cobas®

Roche

Urisys 1100® urine analyzer

Operator's Manual

Publication version 10.0

Publication information

General information

This document is intended for the US market only.

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Revision history

Publication version	Software version	Revision date	Amendments
9.0 and lower	6.x	2012 - 2021	Before device's update
10	7.x	July 2023	• General update of the Operator's Manual. • Documentation updates resulting from the device's update which is applicable for devices with a serial number starting with *UX11*.

Revision history

Where to find information

The **Operator's Manual** and the **User Assistance** contain all information about the product, including the following:

- Routine operation
- Maintenance
- Safety
- Troubleshooting information
- Software reference
- Configuration information
- Background information

The **Operator's Manual** and the **User Assistance** contain important safety information. You must read them before operating the device.

The **Quick Reference Guide** gives a brief introduction to important routine tasks.

Privacy notice

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

Viewing events are analyzed to improve User Assistance content and search functionality. IP addresses are used to classify regional behavior.

⚠ General attention

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

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

⚠ Incident reporting

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

Phone number of Roche Diagnostics Customer Support Center: +1-800-428-4674

User training

The operation of the **Urisys 1100®** and the execution of the Chemstrip® 10 MD and Chemstrip® 10 UA test is described in the **Urisys 1100®** Operator's Manual. No dedicated training is required.

Images

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

Warranty

Roche Diagnostics warrants the **Urisys 1100®** against defects in material and workmanship (except for consumable items) for a period of one year from date of purchase.

Roche Diagnostics will replace the device and all parts which prove to be defective and are subject to such warranty.

This warranty does not apply to a device not used according to instructions or damaged by accident, alteration, misuse, tampering, and/or abuse.

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Open-source and commercial software

Urisys 1100® incorporates components or modules of commercial and open-source software.

This open-source and commercial software and **Urisys 1100**® as a whole can constitute a device regulated in accordance with applicable law. For more detailed information, refer to the corresponding user documentation and labeling.

Note that the respective authorization is no longer valid according to the corresponding legislation should any unauthorized changes be made to **Urisys 1100**®.

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Feedback

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

Approvals

The **Urisys 1100®** meets the requirements laid down in:

IVD

For *in vitro* diagnostic use.

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

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eLabDoc

Electronic user documentation can be downloaded using the eLabDoc e-service on the navify® Portal:

navifyportal.roche.com

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

Additional help

Roche Diagnostics provides technical support. If you have any questions or need assistance, contact Roche Diagnostics Customer Support Center.

Phone number: +1-800-428-4674

Guarantee

The statutory guarantee provisions on rights in consumer goods sales in the country of purchase shall apply.

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Intended use

The **Urisys 1100®** Urine Analyzer is a reflectance photometer designed to automatically read and evaluate the results of Chemstrip® 10 MD[1] urine test strips for various urine analytes: specific gravity, pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin and blood.

Additional information

The **Urisys 1100®** is manufactured for a lifetime of 5 years after date of manufacture, or 35 000 measurements. After reaching the end of lifetime, no measurements can be performed anymore on the device.

Using the **Urisys 1100®** eliminates factors known to affect visual evaluation of urine test strips, such as:

- Variable lighting conditions at the workplace
- Individual skill levels at matching test strip pad colors
- Different reaction times for the test strips
- Clerical errors
- Strong color of the urine sample

Rx only

Caution: Federal law restricts this device to sale by or on the order of a physician.

Symbols and abbreviations

Product names

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

Product name	Descriptor
Urisys 1100®	Device
Chemstrip® 10 MD	Urine test strips
Chemstrip® 10 UA	Urine test strips
Chemstrip® Calibration Strips	Calibration strips
cobas® infinity edge	Service system

Product names

[1] Hospitals may use Chemstrip® 10 UA urine test strips (Cat. No. 11895354160).

Product name	Descriptor
cobas® infinity POC	Data management system

Product names

Symbols used in the Operator's Manual

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

Symbols used in the Operator's Manual

Symbols used in the User Assistance

Symbol	Explanation
•	List item
	Tip, used for extra information on correct use or for useful hints
	Extra information within a task
	Result of an action within a task
	Frequency of a task
	Duration of a task
	Materials that are required for a task
	Prerequisites of a task

Symbols used in the User Assistance

Symbols used for easy recognition of information

Symbol	Explanation
	Safety alert.

Symbols used for easy recognition of information

Symbols used on product and packaging

Symbol	Explanation
	For *in vitro* diagnostic use.
	Biohazardous. Urine can potentially be infectious. The device can come into contact with urine even when used as intended.
	Serial number.
	Issued by Underwriters Laboratories, Inc. (UL) for Canada and the US.
	Refer to safety information included in this publication.
	Used to indicate that the equipment is suitable for direct current only; to identify relevant terminals.
	Manufacturer.
	Date of manufacture.
	Unique device identifier.
	Lot number.

Symbols used on product and packaging

Symbol	Explanation
	Consult instructions for use.
	Temperature limits.
	Humidity limit.
	Catalogue number.
	Global Trade Item Number.
	USB.
	Quantity contained in the package.

Symbols used on product and packaging

Abbreviations

The following abbreviations are used.

Abbreviation	Definition
BIL	Bilirubin
BLD	Blood
CSA	Canadian Standards Association
DMS	Data management system
EC	European Community
EMC	Electromagnetic compatibility
ERY	Erythrocytes
ESD	Electrostatic discharge
GLU	Glucose
IEC	International Electrical Commission
IVD	In vitro diagnostic
IVDR	In vitro diagnostics regulation
KET	Ketones

Abbreviations

Abbreviation	Definition
LEU	Leukocytes
LIS	Laboratory information system
NIT	Nitrite
pH	Potential of hydrogen
PRO	Protein
QC	Quality control
SG	Specific gravity
TR	Trace
UBG	Urobilinogen
UL	Underwriters Laboratories Inc.

Abbreviations

What is new in publication version 10.0

Update

The publication contains updates resulting from the device's update referring to:

- Graphic color display
- Touch screen
- Updated user interface
- Enhanced connectivity (LAN, USB, Wi-Fi, cloud access)
- Larger memory (up to 1000 results can be stored)
- Additional QC functions
- Lot management for strips and QC material
- Option to enter user IDs and lot information using a barcode reader
- Updated user management
- Possibility of remote software updates

Illustrations and screenshots

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

List of available accessories and consumables

Below is a list of globally available accessories and consumables. For ordering information, contact your local Roche representative.

Contents of the package

Product name	Description	Catalogue number
Urisys 1100®	Contents: • Power adapter USB-C • Power cable • Test strip tray, type C • Printer paper • Operator's Manual • Quick Reference Guide	REF 03617556001

Contents of the package

Accessories

Product name	Description	Catalogue number
Spare reference pads (5 pieces)	Spare reference pads	REF 11907131001
Test strip tray, type C	Test strip tray	REF 03666735001
Datalogic QD2590	2D handheld barcode reader with Datalogic USB cable	REF 9831053001

Available accessories

Consumables

Product name	Description	Catalogue number
Thermal paper (20 rolls)	Printer paper	REF 06431321001
Chemstrip® 10 MD (100 test strips)	Test strips	REF 03260763160
Chemstrip® 10 UA (100 test strips)	Test strips	REF 11895354160
Chemstrip® Calibration Strips (50 calibration strips)	Calibration strips	REF 11379194160

Available consumables

Spare parts

Product name	Description	Catalogue number
Power cable	Power cable	REF 4340612001
Power supply unit USB-C/5V/3.6A	Power adapter with USB-C output without power cable	REF 9963138001

Available spare parts

Commercially available accessories

The following commercially available accessories can be connected to the device:

- USB keyboard
- USB device, FAT-32 format (max. 16 GB)
- Wi-Fi stick
- Ethernet LAN cable, quality CAT5 or higher

Safety

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General safety information

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Safety classifications

The safety precautions and important user notes are classified according to the applicable standards. Familiarize yourself with the following meanings and icons:

⚠ Safety alert

- The safety alert symbol is used to alert you to potential physical injury hazards. Obey all safety messages that follow this symbol to avoid possible damage to the system, injury, or death.

These symbols and signal words are used for specific hazards:

⚠ WARNING!

Warning...

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

⚠ CAUTION!

Caution...

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

NOTICE!

Notice...

- ...indicates a hazardous situation which, if not avoided, may result in damage to the system.

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

Tip...

...indicates additional information on correct use or useful tips.

Safety precautions

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

Insufficient knowledge and skills

To ensure correct operation of the device:

- Only healthcare professionals may operate the device.
- Users must have received a comprehensive instruction in the operation, QC, and care of the device.

Safe and proper use of the system

Do not use the device, test and calibration strips, or QC material if they are damaged.

Make sure the power supply of the device is always accessible so that you can disconnect it in an emergency.

The device is only suitable for indoor use.

Non-specified consumables and accessories

Use of non-specified consumables and accessories may result in malfunction of the system and may render the warranty null and void.

- Only use consumables and accessories specified by Roche Diagnostics.

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

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

Electromagnetic compatibility (EMC)

The system complies with the emission and immunity requirements described in IEC 61326-2-6. It has been designed and tested to CISPR 11 Class B.

Electrostatic discharge (ESD)

The device complies with the electrostatic discharge (ESD) immunity requirements as specified in IEC 61326-2-6. Electrostatic discharge (ESD) is an electrical charge at rest, most commonly known as static electricity.

To avoid ESD, do not use the meter in a very dry environment, particularly one in which synthetic materials (e.g., carpets) are present. This might cause damaging static discharges.

Wireless connectivity

The device supports Wi-Fi as an alternative network connection. Be aware that the device transfers sensitive data such as test results, patient IDs, user IDs, etc. to the data management system. Make sure the Wi-Fi connection is configured by the system administrator only and meets your facilities' IT regulations.

Warning messages

⚠ List of warning messages

Failure to observe warning messages may result in death or serious injury.

- Before using the system, read the warning messages with care.

False test measurement

To avoid harmful outcomes resulting from false test measurements, ensure the following:

- Only use a urine sample when running a patient test.
- Regularly perform QC tests.
- Carefully follow the storage, handling, and result interpretation instructions provided by the QC material manufacturer.
- Only use consumables and accessories specified by Roche Diagnostics.
- Do not use the device outside the specified temperature range.
- Test and calibration strips are single use only. Never reuse a strip.
- Do not use expired or damaged consumables.
- Carefully follow the test strip handling described in the package insert and the Operator's Manual.
- Do not use a test strip tray that is in use longer than 18 months.
- Do not touch the reference pad. Carefully handle it during cleaning procedure.
- Do not use any other USB-C power supplies.

Protection against infection and pathogens

Healthcare professionals using the device to run tests must be aware that any object coming into contact with urine samples of human origin is a potential source of infection.
Users must adhere to standard precautions when handling or using the device.
All parts of this system should be considered potentially infectious and are capable of transmitting pathogens between patients, and between patients and healthcare professionals.

- Use disposable gloves.
- Wash hands thoroughly with soap and water before putting on a new pair of gloves and running the next test.
- Dispose of used test strips from patient according to your healthcare facility's infection control policy.
- Follow all local health and safety regulations.

Avoiding electrical shock, fire, and explosions

- Only use the Roche original power cable and power adapter.
- The device must only be operated with the prescribed power adapter (Class III protection). The device is classified as Category II protection for overvoltage and Degree 2 for pollution according to IEC 664.
- Do not use loose power outlets or damaged power supplies, cables, or plugs.
- Do not short circuit the power supplies.
- Do not drop the device or power supply, and protect them against shaking and vibrations.

Risk of injury by electronic equipment

Opening covers or removing parts of the device may expose voltage-carrying components. Connectors can be live, too.

- Do not remove any cover of the device, except where this can be achieved manually without the use of any tools.
- Never try to maintain or repair an open device which is carrying voltage.
- Do not attempt to work in any electronic compartment.

Risk of barcode read errors

If a barcode is read incorrectly, it may lead to patient misidentification and inappropriate therapy decisions.

- When creating patient or user barcodes, always adhere to the applicable international IEC/ISO standards for the respective barcode symbology.
- Make sure barcode size and print quality are adequate as defined in the manual of the used barcode reader.
- Carry out a plausibility check on all data scanned into and displayed by the device.

Caution messages

⚠ List of caution messages

- Before operating, read the caution messages with care. Failure to observe them may result in minor or moderate injury.

Allergy or injury caused by reagents and disinfectants

Direct contact with reagents, or disinfectants may cause skin irritation or inflammation.

- Always wear disposable gloves.
- Observe the cautions given in the package inserts, or healthcare facility instructions of the reagents and disinfectants.

Unauthorized system access and data loss

If the system is connected to a local area network, this network must be protected against unauthorized access. In particular, it must not be connected directly to any other network or the internet.

Users are responsible for the security of their local area network, especially in protecting it against malicious software and attacks. Failure to do so may result in data loss or may make the system unusable.

Roche recommends the following precautions:

- To protect access to all external devices, ensure to use appropriate security equipment. For more information, contact your local Roche representative.
- Make sure that the connected network is free of malicious code.
- Regularly scan attached IT systems for security vulnerabilities.

Password management

Observe your facility's guidelines on password management where available and apply the following rules:

- Passwords must contain between 3 and 32 characters.
- Passwords must contain characters that are defined in the virtual keyboard.
- Passwords are case sensitive.

Notices

⚠ List of notices

Failure to observe the notices may result in damage to the system.

- Before using the system, read the notices with care.

General care

Using cleaning solutions and disinfectants not specified in this publication may result in incorrect operation and possible failure of the device.

- Only clean the device with the recommended cleaning solutions and disinfectants.

Acceptable cleaning solutions and disinfectants (126)

- Make sure the device is thoroughly dried after cleaning and disinfection.

Daily cleaning and disinfecting the device (127)

Safety information for disposal

Disposal of the device

Infection by a potentially biohazardous device.

- The device or its components must be treated as potentially biohazardous waste. Decontamination (i.e., a combination of processes including cleaning and disinfection) is required before recycling, or disposal.
- Dispose of the device or its components according to the appropriate local regulations. For more information, contact your local Roche representative.

Recommendations for the protection of personal data and software security

Potentially sensitive personal information may be stored on the instruments locally and transferred over the network.

After results are sent to the DMS, they remain on the instrument. This is a patient safety measure enabling the user (such as a nurse) to look up previous patient measurement results when the network or DMS is unavailable.

You should consider the following recommendations to prevent unauthorized access or manipulation of data.

Access control

Unauthorized access may lead to data breaches.

- Implement physical access controls to ensure that only authorized personnel operate the system at all times.
- Assign a personal, unique user ID to each user for system access.
- Assign access rights to each user only as high as required for the tasks of the user.
- Delete user IDs from the system for users who no longer work on the system.
- Be aware of password security rules.
- Do not leave a device unlocked in publicly accessible areas.

User authentication

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

- Always enter your password unobserved.
- Do not write down your password anywhere, including in a contact form, in the address book, or in a file on the computer.
- Do not disclose your password to anyone. Roche will never ask you for your password.
- If you ever disclose your password to anyone, change it immediately afterwards.
- Contact your local Roche affiliate if you think your account has been compromised.
- Delete users who are no longer needed on the device and use the standby time function for automatic logoff on inactivity.
- Ensure that users log off the device when they have finished using it.

Network security

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

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

Secure network connections

Use **WPA/WPA2** encryption to protect your data and wireless connection. The default setting on the device is **No**, which means the encryption is disabled.

Secure network environment

When connecting Roche Point of Care devices to a local area network, the network must be protected against unauthorized access. It must be resilient to traffic redirection and eavesdropping. In particular, it must not be linked directly to any other network or the internet.

Protection includes measures such as a firewall to separate the device from uncontrolled networks, or measures to ensure that the connected network is free from malicious code.

Personal computer connections

Any personal computer to which the device is connected must meet the EN 60950, UL 60950/CSA C22.2 No. 60950 requirements for data processing equipment.

Data entry and data transfer

Writing patient-sensitive information can violate protection laws for protected health information.

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

Deleting data from the device

Before disposing of a device, delete the stored data using the corresponding function.

Data security

⚠ CAUTION!

Monitor the system for suspicious activity and report suspected compromise

If you find any of the typical signs of malicious software or unauthorized access to the system (unexpected warning messages, files, or log entries like multiple failed logon attempts; significantly degraded user interface performance; seemingly random crashes of the system; automated typing of text; and so on), the following recommendations are essential:

- Physically disconnect the system from the network.
- Contact the IT responsible in your organization to report and verify the finding.
- Mistrust results produced while the system has been compromised.
- Contact your local Roche representative for evaluation.

⚠ CAUTION!

Data loss or unavailability of the system due to malicious software or unauthorized system access

Malicious software or unauthorized system access can result in data loss or system unavailability.

To avoid infection by malicious software or the unauthorized access and misuse of the system, the following recommendations are essential:

- Make sure other computers and services on the network (for example, the LIS, archiving share, backup share, or service) are properly secured and protected against malicious software and unauthorized access.
- Restrict physical access to the system and server and all attached IT infrastructure (computer, cables, network equipment, and so on).
- Store related removable media in a safe place.
- Ensure that all device components maintaining private data are physically secure (i.e. require a physical key to be accessed or removed).
- Check all external storage devices, like CDs, DVDs, or USB mass storage devices with an antivirus software (on another computer) to ensure that they are free of malicious software, before using them on the system.
- Implement security and authentication measures for removable media (i.e. USB flash drives, CD-ROM/DVD, tapes, etc.).
- Use state-of-the-art security mechanisms (e.g. WPA2 EAP, if supported) to protect Wi-Fi connections, if you use a Wi-Fi stick.
- Allow only defined users to read and write encryption keys (IIS App config/Windows Server Hardening).
- Allow only internet access to trusted web sites and web services.
- Enable Data Execution Prevention for all applications (Windows server).
- Make sure to use secure channels to download software updates of the system.

⚠ CAUTION!

Unauthorized access to the system configuration

Unauthorized access to the system configuration (administration interface, configuration store, query packages) can lead to system failure, corrupted data, and unauthorized disclosure of protected health information.

- Make sure that your Wi-Fi connections are properly secured.
  - If supported, use EAP security for Wi-Fi connections.

⚠ CAUTION!

Unauthorized access to confidential data

Unencrypted communication can lead to unauthorized access to confidential data.

- Use encrypted communication channels from the application.
- Contact IT support of your institution when a security warning related to the digital certificate is displayed.

⚠ CAUTION!

Sensitive data - data tampering in transmission

Unprotected Wi-Fi connections between devices and the application can lead to unauthorized data access and tampering.

- Make sure that your Wi-Fi connections are properly secured, if you use a Wi-Fi stick.
- If supported, use EAP security for Wi-Fi connections.

