

cobas[®] pulse

User Assistance

Publication version 1.0

Software version 01.03



Publication information

Publication version	Software version	Revision date	Change description
1.0	01.03	July 2021	First edition

☰ Revision history

Material number 09515909018

Edition notice This publication is intended for users of **cobas® pulse**.

Every effort has been made to ensure that all the information contained in this publication is correct at the time of publishing. However, the manufacturer of this product may need to update the publication information as output of product surveillance activities, leading to a new version of this publication.

General attention

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

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

Instrument use

The FDA, CDC, and CMS recommend the following:

- ▶ Point of Care blood testing devices such as the **cobas® pulse** instrument should be used only on one patient and not shared.
- ▶ If dedicating blood glucose instruments to a single patient is not possible, the instruments must be properly cleaned and disinfected after every use following the guidelines provided in this manual (see the “Maintenance” section).

Images

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

Warranty	Any customer modification to the instrument renders the warranty or service agreement null and void. For conditions of warranty, contact your local sales representative or refer to your warranty contract partner.
Limited warranty	PLACEHOLDER
Copyright	© 2020–2021, Roche Diagnostics. All rights reserved.
License information	The cobas® pulse instrument software is protected by contract law, copyright law, and international treaties. The cobas® pulse instrument software contains a user license between F. Hoffmann-La Roche Ltd. and a license holder, and only authorized users may access the software and use it. Unauthorized use and distribution may result in civil and criminal penalties.
Open-source and commercial software	This product incorporates software modules developed under open-source licenses. The source code of this software can be requested on a standard data exchange medium from the manufacturer at the following address: Roche Diagnostics GmbH Sandhofer Str. 116 68305 Mannheim Germany This open-source and commercial software and cobas® pulse as a whole can constitute a device regulated in accordance with applicable law. For more detailed information, refer to the corresponding user documentation and labeling. Note that the respective authorization is no longer valid according to the corresponding legislation should any unauthorized changes be made to cobas® pulse.
Trademarks	The following trademarks are acknowledged: COBAS and COBAS INFINITY are trademarks of Roche. All other trademarks are the property of their respective owners.

Feedback

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

Approvals

cobas® pulse meets the requirements laid down in:

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

Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC.

To view the full text of the 2014/53/EU declaration of conformity, go to the Roche DiaLog global website (dialogportal.roche.com) and choose the eLabDoc link. If you are unable to access Roche DiaLog, contact a Roche Service representative.

Compliance with the applicable directives is provided by means of the declaration of conformity.

The following marks demonstrate compliance:



For *in vitro* diagnostic use.



The system fulfills the Canadian and U.S. safety requirements (UL LISTED, in accordance with UL 61010-1 and CAN/CSA-C22.2 No. 61010-1).



This device contains license-exempt transmitter(s)/ receiver(s) that comply with Innovation, Science and Economic Development Canada's license-exempt RSS(s), and complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference
2. This device must accept any interference received, including interference that may cause undesired operation of the device.

FIPS
PLACEHOLDER

Validated under Federal Information Processing Standard (FIPS) 140-3, Security Requirements for Cryptographic Modules.

Contact addresses



Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany

Distributed in the U.S.A. by:
Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46256

Roche affiliates

A list of all Roche affiliates can be found at:

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

eLabDoc

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

dialogportal.roche.com

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

Additional help

For all questions about the **cobas® pulse** system that are not answered in this publication, contact the Roche Customer Support Center at 1-800-440-3638 24 hours a day, 365 days a year.

In order to expedite troubleshooting, please have ready your instrument and all related consumables when you call.

Rx only

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

Page intentionally left blank.

Table of contents

Publication information	2	Reviewing QC test results	126
Contact addresses	5	Adding comments to a test result	128
Intended use	9		
Symbols and abbreviations	9		
Safety			
1 General safety information			
Safety classifications	17		
Safety precautions	18		
Warning messages	20		
Caution messages	22		
Notices	24		
Safety information for disposal	25		
Recommendations for cybersecurity and data security	26		
System description			
2 Overview of the system			
About the system	35		
About the instrument	37		
Overview of the charging station	39		
Overview of the carry case	40		
Overview of the user interface	41		
About tests	49		
About lockouts	66		
List of notifications	72		
Overview of the User Assistance	75		
3 Specifications			
General specifications	85		
Technical specifications	86		
Environmental conditions	87		
Dimensions and weights	88		
List of accessories and consumables	89		
Barcode specifications	90		
Radio equipment specifications	93		
Operation			
4 Frequently performed tasks			
Logging on to the Glucose app	99		
Charging the instrument	104		
Checking notifications	105		
Putting the instrument into standby mode	107		
Waking the instrument from standby mode	108		
Logging off the Glucose app	109		
5 Routine operation			
Entering a patient	113		
Performing a glucose test	116		
Reviewing patient test results	120		
Performing a QC test	122		
		6 Non-routine operation	
		Entering insulin information	131
		Performing a linearity test	135
		Performing an emergency glucose test	139
		Performing a proficiency test	142
		Performing an observed test sequence (OTS)	145
		Adjusting the screen brightness and the volume level	147
		Reviewing the audit trail	148
		Changing your user password	150
		Turning on the instrument	151
		Turning off the instrument	152
		Restarting the instrument	153
		Setting up the charging station	154
		Lot management	155
		Maintenance	
		7 Maintenance	
		About cleaning and disinfecting the instrument	169
		Acceptable cleaning solutions and disinfectants	171
		Cleaning and disinfecting the instrument	172
		Cleaning and disinfecting the charging station	175
		Cleaning and disinfecting the carry case	176
		Replacing the battery	177
		Troubleshooting	
		8 Troubleshooting	
		Resetting the instrument	185
		Running a network status test	186
		Network status test steps	188
		Resetting a synchronization lockout	190
		Deleting instrument data	191
		List of audit trail events	192
		Starting up an instrument with low battery level	193
		9 Error messages	
		About level 1 messages and level 2 errors	209
		Level 1 messages	213
		Level 2 errors	229
		Configuration	
		10 Initial configuration	
		About instrument configuration	365
		About the Settings menu access restrictions	367
		Setting the instrument date and time	368

Configuring by barcode	370
Formats and language configuration	371
QC configuration	376
Data deletion	385
Barcode camera configuration	388
Connectivity	390
11 General configuration	
List of power management options	425
Patient ID handling	427
User ID handling	437
Result range handling	448
Measurement workflow	458
Generic instrument functionality	467

Glossary

Index

Intended use

cobas® pulse is intended for multiple-patient use within professional healthcare settings, including intensive critical care and non-critical care settings. This system is not for screening or diagnosis of diabetes, but is indicated for use in determining dysglycemia.

Symbols and abbreviations

Product names

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

Product name	Descriptor
cobas® pulse system	system
cobas® pulse	instrument
cobas® pulse charging station	charging station
cobas® pulse carry case	carry case
cobas® GLU test strips	test strips
cobas® GLU QC kit	QC kit
cobas® GLU linearity kit	linearity kit
cobas® infinity POC solution	iDMS

☐ Product names and descriptors

Symbols used in the publication

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
$\sqrt{xy}$	Equation, used in cross-references to equations
⚙️	Code example, used in code titles and cross-references to codes
💡	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

☐ Symbols used in the publication

Symbols used on product and packaging

Symbol	Explanation
	Materials that are required for a task
	Prerequisites of a task
	Symbols used in the publication

Symbol	Explanation
	Manufacturer.
	Date of manufacture.
	Catalog number.
	In vitro diagnostic medical device.
	Global Trade Item Number.
	Serial number.
	Unique device identifier
	TÜV SÜD U7-2D
	Biohazardous
	RFID reader.
	Device contains a transmitter.
	Device for near-patient testing
	Symbols used on product and packaging

Symbol	Explanation
	Device not for self-testing
	Temperature limitation
	Humidity limitation
	Refer to safety information included in this publication.
	Consult the instructions for use.

 Symbols used on product and packaging

Abbreviations

The following abbreviations are used:

Abbreviation	Definition
AC	Alternating current
DC	Direct current
DHCP	Dynamic host configuration protocol
DMS	Data management system
DNS	Domain name system
EAP	Extensible authentication protocol
EC	European Community
EMC	Electromagnetic compatibility
EN	European standard
FCC	Federal Communications Commission (USA)
IC	Industry Canada
IEC	International Electrotechnical Commission
ISM	Industrial, scientific and medical
ISO	International Organization for Standardization
OTE	Other test entry
OTS	Observed test sequence
RF	Radio frequency
RFID	Radio frequency identification
RSS	Radio Standards Specification (Canada)
SAR	Specific absorption ratio
TLS	Transport layer security
WLAN	Wireless local area network

 Abbreviations

Page intentionally left blank.

Safety

1	General safety information	15
---	----------------------------------	----

Page intentionally left blank.

General safety information

In this chapter

1

Safety classifications.....	17
Safety precautions	18
Warning messages	20
Caution messages	22
Notices	24
Safety information for disposal.....	25
Recommendations for cybersecurity and data security.....	26

Page intentionally left blank.

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

User qualification Insufficient knowledge and skills

Safe and proper use of the system Non-approved parts

Electromagnetic compatibility (EMC)

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

To ensure correct operation of **cobas® pulse**:

- ▶ Only trained healthcare professionals may operate the instrument.
- ▶ Users must have received comprehensive instruction in the operation, QC, and care of **cobas® pulse**.

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

- ▶ Use only parts and devices approved by Roche Diagnostics.

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.

In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.

The electromagnetic environment in which the **cobas® pulse** system will be operated should be thoroughly evaluated prior to operation of the device.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by powering the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

- Consult the dealer or an experienced radio/TV technician for help.

cobas® pulse complies with both the electromagnetic immunity requirements and radio interference immunity requirements at the frequency and test levels according to ISO 15197.

Electrostatic discharge (ESD)

The **cobas® pulse** system 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. If the meter experiences ESD during a blood glucose test, an error message is displayed and no blood glucose result is displayed by the meter or stored in the meter's memory. The blood glucose test will need to be repeated.

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

Wireless connectivity

Wireless connectivity allows the instrument to send data (test results, patient IDs, user IDs, etc.) to the data management system. The Wi-Fi should be configured by the system administrator. Observe the guidelines of your facility for using wireless local area network connections.

For additional information contact Roche Customer Support Center for technical assistance.

Radio frequency radiation exposure information

The industrial, scientific and medical (ISM) radio frequencies may contain emissions from microwave ovens, heaters, and other non-communication devices. While these types of devices usually pose no threat of interference as they are low-powered devices, the possibility exists that some industrial high-power systems may wipe out any attempted communication use of a WLAN enabled device. Therefore, perform a site survey and interference analysis with a spectrum analyzer to view the entire spectrum, looking for signals that might not only be within the frequency range of the intended WLAN but also could be near or at the same frequency and cause interference.

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 carefully.

Incorrect test measurement

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

- ▶ Only use a blood sample when performing a test measuring blood glucose.
- ▶ Only use an appropriate QC material when performing QC tests.
- ▶ Always wear a new, clean pair of disposable gloves for each test you perform.
- ▶ Use only parts and devices approved by Roche Diagnostics.
- ▶ Do not use the instrument outside the specified temperature range.
- ▶ Do not use the instrument in a hyperbaric chamber.
- ▶ Ensure that there are no traces of food on the fingers or fatty residues from hand cremes or soap products that may contaminate the sample.
- ▶ Ensure that there are no residues of water or disinfectant on the skin that can dilute the drop of blood.
- ▶ Test strips are single use only. Never reuse a test strip.

Protection against infection and blood-borne pathogens

Healthcare professionals using **cobas® pulse** to perform tests must be aware that any object coming into contact with human blood is a potential source of infection.

Users must adhere to standard precautions when handling or using **cobas® pulse**.

All parts of this system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients, and between patients and healthcare professionals.

- ▶ Use disposable gloves. Wear a new pair of clean gloves for testing each patient.
- ▶ Wash hands thoroughly with soap and water before putting on a new pair of gloves and performing the next test.
- ▶ Use an auto disabling single-use lancing device for each patient.
- ▶ Dispose of used lancets in a solid waste/sharps container with lid.
- ▶ Dispose of used test strips from patient and proficiency tests according to your healthcare facility's infection control policy.
- ▶ Follow all health and safety regulations in force locally.

Avoiding electrical shock, fire, and explosions

- ▶ Only use Roche original accessories (cables, power supplies, batteries). Third-party cables, power supplies, and batteries can cause the battery to explode or the instrument to become damaged.
- ▶ Do not use loose power outlets or damaged power supplies, cables, plugs, or batteries.
- ▶ Do not short circuit the power supplies or the battery.
- ▶ Do not drop the instrument, charging station, the power supplies, or the battery, and protect them against shaking and vibrations.

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.
- ▶ Ensure that barcode size and print quality (as defined in ISO/IEC 15416 and 15415) are adequate.
- ▶ Carry out a plausibility check on all data scanned into and displayed by the instrument.

▶ [Barcode specifications \(90\)](#)

Caution messages

Allergy or injury caused by reagents and other working solutions

Safety information for barcode camera and built-in flashlight

Unauthorized system access and data loss

Strong password management

List of caution messages

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

Direct contact with reagents, detergents, cleaning solutions, disinfectants or other working solutions 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, cleaning solutions and disinfectants.
- ▶ If a reagent, QC material, or linearity material come into contact with your skin, wash it off immediately with water.

Exposure to the barcode reader flashlight may be harmful to the eyes

- ▶ Do not look into the flash light when it is turned on.

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 render the system unusable.

Roche recommends the following precautions:

- ▶ To protect access to all external devices, make sure that you use appropriate security equipment. For more information, contact your Roche Service representative.
- ▶ Ensure that the connected network is free of malicious code.

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

- Passwords must not contain the user's account name or parts of the user's full name that exceed two consecutive characters.
- Passwords must be at least eight characters in length.
- Passwords must contain characters from at least three of the following four categories:
 - English **uppercase alphabetic** characters (A through Z)

- English **lowercase alphabetic** characters (a through z)
- **Numeric** characters (0 through 9)
- **Non-alphabetic** characters (for example, !, \$, #, %)

Examples of weak passwords:

- **uhxwze11** contains no upper case letter.
- **UHXW13SF** contains no lower case letter.
- **uxxxx7F** contains the same character more than four times.
- **x12useridF** contains a substring of the user ID longer than four characters.

Notices



List of notices

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

- ▶ Before using the system, read the notices carefully.

General care

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

- ▶ Only clean the instrument with the recommended cleaning solutions and disinfectants.
- ▶ Ensure that the instrument and charging station are thoroughly dried after cleaning and disinfection.

Safety information for disposal

Disposal of the instrument

Infection by a potentially biohazardous instrument.

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

Disposal of electronic equipment



This symbol appears on any component of the system that is covered by the European Directive on waste electrical and electronic equipment (WEEE).

You must dispose of these items through designated collection facilities appointed by government or local authorities.

Contact your city office, waste disposal service, or your Roche Service representative for more information about disposal of your old product.

Constraint:

- It is left to the responsible organization to determine whether electronic equipment components are contaminated or not. If contaminated, treat them in the same way as the system.

Recommendations for cybersecurity and data 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.

Physical access controls

Ensure that the instruments are protected against unauthorized physical access and theft. Since Roche Point of Care instruments are hand-held, an unauthorized user might gain access to data by stealing an instrument, or attempting to interact with it.

User authentication

Protect access to the instrument by using one of the following:

- Scanning a valid user's barcode or RFID tag, and entering the user's password using the virtual keyboard.
- Entering a user name and password using the virtual keyboard.

(see the [User authentication required](#) and User ID validation configuration items).

Include user certificate expiry dates in the DMS (see the [Show user lockout warning prior to user certificate expiration](#) configuration item).

Passwords are the most important access control on the instrument. Users often use the same password for multiple accounts making it easier for an unauthorized person to gain access. Therefore, use strong passwords and do not share accounts.

Set an appropriate value for the minimum password length which is enforced when users set their password (see the [Minimum password length](#) configuration item).

Delete users who are no longer needed on the instruments and use the "standby timeout" function for automatic logout on inactivity (see the **Standby timeout** and **Logon session timeout** configuration items).

Ensure that users log off the instrument when they have finished using it (see "User log off").

When using user lists with passwords in combination with a DMS (see the **User ID validation** configuration item), the instrument has the following options for user passwords:

- Upload user lists with configured passwords
- Upload user lists with empty passwords

The user list with configured passwords is active once uploaded to the instrument.

For user lists with empty passwords, users are prompted to enter a new password when they first log on. Ensure that users set their password immediately on an instrument. This measure ensures that the password is synchronized with the DMS and distributed to all available instruments.

- ▢ [Strong password management \(22\)](#)
- ▢ [User authentication required \(437\)](#)
- ▢ [User ID validation \(439\)](#)
- ▢ [User ID handling \(444\)](#)
- ▢ [Standby timeout \(425\)](#)

Access restrictions for settings

You should configure additional access restrictions to instrument menus based on your needs using the following configuration items:

- **Allow configuration by barcode on the instrument**
- **Allow access to lot management on the instrument,**
- **Allow access to administrator features**
- **Access restrictions to date and time**

During the initial installation of an instrument, ensure that the "Setup password" is set accordingly.

Ensure that the instrument date and time are synchronized with the date and time of IT systems to which it is connected (DMS, cobas infinity edge). Instruments with an incorrect date and time will experience connectivity issues.

✎ [Access restrictions \(467\)](#)

Secure network connections

You should use WPA2 encryption to protect your data and wireless connection. Alternative connection methods (e.g., open, WPA encryption) can be insecure and should only be used in exceptional cases.

Secure network environment

When connecting Roche Point of Care instruments 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 instrument from uncontrolled networks, or measures to ensure that the connected network is free from malicious code.

Authentication of communication end points (use EAP and TLS)

You can use EAP as a safety measure. This measure prevents an attacker behaving like a Roche Point of Care instrument within your network, when communicating with the DMS. You should use TLS encryption when communicating with the DMS (see the [DMS TLS level](#), [DMS TLS certificate check](#) and [DMS TLS certificate](#) configuration items).

✎ [TLS security \(414\)](#)

Unused user accounts

Delete the account of users who no longer use the instrument (including their related local data).

Handling personal data

You should inform users how to handle personal data. This measure should be compliant with your facility's current regulations. For example:

- Do not enter direct identifiers (identifier which links directly to an individual) into free-text comments.
- Be aware of password security rules.
- Do not leave an instrument unlocked in publicly accessible areas.

Asset tracking controls	Ensure that your facility implements controls to track instruments.
Data retention time	Adjust the instrument result retention time and the result deletion algorithm according to your facility's current regulations. See the following configuration items: ▪ Result Deletion Algorithm ▪ Result upload required before result deletion ▪ Result retention period (in days) ▪ Audit trail retention period (in days) ✎ Data deletion (385)
Data minimization options	It is possible to use the instrument without any direct identifiers (e.g., names). The information which is uploaded to the instruments is defined in the DMS.
Wiping data from the instrument	Prior to disposal of an instrument, wipe the stored data using Settings > Administrator > Delete instrument data .

Page intentionally left blank.

System description

2	Overview of the system	33
3	Specifications.....	83

Page intentionally left blank.

