cobas® 6500 urine analyzer series

Version 2.1.0
Operator's Manual
06998437018 (03) 2016-07 EN

Document information

Revision history

Manual version	Software version	Revision date	Change description
1.0.0	2.0	May 2014	First publication
1.0.0	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 particle subclasses. • 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. • Improved manual image analysis. • Definition of STAT racks.

Table 1 Revision history

Edition notice

This information is intended for operators and administrators of the **cobas**® 6500 urine analyzer series, which consists of two fully integrated analyzers, the **cobas u** 601 urine analyzer and the **cobas u** 701 microscopy analyzer.

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

Customer modifications to the instrument may impair instrument safety and may lead to malfunction, incorrect measurements, and incorrect results. Any customer modification to the instrument will render the warranty or service agreement null and void.

Intended use

The **cobas**® 6500 urine analyzer series is a fully automated system for Urine Analysis.

The **cobas**® 6500 urine analyzer series is built by modular use of the **cobas u** 601 urine analyzer in combination with the **cobas u** 701 microscopy analyzer.

The **cobas u** 601 urine analyzer is a fully automated urinalysis system intended for the in vitro 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.

It is designed to read the **cobas u** pack test strips and calibrate with the **cobas u** calibration strip.

The **cobas u** 701 microscopy analyzer is a fully automated urine microscopy system intended for the in vitro quantitative determination of erythrocytes and leukocytes, the semi-quantitative determination of squamous and non-squamous epithelial cells, bacteria, and hyaline casts and the qualitative determination of pathological casts, crystals, yeasts, mucus, and sperm in urine.

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.

The **cobas**® 6500 installation kit for LAS is intended to make the **cobas u** 601 urine analyzer or the **cobas u** 701 microscopy analyzer or the combination of both analyzers ready for uni-directional connection to the laboratory automation systems.

Trademarks The following trademarks are acknowledged:

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

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

Instrument approvals The **cobas**® 6500 urine analyzer series meets the requirements laid down in:

- Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices
- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

The **cobas**® 6500 urine analyzer series is manufactured and tested according to the international safety standards below:

- UL 61010-1, 2nd Edition
- IEC 61010-1, 2nd Edition
- IEC 61010-2-081, 1st Edition
- IEC 61010-2-101, 1st Edition
- CAN/CSA C22.2 No. 61010 2nd Edition
- EN IEC 61326-1 2nd Edition
- EN IEC 61326-2-6 2nd Edition

The Operator's Manual meets the European Standard DIN EN ISO 18113-3.

Compliance with the applicable directives is provided by means of the Declaration of Conformity. The following marks demonstrate compliance:

IVD	For in vitro diagnostic use.
CE	Complies with the provisions of the applicable EU directives.
c UL US	Issued by Underwriters Laboratories, Inc. (UL) for Canada and the US.

Contact address

Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany

Made in Hungary

Table of contents

Troubleshooting

Glossary

Index

Preface

The **cobas**® 6500 urine analyzer series is an automated urine analysis system that consists of two fully integrated analyzers:

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, 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.

The **cobas u** 701 microscopy analyzer (called *microscopy analyzer* in this documentation) is a fully automated urine microscopy system intended for the in vitro quantitative determination of erythrocytes and leukocytes, the semi-quantitative determination of squamous and non-squamous epithelial cells, bacteria, hyaline casts, and the qualitative determination of pathological casts, crystals, yeasts, mucus, and sperm in urine.

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.

The throughput depends on the rate of samples that are processed on the **cobas u** 701 microscopy analyzer (up to 240 samples per hour with test strip analysis only, up to 116 samples per hour with microscopy analysis only)

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.

Symbols The following symbols are used:

Symbol	Comment
•	List item
	Start of procedure
	End of procedure
	Cross-reference
➔	Navigation path indication
	Tip
	Safety alert
	Electrical and electronic equipment marked with this symbol are covered by the European directive WEEE.

Table 2 Symbols used for easy recognition of information

Abbreviations The following abbreviations are used:

Abbreviation	Explanation
A	ampère
BAC	bacteria
BIL	bilirubin
CLA	clarity
COL	color
CRY	crystals
CSA	Canadian Standards Association
CSV	character separated values
e.g.	exempli gratia – for example
EC	European Community
EMC	electromagnetic compatibility
EN	European standard
ERY	erythrocytes and hemoglobin
GLU	glucose
HPF	high-power field
HYA	hyaline casts
Hz	hertz

Table 3 Abbreviations

Abbreviation	Explanation
i.e.	id est – that is to say
IEC	International Electrical Commission
IVD	in vitro diagnostic directive
KET	ketones
LEU	leukocytes
LAS	laboratory automation system
LIS	laboratory information system
max.	maximum
min.	minimum
mm	millimeter
MUC	mucus
n/a	not applicable
NEC	non-squamous epithelial cells
NIT	nitrite
nm	nanometer
PAT	pathological casts
PRO	protein
QC	quality control
RBC	red blood cells
RFID	radio frequency identification
SEC	squamous epithelial cells
SG	specific gravity
SPRM	sperm
STAT	short turn around time
UBG	urobilinogen
UL	Underwriters Laboratories Inc.
UPS	uninterrupted power supply
V	volt
VA	volt-ampère
VAC	volt alternating current
W	watt
WBC	white blood cells
YEA	yeasts

Table 3 Abbreviations

What is new in publication version 2.0.0

General

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 (p. 65)
Operation with input connection unit (p. 144)
To load a priority rack when working with an LAS (p. 145)
To perform a QC measurement when working with an LAS (p. 210)
To clean the inlet water filter (external water supply) (p. 297)
To loosen the floats in the water container for external water supply (p. 300)

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 (p. 71)
Liquid waste with external water supply (p. 72)
To clean the inlet water filter (external water supply) (p. 297)
To loosen the floats in the water container for external water supply (p. 300)

Image zoom function You can now zoom in on individual microscope images.

Using the zoom function (p. 113)

Technical specifications Some values were adjusted.

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

Technical specifications (p. 94)

Safety

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

- Input connection unit
  Input connection unit (p. 65)
- External water supply
  Water container for external water supply (p. 71)
- Racks and tubes
  Racks (p. 67)
  To adjust the probe action (p. 259)

New safety labels were attached.

Safety labels on the equipment (p. 27)

Operation

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 (p. 292)
To load a priority rack when working with an LAS (p. 145)

Result presentation

- To assist people with color vision deficits, in addition to the colors hatching is displayed.

Color coding (p. 121)

- New symbols and data alarms were introduced to provide more information about the status of the result.

Checking the status of processing (p. 145)
Validating results (p. 151)
To review QC results (p. 215)

QC charts

The QC charts function has been improved.

Working with QC charts (p. 117)

Manually analyzing microscope images

The descriptions of manually analyzing images was adapted and extended.

Manually analyzing images (p. 168)

Printing and exporting information

The feature was adapted and applied consistently.

Some changes:

- In the result report, the results of subclasses follow immediately the results of their main class.
- Screenshots are no longer part of the problem report, instead, you can save them separately.
- Particle labels can now be saved with the images.

Printing and exporting information, generating reports (p. 220)

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 (p. 292)

Maintenance

Cleaning the pipetting stage area

The procedure for cleaning the pipetting stage area was adapted.

To clean the pipetting stage area (p. 198)

Cleaning the centrifuge chamber

The procedure for cleaning centrifuge chamber was adapted.

To clean the centrifuge chamber (p. 201)

Replacing the reference plate

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

To replace the reference plate (p. 284)

Configuration

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 (p. 251)

QC materials The conditions for making changes to QC materials have changed.

To change QC material data (p. 213)
To make test parameter related changes (p. 213)
To include or exclude tests from the QC measurements (p. 214)

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 (p. 212)

Report definition The items have been regrouped and complemented.

Defining the look, content, and handling of reports (p. 253)

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

Defining range tables (p. 236)
Defining cross-check rules (p. 234)

Particle subclasses You can now examine particles that cannot be classified as a subclass of an existing main class. Such particles are defined as subclasses of the new generic main class **Others**.

Defining particle subclasses (p. 244)

Semi-quantitative reporting of RBC and WBC A description was added on how to proceed if you want to display RBC and WBC results on a semi-quantitative level.

Displaying RBC and WBC results on a semi-quantitative level (p. 239)

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 (p. 242)

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 (p. 256)

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 (p. 259)

What is new in publication version 2.1.0

General

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 (p. 96)

Operation

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

Managing sample sequence numbers (p. 137)
Rerunning tests when working with Sample sequence number mode and without sample barcodes (p. 165)

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 (p. 151)

Manual particle classification In a given image, you can now classify multiple particles in one go. You can also remove several classifications in one go.

To assign or reclassify particles (p. 171)
To remove the classification from particles (p. 173)

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

Managing invalid SG results (p. 157)

Configuration

Working with Sample sequence number mode The information on defining the validation method has been adapted.

Defining the validation method (p. 233)

STAT racks You can now define dedicated STAT racks.

To define a STAT rack (p. 258)

System description

Safety

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

In this chapter *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

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

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.

Operator qualification

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

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

Environmental conditions Operation outside the specified environmental conditions may lead to incorrect results or malfunction of the instrument. (See *Technical specifications* (p. 94))

Use the instrument indoors only and avoid heat and humidity. (See *Technical specifications* (p. 94))

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.

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

All 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.

For information about the disposal of the analyzer, see: *Disposal of the equipment* (p. 34).

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.

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.

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


WARNING

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.


WARNING

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.


WARNING

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


WARNING

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.

Data security


WARNING

Unauthorized access and data loss due to malicious software and hacker attacks

External storage devices can be infected with and transmit computer malware, which may be used to gain unauthorized access to data or cause unwanted changes to software.

The **cobas**® 6500 urine analyzer series is not protected against malicious software and hacker attacks.

The customers are responsible for IT security of their IT infrastructure and for protecting it against malicious software and hacker attacks. Failure to do so may result in data loss or render the **cobas**® 6500 urine analyzer series unusable.

- Roche recommends the following precautions:
  - Allow connection to authorized external devices only.
  - For the LAN connection between the **cobas u** 601 urine analyzer and the **cobas u** 701 microscopy analyzer use a dedicated cable and not the network connection.
  - Ensure that all external devices are protected by appropriate security software.
  - Ensure that access to all external devices is protected by appropriate security equipment. Roche strongly recommends the use of a firewall of Roche.
  - Do not copy or install any software on the **cobas**® 6500 urine analyzer series unless it is part of the system software or you are instructed to do so by a Roche representative.
  - If additional software is required, contact your Roche representative to ensure validation of the software in question.
  - Do not use the USB ports to connect other storage devices unless you are instructed to do so by official user documentation or a Roche representative.
  - Exercise utmost care when using external storage devices such as CDs, or DVDs. Do not use them on public or home computers while connecting to the **cobas**® 6500 urine analyzer series.
  - Keep all external storage devices in a secure place and ensure that they can be accessed by authorized persons only.

Caution messages


CAUTION

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.

Mechanical safety


CAUTION

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.

To check the location of the labels on the equipment, see *Safety labels on the equipment* (p. 27).

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

NOTICE

List of notices

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

Moving parts

NOTICE

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

NOTICE

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

NOTICE

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

NOTICE

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

NOTICE

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 representative.

Analyzer views

Front view

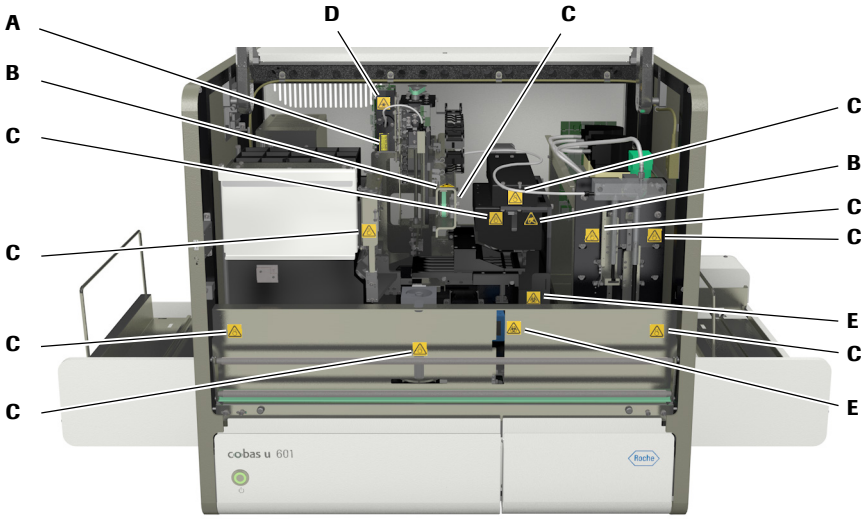


Figure 1-1 Safety labels on the test strip analyzer (front view)

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.

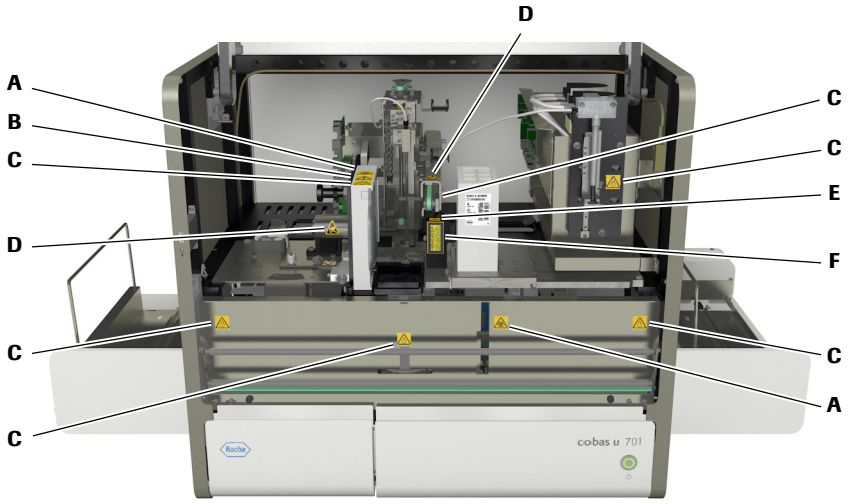
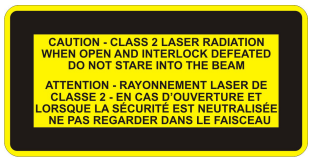


Figure 1-2 Safety labels on the microscopy analyzer (front view)

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 is spilled. Follow Good Laboratory Practices for working with biohazardous materials.
B		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. Any user action is forbidden while the centrifuge is in action.
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		**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.
E		**Laser light source** (Class 1) This label indicates that a laser light source is integrated in the vicinity of the microscope for cuvette detection, but there is no danger of coming into contact with the laser light. The laser is automatically switched of when the main cover is opened. Do not manipulate the safety interlock function.
F		**Laser light source** (Class 2) This label indicates that a laser light source is integrated in the vicinity of the microscope for cuvette detection, but there is no danger of coming into contact with the laser light. The laser is automatically switched off when the main cover is opened. Do not manipulate the safety interlock function.

Back view

Figure 1-3 Safety labels at the rear of the test strip analyzer

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.

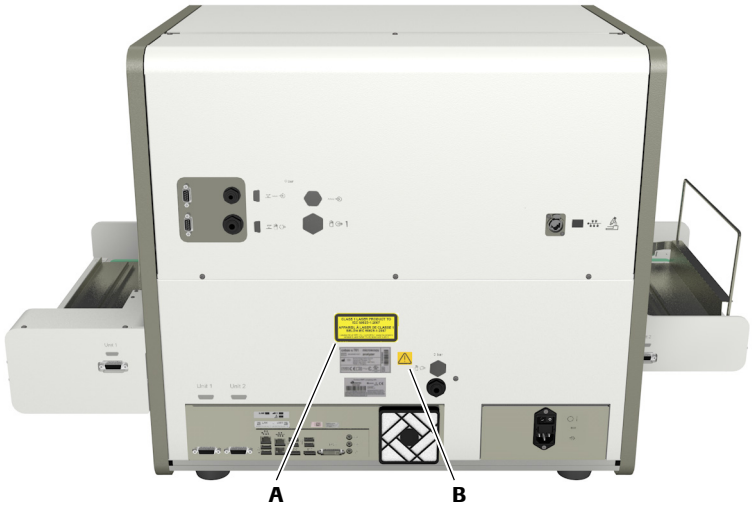


Figure 1-4 Safety labels at the rear of the microscopy analyzer

A 

Laser light source (Class 1)

This label indicates that a laser light source is integrated in the vicinity of the microscope for cuvette detection, but there is no danger of coming into contact with the laser light. The laser is automatically switched of when the main cover is opened. Do not manipulate the safety interlock function.

B 

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

Figure 1-5 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.

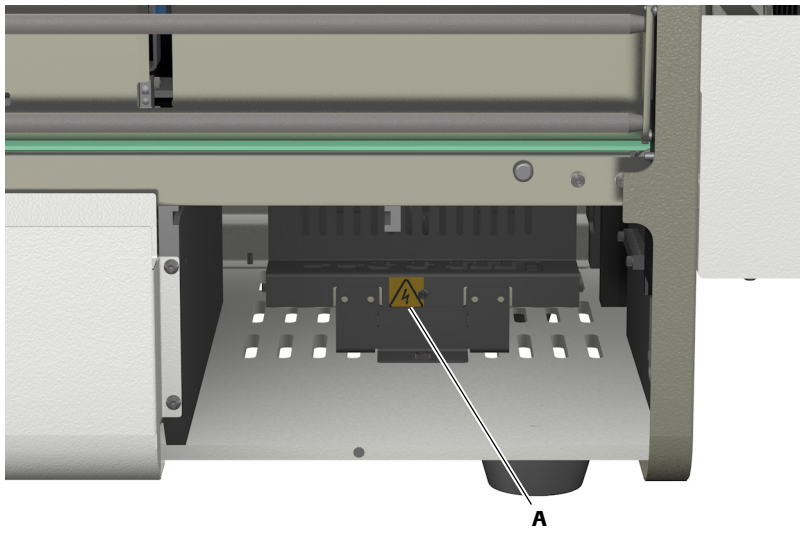


Figure 1-6 Safety labels on the test strip analyzer (waste drawer removed)

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.

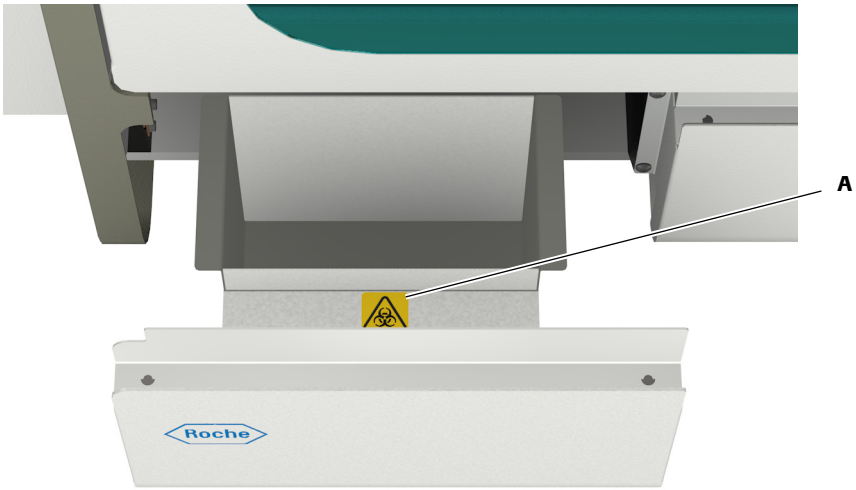


Figure 1-7 Safety labels on the microscopy analyzer (waste drawer)

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.

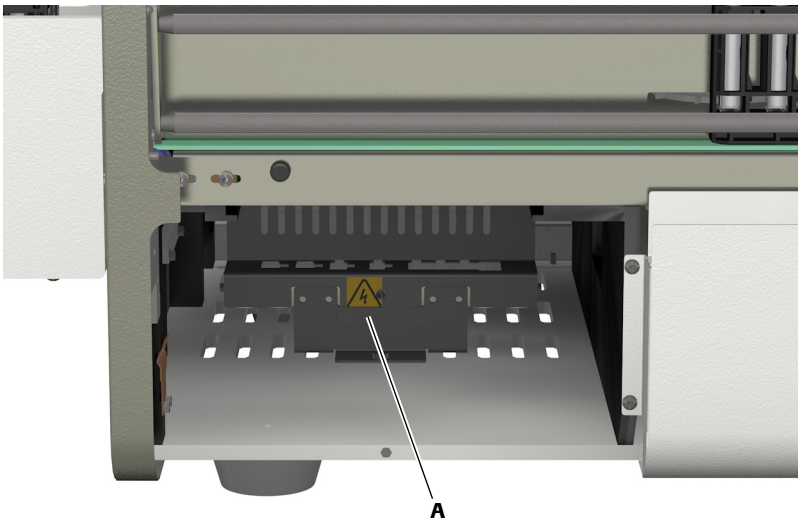


Figure 1-8 Safety labels on the microscopy analyzer (waste drawer removed)

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

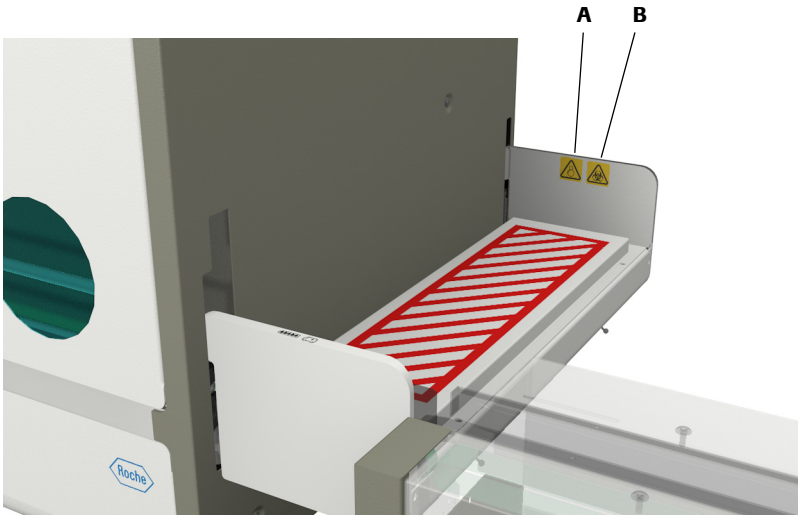


Figure 1-9 Safety labels on the input connection unit

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 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.

WARNING

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.

Introduction

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

In this chapter *Chapter* 2

Table of contents

General description

The **cobas**® 6500 urine analyzer series is a fully automated urine analysis system that consists of two integrated analyzers, the **cobas u** 601 urine analyzer (called *test strip analyzer* in this documentation) for photometric determination of analytes and the **cobas u** 701 microscopy analyzer (called *microscopy analyzer* in this documentation) for microscopic determination of particles.

The throughput depends on the rate of samples that are processed on the **cobas u** 701 microscopy analyzer (up to 240 samples per hour with test strip analysis only, up to 116 samples per hour with microscopy analysis only).

cobas u 601 urine analyzer

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

Table 2-1 Parameters measured by the test strip analyzer

cobas u 701 microscopy analyzer

The **cobas u** 701 microscopy analyzer is a fully automated urine microscopy system for the in vitro quantitative, semi-quantitative, or qualitative determination of particles in urine.

It can process up to 116 tests per hour and urine can be tested for the following particles:

Test	Test characteristics
RBC	Red blood cells
WBC	White blood cells
NEC	Non-squamous epithelial cells
SEC	Squamous epithelial cells
YEA	Yeasts
CRY	Crystals
BAC	Bacteria
HYA	Hyaline casts

Table 2-2 Parameters measured by the microscopy analyzer

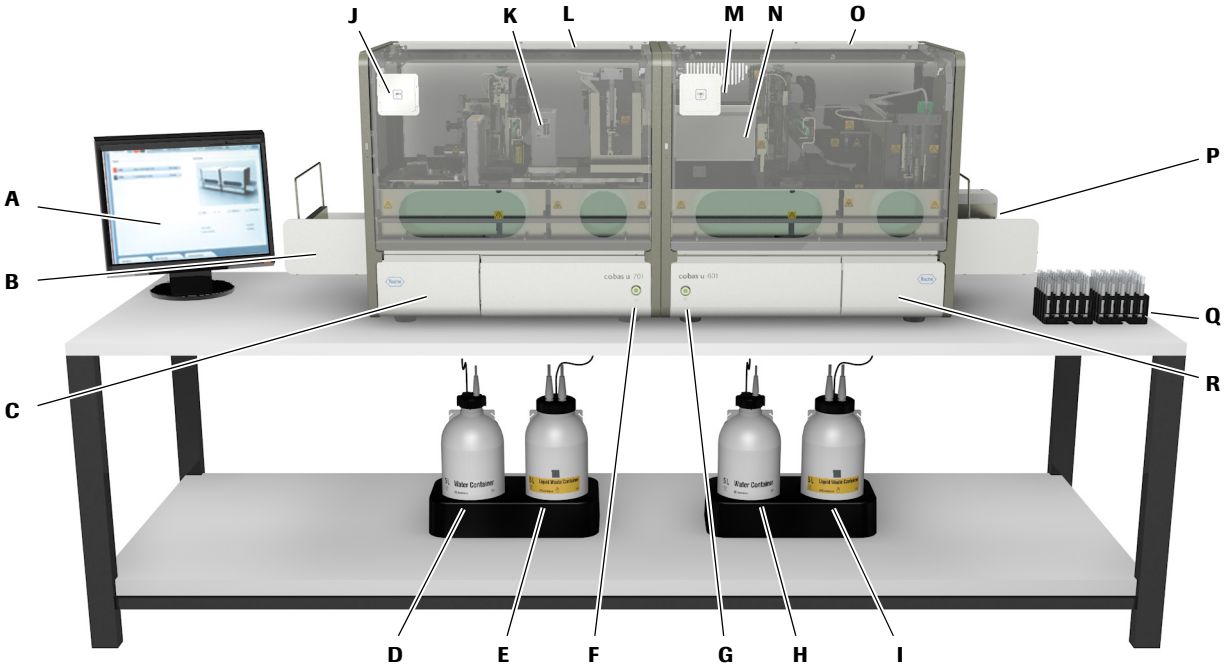
Test	Test characteristics
SPRM	Sperm
MUC	Mucus
PAT	Pathological casts

Table 2-2 Parameters measured by the microscopy 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 analyzers

The following illustration shows the complete **cobas**® 6500 urine analyzer series.



A Touch screen
B Output buffer
C Solid waste container (microscopy analyzer)
D Water container (microscopy analyzer)
E Liquid waste container (microscopy analyzer)
F On/off switch (microscopy analyzer)
G On/off switch (test strip analyzer)
H Water container (test strip analyzer)
I Liquid waste container (test strip analyzer)
J RFID reader for QC materials (microscopy analyzer)
K Cuvette cassette
L Microscopy analyzer
M RFID reader for QC materials (test strip analyzer)
N Test strip cassette compartment
O Test strip analyzer
P Input buffer
Q Sample racks
R Solid waste container (test strip analyzer)

Figure 2-1 Main hardware elements

Operator assistance

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

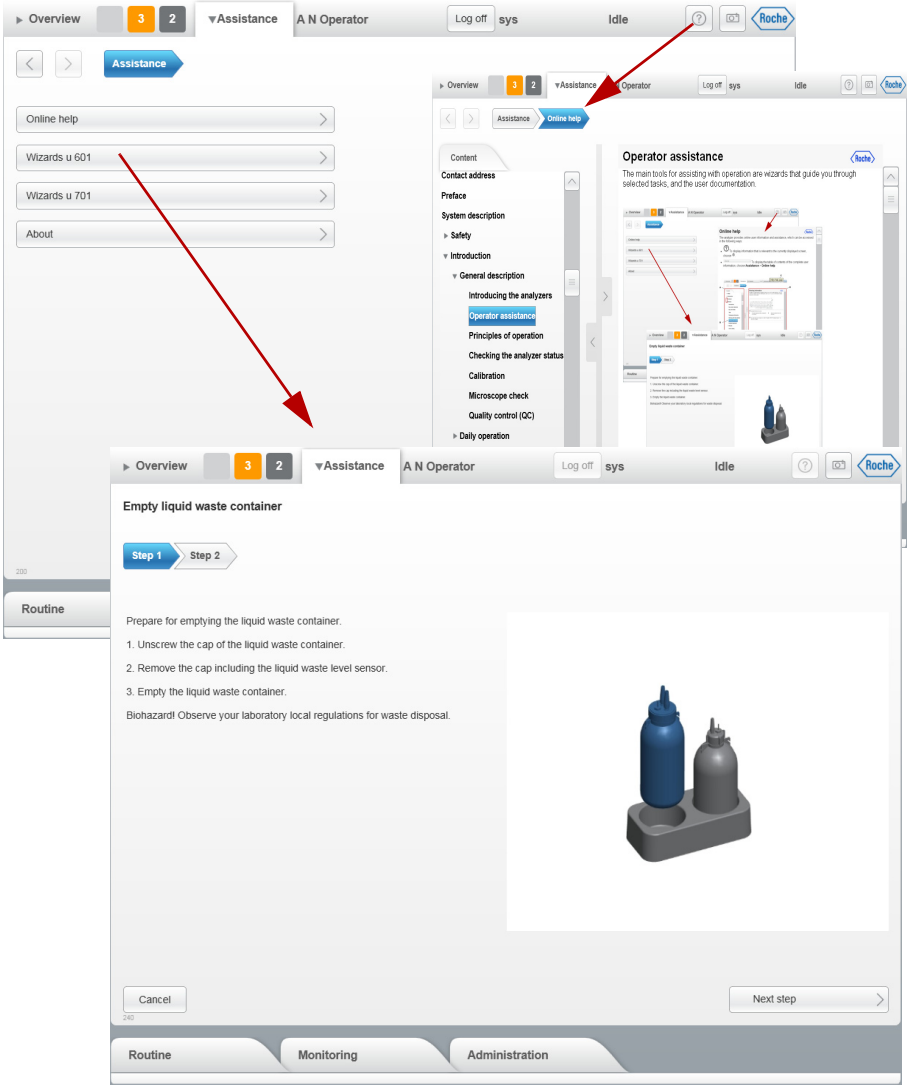


Figure 2-2 Assistance tab

See *Wizards* (p. 119).
See *Online help* (p. 122).

Principles of operation

The **cobas**® 6500 urine analyzer series gives you the opportunity to either perform test strip or microscopy analysis tests, to automatically perform both for the same sample, or to perform microscopy analysis depending on results of the test strip analysis (sieving).

The system is basically 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.

When working with test profiles that involve both analyzers (**u 601 & u 701, u 601 reduced & u 701**, **u 601 sieve to u 701**), test strip analysis is always performed first.

Performing a test consists of the following activities and tasks:

The following description assumes that you perform both test strip and microscopy tests, and that you work with sample barcodes.

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.

   (The minimal sample volume required depends on the test profile. See *Minimal sample volumes (dependent on test profile)* (p. 95))
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. When all sample tubes of the rack are processed, the rack is moved to the pipetting location on the microscopy analyzer.
14. The sample is mixed inside the sample tube.
15. Sample is aspirated into the fluid system and a cuvette is removed from the cassette and placed on the pipetting stage.

    (The minimal sample volume required depends on the test profile. See *Minimal sample volumes (dependent on test profile)* (p. 95))
16. The exact amount of sample is pipetted into the cuvette.

    The probe is washed after the pipetting action to avoid carryover.
17. The cuvette is transported to the centrifuge.
18. The cuvette is centrifuged.
19. The cuvette is transported to the microscope stage.
20. 15 microscopic images are taken of the sample in the cuvette. (The photographed area is divided into fifteen equal subareas, which are photographed separately.)
21. The particle recognition software analyzes all valid images for all parameters and generates either a quantitative, semi-quantitative or qualitative result.
22. The cuvette is discarded into the solid waste container.
23. On the **Routine** work area, the results and images are available and can be validated.
24. 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.

Checking the analyzer status

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

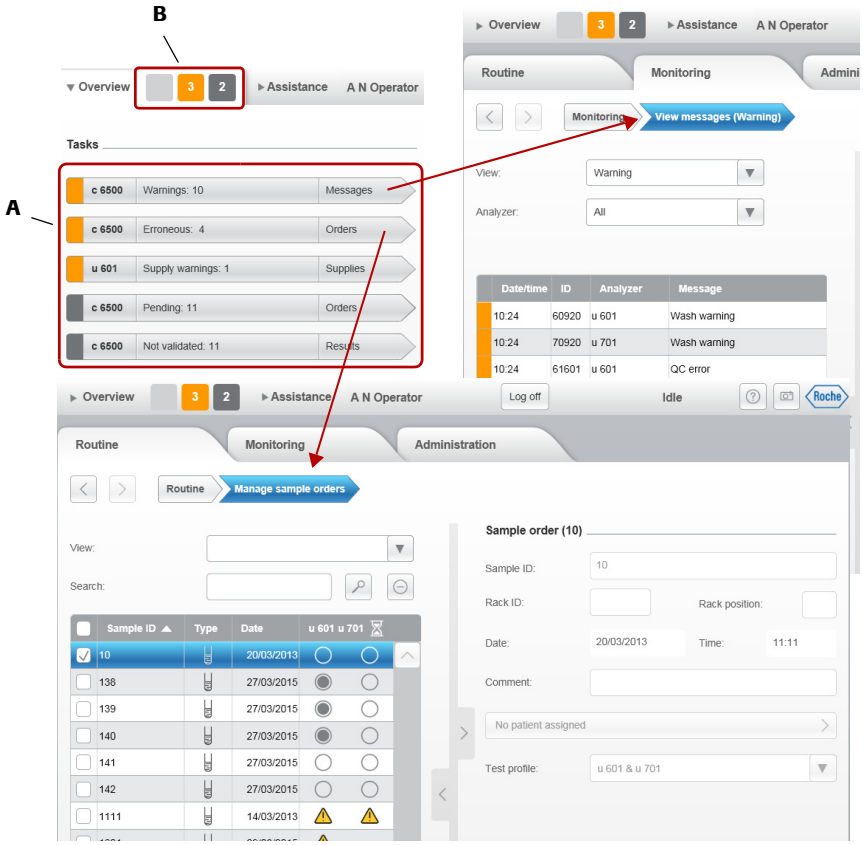


Figure 2-3 Task indicator and task list

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	Interpretation
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.

Table 2-3 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).

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.

See *Calibrating the photometer unit* (p. 205).
See *Calibrating the measuring cell* (p. 206).

Microscope check

In order to ensure proper functioning of the focusing mechanism in the microscope, a microscope check needs to be performed every 4 weeks. This is done by performing a predefined sequence of photographic measurements of a reference cuvette. This cuvette contains a transparent material with erythrocyte like particles etched in it. The system must be able to recognize these and count them correctly.

A message in the message list informs you when microscope check is due. Results that are generated with microscope check results that are no longer valid are marked with **Cm** in the ⚑ column.

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

Daily operation consists of the following phases:

1. Preparing the system
   - Ensure that all consumables are available, the water containers are full, and the liquid waste containers are 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. If the next shift does not follow immediately after, performing end of shift activities
   - Archive the results according to your laboratory procedures.
   - 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 detectors.
   - Clean the pipetting stage and pipetting area and the inside of the centrifuge chamber.
   - Clean the microscope stage area.
   - 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.

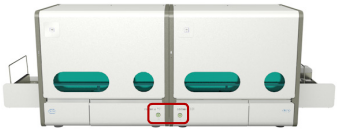
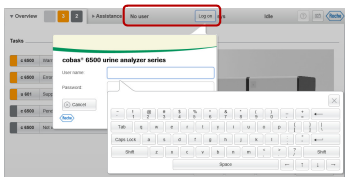
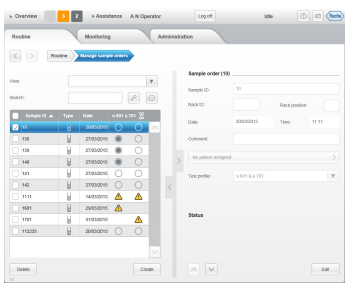
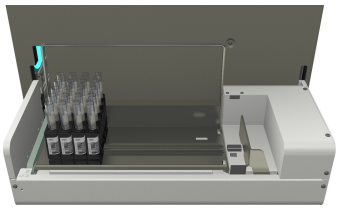
Step	Task		Procedure
1	Starting the analyzer		1. Ensure that all covers are closed. 2. Power on the test strip analyzer. 3. Power on the microscopy analyzer. 4. Wait until the **Overview** work area is displayed. This may take a few minutes.
2	Logging on		1. On the **Overview** work area, choose the **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 containers.(1) If they are not full, start the appropriate wizards and fill them. 3. Check the liquid waste containers.(1) If they are not empty, start the appropriate wizards and empty them. 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. 5. Check the cuvette 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.)

Table 2-4 Short guide for performing tests

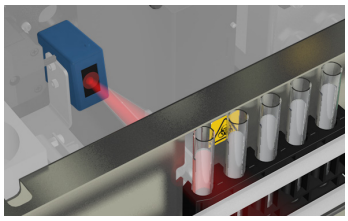
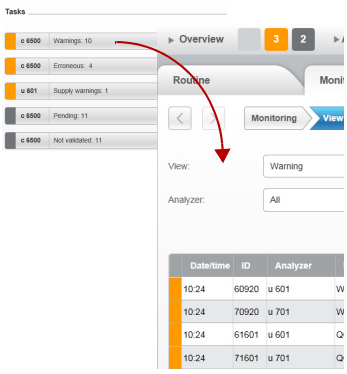
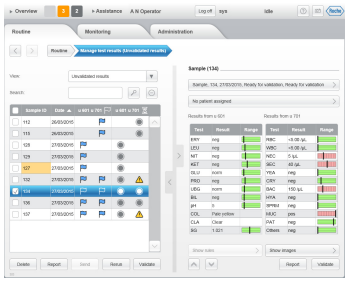
Step	Task		Procedure
6	Start testing		Testing starts automatically.
7	Monitoring the analyzer		1. On the **Overview** work area, check the task indicator and the task list. Address all red or orange items in the task list. 2. Choose a task button. If the message list is displayed, choose a message, check 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.

Table 2-4 Short guide for performing tests

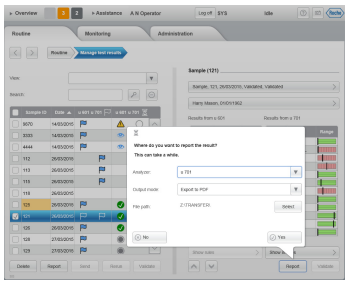
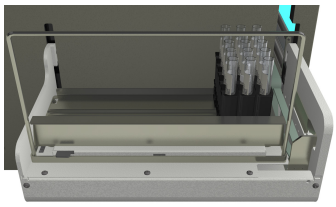
Step	Task		Procedure
9	Printing or exporting the results		To print selected or all results, choose **Routine** > **Manage test results**. 1. In the result list, select the check box of all results that you want to print or save to a PDF file. 2. Choose the **Report** button. 3. Choose the analyzer and whether to print the results or save them to a file. 4. Choose the **Yes** button. 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 the analyzer. 4. Choose whether to print the results or save them to a file. 5. Define which results you want to print. 6. Choose the **Yes** button.
10	Clearing the output buffer		1. Remove the rack tray and replace it with an empty one.
11	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 both probe bend detectors. 8. Clean the pipetting stage, pipetting area, and the inside of the centrifuge chamber. 9. Clean the microscope stage area. 10. Remove spills and soiling from the analyzer housing.

Table 2-4 Short guide for performing tests

Result handling

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, and with microscopy, particles can be reclassified if necessary.

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 so-called 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.

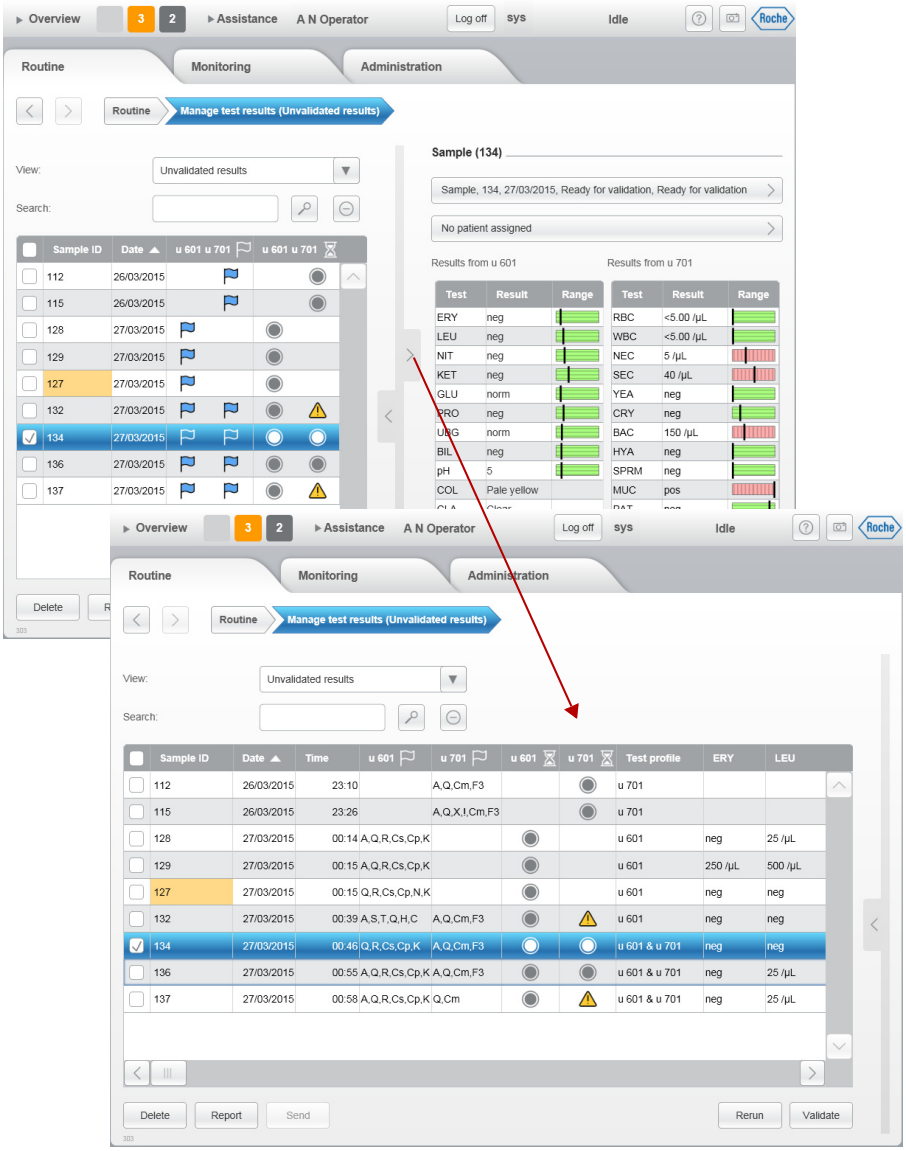


Figure 2-4 Result display

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* (p. 233).

