions performed with range tables.
Color range definitions for COL parameter	**Administration > System settings > Measurement settings > u 601 > Color range configuration**		

Printing and exporting information, generating reports

(1) This option is available for all types of information.

To print or export information

1 Access to the relevant screen and select the data, if required.

2 Choose the **Report** button.
➔ A callout is displayed.

3 In the callout, define whether the data should be printed on a printer or exported to files, for example in PDF format or, for images, in a graphics file format (**Output mode**).

4 In the callout, if you want to save the data to a location other than the default location, choose the **Select** button and define the **File path**. (This can either be a USB storage device connected with the USB port, preferably on the front of the instrument, or a mapped network path.)

For information on defining default values, see:

Defining the look, content, and handling of reports (274)

5 In the callout, choose the **Yes** button.

➔ The information is processed as defined.

Configuration

This chapter describes how to adjust the operating environment to your local needs.

In this chapter 6

User management

User management consists of the following tasks:

- Defining new users
- Changing user data
- De-activating users
- Defining new passwords
- Resetting passwords

In this section

Defining a new user

For defining user data you must have **Supervisor** rights.

During the installation of the analyzer, a user of the **Supervisor** and **User** user group are defined.

User group rights

User group	Description
User	Users with **User** rights can perform all actions that are required for daily operation. • Order management • Test activities • Calibration activities • QC activities • Result handling • Result reporting • Daily maintenance • Reporting and exporting system settings
Supervisor	In addition to all actions of the **User** group, users with **Supervisor** rights can perform the following tasks: • User configuration • System settings (test definition, profiles) • User interface language installation • System configuration (operating system, communication) • Screen sharing
Service	In addition to all actions of the **User** and **Supervisor** groups, users with **Service** rights can perform the following tasks: • Software installation

List of user group rights

User statuses

Status	Description
Active	The user can log on to the analyzer.
Inactive	The user cannot log on to the analyzer but remains on the analyzer and can be activated any time. Activating and deactivating a user (250)

List of user statuses

To define a new user

1 Choose **Administration > User management**.

2 Choose the **Create** button.

➔ A detail panel is displayed that contains all items that need to be defined.

Items marked with an asterisk are mandatory.

3 Define the user's first name.

ℹ Enter 1 to 32 alphanumeric characters, spaces are allowed. This name will be displayed in the global information area of the screen. This entry is compulsory.

4 Define the user's last name.

ℹ Enter 1 to 50 alphanumeric characters, spaces are allowed. This name will be displayed in the global information area of the screen. This entry is compulsory.

5 Define the user name.

ℹ Enter 4 to 20 alphanumeric characters. This will be required during logon and it will be displayed with results and log information.

6 Choose the user group. (247)

7 Choose the user status. (247)

ℹ Because every result must be associated with a user, you cannot delete users from the database, they are deactivated instead.

8 Choose the **Create password** button.
   - If you work with **Simple password mode**, enter the password in the callout and choose the **Confirm** button.
   - If you work with **Strong password mode** the system automatically defines a password and displays it in a callout. Choose the **Confirm** button. The user will have to change the password when logging on for the first time and from then on every 60 days.

When working with **Simple password mode**, password information is case-sensitive and must contain at least one alphanumeric character. Spaces are allowed.

When working with **Strong password mode**, password information is case-sensitive and must meet the following conditions:

- At least eight characters
- At least one upper case letter
- At least one lower case letter
- At least one digit
- Must not repeat a character more than four times
- Must not contain any part of the user name of more than four characters
- Must not be identical to the previous password

9 Choose the **Save** button.

Changing user data

For changing user data you must have **Supervisor** rights.

To change user data

1 Choose **Administration > User management**.

2 In the main panel, choose the user whose data you want to change.
   ➔ In the detail panel, this user's details are displayed.

3 Choose the **Edit** button and change the information as required. (247)

4 Choose the **Save** button.

Resetting the password

For resetting a password, you must have **Supervisor** rights.

To reset the password

1 Choose **Administration > User management**.

2 In the main panel, choose the user whose password you want to reset.
➔ In the detail panel this user's details are displayed.

3 Choose the **Edit** button.

4 Choose the **Create Password** button.
➔ A callout is displayed.

5 If you work with **Simple password mode**, enter the password twice in the callout and choose the **Confirm** button.

6 If you work with **Strong password mode**, make a note of the password and in the callout choose the **Confirm** button.

7 Choose the **Save** button.

Activating and deactivating a user

Active users can log on to the analyzer, inactive users cannot, but they remain on the analyzer and can be reactivated any time.

Because every result must be associated with a user, you cannot delete users from the database, they are deactivated instead.

For activating and deactivating a user, you must have **Supervisor** rights.

To activate or deactivate a user

1 Choose **Administration > User management**.

2 In the main panel, choose the user that you want to deactivate.
➔ In the detail panel, this user's details are displayed.

3 Choose the **Edit** button.

4 From the **Status** drop-down list, choose **Active** or **Inactive**.

5 Choose the **Save** button.

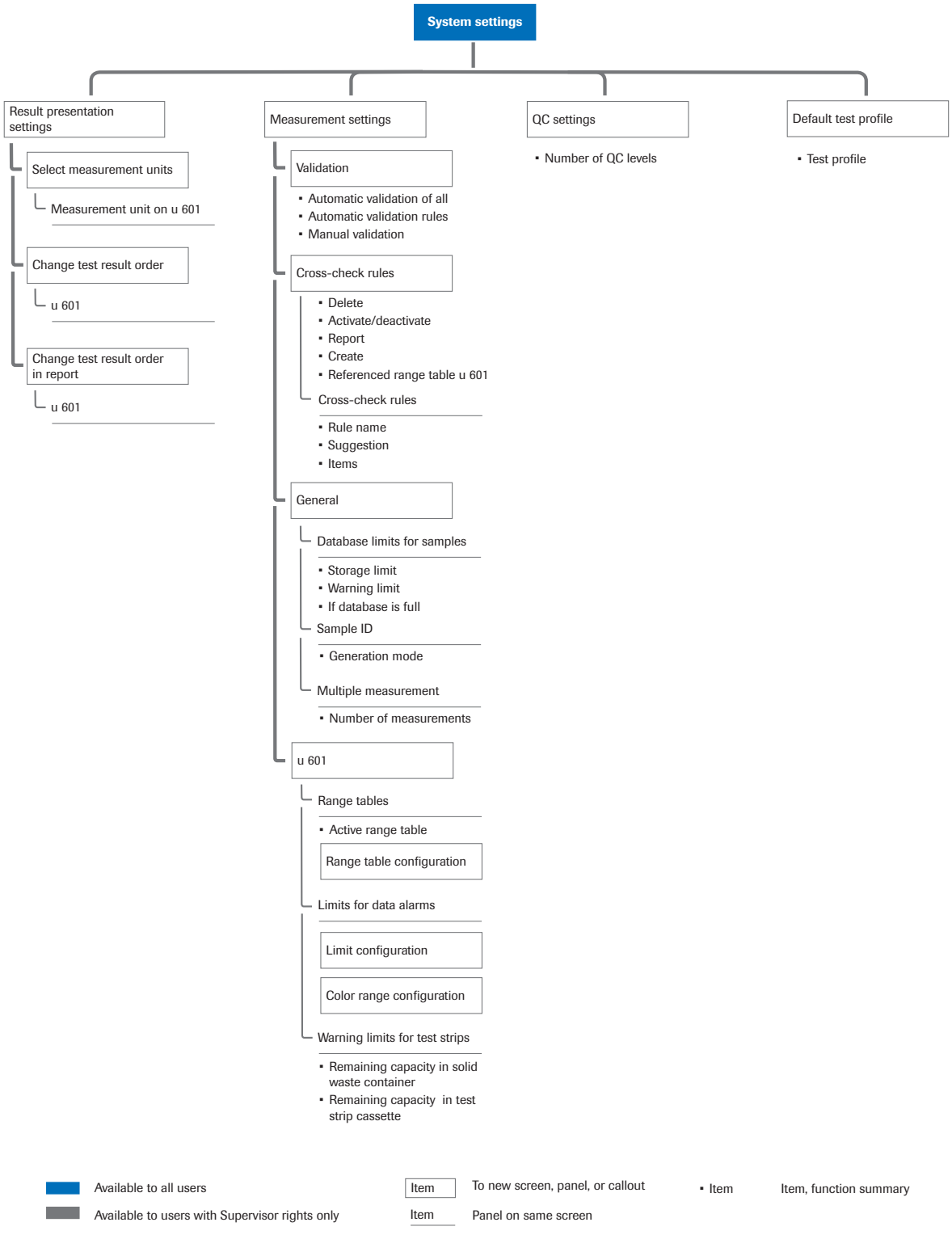
System settings: Defining the test environment

In this section

About system settings

Generally, users with the user group **User** can view all definitions, but to define and change them, you need the **Supervisor** user group. All users can create a problem report and export and report the system settings.

Choose **Administration > System settings** to access the test related settings.



Navigation map for System settings (International)

Defining the units in which results are displayed and reported

You can define the units in which results are displayed and reported.

The following table shows an example of how the results are displayed, depending on the unit convention that was selected.

Display examples for cobas u 601 urine analyzer

Unit	Test column	Result column	Information column
Conventional	GLU	100 mg/dL	
SI	GLU	6 mmol/L	
Arbitrary	GLU	2+	
Conventional and arbitrary	GLU	100 mg/dL	2+
SI and arbitrary	GLU	6 mmol/L	2+

Result display of the **cobas u** 601 urine analyzer, depending on the selected unit convention

To define the display units

1 Choose **Administration > System settings > Result presentation settings > Select measurement units**.

2 Choose the **Edit** button.

3 From the **Measurement unit on u 601** drop-down list, choose the unit convention for the test strip analyzer.

4 Choose the **Save** button.

Defining the order in which test parameters are shown

You can define the order of test parameters as they are displayed in the results displays, printouts, and exports.