Overview of the system

In this chapter

2

About the system	35
About the instrument	37
Overview of the charging station	39
Overview of the carry case	40
Overview of the user interface	41
Overview of the software	41
About the user interface	43
About the charging screen	45
About the Tests screen	46
About the app library	46
About the Glucose app start screen	47
About tests	49
About patient entry	49
About collecting a blood sample	51
About performing a glucose test	52
About glucose test results	54
About performing QC tests	58
About proficiency testing	60
About linearity testing	60
About the observed test sequence (OTS)	62
About adding comments to a test result	62
About the test strip port light	64
About lockouts	66
About the QC lockout	66
Lockout types	68
List of notifications	72
Overview of the User Assistance	75
About the User Assistance	75
Overview of User Assistance functions	76
Accessing the User Assistance online	78

Accessing the User Assistance offline 79

Searching in the User Assistance..... 80

About the system

The **cobas® pulse** system is a blood glucose monitoring system that allows healthcare professionals to measure blood glucose levels near the patient.

The system can do the following:

- Perform patient blood glucose tests and glucose QC tests with QC material.
- Record automatically information related to the performed tests.
- Record tests results and reagent information.
- Record data related to quality assurance.
- Transfer automatically all recorded information to the DMS.

This system comprises the following components:



A Instrument

B Charging station

C Carry case (may not be available in all countries)

 System components

System extension

Through the app library, the system provides the option to extend its functionality by installing additional (Roche-controlled) apps with other functionalities.

► [About the app library \(46\)](#)

Configuration options

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

Testing principle

An enzyme on the test strip converts the glucose in the blood sample to gluconolactone. This reaction creates a harmless DC electrical current that the instrument interprets and converts into a blood glucose result. The sample and environmental conditions are also evaluated using AC and DC signals.

For detailed information, refer to the test strip package insert.

About the instrument



- A

Charge indicator
- B

Touch screen
- C

On/off button
- D

Test strip port and light
- E

Battery compartment cover
- F

Built-in flashlight
- G

Barcode camera
- H

Instrument information
- I

RFID reader

 Main instrument components front (left) and rear (right)

The instrument has the following elements:

- Charge indicator

Status indicator that shows the status of the charging process.
- Touch screen

Enables you to interact with the instrument by tapping the appropriate interface elements on the screen.
- On/off button

Turns the instrument on and off. Puts instrument into and out of standby mode.

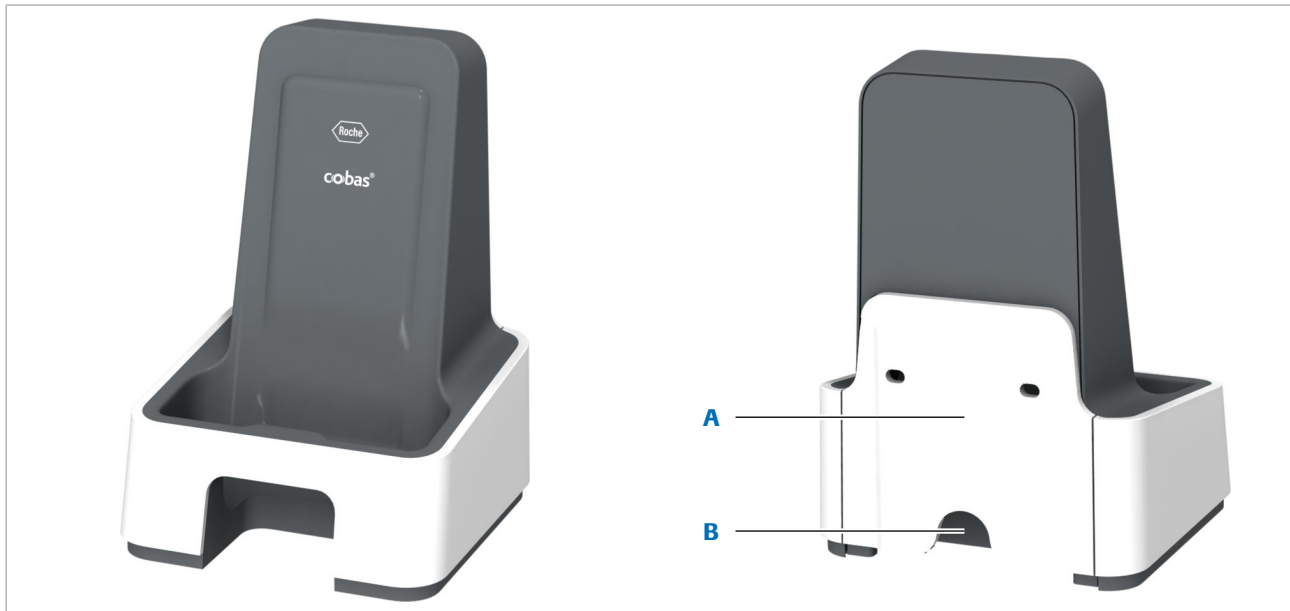

[Putting the instrument into standby mode \(107\)](#)
- Test strip port

Port for test strip insertion. Lighting indicates test-strip-related actions that should be taken.

Battery compartment cover	Cover by which the battery is accessed.
Barcode camera	You use the integrated barcode camera to do the following: ▪ Read user and patient IDs ▪ Read test strip container barcodes ▪ Read QC material bottle barcodes ▪ Read Linearity material bottle barcodes ▪ Configure the instrument
Built-in flashlight	Illuminates the barcode for scanning.
Instrument information	Contains the following information: ▪ Approval symbols ▪ Regulatory symbols ▪ Safety symbols ▪ Instrument specific symbols ▪ Technical data ▪ Barcode linking to additional information The information is laser etched onto the instrument. ▢ Publication information (2) ▢ Symbols and abbreviations (9)
RFID reader	The RFID reader is used to read the following: ▪ User IDs ▪ Patient IDs

Overview of the charging station

The charging station enables you to charge the instrument when it is not being used.



A Rear panel

B Access to power inlet

Charging station

The panel contains 2 holes which can be used to mount the charging station, on a wall for example.

The power supply is attached at the rear of the charging station.

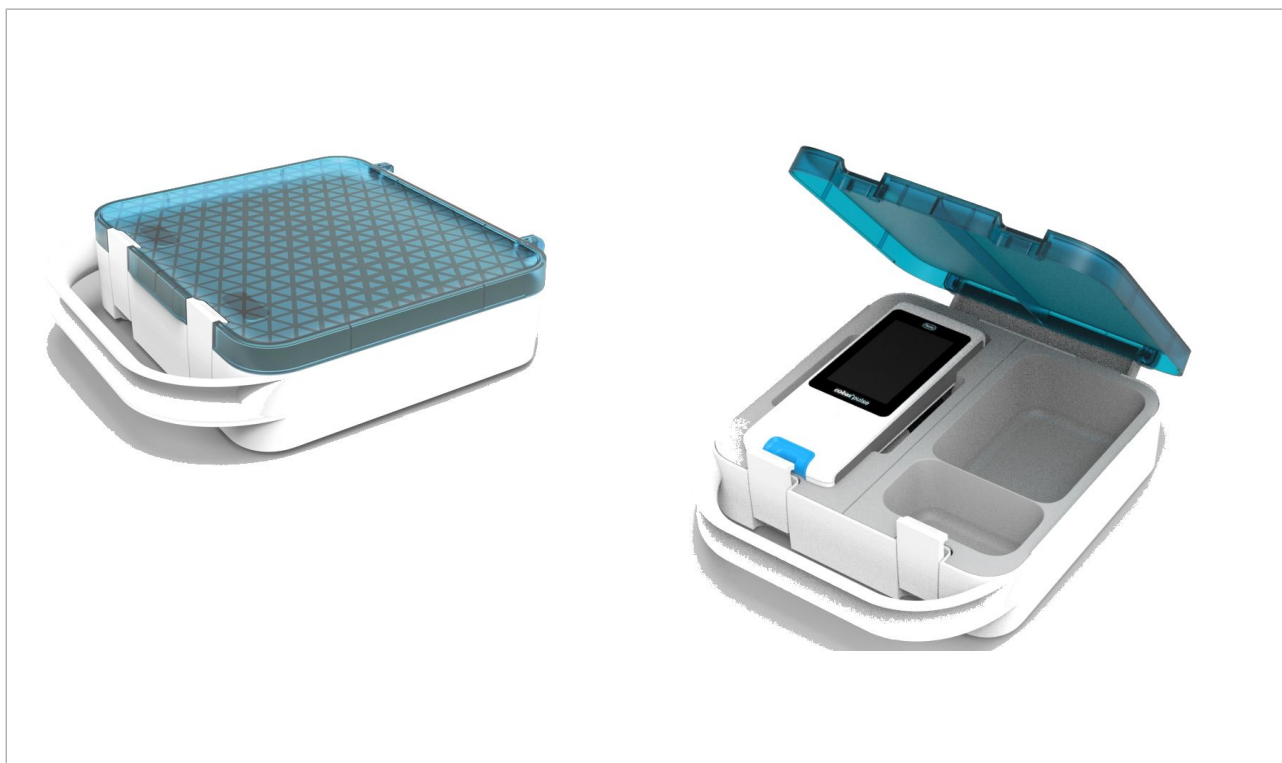
To charge the instrument, you place it in the cradle.

• [Setting up the charging station \(154\)](#)

Overview of the carry case

The carry case provides an area for storing and transporting consumables needed for performing blood glucose tests.

The carry case may not be available in all countries.



 Carry case

Overview of the user interface

In this section

Overview of the software (41)

About the user interface (43)

About the charging screen (45)

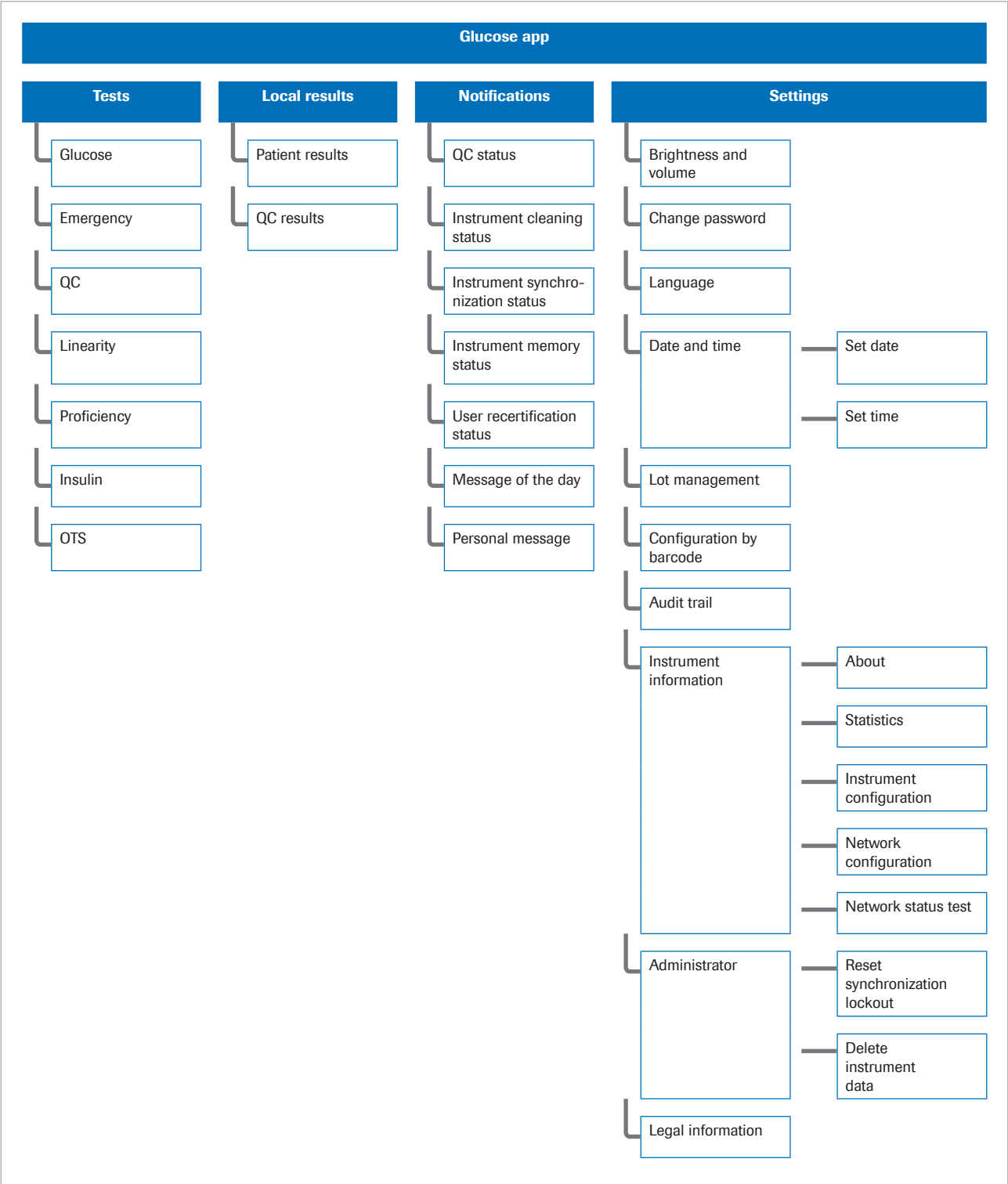
About the Tests screen (46)

About the app library (46)

About the Glucose app start screen (47)

Overview of the software

The figure contains the software items. Instrument configuration and user rights determine what you can access on your instrument.



Overview of the cobas pulse software

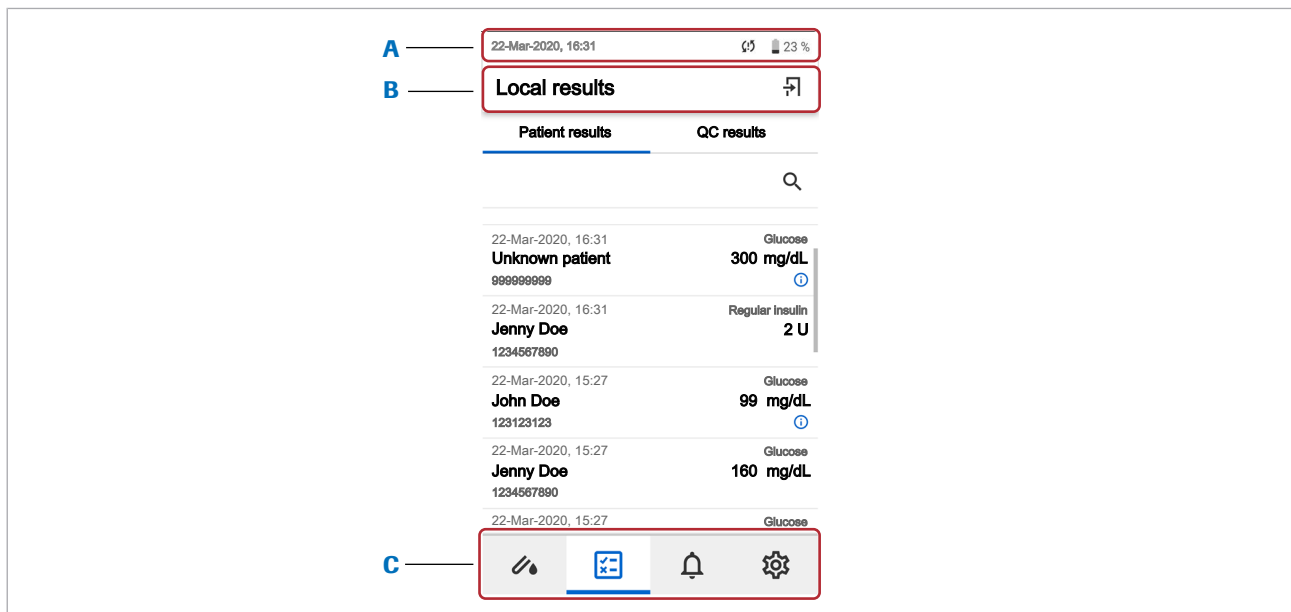
The **Instrument configuration** menu item contains the following sub menu items (not shown in the overview):

- **ID configuration**
- **QC interval**
- **Range configuration**

About the user interface

The user interface enables you to perform tasks on the instrument.

The user interface layout reflects the workflows of the tasks that you perform on the instrument.



A Status bar

B App bar

C Navigation bar

User interface

The user interface has 3 main components:

- Status bar
- App bar
- Navigation bar

Depending on the task you are performing, the navigation bar is not always displayed. For example, when you are performing a glucose test

Status bar

The status bar contains the following components:

- Current date and time
- Synchronization warning
- Battery level

The status bar does not interact with any of the tasks you perform, and is always visible.

The synchronization warning icon displayed in the status bar indicates that the instrument has not synchronized data with the DMS. In particular, recently measured test results and new patients, and additionally events, updated user lists and changes to the instrument configuration.

App bar

The app bar contains a screen title, indicating the user interface submenu in which you are working, or the activity that you are performing. For example, glucose test, QC test, results.

It also contains user interface elements with which you navigate between screens.



Move to previous screen



Close the current screen/dialog box



Log off

Navigation bar

The navigation bar provides direct access to the 4 main activity areas of the user interface. It contains 4 buttons.



Tests



Local results



Notifications



Settings

The  button provides access to the available tests:

- Glucose test
- QC test
- Emergency test
- Linearity test
- Proficiency test
- Insulin entry

Depending on your instrument's configuration, not all of the tests may be available.

The  button provides access to the results that are currently stored on the instrument

- Patient results
- QC results

The  button provides access to the **Notifications** screen which is used for the following:

- Reminders (for example, QC test is due)
- Messages (for example, message of the day, personal messages)
- Logging cleaning

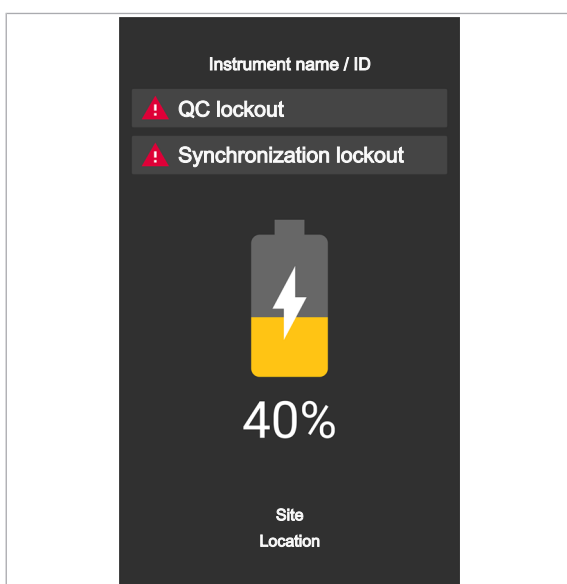
A blue notification badge on the button () indicates that notifications require a response from you. After you have responded, the blue badge disappears.

The  button provides access to the **Settings** screen which contains options to manage different aspects of your instrument (for example, setting the date and time, brightness and volume).

▶ [List of notifications \(72\)](#)

About the charging screen

The charging screen is displayed when the instrument is docked in the charging station.



It contains the following information:

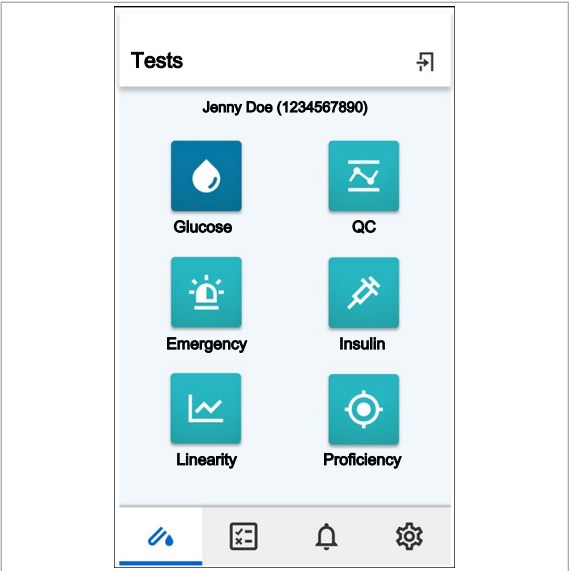
- Battery level of the instrument.
- Lockout notifications if applicable (2 items maximum).
- Instrument name and/or ID if configured (top of screen).
- Site and location where the instrument is used if configured (bottom of screen).