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).
- For microscopy results, you can also display the individual images and you can reclassify particles in unvalidated results.
- 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 save the related images as individual files in a graphics file format and 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 detectors.
8. Clean the pipetting stage and pipetting area and the inside of the centrifuge chamber.
9. Clean the microscope stage area.
10. 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 *Chapter* 3

Safety

Read and understand the information in the Safety chapter

See p. 17.

The following safety messages are particularly relevant:

Warning messages:

- *Electrical safety* (p. 22)
- *Biohazardous materials* (p. 22)

Caution messages

- *Mechanical safety* (p. 24)

Notice messages

- *Excessive ambient humidity* (p. 26)
- *Spillage* (p. 26)

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 define in *Allowed tilt* (p. 94).
- Adjust the height of the surface so all operating personnel can comfortably open and close the main cover.

NOTICE

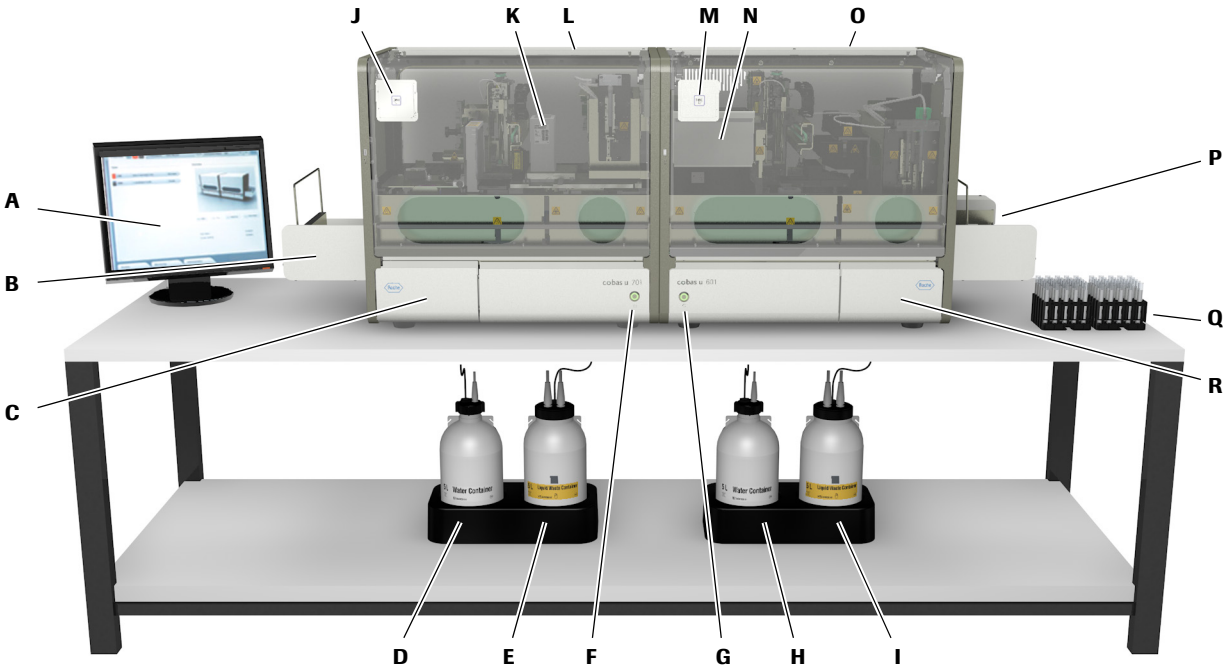
Malfunction due to incompatible monitor drivers

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 Output buffer
C Solid waste container (microscopy analyzer)
D Water container (microscopy analyzer)
E Liquid waste container (microscopy analyzer)
F On/off switch (microscopy analyzer)
G On/off switch (test strip analyzer)
H Water container (test strip analyzer)
I Liquid waste container (test strip analyzer)
J RFID reader for QC materials (microscopy analyzer)
K Cuvette cassette
L Microscopy analyzer
M RFID reader for QC materials (test strip analyzer)
N Test strip cassette compartment
O Test strip analyzer
P Input buffer
Q Sample racks
R Solid waste container (test strip analyzer)

Figure 3-1 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

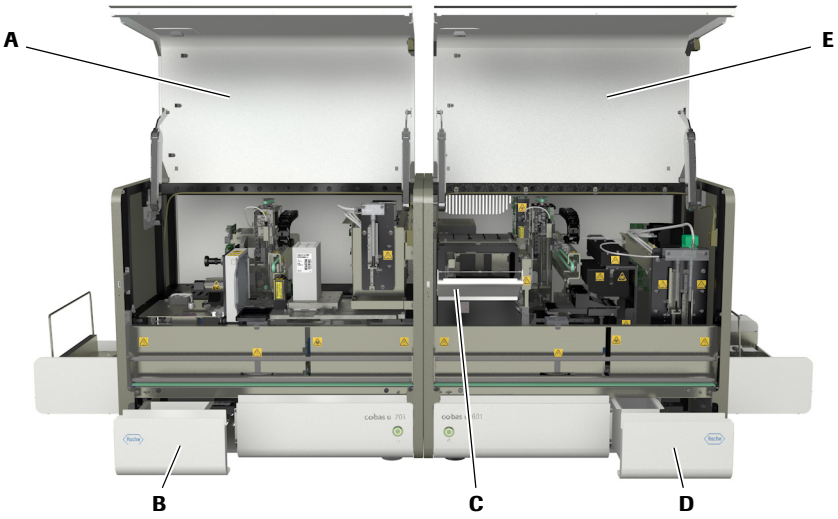
Loss of data and sample due to opening covers or drawers

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
When you have accidentally pulled the waste drawer during operation (p. 293).
Recovering from an irregular stop (p. 290)



A Main cover (microscopy analyzer)
B Waste drawer (microscopy analyzer)
C Cassette compartment door
D Waste drawer (test strip analyzer)
E Main cover (test strip analyzer)

Figure 3-2 Covers

Connectors

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

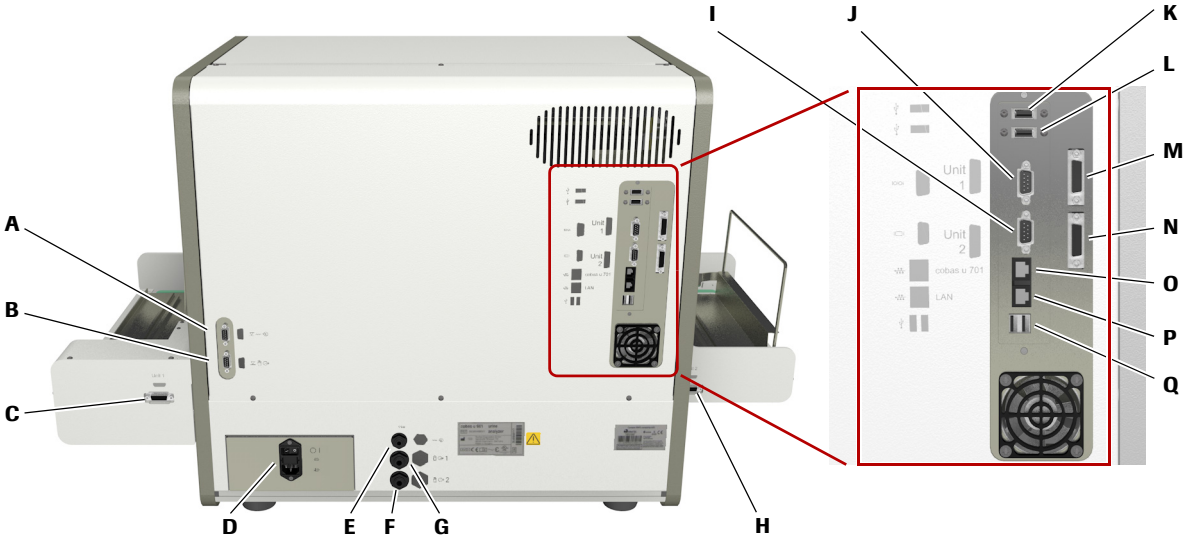
The fittings of the external liquid connectors differ to prevent mix-up.

CAUTION

Damage to the analyzer due to connecting inappropriate devices

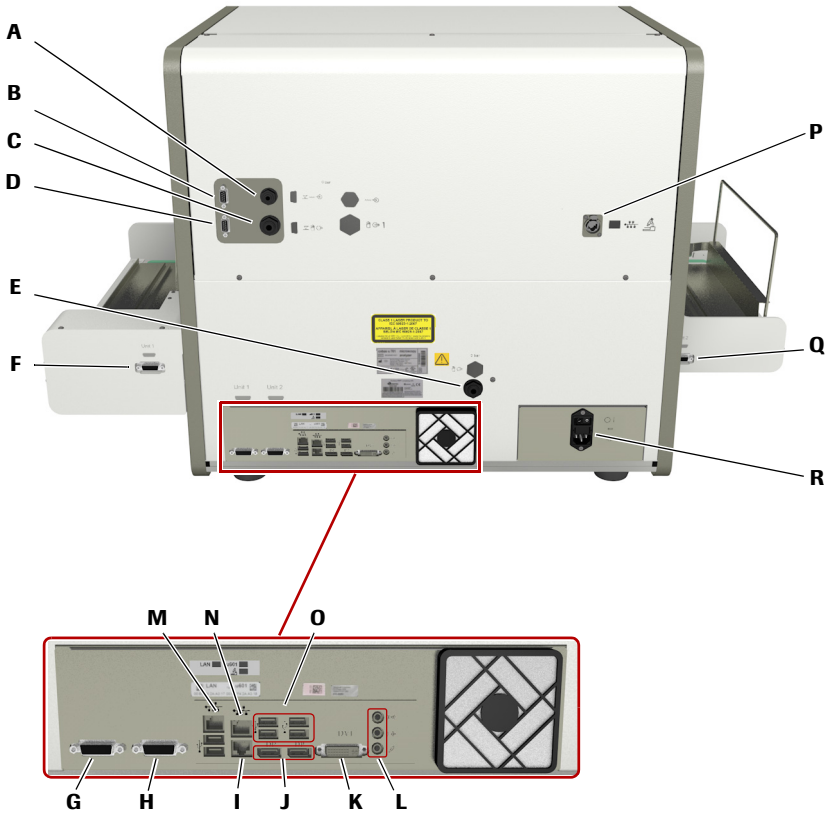
Connecting external devices that are not intended to be used with the analyzer may damage the analyzer or impair its functioning.

- 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 either mouse, keyboard, or 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 ports to either mouse, keyboard, or printer

Figure 3-3 Connectors on the test strip analyzer



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

Figure 3-4 Connectors on the microscopy analyzer

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

Figure 3-5 Connectors on the input connection unit

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 (test strip analyzer)

B Liquid waste level sensor connector (test strip analyzer)

C System water inlet (test strip analyzer)

D Liquid waste outlet (test strip analyzer)

E Liquid waste safety outlet (test strip analyzer)

F System water inlet (microscopy analyzer)

G Water level sensor connector (microscopy analyzer)

H Liquid waste level sensor connector (microscopy analyzer)

I Liquid waste outlet (microscopy analyzer)

J Liquid waste safety outlet (microscopy analyzer)

K Tubing for system water

L Water level sensor connection

M Tubing for liquid waste

N Tubing to liquid waste safety outlet

O Liquid waste level sensor connection

P Liquid waste container

Q Water container

Figure 3-6 Liquid connectors

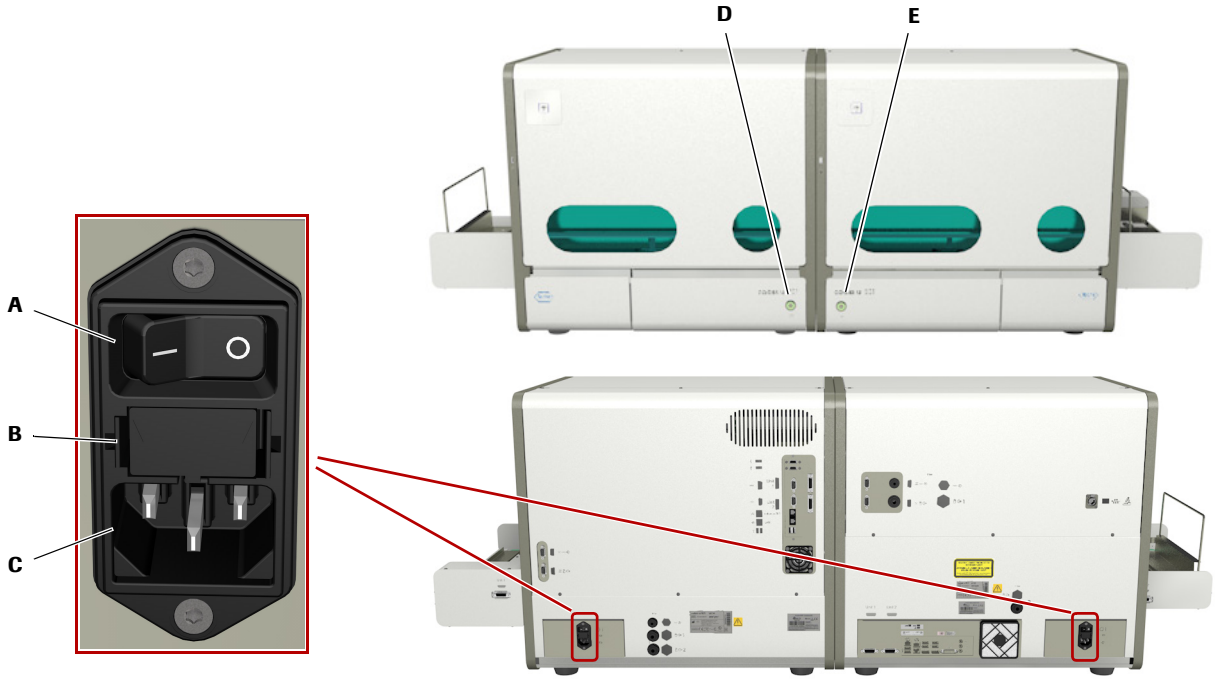
With external water supply

With external water supply, the laboratory water supply is connected to the bespoke 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.

To turn on the system, first power on the test strip analyzer (E) and then the microscopy analyzer (D).



A Power switch
B Fuse compartment
C Mains connector
D On/off switch (microscopy analyzer)
E On/off switch (test strip analyzer)

Figure 3-7 Power switches

Pressing the on/off switch shortly while the analyzer is processing does have no effect. 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* (p. 290).

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. See *Uninterruptible power supply (UPS)* (p. 95).

For information on recovering from such an emergency situation, see *To recover from a power cut* (p. 294).

Input and output buffers

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

CAUTION

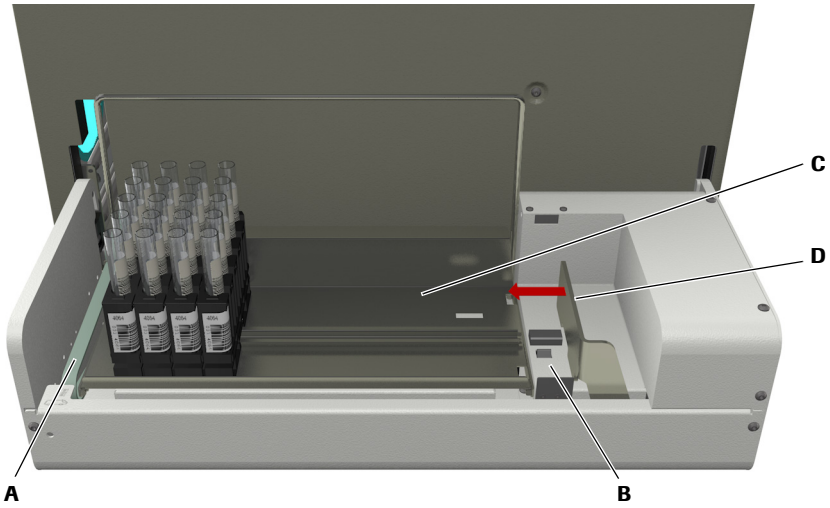
Personal injury due to contact with moving parts

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.

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.

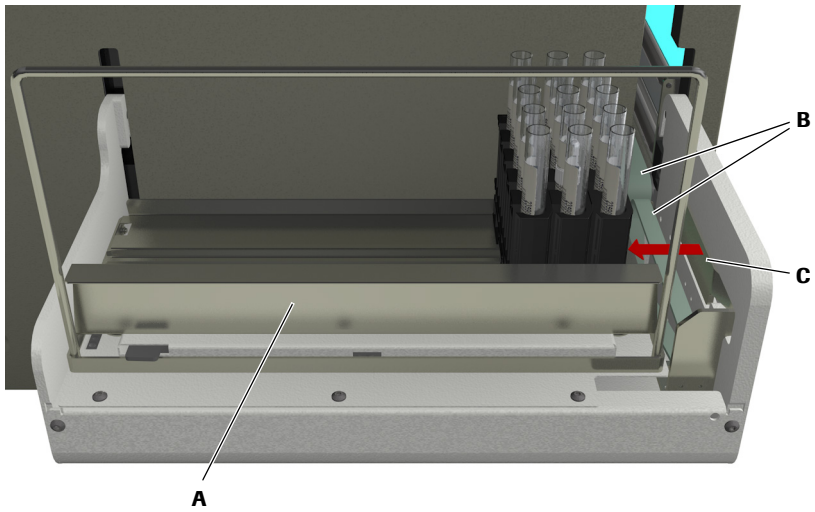


A Priority rack slot
B Single rack slot
C Rack tray
D Rack pusher

Figure 3-8 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

Figure 3-9 Output buffer

Input connection unit

For automated rack input, you can link the **cobas**® 6500 urine analyzer series 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.

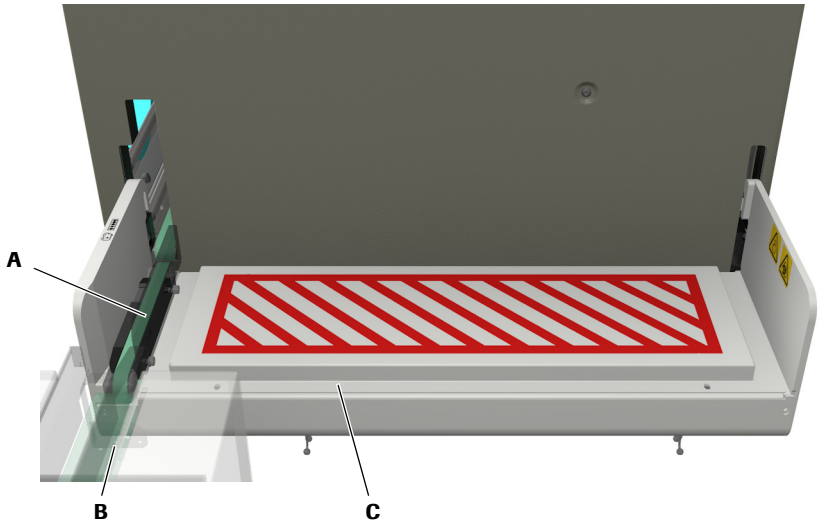
Racks with unsuitable colors may lead to barcode reading errors.

- Only use racks defined in table 3-1 (p. 67).

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

Figure 3-10 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.

See *To load a priority rack when working with an LAS* (p. 145)
See *To perform a QC measurement when working with an LAS* (p. 210)
See *To wash the fluid system when working with an LAS* (p. 186)

Tubes, racks, and rack trays

This section introduces the containers for handling samples.

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 (grey)	✓	✓	✓	x	✓	✓	✓
RD 5 wash rack (green)	✓	✓	✓	x	✓	x	x
RD 5 QC rack (white)	✓	✓	✓	x	✓	✓	✓
URISYS rack (yellow)	x	✓	x	x	✓	x	x

Table 3-1 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 dimensions defined in table **3-1** and that are not defined for this analyzer may lead to malfunction or pipetting errors and consequently to incorrect results.

- Only use tubes defined in table **3-1** (p. 67).
- Only use the tubes defined for this analyzer.

Racks

The analyzer is designed to handle the racks defined in table **3-1** (p. 67). 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 table 3-1 (p. 67).

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.

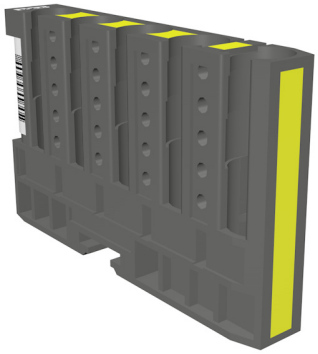
A Sample barcode
B Rack barcode
C Rack rubber disk
D Racks on a rack tray that is placed on the input buffer

Figure 3-11 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 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.

See *Optional components* (p. 96)

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* (p. 258).

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* (p. 258).

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.

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.

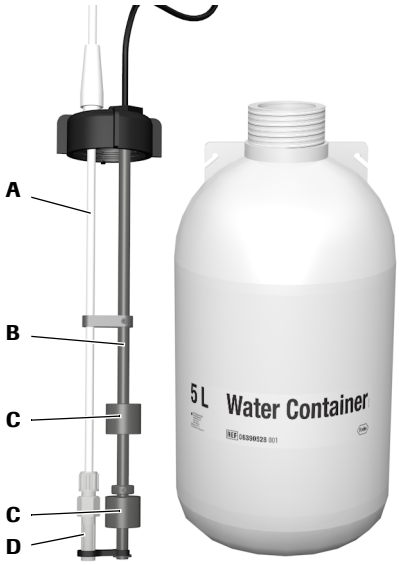
There are separate water and waste containers for both the test strip and the microscopy analyzer.

Water container

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* (p. 95).



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

Figure 3-12 Water container

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 quality defined in *Water quality* (p. 95).

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. See *To clean the water container for external water supply* (p. 269).

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.

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.

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

Figure 3-13 Water container for external water supply

Liquid waste container

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

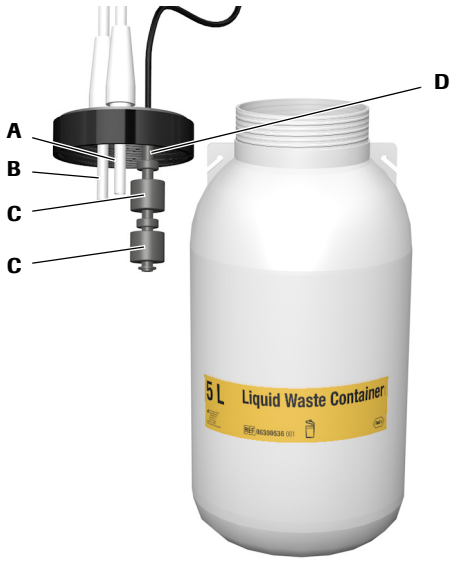
CAUTION

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.

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.



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

Figure 3-14 Liquid waste container

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 containers

The solid waste containers are designed to hold at least as many test strips and cuvettes as are contained in their respective full cassettes. There is a bespoke disposable Waste Box Carton that must be installed properly. The analyzers monitor whether the drawers are closed properly. The fill levels are 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* (p. 243)

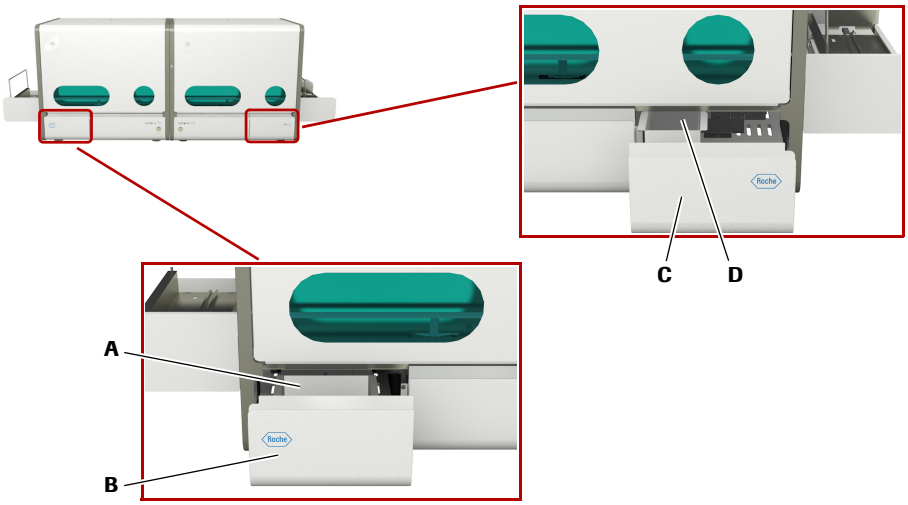
NOTICE

Analyzer damage due to overfilled solid waste container

If the solid waste container is full, test strips or cuvettes may get stuck in the waste chute and they may interfere with the measuring mechanisms.

- 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 or cuvette cassette.

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



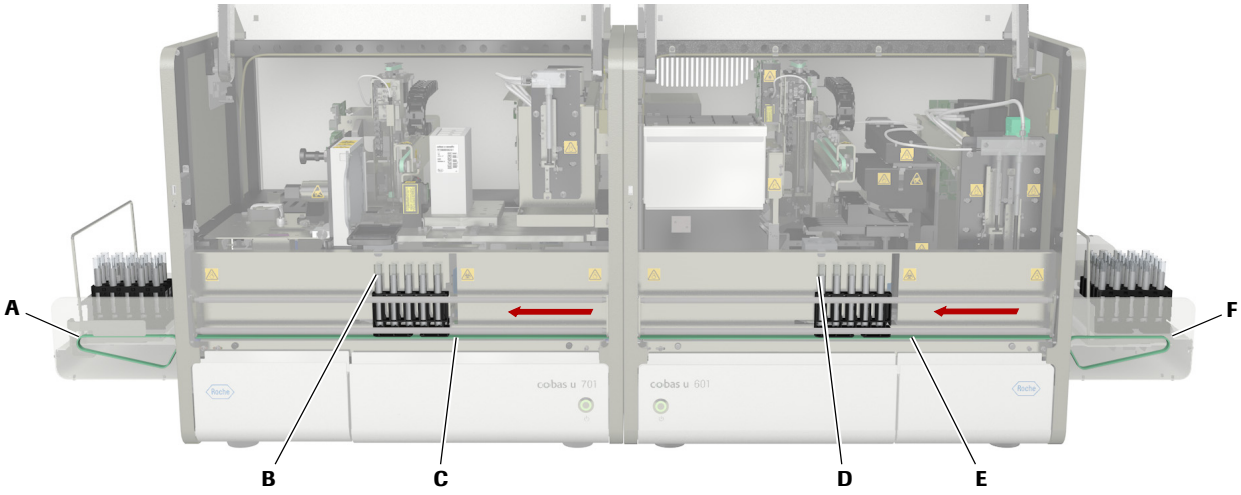
A Solid waste container (microscopy analyzer)
B Waste drawer (microscopy analyzer)
C Waste drawer (test strip analyzer)
D Solid waste container (test strip analyzer)

Figure 3-15 Solid waste containers

Rack transport unit

The rack conveyor picks up the racks at the input buffer and transports them to the first sampling position. When all tubes are processed the rack is transported to the second 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	**C**	Rack conveyor on microscopy analyzer	**E**	Rack conveyor on test strip analyzer
B	Sampling position on microscopy analyzer	**D**	Sampling position on test strip analyzer	**F**	Input buffer rack conveyor

Figure 3-16 Rack transport unit

Rack handling consists of the following steps:

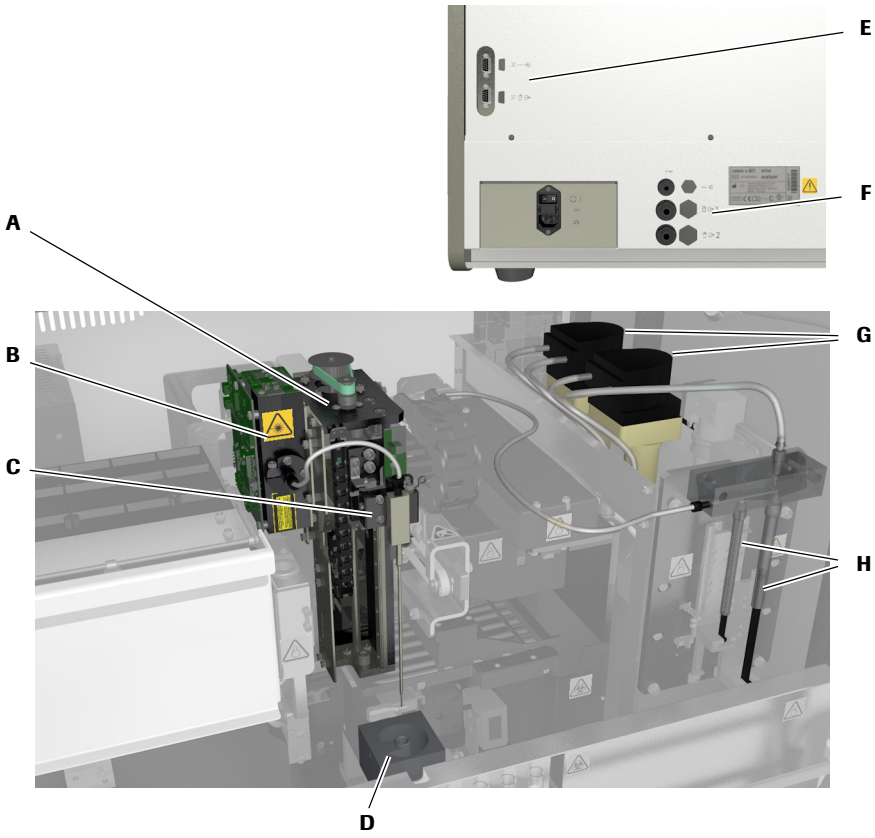
1. The operator loads the rack on the input buffer, either on the rack tray, the single rack slot or the priority rack slot.
2. The rack pusher moves the rack, if required, to the priority rack slot, which also serves as the feed to the rack conveyor.
3. The rack conveyor moves the rack to the sampling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

   All samples on the rack that need test strip analysis are pipetted.
4. If microscopy analysis is required for at least one of the samples, the rack conveyor then moves the rack to the sampling position of the microscopy analyzer.

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

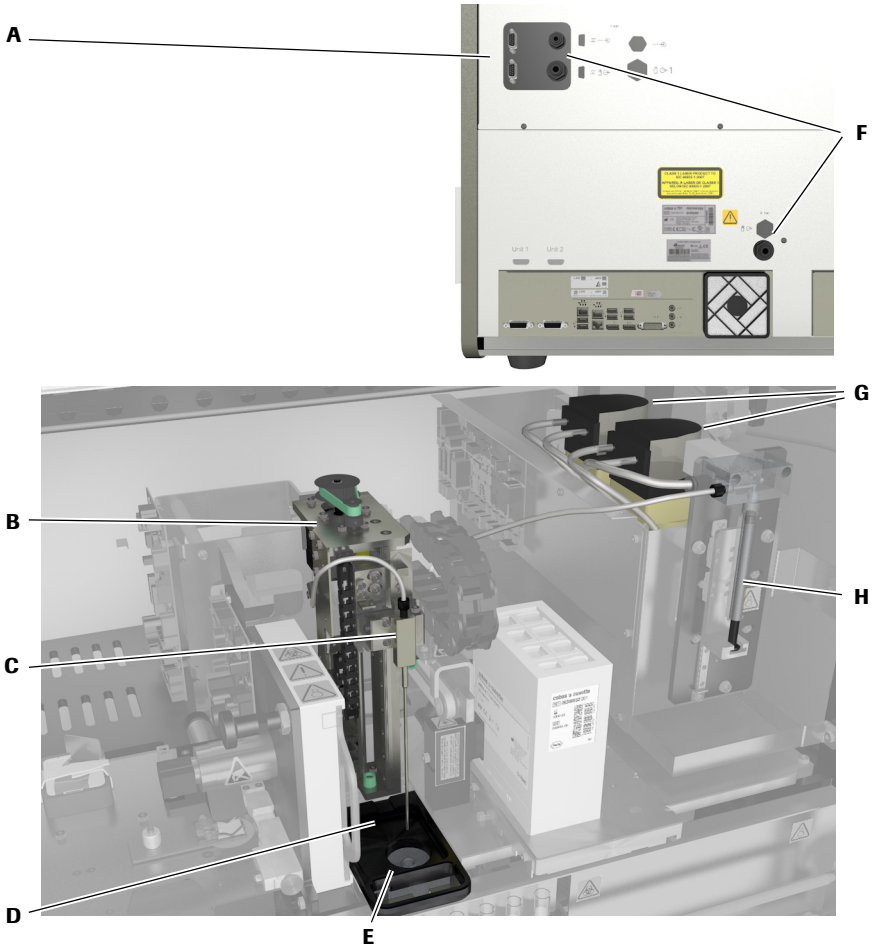
Fluid system

Both the test strip and microscopy analyzers have independent fluid systems. They consist of all the valves, pumps, tubing, syringes, fluid sensors, water and waste containers, the rinse station, and the probe. In the test strip analyzer, it also includes the measuring cell. 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 and cuvettes.



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

Figure 3-17 Fluid system of the test strip analyzer



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

Figure 3-18 Fluid system of the microscopy analyzer

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.

For details see *Pipetting unit* (p. 77).

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* (p. 272).

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.

For details see *Rinse station* (p. 79).

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.

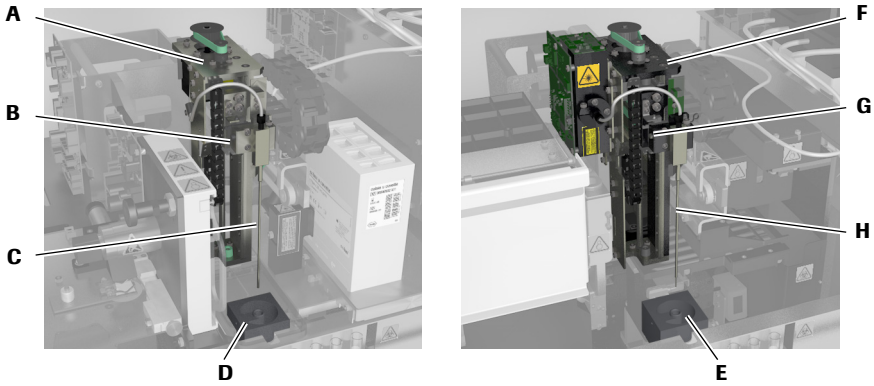
You can connect the liquid waste to the waste system of your facility. Ensure that the facility installation is lower than the connector on the analyzer (gravity driven).

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

For details see *Liquid connectors* (p. 60).

Pipetting unit

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.



A Transfer head (microscopy analyzer)
B Probe release button (microscopy analyzer)
C Probe (microscopy analyzer)
D Rinse station (microscopy analyzer)
E Transfer head (test strip analyzer)
F Rinse station (test strip analyzer)
G Probe release button (test strip analyzer)
H Probe (test strip analyzer)

Figure 3-19 Pipetting unit

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.

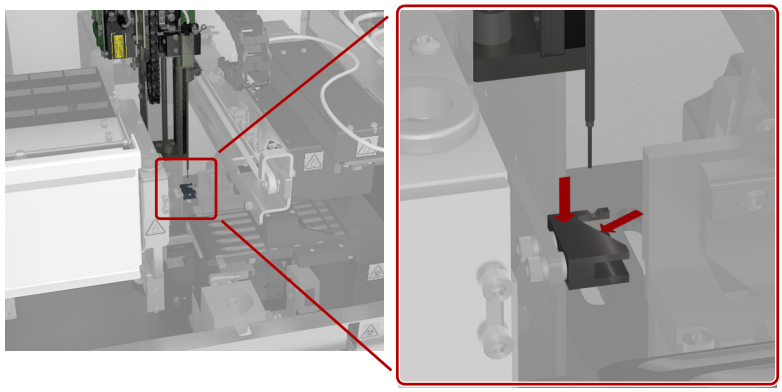


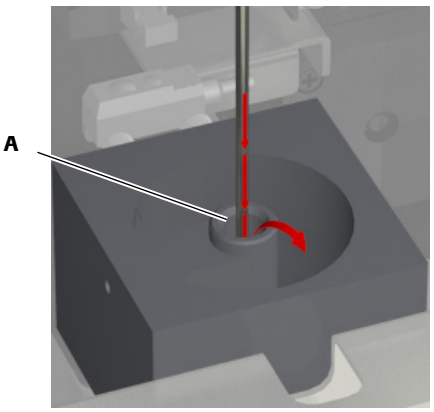
Figure 3-20 Probe bend detector on the test strip analyzer

Figure 3-21 Probe bend detector on the microscopy analyzer

Rinse station

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 aspires 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.



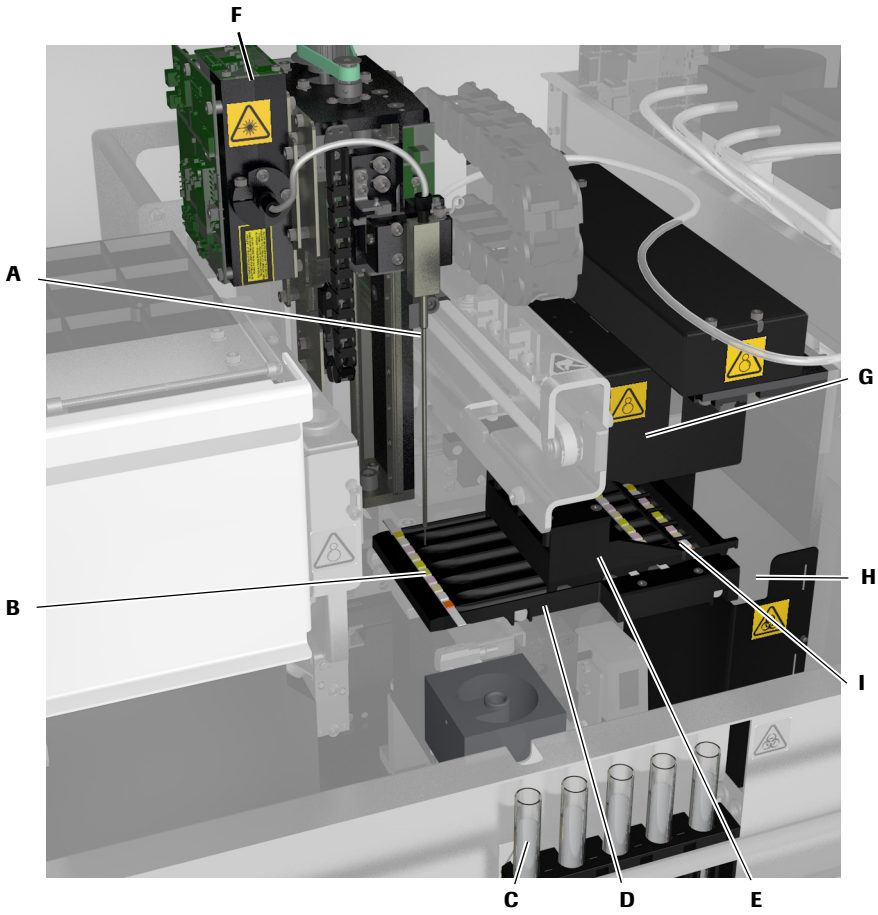
A Probe chamber

Figure 3-22 Rinse station

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.

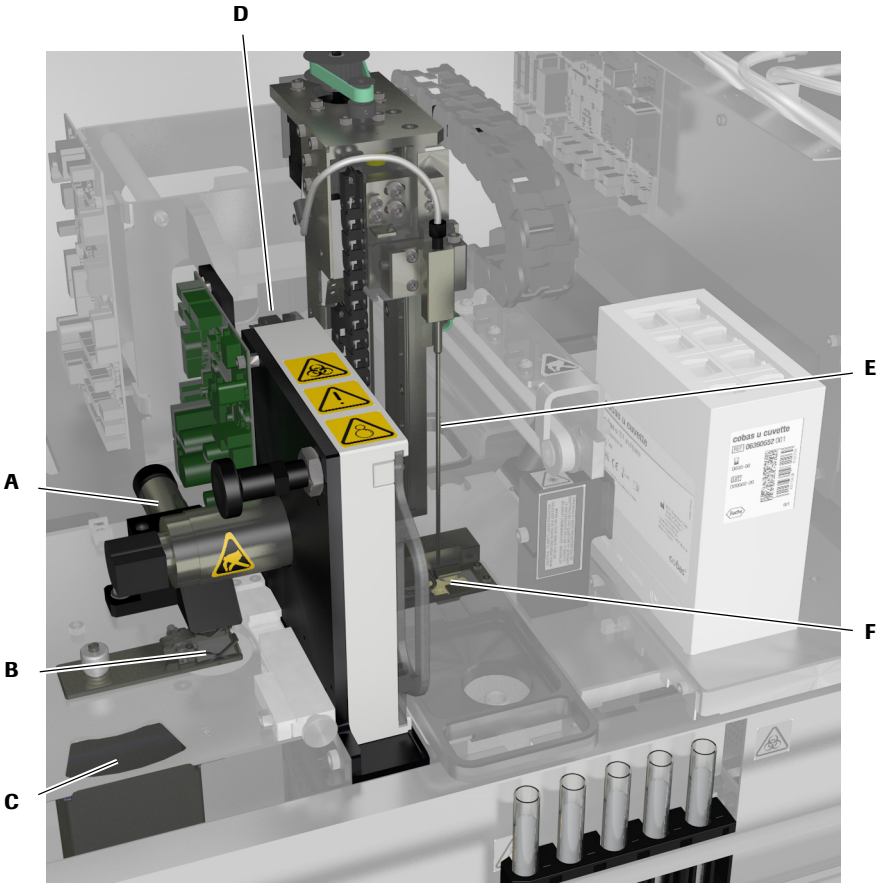
Test strip analyzer The probe aspirates urine, which is then passed through the tubing to the measuring cell, where clarity and specific gravity are measured. Then, the predefined amount of urine is pipetted on each test pad on the test strip. The test strip is then moved along the test strip tray in 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

Figure 3-23 Sample stages on the test strip analyzer

Microscopy analyzer The probe aspirates urine and then dispenses the exact amount into the cuvette. The cuvette is then centrifuged to collect the particles in one layer in the cuvette in preparation for analysis under the microscope. The cuvette is then placed on the microscope stage and photographed, and finally discarded into the solid waste container.