⚠ CAUTION!

Data loss and disaster recovery

Unexpected disasters, such as hard disk failures, system software failures, or natural disasters such as fires or floods can occur.

- The Customers IT department must assemble a disaster recovery kit to protect the entire system.
- Ensure that backups are made regularly (ideally ever day) and stored securely.

NOTICE!

Data transmission is not secured

Unsecured communication can compromise the integrity and confidentiality of the transmitted data. It is the customer's responsibility to ensure that the network infrastructure provides appropriate protection for the transmitted data.

- Such protection can be achieved by system level tunneling protocols or other means of network encryption.

NOTICE!

Data is not encrypted

- Data in the database is not generally encrypted. It is the customer's responsibility to ensure that access to the data storage and backup files is permitted only to authorized entities.

Secure data storage

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

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

Cybersecurity and privacy awareness

Insufficiently informed employees can endanger security.

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

Use of storage devices

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

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

Data backup

Data may get lost due to memory failures.

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

Non-approved third-party software

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

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

System description

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Overview of the system

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About the system

The **Urisys 1100**® is a reflectance photometer designed to read and evaluate urine test strips.

The system can do the following:

- Perform patient tests and QC tests with QC material.
- Perform calibration.
- Print out test results.
- Store test results and consumable information (lot number, expiry date).
- Display stored information.
- Export stored information via network or to USB mass storage.

This system comprises the following components:

A Device
B Power adapter (with USB-C connector and status LED)
C Power cable (with connector to power inlet)
D Test strip tray (type C)
E Printer paper

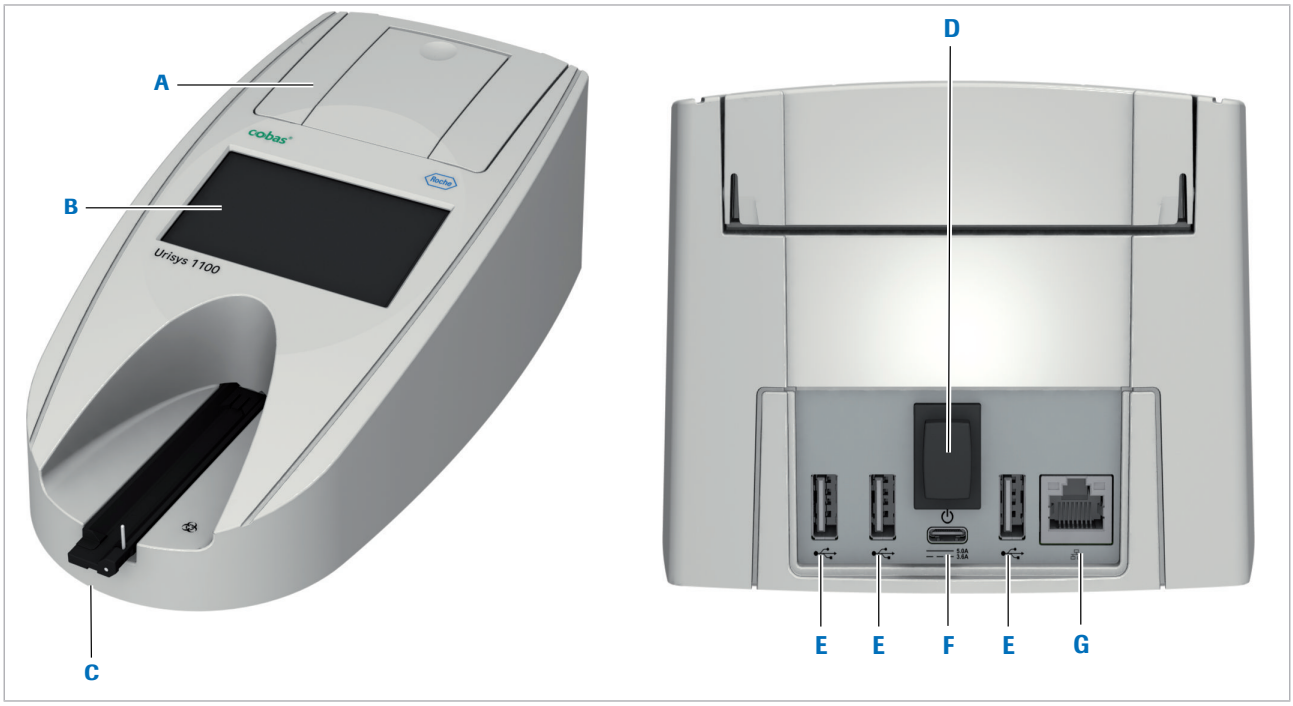
System components

Configuration options

The system is configurable. For that reason, some screens and procedures in your healthcare facility might differ slightly from the ones in this publication.

About the device

Components



A Printer cover
B Display/touch screen
C Test strip tray (with retaining bar)
D Power switch
E USB-A port
F USB-C port to connect the power adapter
G LAN port (Ethernet RJ-45)

Main device components top and front (left) and rear (right)

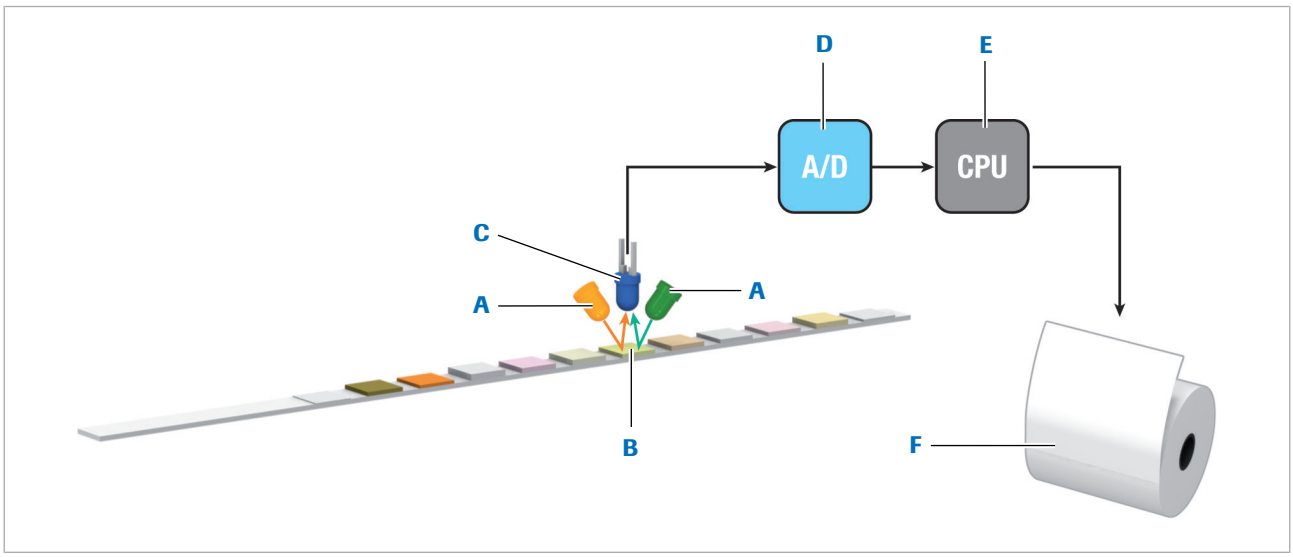
The components of the device have the following functions:

Printer cover	Covers the printer and the printer paper.
Display/touch screen	Enables you to interact with the device by tapping the appropriate interface elements on the screen.
Test strip tray (with retaining bar)	Holds and anchors the strip.
Power switch	Powers the device on.
USB-A port	Enables connection to accessories (e.g., a keyboard, a USB device, a Wi-Fi stick, or a barcode reader).
USB-C port	Connects the device to the power adapter only.
LAN port (Ethernet RJ-45)	Enables connection to a wired network.

Measuring principle

The test strip is placed on a sliding tray. A stepping motor moves it under the reading head, which remains stationary. The device reads the reference pad, followed by each of the test pads on the strip.

The reading head contains LEDs that emit light at various wavelengths. Reading is done electro-optically, as follows:



A LED
B Test pad
C Phototransistor
D Analog-to-digital (A/D) converter
E Microprocessor
F Result

Measuring principle

The LED (**A**) emits light of a defined wavelength onto the surface of the test pad (**B**) at an optimum angle. The light hitting the test zone is reflected proportional more or less intensely depending on the color produced on the test pad, and is picked up by the detector, a phototransistor (**C**) positioned directly above the test zone. The phototransistor sends an analogue electrical signal to an analog-to-digital converter (**D**), which converts it to digital data. The microprocessor (**E**) then converts this digital reading to a relative reflectance value by referring it to a calibration standard.

Finally, the device compares the reflectance value with the defined range limits (reflectance values that are programmed into the device for each parameter) and outputs a semi-quantitative result (**F**).

Each test pad is read photometrically after about 55 seconds. In strongly alkaline urine samples, the device automatically corrects the result of the specific gravity test.

Software overview

The software provides a user interface that enables all specific settings and recurrent functions to be selected via the touch screen display.

For more information, see:

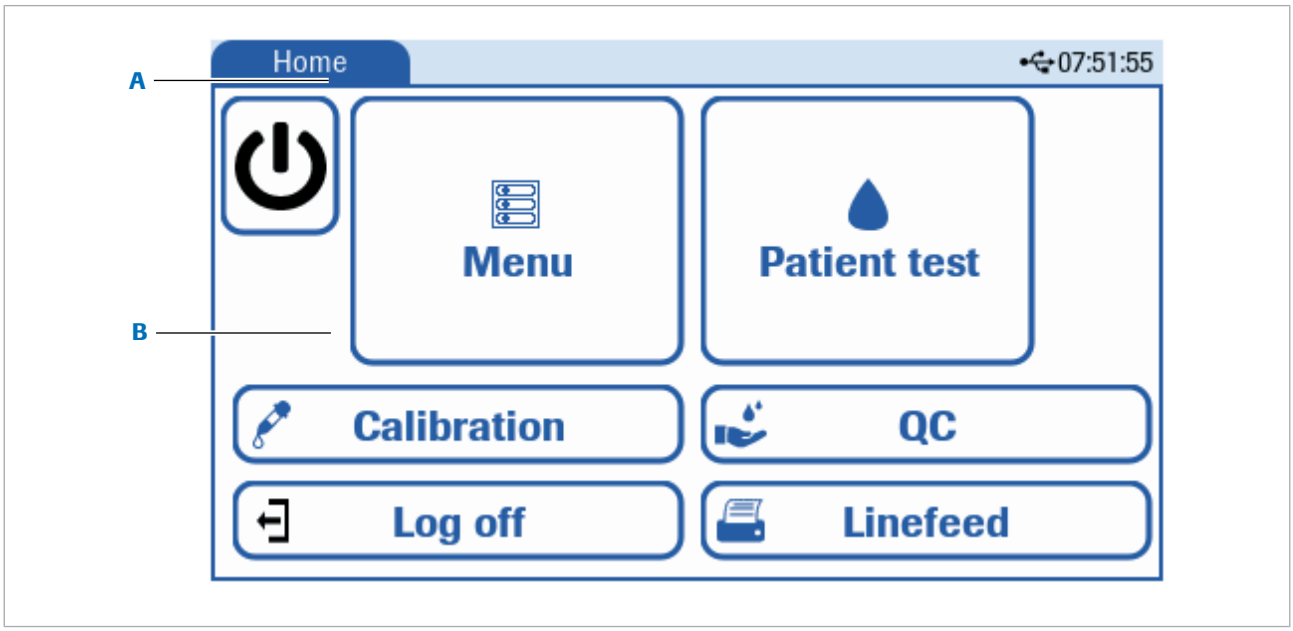
Menu structure (Flowchart) (45)

The user interface is designed to be self-explanatory, therefore only details of the major functions are presented here.

The device switches from the Ready-to-Measure status or the status displayed, respectively, to the Standby mode after the configured time of inactivity. During Standby, the date and time are displayed. The Ready-to-Measure status can be resumed by tapping the touch screen, except when certain error messages are displayed.

For more information, see:

Error messages and troubleshooting (130)



A Status bar

B Main panel

User interface

The screen has 2 components:

- Status bar
- Main panel

Status bar

The status bar contains the following information:

- Current time
- Status information (e.g., warnings, or connected USB device)
- Navigation path

Status bar icons (48)

Main panel

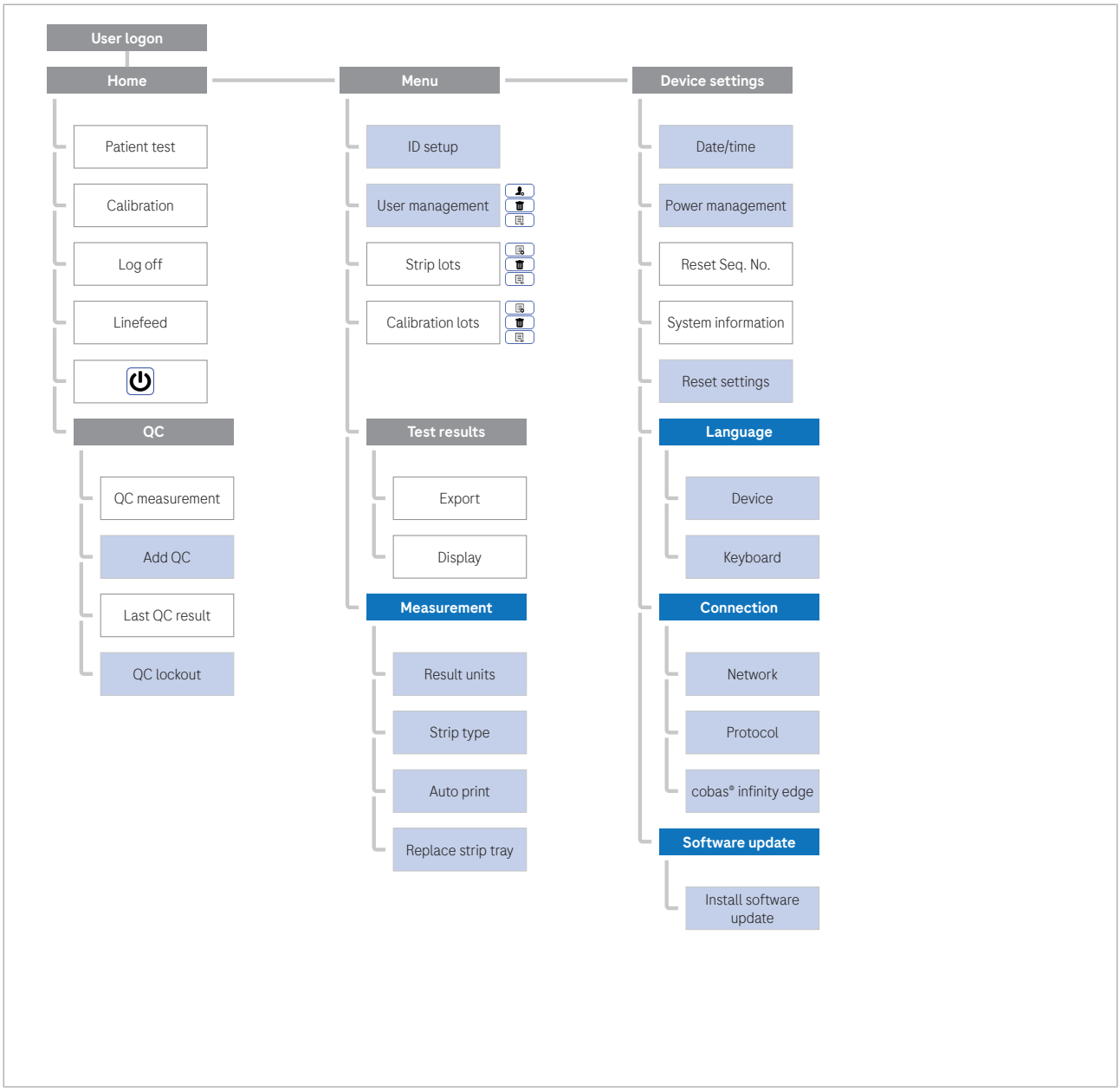
The main panel contains all menu functions. By tapping the appropriate buttons on the touch screen display, you can run measurements, perform calibrations and QC tests, and manage settings and results.

Menu structure (Flowchart)

The flowchart below provides a visual overview of the menu structure and how to access the various device settings and functions.

Device configuration and user rights determine what you can access on your device.

Functions highlighted in blue are only accessible with administrator rights.



Menu structure

Buttons and icons overview

The following buttons and icons are displayed on the screen during operation.

Buttons and icons in the main panel

Button/icon	Meaning
	Insert strip
12H	12 h time format
24H	24 h time format
	Add
AM	Before noon
PM	After noon
	Navigation to the right
	Navigation to the left
	Navigation down
	Navigation up
	Backspace
	Calibration
	Cancel/discard
	Cursor backwards
	Cursor forward
	Edit
	Error
	Transfer
	Hide
	Home

Buttons and icons in the main panel

Button/icon	Meaning
	Info
	QC material level 1
	QC material level 2
	QC material level 3
	Navigate to the previous screen
	Logoff
	Menu
	Multi-select
	Define a new user
	Power off
	OK/save
	Initial password
	Add
	Print
	Linefeed
	QC
	Redo
	Reset to default
	Display
	Test
	Timer. Wait until the action is complete
	Delete
	Warning
	Selected check box

Buttons and icons in the main panel

Button/icon	Meaning
	Cleared check box
	Chosen *All* option for multiselection
	Chosen option

Buttons and icons in the main panel

Status bar icons

Button/icon	Meaning
	cobas® infinity edge connected
	LAN connected
	Printing
	Uploading
	Download available
	USB device connected
	Warning
	Wi-Fi connected

Status bar icons

Results table

Urine test strip measurement values can be reported in either conventional units, SI units, or arbitrary units. The following table lists the concentration levels that are reported for each format.