The battery level is indicated by a percentage value and a color coded battery indicator. The color coding is determined as follows:

- Red = 15% and below
- Yellow = 16% to 89%
- Green = 90% and above

The battery indicator color corresponds with the instrument's charge indicator color.

About the Tests screen



The **Tests** screen contains the tests that are available for use, and indicates who is logged on to the **Glucose** app.

You access the **Tests** screen in 2 ways:

- When you log on to the **Glucose** app.
- On the navigation bar, by tapping the  button.

Each test is represented by a button. The following tests can be configured to be on the **Tests** screen:

- **Glucose** test
- **QC** test
- **Emergency** test
- **Linearity** test
- **Proficiency** test
- **Insulin** entry
- **OTS** (observed test sequence)



When there are more than 6 tests available, scroll the screen to view them all.

To perform a test, you tap the corresponding button.

A  icon on a test button indicates that the test cannot be performed due to a lockout. You must remove the lockout before a test can be run.

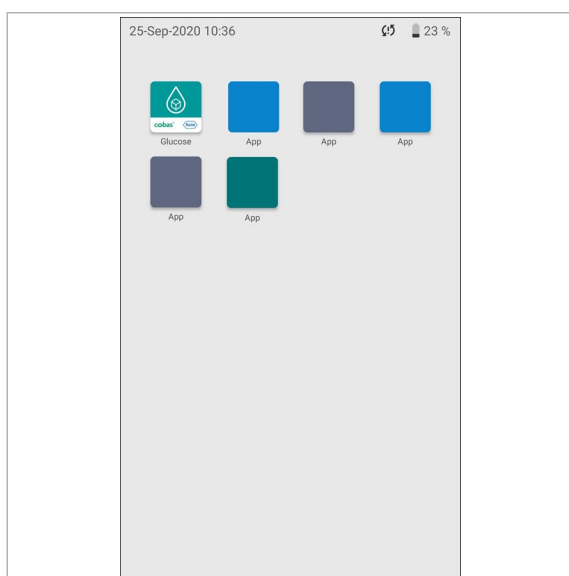
Tapping the test button displays a dialog box that provides guidance on what you must do to remove the lockout.

When you have finished working in the **Glucose** app, you can log off by tapping the  button.

• [About lockouts \(66\)](#)

About the app library

The app library contains the apps that you can use on the instrument.



Depending on your instrument's configuration, the app library is accessible as follows:

- From the **Glucose** screen by tapping the app library button.
- Directly when you log on.

There are 2 categories of apps:

- Apps of the cobas pulse system
- Other apps

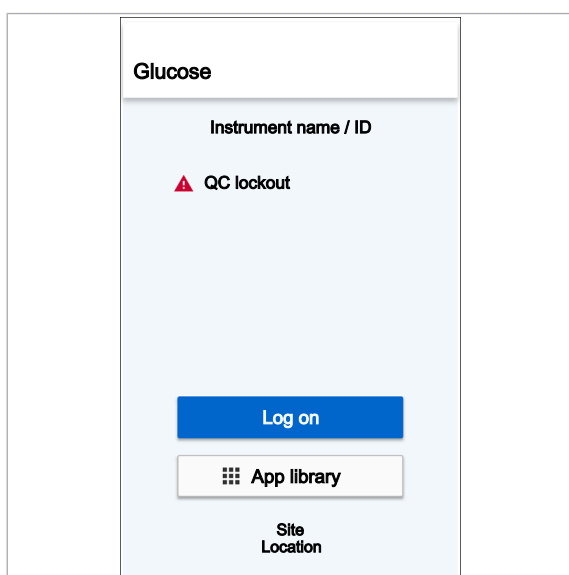
Apps of the cobas pulse system are those which are provided with cobas pulse, including the **Glucose** app.

Other apps are provided by Roche or by third parties. Your healthcare facility determines which apps are in the app library.

You use cobas pulse dedicated apps to perform tests.

About the Glucose app start screen

Depending on your instrument's configuration, you can log on to the in the **Glucose** app using the **Glucose** screen.



Depending on how your instrument is configured, the **Glucose** screen is accessible as follows:

- When you exit standby mode, or when you turn on the instrument.
- When you take the instrument out of the charging station.
- From the app library by tapping the **Glucose** app.

How you log on depends on your instrument's configuration:

- If a user ID and password is required, tap the **Log on** button, and then follow the logon procedure.
- If a user ID only is required, tap the **Log on** button, and then follow the logon procedure.
- If a user ID and password is not required, tap the **Proceed** button which takes you directly to the **Tests** screen.

The **Glucose** screen displays lockout notifications. Up to 5 items can be displayed.

The **Glucose** screen can be configured to display the following:

- Instrument name and/or ID (top of screen).
- Site and location where the instrument is used (bottom of screen).

About tests

In this section

About patient entry (49)

About collecting a blood sample (51)

About performing a glucose test (52)

About glucose test results (54)

About performing QC tests (58)

About proficiency testing (60)

About linearity testing (60)

About the observed test sequence (OTS) (62)

About adding comments to a test result (62)

About the test strip port light (64)

About patient entry

The way in which your instrument manages patient IDs depends on how it has been configured.

You enter patients in the following tests:

- Glucose test
- Insulin entry
- OTS

The following configurations can be made to your instrument, and determine how it manages patient entry.

- Entry methods
- Autocomplete
- ID pattern recognition
- ID validation
- Confirmation

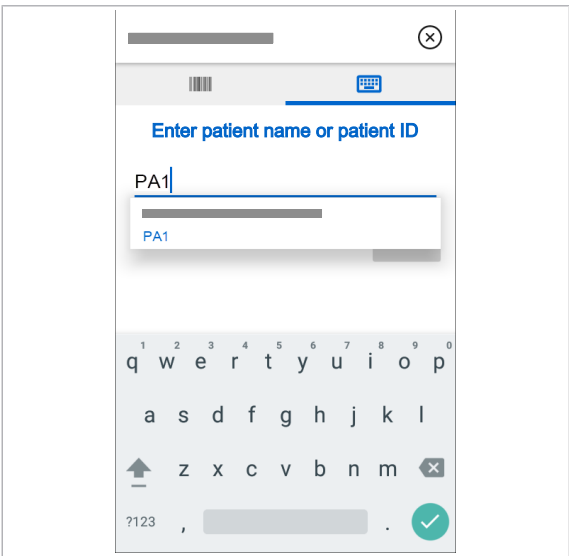
Entry methods

The entry methods are:

- RFID tag 
- Barcode scanning 
- Keyboard entry 

Your instrument can be configured to determine which entry methods you can use.

Autocomplete



Patient ID entry by keyboard can be configured to be any combination of up to 20 alphanumeric characters, with specified minimum and maximum lengths.

Patient entry by barcode scanning only works using supported barcode types.

▸ [Barcode specifications \(90\)](#)

When configured, autocomplete provides a quick way to enter a patient when using keyboard entry.

After entering 2 alphanumeric characters in the **Patient name or patient ID** field, a drop-down list is displayed. It contains all patient names or IDs containing the same 2 alphanumeric character sequence.

You then select the patient from the drop-down list.

💡 When entering a patient with autocomplete activated, case sensitivity does not apply. When autocomplete is not activated you must enter the patient ID in full using the correct capitalization.

ID pattern recognition

Your instrument can be configured to validate a configured "pattern" in a patient ID.

For example, a pattern is configured so that all patient IDs begin with "PA" followed by 6 numerals. In this case, when entering a patient ID by keyboard:

- "PA123456" is a valid patient ID.
- "P123456" is an invalid patient ID.

The same function operates for patient ID entry by barcode scanning.

ID validation

Your instrument can be configured to validate the patient ID entered in one of 3 ways.

- Pattern only
- List based
- List based. Allow new entries if not in list.

"Pattern only" validation checks that the patient ID entered matches the configured patient ID pattern. For example, that the patient ID always starts with "PA". If it does not, an error message is displayed.

"List based" validation checks that the patient ID entered matches an entry in the patient list on your instrument. If it does not, an error message is displayed.

"List based. Allow new entries if not in list" validation checks that the patient ID entered matches an entry on the patient list on your instrument. If the patient is not found, you are still able to enter the patient ID.

This option caters for situations where a patient ID is in the DMS but has not been synchronized with your instrument.

Patient confirmation

Your instrument can be configured to display the **Confirm patient** dialog box. It enables you to ensure that the patient that you entered is the correct patient. After confirming, you continue with the test.



The **Confirm patient** dialog box contains the patient information that has been transmitted from the DMS to the instrument:

- Patient name
- Patient ID
- Gender
- Age
- Date of birth

The patient ID is mandatory. The other items are optional.

Related topics

- [Performing a glucose test \(116\)](#)
- [Entering insulin information \(131\)](#)

About collecting a blood sample

You collect a blood sample from a patient in order to perform a blood glucose test.

Prepare the selected puncture site and collect blood from the patient per healthcare facility policy.

If no healthcare facility policy exists for collecting capillary blood, the patient's hands (or heel in the case of small children) should be thoroughly cleaned and dried.

WARNING!

Incorrect results due to residues on skin

Traces of food on the fingers or fatty residues from hand cremes or soap products may contaminate the sample and lead to incorrect results.

Residues of water or disinfectant on the skin can dilute the drop of blood and lead to incorrect results.

- ▶ Wash the puncture site thoroughly and rinse with plenty of water.
- ▶ After washing and disinfecting the site, ensure that the patient's skin is completely dry before using the lancing device to collect a capillary blood sample.



You should take the capillary blood sample from the side of the fingertip as this part is the least sensitive to pain.

Related topics

- [Performing a glucose test \(116\)](#)

About performing a glucose test

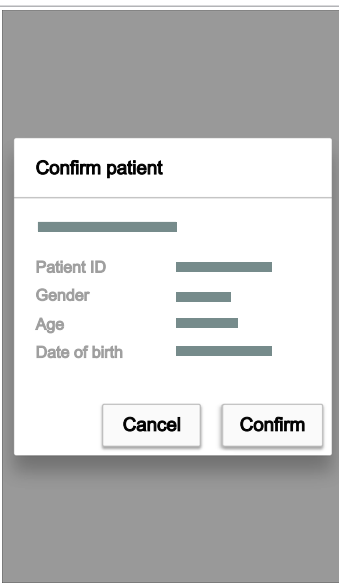
The actions that you take when performing a glucose test depend on how your instrument is configured.

The following steps in a glucose test are configurable:

- ID confirmation
- Sample type selection
- Test trip ejection
- Comment handling
- Glucose test series
- Insulin entry

Patient confirmation

Your instrument can be configured so that you must confirm that the patient entered is correct.



When configured, this occurs after you have entered the patient. The **Confirm patient** dialog box is displayed containing the following information:

- Name
- Patient ID
- Gender
- Age
- Date of birth

When you confirm that you have entered the correct patient you move to the next stage of the test. If it is not the correct patient you can cancel and then re-enter the patient.

Sample type selection

The **Choose sample type** screen contains the sample types that you can use in a glucose test. When enabled, you can select the sample type used in the glucose test.

The available sample types are:

- Capillary blood
- Venous blood
- Arterial blood
- Heel-stick blood

Depending on how your instrument is configured, the **Choose sample type** screen is displayed after you enter the patient, or after confirming that the you have entered the correct patient.

Test strip ejection

The point in the glucose test at which the test strip is ejected from your instrument is configurable.

Your instrument can be configured to eject the test strip before or after the test result confirmation.

Comment handling

When and how you add comments to a glucose test depends on your instrument's configuration.

Comment entry for glucose tests on the instrument can be configured as follows:

- Disabled
- Optionally required
- Always required

- Required when a test result is above or below the configured result range limits.

✎ [About adding comments to a test result \(62\)](#)

Glucose test series

Your instrument can be configured to perform consecutive tests for the same patient.

When configured, the **Options** dialog box is displayed at the end of the first test and you can choose to repeat the glucose test.

Since the patient is already selected, you start the second test by inserting a test strip.

Insulin entry

Your instrument can be configured to enter insulin information after a glucose test has been performed.

When configured, the **Options** dialog box is displayed at the end of the first test and you can choose to enter the insulin information since the patient is already selected.

After confirming the insulin entries, you return to the **Tests** screen.

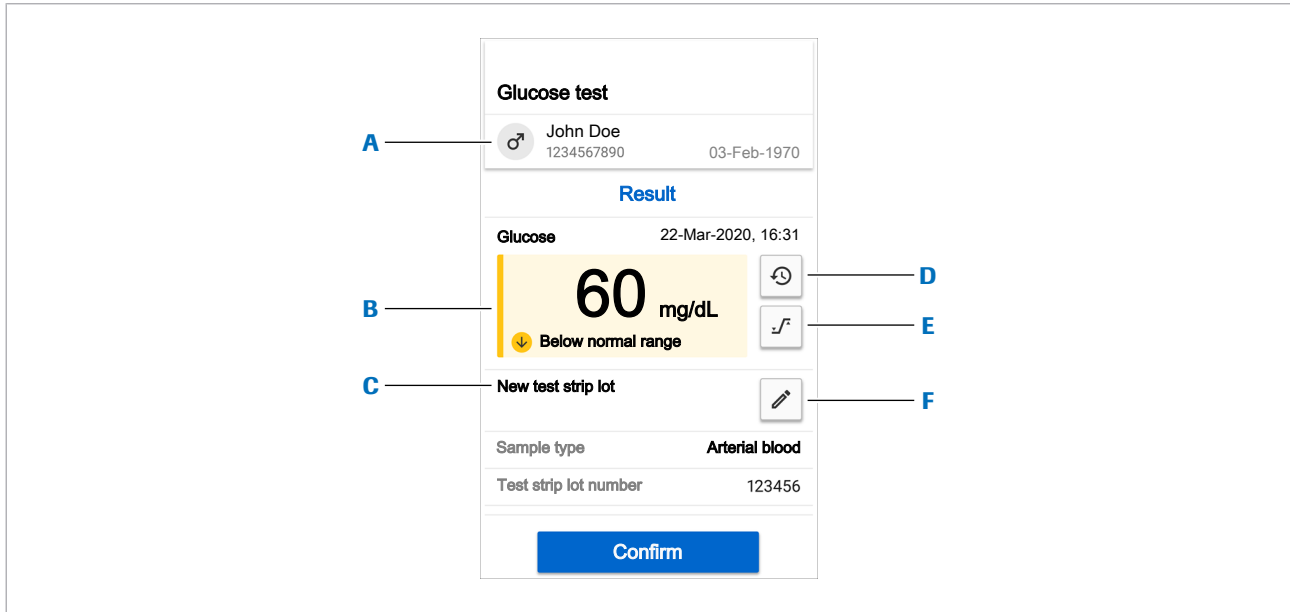
✎ **Related topics**

- [Performing a glucose test \(116\)](#)
- [About adding comments to a test result \(62\)](#)
- [Adding comments to a test result \(128\)](#)
- [Entering insulin information \(131\)](#)

About glucose test results

The information that is displayed in the glucose test result screen and the actions you take depends on how your instrument is configured.

The **Glucose test result** screen is displayed after the blood sample has been measured.



- A

Patient details
- B

Glucose test result
- C

Comment
- D

Patient local results history
- E

Test range details
- F

Edit comments

Glucose test result

Patient details

Displays the patient information that has been provided by the DMS:

- Patient ID
- Patient name
- Gender
- Date of birth

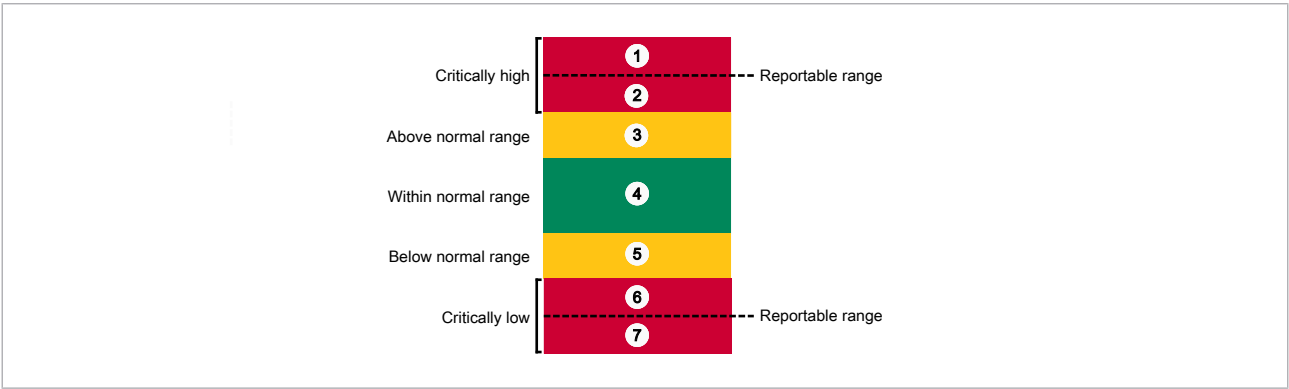
The patient ID is mandatory. The other 3 items are optional.

Glucose test result

A glucose test result is color coded, based on the values of the test result ranges with which your instrument is configured.

You can view the values of the test result ranges by tapping the button.

The color coding used for the test result ranges is indicated in the figure.



Test result ranges color coding

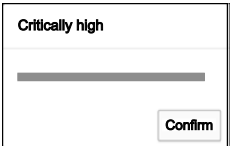
The following types of measuring ranges can be distinguished:

- System measuring range
- Institution-set measuring range

The ranges define details of the glucose result screen (such as the color coding and showing quantitative or qualitative result values) and can be used to trigger specific messages.

For glucose test strips, the system measuring range is 10 to 600 mg/dL (0.6 to 33.3 mmol/L).

The table contains examples of glucose test results in the different ranges. The numbering of the examples corresponds with the numbering in the color coding image above.



Critically high result message. The message text can be configured via the DMS.

1

HI

↑ Critically high

The test result value is critically high (HI).

2

300 mg/dL

↑ Critically high

The test result value is critically high.

3

160 mg/dL

↑ Above normal range

The test result value is above the normal range but not yet critically high.

4

95 mg/dL

✓ Normal range

The test result value is within the normal range.

5

60 mg/dL

↓ Below normal range

The test result value is below the normal range but not yet critically low.

- 6  The test result value is critically low.
- 7  The test result value is critically low (LO).
-  Critically low result message.
The message text can be configured via the DMS.

Your instrument can be configured to display a warning message for test result values which are within the following ranges:

- Above the upper reportable range
- Critically high
- Critically low
- Below the lower reportable range

Patient results history

Tapping the  button displays the **Local results** dialog box. It contains details of all test results for the patient being tested that are stored locally on the instrument:

- Date and time
- Type of test (glucose, insulin)
- Result value

Result range details

Tapping the  button displays **Range details** dialog box. It contains the high and low values configured by your healthcare facility for the following ranges:

- Normal range
- Critical range
- Reportable range

Comments

The  button indicates that comments can be added to the glucose test result.