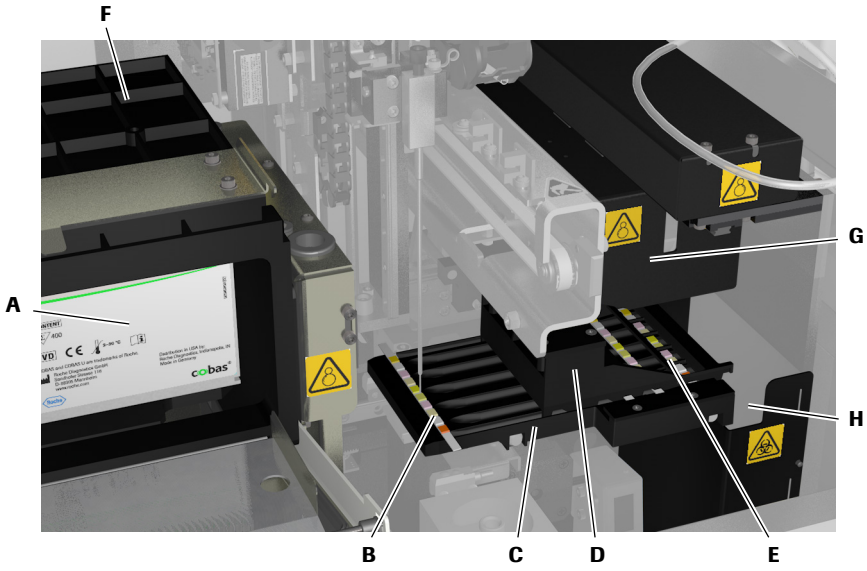


A Microscope lamp
B Cuvette measurement position
C Waste chute
D Centrifuge
E Probe
F Cuvette pipetting position

Figure 3-24 Sample stages on the microscopy analyzer

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

Figure 3-25 Hardware involved in test strip handling

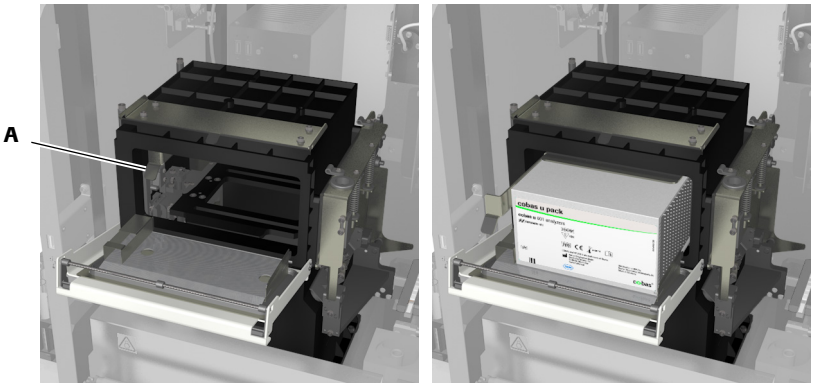
Test strip cassette

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.

Figure 3-26 Test strip cassette

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 18-32 °C (64-90 °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

Figure 3-27 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* (p. 94).
- Open this compartment only for replacing the test strip cassette.

CAUTION

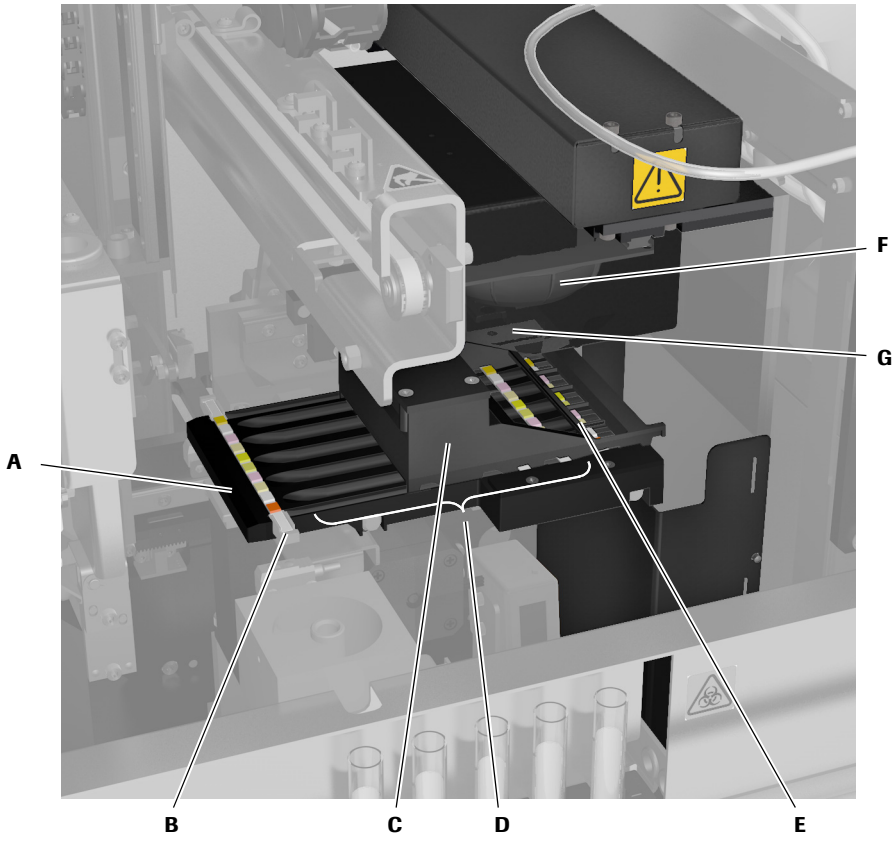
Incorrect results due to excessive ambient humidity

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* (p. 94).
- Always load the test strip cassette immediately after removing it from its airtight packaging. Follow the instructions given in the Instructions for Use.

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)

Figure 3-28 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.

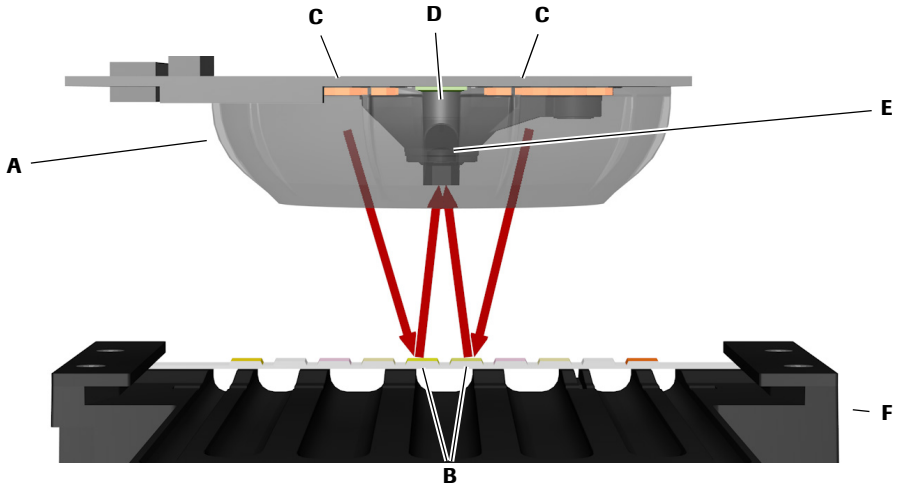
The reference plate is measured with each test strip measurement and the results are taken into account when calculating the test results.

Do not touch or soil the reference plate.

Reflectance photometric measuring

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 LED's of four different wavelengths (465, 525, 560, and 615 nm). The LED's 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	**D**	Image sensor
B	Test strip pads in measurement positions	**E**	Optical lens
C	LED ring	**F**	Test strip tray

Figure 3-29 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.

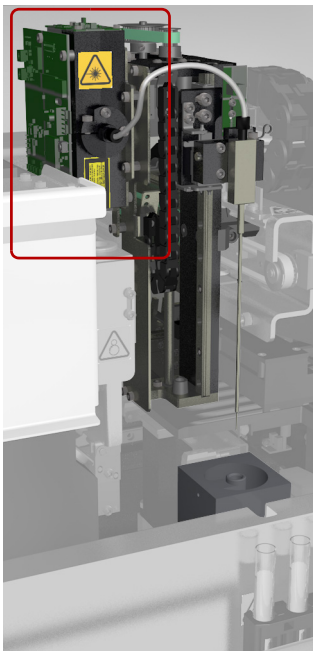


Figure 3-30 Measuring cell

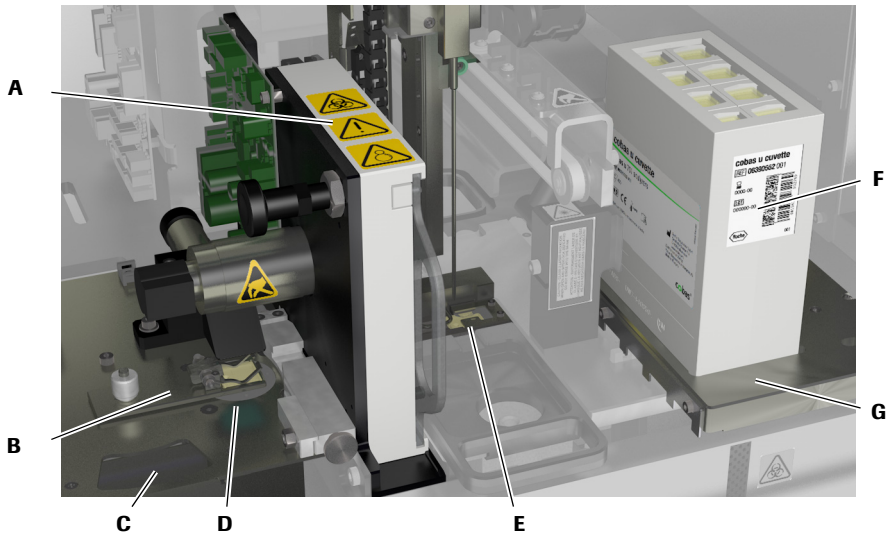
The specific gravity is the ratio of the density of analyte to the density of water at a specified temperature.

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).

Cuvette handling

During the testing process, a cuvette is removed from the cuvette cassette and placed on the pipetting stage. The exact amount of urine is pipetted into the cuvette, which is then moved to the cuvette holder on the centrifuge. After centrifuging, the cuvette is placed on the microscope stage, where it is photographed. The photographic images are analyzed using image evaluation software and results are calculated. The cuvette is then discarded into the solid waste container.

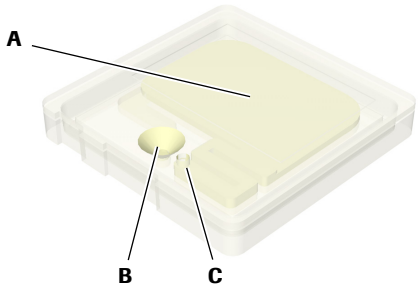


A Centrifuge
B Microscope arm
C Waste chute
D Microscope stage
E Pipetting stage
F Cuvette cassette
G Cuvette cassette compartment

Figure 3-31 Hardware involved in cuvette handling

Cuvettes

Sample is pipetted through the injector hole and is then distributed across the photographic area of the cuvette. The capillary qualities of the cuvette ensure even distribution. Centrifuging collects the particles in one layer in the cuvette, which then can be photographed under the microscope.



A Photographic area, holds urine
B Injector hole
C Overflow area

Figure 3-32 Cuvette

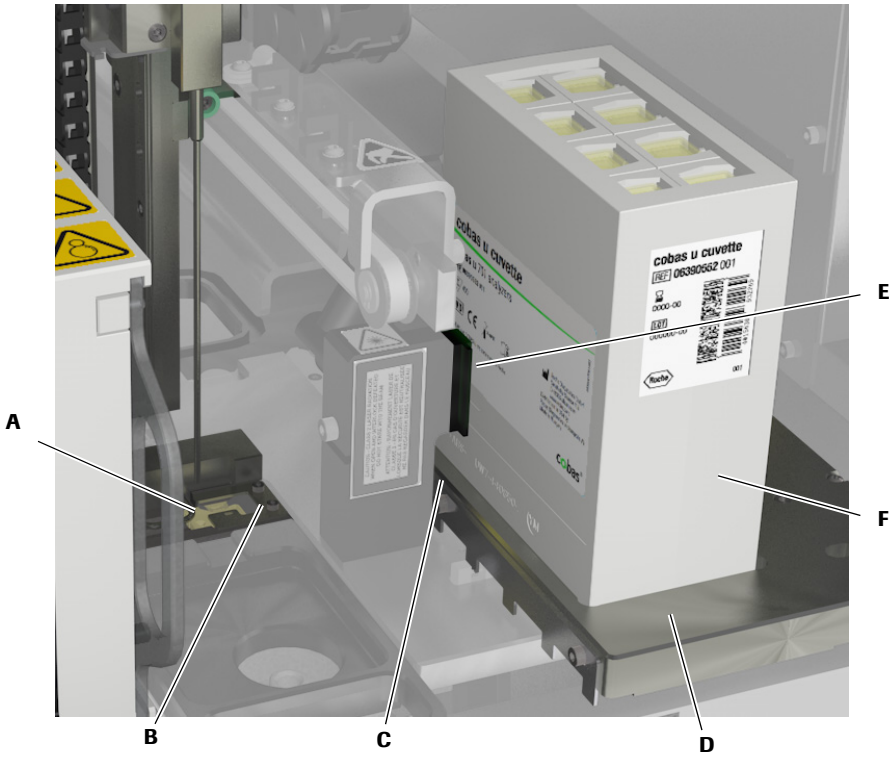
Cuvette cassettes

A cuvette cassette (**cobas u** cuvette) holds 400 cuvettes. Each cuvette cassette is identified by a unique ID contained in the radio frequency identification (RFID) tag. This tag also contains the date of manufacturing, lot number, and the number of cuvettes left in the cassette.

Figure 3-33 Cuvette cassette

Cuvette cassette compartment

The cuvette cassette compartment holds the cuvette cassette, and it provides the mechanism for releasing cuvettes to the cuvette transporter.

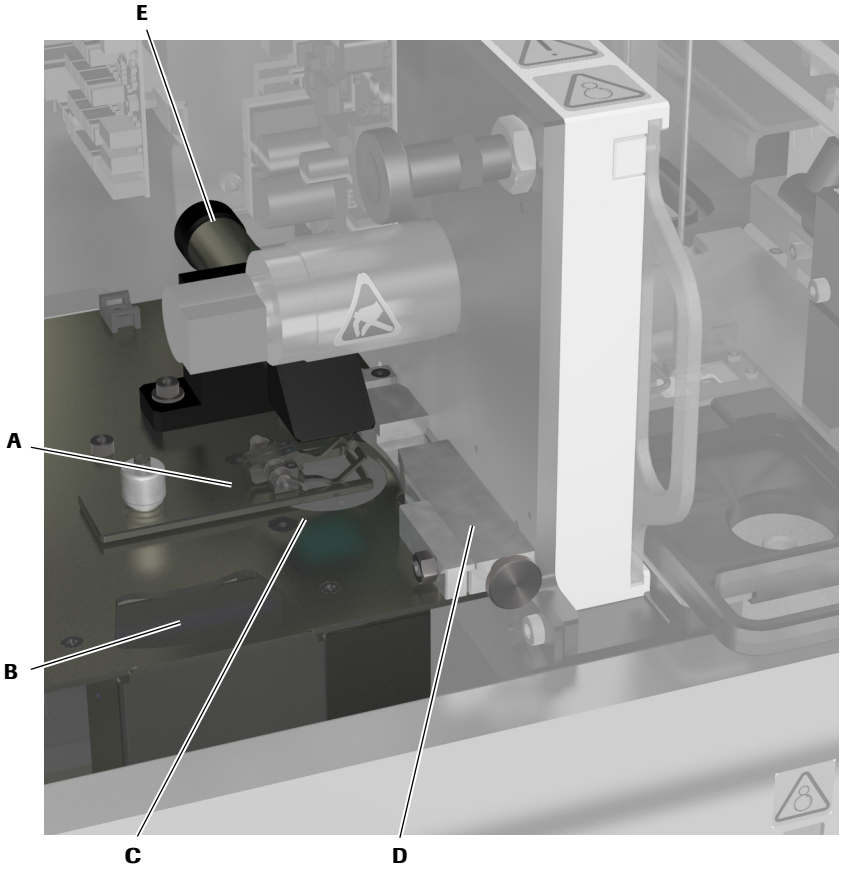


A Cuvette pipetting position
B Cuvette transporter
C Cuvette discharging position
D Cuvette cassette compartment
E RFID reader
F Cuvette cassette

Figure 3-34 Cuvette cassette compartment

Microscopy

Microscopy is used for quantitative, semi-quantitative, and qualitative determination of particles in urine. The sediment in a cuvette is photographed and the individual particles are identified and quantified using sophisticated image evaluation software.



A Microscope arm
B Waste chute
C Microscope stage
D Cuvette rail
E Microscope lamp

Figure 3-35 Microscope

The photographic area on the cuvette is divided into 15 equal virtual sections. For the test measurement, each section is photographed separately.

Focusing

Various sizes of sediment particles are present in the urine. The subsidence level is also different for the different particles. Therefore, to achieve maximum contrast, the optimal focus level is established separately for each section on the photographic area of the cuvette.

Barcode reader

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

WARNING

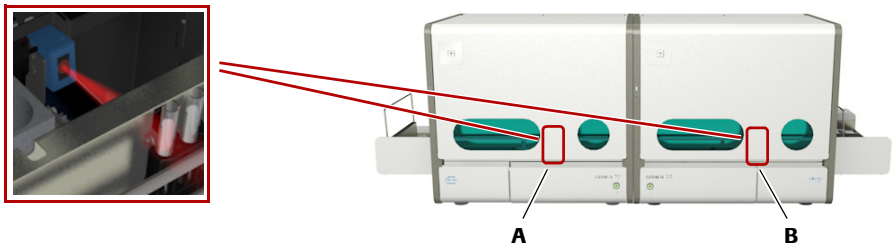
Loss of sight

The intense light of the LEDs may damage you 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

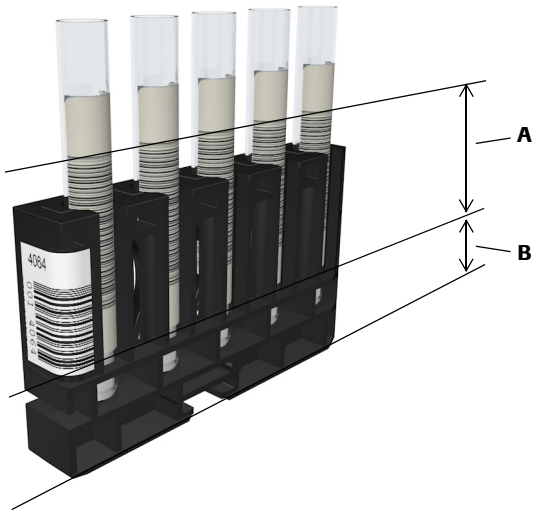


A Microscopy analyzer **B** Test strip analyzer

Figure 3-36 Barcode reader

Barcodes

Barcodes are used on racks and sample tubes. The minimum resolution 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.



A Barcode height max. 72 mm **B** Distance from base min. 35 mm

Figure 3-37 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

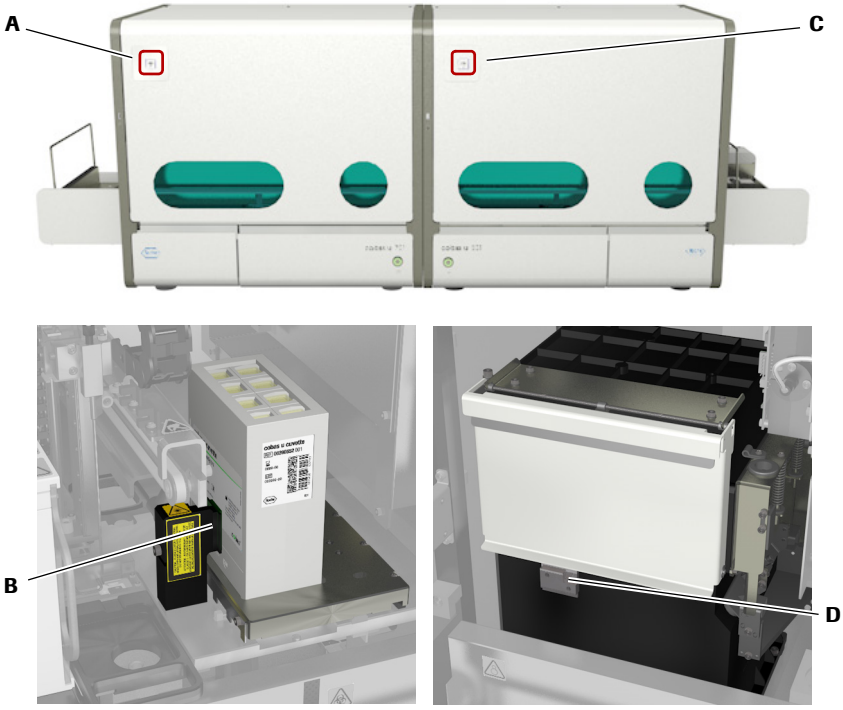
Barcode reading errors could potentially go undetected if a checksum is not used, which could lead to sample mismatch.

- 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 and cuvette cassettes with RFID tags.



A RFID reader for QC materials on the microscopy analyzer

B RFID reader for cuvette cassette

C RFID reader for QC materials on the test strip analyzer

D RFID reader for test strip cassette

Figure 3-38 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
	**cobas u** cuvette	• Lot number • Expiry date • Number of cuvettes left
	QC material	• QC level • Target ranges • Lot number • Expiry date

Table 3-2 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.

Storage conditions

Temperature range	5 °C to +40 °C (-41 °F 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

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

Physical dimensions

Width (with buffers)	176.6 cm (69.53 in)
Width (with output buffer and input connection unit)	173.2 cm (68.19 in)
Width (without buffers)	137.4 cm (54.10 in)
Depth	53.2 cm (20.94 in)
Height	64.4 cm (25.35 in)
Weight (with buffers)	169.3 kg (373.2 lb)
Width (with output buffer and input connection unit)	166.0 kg (366.0 lb)
Weight (without buffers)	157.1 kg (346.3 lb)

Effective footprint

Width	176.6 cm (69.53 in)
Depth	130.0 cm (51.18 in)

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

Allowed tilt

Incline < 3°

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	Max. 290 VA, typical 240 VA

	Effective power consumption	See the name plates on the analyzers.
	Line fuse	2 x T8AL
	Insulation coordination	Installation category II (EN/IEC 61010-1)
Uninterruptible power supply (UPS)	Output power capacity	1500 VA
	Battery runtime	Min. 5 min
Heat output	Heat dissipation	215 W
	Thermal load	734 Btu/h (774 kJ/h)
Measurement principles	Reflectance photometry	
	Refractometry	
	Turbidimetry	
	Automated microscopy	
	Automatic image evaluation	
Interfaces	USB1.1/2.0	Connection to external storage devices
	USB1.1/2.0	Connection to peripherals
	RJ45	Connection to network
Throughput	Test strip analysis	240 samples per hour
	Microscopy analysis	116 samples per hour
Minimal sample volumes (dependent on test profile)	Test strip & microscopy	2.8 mL
	Test strip	2.0 mL
	Test strip reduced volume (no measuring cell measurements)	1.5 mL
	Microscopy	2.0 mL
	Test strip reduced volume & microscopy	2.3 mL
Water quality	Type II/IF (according to CLSI C3-A4 guidelines) (Conductivity: 1µS/cm; 25 °C) Water temperature between 18 °C and 32 °C.	
Wash solution	Recommended solution for performing the daily wash action:	1.2% - 4% Na-hypochlorite 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:	• Ethanol • Mikrozid® (EtOH/Propanol)

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)
	Solid waste container for cuvettes	Capacity: 400 cuvettes Inside dimensions: (W x D x H): 13.34 cm x 8.34 cm x 11.82 cm (5.25 in x 3.28 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)
Display	Touch screen	19 inch (1280 x 1024 pixels)
Keyboard	Standard US QWERTY layout	Only use supplied keyboard.
Mouse		Only use supplied mouse.

Standard supplies

The analyzer has been tested for the following Roche supplies:

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

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

Performance data

The following section provides representative performance data for SG and CLA.

For performance data of the urine test strips used on the **cobas u** 601 urine analyzer, see https://e-labdoc.roche.com (document number: 07137940001)

For performance data of the **cobas u** 701 microscopy analyzer, see https://e-labdoc.roche.com (document number: 07226306190).

The website displays either the version listed here or, if available, any later version that is also valid for this product code.

Performance data for SG and Clarity

The measurement range of a parameter is the interval that reveals the results of the performance data evaluation (e.g. for SG this range is 1.002 - 1.050). The measuring range reflects the interval of the parameter that is technically displayed by the analyzer (e.g. for SG this range is 1.000 - 1.050).

Representative performance data on the analyzers are given below.

Results obtained in individual laboratories may differ.

Performance data for test strip parameters are presented in the method sheet.

Parameter	SG	Clarity[1]
Method comparison	Deming regression:	Concordance rates:
Versus Urisys 2400 with human urine samples	• y = 1.04*x - 0.0417 • Pearson's r = 0.995 Measurement range: • 1.002 - 1.050	• clear: 89% • light turbid: 80% • turbid: 84%
	Number of samples measured: • n = 1334	Number of samples measured: • n = 1364

Table 3-3 Performance data for SG and Clarity for the **cobas u** 601 urine analyzer

Parameter	SG	Clarity(1)
Precision Measured over 21 days with 2 aliquots per control with 2 replicates each, total n=84	**Repeatability**: Control 1: (Bio-Rad Liquichek Level 1) • Mean: 1.013 • Standard deviation = 0.000	**Repeatability**: Control 1: (Bio-Rad Liquichek Level 1) Agreement: • 100% are clear • 0% are light turbid • 0% are turbid
	Control 2: (Bio-Rad Liquichek Level 2) • Mean: 1.022 • Standard deviation = 0.000	Control 2: (Bio-Rad Liquichek Level 2) Agreement: • 100% are clear • 0% are light turbid • 0% are turbid
	Intermediate: Control 1: (Bio-Rad Liquichek Level 1) • Mean: 1.013 • Standard deviation = 0.000	**Intermediate**: Control 1: (Bio-Rad Liquichek Level 1) Agreement: • 100% are clear • 0% are light turbid • 0% are turbid
	Control 2: (Bio-Rad Liquichek Level 2) • Mean: 1.022 • Standard deviation = 0.000	Control 2: (Bio-Rad Liquichek Level 2) Agreement: • 100% are clear • 0% are light turbid • 0% are turbid

Table 3-3 Performance data for SG and Clarity for the **cobas u** 601 urine analyzer

(1) Clarity is determined by the relation of scattered light and direct light measured with two separate detectors.

Concentration ranges

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

Test parameter	Range		
	Conventional	SI	Arbitrary
PH	5	5	5
	6	6	6
	6.5	6.5	6.5
	7	7	7
	8	8	8
	9	9	9
LEU	neg	neg	neg
	25/µL	25/µL	1+
	100/µL	100/µL	2+
	500/µL	500/µL	3+
NIT	neg	neg	neg
	pos	pos	pos

Table 3-4 International concentration ranges for the **cobas u** 601 urine analyzer

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

Table 3-4 International concentration ranges for the **cobas u** 601 urine analyzer

The following table lists the international concentration ranges for the **cobas u** 701 microscopy analyzer.

Test parameter	Conventional		Field of view		Arbitrary
	Range	Unit	Range	Unit	Range
RBC(1)	n/a	/µL	n/a	/HPF	n/a
WBC(2)	n/a	/µL	n/a	/HPF	n/a
NEC	neg		neg		neg
	5	/µL	1	/HPF	1+
	15	/µL	3	/HPF	2+
SEC	neg		neg		neg
	15	/µL	3	/HPF	1+
	40	/µL	8	/HPF	2+
	75	/µL	15	/HPF	3+
YEA	neg		neg		neg
	pos		pos		pos
CRY	neg		neg		neg
	pos		pos		pos
BAC	neg		neg		neg
	150	/µL	30	/HPF	1+
	500	/µL	100	/HPF	2+
	1000	/µL	200	/HPF	3+
HYA	neg		neg		neg
	5	/µL	1	/HPF	1+
	15	/µL	3	/HPF	2+
SPRM	neg		neg		neg
	pos		pos		pos
MUC	neg		neg		neg
	pos		pos		pos
PAT	neg		neg		neg
	pos		pos		pos

Table 3-5 International concentration ranges for the **cobas u** 701 urine analyzer

(1) quantitative parameter, measuring range: 0 - 1800

(2) quantitative parameter, measuring range: 0 - 900

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

Chapter **4**

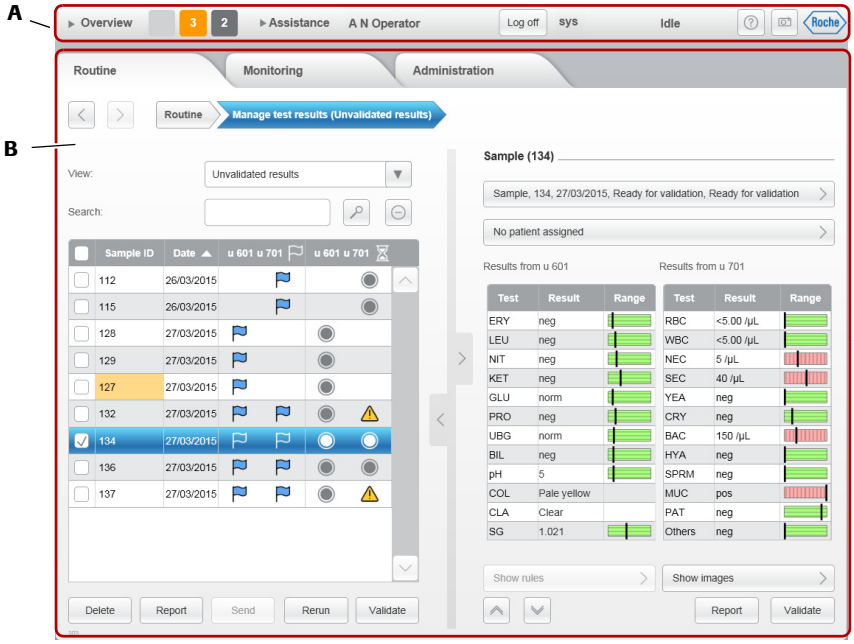
Introduction

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.

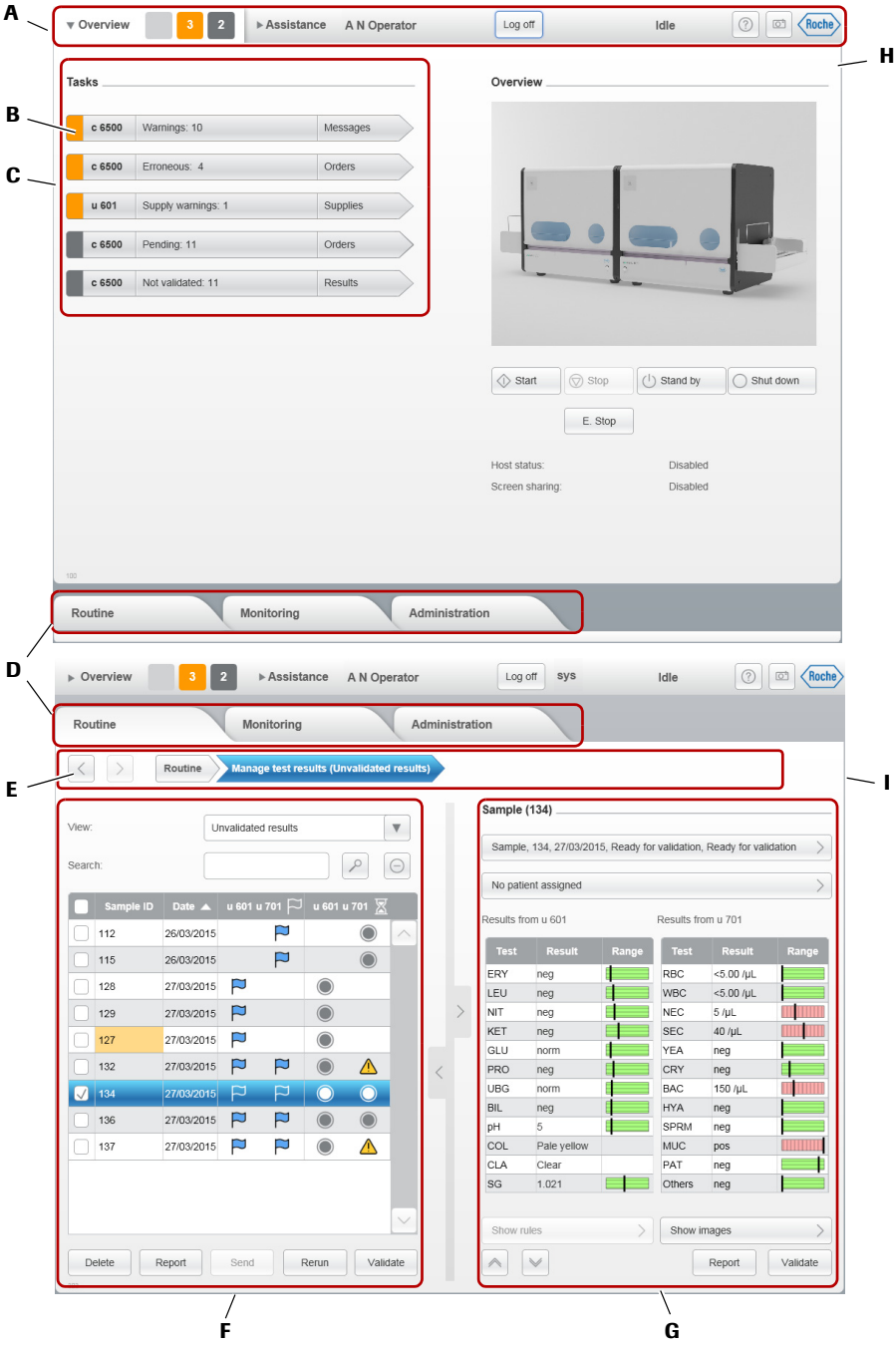


A Global information area **B** Work area

Figure 4-1 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

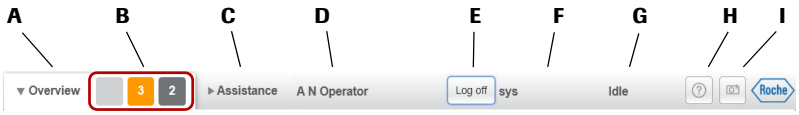
H **Overview** work area

I **Routine** tab in split-screen mode display (two panels)

Figure 4-2 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

Figure 4-3 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.

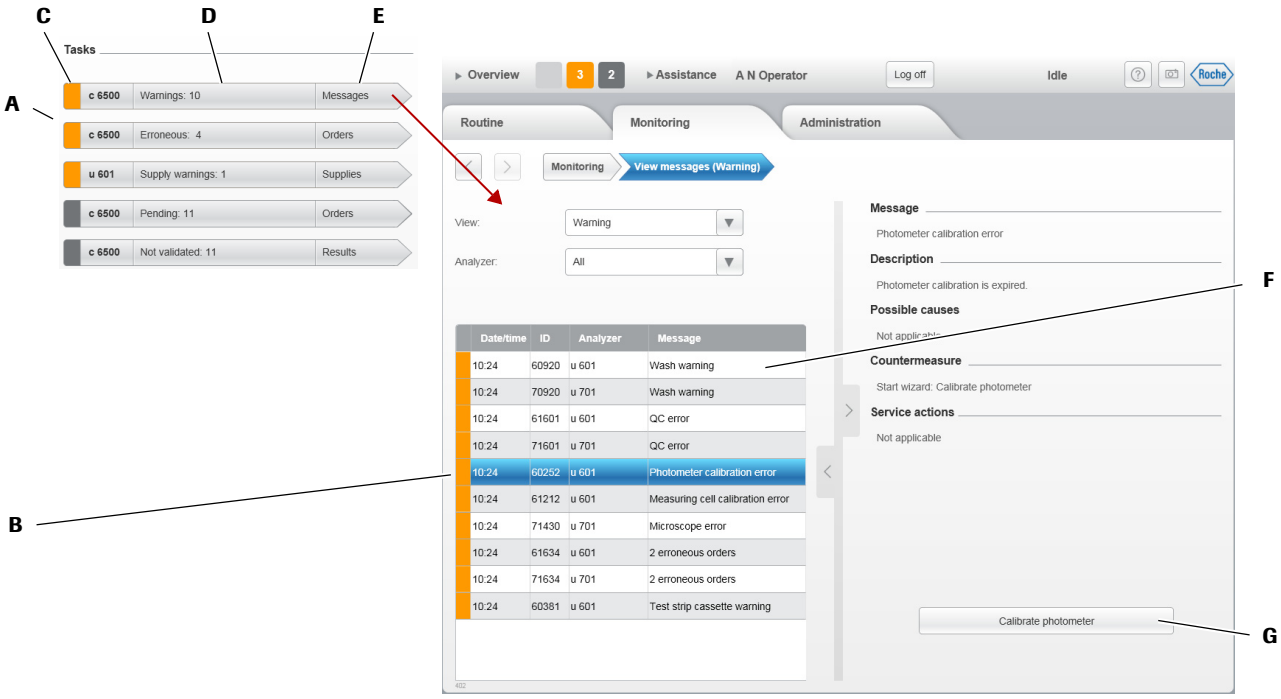
Color	Interpretation
Red	The task requires immediate operator intervention. Operation may have stopped. When such a task is generated, an acoustic signal is sounded as well, unless this function is turned off.
Orange	The task requires early operator intervention, operation may otherwise stop. When such 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.

Table 4-1 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.

Key screen elements



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

Figure 4-4 Example of using task buttons, lists and buttons

Tabs

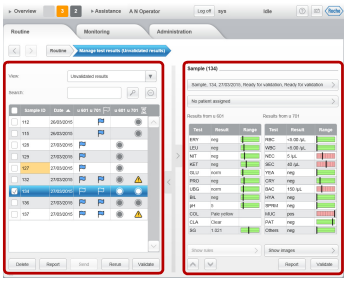
Tabs group information and tasks of the work areas such as performing tests and result handling, maintenance actions, or defining the analyzer work environment.

For details on tabs, see *Tabs* (p. 110).

Navigation bar

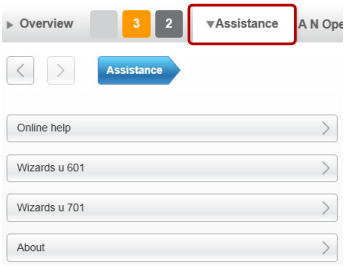
The navigation bar helps you move between the various panels. A "history" function registers which panels have been displayed so far, use the back and forward buttons to display the previous or next panel within this history. The navigation path tells you how to navigate to the current panel (the blue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

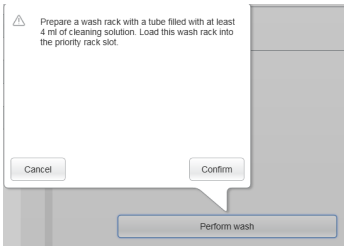
Assistance



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

For details on the Assistance work area, see *Wizards* (p. 119) and *Online help* (p. 122).

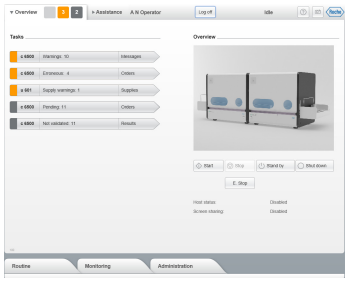
Callouts



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.

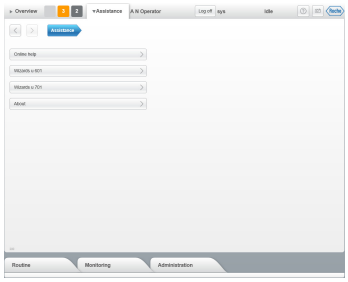
Key work areas

Related tasks are grouped in separate work areas.



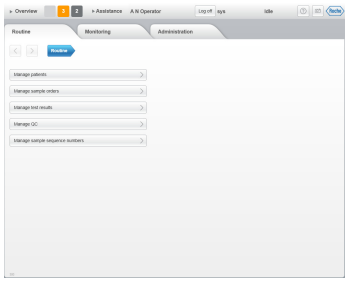
The **Overview** work area is displayed when you start the analyzer. It contains general status information of the analyzer and lists the user actions that are due to ensure the proper functioning of the analyzer and the smooth progress of tasks and actions. Its main elements are:

- 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.



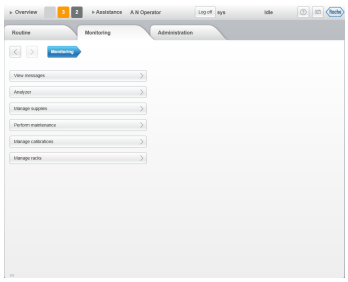
The **Assistance** work area provides operation aids such as:

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



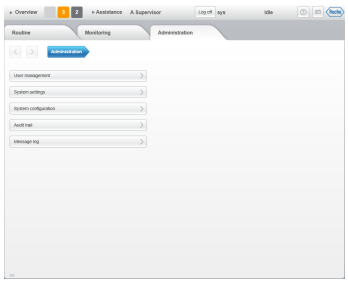
The **Routine** tab encompasses all activities directly related to performing tests and handling results.

- 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.