To define the order in which parameters are displayed in result displays

1 Choose **Administration > System settings > Result presentation settings**.

2 Choose where the order applies.
- To define the order for on-screen displays choose the **Change test result order** button.
- To define the order for result printouts and exports, choose the **Change test result order in report** button.

3 Choose the **Edit** button.

4 Select a parameter and choose ⇧ or ⇩ to move it up or down in the list.

5 Do the same for all parameters you want to move.

6 Choose the **Save** button.

Defining the validation method

You can set up the analyzer to automatically accept all results or to exclude results from automatic validation if they have certain data alarms associated with them. You can also choose to validate all results manually.

Validation methods

Methods	Description
Automatic validation of all	All results are automatically validated. If you work with a LIS validated results are automatically sent to the host.
Automatic validation rules	All results are automatically validated, unless an additional condition (rule) applies, (a cross-check rule was triggered, a trace, sieve, or SG alarm was generated, an abnormal result was generated). If you work with a LIS validated results are automatically sent to the host.
Manual validation	All results must be validated manually.

List of validation methods

To define the validation method

1 Choose **Administration > System settings > Measurement settings > Validation**.

2 Choose the **Edit** button.

3 From the drop-down list, choose a method. (254)

In the following situations, automatic validation is never applied:

- The sample barcode could not be read (if you work with the generation mode **Barcode**).
- There already exists an order for this result.

4 If you chose the **Automatic validation rules** condition, select all boxes of the rules that you want applied.

5 Choose the **Save** button.

Defining cross-check rules

In this section

Defining a cross-check rule

Cross-check rules serve to define additional actions that should be taken as a result of certain result qualities or values.

- Each cross-check rule is, when it is defined, associated with the currently active range table.
- You can activate and deactivate a cross-check rule that is associated with a result, but you cannot change or delete it.
- You can make changes to a cross-check rule or delete it if it is not associated with a result and if it is associated with the currently active range table.
- You can print and export the cross-check rules.

To define a cross-check rule

1 Choose **Administration > System settings > Measurement settings > Cross-check rules**.

2 Choose the **Create** button.

3 Enter or select the values.

ⓘ **Rule name**: Alphanumeric characters.
Suggestion: Describe what needs to be done if the rule applies.
Item: Choose values from the drop-down lists to define a condition.

4 Choose the **Save** button.

5 In the main panel, choose the **Activate / deactivate** button.

Changing a cross-check rule

You can make changes to a cross-check rule if it is not associated with test results. If you need to make changes to a cross-check rule that is associated with test results, you have to define a new cross-check rule.
You can activate or deactivate a cross-check rule if it is associated with the active range table.

To change a cross-check rule

1 Choose **Administration > System settings > Measurement settings > Cross-check rules**.

2 In the detail panel, choose the **Edit** button.

3 Change the values as required.

ⓘ **Rule name**: Alphanumeric characters.
Suggestion: Describe what needs to be done if the rule applies.
Item: Choose values from the drop-down lists to define a condition.

4 Choose the **Save** button.

Deleting a cross-check rule

You can delete a cross-check rule if it is not associated with results.

To delete a cross-check rule

1 Choose **Administration > System settings > Measurement settings > Cross-check rules**.

2 In the rule list, choose the rule you want to delete.

3 Choose the **Delete** button.

4 In the callout, confirm the deletion.
➔ The rule is deleted.

Managing the result storage capacity

You can define what should happen when the storage capacity for result data is exhausted.

To manage the sample storage capacity

1 Choose **Administration > System settings > Measurement settings > General**.

2 Choose the **Edit** button.

3 In the **Storage limit** field, enter the maximum number of sample test results that can be stored (1000-10 000). The limits for QC, photometer calibration and measuring cell calibration are 300 each and cannot be changed.

4 In the **Warning limit** field, enter the threshold value when a messages should be added to the message list.

5 Define whether the oldest data should be overwritten when the database is full or whether processing should stop.

6 Choose the **Save** button.

Defining how the sample IDs are generated

Sample IDs are either read from the sample barcode or they are automatically generated using a sample sequence number.

If the analyzer is connected to an LAS, the **Generation mode Sample sequence number** is not available. The mode is automatically set to **Barcode** during startup of the system.

Generation modes

Mode	Description
Barcode	Use this value if you work with sample barcodes and the sample ID is contained in your sample barcodes.
Sample sequence number	Use this value if you do not work with sample barcodes.

Generation modes

To define how the sample IDs are generated

1 Choose **Administration > System settings > Measurement settings > General**.

2 Choose the **Edit** button.

3 Define the **Generation mode**. (258)

4 The number of measurements for each sample is set by the manufacturer. Your Roche Service representative can change it.

5 Choose the **Save** button.

Defining range tables

Test results, QC materials, and cross-check rules are always associated with the range table that was active when they were generated or defined. The associated range table is indicated when you display the results, QC materials, or cross-check rules.

Range tables that are associated with a result, cross-check rule or a QC material cannot be changed. If you need changes in such a range table, you first need to define a new range table or delete the associated results.

Changing reflectance values leads to different evaluation sensitivities of the respective test

Lowering the reflectance value of the negative (**neg**) range leads to a decrease of the sensitivity of the test evaluation, raising it increases the sensitivity. In this way, the sensitivity can be adjusted to the requirements of the individual laboratory.

The accuracy of results obtained after changing the ranges or reflectance values is not warranted by Roche. The user is responsible for validating the consistency of results after changes have been made.

Choosing a different range table as the active range table affects some settings:

- It deactivates the cross-check rules and QC materials. Therefore, you need to define the QC materials anew and, if required, define new cross-check rules.
  The deactivated cross-check rules and QC materials can only be reactivated by choosing the associated range table again, but they can be deleted if they are not associated with any results.
- It resets the limits of ranges to their default values.

To define the limit values (265)

Range table types

Table type	Description
International	The predefined range table reflects the legal and customary requirements for result validation.
Name of user-defined range tables	For details on such range tables, see: To define a new range table (260)

Range table types

Use a predefined range table as the basis for a new range table and then change the ranges as required. You cannot use a user-defined range table as the basis for a new one.

You can change user-defined range tables, provided they are not associated with any test results, QC material, or cross-check rule. If you need to make changes to a range table that is associated with any test results, you need to define a new one instead.

You cannot change or delete predefined range tables.

In this section

Choosing the range table

To choose the range table

1 Choose **Administration > System settings > Measurement settings**.

2 Choose the **u 601** button.

3 Choose the **Edit** button.

4 From the **Active range table** drop-down list, choose the range table.

For more information on range table types, see:
Range table types (259)

5 Choose the **Save** button.

6 Define new QC materials. (230)

7 Define new cross-check rule, if required. (255)

Defining a new range table

To define a new range table

1 Choose **Administration > System settings > Measurement settings**.

2 Choose the **u 601** button.

3 Choose the **Range table configuration** button.

4 From the **Range table** drop-down list, choose the base range table.

5 Choose the **Create** button.

6 In the callout, enter the name of the new table, then choose the **Save** button.
➔ The values of the base range table are displayed.

7 Choose a parameter.
➔ The current ranges are displayed in the detail panel.

8 Use the panel splitter to display the complete range.

9 Choose the **Edit** button.

10 If there are no values displayed for the selected parameter, choose the **Create range** button.

11 Choose the first of the range fields and enter the required new value. Choosing Enter on the keyboard takes you to the next field.
ℹ The fields of changed values and empty fields that must contain a value are marked yellow .
If you want to revert to the original values of the base range table, choose the **Set to default** button. This discards all changes that you have made so far.

You can also delete an existing range and add new ranges.

- If you add a new range, it is added at the bottom of the table.
- **Delete range** always deletes the last range in the table.

12 Choose the **Save** button.

13 Activate the table. (260)

14 Define new QC materials. (230)

15 Define new cross-check rules, if required. (255)

Making changes to range tables

To make changes to range tables

1 Choose **Administration > System settings > Measurement settings**.

2 Choose the **u 601** button.

3 Choose the **Range table configuration** button.

4 In the **Range table configuration** panel, choose a parameter.
➔ In the detail panel, the range values are displayed.

5 Use the panel splitter to display the complete range.

6 Choose the **Edit** button.

7 Choose a value you want to change and enter the new value. Do this for all items you want to change.
ℹ The fields of changed values and empty fields that must contain a value are marked yellow .
If you want to revert to the original values of the base range table, choose the **Set to default** button. This discards all changes that you have made so far.

You can also delete an existing range and add new ranges.

- If you add a new range, it is added at the bottom of the table.
- **Delete range** always deletes the last range in the table.

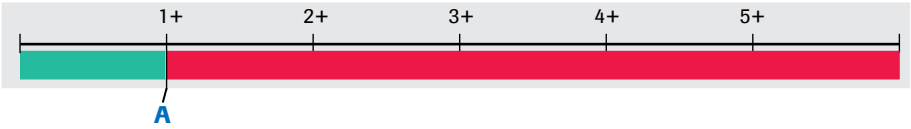
8 Choose the **Save** button.
➔ In the **Range table configuration** main panel, the parameter name is marked yellow to indicate that a range has been changed.

Limit configuration

Value ranges and limits are used to determine whether a result is positive or negative and whether to trigger data alarms and actions such performing additional tests.