Parameter	Conventional units (Conv.)	SI units (SI)	Arbitrary units (Arbitr.)
SG (Specific gravity)	1.000	1.000	1.000
	1.005	1.005	1.005
	1.010	1.010	1.010
	1.015	1.015	1.015
	1.020	1.020	1.020
	1.025	1.025	1.025
	1.030	1.030	1.030
pH	5	5	5
	6	6	6
	6.5	6.5	6.5
	7	7	7
	8	8	8
	9	9	9
LEU (Leukocytes)	neg	neg	neg
	25 Leu/µL	25 Leu/µL	TR
	75 Leu/µL	75 Leu/µL	+
	500 Leu/µL	500 Leu/µL	++
NIT (Nitrite)	neg	neg	neg
	pos	pos	+
PRO (Protein)	neg	neg	neg
	TR	TR	TR
	30 mg/dL	0.30 g/L	+
	100 mg/dL	1.00 g/L	++
	500 mg/dL	5.00 g/L	+++

Results table

Parameter	Conventional units (Conv.)	SI units (SI)	Arbitrary units (Arbitr.)
GLU (Glucose)	norm	norm	norm
	50 mg/dL	3 mmol/L	TR
	100 mg/dL	6 mmol/L	+
	250 mg/dL	14 mmol/L	++
	> 1000 mg/dL	> 56 mmol/L	+++
KET (Ketone)	neg	neg	neg
	15 mg/dL	1.5 mmol/L	+
	50 mg/dL	5 mmol/L	++
	150 mg/dL	15 mmol/L	+++
UBG (Urobilinogen)	norm	norm	norm
	1 mg/dL	17 µmol/L	+
	4 mg/dL	68 µmol/L	++
	8 mg/dL	135 µmol/L	+++
	≥ 12 mg/dL	≥ 203 µmol/L	++++
BIL (Bilirubin)	neg	neg	neg
	1 mg/dL	17 µmol/L	+
	3 mg/dL	50 µmol/L	++
	6 mg/dL	100 µmol/L	+++
BLD (Erythrocytes)	neg	neg	neg
	TR	TR	TR
	50 Ery/µL	50 Ery/µL	+
	250 Ery/µL	250 Ery/µL	++

Results table

Technical specifications

Item		Value
Dimensions	Width	150 mm
	Depth	287 mm
	Height	102 mm
Weight		≤ 1.0 kg
Power supply		USB-C power supply
	Input	100–240 V AC, 50/60 Hz, 600 mA
	Output	5 V DC, 3.6 A
Consumption	Operating	Max. 18 W
	Standby	1.3 W
Noise level		50 dB
System description	Type	Reflectance photometer
	Light source	6 LEDs (light-emitting diodes)
	Wavelengths	• 555 nm (green) 3x • 610 nm (orange) 3x
	Reader head	1 head with 6 LEDs
	Measuring cycle	• approx. 70 s
	Incubation time	Approx. 55 s
	Printer	Thermal printer
	Display	• 4.3" color touch screen • RGB TFT-display with 480 x 272 pixels
	Memory	1000 samples
	Date, time	Integrated clock
Interfaces	Devices	3 × USB port type A
	Network	LAN port (Ethernet RJ-45)
	Communication	• CSV file export to USB device • **cobas® infinity** POC system (unidirectional, bidirectional, or ASTM) • **cobas® infinity** edge system
	Barcode reader	Via USB port type A
	Keyboard	Via USB port type A
Registrations		• CLIA • cULus
Consumables	Test strips	• Chemstrip® 10 MD • Chemstrip® 10 UA
	Calibration strip	• Chemstrip® Calibration Strips

Technical specifications

Item		Value
Operating conditions	Location	The device is designed for indoor use only.
	Altitude	2000 m
	Temperature	• +15°C to +32°C • +59°F to +90°F
	Relative humidity	20% to 80%
Storage conditions	Temperature	• -5°C to +45°C • +23°F to +113°F
	Relative humidity	Up to 85%
Transport conditions	Temperature	• -25°C to +70°C • -13°F to +158°F
	Relative humidity	Up to 85%
Lifetime	Test strip tray	18 months after first date of use, or after 10 000 measurements
	Device	5 years after date of manufacture, or after 35 000 measurements
Strip throughput		• Approx. 45 strips/hour
Extraneous light	In-house	Without influence on measured values: • 20 000 lux daylight • 1000 lux artificial light

Technical specifications

Operation

3 Installation 55
4 Routine and non-routine operation 63

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Installation

In this chapter 3

Getting started 57
About logging on/off 59
Logging on using auto logon 59
Logging on manually 60
Logging off 60
Waking the device from standby mode 61

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Getting started

⚠ WARNING!

Read the Operator's Manual carefully before installation, so as to ensure proper operation of the device from the outset.

NOTICE!

If your device has been exposed to considerable changes in temperature and/or humidity, wait for it to acclimatize sufficiently for at least 4 hours before using it.

NOTICE!

Upon receipt, check the contents of the packaging for completeness. If the contents have suffered any damage in transport, contact your local Roche representative.

⚠ CAUTION!

To ensure your readings are always accurate, do not set up the device in close proximity to devices that create high-frequency fields, as they may interfere and produce false results. Such devices include, for instance, walkie-talkies, mobile telephones, microwave ovens, and diathermic equipment.

To get started

1 Unpack the system and place it on a stable, level surface.

ⓘ Do not expose the device to direct sunlight or other source of direct light (for example a spot lamp). Make sure the power supply of the device is always accessible so that you can disconnect it in an emergency.

2 Insert the test strip tray. Inserting the test strip tray (81)

3 Insert the printer paper roll. Inserting printer paper (82)

4 Connect the power cable to the power adapter and to a readily accessible mains connector.

- The status LED lights up green when the power cable is connected to mains power and the adapter is ready to power the device.

5 Connect the power adapter to the USB-C port at the rear of the device.

To power on the device

1 At the back of the device, press the power switch.
   ➔ The device is powered on and performs a self-check.
   ➔ On completion of the self-check, the test strip tray is transported to the start position and the retaining bar opens. A printout containing the **Self check OK** info and the date and time stamp is generated.
   ➔ Depending on your defined user identification option, the **User logon** or the **Home** screen is displayed.

To power off the device

1 On the **Home** screen, tap the ⏻ button.
   ➔ The devices is powered off.

Related topics

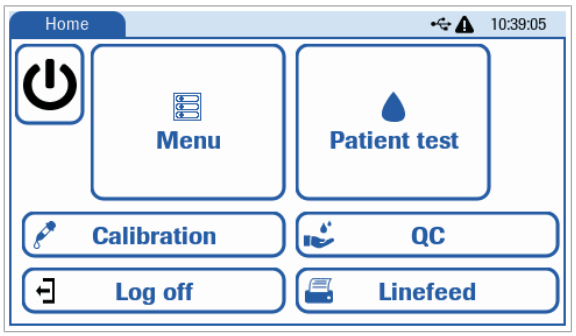
- About the system (39)
- About the device (40)

About logging on/off

After powering on the device or waking it from the standby mode, a logon is required. Depending on your defined user identification option, you are either automatically logged on or you have to enter your credentials.

For more information on user identification options, see:

ID setup (114)



If you log on after powering on the device, the **Home** screen is displayed.

In this section

Logging on using auto logon (59)

Logging on manually (60)

Logging off (60)

Waking the device from standby mode (61)

Logging on using auto logon

If you enabled either the **Auto logon (Administrator)** option or the **Auto logon (Operator)** option, you do not have to enter a user ID and/or a password.

To log on using auto logon

1 Power on the device or wake it from standby mode.
   ➔ You are automatically logged on.
   ➔ The **Home** screen or your previously active screen is displayed.

Logging on manually

You can enter logon information either by using the keyboard or by scanning the appropriate barcode using a barcode reader.

Connecting USB devices (117)

Barcode reader setup (119)

To log on manually

1 On the **User logon** screen, enter your user ID or choose it from the user list and tap the ✓ button.

➔ If you enabled the **No password required** option, you are logged on.

2 Enter your password and tap the ✓ button.

When entering your password, the characters are displayed as asterisks (*). By choosing the button, you can make your password visible to, e.g., check for correctness. To hide your password again, choose the button again.

➔ If you enabled the **Password** option, you are logged on.

➔ The **Home** screen or your previously active screen is displayed.

Logging off

After measurements are complete and you are not using the device anymore, log off the currently logged on user.

You can also define an auto logoff timeout, for more information see:

Auto logoff timeout (66)

To log off

1 On the **Home** screen, tap the **Log off** button.

➔ The user is logged off and the **User logon** screen is displayed.

Waking the device from standby mode

Depending on your **Power management** settings, the device switches to standby mode after the defined time of inactivity.

Setting the power management options (101)

To wake the device from the standby mode

1 Tap on the screen.
   ➔ The device wakes from standby mode.
   ➔ Depending on the device's configuration, the **User logon** screen or the previously active screen is displayed.

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Routine and non-routine operation

In this chapter 4

About reading test strips 65
Entering information about consumables 67
Entering test strip lot information 67
Entering calibration lot information 69
Entering QC material information 70
Performing a measurement 72
Result handling 76
About test results 76
About the patient report 77
Displaying test results 78
Deleting, uploading, or printing test results 79
Exporting test results or log files 80
Inserting the test strip tray 81
Inserting printer paper 82
Calibration 83
Performing a calibration 83
Quality control (QC) 86
Performing a QC measurement 86

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About reading test strips

A test is performed as follows:

- After tapping the **Patient test** button, the **Patient test** screen is displayed.
- The display instructs you to insert the test strip. Insert the test strip and start the measurement process.

The device automatically waits for the test strip to incubate for 55 seconds before it reads the first test pad. 70 seconds after you have tapped the **Patient test** button, the measurement is completed and the test strip tray moves to the start position. Throughput is approximately 45 strips per hour.

Each time a test strip is read, the grey reference pad in the test strip tray is evaluated to compensate for temperature and aging effects that may influence the optical system. If the compensation needed is excessive, for example because the reference pad is badly soiled or an LED is defective and cannot emit the required amount of light, an error message is displayed.

Sequence number

To each measurement, the device assigns a consecutive sequence number (sample sequence number) of maximum 5 digits. You can reset the sequence number to 1 using **Menu > Device settings > Reset Seq. No.**, e.g., when one series of measurements has been completed and another one is due to begin.

Patient ID

You have the following options to enter patient IDs:

- The device can automatically assign a patient ID (**Pat. ID**) to each measurement. These unique numbers are ascending serial numbers based on the total number of tests performed on the device and cannot be altered nor cleared. You can enable automatic patient IDs in **Menu > ID setup > Auto patient ID**.
- You can manually enter the patient IDs or add them using a barcode reader.
- You can leave the **Pat. ID** field empty.

Standby mode

If enabled, the device automatically switches to standby mode after the configured time of inactivity. The test strip tray advances slightly so as to close the retaining bar, and the display shows the date and time. The device resumes Ready-to-Measure status when the display is touched. You can define the standby mode in **Menu > Device settings > Power management > Standby time**.

Auto logoff timeout	If enabled, the logged on user is automatically logged off after the configured time of inactivity. You can define the automatic logoff in **Menu > Device settings > Power management > Auto logoff timeout**.

Entering information about consumables

The device stores and uses information about consumables used for patient tests, QC, and calibration. This information has to be entered before any test can be performed. The device stores the following information:

- Test strip lots
  - Strip lot type (automatically preselected)
  - Strip lot number
  - Expiry date
- Calibration strip lots
  - Strip lot type (automatically preselected)
  - Strip lot number
  - Expiry date
- QC
  - QC material
  - QC lot number
  - Expiry date
  - Level
  - Target ranges

In this section

Entering test strip lot information (67)

Entering calibration lot information (69)

Entering QC material information (70)

Entering test strip lot information

The test strip lot information to be entered on the device can be found on the packaging/container of the test strips.

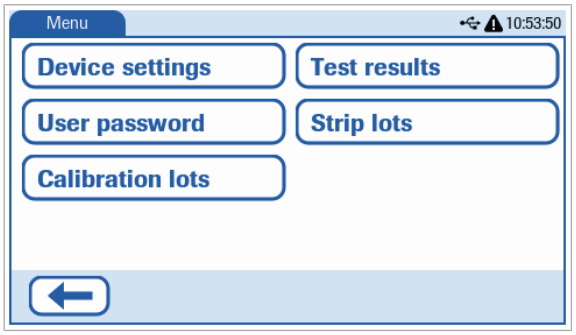
You can enter test strip lot information the following ways:

- By using the keyboard and tapping on the screen
- By scanning the appropriate barcode on the packaging of the test strips using a barcode reader.

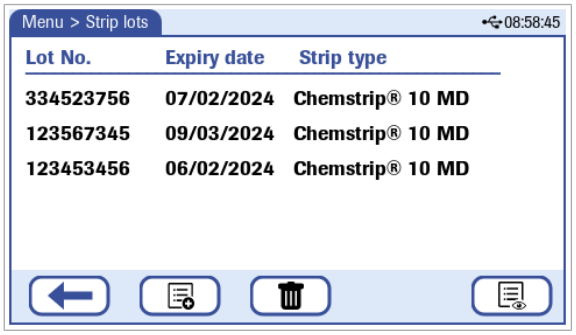
Connecting USB devices (117)

Barcode reader setup (119)

To enter strip lot information

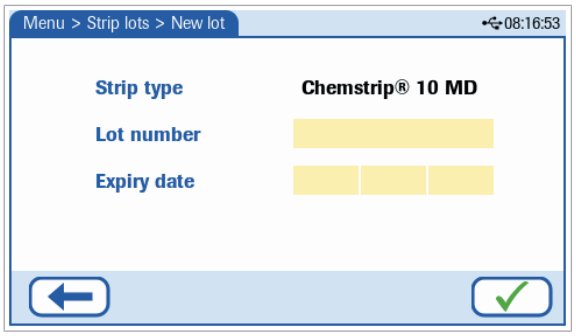


1 Choose **Home > Menu > Strip lots**.



2 To enter a new strip lot, on the **Strip lots** screen, tap the button.

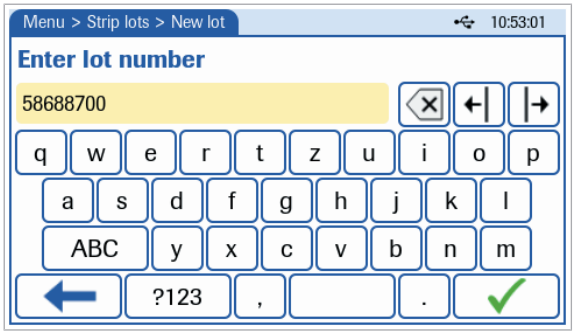
➔ The **Menu > Strip lots > New lot** screen is displayed.



3 To enter the strip lot information using a barcode reader:

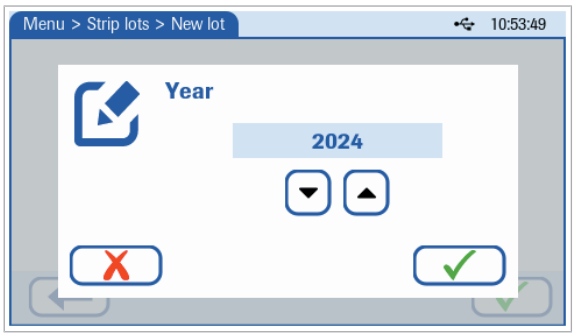
- When the **Menu > Strip lots > New lot** screen is displayed, scan the barcode on the packaging of the test strips.

➔ The lot number and expiry date of the test strips are automatically entered.



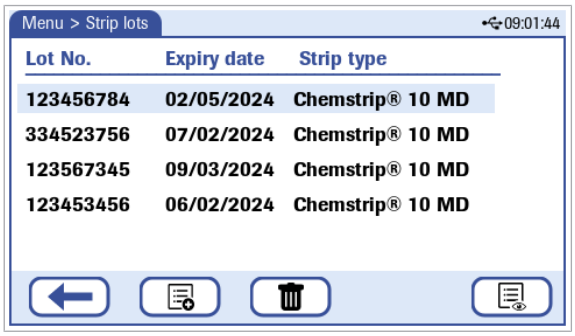
4 To enter the lot number using the keyboard, tap the yellow-highlighted **Lot number** entry field.

- To save, tap the ✓ button.



5 To manually define the expiry date of the strip lot, tap the yellow-highlighted empty fields for **Expiry date**.

- To adjust **Year**, **Month** and **Day** tap the ▲ and ▼ buttons.



6 To save your settings, tap the ✓ button.
→ The new lot is displayed in the **Strip lots** list.

Entering calibration lot information

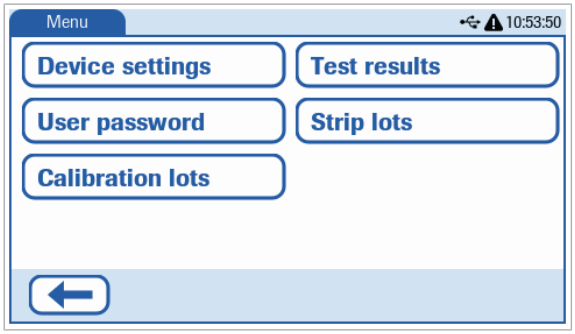
The calibration lot information to be entered on the device can be found on the packaging/container of the calibration strips.

You can enter calibration lot information the following ways:

- By using the keyboard and tapping on the screen
- By scanning the appropriate barcode on the packaging of the calibration strips using a barcode reader.

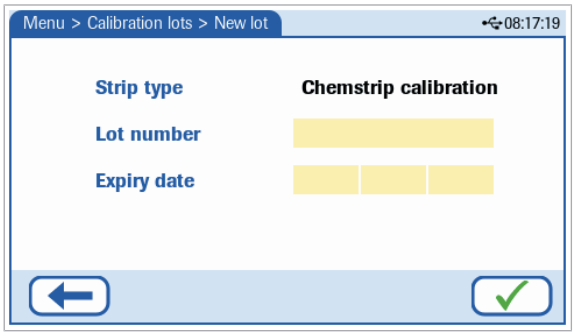
Connecting USB devices (117)
Barcode reader setup (119)

To enter calibration lot information



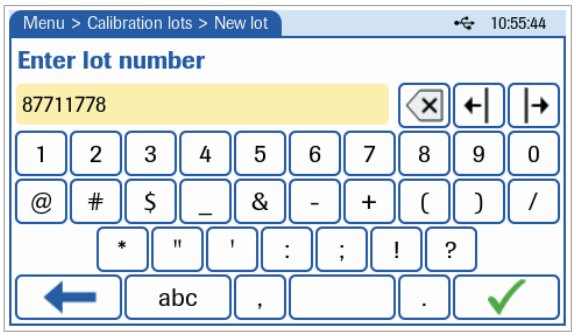
1 Choose **Home > Menu > Calibration lots**.

2 To enter a new strip lot, on the **Calibration lots** screen, tap the button.
→ The **Menu > Calibration lots > New lot** screen is displayed.

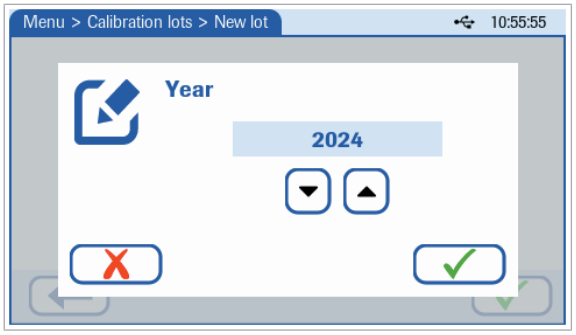


3 To enter the strip lot information using a barcode reader:
- When the **Menu > Calibration lots > New lot** screen is displayed, scan the barcode on the packaging of the calibration strips.