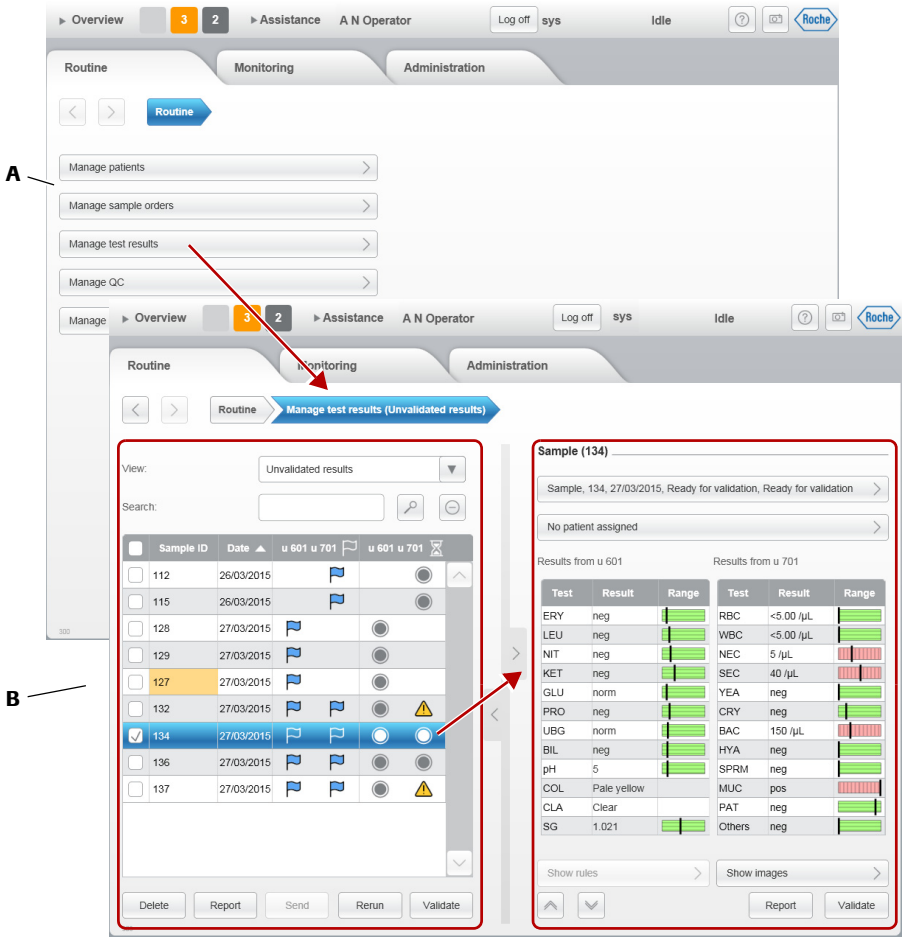


Figure 4-5 Main elements in a tab

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

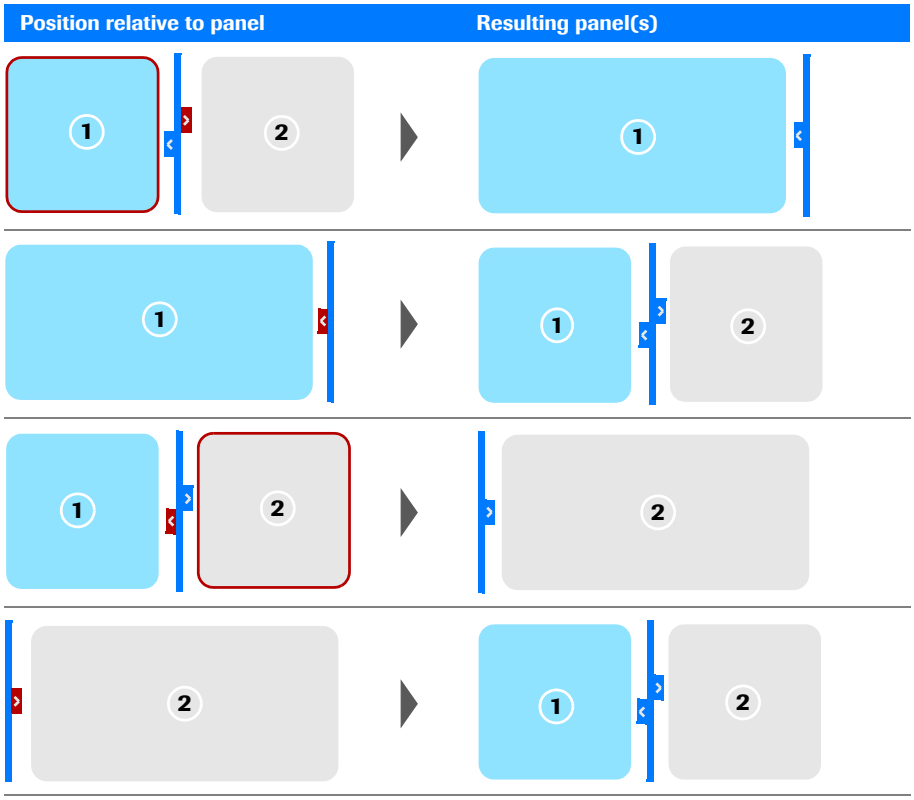
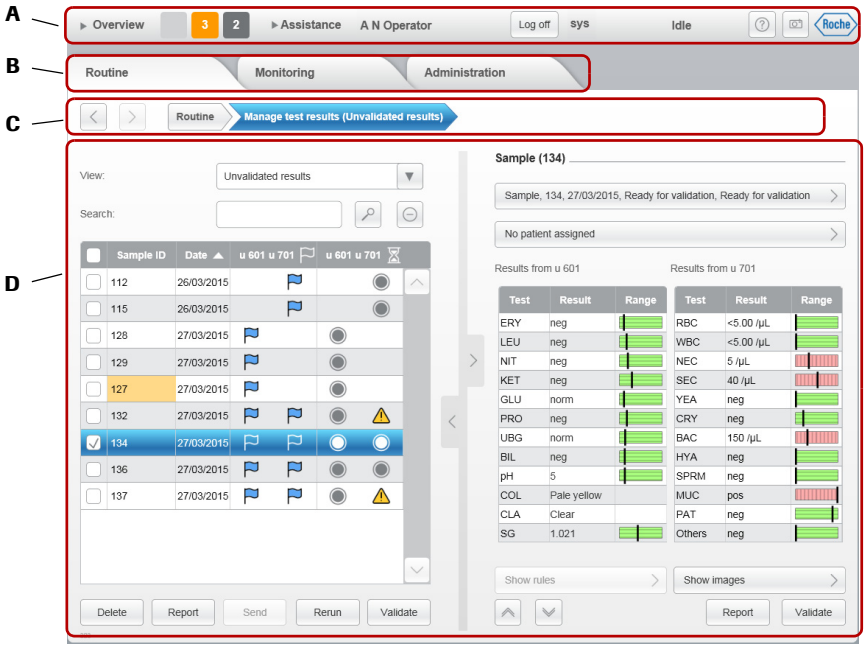


Table 4-2 Functions of the display-mode buttons (panel splitters)

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.

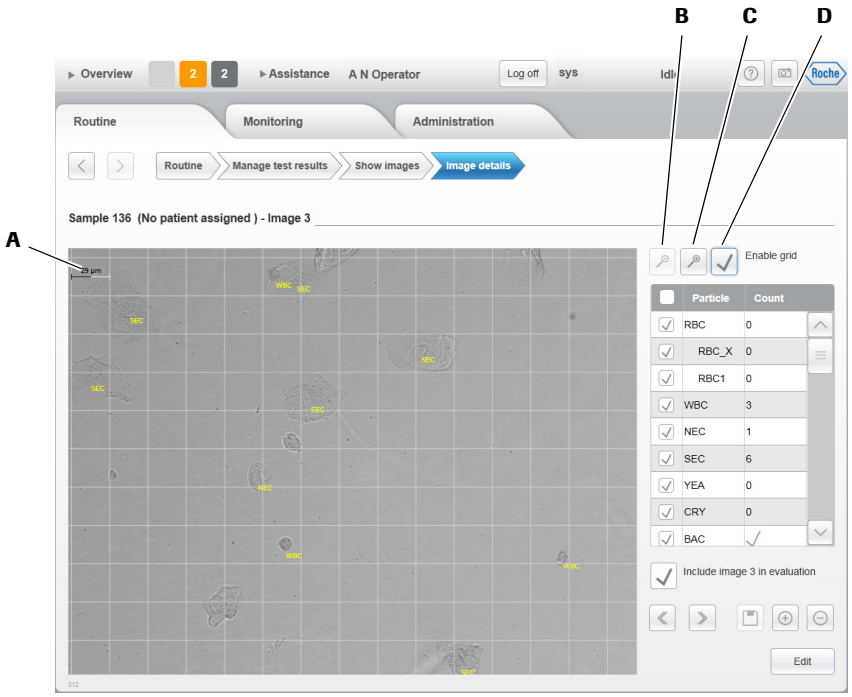


A Global information area
B Tabs
C Navigation bar
D Panels

Figure 4-6 Features for accessing information and functions

Using the zoom function

For studying details of microscopic images, a zoom function is provided.



A Grid scale
B Zoom out
C Zoom in
D **Enable grid** toggle button

Figure 4-7 Image details screen

To use the zoom functions

1. Choose **Routine** > **Manage test results** > **Show images**.
2. Choose the image.
3. Select the **Enable grid** toggle button to display the grid, if required (☑).

   If you display the grid, the current scale is indicated. (A).

4 Choose the Zoom in button.

If you work with a mouse, the mouse pointer changes to the symbol.

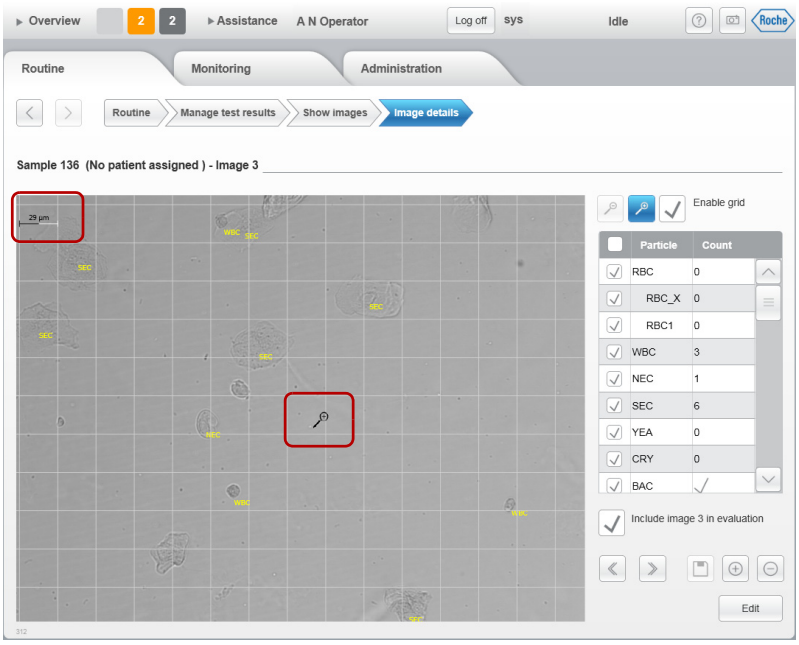


Figure 4-8 Grid scale

5 In the image, touch the area you are particularly interested in.

The image is enlarged and the spot where you touched the image is in the center of the image.

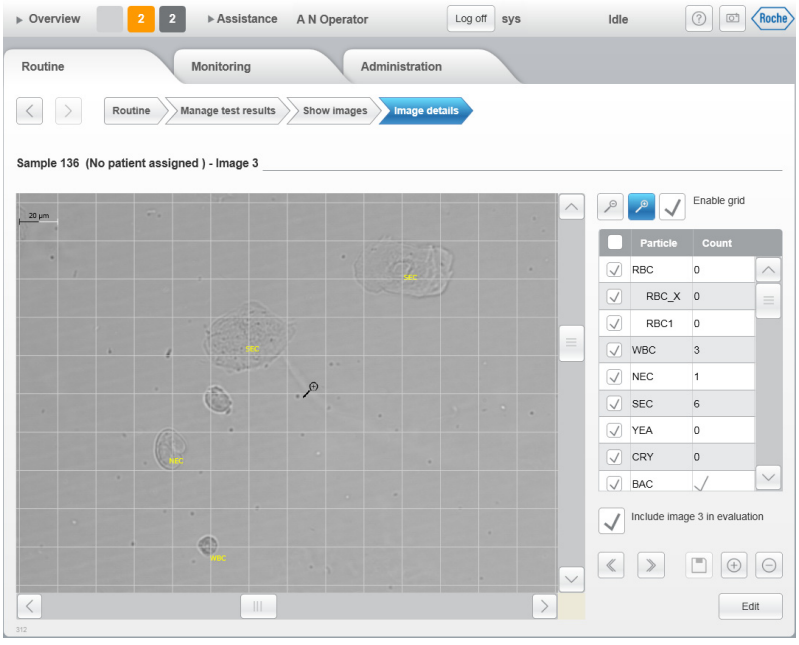


Figure 4-9 Zoomed image

The grid label indicates the current scale.

6 Use the scroll bars to display the area of interest, if required.

7 To enlarge the image further, make sure the Zoom in button is blue and touch the area you are particularly interested in.

You can enlarge an image up to three times (200%, 300%, 400%).

8 To return to the normal view, choose the Zoom out button.

Choosing the Zoom out button always sets the image to its normal size (100%).

■

Working with lists (tables)

Sorting You can sort lists by choosing a column head.

Figure 4-10 Sorting lists

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

Filtering 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.

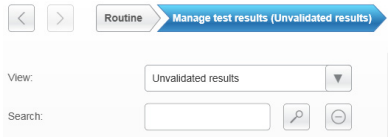


Figure 4-11 Filtering table information

Press the button to cancel the search.

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

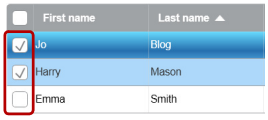


Figure 4-12 Selecting table items

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.

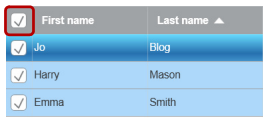


Figure 4-13 Selecting all items in a table

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

Figure 4-14 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.

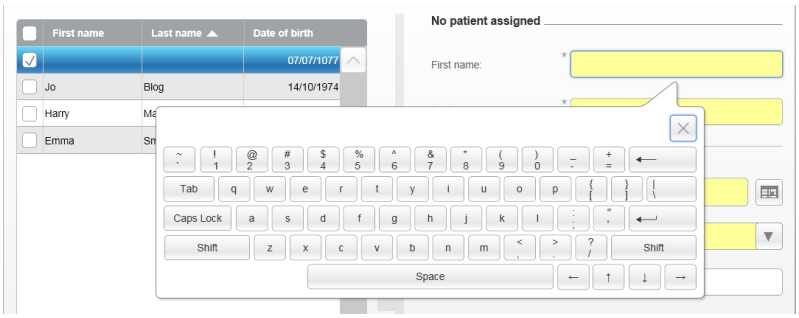


Figure 4-15 Compulsory entry fields

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 is has its normal active display (B).

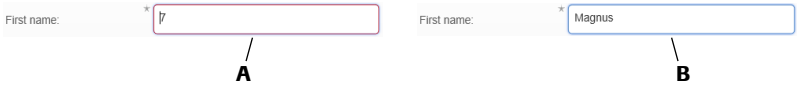


Figure 4-16 Validity checking of text entries

Working with QC charts

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

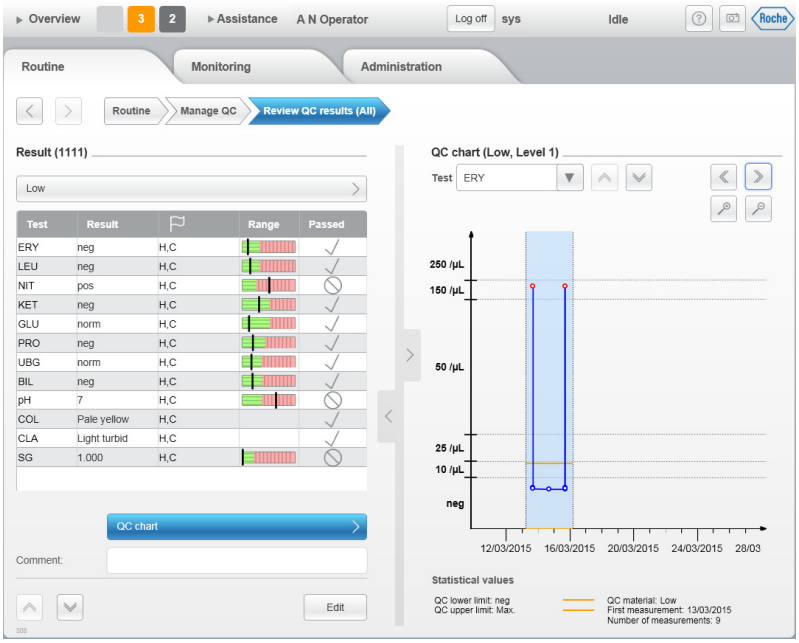


Figure 4-17

	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**).

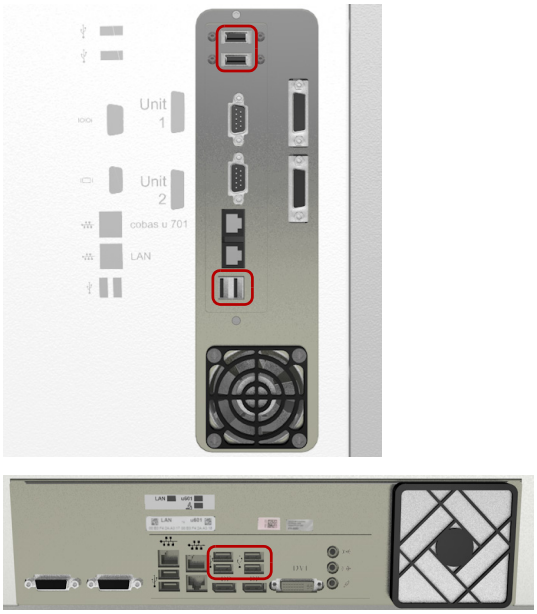


Figure 4-18 USB ports

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

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

To start a wizard

1 Choose **Assistance** > **Wizards**.

- Choose **Assistance** > **Wizards u 601**
  or,
- Choose **Assistance** > **Wizards u 701**

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

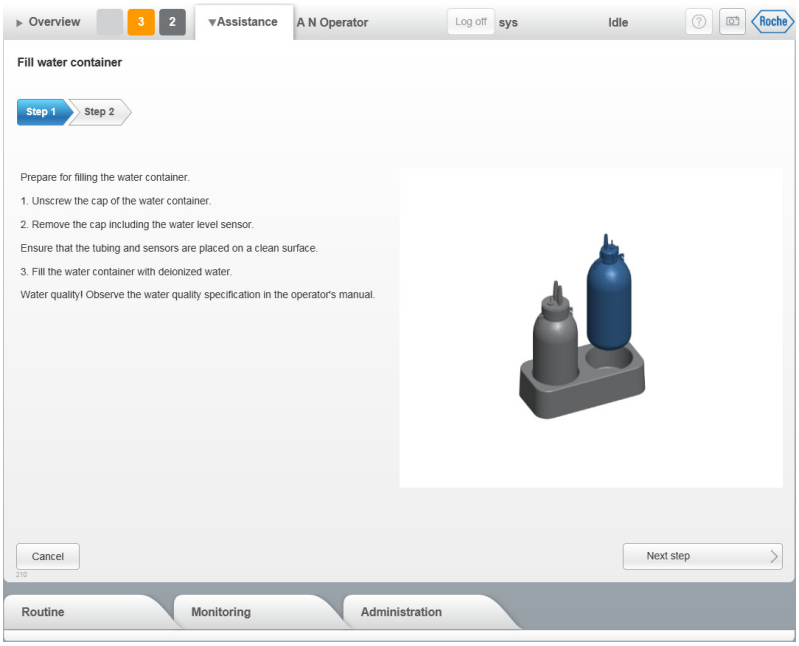


Figure 4-19 Example of a wizard panel

■

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.

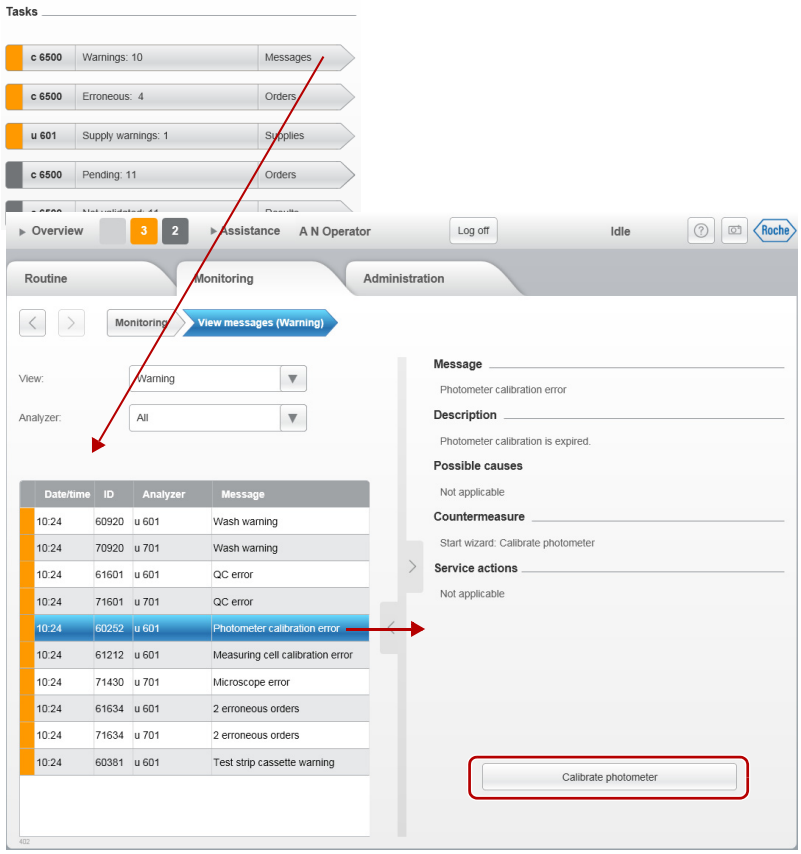


Figure 4-20 Starting a wizard from the task list

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	Interpretation
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.

Table 4-3 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.

Table 4-4 Color concept for degree of pathology in results

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

Color	Interpretation
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.)

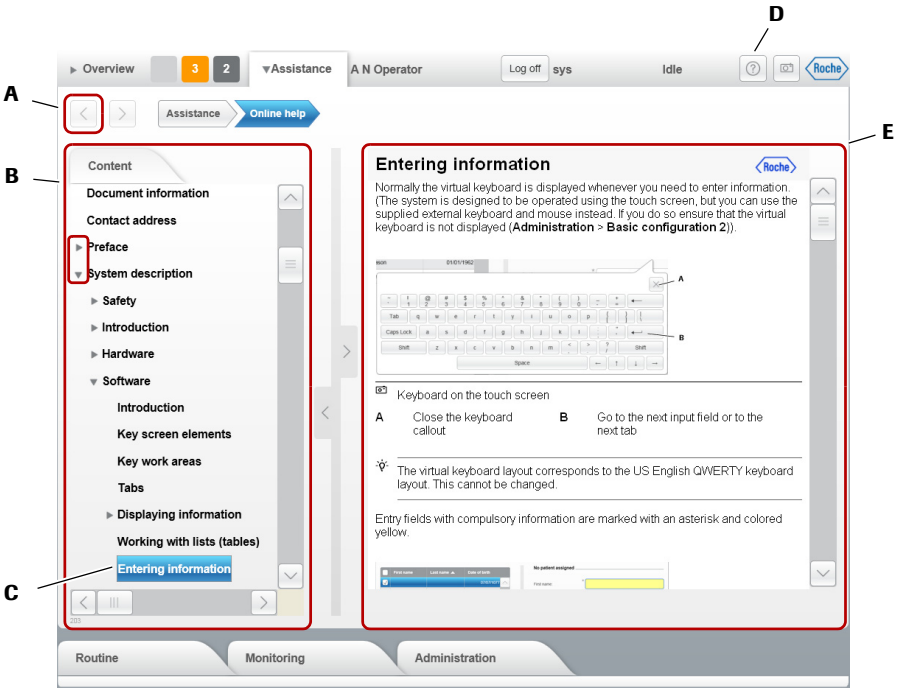
Table 4-5 Color concept for severity of measurement errors in the measuring cell

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

Figure 4-21 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 *Chapter* 5

Safety

Read and understand the information in the Safety chapter

See p. 17.

The following safety messages are particularly relevant:

Warning messages:

- *Biohazardous materials* (p. 22)
- *Waste* (p. 23)

Caution messages

- *Mechanical safety* (p. 24)
- *Working solutions* (p. 25)
- *Influence of vibrations* (p. 25)

Notice messages

- *Spillage* (p. 26)
- *Excessive ambient humidity* (p. 26)

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 ambient conditions defined in *Environmental conditions* (p. 94).

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, and they may influence the image evaluation.

- 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.

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.

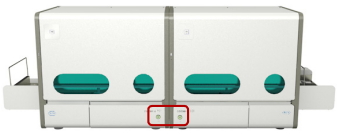
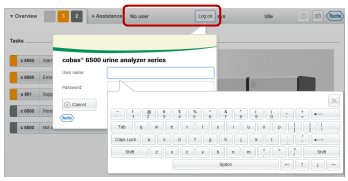
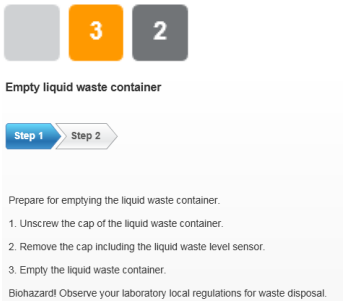
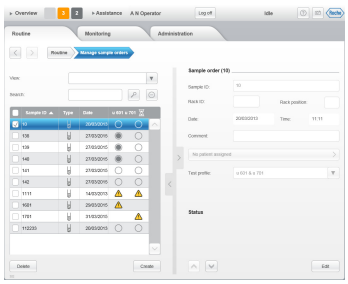
Step	Task		Procedure
1	Starting the analyzer		1. Ensure that all covers are closed. 2. Power on the test strip analyzer. 3. Power on the microscopy analyzer. 4. Wait until the **Overview** work area is displayed. This may take a few minutes.
2	Logging on		1. On the **Overview** work area, choose the **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 containers.(1) If they are not full, start the appropriate wizards and fill them. 3. Check the liquid waste containers.(1) If they are not empty, start the appropriate wizards and empty them. 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. 5. Check the cuvette 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.

Table 5-1 Short guide for performing tests

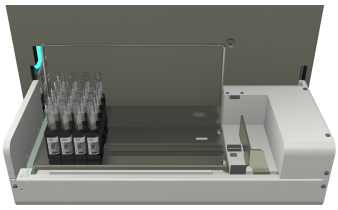
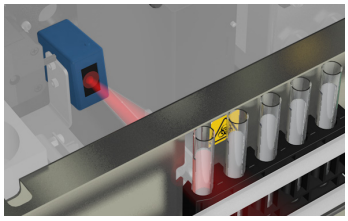
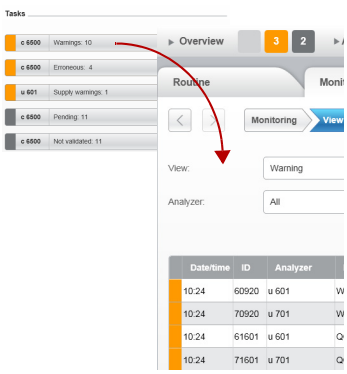
Step	Task		Procedure
5	Loading the samples and racks		• Ensure that the sample barcodes point towards that long side of the rack where the rack barcode is affixed. • Ensure that the rack barcodes point outwards and towards the back of the analyzer when placed on the input buffer. The analyzer detects 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.
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.

Table 5-1 Short guide for performing tests

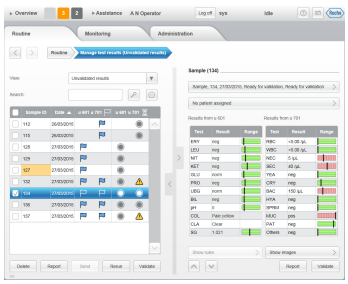
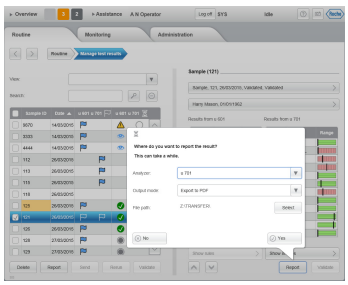
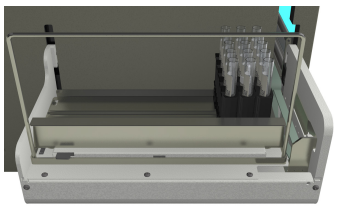
Step	Task		Procedure
8	Validating the results		1. Choose **Routine** > **Manage test results**, if required. 2. Select a result in the list and check for data alarms and the range graphics. Green: negative Yellow: positive (low pathological) Red: positive (pathological) If you work with patient demographics 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 the 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 the analyzer and whether to print the results or save them to a file. 4. Choose the **Yes** button. 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 the analyzer. 4. Choose whether to print the results or save them to a file. 5. Define which results you want to print. 6. Choose the **Yes** button.
10	Clearing the output buffer		1. Remove the rack tray and replace it with an empty one.

Table 5-1 Short guide for performing tests

Step	Task		Procedure
11	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 both probe bend detectors. 8. Clean the pipetting stage, pipetting area, and the inside of the centrifuge chamber. 9. Clean the microscope stage area. 10. Remove spills and soiling from the analyzer housing.

Table 5-1 Short guide for performing tests

Routine operating tasks

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

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 To turn on the system, first power on the test strip analyzer (B) and then the microscopy analyzer (A).

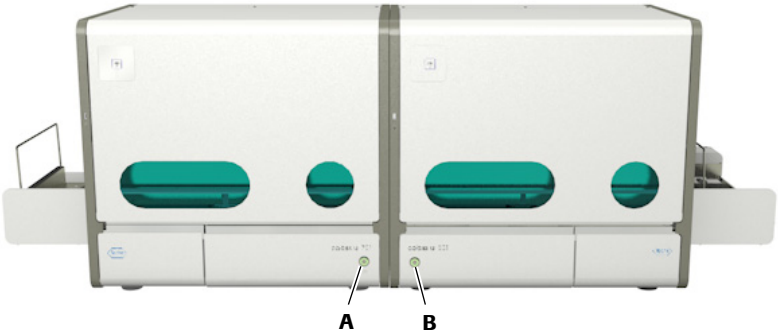


Figure 5-1

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.

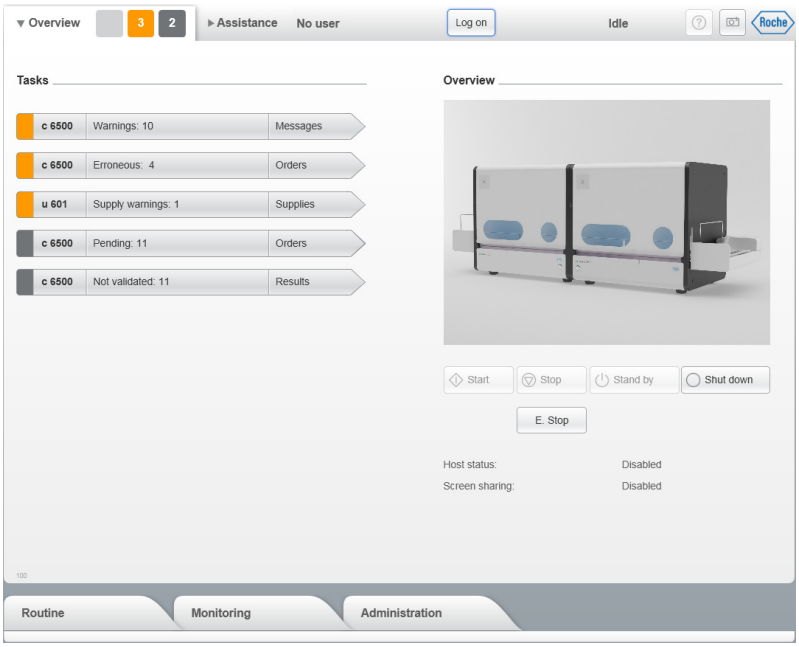


Figure 5-2

■

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.) See *Changing the password* (p. 218).

3 Choose the **Log on** button.

Your name is displayed in the global information area.

Figure 5-3

■

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.

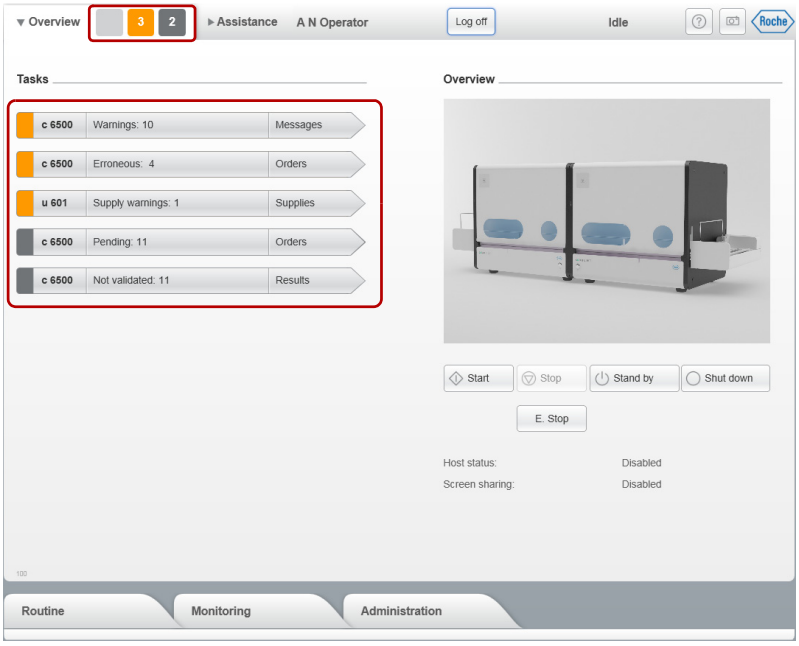


Figure 5-4

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.

For details, see *Checking the status of the system* (p. 181).

3 Choose **Monitoring** > **Manage supplies**.

4 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**.

5 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.


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 their Instructions for Use.

6 Choose **Cuvette** and check the number of available cuvettes. Ensure that you have a new cuvette cassette available to replace the installed one when it is empty.

7 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.


CAUTION

Loss of results due to resetting the sample sequence number

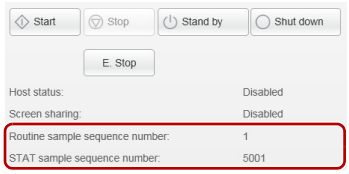
If you reset the sample sequence number counter, all associated results are deleted.

- Only reset the sample sequence number if you do no longer need the results.

See *Managing sample sequence numbers* (p. 137)

■

Managing sample sequence numbers



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:

1. The analyzer works in **Sample sequence number** mode.
   See *Defining how the sample IDs are generated* (p. 236)
2. Ranges for sample sequence numbers are defined for routine and STAT samples.
   See *To define the sample sequence number ranges* (p. 137)
3. The counters for the sample sequence numbers are reset to ensure sufficient available numbers.

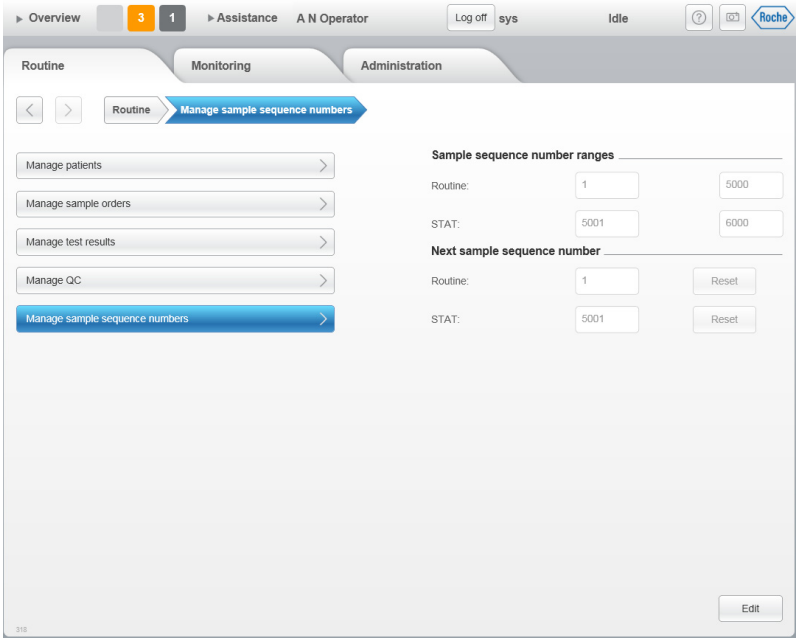


Figure 5-5 Managing sample sequence numbers

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.

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

4 Choose the **Save** button.

■

To define the next sample sequence number to be used

The procedure is the same for routine and STAT samples.

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

The system is basically 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.

For information on sample IDs, see *To define how the sample IDs are generated* (p. 236).

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

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.

1 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.

■

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

See *Managing patients* (p. 179).

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

8 If you use the **u 701** test profile, you can enter a dilution factor (≥1.00: dilution, <1.00: concentration) in the **Dilution** field, if required. (If previously no result could be generated for this sample, the sample can be diluted or concentrated and measured again.)

If you entered a dilution factor ≠1.00, the result will be marked with **D** in the ⚑ column.

WARNING

Incorrect results due to cell lysis

Dilution of sample may lead to cell lysis and therefore incorrect results may be obtained.

▶ Always use appropriate dilution procedures.

9 In the detail panel, choose the **Save** button.

The order is now defined.

10 To process the order, place the rack with the sample tube on the correct position on the analyzer.

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

■

Loading racks

For general information on racks, see *Racks* (p. 67).

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

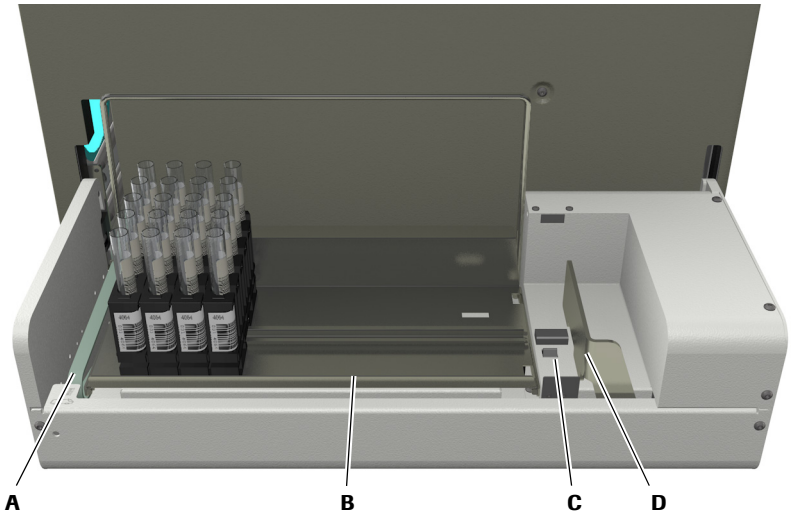
Malfunction and analyzer damage due to obstructions

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

Figure 5-6 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)

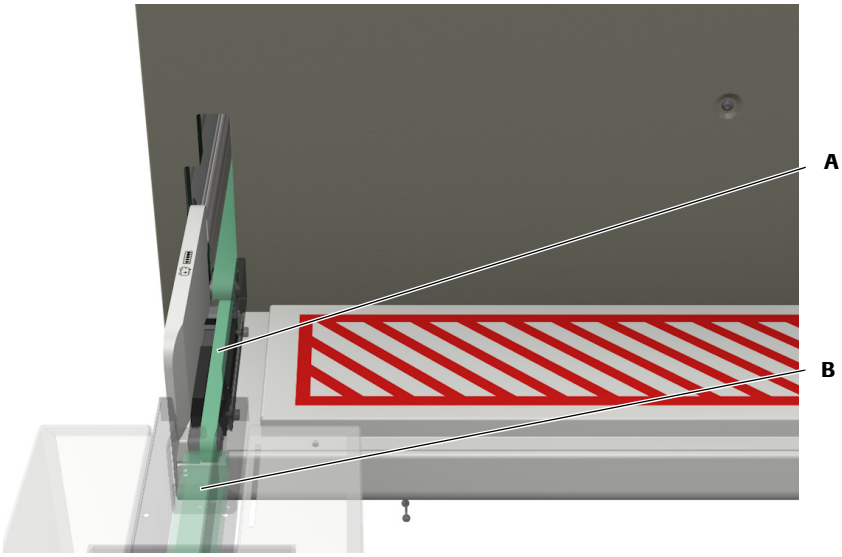
In all cases, the analyzer automatically registers that a rack is present and proceeds to process the rack on the priority rack slot or the one nearest to it.

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

Figure 5-7 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

Figure 5-8 Rack loading with an input connection unit

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).

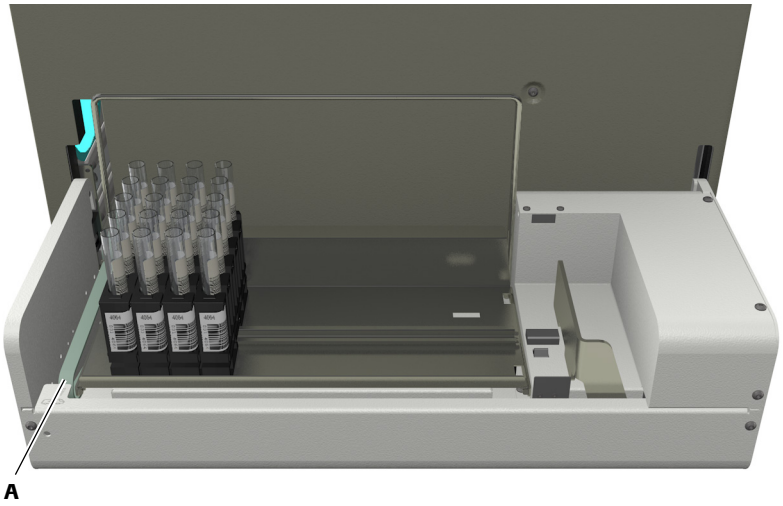


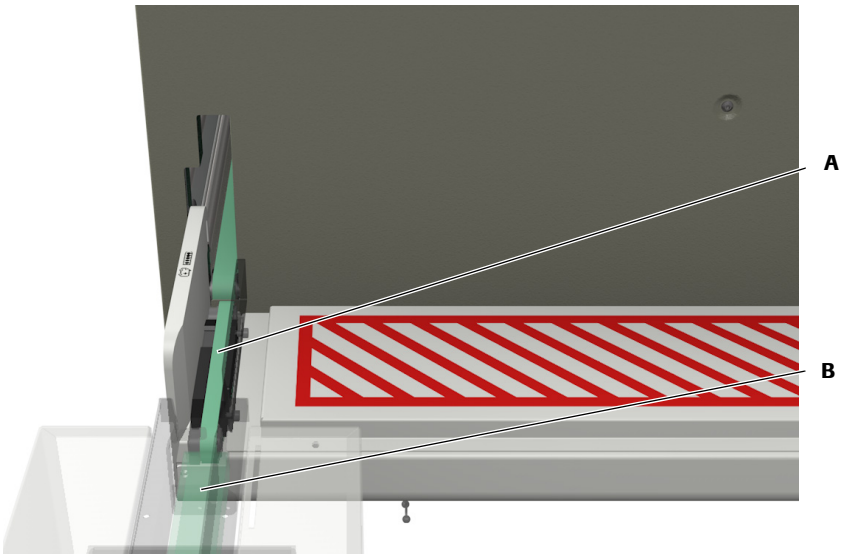
Figure 5-9 Priority rack slot

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

For further details, see *To load a priority rack* (p. 145).

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 unit

Figure 5-10 Rack loading with an input connection unit

For further details, see *To load a priority rack when working with an LAS* (p. 145).