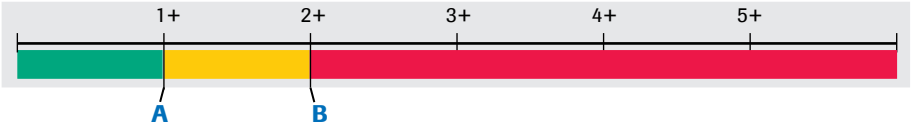
Limits are used in several ways: In a straight limit, a result is either below or above the limit value and renders a positive or negative result. In a range, two limit values are defined, which can be interpreted in two ways: The result is either within the range (negative) or outside the range (positive); or the values within the range render a "soft" positive result and values outside the range render a positive and negative result.

The following illustrations show examples of how different kinds of data alarm can be triggered.



A Limit for abnormal data alarm

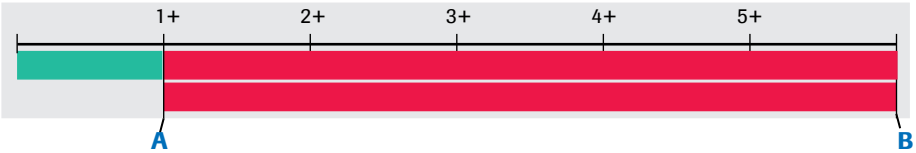
Limit for abnormal data alarms



A Limit for trace data alarm

B Limit for abnormal data alarm

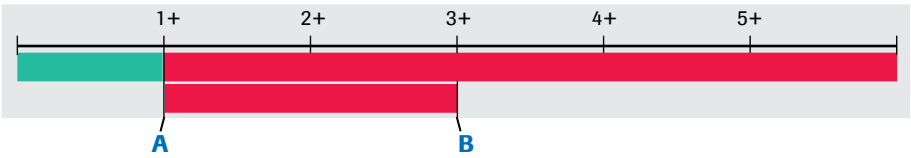
Limits for abnormal and trace data alarms



A Limit for abnormal data alarm
Lower limit for sieve data alarm

B Upper limit for sieve data alarm

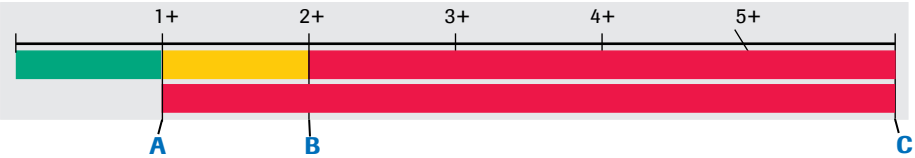
Limits for abnormal and sieve data alarms



A Limit for abnormal data alarm
Lower limit for sieve data alarm

B Upper limit for sieve data alarm
Results within the range of 1+ and 3+ trigger a sieve data alarm

Limits for abnormal and sieve data alarms

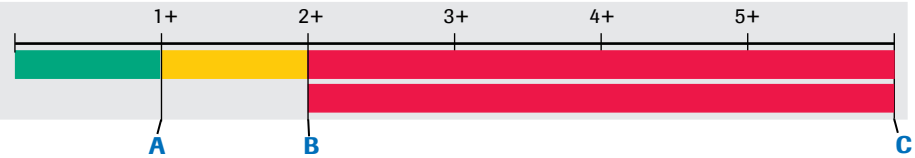


A Limit for trace data alarm
Lower limit for sieve data alarm

B Limit for abnormal data alarm

C Upper limit for sieve data alarm
Results ≥ 1+ trigger a sieve data alarm

Limits for abnormal, trace and sieve data alarms



A Limit for trace data alarm

B Limit for abnormal data alarm
Lower limit for sieve data alarm

C Upper limit for sieve data alarm
Results ≥ 2+ trigger a sieve data alarm

Limits for abnormal, trace and sieve data alarms

In a sieve limit, the limit value is usually arrived at on the basis of range values. It determines whether microscopy analysis should be performed after test strip analysis.

You can also define your own ranges by creating new range tables.

To define a new range table (260)

Limit values

Value	Description
Trace value	Value that defines when a sample should have a follow-up test. It must be ≤ Abnormal value.
Abnormal value	Values ≥ this value are outside the normal or trace range. It must be ≥ Trace value.
Sieve lower limit	Values ≥ this value trigger an additional test.
Sieve upper limit	Values ≤ this value trigger an additional test.

Limit values

To define the limit values

1 Choose **Administration > System settings > Measurement settings**.

2 Choose the **u 601** button.

3 Choose the **Limit configuration** button.

4 In the main panel, choose a test and then choose the **Edit** button in the detail panel.

5 Define the values as required (263), then choose the **Save** button.

6 Define the values for the other tests in the same manner.

Defining the ranges for the colors of COL

It is possible that the color that is displayed in the results table does not quite agree with the actual color of the urine. If a regular pattern is recognized, you can adjust the color ranges to reflect this.

Results generated with adjusted colors will be marked with the **K** data alarm.

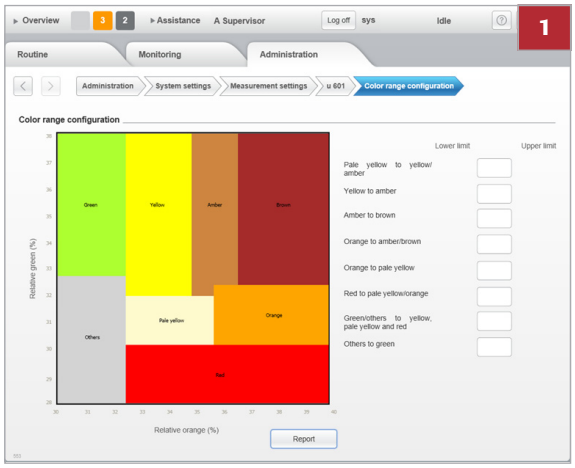
Possible color changes for COL

Selected color field	Available fields in value table
Pale yellow	Pale yellow to yellow/amber
	Orange to pale yellow
Yellow	Yellow to amber
Amber	Amber to brown

Possible color changes for COL

Selected color field	Available fields in value table
Orange	Orange to amber/brown
Brown	None, select Orange or Amber instead
Red	Red to pale yellow/orange
Green	Green/others to yellow, pale yellow and red
	Others to green
Other	None, select Green instead

Possible color changes for COL



To adjust the color ranges

1 Choose **Administration > System settings > Measurement settings > u 601 > Color range configuration**.

2 Choose the **Edit** button.

3 In the color board, choose the area of the color that you want to change. (265)

ℹ The corresponding current values are displayed in the fields on the right.

4 Choose the percentage field and enter the new value.

5 Choose the **Save** button.

Defining warning limits for supplies and solid waste

To define the warning limits

1 Choose **Administration > System settings > Measurement settings**.

2 Choose the **u 601** button.

3 Choose the **Edit** button.

4 Define the limits.

5 Choose the **Save** button.

Defining the QC environment

If you define a new QC material using the RFID reader and this QC material has more levels than the currently defined maximum number, this maximum number is automatically increased to the number of levels of the new QC material.

To define the number of QC levels

1 Choose **Administration > System settings > QC settings**.

2 Choose the **Edit** button.

3 Enter the number of levels you want to work with.
ⓘ You can work with up to five levels.

4 Choose the **Save** button.

Defining the default test profile

Default test profiles

Profile	Description
u 601	The samples are tested for all test strip analysis parameters.
u 601 reduced	The samples are tested for all test strip analysis parameters, but no measuring cell measurements (SG, CLA) are performed.