Comment entry optional



Comment entry mandatory

When comment entry is mandatory, you can only perform the next test step after at least 1 comment has been entered and saved.

Tapping the  button displays the **Comments** dialog box in which you can enter up to 3 comments for the glucose test result as required.

For glucose tests, the instrument can be configured so that a comment must be entered when a result is within one of the following categories:

- Outside the normal range.
- Below the critical range lower limit, or above the critical range upper limit.
- Below the reportable range lower limit or above reportable range upper limit.

To edit comments entered, tap the  button and the **Comments** dialog box is displayed in which you can edit the comments.

➤ [About adding comments to a test result \(62\)](#)

Other information

If your instrument is configured to record the sample type used in the glucose test, the **Sample type** field is displayed on the test result screen. It contains the type of sample recorded.

The **Test strip lot number** field contains the lot number of the test strip used in the glucose test. The first 6 digits of the lot number are displayed on the screen. All 8 digits of the lot number are shown on packaging and the test strip container.

About performing QC tests

Accurately testing known levels of glucose ensures that the system and the technique used in testing provide accurate results on patient samples.

QC lockout

The system may be configured to require QC testing before patient testing is allowed. This is called QC lockout, and the system prevents patient and proficiency testing when the QC results are not within the accepted range.

QC intervals

The intervals between running QC tests are determined by your healthcare facility. These intervals are entered when the system is configured. At the end of the specified interval (or after a specific event such as

starting to test with a new test strip lot), a warning is displayed when the instrument is powered on and when the Glucose Test function is selected.

QC tests should be run in the following circumstances:

- Before using the instrument for patient testing the first time.
- At the QC intervals established by your healthcare facility.
- When using a new test strip container for the first time.
- When using a new test strip lot for the first time (and as a result a new test strip ID).
- If a test strip container was left open.
- If questionable test results occur repeatedly.
- If you wish to test the performance of the system.

In addition, the following events can be specified during setup as a reason for a QC test:

- If a previous QC test failed.
- If glucose QC tests were not run at the proper intervals.

When a QC test is required, you will not be able to test blood glucose until the QC tests have been run successfully.

For emergencies, override QC can be configured on the instrument. This allows the instrument to perform a limited number of blood glucose tests, if circumstances require, despite the instrument being in a QC lockout.

When a QC lockout is activated due to a failed QC test result, it is not possible to override QC lockout.

Information stored during QC testing

The following information is stored for every QC test using a QC material:

- QC test result
- Lot number of the QC material
- User ID (if configured)
- Level of QC material (level 1 or level 2)
- Lot number of the test strips
- Time and date of test
- Comments (if applicable)

QC materials

For blood glucose test strips, QC materials for glucose tests that have 2 QC levels:

- Level 1 (L1): Low (low values in test results)

- Level 2 (L2): High (high values in test results)

Custom deviation

It is possible to change the pre-defined default deviations for each QC level in accordance with applicable regulations.

The custom deviations (to be configured for level 1 and level 2 in mg/dL or mmol/L) define, in combination with the given target level of each QC level, the permitted result range to have a QC PASS result.

Related topics

- [Performing a QC test \(122\)](#)
- [About the QC lockout \(66\)](#)
- [Lockout types \(68\)](#)

About proficiency testing

You perform proficiency tests on samples provided to you by an independent organization.

Some regulatory agencies require that these proficiency samples be tested as part of an institution's quality assurance program before certification of the healthcare facility is allowed.

Information stored during proficiency testing

The following information is recorded for a proficiency test:

- Test result
- Sample ID
- Lot number of the test strips
- Time and date of test
- Comments (if applicable)
- User ID (if configured)

About linearity testing

Linearity tests help you check the function and accuracy of the entire system over the full range of specified values.

Linearity samples should be treated in the same manner as the QC materials used in QC testing.

The term “linearity” describes the ability of the system to maintain a constant accuracy over the full range of specified values.

If test results were plotted against expected values as a curve over the full range of these values, the ideal (high linearity) would be a straight line. Linearity is the range of values from the lowest to the highest for which the instrument is proven capable of giving accurate results.



The instrument does not perform a linear regression.

Linearity testing intervals

The linearity of the system should be checked before it is used the first time for patient testing.

Linearity testing can also be run when you want to check the overall performance of the system.

The intervals for subsequent linearity tests are determined by the healthcare facility that operates the system.

The instrument passes a linearity test when all 12 results (each level is measured twice) were within the specified target range of each level.

Information stored during linearity testing

The following information is recorded for a linearity test:

- Test result
- Lot number of the linearity material
- Linearity level (level 1 to level 6)
- User ID (if configured)
- Lot number of the test strips
- Time and date of test
- Comments (if applicable)

Linearity kit

The linearity kit contains glucose solutions in 6 levels (6 bottles, 2.5 mL each). For additional information about the contents and handling of the kit, refer to the package insert.

About the observed test sequence (OTS)

The observed test sequence (OTS) enables an observer (supervisor) to assess and record a user’s ability to perform a glucose patient test (for recertification purposes, for example).

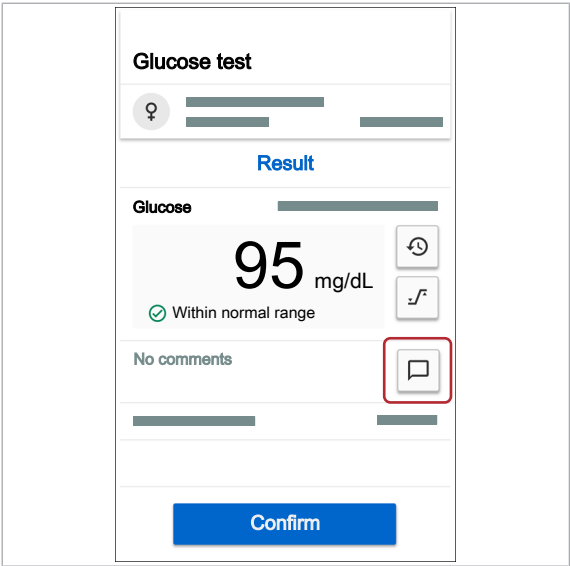
The observer monitors a user performing a test to check that the test is being performed according to recommended procedures.

The supervisor then evaluates the performance and passes or fails the user. This assessment is saved together with the glucose test result and any necessary comments.

If a user’s current certification expires, they are locked out from performing tests. The user can be notified by a personal message, in advance, that they must recertify. The notification is configured using the [Show user lockout warning prior to user certificate expiration](#) configuration item.

About adding comments to a test result

Comments enable you to add supplemental information to a test result.



A  button or a  button in a test result screen indicates that you can enter comments for that result. All test types can be configured for comments to be entered for a test result.

The color of the comment button indicates that comment entry is optional or mandatory. When comment entry is mandatory, the next step in the test can only be performed after at least one comment has been entered.

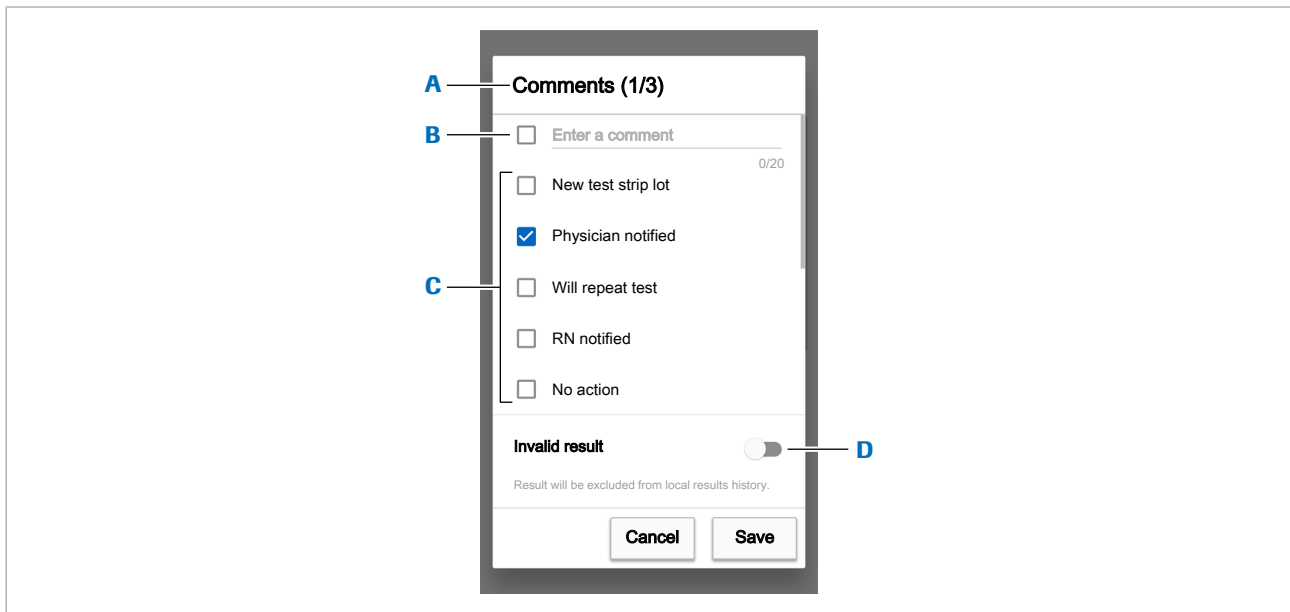


Comment entry optional



Comment entry mandatory

To enter a comment you tap the  button in the test result screen and the **Comments** dialog box is displayed. You can enter a maximum of 3 comments for a test result. The number of comments entered is indicated on the title bar of the **Comments** dialog box.



A Title indicating the number of comments entered

B Custom comment (free text)

C Predefined comments

D Toggle button to invalidate results (patient-related tests only)

 **Comments** dialog box

Comment types

Each test type has a set of predefined comments to select from. They are defined on the DMS.

You select a comment by tapping it. You can enter 1 custom comment (free text) of up to 20 characters. The keyboard is displayed when you tap the text field.

Editing comments

After you have entered and saved comments, the  button in the test result screen changes to the  button. To edit comments entered, tap the  button and the **Comments** dialog box is displayed again in which you can edit the comments.

Patient-related test comments

For glucose tests, emergency tests, and OTS the instrument can be configured so that a comment must be entered when a result is within one of the following categories:

- Outside the normal range.
- Below the critical range lower limit, or above the critical range upper limit.
- Below the reportable range lower limit or above reportable range upper limit.

Quality-related comments

For QC tests and linearity tests, the instrument can be configured so that a comment must be entered when a test fails.

Invalid result toggle button

For patient-related tests (glucose tests, emergency tests, and OTS) the lower area of the **Comments** dialog box contains the **Invalid result** toggle button.

The **Invalid result** toggle button is used to remove an "invalid result" from the **Patient results** on the **Local results** screen. For example, when an error was made while performing a test (dirt on the hand). The result is still transmitted to DMS (flagged as invalid).

- Related topics
- [Performing a glucose test \(116\)](#)
 - [Performing a QC test \(122\)](#)

About the test strip port light

The test strip port light indicates when you should take test strip-related actions.

The table indicates the different colors used in the test strip port light and the corresponding statuses and required actions.

The colors apply to both glucose tests and QC tests.



Test strip port is not illuminated

- Instrument is turning on
- Error during self-checks
- Errors during measurement
- Test strip ejected



White

- Ready for test strip insertion

**Blue**

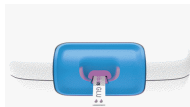
- Test strip inserted and recognized
- Test strip checked and passed

**White**

- Ready for sample application

**Blue**

- Sufficient sample has been applied and processing is underway

**Magenta**

- Eject test strip

About lockouts

In this section

About the QC lockout (66)

Lockout types (68)

About the QC lockout

A QC lockout on an instrument occurs when a QC test is due. It is probably the most common type of lockout. You remove a QC lockout by performing QC tests.



QC lockout is indicated on the charging screen and on the **Glucose** screen.

On the **Tests** screen QC lockout is indicated on a test button by a  symbol on its top right corner.

You cannot make measurements on the instrument until the lockout has been removed. You remove a QC lockout by performing and passing a QC test. Depending on the QC lockout configuration, this can be at QC level 1 or 2, or level 1 and 2.



If your instrument is configured to allow you to override a QC lockout, you can perform a test despite a QC lockout, when the QC lockout was the result of a QC algorithm configuration condition.

Your instrument can be configured to allow you to override a QC lockout up to 9 times before you must perform a QC test.

However, if the QC lockout was the result of a failed QC test, the QC lockout cannot be overridden.

A QC lockout is triggered by the following;

- By fulfilling a QC algorithm configuration condition
- A failed QC test
- After certain software updates

The QC algorithm is configured on the instrument through the DMS, or by using a QR code. The following configurations are possible:

- **QC disabled**

- **Until failed QC**
- **Time interval**
- **Shift**
- **Test strip count**
- **Time of day**

With the exception of the **QC disabled** and **Until failed QC** configurations, a configured QC lockout can be *alternating* or *non-alternating*.



You can view your instrument's QC configuration by going to  **> Instrument information > QC interval.**

Disabled	QC lockout is disabled. Glucose tests can be performed at any time, regardless of the result of a possible QC test.
Until failed QC	A QC lockout is activated only when a QC test failed. With this configuration, a QC lockout also occurs the first time the instrument is used. In both cases, to remove the QC lockout, you must run and pass a QC test at QC level 1 and one at QC level 2.
Time interval	A QC lockout is activated after a specified number of hours. To remove the QC lockout, you must run and pass a QC test at QC level 1 and one at QC level 2. The hour counter is reset to "0".
Shift	A QC lockout is activated with each changeover of user work shifts. To remove the QC lockout, you must run and pass a QC test at QC level 1 and one at QC level 2.
Time of day	A QC lockout is activated at a specified time of day. Up to six times per day can be configured. To remove the QC lockout, you must run and pass a QC test at QC level 1 and one at QC level 2.
Test strip count	A QC lockout is activated after a pre-defined number of tests have been performed.

Only successful measurements are included in the test strip count.

To remove the QC lockout, you must run and pass a QC test passed both QC test levels.

New test strip lot

You can configure the instrument to handle new test strip lots in one of the following ways:

- Using a new test strip lots is possible without having a QC test passed for it.
- Using a new test strip lot is only possible after having a QC test passed for both QC levels.

Alternating / non-alternating QC lockout

To remove an alternating QC lockout, you perform a QC test where the required QC level alternates. If you remove the first QC lockout with a QC test passed for QC level 1, you remove the next one with a QC test for QC level 2, and so on.

To remove a non-alternating QC lockout, you must perform QC tests with QC level 1 and 2 passed.

Software update

A software update (from Roche) can be configured to trigger a QC lockout. The QC lockout applies irrespective of any other QC lockout that was configured.

To remove the lockout, you must run and pass a QC test at level 1 and one at level 2. This applies even if an alternating QC lockout is configured.

Related topics

- [Lockout types \(68\)](#)

Lockout types

A lockout stops you from performing specific actions on the instrument until you take the appropriate corrective action.

There are different types of lockout:

- QC
- Instrument synchronization
- Temperature
- Low battery
- Memory
- User certification

The lockout type determines the corrective action you should take. By tapping a button with a lockout badge a dialog box is displayed providing guidance.

QC lockout

A QC lockout is triggered by the following;

- By fulfilling a QC algorithm configuration condition
- A failed QC test
- After certain software updates

▶ [About the QC lockout \(66\)](#)

Synchronization lockout

A synchronization lockout occurs when the instrument has not synchronized with the DMS in a defined time period.

The period of time between the last synchronization with the DMS and the synchronization lockout is calculated in terms of a warning of the lockout and the lockout itself.

The lockout warning displays after a defined period of time since the last DMS synchronization. The time period is set using the [Show synchronization lockout warning prior to actual lockout \(in hours\)](#) configuration item.

The synchronization lockout occurs after a defined period of time after the warning was displayed. The time period is set using the [Synchronization lockout \(in hours\)](#) configuration item.

The following are unavailable due to the lockout;

- Glucose test
- Proficiency test
- QC test
- Linearity test
- Insulin entry
- OTS

Synchronization lockout can be overridden for a pre-determined number of times. The [Allow QC / synchronization lockout overrides](#) configuration item enables the override. The number of times the override can be used (9 maximum) is set using the [Number of lockout overrides allowed](#) configuration item,

If the override is enabled, you can perform emergency tests and override lockouts for glucose tests. This is possible as long as the override lockout counter value has not been exceeded.

Synchronization lockout is resolved by synchronizing the instrument with the DMS.

Additionally a user with administration rights can reset synchronization lockout by choosing  [Administrator > Reset synchronization lockout](#)

Temperature lockout

A temperature lockout occurs when the instrument temperature is too high or too low for the test strips to operate correctly.

The following are unavailable due to the lockout;

- Glucose test
- Emergency test
- OTS
- Proficiency test
- QC test
- Linearity test
- Override QC lockout

Temperature lockout stops when the instrument temperature is within the acceptable operating temperature range.

• [Environmental conditions \(87\)](#)

Battery lockout

A battery lockout occurs when the instrument battery level is too low for measurements to take place.

The following are unavailable due to the lockout;

- Glucose test
- Emergency test
- OTS
- QC test
- Linearity test
- Override QC lockout

A battery lockout stops when the instrument battery has recharged sufficiently (15%).

• [Replacing the battery \(177\)](#)

Memory lockout

A memory lockout occurs when the maximum memory of the instrument database is reached and no further test data can be stored.

The following tests can be unavailable due to the lockout. Since the tests have different data storage requirements, only the test you select will be locked.

- Glucose test
- Emergency test
- OTS
- Proficiency test
- QC test
- Linearity test
- Insulin entry

Memory lockout is resolved by synchronizing the instrument with the DMS to ensure it has sufficient free memory.

User lockout

User lockout occurs when a user's certificate expires and they require recertification.

The instrument can be configured to display a user certification expiration warning in advance of the individual user certification expiration.

The lockout is displayed on the home screen when a user requiring certification is logged in. The warning and lockout is shown on the  tab.

Only the observed test sequence (OTS) is available in this lockout type.

The lockout is resolved by the user taking and passing an OTS. As a result, the user's name is added to an updated user list which is distributed to all instruments. This enables the user who was locked out to perform tests again.

•  [User certification status \(74\)](#)

•  [Performing an observed test sequence \(OTS\) \(145\)](#)

List of notifications

Notifications provide you with reminders and messages.

You access the **Notifications** screen by tapping the  button on the navigation bar. A new notification is indicated by a blue badge on the button .

You may receive the following notification types:

- QC status
- Instrument cleaning status
- Instrument synchronization status
- Instrument memory status
- User certification status
- Message of the day
- Personal message

The order in which the notification types appear on the **Notifications** screen (above) is fixed.

QC status

The notification indicates either:

- When the next QC test is due (the date, or the number of tests remaining before hand).
- The date since the instrument has been in QC lockout (shown in red).

Tapping the  button to the right of the notification message displays the **QC test** screen, from which you can run a QC test.

A different lockout type may prevent you from performing a QC test. Tapping the  button displays a dialog box for each of the lockout types preventing you.

The QC lockout notification is determined by the **QC algorithm** configuration item.

•  [QC algorithm \(376\)](#)

Instrument cleaning status

This notification indicates that either:

- Instrument cleaning is due (date/event).
- Cleaning can be logged.

If a cleaning interval is configured, an icon and an indication of when the next cleaning is due are displayed. If only cleaning after a measurement is required, an instruction is displayed.

When instrument cleaning is overdue, a red warning icon and the date and time of the instrument cleaning is displayed.