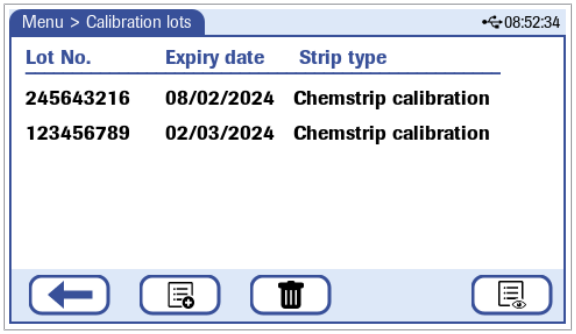
→ The lot number and expiry date of the calibration strips are automatically entered.



4 To enter the lot number using the keyboard, tap the yellow-highlighted **Lot number** entry field.
- Enter the lot number.
- To save, tap the ✓ button.



5 To manually define the expiry date of the strip lot, tap the yellow-highlighted empty fields for **Expiry date**.
- To adjust **Year**, **Month** and **Day** tap the ▲ and ▼ buttons.



6 To save your settings, tap the ✓ button.
→ The new lot is displayed in the **Calibration lots** list.

Entering QC material information

The QC lot information to be entered on the device in the next step can be found in the package insert of the QC material.

You will find the following information in the package insert:

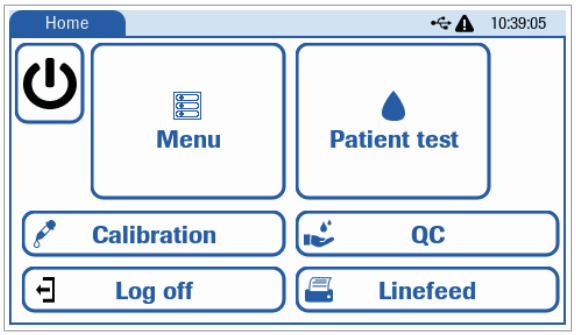
- Name of the QC material (**QC mat.**)
- Expiry date (**Expiry**)
- Lot Number (**Lot No.**)

In the package insert of the QC material, look for the following information:

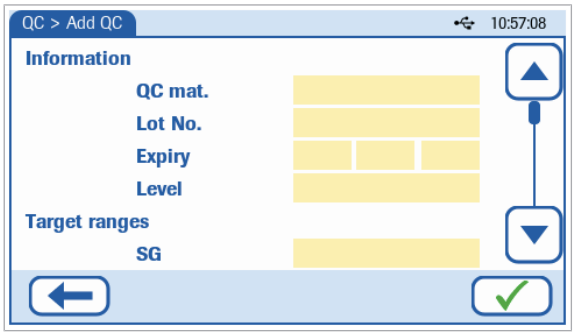
- Level 1 target ranges
- Level 2 target ranges
- Level 3 target ranges

Make sure to enter the target ranges for the **Urisys 1100®**.

To enter QC material information



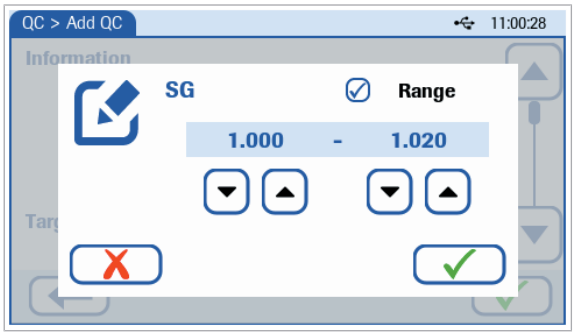
1 Choose **Home > QC > Add QC**.



2 To enter the required QC material information, in the **Information** section, tap the individual yellow-highlighted empty entry fields.

- To save your individual settings, tap the ✓ button.

ⓘ To scroll through all the entries available for the QC material, use the ▲ and ▼ buttons on the right side.



3 To define target values for the QC material, in the **Target ranges** section, tap the individual yellow-highlighted empty fields for the different parameters. You have the following options to define values:

- If the **Range** option is enabled (☑), you can define a target range.
- If the **Range** option is disabled (☐), you can define 1 target value.
- For the **NIT** parameter, choose the **neg** or **pos** option.

ⓘ To adjust values and ranges, tap the ▲ and ▼ buttons.

➔ To save, tap the ✓ button.

You can enable or disable the **Range** option by tapping the ☑ or ☐ check box left to **Range**.

4 To save all your settings, on the **Add QC** screen, tap the ✓ button.

Performing a measurement

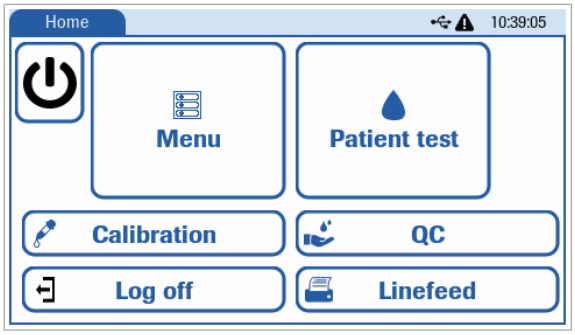
NOTICE!

To ensure that urinalysis is carried out correctly, read the package insert included in the test strip package.

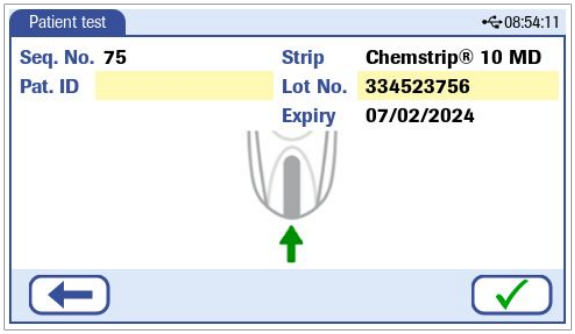
You have to enter the test strip lot information on the device before performing a measurement.

Entering test strip lot information (67)

To perform a measurement

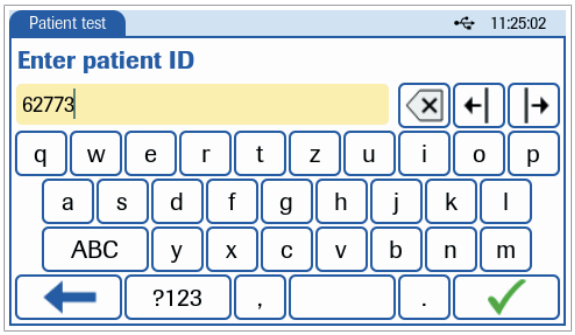


1 On the **Home** screen, tap the **Patient test** button.



2 On the **Patient test** screen, tap the yellow-highlighted **Pat. ID** entry field to enter a patient ID.

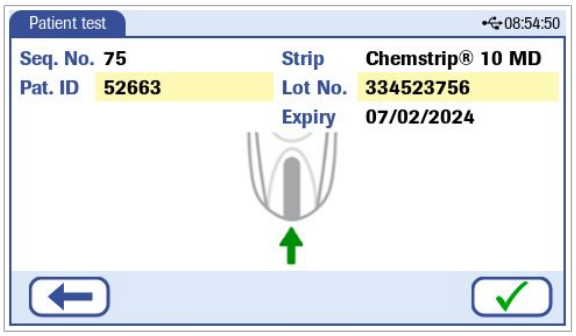
If you work with automatic patient IDs, this step does not apply.



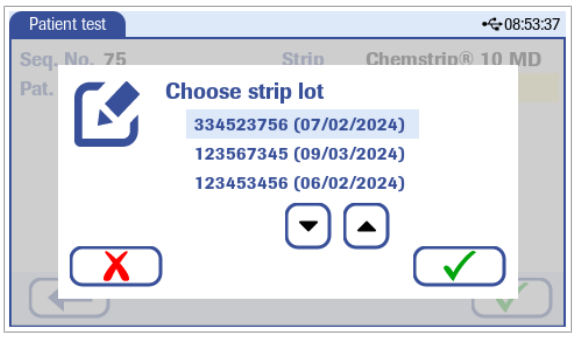
3 Enter the patient ID using the virtual keyboard or scan it using the barcode reader.

- To save and return to the **Patient test** screen, tap the ✓ button.

If you work with automatic patient IDs, this step does not apply.



4 On the **Patient test** screen, tap the yellow-highlighted **Lot No.** entry field to choose the strip lot you want to use.



5 To choose the strip lot you want to use, tap the ✓ button.

ⓘ If more than 3 lots are available, tap the ▲ and ▼ buttons to scroll.

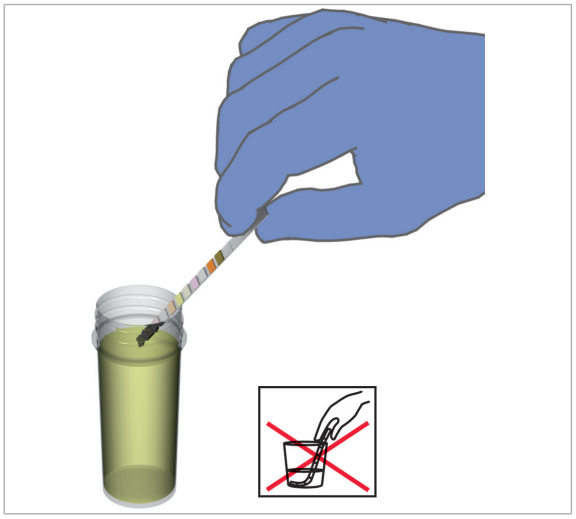
6 Tap the ✓ button.

➔ You return to the **Patient test** screen.

7 **NOTICE! To avoid incorrect readings due to a discoloration of the test strip pads, the vial of strips must be closed immediately after removal of a test strip, using the original desiccant-filled stopper.**

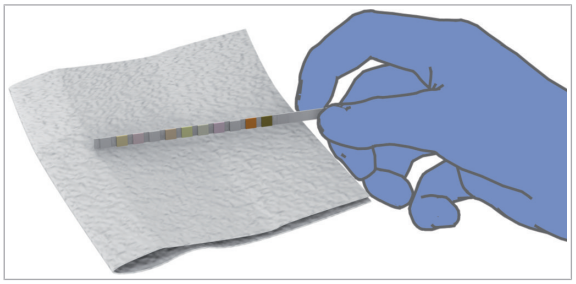
Take a test strip from the vial of strips.

8 Dip the test strip briefly (1 s) in the urine sample.



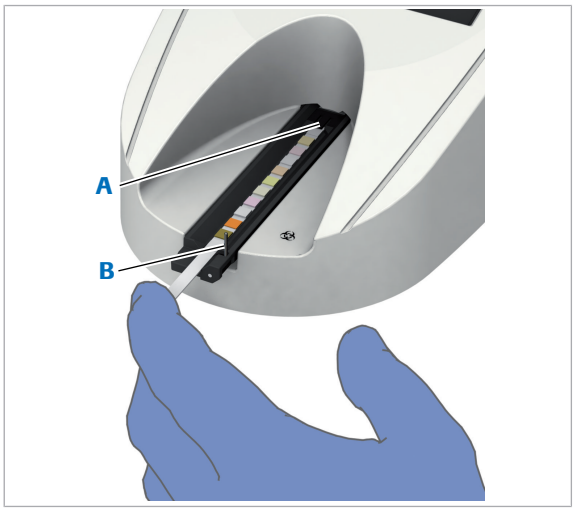
9 **CAUTION! Do not bend the test strip.**

Draw the long edge of the test strip along the rim of the sample container to remove excess urine.



10 Dab the long edge of the test strip lightly on absorbant paper to remove excess urine.

- Make sure that each pad is blotted.



11 Place the test strip, with the test pads facing upwards, on the test strip tray so that its leading edge is held by the clip (**A**) at the front end of the insertion slot. The retaining bar (**B**) must be open.

ⓘ About 2 mm of the test strip must be held under the clip (**A**). Do not bend the test strip.

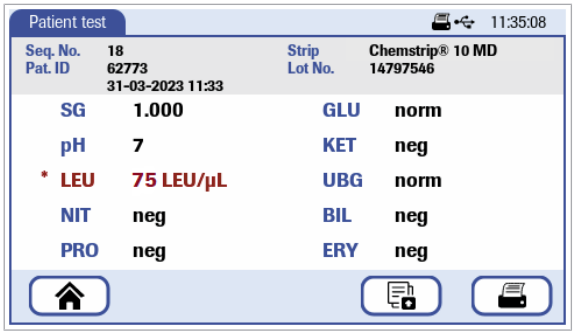
It is important that the test strip is correctly positioned and ready to be read within 5-10 seconds of dipping the test strip.

12 On the **Patient test** screen, to start the measurement process, tap the ✓ button

➔ After warming up, the test strip tray advances slightly, the retaining bar (**B**) closes, and the grey reference pad on the test strip tray is read.

13 CAUTION! If the test strip is not correctly located in the middle of the test strip tray, move it gently to the side until it is properly aligned (B).
Be careful not to move the test strip tray.

Ensure that the retaining bar is locked into place and that the test strip is in the correct position.

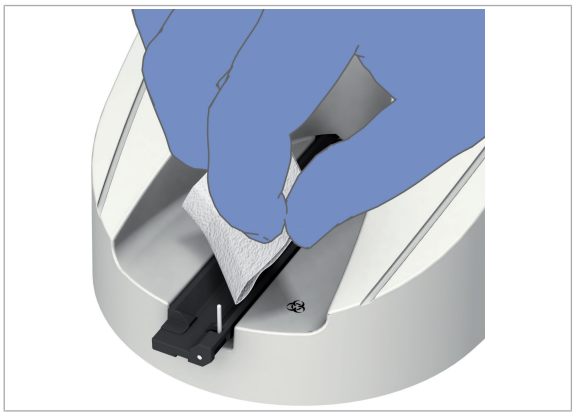


14 55 seconds after the measurement process has been started, the first test pad is measured, followed by the others.

➔ After that, the test strip tray returns to the start position and the retaining bar opens.

➔ The result will be displayed and, depending on your printing settings, printed out.

15 Remove and dispose of the test strip.



16 Wipe off any urine residues from the test strip tray with a lint-free cloth.

17 On the **Patient test** screen displaying the test results, to return to the **Home** screen, tap the ⌂ button.

Result handling

In this section

About test results (76)

About the patient report (77)

Displaying test results (78)

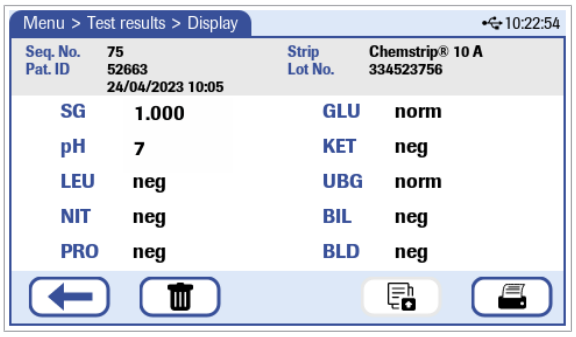
Deleting, uploading, or printing test results (79)

Exporting test results or log files (80)

About test results

Test results are stored for 60 days on the device.

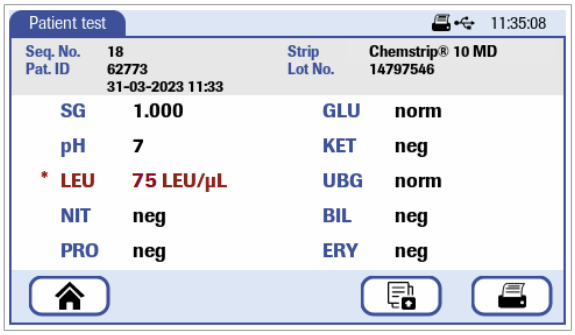
- After this time, they are automatically deleted from the database when powering on the device.
- If there are more than 50 test results to be deleted when powering on the device, a message informs you to wait until the deletion process has finished.



After each measurement, the test results are displayed (and stored) together with the following information:

- Sequence number (**Seq. No.**)
- Patient ID (**Pat. ID**)
- Date and time
- Strip type used for measurement
- Lot No. of used strip type

If you want to display test results at a later point in time, you can do so by choosing **Home > Menu > Test results > Display**. Tap the required patient report and tap the button.



Test results which diverge from negative, normal, or trace values are:

- Flagged with an asterisk before the parameter concerned.
- Highlighted red.

For choosing the result units in the patient report, see the following section:

Setting the result unit (107)

About the patient report

Depending on your device's configuration, after each measurement, the patient report is automatically printed. Alternatively, you can print it by tapping the button. You can define your print settings in **Home > Menu > Measurement > Auto print**.
If you want to print the patient report at a later point in time, you can do so by choosing **Home > Menu > Test results > Display**. Tap the required patient report and tap the button.

The patient report contains the test results and is printed together with the following information:

- Serial number of the device (**Ser. No.:**)
- User ID
- Date and time
- Sequence number (**Seq. No.:**)
- Patient ID (**Pat:**)

If you are logged on with the **Auto logon (Administrator)** or **Auto logon (Operator)** option, the user ID is not printed in the patient report.

Test results which diverge from negative, normal, or trace values are flagged with an asterisk before the parameter concerned.

If required, tear off the printout by pulling it horizontally over the edge.

⚠ WARNING!

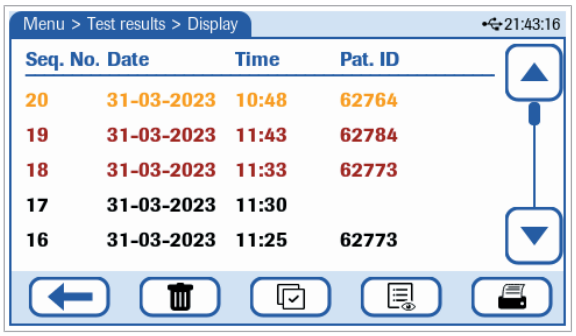
Thermal printing paper is sensitive to light and subject to fade with prolonged exposure to bright light. Patient reports are, thus, best kept in a place away from direct light and high temperature. For anticipated storage beyond 5 years it is recommended that reports are photocopied for storage.

Displaying test results

After the measurement, test results are stored on the device. Via the menu, you can display them.

About the patient report (77)

To display test results



1 Choose **Home > Menu > Test results** and tap the **Display** button.

➔ All patient reports are displayed in a list.

According to the status or findings, test result entries are displayed in the following colors:

- Black: The test results are negative.
- Red: The patient report contains positive findings.
- Orange: No patient report exists due to **Strip measurement error**.