Default test profiles

To define the default test profile

1 Choose **Administration > System settings > Default test profile**.

2 Choose the **Edit** button.

3 From the drop-down list, choose the profile. (267)
ⓘ Test profiles are predefined and cannot be changed.

4 Choose the **Save** button.

System configuration: Defining the operating environment

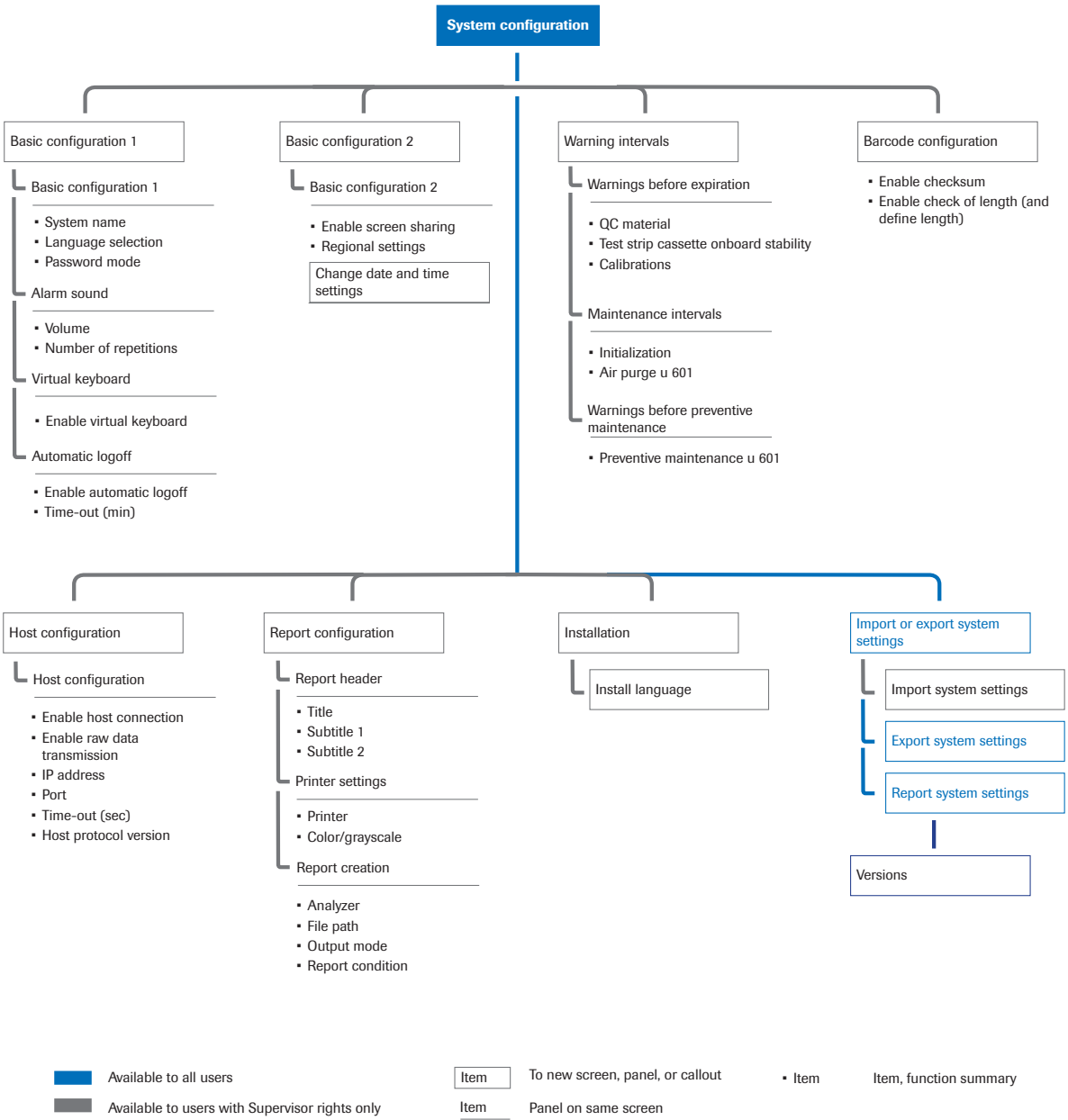
In this section

Defining the operating environment

In this section

About defining the operating environment

Choose **Administration > System configuration** to access configuration items that define the operating environment.



Navigation map for System configuration

About the Basic configuration 1 panel

This panel serves to define the following items:

- Name of the system
- User interface language
- The way passwords are generated and checked
- The volume of the alarm sounds and how often they should be repeated
- Whether the virtual keyboard should be displayed on screen
- Whether and if so after what period of inactivity on the analyzer users should automatically be logged off

Basic configuration 1 items

NOTICE

Using both virtual and external keyboard

Using the virtual keyboard and the external keyboard at the same time could lead to operating complications.

▶ Do not use both keyboards at the same time.

Item	Description
System name	Any alphanumeric characters. This is displayed in the global information area.
Language selection[1]	**de**: German **en**: English **es**: Spanish **fr**: French **it**: Italian **ko**: Korean **pl**: Polish **pt**: Portuguese **ru**: Russian **tr**: Turkish **zh**: Chinese Only the installed languages are available.
Password mode	• **Simple password mode**: The password is defined manually during user definition. It cannot be changed by the general user. • **Strong password mode**: The system generates a random password of 8 character length during user definition, which has to be changed at the first logon by the user, and consequently every 60 days. To define a new user (248)

Basic configuration 1 items

Item	Description
Enable virtual keyboard	Clear the check box if you want to use the external keyboard instead of the virtual keyboard.
Enable automatic logoff	If you select the check box also enter a time-out value between 1 and 1000 minutes.

Basic configuration 1 items

(1) This list is not necessarily complete, further languages may become available and different languages may be installed on your analyzer.

Related topics

- Performing basic configuration (271)

About the Basic configuration 2 panel

This panel serves to define the following items:

- Whether screen sharing with remote access is permitted
- The way lower measurement limit values are reported
- The geographic area where the system is installed
- Date and time settings

Basic configuration 2 items

Item	Description
Enable screen sharing	Allow screen sharing when remote service is active.
Regional settings	Regional settings as supported by the operating system.
Change date and time settings	Define system date and time. Note that the format in which date and time are displayed is linked to the **Regional settings** and cannot be changed.

Basic configuration 2 items

Related topics

- Performing basic configuration (271)

Performing basic configuration

To perform configuration

1 Choose **Administration > System configuration > Basic configuration 1** or **Basic configuration 2.**

2 Choose the **Edit** button.

3 Define the items as required.

For more information, see:

About the Basic configuration 1 panel (270)
About the Basic configuration 2 panel (271)

4 Choose the **Save** button.

Defining when notifications should be generated

You can adjust some intervals to suite your local laboratory requirements. They are divided into groups:

- **Warnings before expiration**
  - Advanced expiry warnings for QC materials, test strip cassettes, and calibrations.
- **Maintenance intervals**
  - Frequency for system initialization.

    Periodic initialization is required to ensure the proper functioning of the analyzer, for example for the correct probe bend detection.
  - Frequency for air purge.

    Air purge is periodically performed to remove any possible air bubbles in the tubing. Your Roche Service representative can change this interval.
- **Warnings before preventive maintenance**
  - Frequency for preventive maintenance.

    During preventive maintenance, a number of items are cleaned or replaced, for example the tubing and filters are replaced.

    This interval reflects the number of tests performed and the time since the last maintenance. Your Roche Service representative can reset the counter for this interval.

To adjust selected advance notification times

1 Choose **Administration > System configuration > Warning intervals**.

2 In the detail panel, choose the **Edit** button.

3 From the drop-down lists, choose the required time indications.

4 Choose the **Save** button.

Defining the barcode check parameters

Enabling the checks increases the reliability of the barcode readings.

⚠ CAUTION

Incorrect results due to undetected reading errors

Barcode reading errors could potentially go undetected if a checksum is not used, which could lead to sample mismatch.

- Use only barcodes with checksum.
- Use only barcode labels of a good print quality.

Barcodes contain checksum characters?	Enable checksum check?	Transmit and show checksum characters?(1)
Yes	Yes	Yes The checksum character is transmitted to the host and also included in the sample ID.
		No The checksum character is not transmitted to the host and it is not included in the sample ID.
No	No(2)	No

Recommended barcode checksum configurations

(1) Definition made by Roche Service representative during installation of the analyzer

(2) Enabling checksum checking while using barcodes that do not contain checksum characters causes the analyzer to generate its own sample IDs.

To define the barcode checks that are applied

1 Choose **Administration > System configuration > Barcode configuration**.

2 Choose the **Edit** button.

3 Define whether the checksum should be checked.

4 Define whether the barcode length should be checked.

5 If you defined that the barcode length should be checked, use the slider to define how many characters long the checksum should be.

6 Choose the **Save** button.

Configuring the host connection

The exact values depend on your IT infrastructure. Refer to the relevant documentation of your IT components.

Instrument priority when working with **Sample sequence number** mode

Orders are always processed and results marked according to the type of rack and the way it was loaded on the analyzer, irrespective of the order type (e.g. STAT) that might have been issued by the host.

Port settings

Port	Description
c 6500	Host protocol versions 8 and older.
c 6500_09	Host protocol versions 9 or more recent. This version is not backward compatible with version 8 and older.

Port settings

To configure the host connection

1 Choose **Administration > System configuration > Host configuration**.

2 Choose the **Edit** button.

3 Select or clear the check boxes and enter the information in the fields as required.

Port settings: Refer to the relevant documentation for the host interface and drivers you are using.

For more information on port settings, see the following table:

Port settings (274)

4 Choose the **Save** button.

Defining the look, content, and handling of reports

Reports are usually used as handouts to physicians, either as printed copies or as PDF files.

You can define default values for the content of the report header, the printer, the analyzer whose results should be reported, the file location and the type of reporting you want to use.

	Parameter	Description
Report header		The **Report header** definitions are used for patient reports.
	Title	e.g. facility name.
	Subtitle 1	e.g. laboratory name.
	Subtitle 2	e.g. department name.
Printer settings	**Printer**	Printer that is connected to the analyzer or any defined network printer.
Report creation		The **Report creation** definitions are used as default values in all reports. They can be changed during report creation.
	File path	The paths the user can select when saving data to files or creating a report. It must be a mapped network drive. **Axeda** is intended for direct upload to Roche Service.
	Output mode	**Print**: Send the report to the printer. **PDF**: Save the report as a PDF file.
	Report condition	**Automatic**: Generate a report for every result. **Data alarm**: Generate a report for results with the data alarms listed in **Assigned data alarms**. (To include a data alarm in this list, choose the data alarm from the **Available data alarms** drop-down list and then choose the **Create** button. To remove the data alarms from the list, choose the **Clear** button.) **Manual**: Only generate a report when requested to do so.

Report items

To define how reports should look, what they should contain and where they should be printed or saved

1 Choose **Administration > System configuration > Report configuration**.

2 Choose the **Edit** button.

3 Define the items as required.(274)

4 Choose the **Save** button.

Installing a new language

You can update language files and add additional languages. The language code in the file name defines the language.(1)

Code	Definition
de	German
en	English
es	Spanish
fr	French
it	Italian
ko	Korean
pl	Polish
pt	Portuguese
ru	Russian
tr	Turkish
zh	Chinese

Language codes

To install a new language or update it

1 Choose **Administration > System configuration > Installation > Install language**.

2 Navigate to the folder where the language file is stored and select the language file.

3 Choose the **Install** button.

ℹ A callout is displayed when the installation is complete.

4 Choose the **OK** button.

Changing the user interface language

You can change the user interface language any time to any language that is currently installed on the analyzer.

Code	Definition
de	German
en	English
es	Spanish
fr	French

User interface languages

(1) This list is not necessarily complete, further languages may become available and different languages may be installed on your analyzer.

Code	Definition
it	Italian
pl	Polish
pt	Portuguese
ru	Russian
tr	Turkish
zh	Chinese

User interface languages

This list is not necessarily complete, further languages may become available and different languages may be installed on your analyzer.