The instrument cleaning notification is determined by the following configuration items:

- **Cleaning notification after each patient test**
- **Time interval for cleaning notification (in hours)**

▸ [Cleaning notification after each patient test \(480\)](#)

▸ [Time interval for cleaning notification \(in hours\) \(480\)](#)

Instrument synchronization status

This notification only shows when a synchronization warning or lockout have occurred.

A synchronization lockout occurs when the instrument has not synchronized with the DMS within a defined time period.

It indicates:

- The number of unsynchronized results
- The date and time of the synchronization lockout, either:
 - When the lockout is expected.
 - When the lockout occurred (warning icon and time of lockout displayed in red)

Synchronization lockout is resolved by synchronizing the instrument with the DMS.

The instrument synchronization notification is determined by the following configuration items:

- **Show synchronization lockout warning prior to actual lockout (in hours)**
- **Synchronization lockout (in hours)**

▸ [Show synchronization lockout warning prior to actual lockout \(in hours\) \(390\)](#)

▸ [Synchronization lockout \(in hours\) \(391\)](#)

Instrument memory status

This notification only shows when an instrument memory warning or lockout have occurred.

It indicates that either:

- The instrument will run out of memory soon
- A memory lockout has occurred (warning icon and displayed in red)

Instrument memory lockout is resolved by synchronizing the instrument with the DMS to ensure it has sufficient memory.

User certification status

This notification only shows when there is a certification warning for the user currently logged on or their recertification is due.

It indicates either:

- The date when the recertification is required.
- The recertification is overdue (warning icon and displayed in red)

When the instrument is not configured to use user lists, or to show user certificate expiration, this notification never displays.

Message of the day

This notification only shows if a message is configured for the instrument.

It has the header "Message of the day", with the message below it. If the message is longer than one line, it is indicated by an ellipsis (...) at the end of the line.

Tapping the notification opens a dialog box containing the message.

The message of the day notification is determined by the **Message of the day** configuration item.

► [Message of the day \(479\)](#)

Personal message

This notification is only shown for instruments using user lists, and when a personal message has been set for the user currently using the instrument.

It has the header "Personal message", with the message below it. If the message is longer than one line, it is indicated by an ellipsis (...) at the end of the line.

Tapping the notification opens a dialog box containing the message.

Overview of the User Assistance

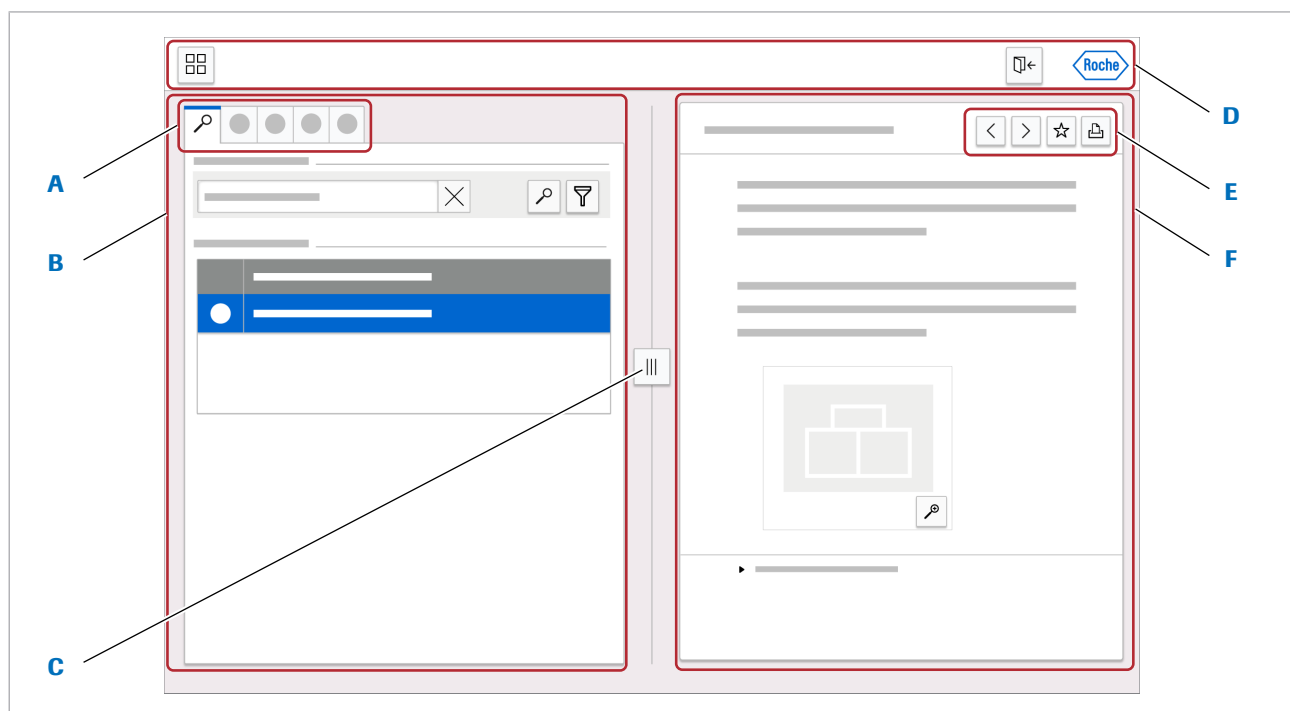
In this section

- About the User Assistance (75)
- Overview of User Assistance functions (76)
- Accessing the User Assistance online (78)
- Accessing the User Assistance offline (79)
- Searching in the User Assistance (80)

About the User Assistance

The User Assistance supports you in your daily work. It is available in different formats (e.g., online, offline,...). The functionalities provided by the user interface are similar across all formats.

The User Assistance window is divided into a main panel and a detail panel.



- | | |
|---|---|
| A Tabs for selective information access (tabs available depend on configuration) | D Global information area |
| B Main panel | E Buttons for navigation and other functions |
| C Panel splitter | F Detail panel |

Overview of the User Assistance window

Tabs in the main panel



Home

To view the description of the available tabs. From here, you can access each tab directly.



Search in this publication

To search for information in the whole User Assistance.



Table of contents

To get an overview of the User Assistance publication.



Recently viewed

To get a list of the most recent topics that you have viewed.

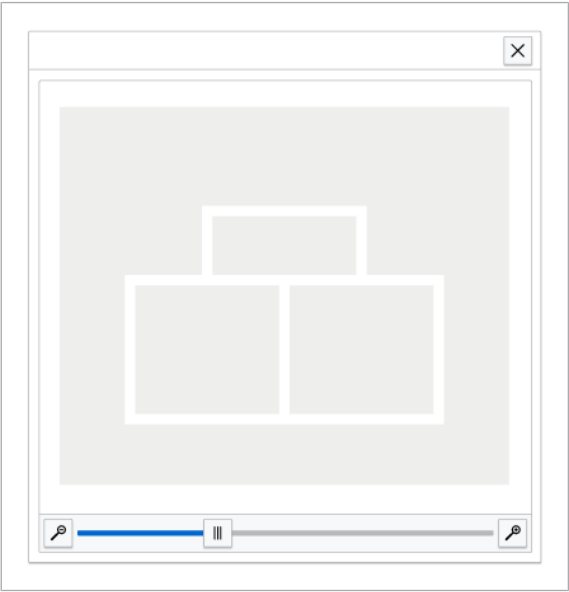


Favorites

To store your frequently used topics for direct access at any time.

Overview of User Assistance functions

Enlarging images



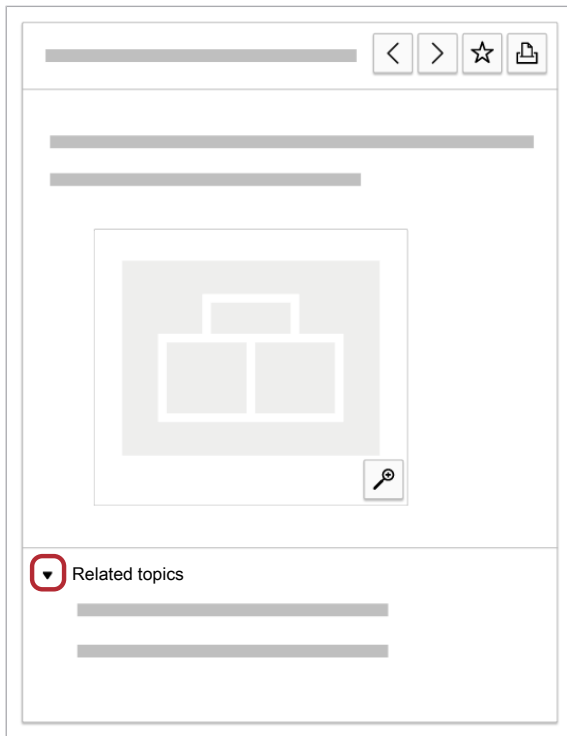
You can enlarge an image by choosing the  button beside it. The image is displayed in a callout in which you can further zoom in using the zoom slider.

Browsing history



You can use the  and  navigation buttons to go backwards and forwards in your browsing history.

Related topics



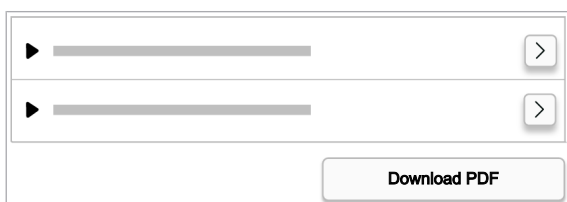
At the end of some topics, there is a list of links to other topics that contain related information. You can go back to the original topic using the  button.

Viewing descriptions of terms



The  button in text indicates that you can view information about the term to the button's left. When you choose the  button, a callout is displayed containing a description of the term.

Downloading a PDF



You can download the publication to your computer in PDF format using the **Download PDF** button.

Giving feedback

Send feedback

☐ Yes

☒ No

☐ Was not the topic that I was looking for

☐ Topic was not clear/understandable

Enter an email address

Enter your feedback here

✕ Cancel

✉ Send

In the User Assistance online, at the bottom of each topic, you can give feedback on that topic. We use your feedback to improve the next update of our publications.

Accessing the User Assistance online

When accessing the User Assistance online, the latest content is always available.



If you have no internet access, contact your Roche representative for a standalone version of the User Assistance.



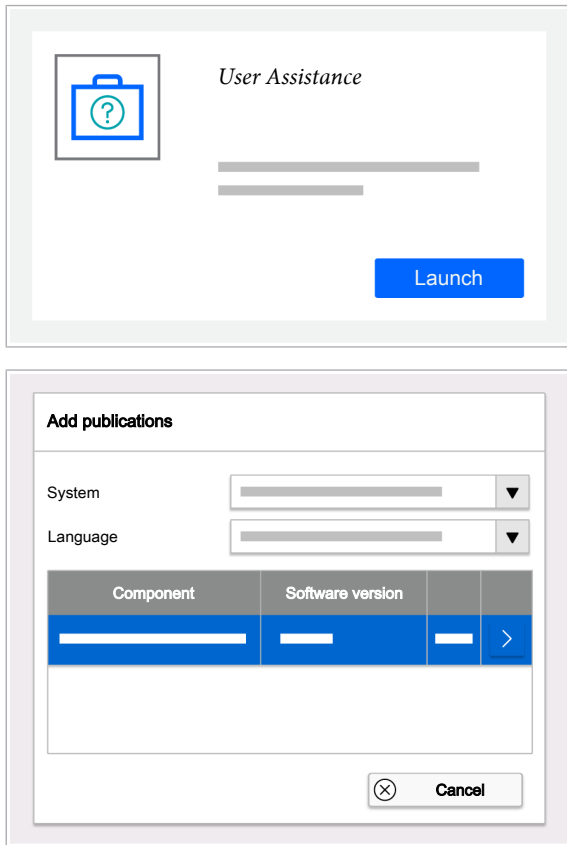
- ☐ PC, tablet, or smartphone (iOS or Android)
- ☐ Connection to internet
- ☐ Internet browser (Safari or Chrome)



- ☐ Access to the Roche DiaLog portal provided by your Roche representative

► To use the User Assistance online

- 1 In the browser, enter the link to the Roche DiaLog portal (*dialog.roche.com*).
- 2 Choose the **Log on** button and enter your Roche DiaLog user name and password.



- 3 In the list of e-services, find the **User Assistance** card, and then choose the **Launch** button in the card.
→ The User Assistance publication selector is displayed.
- 4 Use the filter settings to find the publication you want.
- 5 Select the publication that you want, and then choose the **Add publication** button, and then the **Add to list** button.
- 6 To access a User Assistance, choose the desired publication and then, on the detail panel, choose the **Open publication** button.

Accessing the User Assistance offline

You can use the standalone User Assistance offline on your PC. No internet connection is required.



To get the installer for the standalone User Assistance, contact your Roche representative.



- ☐ PC
- ☐ Installer for standalone User Assistance

► To access the User Assistance offline

- 1 Copy the installer for the standalone User Assistance to your PC.
- 2 Double-click the installer file, and then follow the instructions in the installation wizard.
- 3 Once installed, start the User Assistance, by double-clicking the User Assistance icon on your desktop.

Searching in the User Assistance

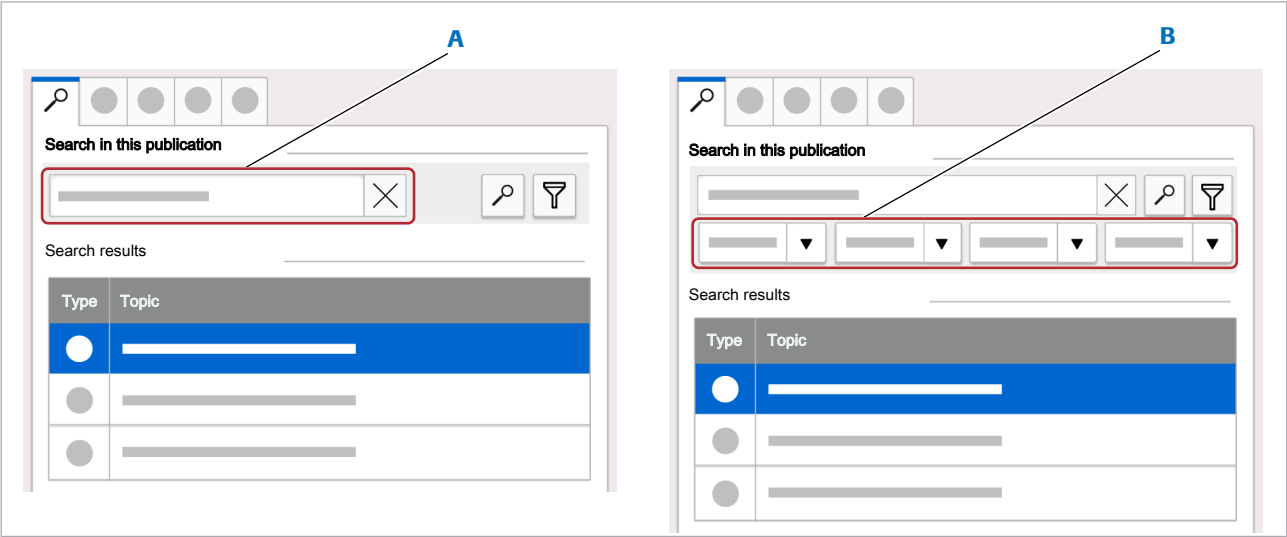
Use the search function in the User Assistance to find information directly.

Search options

There are 2 search options in the User Assistance:

- Text search: Searches the text entered in the search field.
- Faceted search: Limits the number of search results using filters.

You can combine both search options.



A Text search function

B Faceted search function

 Search options

Search results

The **Search results** table lists the 20 topics with the highest ranking.

The term you searched for is highlighted. If you searched for a deprecated term, the preferred term is highlighted.

Topic types

The icon on the left of the search results shows you the topic type:



Description

Explains concepts and gives additional background information.



Procedure

Explains how to perform a task step-by-step.

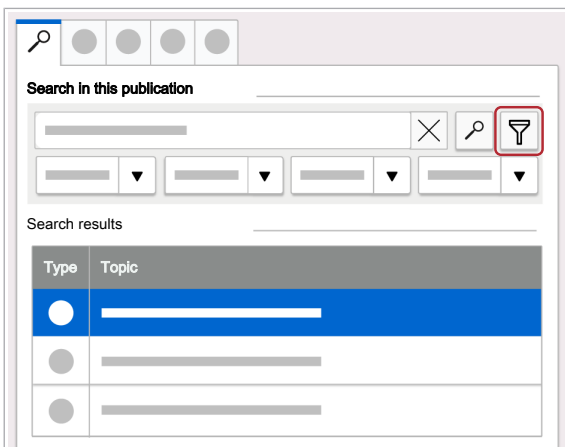
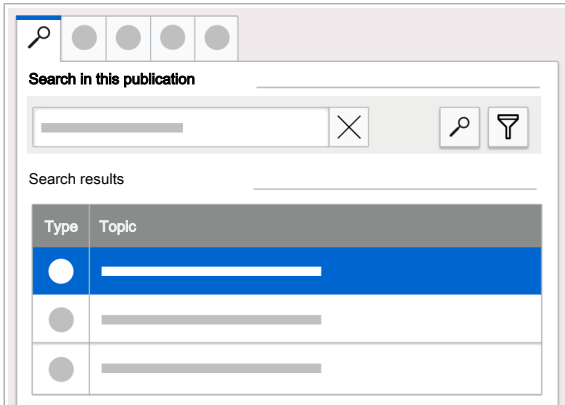


Reference

Provides reference information.

► To perform a search in the User Assistance

- 1 In the User Assistance, choose the 🔍 tab.
- 2 To perform a simple search, enter full or partial text entries, and then choose the 🔍 button.
- 3 To perform a faceted search, choose the 🗑️ button.
→ The filter drop-down lists are displayed.
- 4 From the drop-down lists, choose one or more search filters.



Page intentionally left blank.

Specifications

In this chapter

3

General specifications.....	85
Technical specifications	86
Environmental conditions	87
Dimensions and weights.....	88
List of accessories and consumables.....	89
Barcode specifications.....	90
Radio equipment specifications	93

Page intentionally left blank.

General specifications

The instrument has the following basic characteristics:

System		
Data storage		▪ up to 100 proficiency test results ▪ up to 2000 patient result records ▪ up to 3 comments for each test record ▪ up to 500 glucose QC result records ▪ up to 50 linearity test results ▪ up to 300 test strip lot code containers ▪ up to 15000 user ID records ▪ up to 15000 patient records ▪ up to 200 OTE reagents records ▪ up to 50 QC lot records ▪ up to 10 linearity lot records ▪ up to 5000 entries audit trail records
Screen resolution	Instrument	480 x 800 pixel
Interfaces	Instrument	▪ Wireless power transfer (WPT) ▪ Barcode camera ▪ RFID reader ▪ WLAN IEEE 802.11 a/b/g/n/ac (single stream n) ▪ Bluetooth® LE
	Charging station	▪ Wireless power transfer (WPT)
	Power supply	▪ DC connector ▪ Replaceable AC input contacts

☰ General specifications

Technical specifications

The power supply must fulfill the following requirements.
Never operate the system if one of the environmental conditions is not fulfilled.