Starting the testing process

To start sample testing

1 Place the rack on the input buffer.

Processing starts automatically.

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.

See *Non-routine situations* (p. 163).

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.

■

To load 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.

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.

See also *Checking the status of the system* (p. 181).

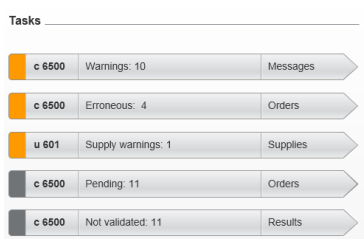
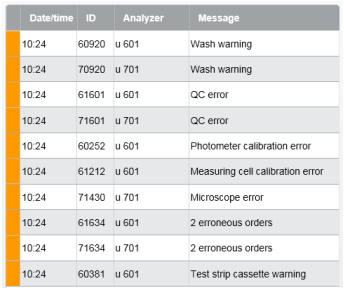
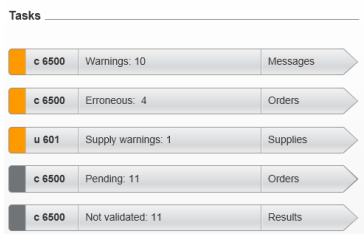
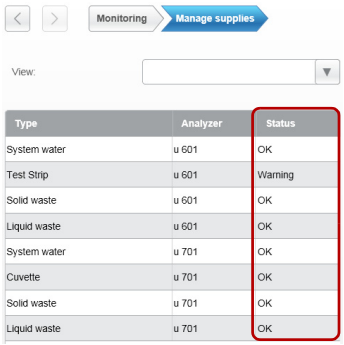
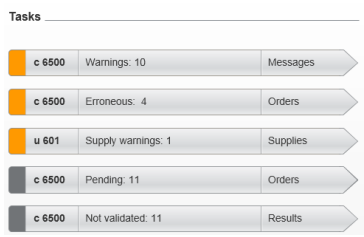
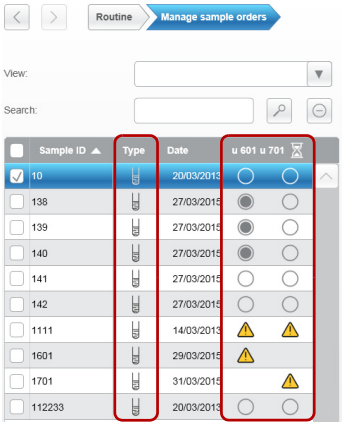
Task list	Tab or panel	Key status elements	
	Message list 	Red	Immediate user intervention is required.
		Orange	Earliest possible user intervention is required.
		Gray	Information about ongoing tasks. If operator intervention is required, perform it.
		Light gray	There are no messages. No operator intervention is required.
	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.
			The order is complete.
			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)
			No measurement is required on this analyzer.
			Order for routine sample testing.
			Order for STAT sample testing.
			Order for QC testing.

Table 5-2 Checking the operation status

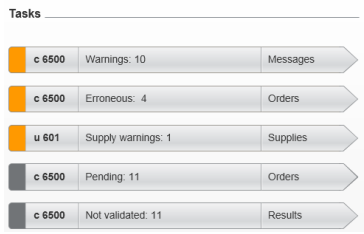
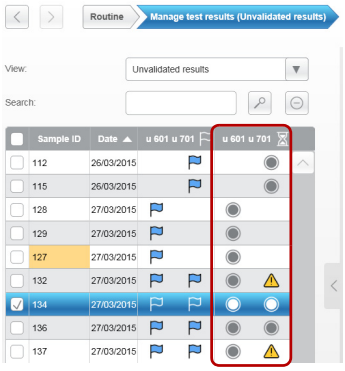
Task list	Tab or panel	Key status elements
	Result list 	 Pending, measurement has not started yet.
		 The order is being processed. Measuring or under evaluation.
		 Ready for validation.
		 Validated.
		 Validated and successfully sent to the host computer.
		 An error occurred during measurement, 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.

Table 5-2 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.

To check the status of order processing

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

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.

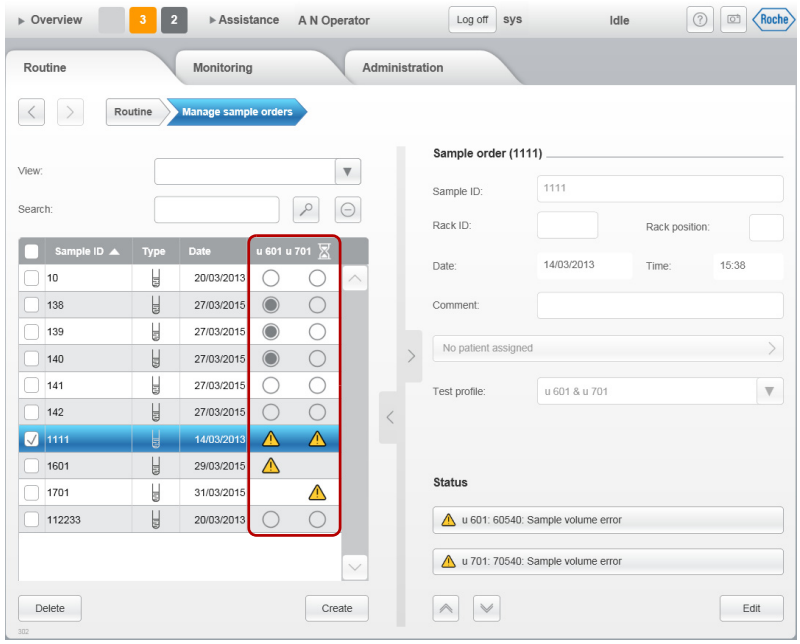


Figure 5-11

	Pending, measurement has not started yet.
	The order is being processed.
	Complete.
	An error occurred during measurement, no result was generated. (Check for messages in the message list, you may need to rerun the test.)
	Not applicable. No measurement is required on this analyzer.
	Order for routine sample testing
	Order for STAT sample testing
	Order for QC testing

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.

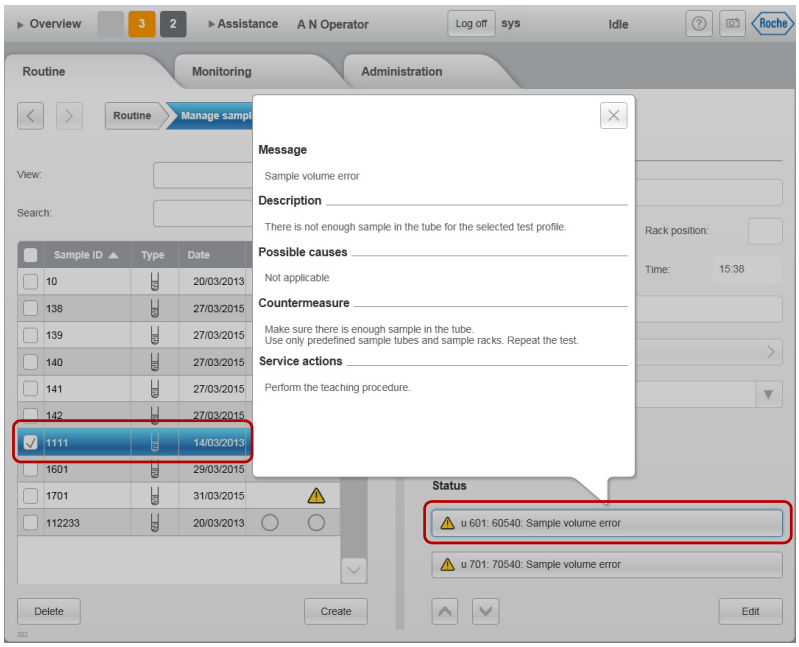

Overview
Assistance
A N Operator
Log off
sys
Idle
Roche
Routine
Monitoring
Administration
Routine
Manage sampl
View:
Search:
Sample ID
Type
Date
10
20/03/2013
138
27/03/2015
139
27/03/2015
140
27/03/2015
141
27/03/2015
142
27/03/2015
1111
14/03/2013
1601
29/03/2015
1701
31/03/2015
112233
20/03/2013
Message
Sample volume error
Description
There is not enough sample in the tube for the selected test profile.
Possible causes
Not applicable
Countermeasure
Make sure there is enough sample in the tube.
Use only predefined sample tubes and sample racks. Repeat the test.
Service actions
Perform the teaching procedure.
Rack position:
Time:
15:38
Status
u 601: 60540: Sample volume error
u 701: 70540: Sample volume error
Delete
Create
Edit

Figure 5-12

■

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, measuring cell calibration, and microscope check.

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.

For information on how to perform result backup, see *Managing the result storage capacity* (p. 270).

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 so-called 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. To view microscopy images, choose the **Show images** button (see *Manually analyzing images* (p. 168)).
7. 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.

  For information on setting up the analyzer, see *Defining the validation method* (p. 233).

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.
- For microscopy results, you can also display the individual images and reclassify particles.
- 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* (p. 164)
- *Managing invalid SG results* (p. 157)
- *Generating reports* (p. 160)
- *Non-routine situations* (p. 163)

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

- *Assigning patients* (p. 160)

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.)

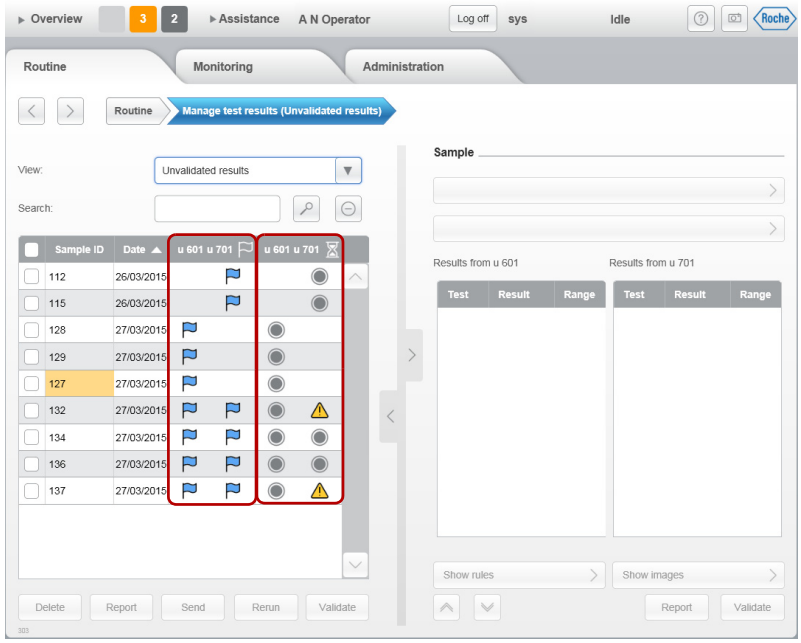


Figure 5-13

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

In the column, the progress status is indicated:

	Pending, measurement has not started yet.
	The order is being processed. Measuring or under evaluation.
	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.
	Not applicable. No measurement is required on this analyzer.

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. See *Adjusting sample information* (p. 179).

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

The results are displayed in the detail panel.

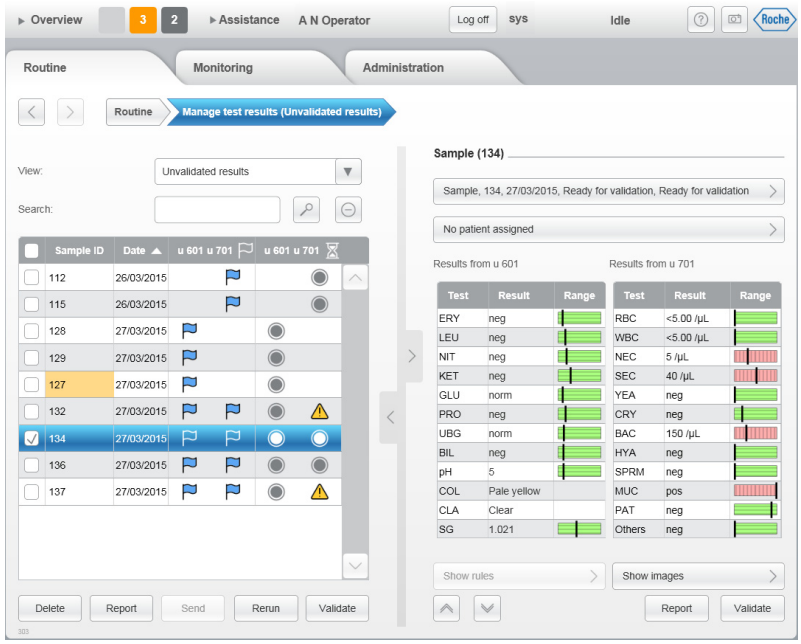


Figure 5-14

5 Observe the status information in the detail panel.

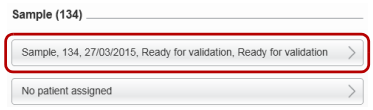


Figure 5-15

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. See *Non-routine situations* (p. 163)
- There already exists an order for this result. Delete the order or rerun the test. See *To rerun a test* (p. 164)
- Fewer than five images yielded an automatic result. You need to include at least five images. To achieve this number, you need to manually analyze images. See *Manually analyzing images* (p. 168).

6 Choose the ‹ panel splitter to display the detailed values and settings.

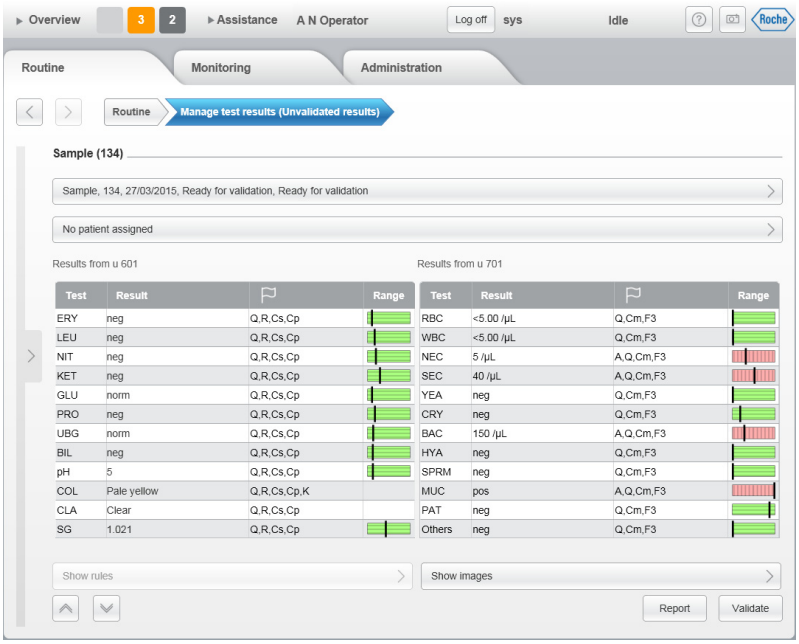


Figure 5-16

7 Check for data alarms in the ⚑ column.

	No data alarm was generated.
	No measurement required.
!	The result was manually changed.
A	Abnormal result.
Cm	Calibration. The microscope check results were no longer valid when the result was generated.
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.
D	Dilution. The customer has set a dilution factor in the sample order.
F1	Defocused image found. All particle counts are zero. Review the images and repeat measurement.
F2	Defocused image found. The focus position deviates too much from that of the previous image. Review the images and repeat measurement.
F3	Defocused image found. The focus position is outside the predefined range. Review the images and repeat measurement.
F4	Defocused image found. Inhomogeneous MUC distribution in the images. Review the images and repeat measurement.
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.)
M	The result of the image was manually changed.

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.
Ub	Unreliable image found. There may be bubbles in the cuvette. Review is recommended. If between 5 and 14 images yielded an automatic result you can validate the test result manually straight away, or you can adjust the values for any of the images first (either by defining the results directly or by reassigning particles) and then validate the test result. If you adjust any values before validating the result, the **M** or **!** data alarm will be added to the result. You can decide not to validate the test result and to repeat the test. See *Editing microscopy counts and concentrations* (p. 177). See *Rerunning tests* (p. 164). (If fewer than 5 images yielded an automatic result, no test result is displayed and you must first ensure that there are results for at least 5 images (either by defining the results directly or by reassigning particles) before you can validate the test result. The **M** or **!** data alarm will be added to the resulting test result.)
Uc	Unreliable image found. There are too many cells in the image (crowded), automatic evaluation is not possible. Review is recommended. If between 5 and 14 images yielded an automatic result you can validate the test result manually straight away, or you can adjust the values for any of the images first (either by defining the results directly or by reassigning particles) and then validate the test result. If you adjust any values before validating the result, the **M** or **!** data alarm will be added to the result. You can decide not to validate the test result and to repeat the test. See *Editing microscopy counts and concentrations* (p. 177). See *Rerunning tests* (p. 164). (If fewer than 5 images yielded an automatic result, no test result is displayed and you must first ensure that there are results for at least 5 images (either by defining the results directly or by reassigning particles) before you can validate the test result. The **M** or **!** data alarm will be added to the resulting test 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.

8 Check the **Information** column.

- Whether there is an **Information** column depends on the measurement units you work with, e.g. with **Arbitrary and counts**.
- Values in the **Information** column that are preceded by "~" do not have an upper limit associated with them.

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

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

11 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.

12 To examine the sediment images, choose the **Show images** button.

See *To analyze images* (p. 170) step **4** ff.

13 To validate the result, choose the **Validate** button.

Accepted (validated) results are marked with ✓ in the status column in the result list.

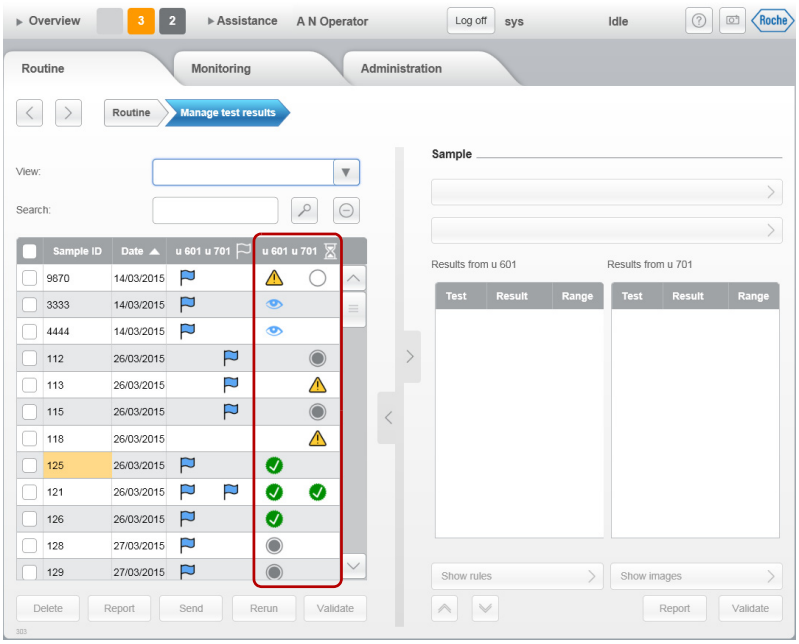


Figure 5-17

14 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.

See *Defining the validation method* (p. 233)

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 .

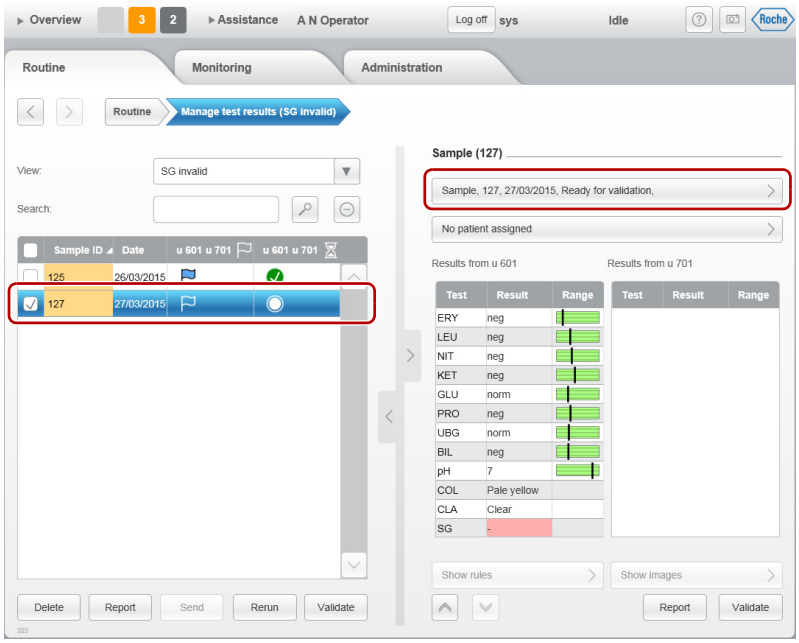


Figure 5-18

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.

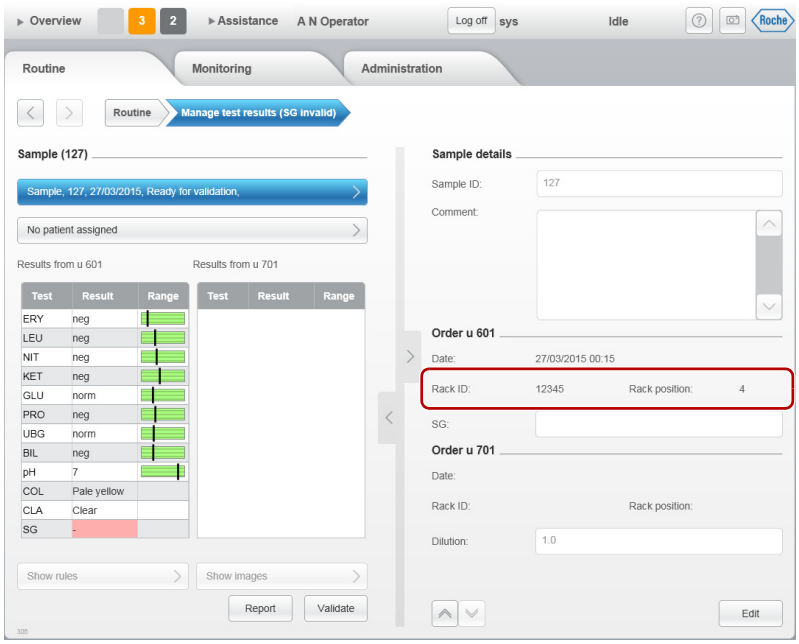


Figure 5-19

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.

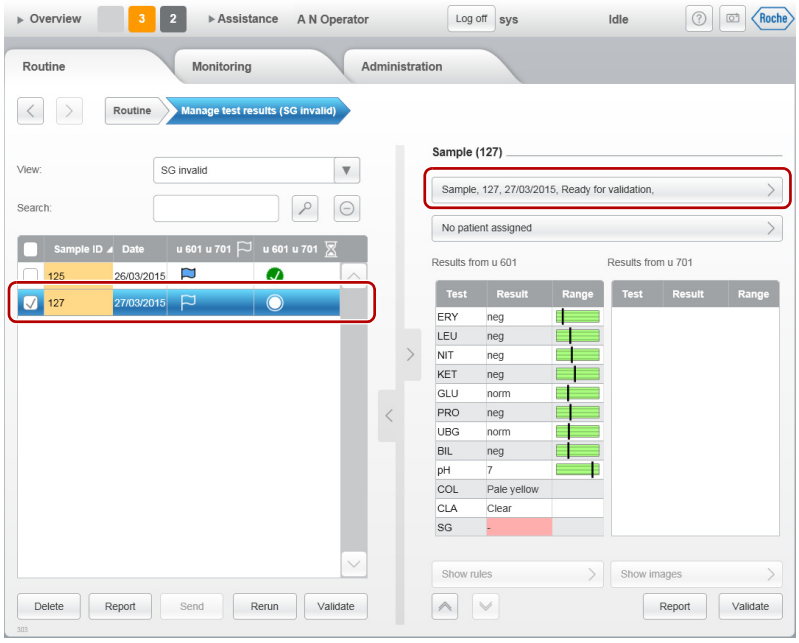


Figure 5-20

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.

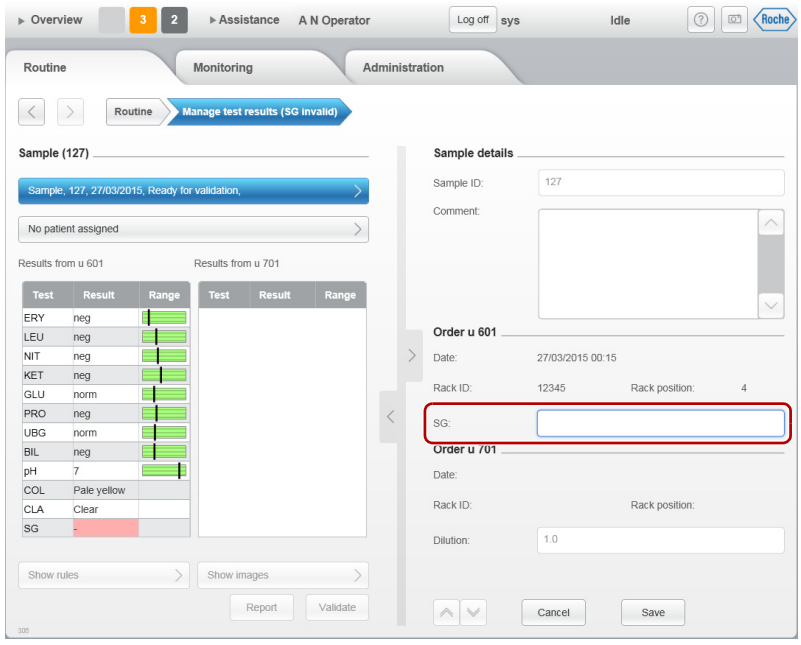


Figure 5-21

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

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.

For details on managing patient demographics, see *Managing patients* (p. 179).

For details on reporting results of a patient, see *Generating reports* (p. 160).

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 save the related images as individual files in a graphics file format and 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 to a CSV file, see *To export all results* (p. 270).

Result report

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

See *To print results (result report)* (p. 161)
See *To save results to files (result report)* (p. 162)

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.

See *To print results (patient report)* (p. 161)
See *To save results to files (patient report)* (p. 162)

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

For information on defining what information of a result is printed and how, see *Defining the look, content, and handling of reports* (p. 253).

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.

   For details on using these functions, see *Filtering information* (p. 115).
3. Choose the **Report** button.

   A callout is displayed.
4. From the **Analyzer** drop-down list, choose the analyzer whose results you want to print.
5. From the **Output mode** drop-down list, choose **Print** to print the results on your default printer.

   (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.)
6. 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.

   For details on using these functions, see *Filtering information* (p. 115).
3. Choose the **Report** button.

   A callout is displayed.
4. From the **Analyzer** drop-down list, choose the analyzer whose results you want to print.
5. Select one of the **Result selection** options.
6. From the **Output mode** drop-down list, choose **Print** to print the results on your default printer.

   (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.)
7. 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.

For details on using these functions, see *Filtering information* (p. 115).

3 Choose the **Report** button.

A callout is displayed.

4 From the **Analyzer** drop-down list, choose the instrument whose results you want to save to a file.

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**.
  or,
- To save each image in a file in a graphics file format, choose **Export images only**. (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.)

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 connected USB storage device or a mapped network path.)

6 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.

For details on using these functions, see *Filtering information* (p. 115).

3 Choose the **Report** button.

A callout is displayed.

4 From the **Analyzer** drop-down list, choose the instrument whose results you want to save to a file.

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

6 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**.
  or,
- To save each image in a file in a graphics file format, choose **Export images only**. (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.)

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 connected USB storage device or a mapped network path.)

7 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.	*To rerun a test* (p. 164)
	Perform maintenance actions as indicated in a message in the message list and then rerun the test.	
	Dilute the sample and rerun the test.	
	Examine the images and reclassify particles or adjust the results.	*Manually analyzing images* (p. 168) *Editing microscopy counts and concentrations* (p. 177)
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* (p. 179)
	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.	*To rerun a test* (p. 164)
	If a questionable result was generated: • Rerun the test using the **Rerun** function.	*To rerun a test* (p. 164)
	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.	*To rerun a test that did not yield a result* (p. 165) *Adjusting sample information* (p. 179) *Supported tube types for allowed rack types* (p. 67)
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.	

Table 5-3 Exceptional processing situations

Rerunning tests

You would typically rerun a test if there is a discrepancy between the test strip analysis and the microscopy analysis results or if no result could be generated, for example because of particle "crowding" and the sample needs to be diluted. You may also 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.)

The procedures differ depending on whether you work with or without sample barcodes.

Rerunning tests when working with sample barcodes (p. 164)

Rerunning tests when working with Sample sequence number mode and without sample barcodes (p. 165)

WARNING

Incorrect results due to cell lysis

Dilution of sample may lead to cell lysis and therefore incorrect results may be obtained.

- Always use appropriate dilution procedures.

Rerunning tests when working with sample barcodes

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

To rerun a test

1. Choose **Routine** > **Manage test results**.
2. From the result list, choose the result.
3. Choose the **Rerun** button.

   A callout is displayed.
4. In the callout, choose the test profile, then choose the **Create order** button.

   The new order is added to the orders list.
5. If dilution or concentration is needed, enter the dilution factor (>1.00: dilution, <1.00: concentration).
6. Prepare the sample, if required. If dilution or concentration is needed, dilute or concentrate the sample.
7. Place the sample tube on a rack exactly as defined in the order and load the rack on the input buffer.

   The sample is processed automatically.

■

To rerun a test that did not yield a result

A message in the message list would have alerted you to the fact that no result was generated. In such a case, the order would still be on the analyzer.

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

2 In the main panel, choose the order.

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

4 Enter the rack ID and tube position.

5 Choose the test profile, if required.

6 If dilution or concentration is needed, enter the dilution factor (≥1.00: dilution, <1.00: concentration).

7 Choose the **Save** button.

8 Prepare the sample, if required. If dilution or concentration is needed, dilute or concentrate the sample.

9 Place the sample tube on a rack exactly as defined in the order and load the rack on the input buffer.

■

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

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.	• 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.

Table 5-4 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
No results were generated	• 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.	
	• 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 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 *original sample ID*. (Not possible 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 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 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.

Table 5-4 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 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 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.

Table 5-4 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.

Table 5-5 Rectifying sample mismatch

Manually analyzing images

Results that fail certain internal checks are automatically excluded from the overall result calculation. You can manually examine individual images, adjust the counts and then include the results in the calculation.

- Only non-validated results can be manually changed.
- You can only reclassify individual particles or change results if the analyzer has been configured to do so. See *To define image handling* (p. 243).
- The same images are taken into account for result calculation, both for a main class and all its subclasses. Therefore, if you classify or reclassify particles of a subclass, do so for all images that are taken into account.

You can adjust counts by doing one of the following:

- Reclassifying individual particles
  See *To assign or reclassify particles* (p. 171)
- Changing the count values of particles
  See *To reclassify particles using the count table* (p. 173)
- Identifying and assigning particles
  See *To assign or reclassify particles* (p. 171)
- Editing the counts
  See *To adjust the total count or the concentration for a particle* (p. 177)
- Editing the concentrations
  See *To adjust the total count or the concentration for a particle* (p. 177)

If particles were classified or reclassified manually in an image, the corresponding parameter entries are marked with **M** in the ⚑ column of the result list.

If concentrations and counts were adjusted manually, the corresponding parameter entries are marked with **!** in the ⚑ column of the result list.

Result adjustments for consistency with standard manual microscopy result presentation

The counts generated by the microscopy analyzer do not correspond with those that would result from standard manual microscopy (p/HPF).

The differences relate to the examined sample volumes, the methods of particle recognition, and the units the results are reported in.

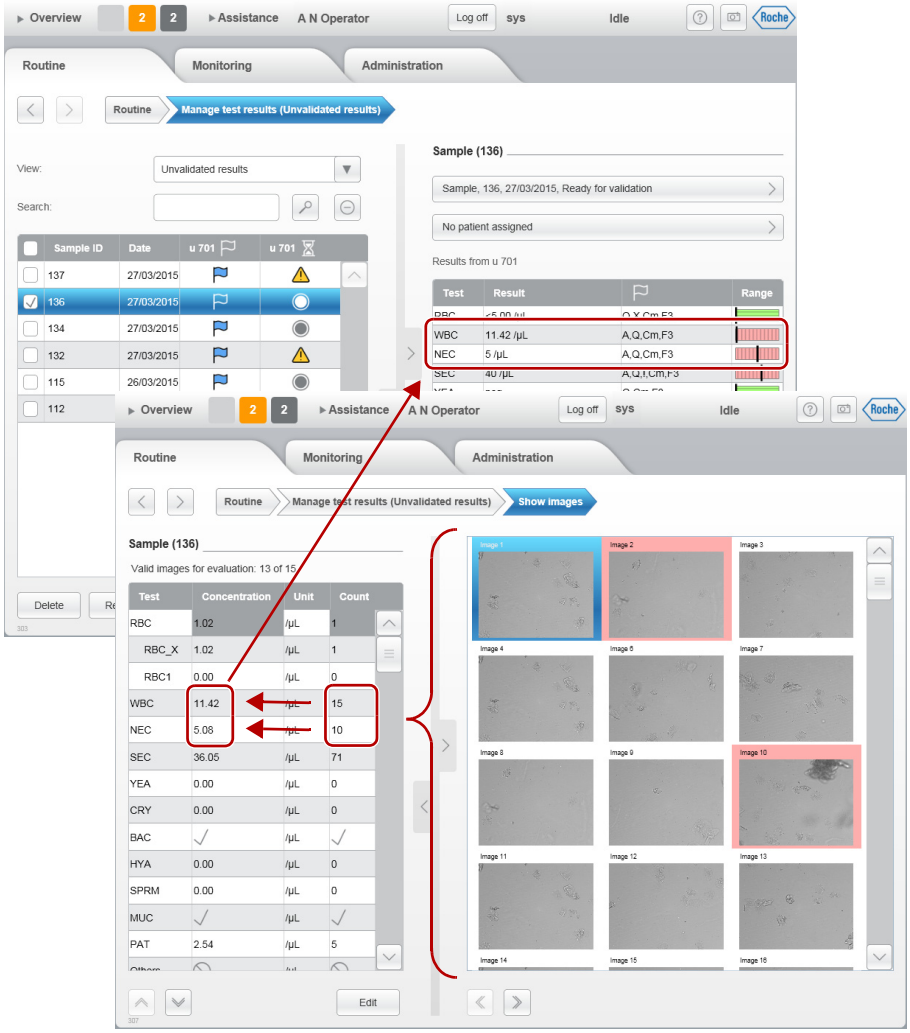


Figure 5-22 Counts and concentrations

The analyzer recalculates the total count when you reclassify particles of one or several images. If you do not adjust the counts for all images that are taken into account, the result may be lower than expected.

To analyze images

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

2 In the result list, choose the result that you want to examine.

The result details are displayed in the detail panel.

3 In the detail panel, choose the **Show images** button.

The image gallery is displayed.

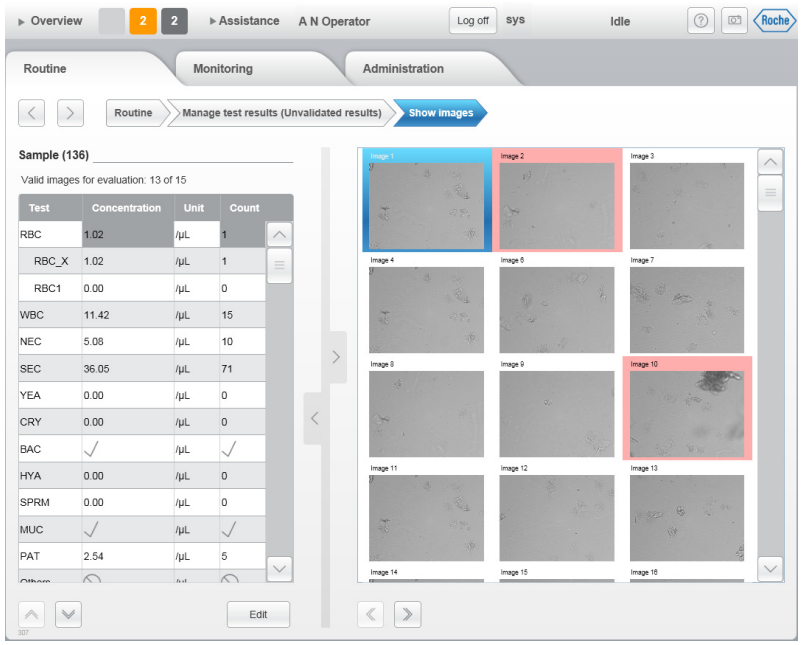
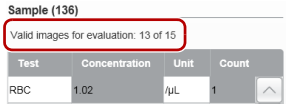


Figure 5-23

	Blue	This image is selected.
	Yellow	This image has been reclassified.
	Red	This image did not yield a reliable result, it is excluded from the result calculation. Manual examination is recommended. See also the indication at the top of the tests list. 

On this screen, you can edit the total count or the concentration of the particles.

See *To adjust the total count or the concentration for a particle* (p. 177)

4 Choose an image.

The image is displayed.

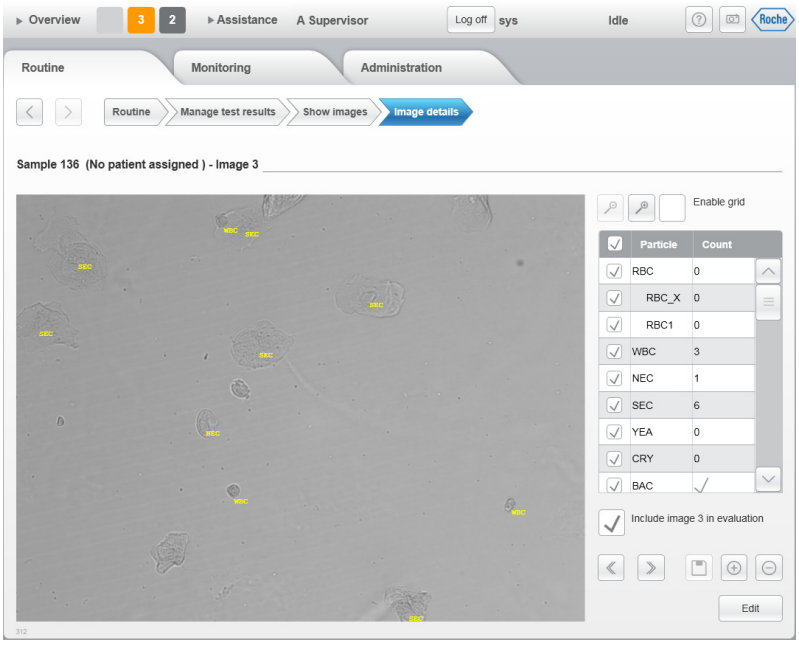


Figure 5-24

5 Enlarge the image if required.

See *Using the zoom function* (p. 113).

6 Classify or reclassify the particles, if required.

You can either reclassify individual particles in the image or correct the count in the count table.

See *To assign or reclassify particles* (p. 171).
See *To reclassify particles using the count table* (p. 173).
See *To remove the classification from particles* (p. 173)

7 Check that the **Include image in evaluation** check box is selected.

If you cannot satisfactorily analyze the image manually, exclude the image from the result calculation by clearing the **Include image in evaluation** check box.

- Excluding the image this way does not change the definitions made in the particle table.
- Enabling and disabling main classes enables and disables their subclasses as well.

■

To assign or reclassify particles

1 In the count table, choose the particle that you want to assign.

2 Choose the ⊕ button, if required.

3 Enlarge the image if required.

See *Using the zoom function* (p. 113).

4 In the image, select the particles of the selected type that need assigning or changing.

To change a labeled particle to the current one, simply select it.

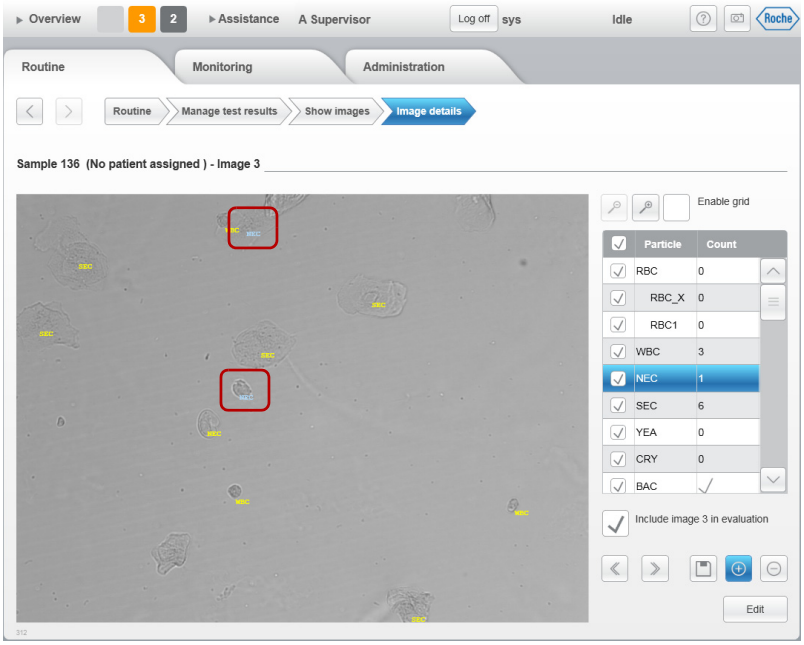


Figure 5-25

The appropriate blue particle label is added to each particle as soon as you select it.

The counts in the table are not yet updated.

5 To save the classifications, choose the ▣ button.

Figure 5-26

This action may take a few seconds.

The affected entries in the table are marked yellow; the old values are given in brackets.

■

To reclassify particles using the count table

1 Choose the **Edit** button.

2 In the table, choose the particle whose count you want to change and then choose its count number.

The virtual keyboard is displayed.

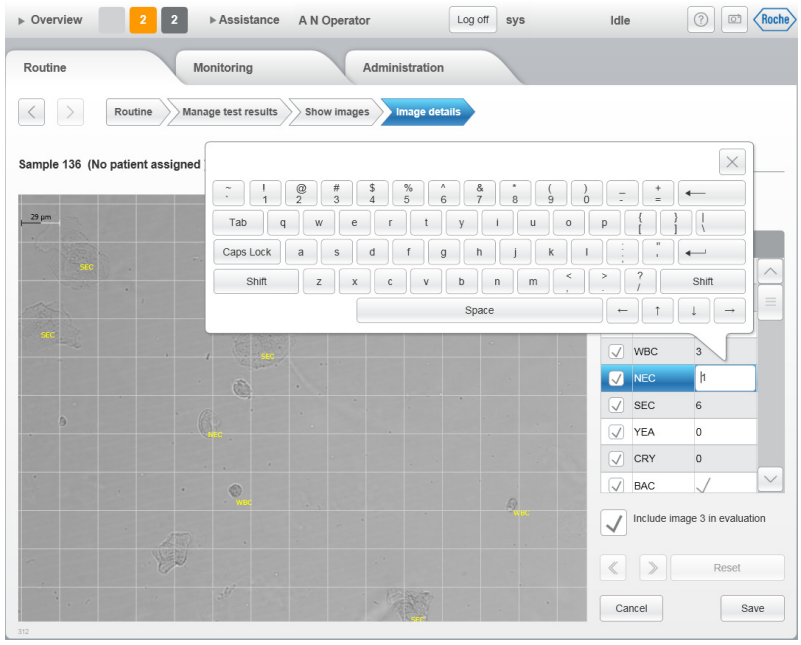


Figure 5-27

3 Enter the correct number.

4 If you want to undo all the changes you have made so far, choose the **Reset** button.

5 Choose the **Save** button.

The affected entry in the table is marked yellow; the old value is given in brackets.