To change the user interface language

1 Ensure that the analyzer is not performing any test or action.

2 Choose **Administration > System configuration > Basic configuration 1**.

3 In the detail panel, choose the **Edit** button.

4 In the **Language selection** drop-down list, choose the language you want to use. (276)

5 Choose the **Save** button.
➔ A callout is displayed.

6 On the callout, choose the **Restart** button.
➔ The system software will be restarted. Wait until the **Overview** work area is displayed, it will be in the new language.

Importing and exporting system settings

The system settings do *not* include data that relate to users, patients, results, orders, and maintenance counters.

You need to delete all sample and QC results before you can import system settings.

Importing system settings

You can import system settings that were previously exported, even if they were saved with a different software version. In the latter case, you need to have installed software version 2.1.1 or more recent.

- If the configuration file to be imported contains an item that does not exist in the current setup it is ignored and not imported.
- If a setting value does not exist in the configuration file to be imported, but is defined in the current software, the default value is set during next software startup.

System settings report

The system settings report provides the system settings in an easily readable form.

All users can generate a report of the system settings.

To import the system settings

1 Choose **Administration > System configuration > Import or export system settings > Import system settings**.

2 In the callout that is displayed, confirm the action.
- If there are results on the analyzer, choose the **Yes** button to confirm their deletion and to continue with the import.
- If there are no results on the analyzer, choose the **Confirm** button to continue.

3 Choose the device where the settings file is stored, e.g. a USB storage device.

4 Choose the **Open** button.
➔ The analyzer software will shut down and restart automatically.
➔ When the **Overview** tab is displayed again and the analyzer status is **Idle** the import has been successful.

To export the system settings

1 Choose **Administration > System configuration > Import or export system settings > Export system settings**.
ⓘ All users can export the system settings.

2 In the callout, choose the device where the settings file should be stored, e.g. the USB storage device, then choose the **Save** button.

To generate a report of the system settings

1 Choose **Administration > System configuration > Import or export system settings > Report system settings**.

2 In the callout, choose the output mode.
- If you choose **Export to PDF**, also choose the **Select** button to define the file path.

➔ If you choose **Print**, the report will be printed on your default printer.

3 In the callout, choose the **Yes** button.

Checking the versions of the installed software components

This information may be helpful for the Roche Service representative during troubleshooting.

All users can view the system information.

To display the versions of the installed software components

1 Choose **Administration > System configuration > Versions**.

➔ The information is displayed in the detail panel.

Managing racks

You can define STAT racks, QC racks, and wash racks, which means that STAT testing, QC testing and the wash action start automatically as soon as you place such a rack on the input buffer. This is achieved by assigning certain rack IDs to the STAT testing, QC testing and wash actions.

Rack IDs (87)

⚠ WARNING

Sample mismatch due to inconsistent rack ID definition

It may be possible that you have several racks with the same rack ID. For a given analyzer, rack IDs must be unique.

- Make sure that the rack IDs that you assign to STAT racks are not used at the same time for routine racks that might be processed on your analyzer.

To define a STAT rack

1 Choose **Monitoring > Manage racks**.

2 Choose the **Create** button.

3 Note the human readable rack ID of the rack you want to use as the STAT rack and enter it without any spaces or special characters in the **Rack ID** field.

4 From the **Assignment** drop-down list, choose **STAT**.

5 Choose the **Save** button.

To define a wash rack

1 Choose **Monitoring > Manage racks**.

2 Choose the **Create** button.

3 Note the human readable rack ID of the rack you want to use as the wash rack and enter it without any spaces or special characters in the **Rack ID** field.

4 From the **Assignment** drop-down list, choose **Wash**.

5 Choose the **Save** button.

To define a QC rack

1 Choose **Monitoring > Manage racks**.

2 Choose the **Create** button.

3 Note the human readable rack ID of the rack you want to use as a QC rack and enter it without any spaces or special characters in the **Rack ID** field.

4 From the **Assignment** drop-down list, choose **QC**.

5 Define at least one rack position for each QC level you are using by choosing a QC level from the drop-down list. You can assign the same level to several positions.

The positions do not have to be adjacent, but Roche recommends to choose positions that are easily remembered.

6 Choose the **Save** button.

Adjusting the probe action

If you decide to use a different type of tube or rack on the **cobas u** 601 urine analyzer, a teaching procedure for the probe must be performed.

This ensures that the probe does not touch the tube bottom and that it is properly immersed in liquid when aspiring.

You perform this task with the help of the **Adjust rack and tube** wizard.

Urine Monovettes

For Urine Monovettes, performing the standard teaching procedure is not sufficient to guarantee trouble-free operation. In this case, your Roche Service representative must perform the rack and tube teaching.

Materials required

- ☐ 5 mL pipette with selection of variable volumes
- ☐ 1 sample rack with a tube containing 1.8 mL tap water on position 1 and a tube containing 1.3 mL tap water on position 2
- ☐ 1 wash rack with a tube containing 3.8 mL tap water on rack position 1

The values for the sample rack are automatically valid for the QC rack as well, therefore, no QC rack needs to be prepared.

To adjust the probe action

1. Choose the **Assistance** tab.
2. Choose the **Wizards on u 601** task button.
3. To start the wizard, choose the **Adjust rack and tube** task button.
4. Follow the on-screen instructions.

Maintenance

Maintenance

In this chapter, you find instructions on how to perform maintenance actions that are not part of the daily routine operation.

In this chapter 7

Safety

⚠ Read and understand the information in the Safety chapter

The following safety messages are particularly relevant:

Warning messages:

- Biohazardous materials (31)
- Waste (31)

Caution messages:

- Mechanical safety (36)
- Working solutions (36)
- Influence of vibrations (37)

Notice messages:

- Spillage (39)
- Excessive ambient humidity (39)

NOTICE

Damage to the analyzer due to use of inappropriate cleaning solution

Using inappropriate cleaning solutions may damage the parts you cleaned.

- Only use recommended cleaning solutions.
  - Cleaning solutions (119)
- Never use the wash solution for manually cleaning the analyzer.

Routine maintenance

All routine maintenance actions can be performed using wizards. They are grouped into actions relating to consumables (supplies) and actions related to keeping the analyzer working (maintenance).

When a maintenance action is due you are informed by a message in the task list. Choosing such a message displays detailed information including a description, possible causes and recommended remedies. If a wizard is available, its button is available in the detail panel.

The following table provides an overview of when a routine maintenance action is due.

Interval	Routine maintenance action
Daily	Washing the fluid system (203)
End of shift	Cleaning the input and output buffers (216)
	Cleaning the analyzer housing (217)
	Cleaning the rack conveyors (217)
	Cleaning the rack trays (218)
	Cleaning the test strip tray and transporter (221)
	Cleaning the probe bend detector (224)
	Cleaning the test strip pipetting area (224)
Every 14 days	Replacing the test strip cassette (208)
	Only required, if the onboard stability of 14 days is due.
Every 4 weeks	Calibrating the photometer unit (225)
	Calibrating the measuring cell (227)
	Cleaning the water container (291)

Intervals of routine maintenance actions

You can always start consumables related wizards by choosing **Assistance > Wizards** or **Monitoring > Manage supplies**.

Wizard name	When to be performed	Purpose
Fill water container	At the beginning of a shift or when prompted to do so	The fill level is monitored and a message is generated when the level gets low. When the container is empty processing stops. Use type II/IF water. Filling the water container (205)
Exchange test strip cassette	When prompted to do so	The fill level is monitored and a message is generated when the level gets low. When the cassette is empty processing stops. Replacing the test strip cassette (208)
Empty the solid waste container	When loading a new test strip cassette or when prompted to do so	The fill level is monitored and a message is generated when the level gets high. If the solid waste container is full, test strips may get stuck in the waste chute or the test strip tray and interfere with the measuring mechanism. Dispose of the waste according to the relevant local regulations. Emptying the solid waste container (207)
Empty the liquid waste container	When filling the water container or when prompted to do so	The fill level is monitored and a message is generated when the level gets high. When the container is full processing stops. Dispose of the waste according to the relevant local regulations. Emptying the liquid waste container (206)
Calibrate photometer	When prompted to do so	Calibration of the photometer is required every 4 weeks to ensure its proper functioning and correct result calculation. Calibrating the photometer unit (225)
Exchange probe	When prompted to do so *To avoid processing delays, Roche recommends to keep a replacement probe on site.*	If the automatic probe positioning calibration test fails or the probe is visibly damaged, e.g. bent, the probe needs to be replaced. To replace the probe (297)
Adjust rack and tube	When a different tube type is going to be used.	To avoid probe crashing and to ensure correct and accurate pipetting, the pipetting mechanism must be adjusted to the new tube dimensions. Adjusting the probe action (282)

Wizards on the **cobas u** 601 urine analyzer

You can always start following wizards by choosing **Monitoring > Perform maintenance**.

Task name	When to be performed	Purpose
Create problem report	As part of troubleshooting	The problem report contains the most recent 1000 messages and the most recent 10 000 entries in the audit trail, as well as information on the installed software versions, languages, online help, and the current counter values. To create a problem report (309)
Export screenshots	As part of troubleshooting	Export all screenshots that were created using the screenshot button, so they can be viewed by the user. When you create a screenshot, it is stored internally. Up to 100 screenshots can be stored internally. Screenshots (307)
Initialize system	As part of troubleshooting or when prompted to do so	System initialization resets the hardware elements to their default positions and so establishes a clean state from where to proceed.
Backup database	For data security, as part of troubleshooting	The database backup includes all database content, including order and result data, user and encrypted patient demographics, as well as all setup, definition and logging data. If the database backup is generated for troubleshooting purposes, exclude the patient demographics by selecting the **Create anonymized database backup** check box in the callout. To back up the database (295)
Restore database	As part of troubleshooting	Import a database that was generated using the **Backup database** function.
Export data in CSV format	As part of troubleshooting or when prompted to do so	Export of result data. To export all results (293)
Perform wash	As part of shutting down the system	To remove soiling and prevent proteinization and buildup of other pollutants in the probe and the fluid system, in particular the rinse station, the fluid system needs to be washed daily. Washing the fluid system (203)
Unload rack	In emergency situations	Move the rack that is on the conveyor to the output buffer.