Input voltage	Instrument	Wireless charging
	Charging station	+ 12 V DC
	Power supply	100-240 V AC, 50-60 Hz
Input current	Instrument	Wireless charging
	Charging station	2.5 A (max)
	Power supply	0.6-0.3 A
Battery voltage type	Instrument	3.6 volt rechargeable (lithium technology)
Data transfer rate	Instrument	WLAN IEEE 802.11 a/b/g/n/ac (single stream n):
		▪ up to 65 Mbps (2,4 GHz) ▪ up to 433 Mbps (5 GHz)

 Technical specifications

Environmental conditions

The location must comply with the following conditions:

		International (Europe)	US / Canada
Ambient temperature during operation	Instrument	12-40 °C	54-104 °F
	Charging station	12-40 °C	54-104 °F
	Power supply	0-45 °C	32-113 °F
	Carry case	12-40 °C	54-104 °F
Ambient temperature during long-term storage	Instrument	5-40 °C	41-104 °F
	Charging station	5-40 °C	41-104 °F
	Power supply	-40-70 °C	-40-158 °F
	Carry case	5-40 °C	41-104 °F
Ambient Temperature short term transport	Instrument	-25-70 °C	-13-158 °F
	Charging station	-25-70 °C	-13-158 °F
	Power supply	-40-70 °C	-40-158 °F
	Carry case	-25-70 °C	-13-158 °F
Ambient humidity during operation	Instrument	10-90% (non-condensing)	
	Charging station	10-90% (non-condensing)	
	Power supply	0-95% (non-condensing)	
	Carry case	10-90% (non-condensing)	
Ambient humidity during long-term storage	Instrument	5-85% (non-condensing)	
	Charging station	5-85% (non-condensing)	
	Power supply	5-95% (non-condensing)	
	Carry case	5-85% (non-condensing)	
Maximum operating height (above sea level)	Instrument	4,300 m	14,107 feet
	Charging station	4,300 m	14,107 feet
	Power supply	4,300 m	14,107 feet
Sample temperature	Instrument	Refer to the package insert for information	

☒ Environmental conditions

Dimensions and weights

The system components have the following dimensions and weights:

Instrument	International (Europe)		US	
	Depth	30 mm	Depth	1.18 in
	Width	77 mm	Width	3.03 in
	Height	210 mm	Height	8.27 in
	Weight	390 g (inc. battery)	Weight	0.86 lb

☐ Dimensions and weight of the instrument

Charging station	International (Europe)		US	
	Height	140 mm	Height	5.51 in
	Width	100 mm	Width	3.94 in
	Depth	95 mm	Depth	3.74 in
	Weight	250 g	Weight	0.55 lb

☐ Dimensions and weight of the charging station

Power supply	International (Europe)		US	
	Depth	34 mm (without AC plug)	Depth	1.34 in
	Width	55 mm	Width	2.17 in
	Height	90 mm	Height	3.54 in
	Weight	260 g	Weight	0.57 lb

☐ Dimensions and weight of the power supply

Carry case	International (Europe)		US	
	Depth	80 mm	Depth	3.15 in
	Height	250 mm	Height	9.85 in
	Width	305 mm	Width	12 in
	Weight	1000 g	Weight	2.20 lb

☐ Dimensions and weight of the carry case

List of accessories and consumables

You should ensure that you use the correct accessories and consumables when performing tests and measurements.

Product name	Description	Catalog number
cobas [®] GLU test strips	Test strips	09009582
cobas [®] GLU QC kit	QC kit	08275858
cobas [®] GLU linearity kit	Linearity kit	08275866

☐ Consumables and reagents

Product name	Description	Catalog number
cobas [®] pulse	Instrument	08990824
cobas [®] pulse charging station	Charging station	09009272
cobas [®] pulse carry case	Carry case	09314539
cobas [®] pulse battery	Battery	08726388
cobas [®] pulse power supply	Power supply	08689008
POC Access Point	Wi-Fi access point	09187316

☐ Accessories and other components

Barcode specifications

Barcodes provide a means of entering data in the cobas pulse system (user ID/patient ID entry, instrument configuration).

WARNING!

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 type.
- ▶ Ensure that barcode size and print quality (as defined in ISO/IEC 15416 and 15415) are adequate.
- ▶ Carry out a plausibility check on all data scanned into and displayed by the instrument.

To reduce the probability of a barcode being misread, it is strongly recommended that you use the configuration options for patient and/or user ID validation as applicable to your specific workflow. These options are:

- Check the ID against a list
- Check ID for length⁽¹⁾
- Use barcodes with check digits

In combination with the above options or as a single measure, use an appropriate barcode mask if this is compatible with the structure of your barcode content.

When scanning, ensure that the barcode is completely inside the camera frame.



EAN 13 barcodes, although widely used in retail, are less appropriate for patient/user barcodes. If used, they demand the very highest quality standards of barcode creation and reproduction.



The instrument can be configured to enable and disable the barcode types used for scanning patient IDs and user IDs.

For questions regarding working with barcodes that are not covered in this publication and for best practice guidelines on creating and reading barcodes, contact your Roche representative.

⁽¹⁾ If no user/patient list can be used, you should set a minimum length for the respective ID, even if your healthcare facility uses IDs of varying length.

The barcode samples shown here are for illustration purposes only. If printed out, they can be used to check the barcode camera. However, they are not meant to be used as a reference for size or resolution of real patient or user ID barcodes.

When creating patient or user barcodes, always refer to the relevant standard ISO/IEC 15416 and 15415 for size and resolution requirements and to the specifications listed in the table.

	Recommended specification	Comment
Print resolution	300 dpi preferred 200 dpi minimum	At 200 dpi issues with the wide-to-narrow ratio may exist.
Reflective contrast	70% or greater	Matte finish is preferred over glossfinish.
Symbol grade	Grade C or above Grade B is preferred Symbol grades are A-F based on analysis of several quality elements.	Depending on quality grade parameters for a specific barcode, grade C may not be sufficient when motion, reflection, or poor lighting occur.
Module width (minimum)	0.16 mm (1D barcodes) 0.20 mm (2D barcodes)	

☐ Recommended specifications for barcode labels



Ensure that your printer can print the module width of the barcode with the required resolution, that is, that there is no mismatch between print resolution and module width.

Supported barcode types



1234567890

Codabar



1234567890

Code 39



ABC123-/+

Code 93



1234567890

Code 128



1 112223 334448

EAN 13



(01)01234567890128

GS1 DataBar Limited



1234567890

Interleaved 2 of 5 without checksum



012345678905

Interleaved 2 of 5 with checksum



cobas pulse

PDF417



cobas pulse

Aztec



cobas pulse

DataMatrix



cobas pulse

QR code

Radio equipment specifications

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines. This equipment is tested for specific absorption ratio (SAR) and complies with FCC/IC radiation exposure limits set forth for an uncontrolled environment. This device complies with FCC/IC SAR limit of 1.6 W/kg.

The device for operation in the band 5150-5250 MHz is only for indoor use to reduce the potential for harmful interference to co-channel mobile satellite systems.

Changes or modifications made to this equipment not expressly approved by Roche Diagnostics may void the FCC authorization to operate this equipment.

Instrument	
Frequency (MHz)	2400 - 2472 MHz and 5180 - 5835 MHz
Maximum radio-frequency power (mW)	63
Number of RFID readers	1
Number of RFID antennas	1

☐ Radio equipment specifications

Page intentionally left blank.

Operation

4	Frequently performed tasks.....	97
5	Routine operation.....	111
6	Non-routine operation.....	129

Page intentionally left blank.

Frequently performed tasks

In this chapter

4

Logging on to the Glucose app	99
Charging the instrument	104
Checking notifications	105
Putting the instrument into standby mode.....	107
Waking the instrument from standby mode	108
Logging off the Glucose app	109

Page intentionally left blank.

Logging on to the Glucose app

If your instrument is switched off you must turn it on and log on in order to use it.

After turning on your instrument, depending on your instrument's configuration, there are 3 options:

1. You must always log on.
2. You need only log on to perform a QC test.
3. You do not need to log on.

For options 1 and 2, depending on your instrument's configuration, you log on using one of the following methods:

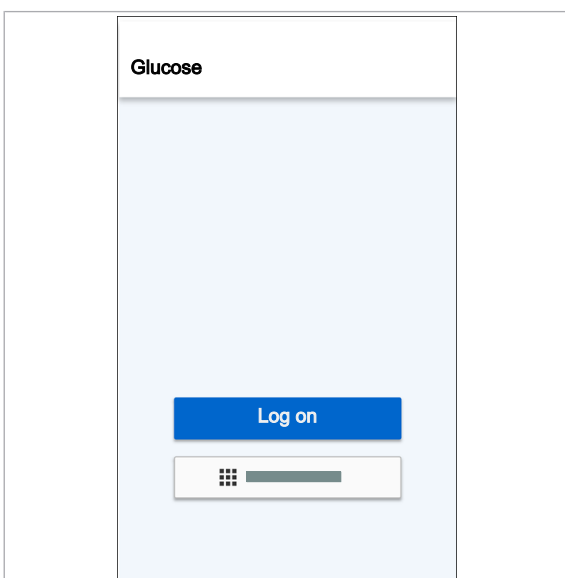
- RFID tag
- Barcode scan
- Keyboard entry

All options and logon methods are explained in this task.

- ▶ [To log on to the Glucose app using an RFID tag \(99\)](#)
- ▶ [To log on to the Glucose app using a barcode \(100\)](#)
- ▶ [To log on to the Glucose app using the keyboard \(102\)](#)
- ▶ [No logon required \(103\)](#)

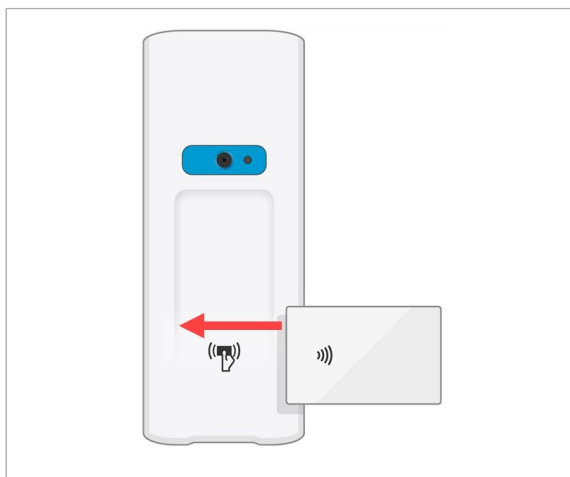


- ☐ You have a valid user ID



▶ To log on to the Glucose app using an RFID tag

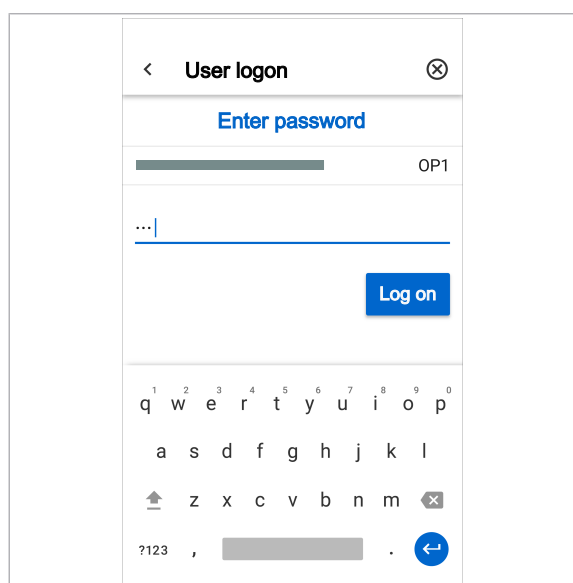
- 1 Remove the instrument from the charging station and do one of the following:
 - In the **Glucose** screen, tap the **Log on** button.
 - If the app library is displayed, tap the **Glucose** app and then in the **Glucose** screen, tap the **Log on** button.
- The **User logon** screen is displayed.



2 Swipe your RFID tag over the RFID icon on the rear of your instrument, as shown by the animation.

→ If a password is required the **Enter password** screen is displayed.

→ If a password is not required the **Tests** screen is displayed. Log on is complete.



3 In the **Enter password** screen, enter your password in the **Password** field and then tap the **Log on** button.

→ The **Tests** screen is displayed. Logon is complete.

4 When you have finished using the instrument, dock it in the charging station.

→ You are logged off automatically.

► To log on to the Glucose app using a barcode

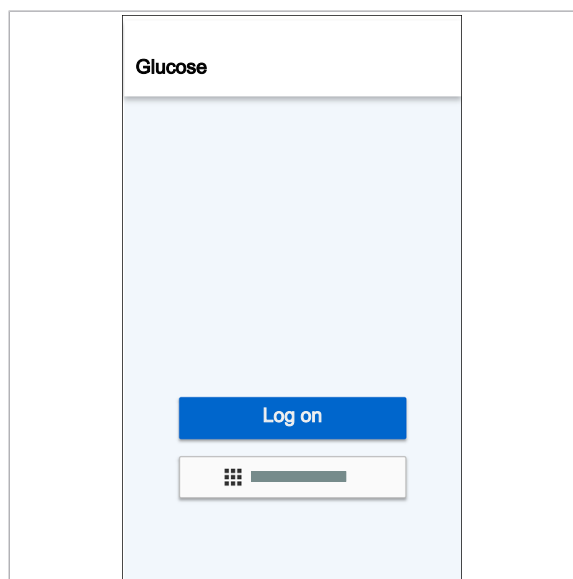
1 Remove the instrument from the charging station and do one of the following:

- In the **Glucose** screen, tap the **Log on** button.
- If the app library is displayed, tap the **Glucose** app and then in the **Glucose** screen, tap the **Log on** button.

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

2 In the **User login** screen, if the **Scan user ID** tab is not displayed, tap the **|||||** tab.

→ The barcode camera is activated,

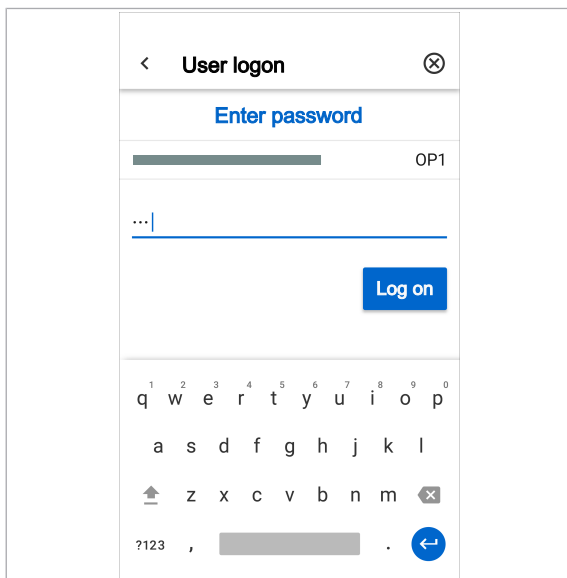




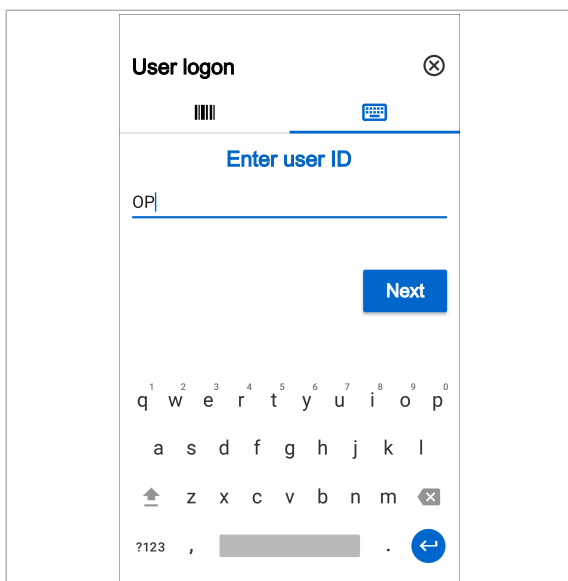
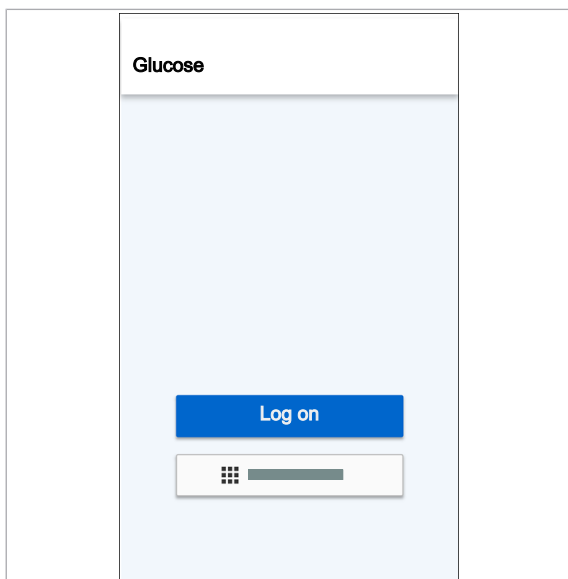
- 3 CAUTION!** Ensure that the barcode is flat and not damaged.

Position the instrument so that the barcode is visible on the screen and inside the white frame.

- ❗ If there is insufficient light, tap the button to turn on the built-in flashlight.
- If a barcode is detected the frame turns green and the **Enter password** screen is displayed. Password entry is required. Go to the next step.
- The frame turns green the **Tests** screen is displayed (if configured). Password entry is not required. Log on is complete.
- The frame turns red and a message is displayed at the bottom of the screen. The barcode content may be invalid.
- If no barcode is detected the frame remains white and the scan times out. The barcode may be degraded and requires checking. Use the keyboard entry if available.



- 4** In the **Enter password** screen, enter your password in the **Password** field and then tap the **Log on** button.
- The **Tests** screen is displayed. Logon is complete.
- 5** When you have finished using the instrument, dock it in the charging station.
- You are logged off automatically.

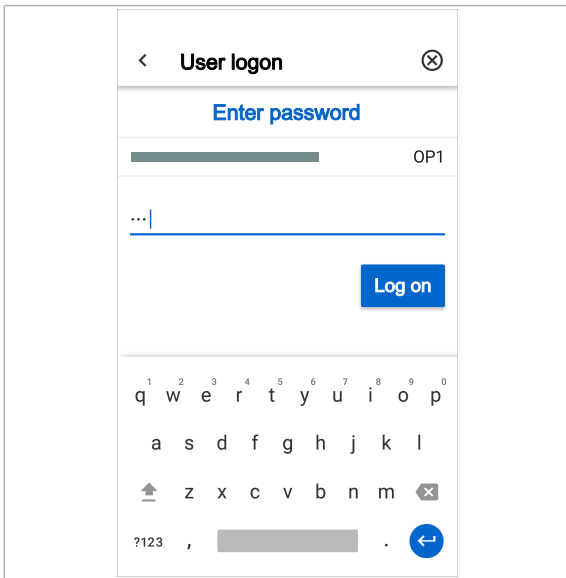


► To log on to the Glucose app using the keyboard

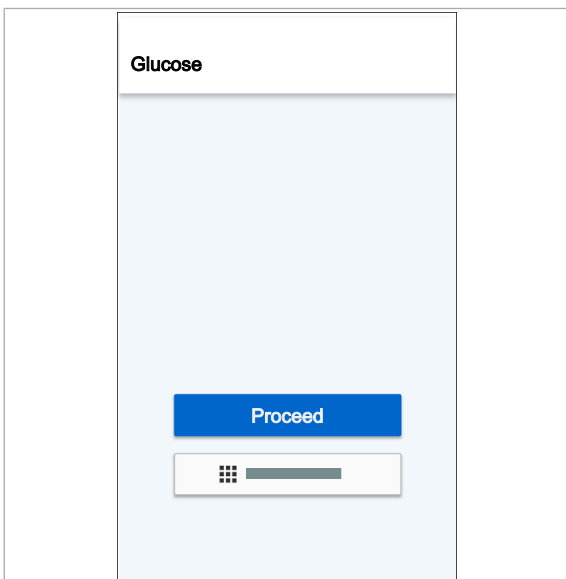
- 1 Remove the instrument from the charging station and do one of the following:
 - In the **Glucose** screen, tap the **Log on** button.
 - If the app library is displayed, tap the **Glucose** app and then in the **Glucose** screen, tap the **Log on** button.
 → The **User login** screen is displayed.
- 2 In the **User login** screen, tap the  tab.