E3 Strip measurement error (131)

2 To choose a specific patient report, tap on the corresponding entry.

ⓘ To navigate through the list, tap the ▲ and ▼ buttons if required.

➔ The entry is highlighted blue.

3 To display the patient report, tap the button.

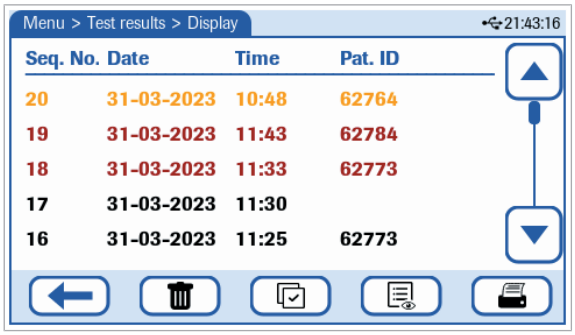
By tapping the displayed buttons, you have the following options:

- : Delete the patient report.
- : Upload the patient report.
- : Print the patient report.

Deleting, uploading, or printing test results (79)

Deleting, uploading, or printing test results

After the measurement, test results are stored on the device. Via the menu, you can delete, upload, or print them.



To delete, upload, or print test results

1 Choose **Home > Menu > Test results** and tap the **Display** button.

➔ All patient reports are displayed in a list.

According to the status or findings, test result entries are displayed in the following colors:

- Black: The test results are negative.
- Red: The patient report contains positive findings.
- Orange: No patient report exists due to **Strip measurement error**.

E3 Strip measurement error (131)

2 To delete a patient report, tap the button.

To delete more than 1 patient report, first tap the button, choose the required patient reports and tap the button.

3 To upload patient reports via LAN or Wi-Fi to the host, choose the button.

- Choose the required patient reports by tapping them individually.
- Tap the button. In the status bar, the icon is displayed.

4 To print test results, highlight the required test result and tap the button.

ⓘ To print more than 1 patient report, first tap the button and highlight the required patient reports.

➔ The patient report is printed.

Exporting test results or log files

You can export 2 file types: test results as CSV files and log files, which contain relevant system events (e.g., for audit purposes).

To export test results

1 Choose **Home > Menu > Test results** and tap the **Export** button.

ⓘ Depending on the amount of data the export may take several minutes.

2 To export log files, tap the **Export log files** button.

➔ The log files are exported to the connected USB device.

3 To export test results as CSV files, tap the **Export CSV file** button.

➔ The CSV files are exported to the connected USB device.

4 To edit the name of the CSV file, tap the **Edit CSV file name** button.

- Using the virtual keyboard, edit the file name and tap the ✓ button.

Inserting the test strip tray

To insert the test strip tray

1 **CAUTION! Be careful not to touch the grey reference pad (A). Contamination of the reference pad may impair the quality of the results obtained.**

Pick up the test strip tray with the retaining bar nearest to you and closed (down).

The test strip tray must be replaced 18 months after first date of use or if the device cannot be calibrated despite several attempts.

For more information see:

Calibration (83)

2 Slide the test strip tray into the slot below the touch screen, so that the near edge of the test strip tray is flush with the near edge of the device.

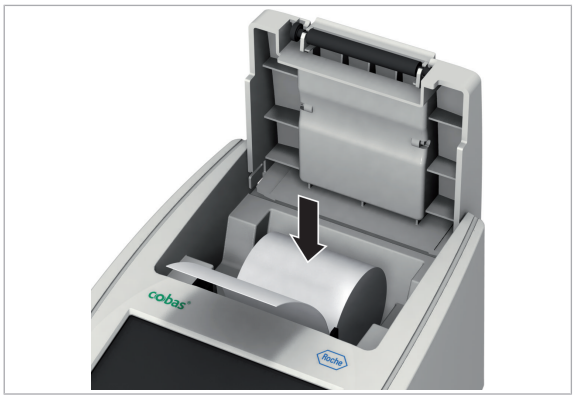
Inserting printer paper

Inserting printer paper

1 To insert printer paper, press down the hollow on the printer cover.

➔ The printer cover flap slightly flips up.

2 Open the printer cover completely.



3 Insert a roll of printer paper.

ⓘ Make sure the glossy side of the paper faces towards you, otherwise the printer is not working properly.

4 Close the printer cover and press down the printer cover flap until you hear a clicking sound.

Calibration

The device is calibrated before leaving the factory. When installed, it must be recalibrated with the specified calibration strip before the first samples are read, and thereafter every 7 days. Calibration strips consist of a grey plastic material that is standardized to give constant, defined reflectance readings. The purpose of calibrating the device is to compensate for aging effects that influence the optical system and the grey reference pad in the test strip tray. If the compensation needed is excessive, for example because the reference pad is badly soiled, or an LED is defective and cannot emit the required amount of light, an error message is displayed (see below).

The device automatically requests a new calibration. A corresponding message is shown when a calibration is due.

Only use the specified calibration strips:

Technical specifications (51)

You have to enter the calibration lot information on the device before performing a calibration.

Entering calibration lot information (69)

Performing a calibration

⚠ CAUTION!

Potentially incorrect results

Regular calibration is necessary to ensure the quality of the results obtained. Roche Diagnostics cannot warrant the correctness of results if the device is not calibrated regularly.

- Perform calibrations regularly.

⚠ CAUTION!

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.
- Do not bend the calibration strip during operation.
- Do not re-use calibration strips. Always use a new calibration strip for each calibration, including repeats. Dispose of the strip after calibration.

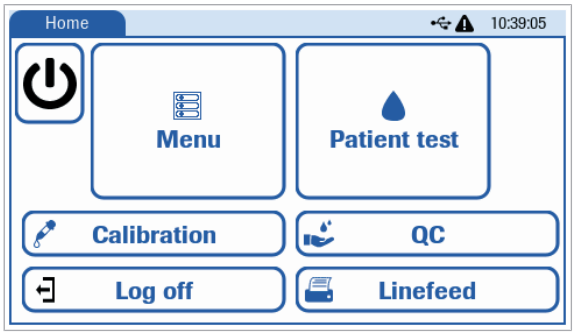
Before calibrating, ensure that the test strip tray is clean and dry.

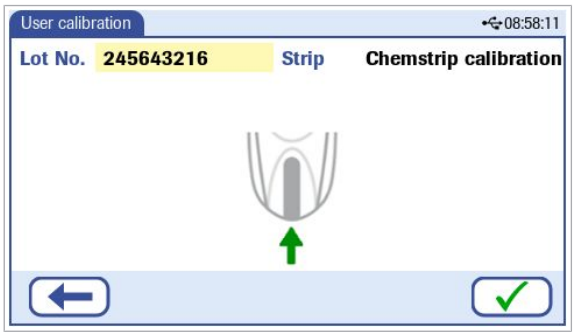
To perform a calibration

1 When the notification about a required calibration (**No valid user calibration**) is displayed, to directly start the calibration process, tap the ✓ button.
→ The **User calibration** screen is displayed.

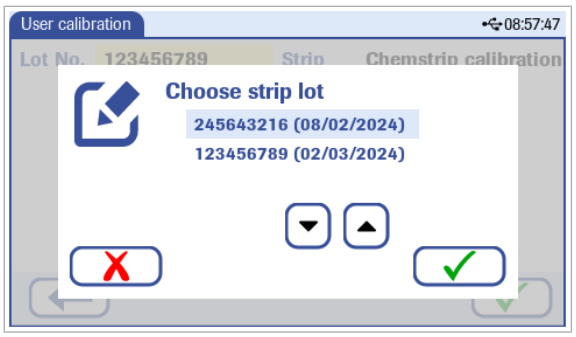
2 To start a calibration without the notification being displayed, do the following:
- On the **Home** screen, tap the **Calibration** button.

→ The **User calibration** screen is displayed.



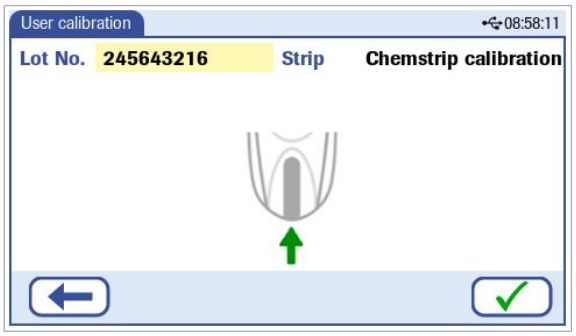


3 To select the required calibration lot, tap the yellow-highlighted **Lot No.** entry field.



4 To select a calibration strip lot, tap the calibration lot entry, or tap the ▲ and ▼ buttons (if more than three lots are available).

5 To confirm the selection and return to the **User calibration** screen, tap the ✓ button.

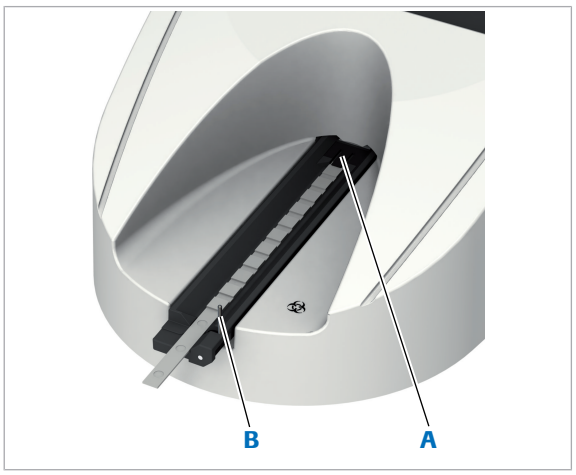


6 On the **User calibration** screen, to start the calibration process, tap the ✓ button.

➔ A callout instructs you to place the calibration strip.

7 Remove a calibration strip from the vial of strips.

ⓘ Be careful not to touch the test pads and do not allow them to come into contact with urine.



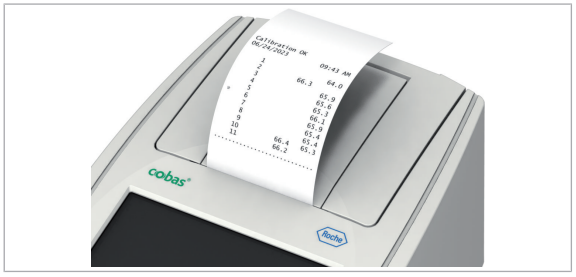
8 Place the calibration strip, with the test pads facing upwards, on the test strip tray so that its leading edge is held by the clip (**A**) at the front end of the insertion slot. The retaining bar (**B**) must be open.

ⓘ Do not bend the calibration strip.

9 To confirm the information screen and to proceed with the calibration process, tap the ✓ button.

➔ After warming up time, the test strip tray advances slightly. The retaining bar closes, and the grey reference pad on the test strip tray and the calibration pads are read.

➔ The test strip tray is then transported back to the start position, and the retaining bar opens.



10 When the calibration process is completed, a corresponding message is displayed and the calibration report together with the date and time is printed.

- To display the calibration report, tap the ✓ button.

If the calibration was not successful and an error message is displayed, refer to:

Error messages and troubleshooting (130)

11 Remove and dispose of the calibration strip.

ⓘ Use each calibration strip only once.

Quality control (QC)

QC measurements ensure the proper functioning of the device. 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.

Use commercially available urine QC material, or other suitable QC material. Run a positive and negative QC measurement daily, or when a new vial of strips is opened.

You have to enter the test strip lot information and the QC material information on the device before performing a QC measurement.

Entering information about consumables (67)

The test strip handling and the measurement procedure in general are described in this section:

About reading test strips (65)

Values obtained for QC material should fall within the limits established by the QC material manufacturer. If the measured results obtained are outside the established limits follow the troubleshooting actions provided in this section:

Error messages and troubleshooting (130)

Performing a QC measurement

⚠ CAUTION!

Potentially incorrect results

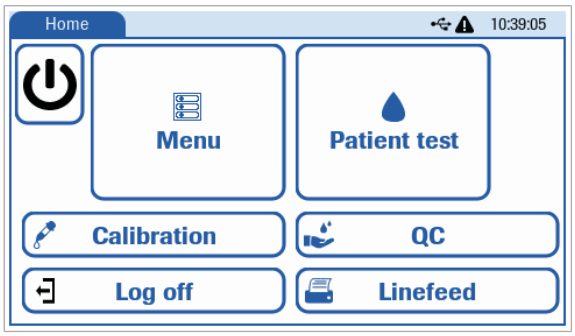
Regular QC measurements are necessary to ensure the quality of the results obtained. Roche Diagnostics cannot warrant the correctness of results if QC measurements are not performed regularly.

- Perform QC measurements regularly.

NOTICE!

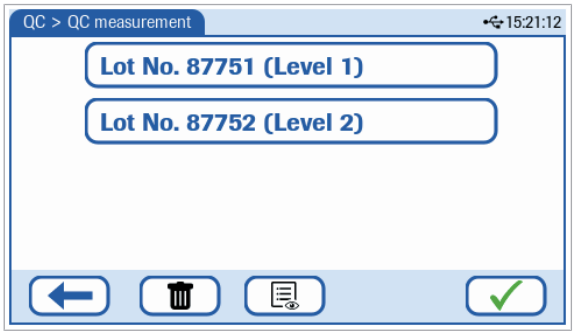
To avoid false positive results, do not pipette or drop the control solutions onto the test pads.

To perform a QC measurement



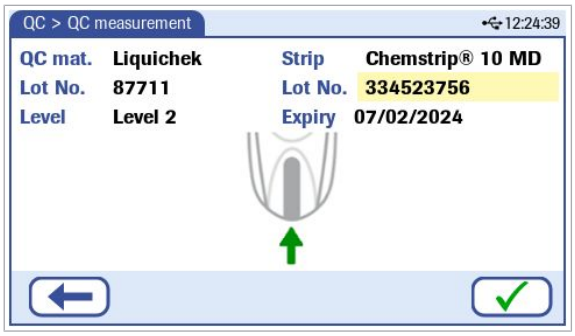
1 On the **Home** screen, tap the **QC** button.

2 On the **QC** screen, tap the **QC measurement** button.



3 On the **QC measurement** screen, to select the QC lot and the level you want to use, tap the QC lot/level entry, or tap the ▲ and ▼ buttons (if more than 3 entries are available).

4 To confirm the selection and to proceed with the test, tap the ✓ button.



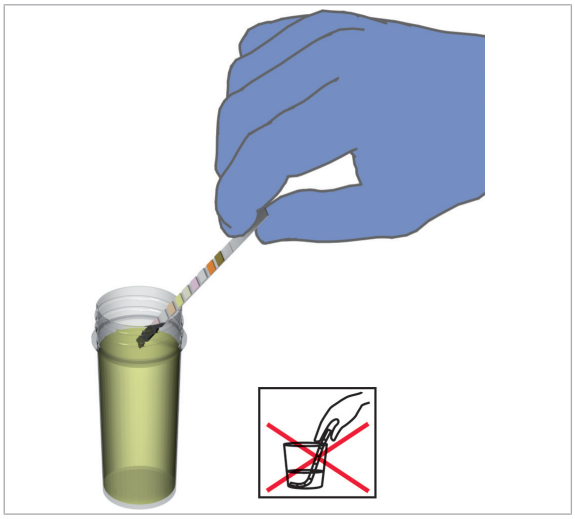
5 On the **QC measurement** screen tap the yellow-highlighted **Lot No.** entry field for the test strip lot, if you want to change the test strip lot. Otherwise continue with step **7**.

6 To confirm the selection and to proceed with the test, tap the ✓ button.

7 **NOTICE! To avoid incorrect readings due to a discoloration of the test strip pads, the vial of strips must be closed immediately after removal of a test strip, using the original desiccant-filled stopper.**

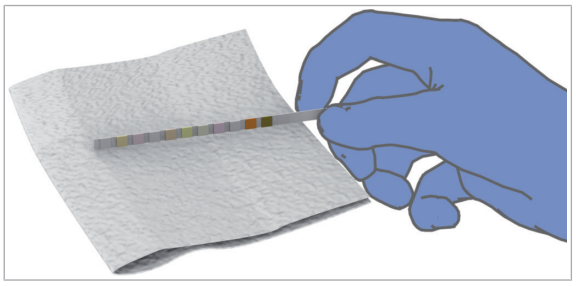
Remove a test strip from the vial of strips.

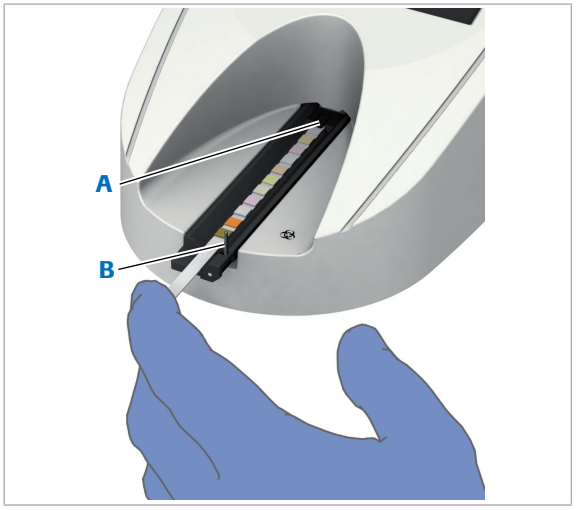
8 Dip the test strip briefly (1 s) in the QC sample.



9 Draw the long edge of the test strip along the rim of the sample container to remove excess control material.

ⓘ Do not bend the test strip.





10 Dab the long edge of the test strip lightly on absorbant paper to remove excess control material.

- Make sure that each pad is blotted.

11 Place the test strip, with the test pads facing upwards, on the test strip tray so that its leading edge is held by the clip (**A**) at the front end of the insertion slot. The retaining bar (**B**) must be open.

About 2 mm of the test strip must be held under the clip (**A**). Do not bend the test strip.

It is important that the test strip is correctly positioned and ready to be read within 5-10 seconds of dipping the test strip.

12 To start the measurement process, tap the ✓ button.

The measurement process is performed as described in section:

Performing a measurement (72)

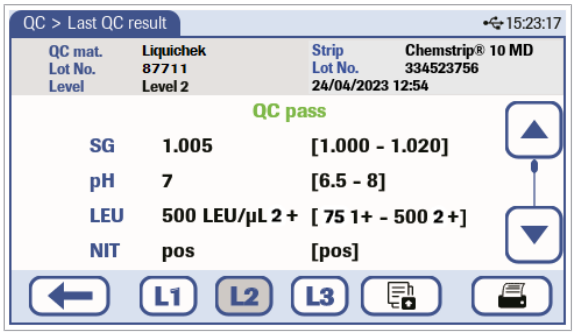
13 After the measurement process, the result is displayed and printed.