Further guided maintenance actions

The following maintenance action is started by choosing **Monitoring > Analyzer > u 601 > Perform air purge**.

Task name	When to be performed	Purpose
Perform air purge	Air purge is automatically performed and does not normally require user intervention. You may also need to perform this action as a result of a message in the message list or as part of troubleshooting.	To remove any possible air pockets in the tubing. This is achieved by pumping system water through the whole fluid system. Air purge (204)

Further maintenance actions

Miscellaneous maintenance actions

Some maintenance actions need to be performed periodically, while others are performed as needed.

In this section

Cleaning the water container

To prevent deposits inside the water container, you can clean it with 1% NaOCl solution.

Clean the standard water container if the analyzer has not been used for some time.

Clean the water container for external water supply once a month.

Materials required

- 1% NaOCl (You can use commercially available 5% NaOCl solution and dilute it 5 times with distilled water.)
- Purified water

Water quality (118)

To clean the water container

1 Start the **Fill water container** wizard.
   ❶ Check whether there are deposits on the inside of the water container.

2 Before you fill the container with water, rinse the container with warm tap water several times.
   ❶ If the water container is visibly soiled, rinse it with 1% NaOCl solution.

3 Rinse the water container with purified water.

4 Fill the container with water and continue as described in the wizard.

5 If the problem persists, contact your Roche Service representative.

To clean the water container for external water supply

1 Turn off the external water supply.

2 Remove the water tubing adapter from the water container.

ⓘ Keep the bottom of the tubing in the water container until water stops running.

3 Empty the water container.

4 Rinse the water container with 1% NaOCl solution.

5 To remove any NaOCl residues, rinse the water container with purified water.

6 Wipe the liquid level detection sensors and the float valve with a cloth damped with 1% NaOCl solution.

7 To remove any NaOCl residues, wipe the level detection sensors and the float valve with a cloth damped with purified water.

8 Insert the water tubing adapter in the water container and screw it on.

9 Turn on the external water supply.

Managing the result storage capacity

Your analyzer can be set up to automatically overwrite the oldest data entry when the database is full or to stop processing when the database is full.

Managing the result storage capacity (257)

A message in the message list will inform you when the database is getting full.

There are two ways of exporting results:

- You can export selected or all results contained in the result list in PDF format to an external storage device.

To save results to files (result report) (186)

- You can export all results on the analyzer, including QC and calibration results, to a file in CSV format and then process them in a spreadsheet program.

To keep the result list manageable and to free space you should periodically delete results.

To export all results

1 Choose **Monitoring > Perform maintenance > Export data in CSV format**.
➔ A callout is displayed.

2 If instructed to do so by your Roche Service representative, select the **Include extended data** check box to include all raw data and compress the data in a ZIP file.
➔ The resulting file is password protected.

3 Choose the **Yes** button to export all results that are currently stored on the analyzer.
➔ A callout is displayed for defining where the files should be saved.

4 Choose a destination.

5 Choose the **Save** button.
➔ A progress indication callout is displayed. This action may take some time.
➔ A CSV file and, if you include the raw data, a ZIP file are generated, their file names start with *RawData_*.

To delete results

1 CAUTION! Loss of result data due to erroneous deletion
Choosing **Delete** while deletion is already in progress may cause a further result to be deleted.
Do not choose **Delete** while deletion is in progress.
Always double-check your result selections before choosing **Delete**.

Display the result list:

- Choose **Routine > Manage test results**.
- Choose **Routine > Manage QC > Review QC results**.

2 Use the **View** and **Search** functions to display the results you want to delete.

3 Select the results you want to delete.

ⓘ Select individual check boxes at the beginning of the result entries or select the check box in the table header to select all results in the list.

4 Choose the **Delete** button.

ⓘ Deleting results from the result list also removes them from the database.

5 In the callout, confirm the deletion.

Keeping your data safe

You can export your setup data and the complete database to an external device and import these data again as required.

In this section

About exporting and importing the setup data

The setup data include all definitions made in **System settings** and **System configuration**. They do not include any order, result, user, or patient related data.

You can backup your setup data by exporting and importing the system settings.

Importing and exporting system settings (277)

Backing up the database

You can back up the database to an external device.

The backup includes all database content, including order and result data, user and encrypted patient demographics, as well as all setup, definition and logging data.

You can create a backup where the patient demographics are not included. In this case, demographic data cannot be recovered using **Database restore**. Patient demographics that are on the instrument are deleted during the restore process.

To back up the database

1 If you want to perform a standard database backup, choose **Monitoring > Perform maintenance > Backup database**.

2 If the database backup is generated for troubleshooting purposes, exclude the patient demographics by selecting the **Create anonymized database backup** check box in the callout.

3 In the callout, confirm the action.

4 In the next callout, choose the destination.

5 Choose the **Save** button.
ⓘ This action may take some time.

Issues with the probe

During initialization of the analyzer the probe positioning is automatically calibrated and its position adjusted. The probe needs to be replaced if during initialization the required corrections are consistently outside the allowed ranges. A message in the message list would alert you to this fact.

⚠ WARNING

Incorrect results due to touching the probe

Touching the probe with bare fingers may leave residues on its surface and consequently influence the accuracy of the results.

- Do not touch the probe except for maintenance as described in this documentation.

⚠ CAUTION

Skin inflammation or injury caused by working solutions

Direct contact with cleaning solutions or other working solutions may cause skin irritation, inflammation, or burns.

- If a cleaning solution or other working solution comes into contact with your skin, wash it off immediately with water and apply disinfectant. Consult a physician.

⚠ CAUTION

Personal injury due to contact with sharp objects

- Avoid contact with the probe tip.

To avoid processing delays, Roche recommends to keep a replacement probe on site.

If initialization is not successful proceed as follows:

1	Repeat the initialization. Choose **Monitoring > Perform maintenance > Initialize system**.
2	If the problem persists, clean the probe bend detector.
▸	Cleaning the probe bend detector (224)
3	If the problem persists, clean the probe.
▸	To clean the probe (297)

Required tasks

4 If the problem persists, replace the probe.

To replace the probe (297)

Required tasks

To clean the probe

1 Start the **Exchange probe** wizard.
- In the message list, choose the message that indicates that the probe needs replacing, then choose the **Exchange probe** button in the detail panel.
- Choose **Assistance > Wizards > Exchange probe on u 601**.

➔ The wizard is started.

2 Follow the on-screen instructions. But instead of removing and replacing the probe just wipe it with a lint-free cloth.

ⓘ Carefully move the cloth from top to bottom, do not use up and down movements.

To replace the probe

1 Start the **Exchange probe** wizard.
- In the message list, choose the message that indicates that the probe needs replacing, then choose the **Exchange probe** button in the detail panel.
- Choose **Assistance > Wizards > Exchange probe on u 601**.

➔ The wizard is started.

2 Follow the on-screen instructions.

If you are not going to use the analyzer for some time

Supplies that remain on the analyzer for a long time may deteriorate. Therefore, if you intend not to use the analyzer for some time, Roche recommend removing them from the analyzer.

1	Remove the test strip cassette.
	Removing the test strip cassette (241)
2	Empty the solid waste.
	Emptying the solid waste container (207)
3	Empty the water container.
	To empty the water container (298)
4	Drain all water from the fluid system.
	To drain the system water (298)
5	Empty the liquid waste.
	Emptying the liquid waste container (206)
6	Shut down the system and switch off the power.
	To shut down the analyzer (299)
	Required tasks

Location of status indicator in the global information area

To empty the water container

1 Choose **Assistance > Wizards > Fill water container on u 601**.

2 Remove the water container and empty the system water.

3 Install the *empty* water container.

4 Finish the wizard.

To drain the system water

1 Choose **Overview >** analyzer illustration of the test strip analyzer **> Perform air purge**.

2 Perform the previous step several times until you cannot see any water in the tubing.

To shut down the analyzer

1 Ensure that the analyzer status in the global information area is **Idle**.

2 Choose **Overview > Shut down**.

➔ A callout is displayed, asking you whether you want to perform the daily wash maintenance action.

3 Choose the **No** button.

➔ The software is shut down and the analyzer is switched off.

4 Put the power switch at the rear of the analyzers in the off position ◯.

Troubleshooting

Troubleshooting

In this chapter, you find information on how to recover from unusual situations.

In this chapter

8

Exceptional situations

The following table lists, in alphabetical order, exceptional situations that may occur and points to ways of how to handle them.