- 3 In the **Enter user ID** screen enter your user ID and then tap the **Next** button.

❗ The user ID is case sensitive.



- 4 In the **Enter password** screen, enter your password in the **Password** field and then tap the **Log on** button.
→ The **Tests** screen is displayed. Logon is complete.



► No login required

- 1 Remove the instrument from the charging station.
- 2 In the **Glucose** screen, tap the **Proceed** button
→ The **Tests** screen is displayed.
- 3 When you have finished using the instrument, dock it in the charging station.

📖 Related topics

- [Performing a glucose test \(116\)](#)
- [Performing a QC test \(122\)](#)
- [Reviewing patient test results \(120\)](#)
- [Reviewing QC test results \(126\)](#)

Charging the instrument

When not being used, the instrument should be placed in the charging station. This ensures that the instrument has sufficient charge to operate.

When the instrument is in the charging station the charging screen is displayed.

If the instrument is turned off when placed in the charging station, it will start up, after which the charging screen is displayed.



If the instrument is turned off and does not start up when placed in the charging station, the battery may have insufficient charge.

▶ [Starting up an instrument with low battery level \(193\)](#)



☐ Charging station is connected to a power source

▶ To charge the instrument

- 1 Place the instrument in the charging station.
- 2 Check that the charging screen is displayed.
 - If the charging screen is not displayed, check that the charging station is connected to a power source.

Checking notifications

Notifications provide you with reminders and messages.

Notifications are accessed by tapping the  button on the navigation bar. A blue badge on the button  indicates a new notification.

After you have taken the appropriate action, the notification is removed from the **Notifications** screen. The action you take depends upon the type of notification.

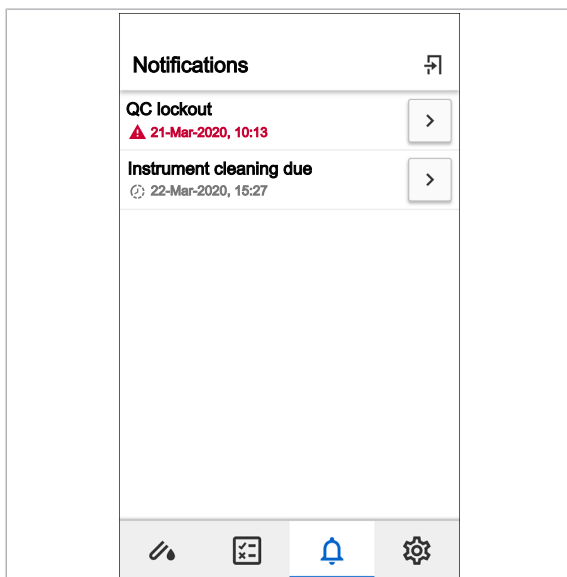
Depending on your instrument's configuration, you can receive any of the following types of notification:

- QC status
- Instrument cleaning status
- Instrument synchronization status
- Instrument memory status
- User certification status
- Message of the day
- Personal message



When there is a blue badge on the  button.

► To check notifications



- 1 On the navigation bar, tap the  button.
 - The **Notifications** screen displays containing one or more notifications.
- 2 For a **QC lockout** notification, tap the  button.
 - ① If one or more other lockouts are preventing you performing the QC test, tapping the  button displays dialog boxes informing you of the lockouts.
 - The **QC test** screen is displayed in which you can perform a QC test.
- 3 For an **Instrument cleaning due** notification, after cleaning the instrument appropriately, do the following:
 - Tap the  button.
 - In the **Instrument cleaning** dialog box, tap the **Confirm** button to confirm that the instrument has been cleaned.
- 4 If a notification warns of, or indicates that there is a lockout due to unsynchronized results, synchronize your instrument the DMS to remove the lockout.

- 5 If a notification warns of, or indicates that there is a lockout due to insufficient memory, synchronize your instrument the DMS to remove the lockout
- 6 For a notification of a message, do the following:
 - Tap the message to display the corresponding message screen.
 - After reading the message, tap the < button to return to the **Notifications** screen.

Putting the instrument into standby mode

When the instrument is not in the charging station and not in use, standby mode can be activated.

In standby mode the instrument is inactive, and saving power as it is not processing or making measurements.

Automatic activation of standby mode is set by the **Standby timeout** configuration item. If enabled it determines the length of time (seconds) an instrument must be inactive before standby mode is activated. The default value is 300 seconds (maximum 3,600 seconds).

Otherwise the instrument can be put into standby mode using the on/off button.

► To put the instrument into standby mode

- 1 Press the on/off button firmly.
 - ❗ The instrument vibrates.
 - The instrument goes into standby mode.

Waking the instrument from standby mode

When the instrument is not in the charging station and not in use, standby mode can be activated.

In standby mode the instrument is inactive, and saving power as it is not processing or making measurements.

The instrument can be configured to wake from standby mode using the **Lift to wake** configuration item. When enabled the instrument in standby mode is 'woken' by movement detection. For example, by lifting the instrument.

Otherwise the instrument can be woken from standby mode using the on/off button.

► To wake the instrument from standby mode

- 1 Press the on/off button firmly.
 - ❗ The instrument vibrates.
 - The instrument wakes from standby mode.
 - Depending on the instrument's configuration the **Glucose** screen or the app library is displayed.

Logging off the Glucose app

When you have finished working in the Glucose app, you should log off.

Depending on how your instrument is configured, after logging off from the Glucose app you are returned to the **Glucose** screen or to the app library.



An instrument can be configured to automatically activate standby mode after a pre-determined time period using the **Standby timeout** configuration item.

► To log off the Glucose app

- 1 Do one of the following:
 - Place the instrument in the charging station.
 - Press the on/off button.
 - In the **Tests** screen, the **Local results** screen, or the **Notifications** screen, tap the  button.
- You are logged off the Glucose app.

Page intentionally left blank.

Routine operation

In this chapter

5

Entering a patient.....	113
Performing a glucose test.....	116
Reviewing patient test results	120
Performing a QC test	122
Reviewing QC test results.....	126
Adding comments to a test result	128

Page intentionally left blank.

Entering a patient

The way in which you enter a patient depends on your instrument's configuration.

You enter a patient in the following tests:

- Glucose test
- Insulin entry
- OTS

The following configurations can be made to your instrument, and determine how you manage patient entry.

- Entry methods (barcode scan, keyboard entry)
- Autocomplete
- ID pattern recognition
- ID validation
- Patient confirmation

▢ [About patient entry \(49\)](#)

You enter a patient ID using one of the following methods:

- RFID tag
- Barcode scan
- Keyboard entry

▢ [To enter a patient using a barcode \(113\)](#)

▢ [To enter a patient using the keyboard \(114\)](#)



- ☐ You are logged on to the instrument.
- ☐ You have selected the appropriate test.
- ☐ Patient ID confirmation dialog is enabled.
- ☐ List-based (allow unknown patient IDs) is enabled.

► To enter a patient using a barcode

- 1 In the test screen (e.g., **Glucose test**), if the barcode camera is not active, tap the  tab.
→ The barcode camera is activated.



- 2 CAUTION!** Ensure that the barcode is flat and not damaged.

Position the instrument so that the barcode is visible on the screen and inside the white frame.

- ❗ If there is insufficient light, tap the button to turn on the built-in flashlight.
- If a barcode is detected the frame turns green and the **Confirm patient** dialog box is displayed. Go to the next step.
- The frame turns red and a message is displayed at the bottom of the screen.
The barcode content may be invalid, or the patient was not found.
- If no barcode is detected the frame remains white and the scan times out. The barcode may be degraded and requires checking. Use the keyboard entry if available.

- 3 CAUTION!** If the **Confirm patient** dialog box is displayed, ensure that the patient details are correct.

Do one of the following:

- If the patient details are correct, tap the **Confirm** button and continue with the test.
- If the patient details do not match the patient, tap the **Cancel** button and stop the patient entry.

- 4** If the scanned patient ID is not on the instrument's patient list a dialog box is displayed. It asks you if you want to perform the test using this patient ID.

Do one of the following:

- Tap the **Confirm** button to perform the test using the scanned patient ID.
- Press the **Cancel** button to stop the patient entry.

► To enter a patient using the keyboard

- 1** In the test screen (e.g., **Glucose test**), if keyboard entry is not active, tap the tab.

2 In the **Enter patient ID** screen, enter the patient ID.

- Patient ID entry is case sensitive.

3 Tap the **Continue** button.

4 If the **Confirm patient** dialog box is displayed, check that the patient details are correct, and then tap the **Confirm** button.

→ The next test screen is displayed. Continue with the test.

5 If the patient ID you entered is not on the instrument's patient list a dialog box is displayed. It asks you if you want to perform the test using this patient ID.

Do one of the following:

- Tap the **Confirm** button to perform the test using the patient ID.
- Press the **Cancel** button to stop the patient entry.

Related topics

- [Performing a glucose test \(116\)](#)
- [Entering insulin information \(131\)](#)

Performing a glucose test

One of the main functions of the instrument is to perform glucose tests.

The procedure outlined in this task contains the main steps that you perform when performing a glucose test.

However, depending on your instrument's configuration, there may be additional steps in the glucose test:

- Patient ID confirmation (after entering the patient).
- Sample type selection (after entering the patient / after **Patient ID validation**).
- Test strip ejection before confirming the test result (not after).
- Comment entry (before result confirmation).
- Running another glucose test for the same patient (after glucose test completion).
- Entering insulin information (after glucose test completion).



A colored test strip port light provides guidance of instrument status and actions you must take.

In the case of a QC lockout, glucose testing cannot be performed until the lockout has been removed. Depending on how QC lockout is configured, you remove it by performing and passing a QC test at level 1, level 2, or level 1 and level 2.



If your instrument is configured to allow you to override a QC lockout, you can perform a test despite a QC lockout, when the QC lockout was the result of a QC algorithm configuration condition.

Your instrument can be configured to allow you to override a QC lockout up to 9 times before you must perform a QC test.

However, if the QC lockout was the result of a failed QC test, the QC lockout cannot be overridden.

WARNING!**Incorrect interpretation of test result when using anticoagulant tubes**

To avoid harmful outcomes resulting from the incorrect interpretation of a test result.

- ▶ When using anticoagulant tubes, do not store the tube after drawing, but apply the blood immediately.

- ▶ [Entering a patient \(113\)](#)
- ▶ [Performing a QC test \(122\)](#)
- ▶ [About performing a glucose test \(52\)](#)



- ☐ Glucose test strips
- ☐ Freshly obtained blood sample
- ☐ New pair of disposable gloves
- ☐ Waste container

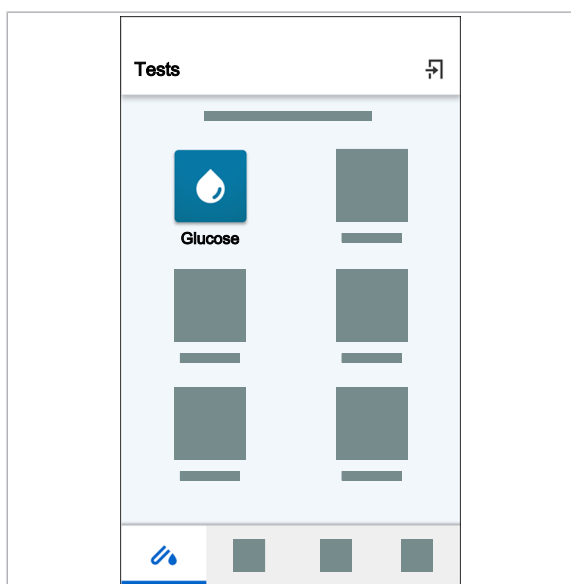


- ☐ You are logged on to the instrument
- ☐ Specified QC tests have been completed successfully

- ▶ [Logging on to the Glucose app \(99\)](#)

▶ To perform a glucose test

- 1 In the **Tests** screen, tap the **Glucose** button.
- 2 Enter the patient ID using one of the following methods:
 - RFID tag
 - Barcode scan
 - Keyboard entry





- 3 CAUTION!** Close the test strip container immediately after removing the test strip.

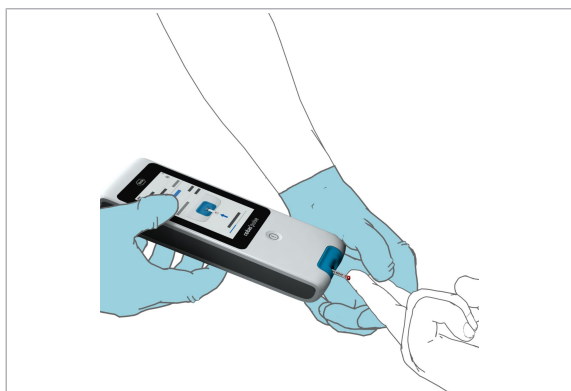
When prompted, insert a test strip by doing the following:

- Remove the test strip from the test strip container and then close it.
- Insert the test strip into the test strip port as far as it will go.

- i** The test strip port light color briefly turns blue (test strip is recognized and checked), and then turns white (instrument is ready for sample application).

An audible signal is emitted.

- The instrument performs checks and notifies you of any issues.



- 4 CAUTION!** Apply the blood sample promptly.

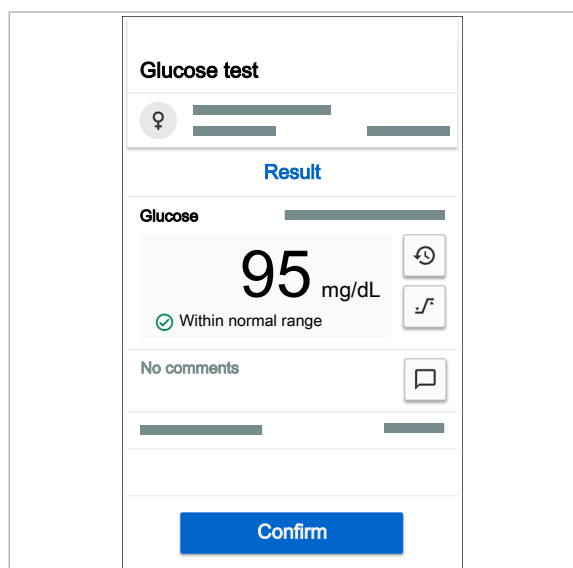
Apply the blood sample to the front edge of the test strip, and not on the top of the test strip.

Ensure that the test strip port is above or on the same level as the blood sample.

- i** The time remaining in which to apply the blood sample is shown on the screen. You have 180 seconds.

When sufficient sample has been applied, the test strip port light color turns blue and an audible signal is emitted.

- The test is processed and the **Result** screen is displayed.

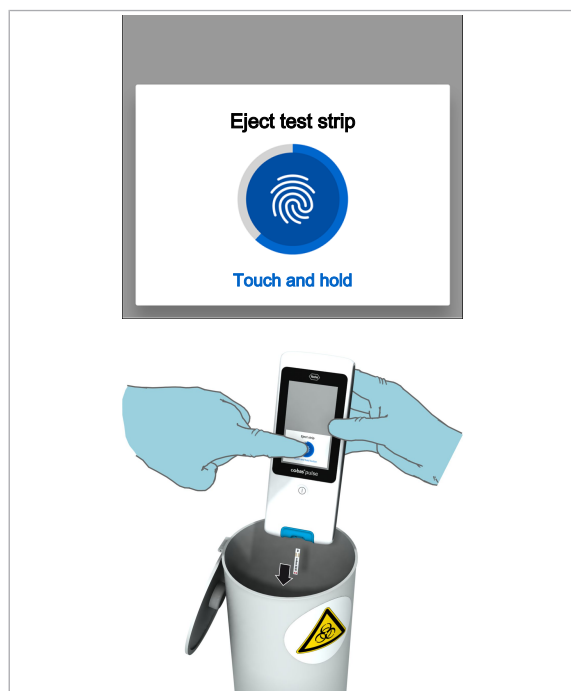


- 5** In the **Result** screen you can do the following:

- Tap the button to view the test history for the patient being tested.
- Tap the button to view the **Range details** dialog box..
- Tap the button to add comments for the result if required.

- 6** Tap the **Confirm** button

- The **Eject test strip** dialog box is displayed.



- 7 CAUTION!** When you eject the test strip, ensure that you dispose of it in accordance with the applicable regulations.

Never pull out the test strip.

Hold the instrument vertically over the waste container.

In the **Eject test strip** dialog box, touch and hold the  button until the blue progress indicator has encircled the  button.

 The test strip port light color turns magenta.

→ The test strip is loosened and falls into the waste container.

If it does not, gently shake the instrument to help test strip to fall out.

Related topics

- [Entering insulin information \(131\)](#)
- [About the QC lockout \(66\)](#)
- [Adding comments to a test result \(128\)](#)
- [About collecting a blood sample \(51\)](#)
- [About the test strip port light \(64\)](#)

Reviewing patient test results

You can review the patient test results that are stored on your instrument.

The period of time for which a test remains on the instrument is configurable.

You view the patient results on the **Local results** screen. Patient results for the following tests types are listed:

- Glucose test
- Emergency test
- Insulin entry

The result list provides a summary of each test result:

- Date and time of the test result
- Patient name and ID
- Test type
- Test result

Tapping a test result displays more information in the **Result details** screen. The information displayed depends upon the test type.

You can locate a patient test result by scrolling through the list of results. Alternatively you can first search for the patient, and then locate the test result.

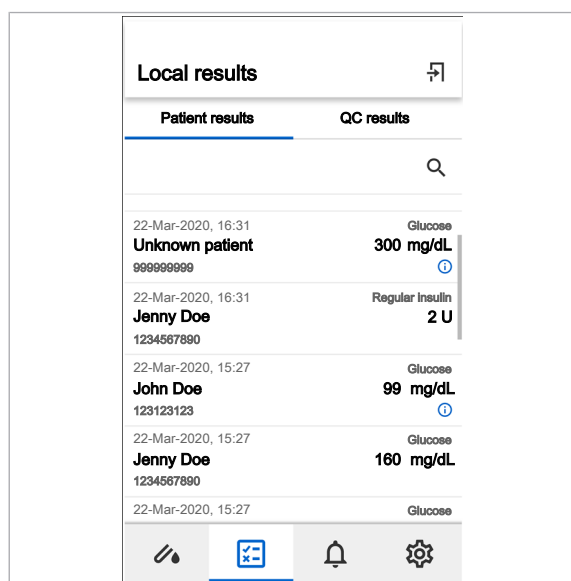


- ☐ Instrument is turned on.
- ☐ You are logged on to the instrument.