In case of an out-of-range measurement, **QC fail** is displayed. The parameter concerned is flagged with an asterisk and highlighted red.

For more information, see:

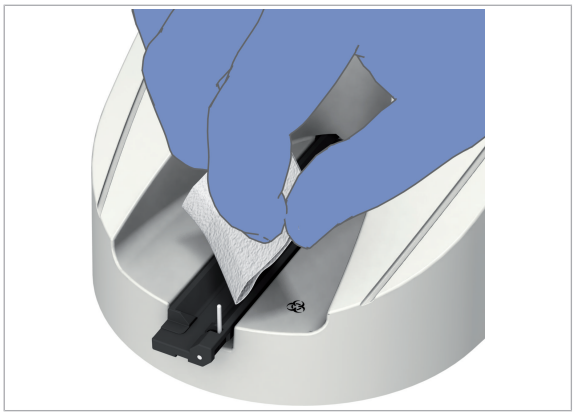
QC results fall outside the target ranges (136)

14 Remove and dispose of the test strip.



15 On the **Last QC result** screen, you have the following options:

- To display the QC results of the last QC measurements for the individual levels, tap the **L1**, **L2**, or **L3** button.
- To transfer the displayed results, tap the button.
- To print the displayed results, tap the button.
- To return to the **Home** screen, tap the button.
- To return to the QC screen and perform another QC test (e.g., with a different level), tap the ← button.



ⓘ To scroll through the results, use the ▲ and ▼ buttons on the right side.

16 Wipe any urine residues from the test strip tray with a lint-free cloth.

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Configuration

5 Configuration 93

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Configuration

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About settings

The following sections describe all settings available to configure the device. Device configuration is divided into the following setting groups:

- **Device settings**
- **Measurement** settings
- **ID setup**
- **User management**
- Managing **Strip lots** and **Calibration lots**
- Managing QC lots

Most settings require administrator rights:

- Settings limited to **administrators**:
  - Advanced device settings
  - **ID setup** and **User management**
  - All **Measurement** settings
  - **Add QC**
- Settings available to **all users**:
  - Managing **Strip lots** and **Calibration lots**
  - **Device settings > System information**
  - **Device settings > Reset Seq. No.**
  - Editing the **User password**
  - Display, export, and print single results
  - Export log files and all data via CSV

Settings summary

Device settings summary

The following table lists all available device settings (**Home > Menu > Device settings**). Settings marked with an asterisk (*) are available to all users, the others only with administrator rights.

For more information, see:
Device settings (100)

Setting	Subsetting	Value	Default value
Date/time	**Date**	• **Year** • **Month** • **Day**	Current date
	Time	• **Hour/minute** • **AM**/**PM**, **12H** or **24H**	• Current time (UTC+1) • **24H**
	Date format	• **YYYY.MM.DD** • **MM.DD.YYYY** • **DD.MM.YYYY**	**DD.MM.YYYY**
	Delimiter	• **-** • **/** • **.**	**/**
	Time zone	• UTC with offsets • -12:00 to + 14:00	+1:00
Power management	**Auto logoff timeout**	• **Disabled** • **5 min** • **10 min** - **120 min** in steps of 10	**Disabled**
	Standby time	• **Disabled** • **20 min** - **180 min** in steps of 20	**Disabled**
Language	**Device**	• **English** • **Deutsch** • **Español** • **Italiano** • **Français**	**English**

Device settings summary

Setting	Subsetting	Value	Default value
	Keyboard	• **English** • **Deutsch** • **Español** • **Italiano** • **Français** • **Svenska** • **Norsk**	**English**
Connection	**Network**: **Connection**	• **Off** • **LAN** • **Wi-Fi**	**Off**
	Connection: **LAN**	• **DHCP** • Manual entry for **Device IP**, **Subnet mask**, **Default gateway**, **DNS**	**DHCP** enabled
	Connection: **Wi-Fi**	• **SSID** • **Encryption** (**No**, **WPA/WPA2**) • **Password**	• n/a • **No** • n/a
	Protocol	• **Unidirectional (UTF8)** • **Bidirectional (UTF8)** • **ASTM** • **Disabled**	**Disabled**
		• **Target IP/port**	n/a
	cobas® infinity edge: **Connection**	• **Enabled** • **Disabled**	**Disabled**
	cobas® infinity edge: **Server (IP/FQDN):port**		n/a
	cobas® infinity edge: **Software download**	• **Enabled** • **Disabled**	**Disabled**
Software update	**Install software update**		n/a
Reset settings		(reset all settings to default)	
Reset Seq. No.*			1
System information*		(display only)	

Device settings summary

Measurement settings summary

The following table lists all available measurement settings (**Home > Menu > Measurement**).

For more information, see:

Measurement settings (107)

Setting	Subsetting	Value	Default value
Result units		• **Conventional** • **SI** • **Arbitrary**	**Conventional**
Auto print		• **Off** • **1 copy** • **2 copies**	**1 copy**
Strip type		• Chemstrip® 10 MD • Chemstrip® 10 UA	Chemstrip® 10 UA
Replace strip tray		(reset the tray usage counter)	1

Measurement settings summary

ID setup summary

The following table lists all available ID setup settings (**Home** > **Menu** > **ID setup**).

For more information, see:

ID setup (114)

Setting	Subsetting	Value	Default value
ID setup	**User ID entry**	• **Auto logon (Administrator)** • **Auto logon (Operator)** • **Enter user ID** • **User list**	**Auto logon (Administrator)**
	Operator ID validation	• **No password required** • **Password**	**No password required**
	Auto patient ID	• **On** • **Off**	**Off**

ID setup summary

User management summary

The following table lists all user management settings (**Home > Menu > User management**).

For more information, see:

User management (109)

Settings	Subsetting	Value	Default value
(Define a new user)	**User ID**	(Text entry)	n/a

User management summary

Settings	Subsetting	Value	Default value
	Role	• **Administrator** • **Operator**	**Operator**
	Status	• **Active** • **Inactive**	**Active**
(View/edit)	**User ID**	(as entered)	n/a
	Role	(as set)	n/a
	Status	(as set)	n/a
(Delete)	(delete selected entry)		n/a

User management summary

If you are logged on as an operator, you see the **User password** button instead of the **User management** button. Use this button to edit your personal password.

Strip lots and calibration lots summary

The following table lists all available strip lots and calibration lots settings.

- **Home > Menu > Strip lots**
- **Home > Menu > Calibration lots**

Setting	Subsetting	Value	Default value
(Add)	**Strip type**	(Text entry, pre-filled with default type)	Default type
	Lot number	(Text entry)	n/a
	Expiry date	• **Year** • **Month** • **Day**	n/a
(View/edit)	**Strip type**	(as entered)	n/a
	Lot number	(as entered)	n/a
	Expiry date	(as set)	n/a
(Delete)	(delete selected entry)		n/a

Strip lots and calibration lots summary

Device settings

Device settings summary (96)

In this section

Setting the date/time options (100)
Setting the power management options (101)
Setting the language (101)
Setting the connection options (102)
Installing a software update (104)
Restoring the default settings (105)
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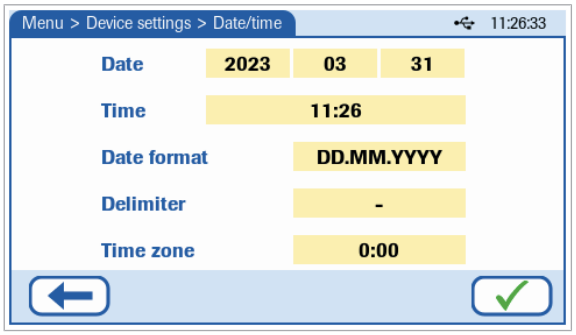
Setting the date/time options



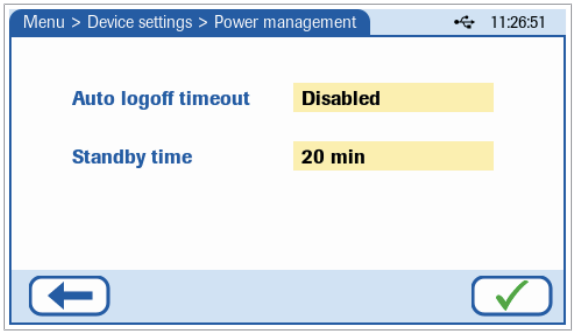
To set the date/time options

1 Choose **Home > Menu > Device settings > Date/time**.
→ In the **Date/time** menu, the yellow-highlighted entry fields display the currently active values or settings.

2 To open the corresponding dialogs, tap the individual entry fields. Enter or select the options as needed.
- Set the **Year**, **Month** and **Day**.
- Set the current **Time** and choose the **12H** (**AM**/**PM**) or **24H** format.
- Choose the **Date format**.
- Choose the **Delimiter** (the character, by which year, month, and date will be separated on the display).
- Choose the UTC (coordinated universal time) **Time zone**, in which you are using the device. The default setting (1:00) represents the CET time zone.

3 To save your settings, tap the ✓ button.
→ You return to the **Device settings**.

Setting the power management options



To set the power management options

1 Choose **Home > Menu > Device settings > Power management**.

➔ In the **Power management** menu, the yellow-highlighted entry fields display the currently active values or settings.

2 To open the corresponding dialogs, tap on the individual entry fields. Enter or select the options as needed.

- To log off operators automatically after the set time, set the **Auto logoff timeout**. This setting only has an effect if the time for auto logoff is shorter than the **Standby time** (if enabled).
- Set the **Standby time**, after which the device will go into standby mode. Any operator currently logged on will automatically be logged off when standby mode becomes active.

3 To save your settings, tap the ✓ button.

➔ You return to the **Device settings**.

Setting the language

To set the language for the device and the keyboard

1 Choose **Home > Menu > Device settings > Language**.

2 In the **Language** menu, do the following:

- To set the language for the user interface on the device, tap on the **Device** button. To save that selection, tap the ✓ button.
- To set the language for an external keyboard, if used, tap on the **Keyboard** button. To save that selection, tap the ✓ button.

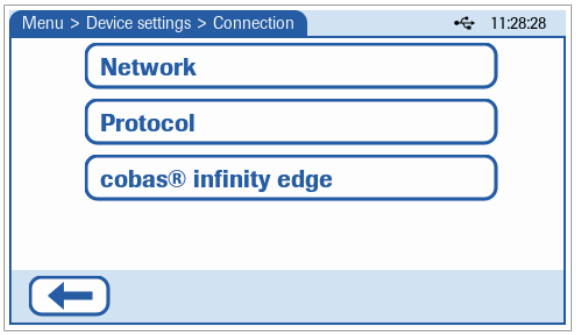
3 To save your settings, tap the ✓ button.

➔ You return to the **Device settings**.

Setting the connection options

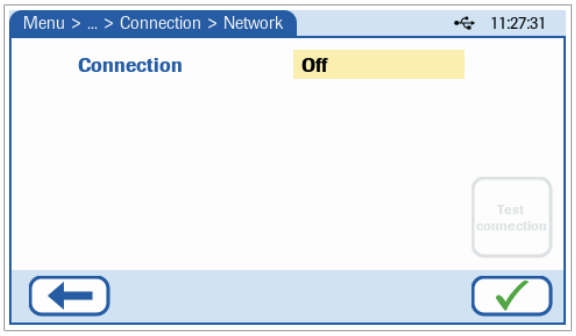
To set the network options

1 Choose **Home > Menu > Device settings > Connection**.

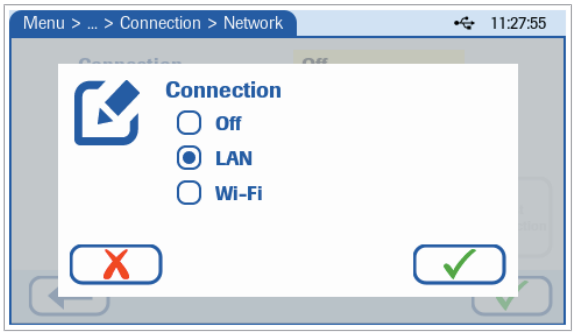


2 In the **Connection** menu, tap on the **Network** button.

➔ In the **Network** menu, the yellow-highlighted entry fields display the currently active values or settings.

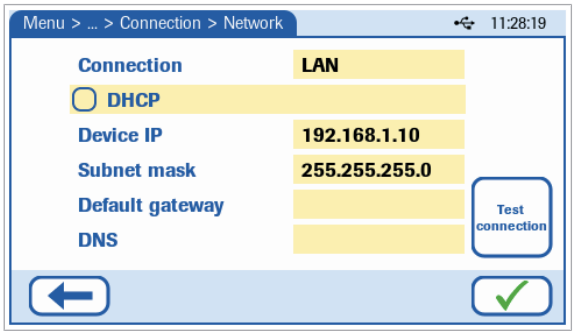


3 To open the corresponding dialog, tap on the yellow-highlighted **Connection** entry field.



4 To disable or enable a network connection, set the **Connection** to the required type. To save, tap the ✓ button.

➔ The **Network** menu now shows the entry fields with the parameters corresponding to the selection you made.



5 To open the corresponding dialogs, tap the individual yellow-highlighted entry fields. Enter the information as needed.

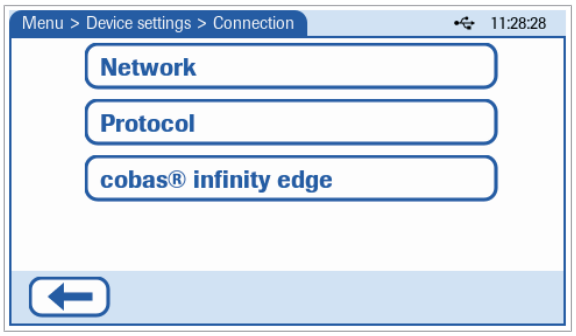
6 When you have finished the settings, to make sure the connection is working properly, tap the **Test connection** button.

7 To save your settings, tap the ✓ button.

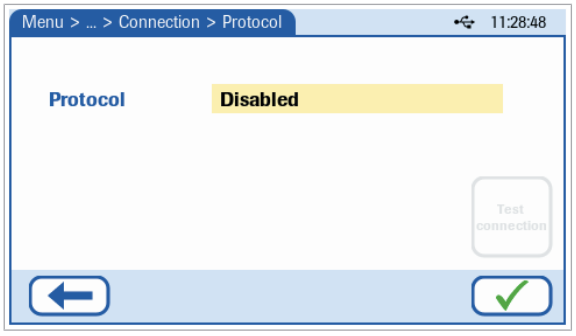
➔ You return to the **Connection** menu.

To set the protocol options

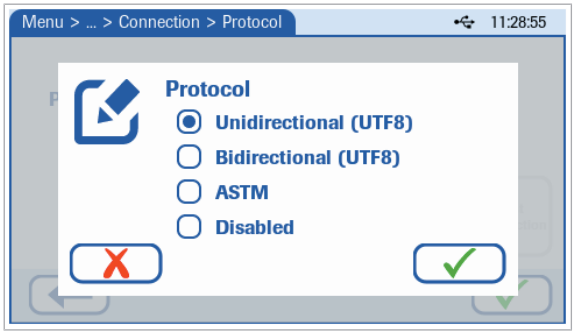
1 Choose **Home > Menu > Device settings > Connection**.



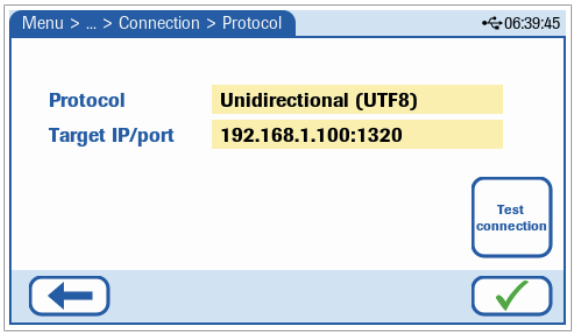
2 In the **Connection** menu, tap the **Protocol** button.
➔ In the **Protocol** menu, the yellow-highlighted entry fields display the currently active values or settings.



3 To open the corresponding dialog, tap on the **Protocol** entry field.



4 To disable or enable a protocol, set the **Protocol** to the desired type. To save that selection, tap the ✓ button.
➔ The **Protocol** menu now shows the entry fields with the parameters corresponding to the selection you made.



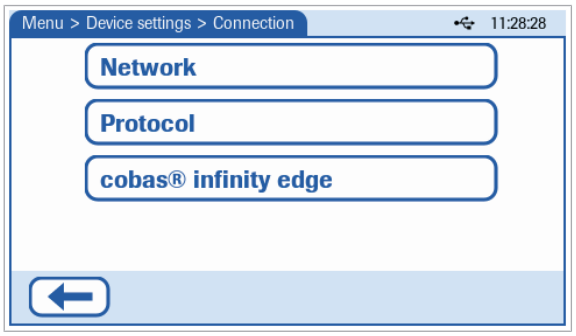
5 To open the corresponding dialogs, tap on the individual yellow-highlighted entry fields. Enter the information as needed.

6 When you have finished the settings, to make sure the connection is working properly, tap on the **Test connection** button.

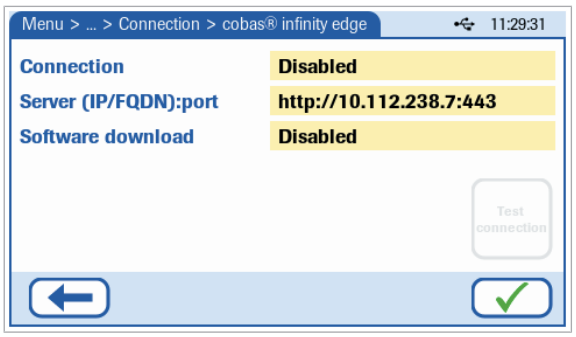
7 To save your settings, tap the ✓ button.
➔ You return to the **Connection** menu.

To set the cobas® infinity edge options

1 Choose **Home > Menu > Device settings > Connection**.

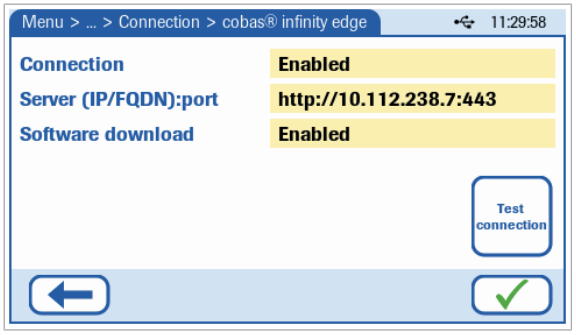


2 In the **Connection** menu, tap the **cobas® infinity edge** button.
➔ In the **cobas® infinity edge** menu, the yellow-highlighted entry fields display the currently active values or settings.