Keyword	Situation	How to handle the situation
Barcodes	Barcode cannot be read. Barcode labels may become detached and stick to parts of the rack transport unit or become wedged between the rack or sample tube and the analyzer parts.	›🗎 Detached barcode labels (311)
Calibration	You cannot calibrate the photometer. Invalid results are produced repeatedly.	›🗎 No photometer calibration can be generated (310)
	You cannot calibrate the measuring cell.	›🗎 No measuring cell calibration can be generated (310)
Cover	You have accidentally opened the main cover.	›🗎 To recover after accidentally opening the main cover (312)
Emergency stop	All mechanical movement must be stopped immediately. The analyzer is stuck in **Processing** or **Init** status.	›🗎 To perform an emergency stop (314)
Filter	Processing stopped due to a clogged inlet water filter.	›🗎 Clogged inlet water filter (318)
Floats	A float in the water or liquid waste container does not move freely or it is blocked. The level indications as indicated by messages might not agree with the actual levels.	›🗎 Blocked floats (321)
Labels	Barcode cannot be read. Barcode labels may become detached and stick to parts of the rack transport unit or become wedged between the rack or sample tube and the analyzer parts.	›🗎 Detached barcode labels (311)
	You may be using a type of rack that is not recommend by Roche	
Log files	All activities on the analyzer are recorded in log files. You can export these files for troubleshooting purposes	›🗎 Log files (308) ›🗎 To create a problem report (309)
Measuring cell calibration	You cannot calibrate the measuring cell. Invalid results are produced repeatedly.	›🗎 No measuring cell calibration can be generated (310)
Photometer calibration	You cannot calibrate the photometer. Invalid results are produced repeatedly.	›🗎 No photometer calibration can be generated (310)
Power outage	After power is cut, you must follow a prescribed procedure to avoid data loss.	›🗎 To recover from a power outage (316)
Problem report	All activities on the analyzer are recorded in log files. You can export these files for troubleshooting purposes.	›🗎 To create a problem report (309)
Safety interlock	A message is displayed informing you that safety interlock in not on.	›🗎 Safety interlock (318)
Shut-down	The screen froze completely and you had to shut down using the On/Off switch.	›🗎 To recover from a forced shutdown (313)

Exceptional situations and how to deal with them

Keyword	Situation	How to handle the situation
Screen	The screen froze completely and you had to shut down using the On/Off switch.	To recover from a forced shutdown (313)
Screenshots	You want to document a particular situation for troubleshooting reasons.	To generate a screenshot (307)
Sensor (floats)	A float in the water or liquid waste container do not move freely any more or that they are blocked. The level indications as indicated by messages might not agree with the actual levels.	Blocked floats (321)
Stop	Processing stopped because you have accidentally opened the main cover.	To recover after accidentally opening the main cover (312)
	Processing stopped because you have accidentally pulled out the waste drawer.	To recover after pulling the waste drawer (315)
	Processing stopped due to a clogged inlet water filter.	Clogged inlet water filter (318)
	The analyzer is stuck in **Processing** or **Init** status.	To perform an emergency stop (314)
	All mechanical movement must be stopped immediately.	To perform an emergency stop (314)
	The screen froze completely and you had to shut down using the On/Off switch.	To recover from a forced shutdown (313)
Stuck	The analyzer is stuck in **Processing** or **Init** status.	To perform an emergency stop (314)
Waste container	A float in the water or liquid waste container does not move freely any more or it is blocked. The level indications as indicated by messages might not agree with the actual levels.	Blocked floats (321)
Water container	A float in the water or liquid waste container does not move freely any more it is blocked. The level indications as indicated by messages might not agree with the actual levels.	Blocked floats (321)
Water filter	Processing stopped due to a clogged inlet water filter.	To clean the inlet water filter (319) To clean the inlet water filter (external water supply) (320)

Exceptional situations and how to deal with them

Screenshots

As part of troubleshooting, in particular if you need to contact a Roche Service representative, it is useful to generate screenshots to capture the exact situation at the time of a problem occurring.

To generate a screenshot

1 In the global information area, choose the button.
➔ An image of the current screen is saved in a file.

2 If you want to examine the screenshot yourself, choose **Monitoring > Perform maintenance > Export screen shots**.
ⓘ This function saves the last 100 screenshots that were generated using the print screen function to a location that is accessible by the user.

Log files

All activities on the analyzer are recorded in log files.

Message log

All users can view the message log, which contains a chronological log of all messages that were generated by the analyzer, including the task messages.

Audit trail

Users with Supervisor user rights can also view the audit trail, which contains a chronological log of all activities and events such as logon, logoff, order handling, sample processing, result validation, QC, calibration, maintenance, software updates, and remote access, as well as those concerning configuration.

Problem report

The problem report is a collection of various logs and comprises the last 1000 messages of the message log, the last 10 000 entries of the audit trail, counter values, and information about the installed versions of the software and online help.

Problem reports do not contain PDF versions of data, they are meant for troubleshooting purposes.

You can export the problem report to an external device, from where it can be sent to experts for analysis.

To view the message log

1 Choose **Administration > Message log**.

➔ The messages are displayed in chronological order.

To view the audit trail

1 Choose **Administration > Audit trail**.

ℹ You need Supervisor user rights to view the audit trail.

➔ The messages are displayed in chronological order.

To create a problem report

1 Choose **Monitoring > Perform maintenance > Create problem report**.

2 In the callout, define the target location for the report.

Axeda is intended for direct upload to Roche Service. Do not use this destination unless instructed to do so by your Roche Service representative.

3 In the callout, define whether the failsafe images should be included.

These are photometer images that were taken when an error was detected and are intended for Roche Service representatives only.

4 Choose the **Save** button.

For details on defining the default file locations, see:

Defining the look, content, and handling of reports (274).

No photometer calibration can be generated

If photometer calibration persistently fails, proceed as follows:

- ☐ Be sure to use a fresh calibration strip with every photometer calibration.
- ☐ Check the calibration strip.
  - Check it for soiling. Use a new one.
  - Check the expiry date of the calibration strips. Only use calibration strips that have not expired.
  - Check the storage conditions for the calibration strips. Calibration strips that were stored vertically may be bent and consequently unsuitable for use.
  - Calibrate the photometer unit.
- ☐ If the problem persists, contact your Roche Service representative.

No measuring cell calibration can be generated

If measuring cell calibration fails proceed as follows:

▸ To obtain a measuring cell calibration

1 Repeat the calibration.

2 If the problem persists, check that you use water of the required quality.
- Change the water, if required, then perform a wash. (**Monitoring > Perform maintenance > Perform wash**)

Only use water with the specified quality:

Water quality (118)

3 If the problem still persists, contact your Roche Service representative.

Detached barcode labels

Barcode labels may become detached and stick to parts of the rack transport unit or become wedged between the rack or sample tube and the analyzer parts. If this happens between the rack entry position and the barcode reader, a message is added to the message list. Processing stops.

To recover from processing stop due to detached barcode labels

1 Display the message details and consult the possible causes.

2 Open the main cover.

3 Ensure that the affected label does not interfere with the rack movement. If necessary remove it.

4 Close the main cover.

5 Choose **Monitoring > Perform maintenance > Unload racks**.

6 Remove the rack from the output buffer.

7 Replace the barcode.
- If the problem concerns a rack barcode label, transfer the tubes to a new rack.
- If the problem concerns a sample tube barcode label, replace the label. You can also just remove the label and place the tube on its original position. In this case the analyzer automatically defines a sample ID and an order using the default test profile.

8 Place the rack in the priority rack slot.
➔ Processing starts automatically.

Recovering from an irregular stop

⚠ CAUTION

Loss of data and sample due to opening the main cover

Opening the main cover during operation interrupts the power supply to all units, processing stops immediately and no status information can be stored. Incomplete tests and other activities will have to be redone.

- Do not open the main cover while the analyzer is performing some activity. Only do so in an emergency.

⚠ CAUTION

Loss of data and sample due to turning off the analyzer using the on/off switch

Pressing the on/off switch for several seconds stops all processing and shuts down the internal PC. No status information can be stored. Incomplete tests and other activities will have to be redone.

- Do not use the on/off switch to turn off the analyzer except in an emergency, e.g. when the screen is “frozen” and analyzer does not react to any user action, on-screen or otherwise.

If during operation you open the main cover, either by accident or deliberately, all processing activities stop immediately (power to all units is cut) and all incomplete tests and other activities will have to be redone.

If for example the screen is “frozen” and the analyzer does not react to any user action on-screen or otherwise, you may be forced to press the on/off switch for several seconds to shut down the analyzer. This stops all processing and shuts down the internal PC. No status information can be stored. Incomplete tests and other activities will have to be redone.

To recover after accidentally opening the main cover

1 Close all covers.

➔ Power is restored to the units.

2 If there is a rack on the conveyor choose **Monitoring > Perform maintenance > Unload racks**.

3 Remove the rack from the output buffer.

4 Choose **Monitoring > Perform maintenance > Initialize system**.
➔ Wait until the **Overview** work area is displayed again.

5 Check the task list and deal with all red and orange items.

6 Replenish the samples, if required.

7 Place the rack in the priority rack slot.

To recover from a forced shutdown

1 Press the on/off switch.
➔ The analyzer software will start automatically.

2 Wait until the **Overview** work area is displayed.

3 If there is a rack on the conveyor choose **Monitoring > Perform maintenance > Unload racks**.

4 Remove the rack from the output buffer.

5 Check the task list and deal with all red and orange items.

6 Check the samples for which there are no results.
➔ Ensure that there is sufficient sample.

7 Place the samples in exactly the same position on the rack where they were removed from.

8 If you work without sample barcodes, redefine the orders. (191)

Emergency stop

Use this function if, for some reason, all activities on the analyzer must be stopped immediately or if the analyzer is stuck in either the **Operating** or **Init** status.

To perform an emergency stop

1 On the **Overview** work area, choose the **E. Stop** button.
➔ All mechanical movement on the analyzer stops.

2 If the analyzer has gone into **Standby** status, do one of the following:
- Initialize the analyzer by choosing **Monitoring > Perform maintenance > Initialize system**.
- Shut down the analyzer by using the **Shut down** button.