■

To remove the classification from particles

1 Choose the ⊖ button, if required.

2 Enlarge the image if required.

See *Using the zoom function* (p. 113).

3 In the image, select all particles whose classification you do not want to remove.

The label is removed from each particle as soon as you select it.

The counts in the table are not yet updated.

4 To save the assignments, choose the button.

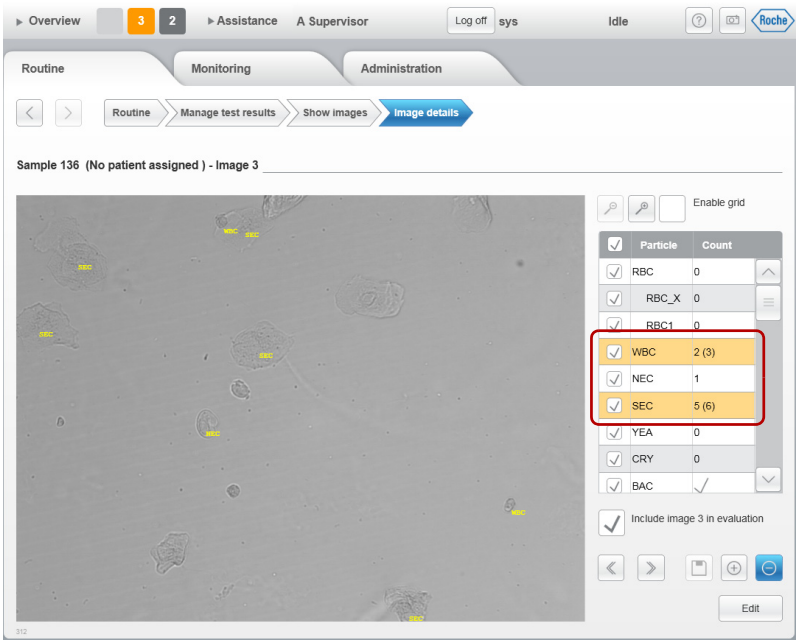


Figure 5-28

This action may take a few seconds.

The affected entries in the table are marked yellow; the old values are given in brackets.

■

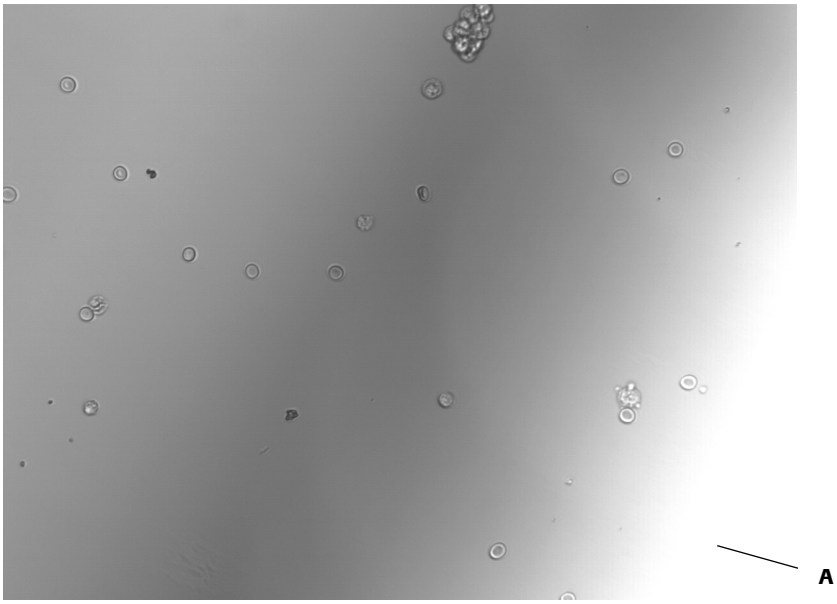
Questionable images

Small drops of liquid on the cuvette or air bubbles inside can make it difficult to identify particles.

If the analyzer generated a result, the liquid drops or air bubbles did not interfere with the measurement to such a degree that a valid result could not be generated.

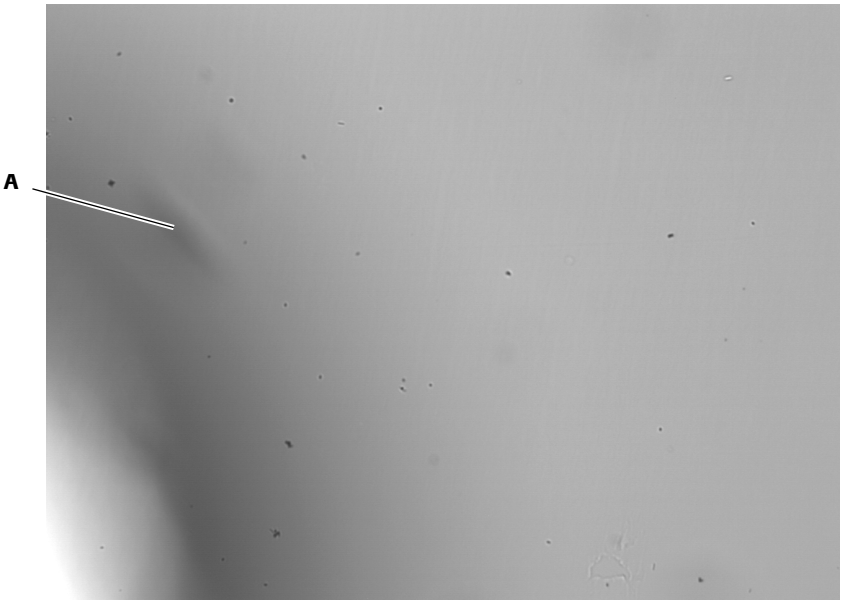
For information on technically unreliable images, see the information on the **U** data alarms in step **7** p. 154.

The following illustrations show some typical examples of images that would trigger a **U** data alarm.



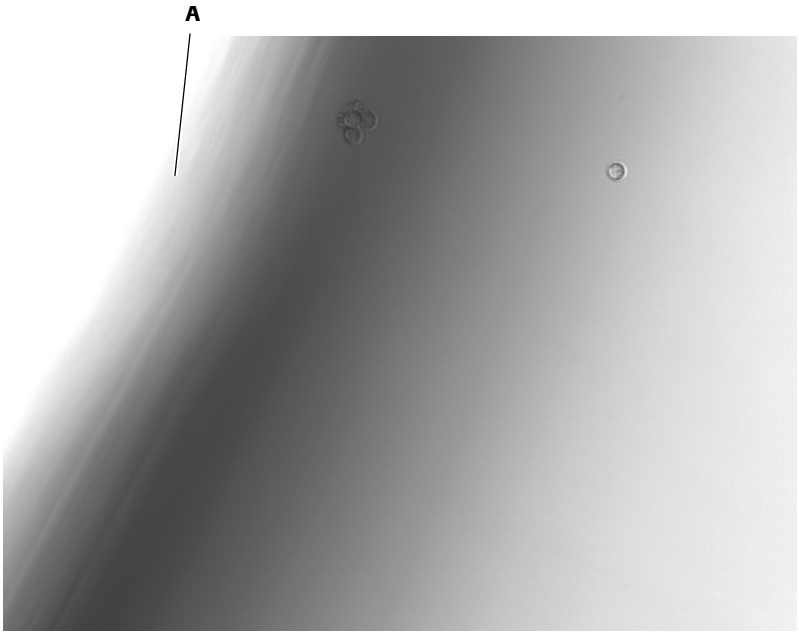
A In this light area, particles cannot be identified.

Figure 5-29 Example of liquid drop



A The drop caused focusing problems, the particles do not have sharp contours.

Figure 5-30 Example of liquid drop



A Edge of the air bubble

Figure 5-31 Example of an air bubble

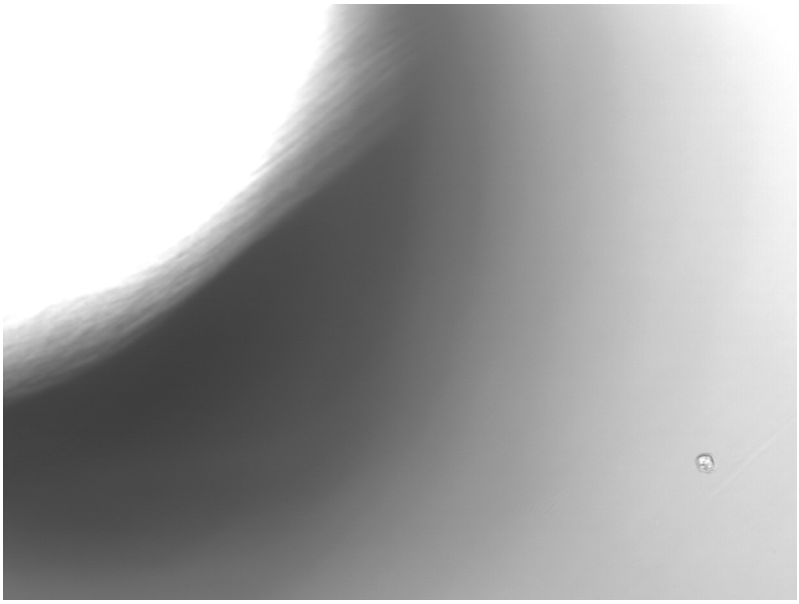


Figure 5-32 Example of an air bubble

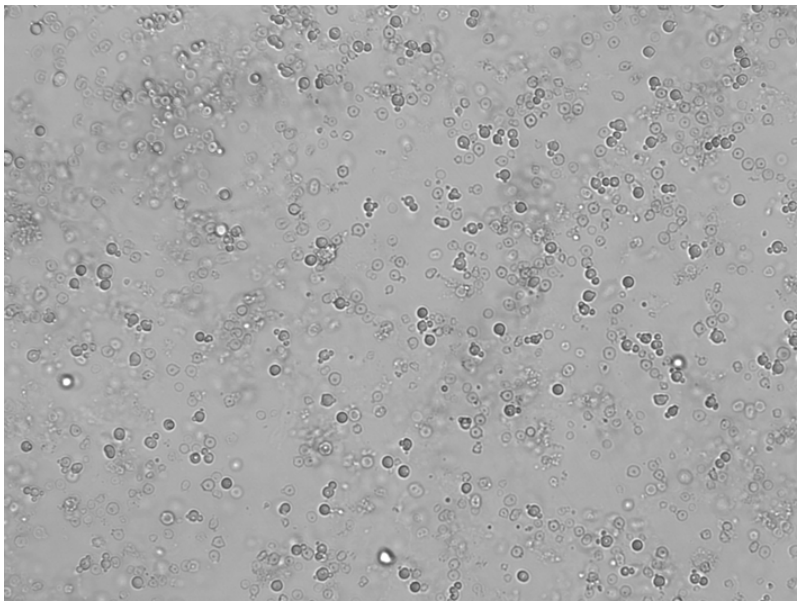


Figure 5-33 Example of a crowded image

Editing microscopy counts and concentrations

Instead of reclassifying particles for individual images, you can adjust the total count or the concentration for a particle.

- You can change counts and concentrations as long as the results have not been validated yet.
- You can change either the count or the concentration of a parameter.

▶ To adjust the total count or the concentration for a particle

- The count is the sum of all particles in all images that rendered a valid result.
- If you change the total count, the result is recalculated.
- At least five images must be reliable, otherwise no concentration or count is displayed.
- Results that are based on a changed total count or concentration are marked with **!**.
- If subclasses are available, the count and concentration of the main class cannot be changed.

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

2 In the result list, choose the result that you want to examine.

The result details are displayed in the detail panel.

3 In the detail panel, choose the **Show images** button.

The image gallery is displayed.

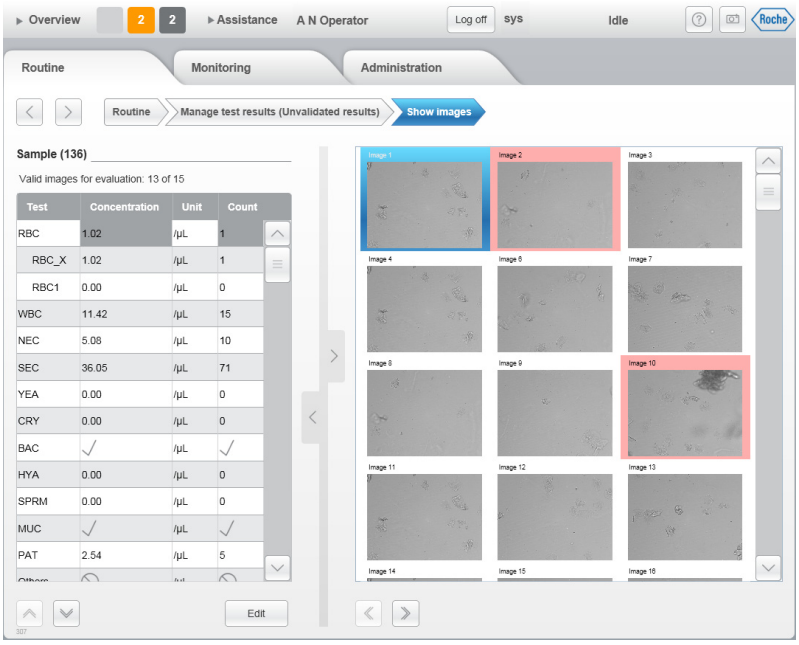


Figure 5-34

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

The **Save** and **Reset** buttons become available.

5 In the main panel, choose the appropriate field.

- To change a count, choose the **Count** field for the particle whose data you want to change.
  or,
- To change a concentration, choose the **Concentration** field for the particle whose data you want to change.

The keyboard is displayed.

6 Enter the correct value.

7 Choose the **Save** button.

If you changed the count, the concentration is recalculated.

If you changed the concentration, the count is *not* recalculated.

The field where you made the changes is colored yellow .

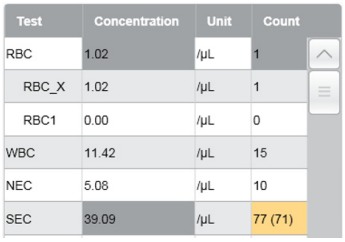


Figure 5-35

If you changed the **Count** you cannot change the **Concentration** later, and if you changed the **Concentration** you cannot later change the **Count**.

■

Adjusting sample information

You typically 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.

See also *Assigning patients* (p. 160).

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

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.

  See *Cleaning solutions* (p. 95)

- 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* (p. 181)
- *Washing the fluid system* (p. 185)
- *Air purge* (p. 186)
- *Filling the water container* (p. 187)
- *Emptying the liquid waste container* (p. 187)
- *Emptying the solid waste container* (p. 188)
- *Replacing the test strip cassette* (p. 189)
- *Replacing the cuvette cassette* (p. 190)

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.

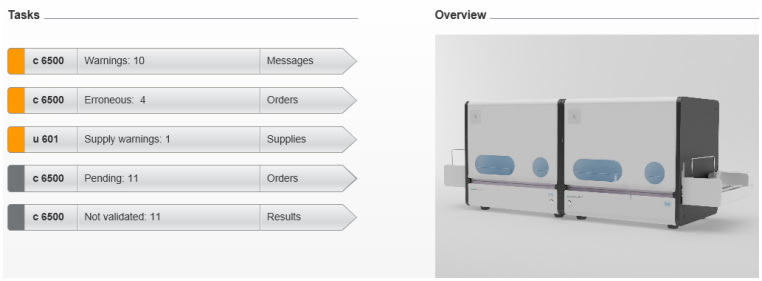


Figure 5-36 Task list in the **Overview** work area

To check the status of order processing

1 See *To check the status of order processing* (p. 147).

■

To check for tasks that need doing

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

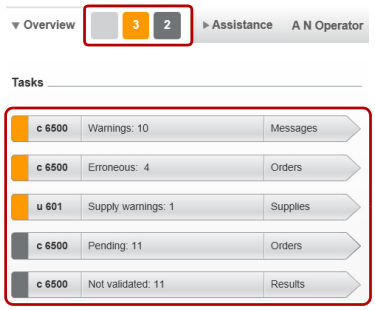


Figure 5-37

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).

Figure 5-38

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.
  or,
- In the supplies list, choose a task with a status *other than* **OK**. See *To check the status of supplies* (p. 184).
  or,
- In the orders list, make the necessary adjustments. See *To define an order manually when working with Sample sequence number mode* (p. 139).
  or,
- In the result list, check for unusual results. See *To view test results* (p. 150).

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

■

To check the current hardware status

1 In the **Overview** work area, choose the analyzer in the **Overview** illustration.

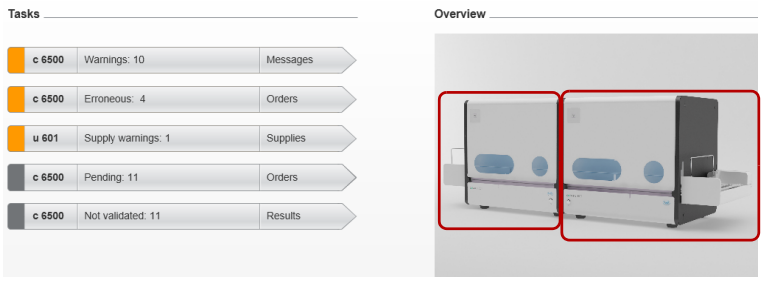


Figure 5-39

A schematic representation of key hardware elements is displayed.

The color of the elements represents the severity of the underlying issues.

Color	Interpretation
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.

Table 5-6 Color coding for hardware elements

2 In the analyzer overview, choose a colored element.

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.

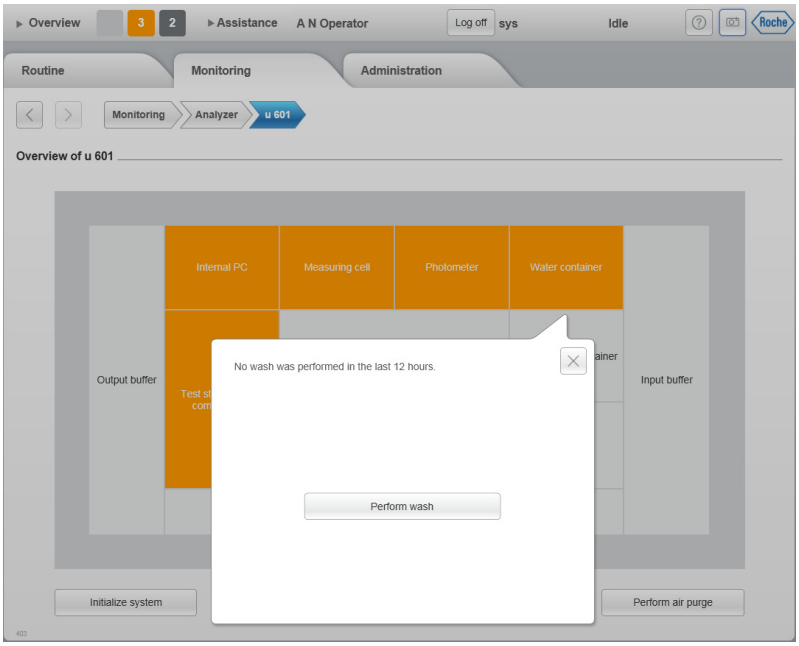


Figure 5-40

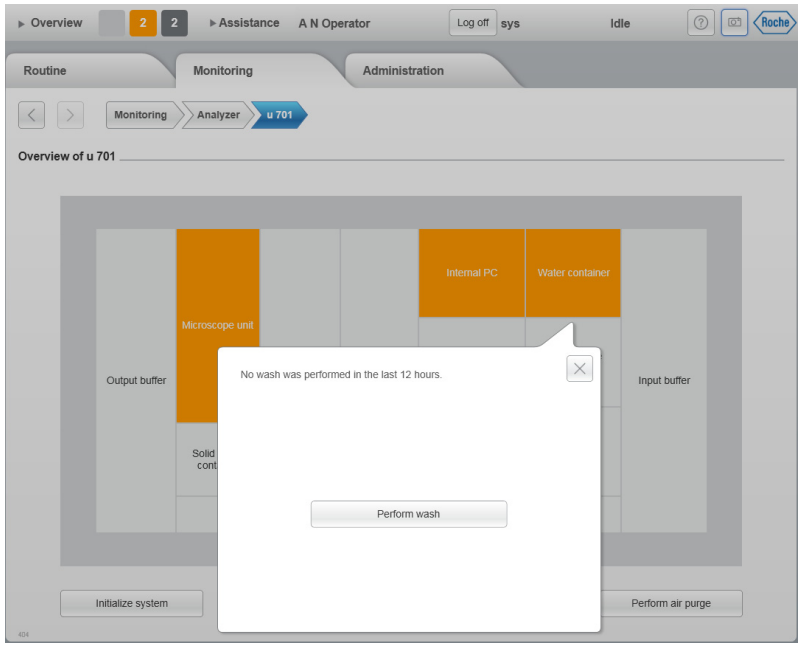


Figure 5-41

3 Address the issues as described on screen.

■

To check the status of supplies

1 Choose **Monitoring** > **Manage supplies**.

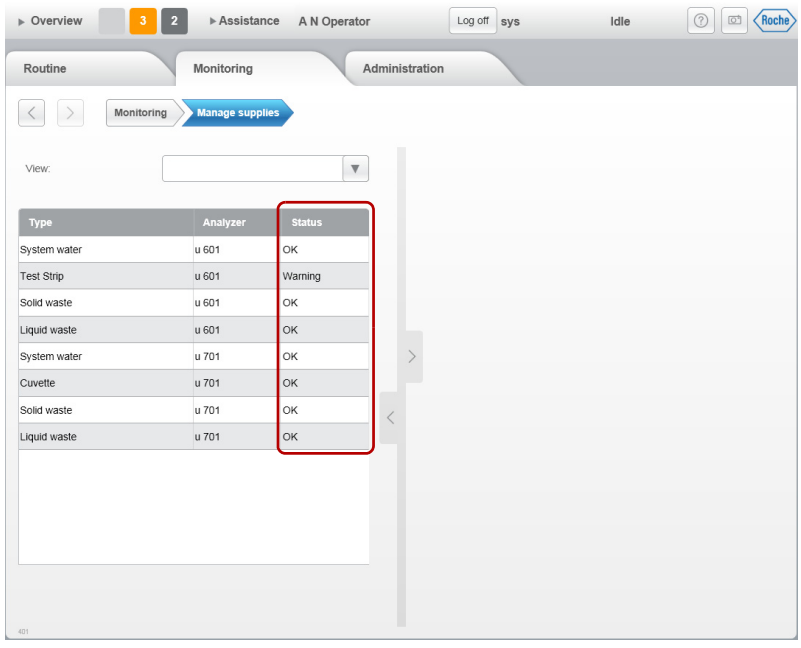


Figure 5-42

In the **Status** column, the status is indicated:

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.

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. (See *Shutting down the analyzer* (p. 191))
- 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.

Preconditions

- A wash rack is defined
  See *To define a wash rack* (p. 258).
- Wash solution is available.
  See *Wash solution* (p. 95).

▶ To wash the fluid system

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.

1 Prepare the wash rack.

Fill a tube with about 10 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 10 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 *Basic configuration 1* (p. 249).

To perform air purge

Air purge is normally performed automatically, without operator intervention.

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.
  or,
- Choose **Monitoring** > **Analyzer** > **u 601** or **u 701**, then choose the **Perform air purge** button.

The 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.

There are separate water containers for both the test strip and the microscopy analyzers.

Roche recommends emptying the corresponding liquid waste container whenever you refill a water container. See *Emptying the liquid waste container* (p. 187).

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 quality defined in *Water quality* (p. 95).

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 quality defined in *Water quality* (p. 95).

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.
  or,
- 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.

There are separate liquid waste containers for both the test strip and the microscopy analyzers.

▶ 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.
  or,
- 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.

CAUTION

Incorrect results due inappropriate removal of the solid waste container

If you remove the solid waste container while the analyzer performs tests, it is possible that a pipetted cuvette remains on the microscope stage. During this time sample evaporation takes place, which could lead to incorrect results when the cuvette is eventually measured.

▶ Do not remove the solid waste container while the analyzer performs tests.

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 or cuvettes 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 or cuvettes 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.
  or,
- 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. See *Emptying the solid waste container* (p. 188).

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.
  or,
- 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.

■

Replacing the cuvette cassette

When the number of cuvettes 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 cuvette cassette. When there is no cuvette left in the cassette no further pipetting takes place and a further message is added to the message list.

Cuvette cassettes are equipped with RFID tags, which contain the following information:

- Lot number
- Expiry date
- Number of cuvettes left

Roche recommends emptying the solid waste container whenever you replace a cuvette cassette. See *Emptying the solid waste container* (p. 188).

To change the cuvette cassette

1 Start the **Exchange cuvette cassette** wizard.

- In the message list, choose the message that indicates that the cuvette cassette needs replacing, then choose the **Exchange cuvette cassette** button in the detail panel.
  or,
- Choose **Monitoring** > **Manage supplies** > **Cuvette**, then choose the **Exchange cuvette 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.

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. (See *Basic configuration 2* (p. 250))

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.

To shut down the analyzer

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.

1 Ensure that the analyzer status in the global information area is **Idle**.

Figure 5-43

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.

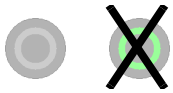
- Prepare the wash rack.
- Load the wash rack on the input buffer.
- On the callout, choose the **Confirm** button.

The wash action starts.

When the wash action is complete, the software is shut down and both analyzers are switched off.

4 If you want to perform the wash later, choose the **No** button.

The software is shut down and both analyzers are switched off.



5 Wait until the on/off switches on both analyzers are off before you start any new action.

■

To put the analyzer into standby

This function sets the analyzer in a state of minimal power consumption.

1 Choose **Overview** > **Stand by**.

The screen goes black.

You can re-activate the analyzer by touching the screen anywhere.

■

To switch 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.

1 Shut down the analyzers.

See *To shut down the analyzer* (p. 192).

2 Put the power switches at the back of the analyzers in the off position ◯ .

Figure 5-44

■

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.

  See *Cleaning solutions* (p. 95)
- 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
  - See *To clean the input and output buffers* (p. 194).
- Rack conveyors
  - See *To clean the rack conveyors* (p. 194).
- Test strip tray and transporter
  - See *To clean the test strip tray and transporter* (p. 195).
- Probe bend detectors
  - See *To clean the probe bend detector* (p. 196).
- Pipetting stage area
  - See *To clean the pipetting stage area* (p. 198).

- Centrifuge chamber
  See *To clean the centrifuge chamber* (p. 201).
- Microscope stage area
  See *To clean the microscope stage area* (p. 204).
- Analyzer housing
  See *To clean the analyzer housing and the input and output buffers* (p. 204).

Materials required
- Paper towel
- Lint-free cotton swabs
- Cleaning solution
  See *Cleaning solutions* (p. 95).

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.

■

To clean the rack conveyors

1 Wipe the rack conveyors near the input and output buffers using a paper towel moistened with cleaning solution.

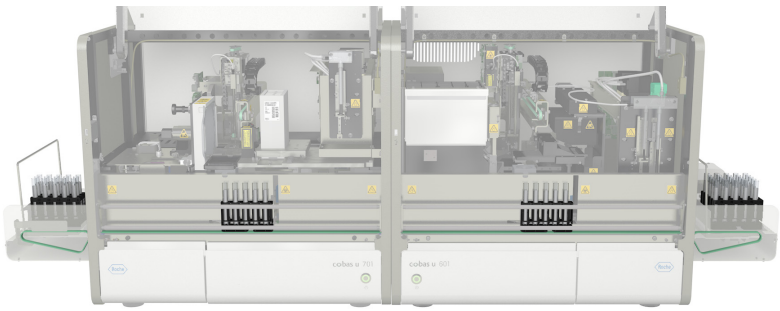


Figure 5-45

2 Fold down the rack transport rails. Hold the rail at both ends and pull it out firmly.

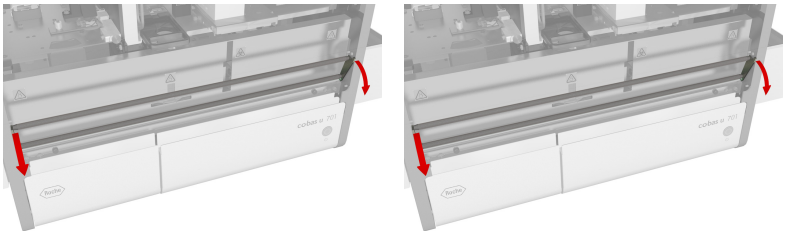


Figure 5-46

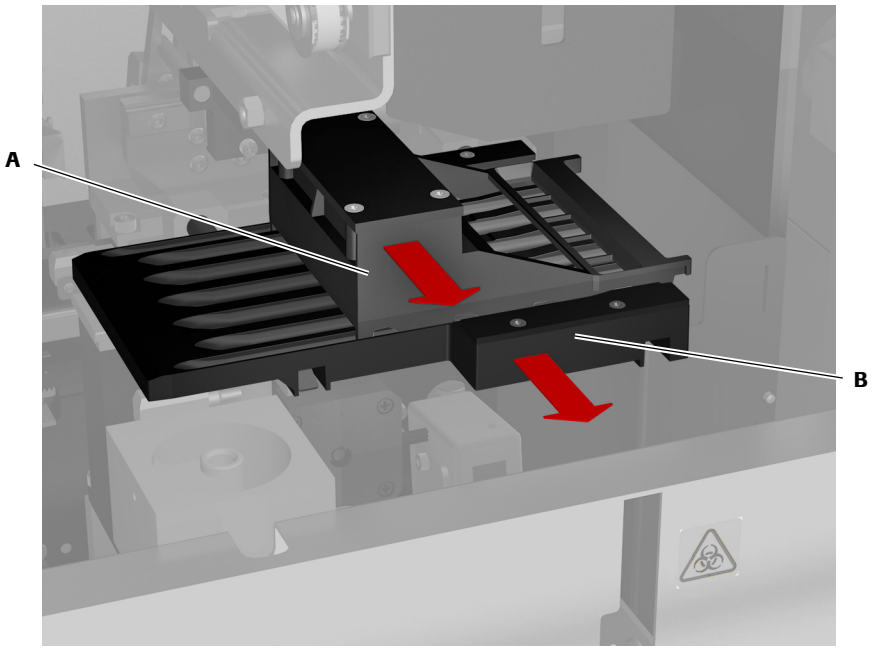
3 Wipe the rack conveyors using a paper towel moistened with cleaning solution.

4 Fold up the rack transport rails. Hold the rails at both ends and push them in firmly.

■

To clean the test strip tray and transporter

1 Pull out the test strip transporter (A).



A Test strip transporter **B** Test strip tray

Figure 5-47

2 Pull out the test strip tray (B).

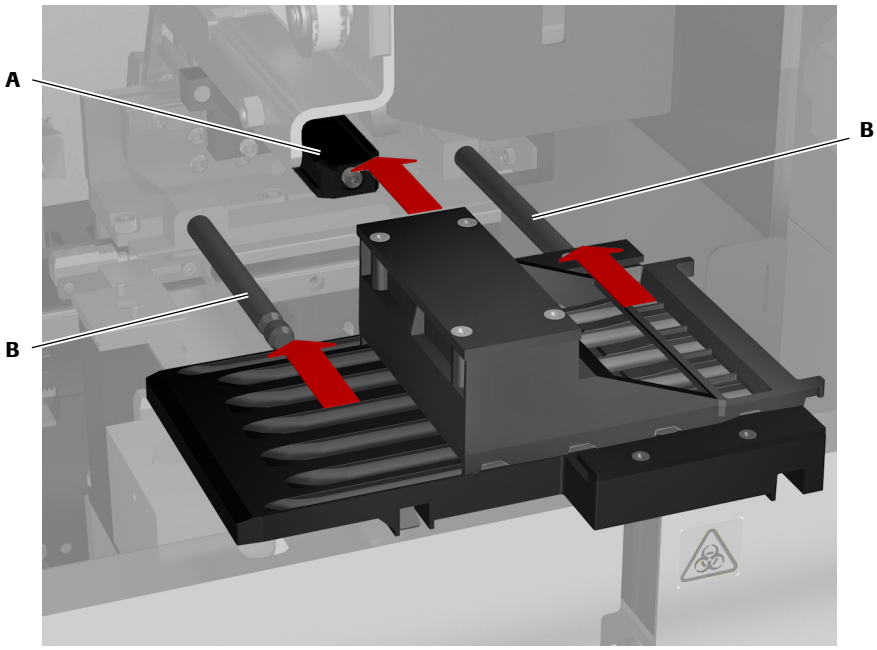
3 Wipe the test strip transporter and the test strip tray using a paper trowel moistened with a recommended cleaning solution.

To give the parts a thorough clean you can wash them using a commercial household detergent.

4 Dry the test strip transporter and the test strip tray using a dry paper towel.

Leave the parts to dry completely.

5 Insert the test strip tray in the two support pins (B) and push it firmly in.



A Support bar for the test strip transporter **B** Support pins for the test strip tray

Figure 5-48

6 Insert the test strip transporter in its support bar (A) and push it firmly in.

■

To clean the probe bend detector

1 Wipe the top and the inside of the probe bend detector using a cotton swab moistened with ethanol.

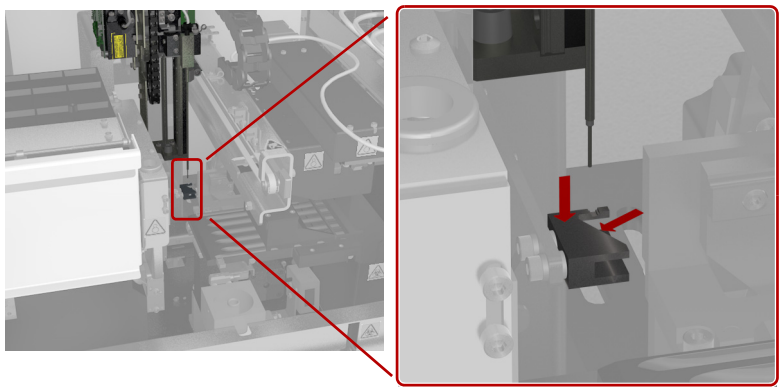


Figure 5-49 Probe bend detector of the test strip analyzer

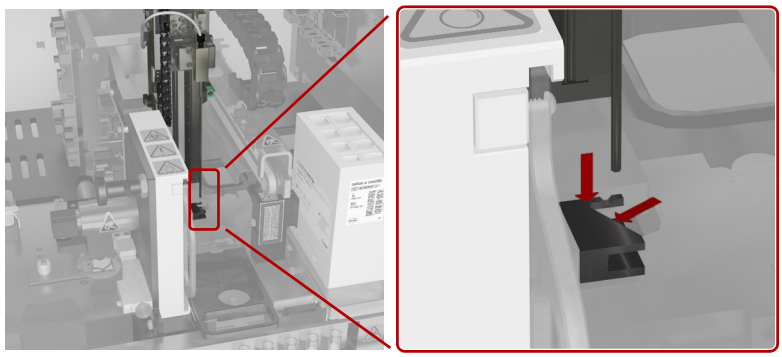


Figure 5-50 Probe bend detector of the microscopy analyzer

2 Wipe the top and the inside of the probe bend detector with a dry cotton swab to remove all residual cleaning solution.

■

To clean the test strip pipetting area

1 Wipe the test strip pipetting area using a paper towel moistened with ethanol.

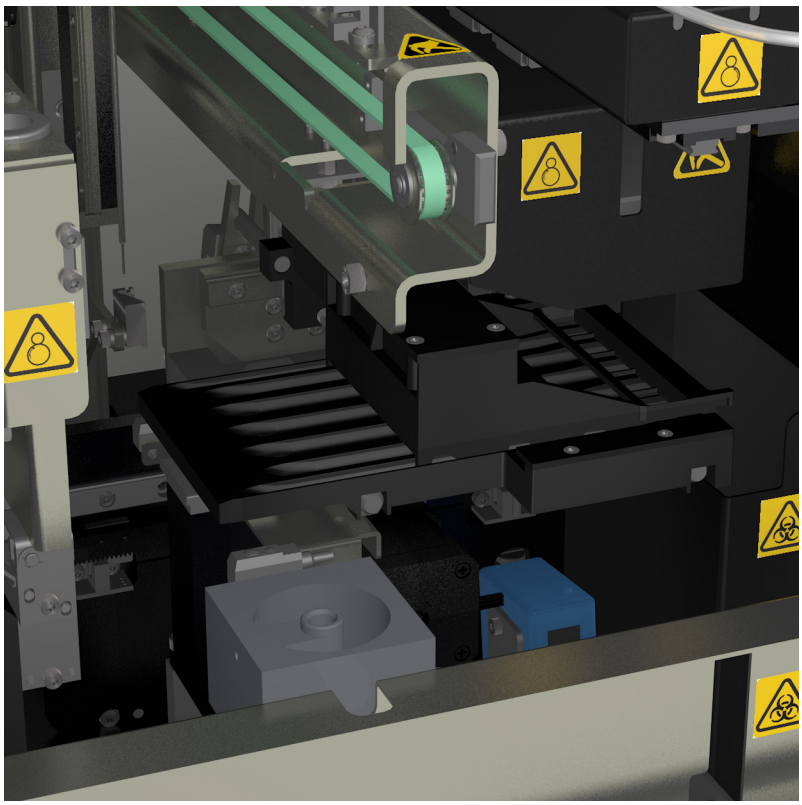


Figure 5-51

2 Wipe the test strip pipetting area with a dry paper towel to remove all residual cleaning solution

■

To clean the pipetting stage area

1 Remove the pipetting stage and wipe it using a paper towel moistened with ethanol. Then dry it with a dry paper towel.

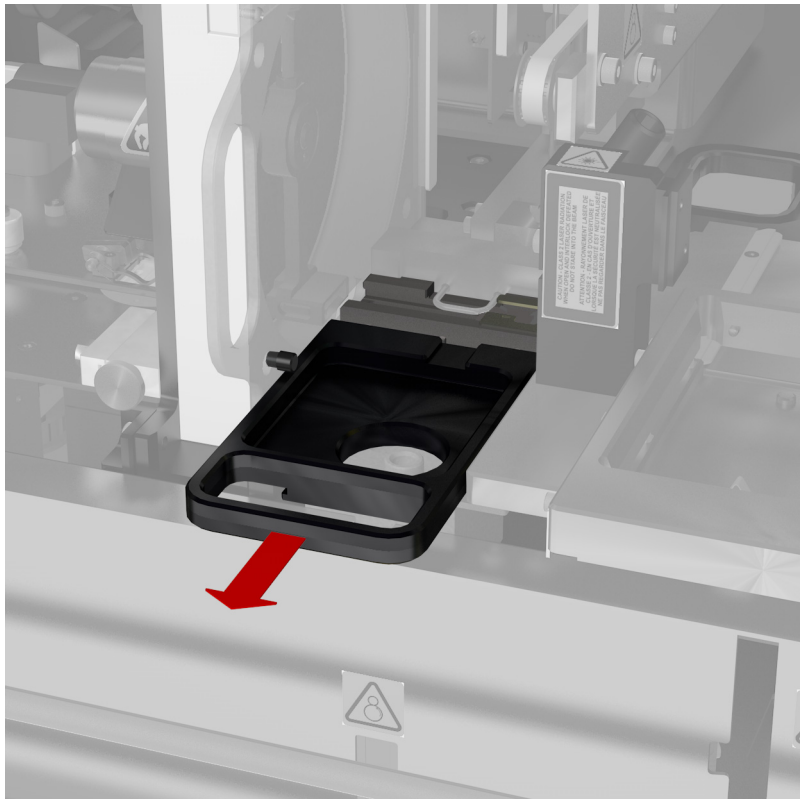


Figure 5-52

2 Wipe the pipetting stage area using a paper towel moistened with ethanol.

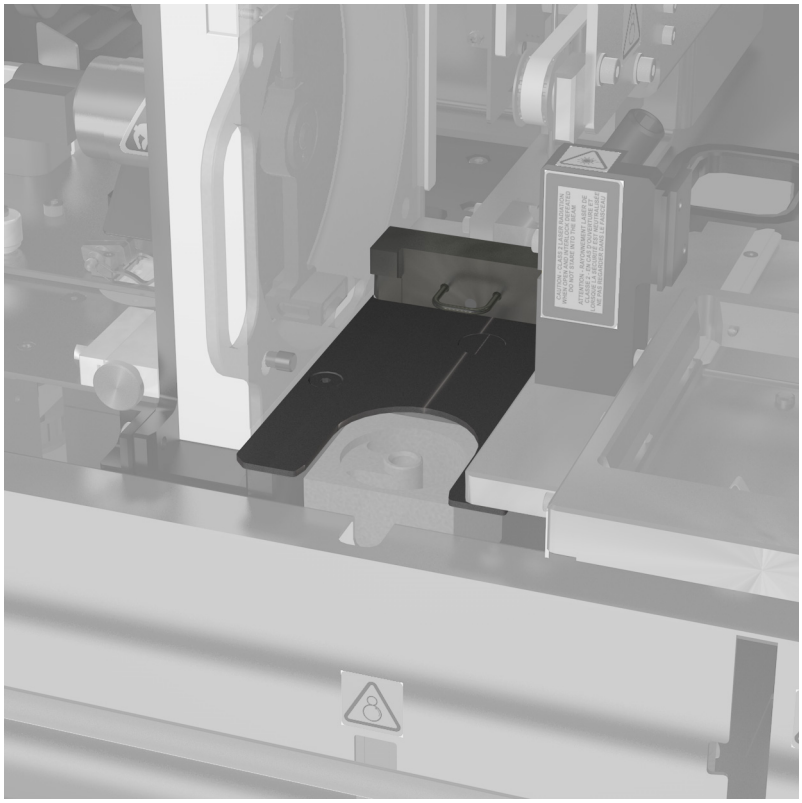


Figure 5-53

3 Wipe the pipetting stage area with a dry paper towel to remove all residual cleaning solution.

4 Insert the pipetting stage. Be sure to insert it below the guide post on the left.

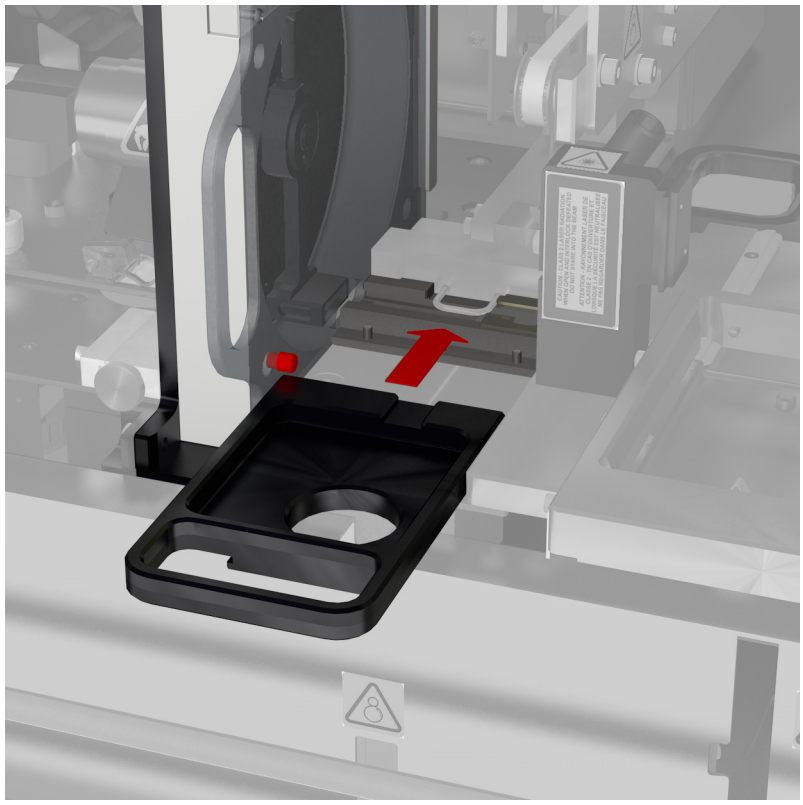


Figure 5-54

■

To clean the centrifuge chamber

CAUTION

Personal injury or damage to the analyzer due to contact with moving parts

- Do not perform any operation or maintenance action while the centrifuge is in action.