3 To open the corresponding dialogs, tap on the individual yellow-highlighted entry fields. Enter the information as needed.

4 To disable or enable the **Connection** or the **Software download** from the server, choose the desired option.



5 Enter the corresponding **Server (IP/FQDN):port** information, if you have enabled the **Connection** option.

6 When you have finished the settings, to make sure the connection is working properly, tap on the **Test connection** button.

7 To save your settings, tap the ✓ button.
➔ You return to the **Connection** menu.

Installing a software update

A software update can be installed from either a connected USB mass storage or via **cobas® infinity** edge.

To install from a USB mass storage:

☐ USB mass storage containing the software update file connected to a USB-A port at the rear of the device.

To install via **cobas® infinity** edge:

☐ Enabled and configured connection to **cobas® infinity** edge.
☐ In the status bar, the ⬇ icon indicates an available software update.

To install a software update

1 Choose **Home > Menu > Device settings > Software update**.

2 In the **Software update** menu, tap the **Install software update** button.

3 Confirm the displayed message by tapping the ✓ button.

ⓘ Make sure not to interrupt the power supply or operate the device during the update process.

➔ The update is downloaded and started from the chosen source.

➔ The device is restarted automatically and a **Self check OK** report is printed.

4 When the software update is completed, a corresponding message is displayed.

- To confirm the message, tap the ✓ button.

➔ The **Home** screen is displayed and the device is ready to be operated.

Restoring the default settings

Restoring the default settings of the device does not delete users and passwords. All other settings are restored to their default values.

NOTICE!

Risk of unauthorized access

Resetting the device to default settings will preserve existing user and password information, but will allow an automatic logon (without authentication) with administrator rights after the reset.

▸ Make sure to set the **ID setup** to the desired options right after the reset, if the device should be further used.

To restore the default settings

1 Choose **Home > Menu > Device settings > Reset settings**.

2 In the message displayed, to confirm the deletion of all settings, tap the ✓ button.

➔ The device is reset to the default configuration.

Resetting the sequence number

Resetting the sequence number can be done by an operator and does not require administrator rights.

To reset the sequence number

1 Choose **Home > Menu > Device settings > Reset Seq. No.**

2 In the message displayed, to confirm resetting the sequence number, tap the ✓ button.

➔ The sequence number is reset to 1.

Displaying system information

Displaying system information can be done by an operator and does not require administrator rights.

To display system information

1 Choose **Home > Menu > Device settings > System information**.

➔ A list containing information on the system is displayed.

2 To return to the **Device settings**, tap the ← button.

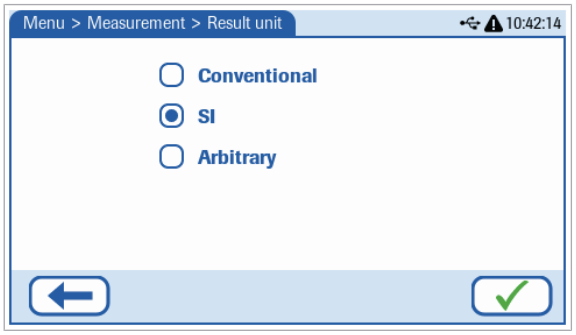
Measurement settings

Measurement settings summary (97)

In this section

Setting the result unit (107)
Setting the auto print option (107)
Setting the test strip type (108)
Resetting the test strip tray usage counter (108)

Setting the result unit



To set the result unit

1 Choose **Home > Menu > Measurement > Result units**.

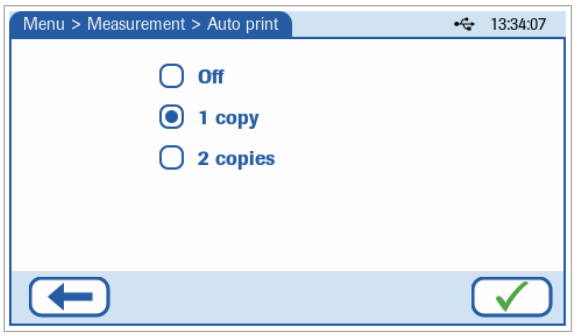
2 In the **Result units** menu, choose the required option.

3 To save your settings, tap the ✓ button.
➔ You return to the **Measurement** menu.

Setting the auto print option

Independent of your defined print option, 1 copy of the following items is always printed:

- Self-check report after powering on the device
- Calibration report
- QC measurement report



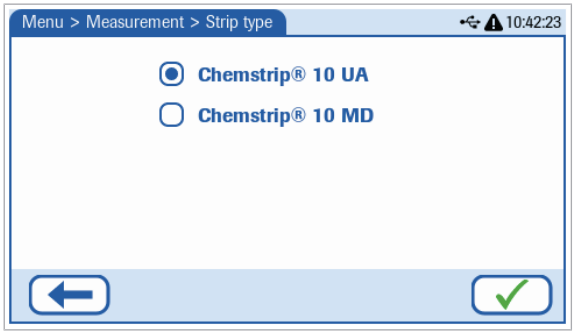
To set the auto print option

1 Choose **Home > Menu > Measurement > Auto print**.

2 In the **Auto print** menu, choose the required option.

3 To save your settings, tap the ✓ button.
➔ You return to the **Measurement** menu.

Setting the test strip type



To set the test strip type

1 Choose **Home > Menu > Measurement > Strip type**.

2 In the **Strip type** menu, choose the required option.

3 To save your settings, tap the ✓ button.
➔ You return to the **Measurement** menu.

Resetting the test strip tray usage counter

When the replacement of the test strip tray is due, a corresponding message is displayed. A replacement is due after 18 months of usage or 10 000 measurements, whichever comes first. When you replace the used strip tray, reset the corresponding tray usage counter to 1.

To reset the test strip tray usage counter

1 Choose **Home > Menu > Measurement > Replace strip tray**.

2 In the message displayed, to confirm the replacement and to reset the counter, tap the ✓ button.
➔ You return to the **Measurement** menu.

User management

User management summary (98)

In this section

About the user management (109)
Defining a new user (110)
Editing a user (111)
Deleting a user (112)
Resetting a user password (112)
Changing a personal password (113)

About the user management

User rights

Users are classified into 2 groups with different access rights:

- Administrators
- Operators

Operators can perform the following routine actions:

- Run tests
- Perform calibrations
- Perform QC measurements
- Send results
- Check system information
- Manage strips
- Export data files

Administrators can perform routine actions and:

- Configure the system
- Add, edit, and delete another administrator and operators
- Install software updates

Maximum 2 active users can have administrator rights.

User status

The status of a user can be set to active and inactive (e.g., in case of a longer absence). Only active users have access to the device.

Passwords

When you add a new user, they are assigned an initial password. New users have to change their initial password to a personal one when they log on for the first time.

Password management (25)

A user's personal password can be reset to a temporary one by the administrator.

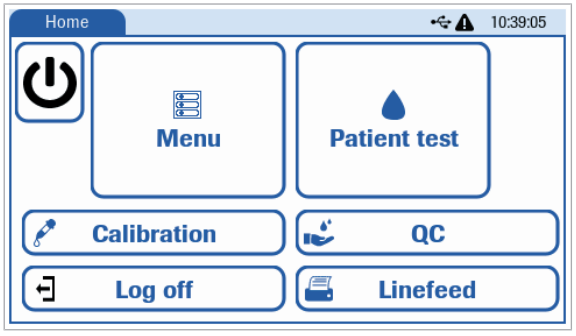
Resetting a user password (112)

Users with operator rights can change their personal passwords in **Home > Menu > User password**.

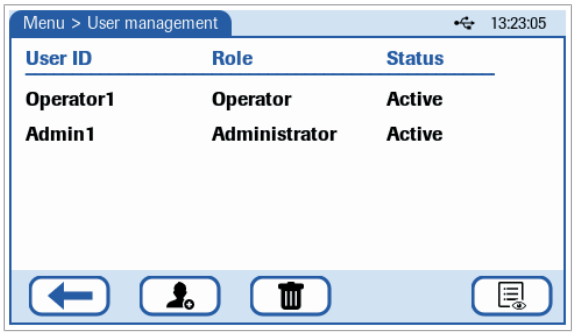
Defining a new user

To define a new user, you require administrator rights.

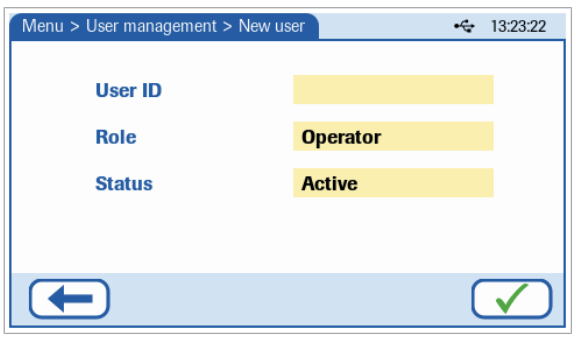
To define a new user



1 Choose **Home > Menu > User management**.



2 Tap the button.
➔ The **Menu > User management > New user** menu is displayed.



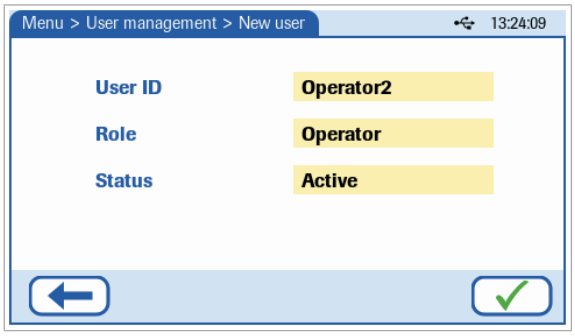
3 To enter the user ID of the new user, tap the yellow-highlighted **User ID** entry field.
- Enter the user ID and tap the ✓ button.

ⓘ You can enter a user ID with between 1–32 alphanumeric characters.

If you exceed the maximum length of 32 characters, the cursor stops. You cannot enter any more characters.

4 To define the new user's rights, tap the yellow-highlighted **Role** entry field.
- Choose the role and tap the ✓ button.

For more information on user rights, see:
User rights (109)



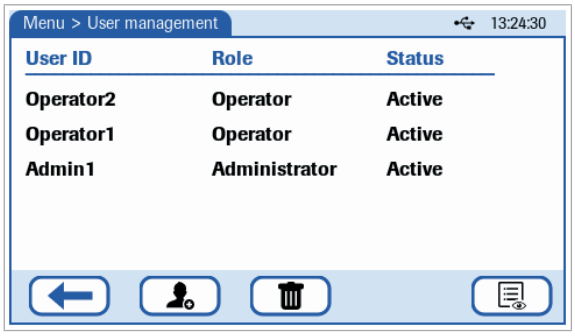
5 To choose the new user's status, tap the yellow-highlighted **Status** entry field.
- Choose the role and tap the ✓ button.

For more information on the user status, see:
User status (109)

6 To save your settings, tap the ✓ button.
➔ A message with the new user's initial password is displayed.
➔ Remember the initial password.

7 To confirm the message, tap the ✓ button.
➔ At the first logon, the new user must first enter the initial password.
➔ The user is then requested to enter, and confirm a new personal password.

For more information on passwords, see:
Passwords (110)



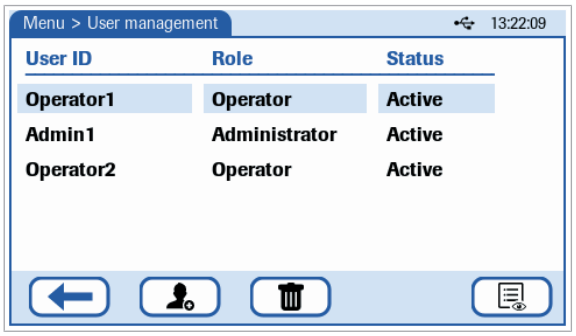
8 The new user is created and displayed in the user list.

Editing a user

To edit a user, you require administrator rights.

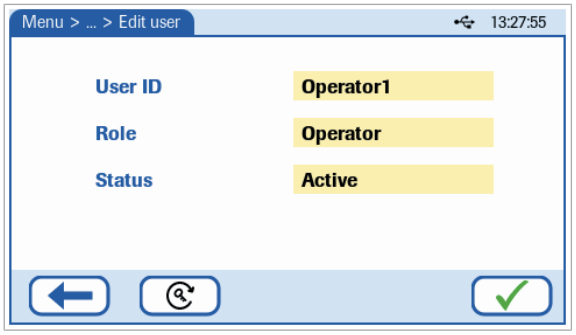
To edit a user

1 Choose **Home > Menu > User management**.



2 Tap the required user.

3 Tap the button.
➔ The **Menu > ... > Edit user** menu is displayed.



4 You can edit the following by tapping the corresponding yellow-highlighted entry field:
- Change the user ID.
- Change the user role.
- Change the user status.

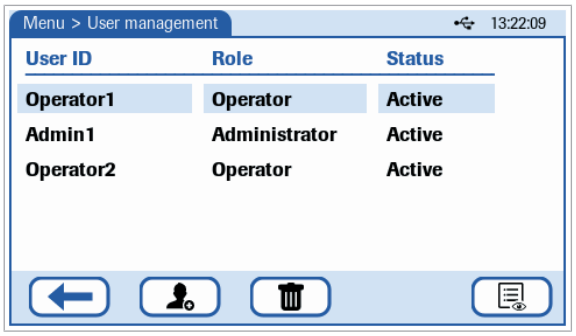
5 To save, tap the ✓ button.

Deleting a user

To delete a user, you require administrator rights.

If you delete a user, they are removed from the database.

To delete a user



1 Choose **Home > Menu > User management**.

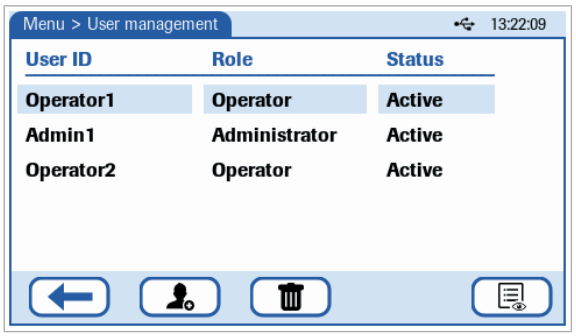
2 Tap on the required user.

3 Tap the button.
➔ A message is displayed whether you really want to delete the user.

4 To confirm the message, tap the ✓ button.
➔ The user is deleted.

Resetting a user password

To reset a user password, you need administrator rights.



You can reset a user's password to a temporary one. The concerned user must change the temporary password to a personal one at the next logon.

To reset a user password

1 Choose **Home > Menu > User management**.

2 Tap on the required user.

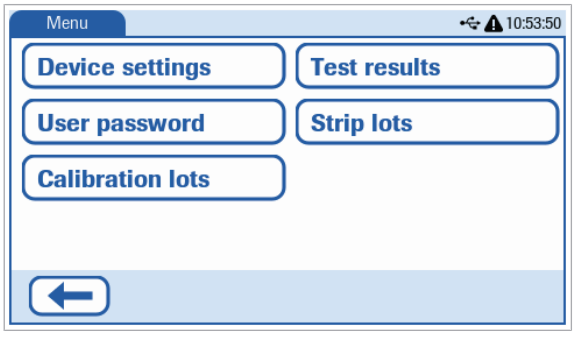
3 Tap the button.
→ The **Menu > ... > Edit user** menu is displayed.

4 Tap the button.
→ A message is displayed with the temporary password.
→ Remember the temporary password.

5 To confirm the message, tap the ✓ button.
→ At the next logon, the concerned user must first enter the temporary password.
→ The user is then requested to enter, and confirm a new personal password.

For more information on passwords, see:
Password management (25)

Changing a personal password



Operators can change their personal password.

To change a personal password

1 As user with operator rights, choose **Home > Menu > User password**.
→ The **Enter password** menu is displayed.

2 Enter your current password.
→ The **Enter new password** menu is displayed.

3 Enter your new password.
- For more information on passwords, see Password management (25).

→ The **Confirm password** menu is displayed.

4 To confirm your password, enter your new password again and tap the ✓ button.
→ Your personal password is changed.

ID setup

In the **ID setup** menu, you can define user logon and patient ID options.

Choose **Home > Menu > ID setup**.

To access the **ID setup** menu, you require administrator rights.

ID setup summary (98)

In this section

About User ID entry (114)

About Operator ID validation (115)

About Auto patient ID (116)

About User ID entry

You have the following options for the logon:

- **Auto logon (Administrator)**
- **Auto logon (Operator)**
- **Enter user ID**
- **User list**

Auto logon

The auto logon user is a special predefined user without a password. You can choose from the following options:

- **Auto logon (Administrator)**: with administrator rights.
- **Auto logon (Operator)**: with operator rights.

If you enable one of these options, any user can operate the device in the according role without entering neither a user ID nor a password.

If you enable the **Auto logon (Operator)** option, the system checks for at least 1 active administrator.

User ID entry

If you choose the **Enter user ID** option, you are required to enter your user ID to log on.

You can enter a user ID with between 1–32 alphanumeric characters using the virtual keyboard, a keyboard connected via USB, or a barcode reader.

The entered user ID is checked against the device's internal user list.

If you enter an incorrect user ID, an error message is displayed.

User list

If you enable this option, all active user IDs are listed on the **User logon** screen. To log on, tap on your user ID or scan it using a barcode reader.

You can either download up to 300 user IDs with corresponding passwords from the host PC via the ASTM protocol.

The device downloads the user list via ASTM protocol every time the device is powered on.

Or you can manually create a user list by adding all users via **Home > Menu > User management**.

The device can only be used by a user defined with ID and password in the list.

If you enable the **Enter user ID** or **User list** option, the user ID is asked for every time the device is powered on or waken from standby mode.

About Operator ID validation

For logging on to the device, you can choose whether for operators a password entry is required or not.

- If you choose **No password required**, operators are not required to enter a password.
- If you choose **Password**, operators are required to enter a password.

Administrator users are always required to enter a password, except when **Auto logon (Administrator)** is enabled.

If you enter an incorrect password, an error message is displayed.

About Auto patient ID

If you enable the **Auto patient ID** option, the internal counter number is used as patient ID when running a test. If you disable this option, the patient ID (**Pat. ID**) is empty by default. You can change the patient ID independent of whether the **Auto patient ID** option is enabled or not.

Connecting to other devices

In this section

Connecting to a wired or wireless network (117)

Connecting USB devices (117)

About working with an external keyboard (118)

Barcode reader setup (119)

Connecting to a wired or wireless network

A network connection can be used to transfer data to a data management system (DMS), to communicate with **cobas® infinity** edge and for downloading software updates.