3 If the analyzer did *not* go into **Standby** status, turn off the analyzer by using the On/Off switch.

4 If you shut down or switched off the analyzer, sort out any hardware problems and restart the analyzer.
(312)

5 If the problem persists, contact your Roche Service representative.

When you have accidentally pulled the waste drawer during operation

⚠ CAUTION

Loss of data and sample due to opening the waste drawer

When you pull the waste drawer while the analyzer is processing tests, all operation stops immediately, the analyzer displays the **Idle** status. Any processing interruption of pipetted samples would affect the incubation time, which is critical for obtaining correct results.

All pipetted test strips are discarded and all incomplete tests need to be performed again.

- Do not open the waste drawer while test processing is going on.

To recover after pulling the waste drawer

1 Close the waste drawer.

2 Choose the **Overview** work area.

3 Choose the hardware graphic.

4 Choose the **Initialize system** button.
➔ This may take a while. Wait until the analyzer is in **Idle** status.

5 Remove the rack from the output buffer.

6 Check the samples for which there are no results.
➔ Ensure that there is sufficient sample.

7 Place the samples in exactly the same position on the rack where they were removed from.

8 If you work without sample barcodes, redefine the orders. (191)

9 Place the rack in the priority rack slot.
➔ New orders are generated and the test are processed.

Recovering from a power outage

⚠ CAUTION

Loss of data and sample due to power outage

Accidentally unplugging the power supply or a power outage stops all processing and no status information can be stored. Incomplete tests and other activities will have to be redone.

- Ensure that the mains cables are placed safely away from areas where personnel might pass through.
- Roche recommends using an uninterruptible power supply.

Uninterruptible power supply (UPS) (117)

⚠ CAUTION

Incorrect results due to power outage

Accidentally unplugging the power supply or a power outage stops all processing. If as a result the test strip cassette shutter remains open, ambient air can enter the test strip cassette and influence the chemistry of the test pads.

- Ensure that the mains cables are placed safely away from areas where personnel might pass through.
- Roche recommends using an uninterruptible power supply.

Uninterruptible power supply (UPS) (117)

To recover from a power outage

1 Restore power to the analyzer.

2 Press the on/off switch.
➔ The analyzer software will start automatically.

3 Wait until the **Overview** work area is displayed.

4 If there is a rack on the conveyor choose **Monitoring > Perform maintenance > Unload racks**.

5 Remove the rack from the output buffer.

6 Check the task list and deal with all red and orange items.

7 Check the samples for which there are no results.
➔ Ensure that there is sufficient sample.

8 Place the samples in exactly the same position on the rack where they were removed from.

9 If you work without sample barcodes, redefine the orders. (191)

Safety interlock

⚠ WARNING

Immediate processing stop due to opening the main cover

Opening the main cover results in immediate power interruption to all units and processing stop.

- Do not open the main cover during routine operation.

This feature can be bypassed by the Roche Service representative for testing and troubleshooting purposes. When this bypass is on, a message is added to the message list.

If a Roche Service representative did not cancel this bypass, contact your Roche Service representative immediately.

Clogged inlet water filter

Impurities in the water may cause clogging of the inlet water filter in the water container. If this is the case, the situation may occur that the analyzer does not receive sufficient water and processing may stop.

If such a situation occurs, proceed as follows:

- ☐ Check that the water quality is of the required standard.
- Water quality (118)
- ☐ Check whether the inlet water filter is soiled or clogged.
- To clean the inlet water filter (319)
- To clean the inlet water filter (external water supply) (320)
- ☐ Check whether the inside of the water container is soiled or shows deposits.
- To clean the water container (291)
- To clean the water container for external water supply (292)

Water container	Water container with external water supply
	

A Water tubing adapter **B** Water tubing

C Inlet water filter

Water container and Water container with external water supply

To clean the inlet water filter

1 Start the **Fill water container** wizard.

ℹ Check for discoloring and soiling of the inlet water filter.

2 Before you fill the container with water, rinse the inlet water filter with 1% NaOCl.

3 CAUTION! Incorrect results due to water contamination
System water that is contaminated with cleaning solution may lead to incorrect results.
Rinse the filter and the other tubing adapter components thoroughly with purified water before filling the container with system water.

Rinse the inlet water filter and the other tubing adapter components thoroughly with purified water.

4 Fill the container with water and continue as described in the wizard.

5 If the problem persists, contact your Roche Service representative.

To clean the inlet water filter (external water supply)

1 To clean the inlet water filter if an external water supply is attached, perform the following steps:

This procedure is not software supported, and it may interfere with analyzer activities if the analyzer is running.

2 Shut down the analyzer. (212)

3 Turn off the external water supply.

4 Remove the water tubing adapter from the water container.

- Keep the bottom of the water tubing in the water container until water stops running.

5 Rinse the inlet water filter with 1% NaOCl.

6 CAUTION! Incorrect results due to water contamination
System water that is contaminated with cleaning solution may lead to incorrect results.
Rinse the filter and the other adapter components thoroughly with purified water before reinserting the water tubing adapter.

Rinse the inlet water filter and the other tubing adapter components with purified water.

7 Insert the water tubing adapter in the water container and screw it on.

8 Turn on the external water supply.

Blocked floats

It may happen that the floats in the water and liquid waste containers do not move freely any more or that they might be blocked. In such situations, the level indications as indicated by messages might not agree with the actual levels.

If such a situation occurs, loosen the floats manually.

⚠ CAUTION

Contamination of the environment by liquid and solid waste

The waste of the analyzer is potentially biohazardous and must be treated in accordance with the relevant laws and regulations.

- When disposing of any waste, do so in accordance with the appropriate local regulations.
- Any substances contained in QC materials and other working materials, which are legally regulated for environmental protection, must be disposed of in accordance with the relevant water discharge facility regulations. For the legal regulations on water discharge, please contact the suppliers of the materials.

⚠ CAUTION

Infection by liquid waste

Contact with liquid waste may result in infection. All materials and mechanical components associated with the waste systems are potentially biohazardous.

- Be sure to wear protective equipment. Take extra care when working with lab gloves; these can easily be pierced or cut, which can lead to infection.
- If any biohazardous material is spilled, wipe it up immediately and apply disinfectant.
- If liquid waste comes into contact with your skin, wash it off immediately with water and apply disinfectant. Consult a physician.
- Observe the safety labels on the equipment.

To loosen the floats in the water container

1 Choose a message that concerns the fill level of water.

2 Remove the water tubing adapter (A) from the water container and place it on a clean surface.

3 Hold one of the floats (B) with two fingers and gently move it back and forth along the float assembly rod. They should move freely.

ℹ Observe the status of the message on screen, depending on the position of the float it should change its color.
Do the same with the other float.

4 If a float does not move freely after you have moved it back and forth or if the massage status does not change, contact your Roche Service representative.

5 Reinsert the water tubing adapter in the water container.

6 If the problem recurs, contact your Roche Service representative.

To loosen the floats in the water container for external water supply

1 Choose a message that concerns the fill level of water.

2 Remove the water tubing adapter (A) from the water container and place it on a clean surface.

3 Hold one of the floats (B) with two fingers and gently move it back and forth along the float assembly rod. They should move freely.

ℹ Observe the status of the message on screen, depending on the position of the float it should change its color.
Do the same with the other float.

4 If a float does not move freely after you have moved it back and forth or if the massage status does not change, contact your Roche Service representative.

5 Install the water tubing adapter on the water container.

6 If the problem recurs, contact your Roche Service representative.

To loosen the floats in the liquid waste container

1 Choose a message that concerns the fill level of liquid waste.

2 Start the **Empty liquid waste container** wizard and follow its instructions.

3 Remove the waste tubing adapter (A) from the liquid waste container and place it on a clean surface.

4 Empty the liquid waste. Dispose of it in accordance with the appropriate local regulations.

5 Hold one of the floats (B) with two fingers and gently move it back and forth along the float assembly rod. They should move freely.

ℹ Observe the status of the message on screen, depending on the position of the float it should change its color.Do the same with the other float.

6 If a float does not move freely after you have moved it back and forth or if the massage status does not change, contact your Roche Service representative.

7 Reinsert the waste tubing adapter in the liquid waste container.

8 If the problem recurs, contact your Roche Service representative.

Glossary

Glossary

The glossary lists terms that are used in the user documentation that may not be familiar to the reader or that carry meaning that is specific to this analyzer environment.

Analyte See Urine analyte.

Arbitrary units Result classification using 1+, 2+, 3+ classes instead of numerical concentration results.

Calibration strip Gray plastic strip used for calibrating the photometer.

Callout Popup window that is displayed on screen to show information or to accept user input as part of performing a certain task.

Cleaning solution Liquid used for cleaning and decontamination of surfaces and parts of a system.

Compensation pad A blank white pad on the test strip that is used for establishing the intrinsic color of the urine with the purpose of compensation for this color value to prevent false results with strongly colored urine samples.

Failsafe image Failsafe images are photometer images that are created when a photometer errors occurs. They are intended for Roche Service representatives only.

Priority rack Any rack that is placed on the priority rack slot for immediate processing.

Qualitative determination The measurement of analytes or features with descriptive (qualitative) result classification such as negative/positive.

Radio frequency identification (RFID) tag

Electronic tag attached to Roche supplies that contains critical information such as product ID, lot number, production date, and a parameter file.

Roche 5-position rack Standard rack that offers space for five tubes.

Semi-quantitative determination The measurement of analytes or features in urine yielding an approximation of the quantity or amount of a substance such as negative/slightly positive/moderate positive/strongly positive.

Specific gravity The ratio of the density of urine to the density of water.

Urine analyte Constituent in urine whose concentration is to be determined.

Wash solution Liquid used for internal washing the fluid system.

Work area Part of the screen, usually a tab, that groups related information and tasks for the convenience of the user, for example tasks relating to performing tests or to setting up the analyzer.

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