1 Disengage the safety pin and at the same time pull out the centrifuge cover.

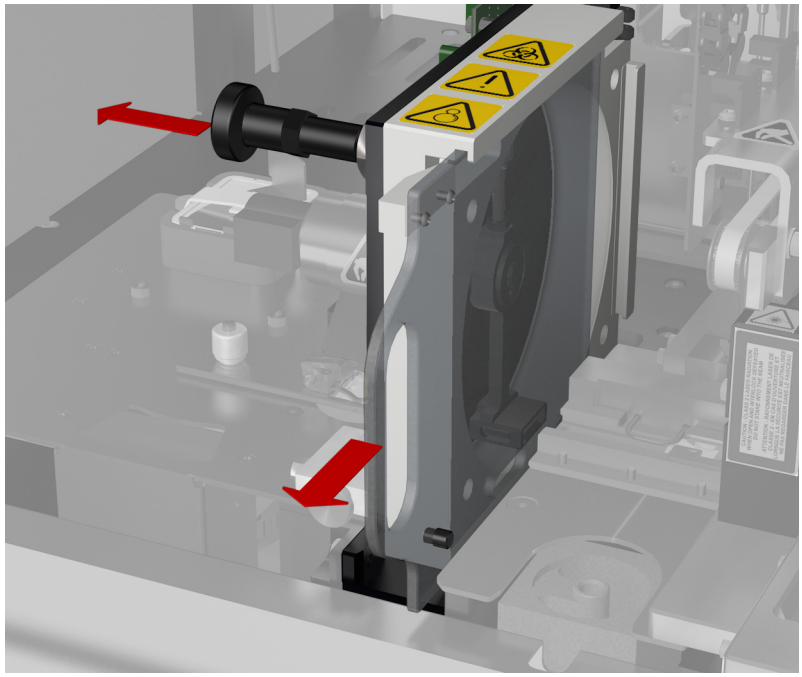


Figure 5-55

2 Turn the centrifuge arm to the horizontal position and remove it. Hold it in the center and lift it off.

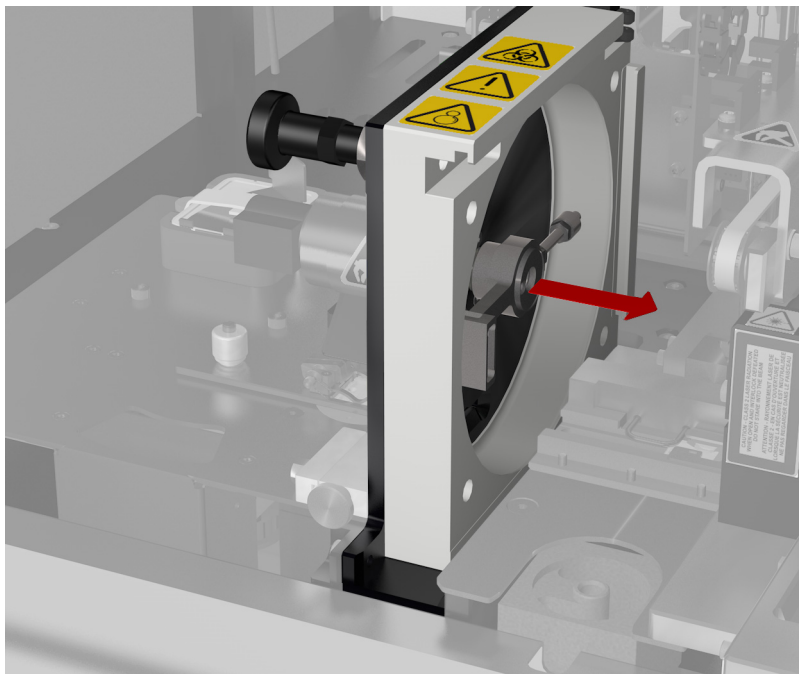


Figure 5-56

3 Wipe the centrifuge cover and the inside of the centrifuge chamber using a paper towel moistened with cleaning solution.

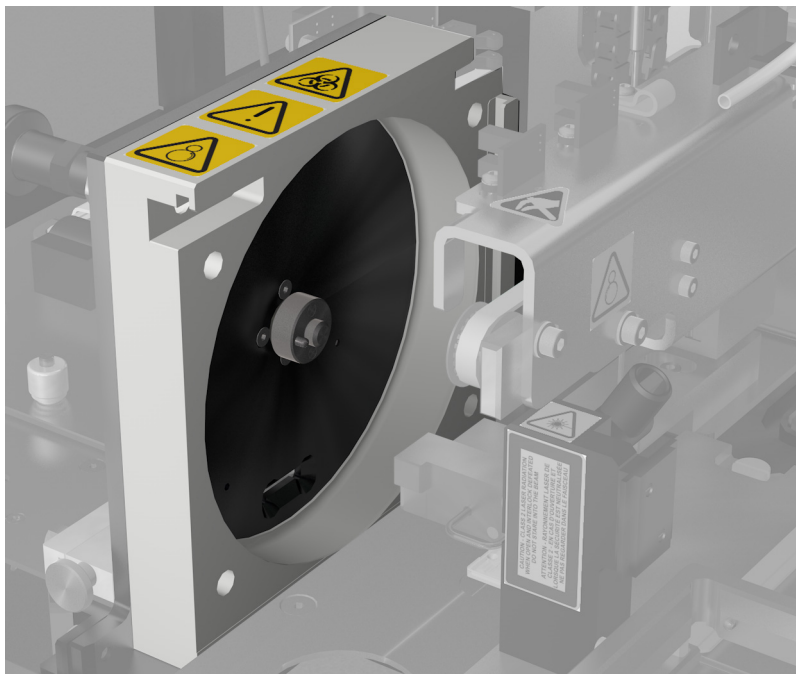


Figure 5-57

4 Wipe the centrifuge cover and the inside of the centrifuge chamber with a dry paper towel to remove all residual cleaning solution.

5 Clean the centrifuge arm with cleaning solution.

6 Wipe the centrifuge arm with a dry paper towel to remove all residual cleaning solution.

7 Insert the centrifuge arm.

- Hold the centrifuge arm in the center.
- Make sure the cuvette holder faces away from the centrifuge chamber.
- Align the holes in the arm with the two pins in the centrifuge chamber.

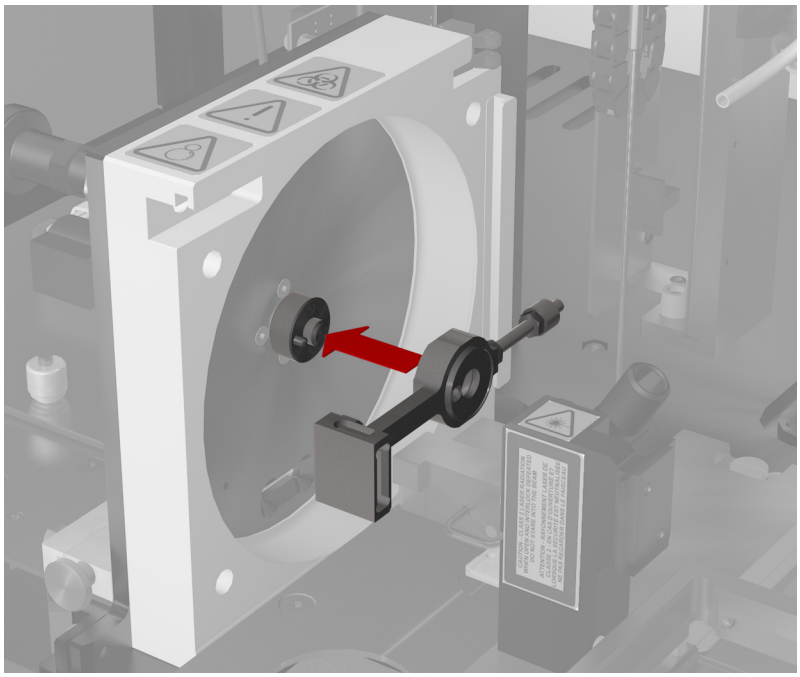


Figure 5-58

- Push in the arm firmly until the pins protrude through the holes in the arm.

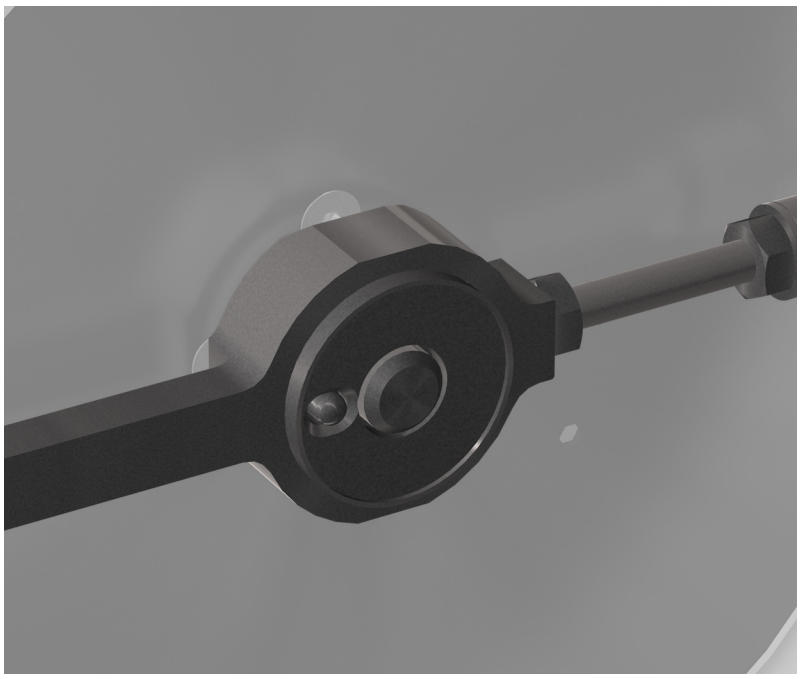


Figure 5-59

8 Insert the centrifuge cover, push it in firmly.

■

To clean the microscope stage area

1 Pull out the cuvette rail (A).

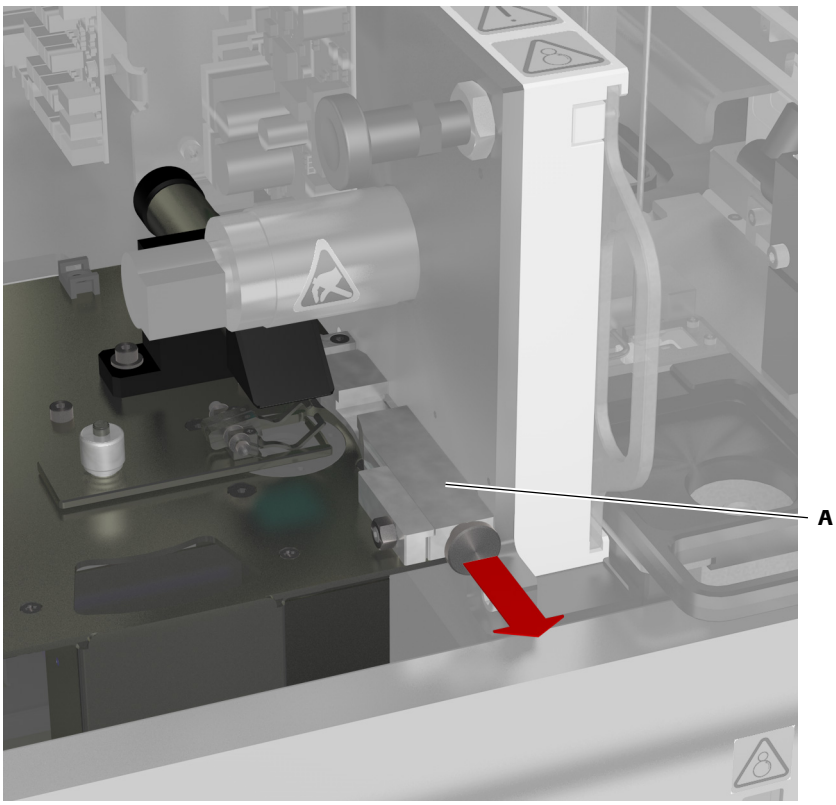


Figure 5-60

2 Wipe the cuvette rail using a paper towel moistened with ethanol, then dry it with a clean paper towel.

3 Wipe the cuvette rail with a dry paper towel to remove all residual cleaning solution.

4 Wipe the microscope stage area using a cotton swab moistened with ethanol, then dry it with a clean cotton swab.

5 Wipe the microscope stage area with a dry paper towel to remove all residual cleaning solution.

6 Re-insert the cuvette rail.

Push it in firmly.

■

To clean the analyzer housing and the input and output buffers

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.

2 Wipe the input buffer using a paper towel moistened with cleaning solution, then dry it with a clean paper towel.

3 Wipe the output buffer using a paper towel moistened with cleaning solution, then dry it with a clean paper towel.

4 Wipe the analyzer housing using a paper towel moistened with cleaning solution, then dry it with a clean paper towel.

■

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.

See For information on how to proceed if calibration is still not successful, see *No photometer calibration can be generated* (p. 283).

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.
  or,
- 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.

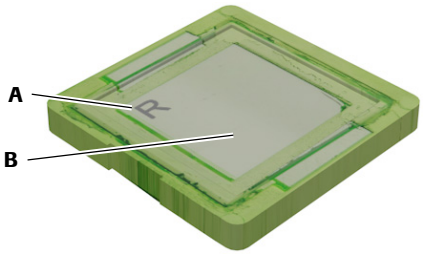
- In the message list, choose the message that indicates that the calibration is due, then choose the **Calibrate measuring cell** button in the detail panel.
  or,
- Choose **Monitoring** > **Manage calibrations** > **Calibrate measuring cell**, then choose the **Calibrate measuring cell** button in the main panel.

The calibration is performed.

■

Checking the microscope focusing mechanism

In order to ensure proper functioning of the focusing mechanism of the microscope, a microscope check needs to be performed every 4 weeks. This is done by performing a predefined sequence of photographic measurements of a reference cuvette. This cuvette contains a transparent material with erythrocyte like particles etched in it. The system must be able to recognize these and count them correctly.



A The reference cuvette is marked with R **B** Measurement area

Figure 5-61 Reference cuvette

A message in the message list informs you when microscope check is due. Results that are generated with microscope check results that are no longer valid are marked with **Cm** in the ⚐ column.

CAUTION

Incorrect results due to soiling of measurement area

Soiling of the measurement area of the reference cuvette may adversely affect the measurements.

- Do not touch the measurement area of the reference cuvette.
- If the cuvette is soiled, you can clean it using a soft lint-free cloth moistened with cleaning solution. (See *Cleaning solutions* (p. 95))

To perform the cuvette check, you need the reference cuvette and the reference cuvette basket. They are stored at the back of the microscope unit (A).

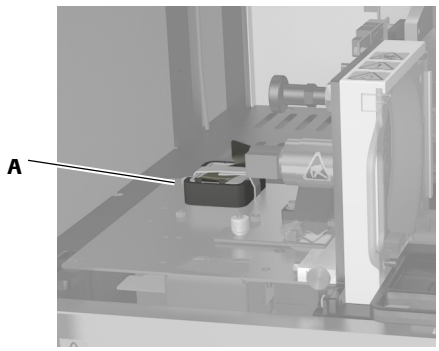


Figure 5-62 Storage place for the reference cuvette and reference cuvette basket

The reference cuvette is designed to be used throughout the shelf life of the analyzer, therefore neither lot number nor expiry date are printed on the reference cuvette box.

To check the microscope focusing mechanism

1 Ensure that the analyzer is in **Idle** status.

2 Start the **Check microscope** wizard.

- In the message list, choose the message that indicates that the microscope check is due, then choose the **Check microscope** button in the detail panel.
  or,
- Choose **Monitoring** > **Manage calibrations** > **Check microscope**, then choose the **Check microscope** button in the main panel.

The wizard is started.

3 Follow the on-screen instructions.

■

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:

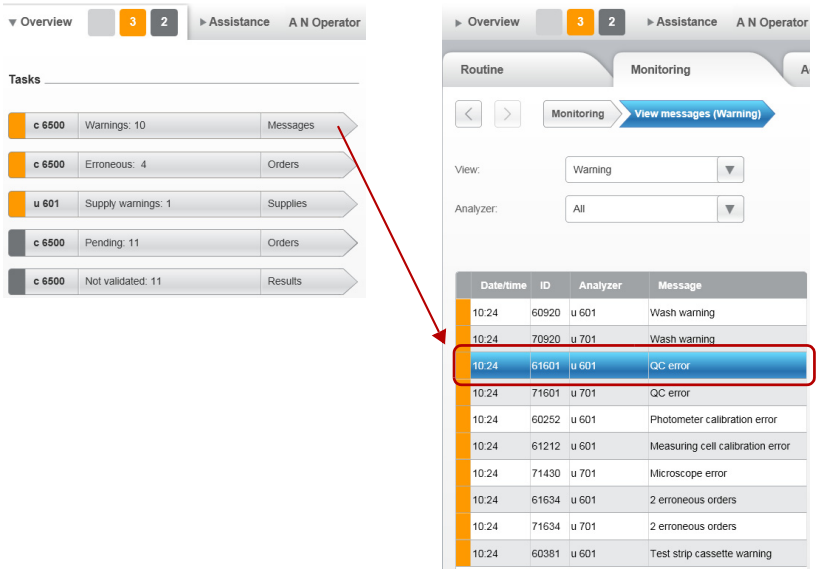


Figure 5-63 Displaying a QC message

See *To check for tasks that need doing* (p. 182).

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.

  For information on defining QC racks, see *Managing racks* (p. 258).

To prepare the QC rack

If you use QC materials of a new lot, define the new lot first. See *Defining QC materials* (p. 211).

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.

■

To perform a QC measurement

1 Prepare the QC rack.

See *To prepare the QC rack* (p. 210).

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.

See *Reviewing QC results* (p. 215).

4 Remove the QC rack from the output buffer.

■

To perform a QC measurement when working with an LAS

1 Prepare the QC rack.

See *To prepare the QC rack* (p. 210).

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.

See *Reviewing QC results* (p. 215).

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 (p. 211)
To define a new QC material by reading the RFID tag (p. 212)
To change QC material data (p. 213)
To include or exclude tests from the QC measurements (p. 214)
To delete QC materials (p. 214)
To print QC results or save them to a file (p. 217)

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.

Figure 5-64

■

To define 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. (See *To define the number of QC levels* (p. 246))
- 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.

1 Choose **Routine** > **Manage QC** > **Manage QC materials**.

2 Present the RFID tag of the QC material to the RFID reader of the microscopy analyzer at a distance of between 1 and 25 mm (0.04-1 in).

Figure 5-65

The QC material data are registered and displayed on screen.

When reading the RFID tag the following data are read and stored on the analyzer:

- QC level
- Target ranges
- Lot number
- Expiry date

- 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.

- 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.

Active materials are marked with ☑ in the **Active** column.

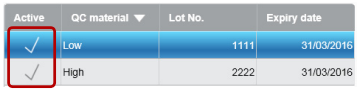


Figure 5-66

■

To change 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.

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.

To make test parameter related changes (p. 213)

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.

■

To make 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.

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 From the drop-down list, choose the analyzer.

5 Choose the **Edit** button.

6 In the test list, use the drop-down lists to enter the new values as required.

7 Choose the **Save** button.

■

To include or exclude 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.

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 From the drop-down list, choose the analyzer.

5 Choose the **Edit** button.

6 To enable or disable a parameter, select or clear its **Enabled** box.

You must enable a parameter before you can change its limit values.

7 Choose the **Save** button.

■

To delete QC materials

You can only delete QC materials that are not currently activated or with which no QC measurements have been performed yet.

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

To review QC results

1 Choose **Routine** > **Manage QC** > **Review QC results**.

The results are displayed.

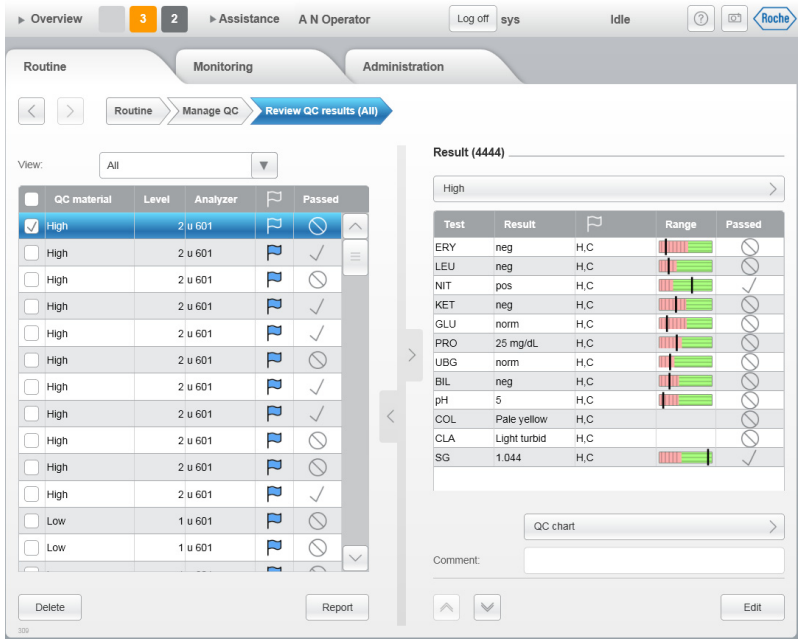


Figure 5-67

2 Select a result.

The details are displayed in the detail panel.

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.
Cm	Calibration. The microscope check results were no longer valid when the result was generated.
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.

F1	Defocused image found. All particle counts are zero. Review the images and repeat measurement.
F2	Defocused image found. The focus position deviates too much from that of the previous image. Review the images and repeat measurement.
F3	Defocused image found. The focus position is outside the predefined range. Review the images and repeat measurement.
F4	Defocused image found. Inhomogeneous MUC distribution in the images. Review the images and repeat measurement.
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.
Ub	Unreliable image found. There may be bubbles in the cuvette. Review is recommended.
Uc	Unreliable image found. There are too many cells in the image (crowded), automatic evaluation is not possible. Review is recommended.
#	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.

3 To view the results in chart format, choose the **QC chart** button.

See *Working with QC charts* (p. 117).

4 To add a comment to the result, choose the **Edit** button and enter the text in the **Comment** field.

■

To delete QC results

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.

1 Choose **Routine** > **Manage QC** > **Review QC results**.

2 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.

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.

For details on using these functions, see *Filtering information* (p. 115).

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 connected USB storage device or a mapped network path.)

6 In the callout, choose the **Yes** button.

■

Additional operating tasks

This section describes some tasks that you may need to perform occasionally.

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:

- 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.

To interrupt sample processing

1 Choose **Overview** > **Stop**.

2 Wait until the system status is **Idle**.

■

To resume sample processing

Ensure that all covers and drawers are closed.

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 **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

To change the password

As a user of the **User** user group, you can change the password only if the system works with **Strong password mode**.

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.

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 *To print or export information* (p. 221).

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 connected USB storage device 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) See also *To print results (result report)* (p. 161) *To save results to files (result report)* (p. 162)	**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) See also *To print results (patient report)* (p. 161) *To save results to files (patient report)* (p. 162)	**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 See also *To print QC results or save them to a file* (p. 217)	**Routine** > **Manage QC** > **Review QC results**		
Photometer calibration results	**Monitoring** > **Manage calibrations** > **Calibrate photometer**		
Measuring cell calibration results	**Monitoring** > **Manage calibrations** > **Check measuring cell**		
Microscope check results	**Monitoring** > **Manage calibrations** > **Check microscope**		

Table 5-7 Printing and exporting information, generating reports

Type of information	Navigation path	Callout items	Comment on callout item
Problem report See also *To create a problem report* (p. 282)	**Monitoring** > **Perform maintenance** > **Create problem report**	**Include failsafe 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 See Table 7-3 *Further guided maintenance actions* (p. 267)	**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 See *To generate a report of the system settings* (p. 257)	**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** > [analyzer] > **Limit configuration**		The report includes the limits of all parameters for trace and abnormal for both analyzers and sieve for the test strip analyzer.
Range table definitions	**Administration** > **System settings** > **Measurement settings** > [analyzer] > **Range table configuration**		
Range table activities	**Administration** > **System settings** > **Measurement settings** > [analyzer] > **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 > **Photometer color adjustment**		

Table 5-7 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 connected USB storage device or a mapped network path.).

   For information on defining default values, see *Defining the look, content, and handling of reports* (p. 253)
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 *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

Defining a new user

For defining user data you need the **Supervisor** user group.

During the initial software installation, a user of the **Supervisor** and **User** user group are defined.

To define a new user

Items marked with an asterisk are mandatory.

1. Choose **Administration** > **User management**.
2. Choose the **Create** button.

   A detail panel is displayed that contains all items that need to be defined.
3. Define the user's first name.

   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.

   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.

   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.

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

7 Choose the user status.

Active	The information can be used during logon.
Inactive	The information cannot be used during logon. It remains on the analyzer and can be activated any time See *Activating and deactivating a user* (p. 227).

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 **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.

If you work with **Simple password mode**, enter the password in the callout and choose the **Confirm** button.

Password information is case-sensitive.

When working with **Strong password mode**, the following conditions must be met:

- 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 need the **Supervisor** user group.

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.

See *To define a new user* (p. 225).

4 Choose the **Save** button.

■

Resetting the password

For resetting a password, you need the **Supervisor** user group.

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

Information that is active can be used during logon, inactive information cannot, but it remains on the analyzer and can be activated any time.

Because every result must be associated with a user, you cannot delete users from the database, they are deactivated instead.

For deactivating a user, you need the **Supervisor** user group.

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

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.

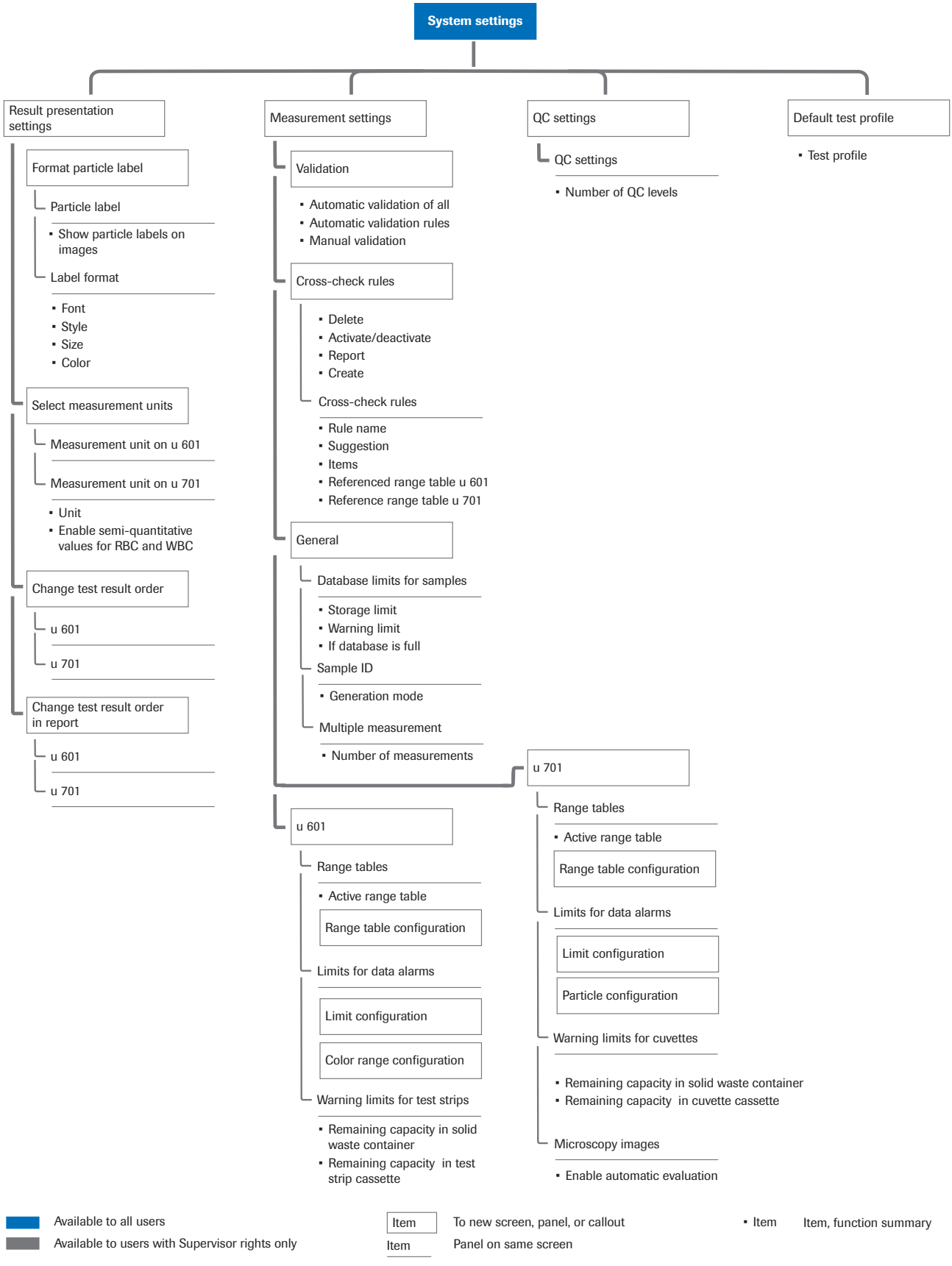


Figure 6-1 Navigation map for System settings

Defining whether and how particle labels are displayed

To define whether and how particle labels are displayed

1 Choose **Administration** > **System settings** > **Result presentation settings** > **Format particle label**.

2 Choose the **Edit** button.

3 Select or clear the **Show particle label on image** check box to define whether labels should be displayed on images or not.

4 In the **Label format** group, define the look of the labels (font family, style, size, color).

5 Choose the **Save** button.

■

Related topics

- *Displaying RBC and WBC results on a semi-quantitative level* (p. 239)

Defining the units in which results are displayed and reported

You can define the units in which results are displayed and reported.

The following tables show examples of how the results are displayed, depending on the unit convention that was selected.

Unit	Test column	Result column	Information column
Conventional	GLU	300 mg/dL	
SI	GLU	17 mmol/L	
Arbitrary	GLU	3+	
Conventional and arbitrary	GLU	300 mg/dL	3+
SI and arbitrary	GLU	17 mmol/L	3+

Table 6-1 **cobas u** 601 result display, depending on the selected unit convention

Quantitative values enabled for RBC and WBC (Enable semi-quantitative values for RBC and WBC is cleared in Administration > System settings > Result presentation settings)				
Unit	**Test column**	**Result column**	**Information column**	**Example for**
Conventional	RBC	181.2/µL		quantitative
	BAC	500/µL		semi-quantitative
	PAT	pos		qualitative
Field of view	RBC	41.1/HPF		quantitative
	BAC	100/HPF		semi-quantitative
	PAT	pos		qualitative
Arbitrary (conventional)	RBC	181.2/µL		quantitative
	BAC	2+		semi-quantitative
	PAT	pos		qualitative
Arbitrary (field of view)	RBC	41.1/HPF		quantitative
	BAC	2+		semi-quantitative
	PAT	pos		qualitative
Conventional and arbitrary	RBC	181.2/µL		quantitative
	BAC	500/µL	2+	semi-quantitative
	PAT	pos	pos	qualitative
Field of view and arbitrary	RBC	41.1/HPF		quantitative
	BAC	100/HPF	2+	semi-quantitative
	PAT	pos	pos	qualitative
Arbitrary and counts (conventional)	RBC	181.2/µL		quantitative
	BAC	2+	~695.4/µL	semi-quantitative
	PAT	pos	~6.2/µL	qualitative
Arbitrary and counts (field of view)	RBC	41.1/HPF		quantitative
	BAC	2+	~157.9/HPF	semi-quantitative
	PAT	pos	~1.4/HPF	qualitative

Table 6-2 **cobas u** 701 display of results with quantitative values enabled for RBC and WBC

Quantitative values disabled for RBC and WBC (Enable semi-quantitative values for RBC and WBC is selected in Administration > System settings > Result presentation settings)				
Unit	**Test column**	**Result column**	**Information column**	**Example for**
Conventional	RBC	150/µL		quantitative
	BAC	500/µL		semi-quantitative
	PAT	pos		qualitative
Field of view	RBC	30/HPF		quantitative
	BAC	100/HPF		semi-quantitative
	PAT	pos		qualitative
Arbitrary (conventional)	RBC	4+		quantitative
	BAC	2+		semi-quantitative
	PAT	pos		qualitative
Arbitrary (field of view)	RBC	4+		quantitative
	BAC	2+		semi-quantitative
	PAT	pos		qualitative
Conventional and arbitrary	RBC	150/µL	4+	quantitative
	BAC	500/µL	2+	semi-quantitative
	PAT	pos	pos	qualitative
Field of view and arbitrary	RBC	30/HPF	4+	quantitative
	BAC	100/HPF	2+	semi-quantitative
	PAT	pos	pos	qualitative
Arbitrary and counts (conventional)	RBC	4+	~181.2/µL	quantitative
	BAC	2+	~695.4/µL	semi-quantitative
	PAT	pos	~6.2/µL	qualitative
Arbitrary and counts (field of view)	RBC	4+	~41.1/HPF	quantitative
	BAC	2+	~157.9/HPF	semi-quantitative
	PAT	pos	~1.4/HPF	qualitative

Table 6-3 **cobas u** 701 display of results with quantitative values disabled for RBC and WBC

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. From the **Measurement unit on u 701** drop-down list, choose the unit convention for the microscopy analyzer.
5. 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.
  or,
- 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.

▶ 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.

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.

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
- The result displays a **Ub** or **Uc** data alarm

- The result displays an **F1** or **F2** or **F3** or **F4** data alarm
- Fewer than five images yielded a valid result
- A dilution factor has been defined

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

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.
- Cross-check rules that concern parameters from both instruments are ignored if tests are performed on one analyzer only.
- 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.

■

To make changes to 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.

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.

■

▶ To delete a cross-check rule

- You can delete a cross-check rule if it is not associated with results.

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, measuring cell calibration, and microscope check 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.

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**.

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.

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.

Range tables are defined separately for each analyzer.

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.

To choose the range table

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. See *To define the limit values* (p. 241).

1 Choose **Administration** > **System settings** > **Measurement settings**.

2 Choose the analyzer

- **u 601**
  or,
- **u 701**

3 Choose the **Edit** button.

4 From the **Active range table** drop-down list, choose the range table.

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* (p. 237).

5 Choose the **Save** button.

6 Define new QC materials.

See *Defining QC materials* (p. 211).

7 Define new cross-check rule, if required.

See *To define a cross-check rule* (p. 234).

■

To define a new range table

Use the **International** range table as the basis for a new range tabbale and then change the ranges as required. You cannot use a user-defined range table as the basis for a new one.

1 Choose **Administration** > **System settings** > **Measurement settings**.

2 Choose the analyzer

- **u 601**
  or,
- **u 701**

3 Choose the **Range table configuration** button.

4 From the **Range table** drop-down list, choose the **International** 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.

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.

See *To choose the range table* (p. 237).

14 Define new QC materials.

See *Defining QC materials* (p. 211).

15 Define new cross-check rules, if required.

See *To define a cross-check rule* (p. 234).

■

To make changes to range tables

- 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 the **International** range table.

1 Choose **Administration** > **System settings** > **Measurement settings**.

2 Choose the analyzer

- **u 601**
  or,
- **u 701**

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.

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.

■

Displaying RBC and WBC results on a semi-quantitative level

RBC and WBC are evaluated on a quantitative level. If you are used to reporting both tests on a semi-quantitative level, you can achieve this by defining a new range table and defining the ranges for RBC and WBC.

Because the **International** range table does not contain values for the RBC and WBC parameters, you first need to create ranges for these.

▶ To display RBC and WBC results on a semi-quantitative level

1 Define a new range table.

See *To define a new range table* (p. 237)

2 Activate the new range table.

See *To choose the range table* (p. 237)

3 Enable semi-quantitative values for RBC and WBC.

- Choose **Administration** > **System settings** > **Result presentation settings** > **Select measurement units**.
- Select the **Enable semi-quantitative values for RBC and WBC** check box.
- Choose **Save**.

■

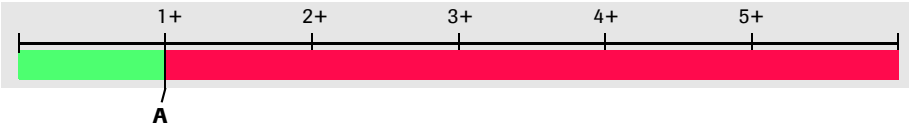
Limit configuration

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.

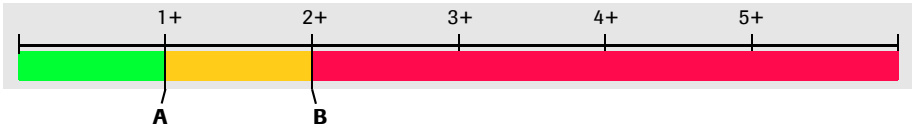
The following illustrations show examples of how different kinds of data alarm can be triggered.

Sieve results are only generated on the test strip analyzer.



A Limit for abnormal data alarm

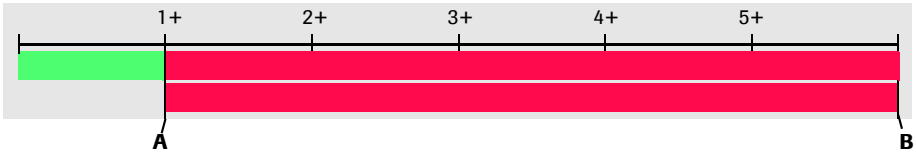
Figure 6-2 Limit for abnormal data alarms



A Limit for trace data alarm

B Limit for abnormal data alarm

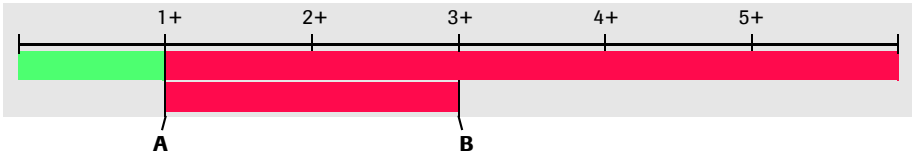
Figure 6-3 Limits for abnormal and trace data alarms



A Limit for abnormal data alarm
Lower limit for sieve data alarm

B Upper limit for sieve data alarm

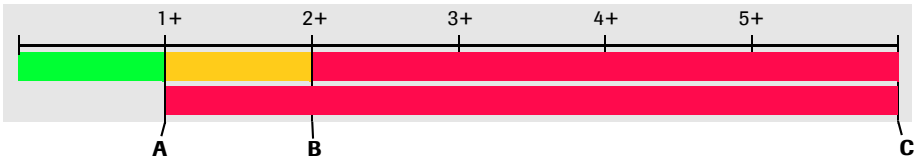
Figure 6-4 Limits for abnormal and sieve data alarms



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

Figure 6-5 Limits for abnormal and sieve data alarms

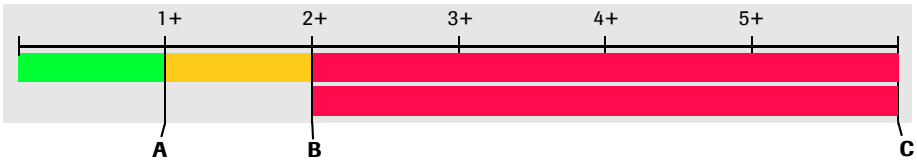


A Limit for trace data alarm
Lower limit for sieve data alarm

B Limit for abnormal data alarm

C Upper limit for sieve data alarm
Results ≥ 1+ trigger a sieve data alarm

Figure 6-6 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

Figure 6-7 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. See *To define a new range table* (p. 237).

To define the limit values

1 Choose **Administration** > **System settings** > **Measurement settings**.

2 Choose the analyzer

- **u 601**
  or,
- **u 701**

3 Choose the **Limit configuration** button.

4 In the main panel, choose a test and then choose the **Edit** button in the detail panel.

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.

5 Define the values as required, 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.

To adjust the color ranges

1 Choose **Administration** > **System settings** > **Measurement settings** > **u 601** > **Color range configuration**.