Setting the connection options (102)

Network connection options

The device can connect to a network in 2 ways:

- Connecting to a wired network via the inbuilt LAN port.
- Connecting to a wireless network via a Wi-Fi stick plugged into 1 of the inbuilt USB ports.

Technical details about the communication protocols for use with a DMS or **cobas® infinity** edge are described in a separate document. For more information, contact your local Roche representative.

Connecting USB devices

In addition to using the on-screen keyboard on the touch screen, you may also use a computer keyboard or a barcode reader to enter information. You may also use a USB mass storage for providing software updates. Just connect these devices to one of the USB A ports on the back of the device.

Barcode reader

A barcode reader may be used to enter user IDs, also for test strip and calibration strip lot numbers and expiry dates.

Barcode readers must meet the following specifications:

- Radio frequency interference class B according to EN 55011
- Electromagnetic interference immunity requirements for industrial locations according to EN 61326-1

There is a recommended barcode reader to read commonly used barcodes such as Codabar, Code 39, Code 128, Interleaved 2 of 5 and 2D barcodes.

Barcode reader setup (119)

USB keyboard

Any standard keyboard as used for PCs with a USB A connector will work with the device. The device supports the following keyboard layouts:

- English
- Deutsch
- Español
- Italiano
- Français
- Svenska
- Norsk

About working with an external keyboard (118)

USB mass storage

You may export CSV files to a USB mass storage. You may also install software updates from a USB mass storage (FAT-32 format, max. 16GB). Insert the drive containing the software update file and start the update process.

Exporting test results or log files (80)

Installing a software update (104)

For more information on connecting USB devices, contact your local Roche representative.

About working with an external keyboard

To enter data, you can use an external keyboard connected via USB.

- When you enter data using the external keyboard, each character immediately appears on the device screen.
- You can delete characters by using the Backspace key.
- To confirm your entered data, press the Enter key.
- To cancel a data entry, press the Escape key.

Barcode reader setup

If you want to use the device together with a barcode reader, you need to initially configure the barcode reader.

Datalogic QD2590

To setup the Datalogic QD2590 Roche barcode reader, scan the code to the left:

Any other barcode reader

To setup any other barcode reader, make sure you configure it to work in *virtual RS-232 simulation* mode. Therefore, follow the instructions in the barcode reader manual.

Related topics

- Connecting USB devices (117)

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Maintenance and troubleshooting

6 Maintenance and troubleshooting 123

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Maintenance and troubleshooting

In this chapter 6

About cleaning and disinfecting the device 125
Acceptable cleaning solutions and disinfectants 126
Daily cleaning and disinfecting the device 127
Daily cleaning and disinfecting the test strip tray 128
Error messages and troubleshooting 130

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About cleaning and disinfecting the device

Ensure that you are fully familiar with the requirements for cleaning and disinfecting the device.

⚠ WARNING!

Protection against infection

Healthcare professionals using the device must be aware that any object coming into contact with urine samples of human origin is a potential source of infection. Users must adhere to standard precautions when handling or using the device.

- Use disposable gloves.
- Use cleaning and disinfection materials of recommended quality only.
- Dispose of used cleaning materials according to your facility's guidelines.
- Follow all health and safety regulations in force locally.

NOTICE!

Damage to the device by using unsuitable cleaning materials

Using unsuitable solutions may result in incorrect operation and possible failure of the system.

- Clean and disinfect the device with recommended materials only. Make sure that the device is thoroughly dried after cleaning and disinfecting.
- Do not use any abrasive cleaning substances or pointed implements to clean the device.
- Do not spray anything onto the device and do not immerse it in liquid.

Acceptable cleaning solutions and disinfectants

Only use recommended cleaning solutions and disinfectants to clean and disinfect the device.

Before using disinfectants on device components, refer to the product labelling for required contact time for disinfectants, and to ensure that the active ingredients are acceptable for use.

Prepare all solutions per the manufacturer's product labelling.

Cleaning solutions

- Tap water.

Disinfectants

- 70% alcohol.

Daily cleaning and disinfecting the device

Cleaning and disinfecting the device ensures that it will function correctly and efficiently.

NOTICE!

Damage to the device by liquids reaching internal parts

Liquids entering internal parts may lead to device malfunction.

- Only wipe the housing, never use sprays.
- Make sure that no liquid enters internal components.
- Do not immerse the device or any parts of it.
- Always ensure that the device is thoroughly dried after cleaning and disinfecting.

To clean and disinfect the device (at the end of each working day)

1. Power off the device, and remove the power adapter from the power socket.
2. Pull the test strip tray out of the device.
3. Moisten a cloth with water and wring it out (the cloth must be slightly dampened, not wet).
   - Clean the exterior parts and surfaces of the device, including the touch screen.
4. Afterwards moisten a cloth with 70% alcohol and wring it out (the cloth must be slightly dampened, not wet).
   - Wipe the exterior parts and surface of the device.

Daily cleaning and disinfecting the test strip tray

⚠ WARNING!

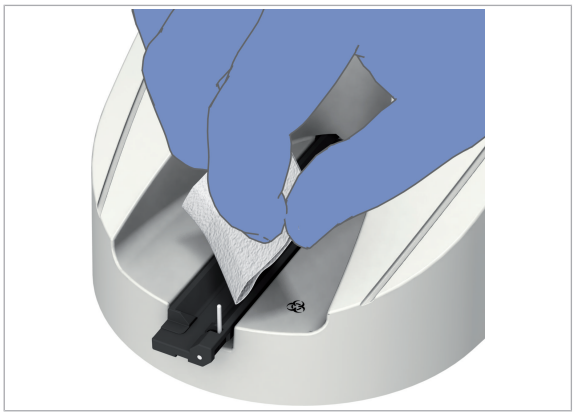
Protection against infection

Liquid waste and strip waste are potentially biologically hazardous.

- Always wear gloves when handling such materials.
- Dispose of the used test strips according to the regulations for handling potentially infectious material.

When inserting and removing test strips, take care that no urine residues come into contact with the retaining bar mechanism.

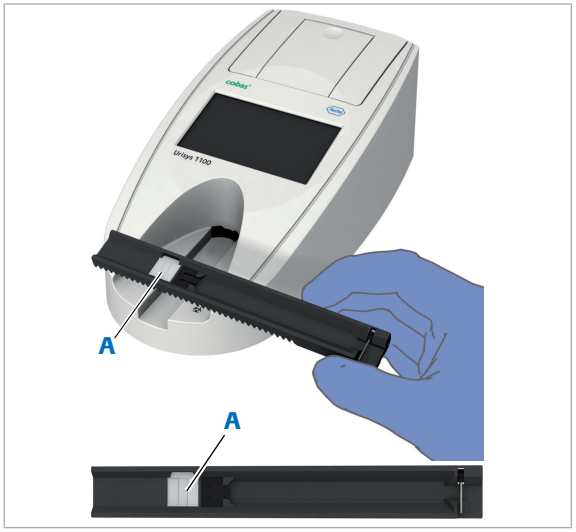
To clean the test strip tray (after each reading)



1 **CAUTION! To prevent carryover and an accumulation of urinary deposit, wipe off urine residues from the test strip tray with a dry, lint-free cloth after each reading.**

Wipe off the test strip tray with a dry, lint-free cloth.

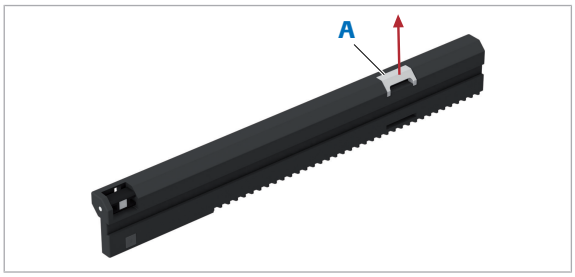
To clean and disinfect the test strip tray (at the end of each working day)



1 Power off the device, and remove the power adapter from the power socket.

2 **CAUTION! Be careful not to touch the grey reference pad (A). Contamination of the reference pad may impair the quality of the results obtained. If the reference pad has been contaminated, replace it by a spare reference pad. After replacing the grey reference pad, the device has to be calibrated. The device will not request the calibration automatically if the replacement happens within the weekly calibration period.**

Pull the test strip tray out of the device.



3 To avoid contamination of the grey reference pad (**A**), you can remove it before cleaning.

4 Rinse the strip tray under running water.

ⓘ Slight crystalline deposits, especially those contaminating the retaining bar mechanism or the cogs on the underside of the test strip tray, may be removed with a soft brush.

5 Disinfect the test strip tray using 70% alcohol.

6 Dry the parts with a dry, lint-free cloth.

7 **CAUTION! Take care not to damage the grey reference pad during cleaning. Ensure that there are no scratches on the surface and it is completely clean and dry before proceeding to read. If needed, replace it by a spare reference pad. After replacing the grey reference pad, the device has to be calibrated. The device will not request the calibration automatically if the replacement happens within the weekly calibration period.**

Insert the reference pad if taken out before cleaning.

8 Pick up the cleaned test strip tray and, with the retaining bar nearest to you and closed (down), slide it into the slot below the touch screen, so that the near edge of the test strip tray is flush with the near edge of the device.

9 If you wish to proceed with the next readings after cleaning the test strip tray, power the device on again.

➔ During the self-check the system will verify that the reference pad is in good condition for reading.

➔ If not, an error message will be displayed.

Error messages and troubleshooting

Error messages are displayed in the display but are not printed out. Following at least 20 minutes of inactivity (time depends on the **Power management** settings), the device switches to Standby mode. The error message is displayed again when the device wakes up from Standby mode. In the event that the device is defective, contact your local Roche representative.

Phone number of Roche Diagnostics Customer Support Center: +1-800-428-4674

E1 Reference pad error (middle part)

Cause

The middle portion of the reference pad on the test strip tray is soiled or damaged.

Action

1. To confirm the message, tap the ✓ button.
2. Power off the device.
3. Remove the strip tray from the device.
4. Check whether the grey reference pad is soiled or damaged (e.g., scratched, etc.).
5. If yes, replace with a spare reference pad.
6. Insert the test strip tray again, then wait for the self-check to finish.
7. If the error message is repeated, use the spare test strip tray.
8. Recalibrate with a calibration strip.

Inserting the test strip tray (81)

Performing a calibration (83)

E15 Reference pad error (bottom part)

Cause

The bottom portion of the reference pad on the test strip tray is soiled or damaged.

Action

1. To confirm the message, tap the ✓ button.
2. Power off the device.
3. Remove the strip tray from the device.
4. Check whether the grey reference pad is soiled or damaged (e.g., scratched, etc.).
5. If yes, replace with a spare reference pad.

6. Insert the test strip tray again, then wait for the self-check to finish.
7. If the error message is repeated, use the spare test strip tray.
8. Recalibrate with a calibration strip.

Inserting the test strip tray (81)
Performing a calibration (83)

E16 Reference pad error (top part)

Cause

The top portion of the reference pad on the test strip tray is soiled or damaged.

Action

1. To confirm the message, tap the ✓ button.
2. Power off the device.
3. Remove the strip tray from the device.
4. Check whether the grey reference pad is soiled or damaged (e.g., scratched, etc.).
5. If yes, replace with a spare reference pad.
6. Insert the test strip tray again, then wait for the self-check to finish.
7. If the error message is repeated, use the spare test strip tray.
8. Recalibrate with a calibration strip.

Inserting the test strip tray (81)
Performing a calibration (83)

E2 Wrong strip

Cause

The test strip used is different from the one for which the device has been programmed.

Action

1. To confirm the message, tap the ✓ button.
2. Repeat the measurement with a correct test strip.

E3 Strip measurement error

Cause

No test strip is present on the test strip tray, or the test strip is incorrectly positioned on the test strip tray, the urine on the test strip has dried, the test strip has not been dipped in urine.

Action

1. To confirm the message, tap the ✓ button.
2. Repeat the measurement with a new test strip.

- Ensure that all test pads are dipped in the urine sample.
- Insert the test strip correctly and ensure that the retaining bar is closed properly after the incubating time has passed and the strip tray starts moving into the device.

E4 Calibration error

Cause

Calibration values differ from those obtained in the last valid calibration.

Action

1. To confirm the message, tap the ✓ button.
2. Repeat the calibration with a new calibration strip taken from a vial of strips.
   - Ensure that the strip is properly positioned under the clip on the test strip tray.
3. If the error persists, replace the reference pad and repeat the calibration.

Daily cleaning and disinfecting the test strip tray (128)

E5 Calibration invalid

Cause

Calibration values are out of the tolerance range.

Action

1. To confirm the message, tap the ✓ button.
2. Check the reference pad for soiling or damage.
3. Clean if necessary, replace if damaged, or use a spare test strip tray.
4. Repeat the calibration with a new calibration strip.

If the error message appears again, the device is defective.

Daily cleaning and disinfecting the test strip tray (128)

E7 Missing strip tray

Cause

No test strip tray inserted or test strip tray not inserted far enough to be engaged by the motor.

Action

1. Insert the test strip tray correctly.
2. To confirm the message, tap the ✓ button.

E8 Strip tray position error

Cause

The retaining bar is open while the test strip tray is advancing or the retaining bar mechanism is fouled with urinary deposit and blocked.

Action

1. To confirm the message, tap the ✓ button.
2. Remove urinary deposits, if there are any, including those on the underside of the test strip tray.
3. Insert the test strip tray again and tap the ✓ button.
   - Ensure that the retaining bar is down and locked into place while the reading is taking place.

If the error message appears again, use the spare test strip tray.

E10 Light barrier error

Cause

The light barrier used to control the position of the test strip tray is defective or the test strip tray transport is blocked.

Action

1. To confirm the message, tap the ✓ button.
2. Pull out the test strip tray and return it to the start position.
3. Restart the measurement procedure.

If the error message appears again, the device is defective.

E11 Motor step error

Cause

The stepping of the motor is out of the tolerance range or the advance of the test strip tray is blocked. This may be due to

- soiling on or between the cogs
- worn or broken cogs
- defective motor.

Action

1. To confirm the message, tap the ✓ button.
2. Carefully clean the test strip tray.
3. Remove any urinary deposits, including those on the underside of the test strip tray and the cogs.
   - If the test strip tray is damaged insert the spare test strip tray.

4. Restart the measurement procedure.

If the error message appears again, the device is defective.

E12 Optics error

Cause The reference pad is missing from the test strip tray, or an LED or the phototransistor is defective.

Action

1. To confirm the message, tap the ✓ button.
2. Attach the reference pad or use the spare test strip tray.
3. Restart the measurement procedure.

If the error message appears again, the device is defective.

E13 Printer paper is missing or printer cover open

Cause The printer cover is open.

Action

1. To confirm the message, tap the ✓ button.
2. Close the printer cover.

Cause No paper has been inserted or paper roll is finished.

Action

1. To confirm the message, tap the ✓ button.
2. Insert a new roll of paper and close the printer cover.

After elimination of printer errors the results can be printed from the device's memory using the button.

E14 Interface error

Cause The protocol transfer to the DMS failed.

Action

1. To confirm the message, tap the ✓ button.
2. In the status bar, make sure the icon is displayed.
3. To check the network connection to the DMS, choose the **Test connection** button.
4. To transfer data, use the button or, to resume the Ready-to-Measure status, tap the button.

If the icon is not displayed, proceed as described in:

Setting the connection options (102)

E17 Invalid password

Cause The entered password does not match.

Action

1. To confirm the message, tap the ✓ button.
2. Enter a correct password.

E18 Invalid user ID

Cause The entered user ID is not valid.

Action

1. To confirm the message, tap the ✓ button.
2. Enter a valid user ID.

E19 List download failed

Cause The new user ID list download failed.

Action

1. To confirm the message, tap the ✓ button.
2. No further action, the old list (if existing) will automatically be used.

E23 cobas® Infinity edge timeout

Cause The connection to **cobas® infinity** edge test failed.

Action

1. Check the connection settings and the network function.
2. In the status bar, make sure the icon is displayed.

If the icon is not displayed, proceed as described in:

Setting the connection options (102)

Values obtained are implausible when compared with those from visual evaluation

Cause

- The test strip is incorrectly positioned, uncharacteristic test pad colors, proper incubation intervals not kept to during serial measurements.
- A wrong test strip was used.

Action

1. Repeat the measurement with a new device-compatible test strip.
   - Follow the directions carefully and ensure the test strip is correctly inserted.

If the problem persists:

1. Repeat the calibration if necessary.
2. Repeat the measurement.

If the problem still persists:

1. Perform a QC.
2. Repeat the measurement.

Cause Electromagnetic interference from other devices.

Action Remove external sources of interference, if there are any.

QC results fall outside the target ranges

Cause Entered target ranges for the QC material are incorrect.

Action Make sure that you entered the correct target ranges according to the package insert of the QC material.

Cause The control was not performed according to the QC material manufacturer's specifications.

Action Make sure the handling of the QC material is fulfilling the QC material manufacturer's instructions of use (e.g., room temperature re-equilibration after storage in the refrigerator, gently mix the QC material prior testing).

Cause Test strips and/or calibration strips and/or QC materials are expired.

Action

- Make sure that all the consumables used are not expired.
- The test strips must always be stored in a sealed vial.
- Perform a calibration with a new calibration strip.
- Repeat the measurement with a new test strip and/or with new QC materials.

Cause There is no valid calibration.

Action
- Check that the device has successfully passed a calibration performed with the calibration test strip in the last seven days.
- If this is not the case, repeat calibration with a new calibration strip followed by the measurement of the negative control.

Cause
- The test strip is incorrectly positioned.
- A wrong test strip was used.

Action
1. Repeat calibration if necessary.
2. Repeat the measurement with a new device-compatible test strip.
   - Follow the directions carefully and ensure the test strip is correctly inserted.

Cause The test strip tray is soiled.

Action
- Clean the test strip tray as described.

Daily cleaning and disinfecting the test strip tray (128)

Cause The test strip tray is older than 18 months and the troubleshooting steps described above failed.

Action
1. Replace the test strip tray by a spare tray.
2. Calibrate the device using a new calibration strip.
3. Repeat the measurement with a new device-compatible test strip.
   - Follow the directions carefully and ensure the test strip is correctly inserted.

Cause Electromagnetic interference from other devices.

Action Remove external sources of interference, if there are any.

Cause The device is older than 5 years and all troubleshooting steps failed.

Action Replace the device.

Cause The device is less than 5 years old and all troubleshooting steps failed.

Action Contact your local Roche representative for support.

No printout

Action

1. Insert paper if needed, and make sure it is correctly positioned. Close the printer cover completely.
2. Enable a print option (**Menu > Measurement > Auto print**).
3. Print an existing patient report.
   - If this fails, choose the **Linefeed** button on the **Home** screen.

If there is still no response, the device is defective.

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