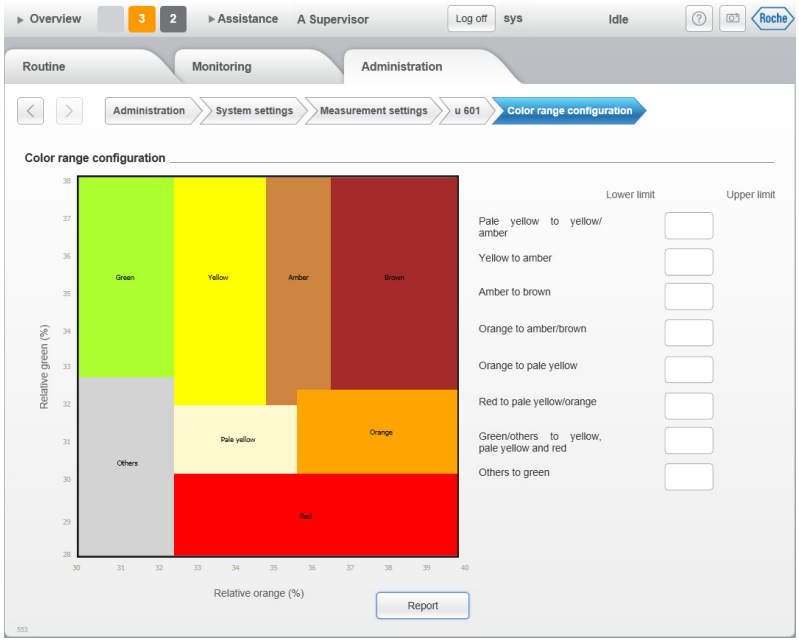


Figure 6-8

2 Choose the **Edit** button.

3 In the color board, choose the area of the color that you want to change.

The corresponding current values are displayed in the fields on the right.

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**
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

Table 6-4 Possible color changes for COL

4 Choose the percentage field and enter the new value.

5 Choose the **Save** button.

■

Defining warning limits for supplies and solid waste

Warning limits are defined separately for each analyzer.

▶ To define the warning limits

1 Choose **Administration** > **System settings** > **Measurement settings**.

2 Choose the analyzer

- **u 601**
  or,
- **u 701**

3 Choose the **Edit** button.

4 Define the limits.

5 Choose the **Save** button.

■

Microscopy related definitions

Image handling

You can define whether automatic image evaluation is used, whether reclassification is allowed, and whether to work with particle subclasses.

You can also define how individual particle counts are treated and how results are handled.

▶ To define image handling

- For disabling automatic evaluation, you need the **Supervisor** user group.
- Your Roche Service representative can additionally enable the following functions:
  Enable reclassification: Allow manual adjustment of results.
  Enable subclasses: Allow the definition of particle subclasses and the manual assignment of particles to such particle subclasses.

1 Choose **Administration** > **System settings** > **Measurement settings** > **u 701**.

2 Choose the **Edit** button.

3 Select or clear the **Enable automatic evaluation** check box.

Clearing this check box stops the analyzer from automatically examining images, no results would be generated and you would have to examine all images manually.

4 Choose the **Save** button.

■

Related topics

- *Manually analyzing images* (p. 168)
- *Particle configuration* (p. 244)
- *Defining particle subclasses* (p. 244)

Particle configuration

You can define which particles are included in the result calculation.

You can include and exclude main classes of particles, not individual subclasses.
You can only exclude particles that are not associated with a result.

To define which particles are taken into account

1 Choose **Administration** > **System settings** > **Measurement settings** > **u 701** > **Particle configuration**.

2 Choose the **Edit** button.

3 To include or exclude particles from result calculation, select or clear the check boxes next to the particle names.

4 Choose the **Save** button.

■

Defining particle subclasses

You can define subclasses to any of the predefined main classes.

If you want to examine and record a particle other than a variant of a predefined main class particle, define a subclass of the **Others** main class, for example trichomonads, macrophages, or artifacts.

- You can delete subclasses only as long as there are no results associated with these subclasses, but you can add subclasses any time.
- Values associated with subclasses are not evaluated, they are based on manual microscopy.

The use of subclasses has the following consequences:

- With the generation of the first subclass of a main class, a generic subclass with the name extension _X is created. The counter for this subclass represents the number of "normal" main class particles.
- The necessary conversion factors are applied during result calculation to achieve result presentation that corresponds to that of standard manual microscopy.
- Subclasses use the range table, limits, and cross-check rule types of their main class. You can define separate cross-check rules for a subclass.

To define a particle subclass

1 Choose **Administration** > **System settings** > **Measurement settings** > **u701**.

2 In the detail panel, choose **Particle configuration**.

The currently defined main and subclasses are displayed.

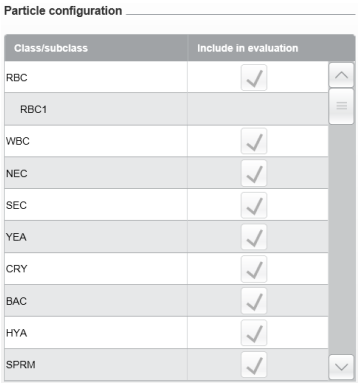


Figure 6-9

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

4 Select the main class for which you want to define a subclass.

The buttons for defining and deleting subclasses are displayed.

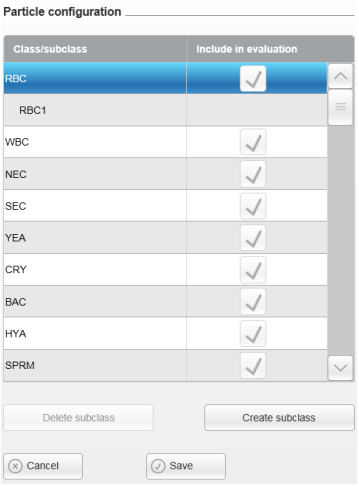


Figure 6-10

5 Choose the **Create subclass** button.

6 In the callout, enter the name of the subclass.

7 In the callout, choose the **Save** button.

The new subclass is displayed.

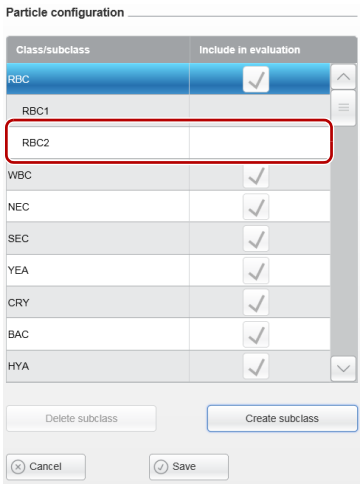


Figure 6-11

8 Choose the **Save** button.

An additional generic subclass with the name extension _X is created. The counter for this subclass represents the number of "normal" main class particles.

The subclasses are available in the image gallery and on the image detail screen.

■

Defining the QC environment

To define the number of QC levels

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.

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

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.

u 601 & u 701	The samples are tested for all test strip and microscopy analysis parameters. This is the default setting.
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.
u 701	The samples are tested for all microscopy analysis parameters.
u 601 sieve to u 701	The samples are tested for all test strip analysis parameters, and if a sieve data alarm was triggered, for all microscopy analysis parameters as well.
u 601 reduced & u 701	The samples are tested for all test strip and microscopy analysis parameters, but no measuring cell measurements (SG, CLA) are performed on the test strip analyzer.

Test profiles are predefined and cannot be changed.

4 Choose the **Save** button.

■

System configuration: defining the operating environment

Choose **Administration** > **System configuration** to access configuration items that define the operating environment.

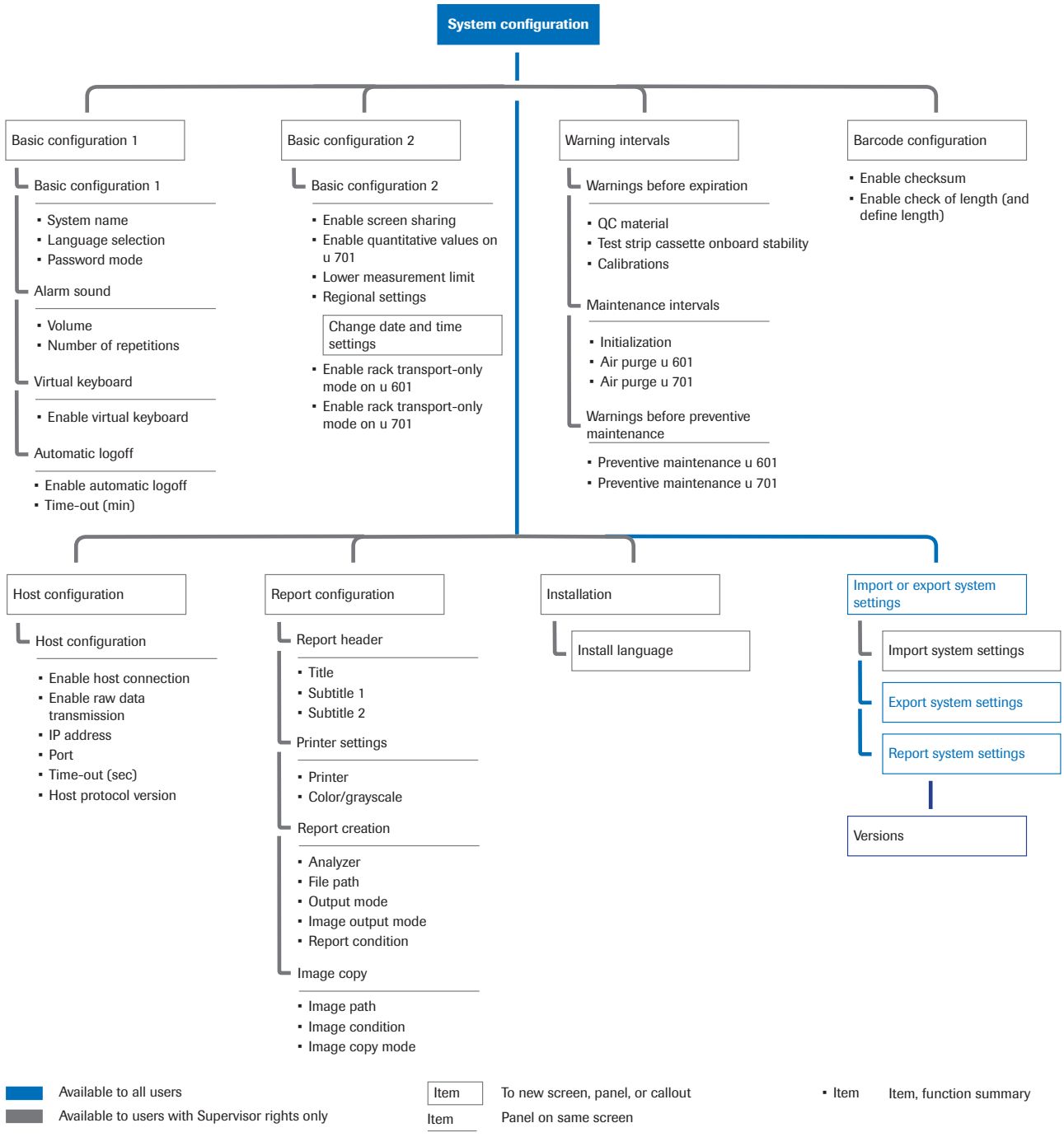


Figure 6-12 Navigation map for System configuration

Basic configuration 1

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

▶ To define the basic configuration items

1 Choose **Administration** > **System configuration** > **Basic configuration 1**.

2 Choose the **Edit** button.

3 Define the items as required.

Here are some hints:

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 **pt**: Portuguese **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. See *To define a new user* (p. 225).
Enable virtual keyboard	Clear the check box if you want to use the external keyboard instead of the virtual keyboard. Do not use the virtual keyboard and the external keyboard at the same time, this could lead to operating complications.
Enable automatic log off	If you select the check box also enter a time-out value between 1 and 1000 minutes.

(1) This list is not necessarily complete, further languages may become available and different languages may be installed on your analyzer.

4 Choose the **Save** button.

■

Basic configuration 2

This panel serves to define the following items:

- Whether screen sharing with remote access is permitted
- Whether quantitative values should be reported on the microscopy analyzer.
- The way lower measurement limit values are reported
- The geographic area where the system is installed
- Date and time settings
- Whether you want to disable the measuring functions on one analyzer

▶ To define the more basic configuration items

1 Choose **Administration** > **System configuration** > **Basic configuration** 2.

2 Choose the **Edit** button.

3 Define the items as required.

Here are some hints:

Enable screen sharing	Allow screen sharing when remote service is active.
Enable quantitative values on u 701	You select this check box to display particle concentration values. Clear the check box if, e.g. for legal reasons, this is not allowed. Clearing this check box has the following effects: • The effects apply only to the microscopy analyzer measurement units **Arbitrary and counts (conventional)** and **Arbitrary and counts (field of view)**. • Results calculated with this setting are preceded with a tilde "~" to indicate that they were not actually evaluated on a quantitative level. • In the result list, the heading of the **Information** columns have an asterisk added, and a legend is displayed informing the user that the values in this column will not be reported in the patient report. In the customer file of the result export to CSV format, the **Information** columns are empty. • If you send the results to a host using a protocol version 8.0 or older, the values are send but the **Information** columns are empty. • If you send the results to a host using a protocol version 9.0 or more recent, no values for the **Information** columns are sent. Note that this setting does not affect RBC and WBC results, these are always quantitative and the **Information** columns are always empty.
Lower measurement limit(1)	This definition affects the quantitative parameters RBC and WBC only. **International**: Limit of Blank(2). Values below the Limit of Blank are reported as < LoB. **US**: Limit of Quantitation(3). Values below the Limit of Quantitation will be reported as < LoQ.
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.
Enable rack-transport-mode only on u601	Select the check box if you want to temporarily use the microscopy analyzer only, because the test strip analyzer cannot perform tests for some reason. This is to allow you to continue using the intact analyzer while you wait for a Roche Service representative to arrive. See *One of the analyzers cannot perform measurements* (p. 302).
Enable rack-transport-mode only on u701	Select the check box if you want to temporarily use the test strip analyzers only, because the microscopy analyzer cannot perform tests for some reason. This is to allow you to continue using the intact analyzer while you wait for a Roche Service representative to arrive. See *One of the analyzers cannot perform measurements* (p. 302).

(1) The Limit of Blank, Limit of Detection and Limit of Quantitation are determined in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP17-A2 requirements.

(2) The Limit of Blank is the 95th percentile value from n ≥ 60 measurements of analyte-free samples over several independent series. The Limit of Blank corresponds to the concentration below which analyte-free samples are found with a probability of 95%.

(3) The Limit of Quantitation is the lowest analyte concentration that can be reproducibly measured with a coefficient of variation (CV) of 60%.

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, pump, syringes 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.

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

Table 6-5 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.

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.

c 6500	Host protocol versions 8 and older.
c 6500_09	Host protocol versions 9 or more recent. This version is not backward compatible.

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.

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.

Here are some hints:

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. **Export only images**: Each image is saved as a separate file in the **File path** location.
	Image output mode	**With labels**: Include the particle labels in the exported images. **Without labels**: Do not include the particle labels in the exported images. **Both**: For each image two copies will be generated, one without particle labels (in GIF format) and one with (in PNG format).
	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.
Image copy		The **Image copy** definitions are used as default values when automatically sending a copy of the images to an external storage device.
	Image path	The external storage device where images are automatically stored.
	Image condition	**No images**: No images are automatically stored in the **Image path** location. **All images**: All images are automatically stored in the **Image path** location. **Pathological images**: Only pathological images (with data alarm **A**) are automatically stored in the **Image path** location.
	Image copy mode	**With labels**: Include the particle labels in the exported images. **Without labels**: Do not include the particle labels in the exported images. **Both**: For each image two copies will be generated, one without particle labels (in GIF format) and one with (in PNG format).

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)

de	German
en	English
es	Spanish
fr	French
it	Italian
pt	Portuguese
tr	Turkish
zh	Chinese

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.

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.

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.(2)

de	German
en	English
es	Spanish
fr	French
it	Italian

(1) This list is not necessarily complete, further languages may become available and different languages may be installed on your analyzer.

(2) The following list is not necessarily complete, further languages may become available and different languages may be installed on your analyzer.

pt	Portuguese
tr	Turkish
zh	Chinese

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.

To import the 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.

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.
  or,
- 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

All users can export the system settings.

1 Choose **Administration** > **System configuration** > **Import or export system settings** > **Export 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

The system settings report provides the system settings in an easily readable form.

All users can 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 chose **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 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.

With QC racks and wash racks, you can furthermore assign these racks to a specific analyzer.

To define a STAT rack


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.

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 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 in the **Rack ID** field.
4. From the **Assignment** drop-down list, choose **Wash**.
5. Choose the analyzer.

You can assign the same rack to both the test strip and microscopy analyzers.

6. 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 in the **Rack ID** field.
4. From the **Assignment** drop-down list, choose **QC**.

5 Choose the analyzer.

You can assign the same rack to both the test strip and microscopy analyzers.

6 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.

7 Choose the **Save** button.

■

Adjusting the probe action

If you decide to use a different type of tube or rack on the **cobas**® 6500 urine analyzer series, 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.

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

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 analyzer

- Choose the **Wizards on u 601** button
  or,
- **Choose the Wizards on u 701** 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 *Chapter* 7

Table of contents

Safety

Read and understand the information in the Safety chapter

See p. 17.

The following safety messages are particularly relevant:

Warning messages:

- *Biohazardous materials* (p. 22)
- *Waste* (p. 23)

Caution messages

- *Mechanical safety* (p. 24)
- *Working solutions* (p. 25)
- *Influence of vibrations* (p. 25)

Notice messages

- *Spillage* (p. 26)
- *Excessive ambient humidity* (p. 26)

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.

  See *Cleaning solutions* (p. 95)
- Never use the recommended wash solution for 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.

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* (p. 187)
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* (p. 189)
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* (p. 188)
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 solid waste container* (p. 188)
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* (p. 205)
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* (p. 273)
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* (p. 259)

Table 7-1 Wizards on the **cobas u** 601 urine analyzer

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* (p. 187)
Exchange cuvette 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 cuvette cassette* (p. 190)
Empty the solid waste container	When loading a new cuvette cassette 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 solid waste container* (p. 188)
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 solid waste container* (p. 188)
Check microscope	When prompted to do so	In order to ensure proper functioning of the focusing mechanism of the microscope, a microscope check needs to be performed every 4 weeks. This is done by performing a predefined sequence of photographic measurements of a reference cuvette. *Checking the microscope focusing mechanism* (p. 207)
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* (p. 273)
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* (p. 259)

Table 7-2 Wizards on the **cobas u** 701 microscopy 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* (p. 282)

Table 7-3 Further guided maintenance actions

Task name	When to be performed	Purpose
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* (p. 281)
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* (p. 271)
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* (p. 270)
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* (p. 185)
Unload rack	In emergency situations	Move the rack that is on the conveyor to the output buffer.

Table 7-3 Further guided maintenance actions

The following maintenance action is started by choosing **Monitoring** > **Analyzer** > **u 601** or **u 701** > **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* (p. 186)

Table 7-4 Further maintenance actions

Miscellaneous maintenance actions

Some maintenance actions need to be performed periodically, others as and when required.

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 (p. 95)

To clean the water container

1 Start the **Fill water container** wizard.

  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.

  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.

See *Managing the result storage capacity* (p. 235).

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, and you can also export the related sediment images in a graphics file format.

  See *To save results to files (result report)* (p. 162).
- 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.

For each analyzer a CSV file and, if you include the raw data, a ZIP file are generated, their file names start with *RawData_*.

■

To delete results

Deleting results from the result list also removes them from the database.

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**.

1 Display the result list:

- Choose **Routine** > **Manage test results**
  or,
- 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.

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.

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.

▶ To back up the analyzer setup data

1 See *Importing and exporting system settings* (p. 256)

■

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 analyzers the probe positioning is automatically calibrated and their position adjusted. A 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.

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.

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.

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.

   See *To clean the probe bend detector* (p. 196).

3. If the problem persists, clean the probe.

   See *To clean the probe* (p. 272).

4. If the problem persists, replace the probe.

   See *To replace the probe* (p. 273).

▶ 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.
  or,
- Choose **Assistance** > **Wizards** > **Exchange probe on u 601** or **Exchange probe on u 701**.

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.
  or,
- Choose **Assistance** > **Wizards** > **Exchange probe on u 601** or **Exchange probe on u 701**.

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.

The following tasks should be performed if you intend not to use the analyzer for some time:

1. Remove the test strip cassette
   See *Removing the test strip cassette* (p. 219).
2. Empty the solid waste
   See *Emptying the solid waste container* (p. 188).
3. Empty the water container
   See *To empty the water container* (p. 273).
4. Drain all water from the fluid system
   See *To drain the system water* (p. 274).
5. Empty the liquid waste
   See *Emptying the liquid waste container* (p. 187).
6. Shut down the system and switch off the power
   See *To shut down the analyzer* (p. 274).

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.

5 Choose **Assistance** > **Wizards** > **Fill water container on u 701**.

6 Remove the water container and empty the system water.

7 Install the *empty* water container.

8 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.

3 Choose **Overview** > analyzer illustration of the microscopy analyzer > **Perform air purge**.

4 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**.

Figure 7-1

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 analyzers are 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 *Chapter* 8

Table of contents

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* (p. 289)
Calibration	You cannot calibrate the photometer.	*No photometer calibration can be generated* (p. 283)
	You cannot calibrate the measuring cell. Invalid results are produced repeatedly.	*No measuring cell calibration can be generated* (p. 287)
	Microscope check does not result in valid results.	*No microscope check results can be generated* (p. 288)
Cover	You have accidentally opened the main cover.	*To recover after accidentally opening the main cover* (p. 290)
Emergency stop	All mechanical movement must be stopped immediately. The analyzer is stuck in **Processing** or **Init** status.	*To perform an emergency stop* (p. 292)
Filter	Processing stopped due to a clogged inlet water filter.	*Clogged inlet water filter* (p. 296)
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* (p. 299)
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* (p. 289)
	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* (p. 282) *To create a problem report* (p. 282)
Measuring cell calibration	You cannot calibrate the measuring cell. Invalid results are produced repeatedly.	*No measuring cell calibration can be generated* (p. 287)
Microscope check	Microscope check does not result in valid results. Invalid results are produced repeatedly.	*No microscope check results can be generated* (p. 288)
Photometer calibration	You cannot calibrate the photometer. Invalid results are produced repeatedly.	*No photometer calibration can be generated* (p. 283)
Power cut	After a power cut, you must follow a prescribed procedure to avoid data loss.	*To recover from a power cut* (p. 294)

Table 8-1 Exceptional situations and how to deal with them

Keyword	Situation	How to handle the situation
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* (p. 282)
Safety interlock	A message is displayed informing you that safety interlock in not on.	*Safety interlock* (p. 295)
Shut-down	The screen froze completely and you had to shut down using the On/Off switch.	*To recover from a forced shutdown* (p. 290)
Screen	The screen froze completely and you had to shut down using the On/Off switch.	*To recover from a forced shutdown* (p. 290)
Screenshots	You want to document a particular situation for troubleshooting reasons.	*To generate a screenshot* (p. 281)
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* (p. 299)
Stop	Processing stopped because you have accidentally opened the main cover.	*To recover after accidentally opening the main cover* (p. 290)
	Processing stopped because you have accidentally pulled out the waste drawer.	*To recover after pulling the waste drawer* (p. 293)
	Processing stopped due to a clogged inlet water filter.	*Clogged inlet water filter* (p. 296)
	One of the analyzers stopped performing tests.	*One of the analyzers cannot perform measurements* (p. 302)
	The analyzer is stuck in **Processing** or **Init** status.	*To perform an emergency stop* (p. 292)
	All mechanical movement must be stopped immediately.	*To perform an emergency stop* (p. 292)
	The screen froze completely and you had to shut down using the On/Off switch.	*To recover from a forced shutdown* (p. 290)
Stuck	The analyzer is stuck in **Processing** or **Init** status.	*To perform an emergency stop* (p. 292)
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* (p. 299)
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* (p. 299)
Water filter	Processing stopped due to a clogged inlet water filter.	*To clean the inlet water filter* (p. 297) *To clean the inlet water filter (external water supply)* (p. 297)

Table 8-1 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

You need Supervisor user rights to view the audit trail.

1 Choose **Administration** > **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* (p. 253).

■

No photometer calibration can be generated

If photometer calibration persistently fails, proceed as follows:

1. Be sure to use a fresh calibration strip with every photometer calibration.
2. Check the calibration strip.
   - Check it for soiling. Use a clean 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.
3. If the problem persists, clean the reference plate.

   Calibrate the photometer unit.
4. If the problem persists, replace the reference plate.

   Calibrate the photometer unit.
5. If the problem persists, contact your Roche Service representative.

To clean the reference plate

Do not touch the surface of the reference plate other than with recommended cleaning materials. Scratches may limit the usability of the reference plate.

1 Shut down the analyzer.

See *To shut down the analyzer* (p. 192).

2 Open the main cover.

3 Pull out the test strip transporter (A).

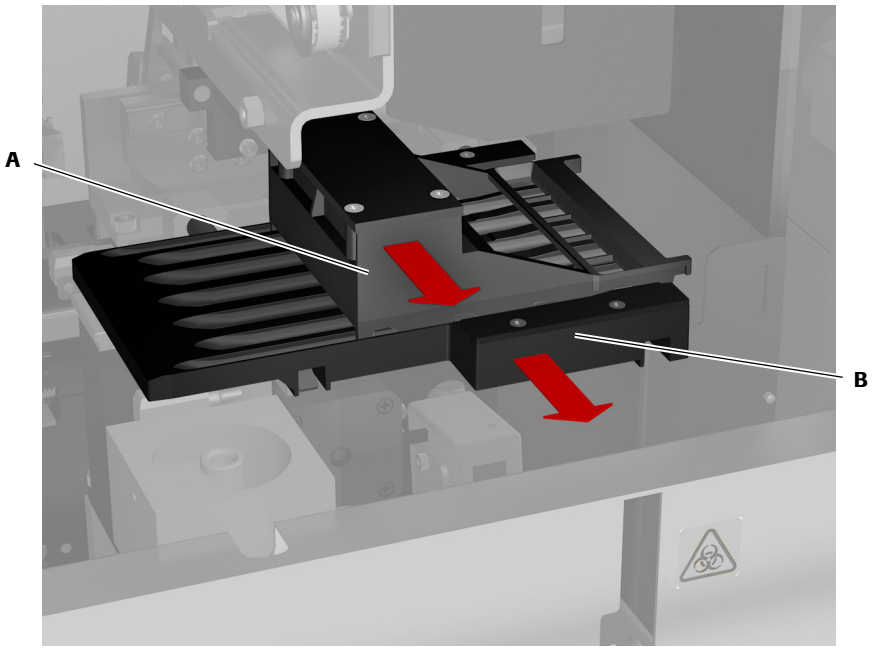


Figure 8-1

4 Pull out the test strip tray (B).

5 Cover a cotton swab with a piece of lint-free cloth that is moistened with ethanol.

For this cleaning action, use ethanol only.

6 Wipe the top surface of the reference plate with this cloth once in one direction, for example from back to front.

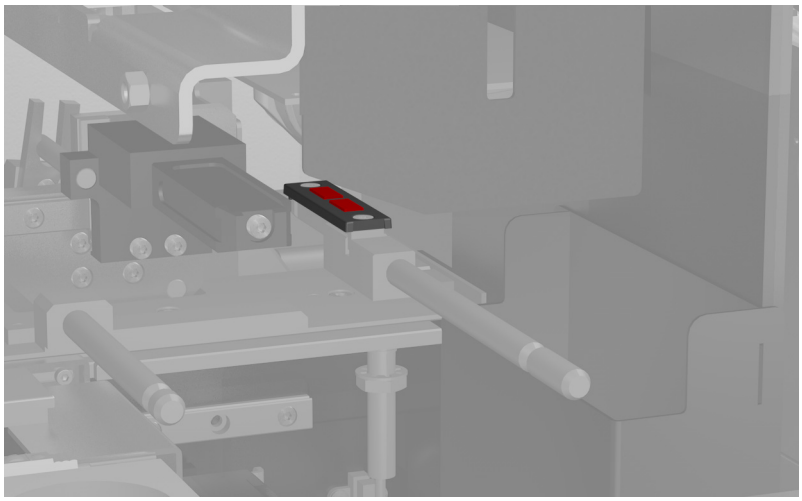


Figure 8-2

7 Leave the reference plate to dry for a few seconds.

8 Insert the test strip tray in the two support pins and push it firmly in.

9 Insert the test strip transporter in the support bar and push it firmly in.

10 Close the main cover.

11 Start the system.

12 When the analyzer is in **Idle** status, calibrate the photometer.

See *Calibrating the photometer unit* (p. 205).

■

To replace the reference plate

CAUTION

Personal injury due to catching items of jewelry and clothing

Due to the limited available space, items of clothing or jewelry may get caught in tight spaces and cause personal injury or get damaged.

- Push or roll back the sleeves of your clothing before you start the procedure.
- Remove all items of jewelry from your hands and arms before you start the procedure.

1 Shut down the analyzer.

See *To shut down the analyzer* (p. 192).

2 Open the main cover.

3 Pull out the test strip transporter (A).

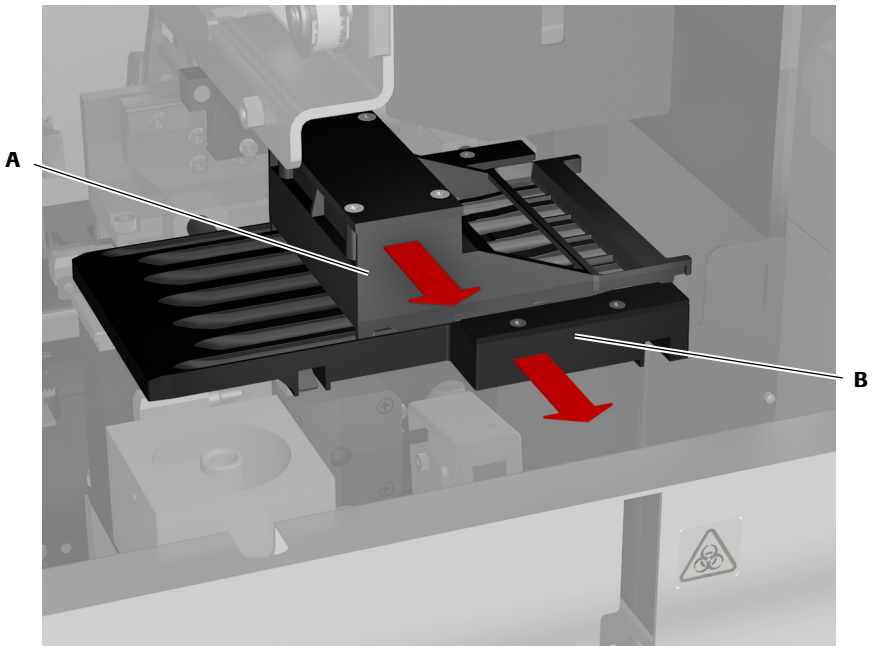


Figure 8-3

4 Pull out the test strip tray (B).

5 To lift the front end of the reference plate, press down the back end of the reference plate.

Be sure not to touch the measurement surface of the reference plate.

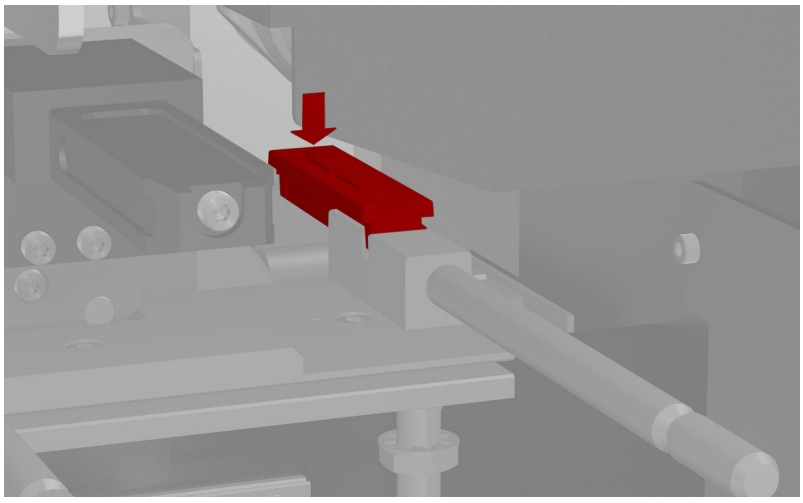


Figure 8-4

You can now take hold of the front end of the reference plate.

6 Lift off the reference plate and remove it.

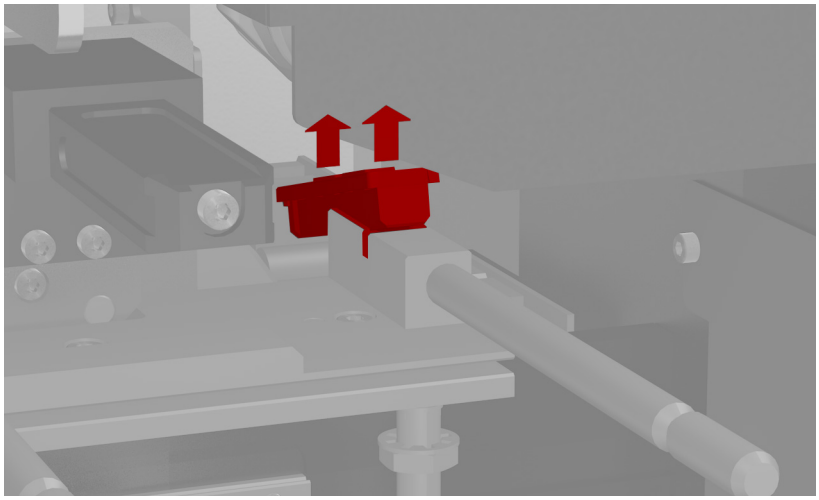


Figure 8-5

7 Place the new reference plate on its base. Be sure not to touch the measurement surfaces of the plate.

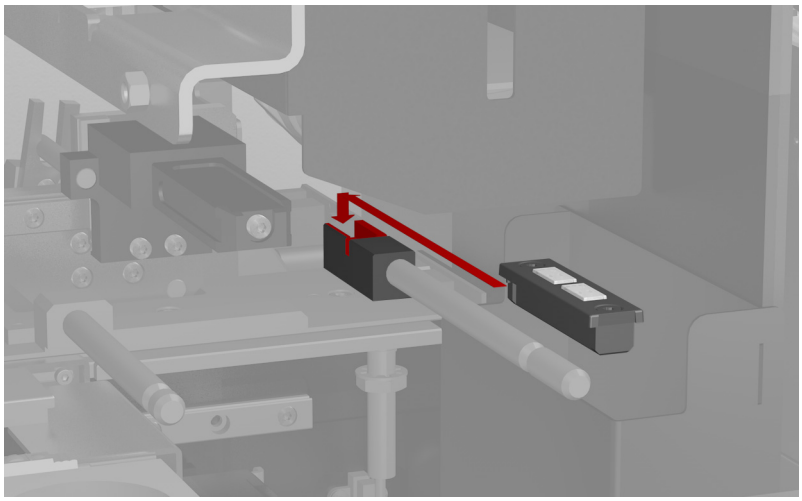


Figure 8-6

8 Insert the test strip tray in the two support pins and push it in firmly.

9 Insert the test strip transporter in the support bar and push it in firmly.

10 Close the main cover.

11 Start the system.

12 When the analyzer is in **Idle** status, calibrate the photometer.

See *Calibrating the photometer unit* (p. 205).

■

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.

See *Water quality* (p. 95).

Change the water, if required, then perform a wash. (**Monitoring** > **Perform maintenance** > **Perform wash**)

3 If the problem still persists, contact your Roche Service representative.

■

No microscope check results can be generated

If no microscope check results can be generated, proceed as follows:

1. Repeat the microscope check.
2. If the problem persists, check the reference cuvette for soiling and scratches.

   If the reference cuvette is soiled, clean it using a cotton bud moistened with one of the recommended cleaning solutions. Dry it with a lint-free soft cloth.

   Repeat the microscope check.

   If the reference cuvette is scratched, perform the microscope check with a new reference cuvette.
3. If the problem still persists, initialize the analyzer (**Monitoring** > **Perform maintenance** > **Initialize system**).

   Repeat the microscope check.
4. If the problem still persists, wipe the underside of the microscope lamp objective (A) using a cotton swab moistened with ethanol.

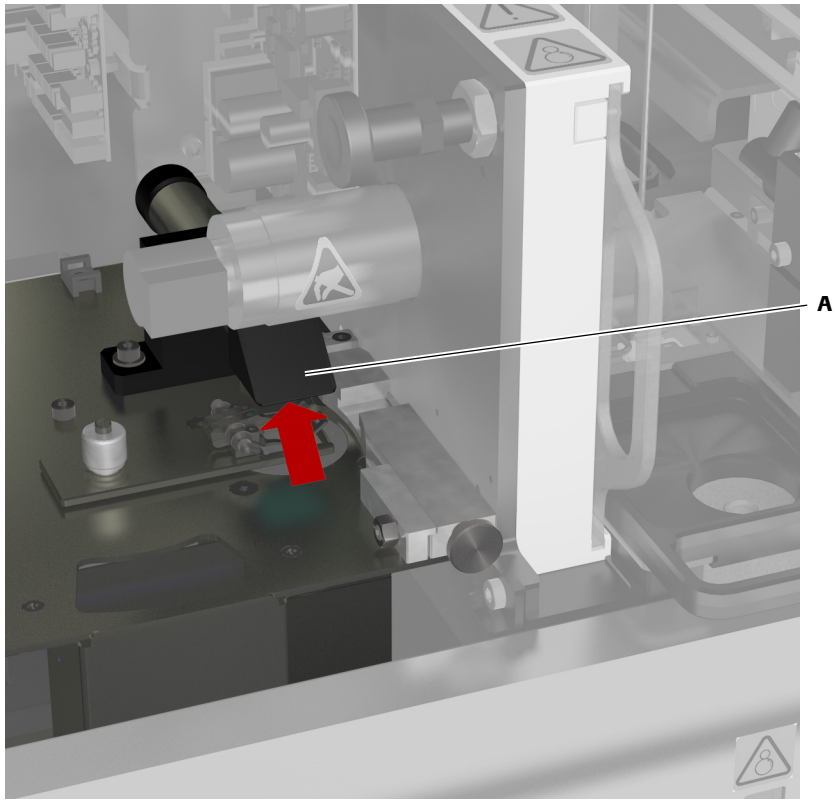


Figure 8-7

Only use ethanol for cleaning the microscope lamp objective, do not use any other cleaning solution for the microscope lamp objective.

Do not touch the underside of the objective with your fingers.

5. 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.

To recover after accidentally opening the main cover

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.

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

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.

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.

See *Rerunning tests when working with Sample sequence number mode and without sample barcodes* (p. 165).

■

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**
     or,
   - 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.

   See *To recover from a forced shutdown* (p. 290)

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 and cuvettes 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.

   See *Rerunning tests when working with Sample sequence number mode and without sample barcodes* (p. 165).
9. Place the rack in the priority rack slot.

   New orders are generated and the test are processed.

■

Recovering from a power cut

CAUTION

Loss of data and sample due to power cut

Accidentally unplugging the power supply or a power cut 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. See *Uninterruptible power supply (UPS)* (p. 95).

CAUTION

Incorrect results due to power cut

Accidentally unplugging the power supply or a power cut 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. See *Uninterruptible power supply (UPS)* (p. 95).

To recover from a power cut

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.

   See *Rerunning tests when working with Sample sequence number mode and without sample barcodes* (p. 165).

■

Safety interlock

WARNING

Immediate processing stop due to opening the main cover

Opening the main cover results in immediate power cut 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:

1. Check that the water quality is of the required standard.
   See *Water quality* (p. 95).
2. Check whether the inlet water filter is soiled or clogged.
   See *To clean the inlet water filter* (p. 297).
   See *To clean the inlet water filter (external water supply)* (p. 297)
3. Check whether the inside of the water container is soiled or shows deposits.
   See *To clean the water container* (p. 269).
   See *To clean the water container for external water supply* (p. 269)

A Water tubing adapter
B Water tubing
C Inlet water filter

Figure 8-8 Water container

A Water tubing adapter
B Water tubing
C Inlet water filter

Figure 8-9 Water container with external water supply

To clean the inlet water filter

1 Start the **Fill water container** wizard.

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 Rinse the inlet water filter and the other tubing adapter components thoroughly with purified water.

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.

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)

This procedure is not software supported, and it may interfere with analyzer activities if the analyzer is running.

1 Shut down the analyzer.

To shut down the analyzer (p. 192)

2 Turn off the external water supply.

3 Remove the water tubing adapter from the water container.

Keep the bottom of the water tubing in the water container until water stops running.

4 Rinse the inlet water filter with 1% NaOCl.

5 Rinse the inlet water filter and the other tubing adapter components with purified water.


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.

6 Insert the water tubing adapter in the water container and screw it on.

7 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.

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.

Figure 8-10 Water container

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.

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.

Figure 8-11 Water container

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.

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

Contamination of the environment by liquid and solid waste

CAUTION

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.

1 Choose a message that concerns the fill level of liquid waste.

2 Start the appropriate **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.

Figure 8-12 Liquid waste container

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.

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.

■

One of the analyzers cannot perform measurements

If for some reason one of the analyzers cannot be used and requires intervention by a Roche Service representative, you can temporarily switch to single analyzer operation by using the **Rack-transport-only mode** function on the affected analyzer.

To successfully switch to single analyzer operation, some conditions must be fulfilled:

- Initialization of the robotic units must be possible.
- The probes must be able to move to their parking positions.

To switch to single analyzer operation

You need **Supervisor** user rights to perform this procedure.

1 Choose **Administration** > **System configuration** > **Basic configuration 2**.

2 Choose the **Edit** button.

3 Choose the analyzer that cannot perform tests any more. Select the check box either for **Transport only for u 601** or **Transport only for u 701**, as appropriate.

- Select the **Enable rack-transport-only mode on u601** check box.
  or,
- Select the **Enable rack-transport-only mode on u701** check box.

  Switching to **rack-transport-only mode** has the following consequences:
  - Wizards and buttons that start actions are not available on the analyzer in **rack-transport-only mode**.
  - Results are shown as usual on the **cobas**® 6500 system, but with one set missing because the tests were not performed.
  - You need to deal appropriately with the orders that could not be fully completed, for example rerun them or define new orders.

4 Choose **Save**.

A callout is displayed.

5 Choose **Restart**.

The system is restarted.

If there are error messages regarding doors and probe position, the procedure was not successful.

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.

Quantitative determination The measurement of analytes or features in urine yielding numeric results such as a concentration.

In quantitative analysis, the recognized particles of all images are counted and added up.

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.

In semi-quantitative analysis the recognized particles of a certain number of images are counted and the result is then extrapolated for the whole sample area.

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.

Index

Index

A

B

C

D

E

F

G

H

I

K

L

M

N

O

P

Q

R

S

T

U

V

W

Z