▶ [Logging on to the Glucose app \(99\)](#)

▶ To review a patient test result

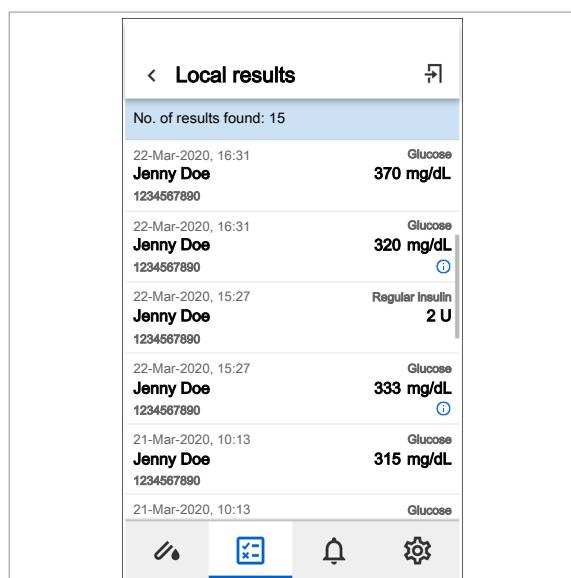
- 1 On the navigation bar, tap the button.



2 In **Local results > Patient results** tap the **Q** button.

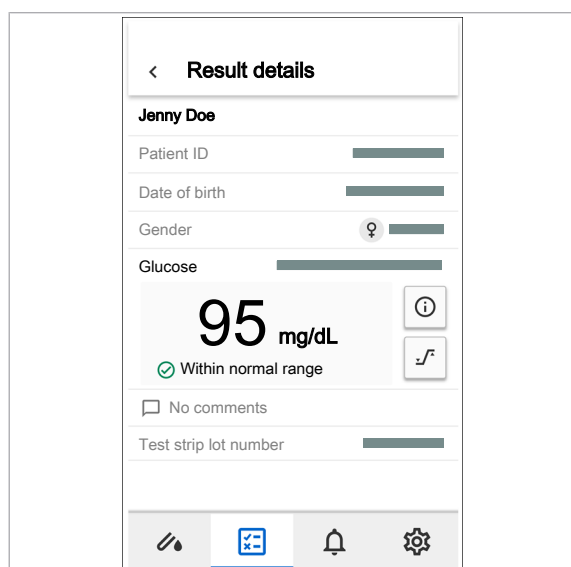
3 To search for a patient whose result you require, do one of the following:

- In the **Keyboard** tab, search for the patient by using the keyboard and entering the patient ID or name.
- Tap the **Barcode** tab, and then scan the barcode of the patient that you require.



4 The search results for the patient are displayed in the **Local results** screen. The number of results found is indicated.

5 Tap a result to view more details.



6 In the **Result details** screen you can do the following:

- View the details of the result.
- Tap the **Range** button to view the **Range details** dialog box.
- Tap the **Info** button to view the **Test details** dialog box.
- Tap the **Back** button to return to the **Local results** screen.

Performing a QC test

Accurately testing known levels of glucose ensures that the system and your technique used in testing give accurate results on patient samples.

A QC test using QC material comprises the following:

- Select the desired QC level for the test.
- Enter the QC material lot number.
- Perform the QC test with the QC material.

For a QC test to be completed successfully, the result must fall within the specified range (as shown on the test strip container label or as defined by configuration). Patient tests can then be performed again.



If your instrument is configured to allow you to override a QC lockout, you can perform a test despite a QC lockout, when the QC lockout was the result of a QC algorithm configuration condition.

Your instrument can be configured to allow you to override a QC lockout up to 9 times before you must perform a QC test.

However, if the QC lockout was the result of a failed QC test, the QC lockout cannot be overridden.

To remove a QC lockout, the levels flagged with **"Required"** (see step 2) must be measured and have a **"PASS"** result.

QC materials for glucose tests have 2 QC levels:

- Level 1 (L1): Low (low values in test results).
- Level 2 (L2): High (high values in test results).

The procedure outlined in this task contains the main steps in a QC test. However, depending on your instrument's configuration, there may be some differences:

- Test strip ejection after confirming the test result (not before).
- Comment entry is mandatory (not optional).

The procedures for performing Level 1 and Level 2 tests are the same.



Colored test strip port light provides guidance of instrument statuses / actions you must take.



Intervals between running QC tests are determined by your healthcare facility.



- ☐ Glucose QC material
- ☐ Glucose test strips
- ☐ Waste container
- ☐ New pair of disposable gloves

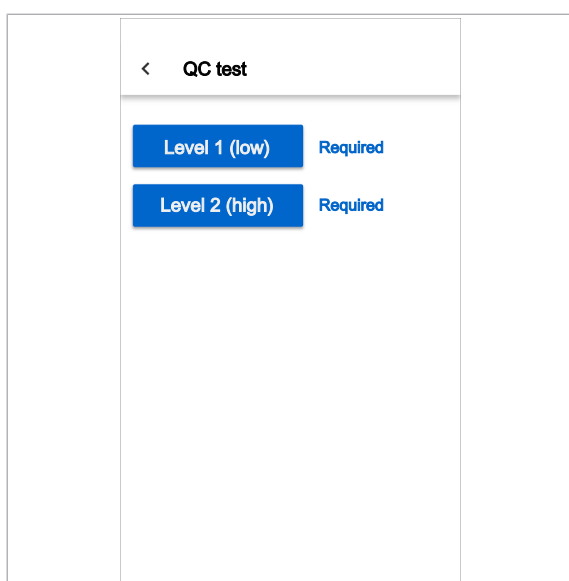
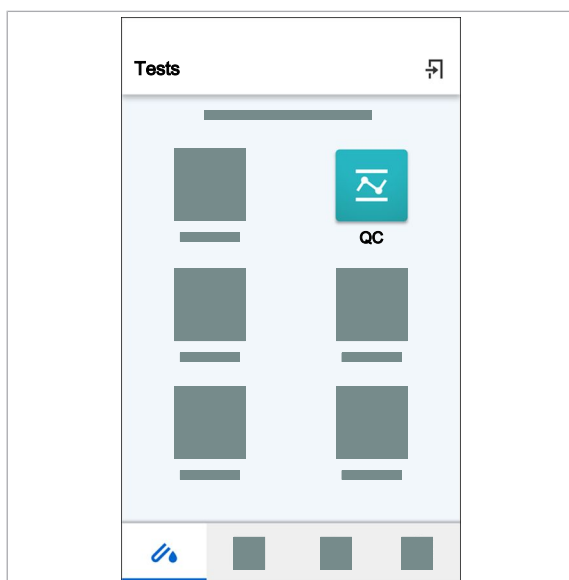


- ☐ The instrument is turned on.
- ☐ You are logged on to the instrument.

» [Logging on to the Glucose app \(99\)](#)

► To perform a QC test

- 1 On the **Tests** screen, tap the **QC** button.



- 2 On the **QC test** screen, do one of the following:
 - To perform a level 1 QC test, tap the **Level 1 (low)** button.
 - To perform a level 2 test, tap the **Level 2 (high)** button.
 - ❗ When a QC test is required (due to a QC lockout), the levels that you must test are indicated by **"Required"**.
- 3 To select the QC lot that you are using, do one of the following:
 - In the **Scan QC level 1 barcode** screen / **Scan QC level 2 barcode** screen, tap the tab and then scan the QC lot number barcode.
 - On the **Choose QC lot** screen, tap the tab, and then tap the lot number that you are using.
 - ❗ The tab might be deactivated in your healthcare facility.



- 4 CAUTION!** Close the test strip container immediately after removing the test strip.

When prompted, insert a test strip by doing the following:

- Remove the test strip from the test strip container and then close it.
- Insert the test strip into the test strip port as far as it will go.

- ❶ The test strip port light color briefly turns blue (test strip is recognized and checked), and then turns white (instrument is ready for sample application).

An audible signal is emitted.

- The instrument performs checks and notifies you of any issues.



- 5 CAUTION!** Do not apply the QC material to the top of the test strip.

When prompted, apply the QC material to the front edge of the test strip.

Ensure that the test strip port is above or on the same level as the QC material.

- ❶ The time remaining in which to apply the QC material is shown at the bottom of the screen. When sufficient QC material has been applied, the test strip port light color turns blue. An audible signal is emitted.

- The QC test is processed after which the **Eject test strip** dialog box is displayed.

- 6 CAUTION!** When you eject the test strip, ensure that you dispose of it in accordance with the applicable regulations.

Never pull out the test strip.

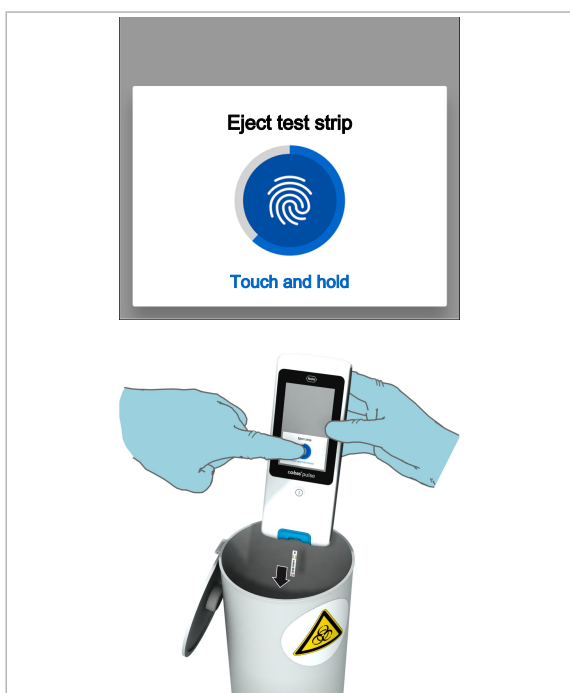
Hold the instrument vertically over the waste container.

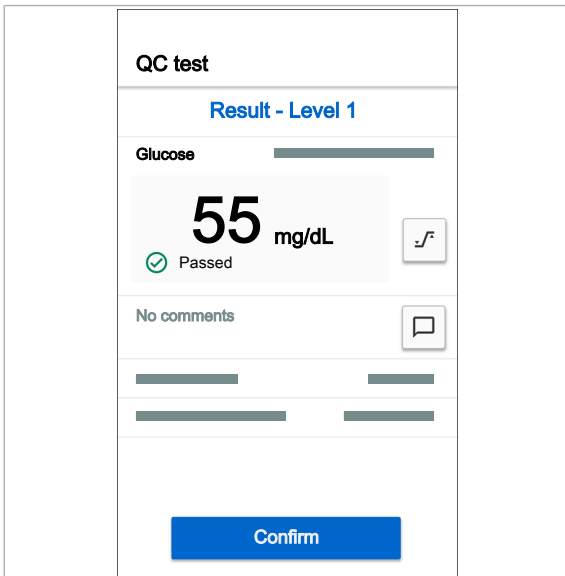
In the **Eject test strip** dialog box, touch and hold the  button until the blue progress indicator has encircled the  button.

- ❶ The test strip port light color turns magenta.

- The test strip is loosened and falls into the waste container.

If it does not, gently shake the instrument to help test strip to fall out.





7 In the test result screen (**Result - Level 1** / **Result - Level 2**), you can do the following:

- Tap the ✓ button to view the **Range details** dialog box.
- Tap the  button to add comments for the result as required.

8 Tap the **Confirm** button.

📖 **Related topics**

- [Adding comments to a test result \(128\)](#)
- [About the test strip port light \(64\)](#)

Reviewing QC test results

You can review the QC test results that were performed on your instrument.

The period of time for which a test result remains on an instrument is configurable.

You view the QC results on the **Local results** screen. Results for the following tests types are listed:

- QC test
- Linearity test
- Proficiency test

The result list provides a summary of each test result:

- Date and time of the QC test
- QC level
- Test result

Tapping a test result displays more information in the **Result details** screen. The information displayed depends upon the test type.

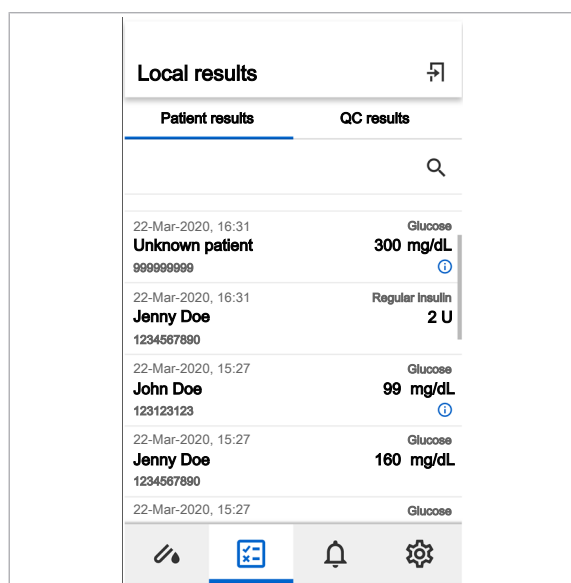


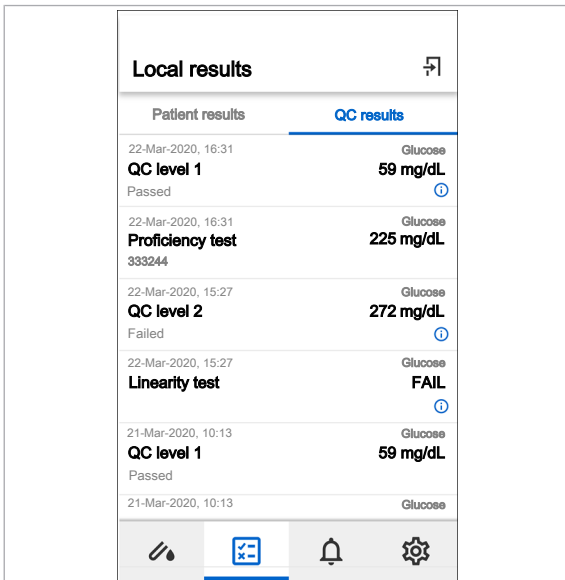
- ☐ Instrument is turned on.
- ☐ You are logged on to the instrument.

▶ [Logging on to the Glucose app \(99\)](#)

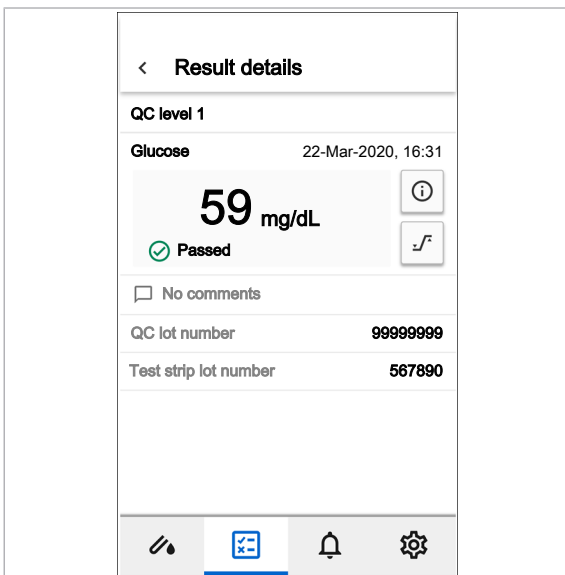
▶ To review a QC test result

- 1 On the navigation bar, tap the button.
- 2 In the **Local results** screen, tap the **QC results** tab.





3 In the **QC results** tab, tap the result that you want to view.



4 In the **Result details** screen you can do the following:

- View the details of the QC result.
- Tap the  button to view the **Range details** dialog box.
- Tap the  button to view further test information.
- Tap the  button to return to the **QC results** tab.

Adding comments to a test result

Comments enable you to add supplemental information to a test result.

A  button or a  button in a test result screen indicates that you can enter comments for that result. All test types can be configured for comments to be entered for a test result.

The color of the comment button indicates that comment entry is optional or mandatory. When comment entry is mandatory, the next step in the test can only be performed after at least one comment has been entered.



Comment entry optional



Comment entry mandatory



► [About adding comments to a test result \(62\)](#)

- ☐ You are performing a test, and are in the result screen.
- ☐ A  button or a  button is available.

► To add comments to a test result

- 1 In the test result screen do one of the following:
 - Tap the  button.
 - Tap the  button.
- 2 In the **Comments** dialog box, select up to 3 options and then tap the **Save** button.
 - ❗ A free-text comment has a maximum of 20 characters.
 - The **Comments** dialog box closes.
- 3 To edit the comments, do the following:
 - To display the **Comments** dialog box, tap the  button.
 - Edit the comments.
 - Tap the **Save** button
 - The **Comments** dialog box closes.

Non-routine operation

In this chapter

6

Entering insulin information.....	131
Performing a linearity test.....	135
Performing an emergency glucose test.....	139
Performing a proficiency test	142
Performing an observed test sequence (OTS).....	145
Adjusting the screen brightness and the volume level	147
Reviewing the audit trail.....	148
Changing your user password	150
Turning on the instrument.....	151
Turning off the instrument.....	152
Restarting the instrument.....	153
Setting up the charging station	154
Lot management	155
About test strip lot distribution	155
Adding a test strip lot to the instrument.....	156
Reviewing test strip lot details on the instrument.....	158
Deleting a test strip lot from the instrument	159
Adding a QC or linearity lot to the instrument.	160
Reviewing QC lots on the instrument.....	161
Deleting a QC lot from the instrument	162

Page intentionally left blank.

Entering insulin information

You can record information about insulin administered to a patient.

Your instrument can be configured to enter insulin information in 2 ways:

- On the **Tests** screen by tapping the **Insulin** button.
- After performing a **Glucose test**.

You enter insulin information on 5 pages, between which you can move using **Next** and **Previous** buttons.

You record the following information:

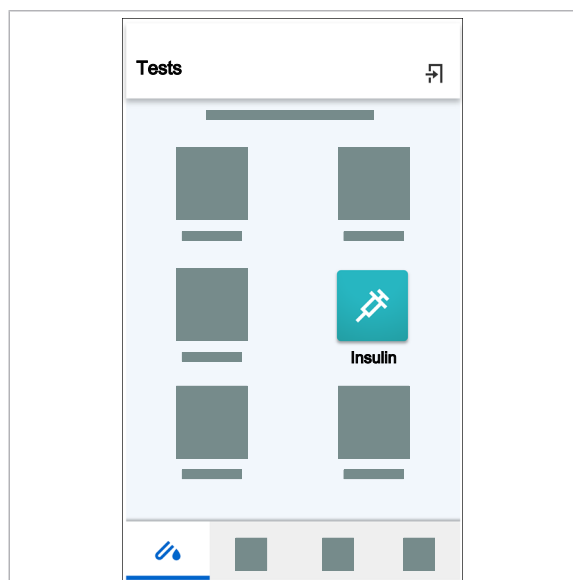
- Patient details
- Date and time of the insulin administration
- Insulin type
- Insulin name
- Comments about the insulin administration

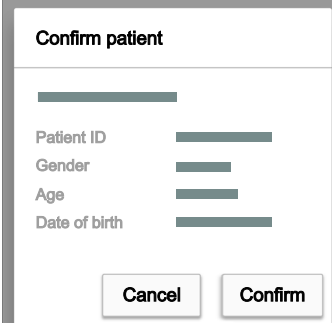


- ☐ Your instrument is turned on and you have logged on.
- ☐ Your instrument is configured to enter insulin information

► To enter insulin information

- 1 Do one of the following:
 - On the **Tests** screen, tap the **Insulin** button.
 - At the end of a glucose test, in the **Options** dialog box, tap the **Enter insulin dose** button, and then go to step 4.
- 2 In the **Insulin entry** screen do one of the following:
 - Scan the patient details barcode.
 - Tap the tab, enter the patient name or the patient ID, and then tap the **Continue** button.





Confirm patient

Patient ID _____

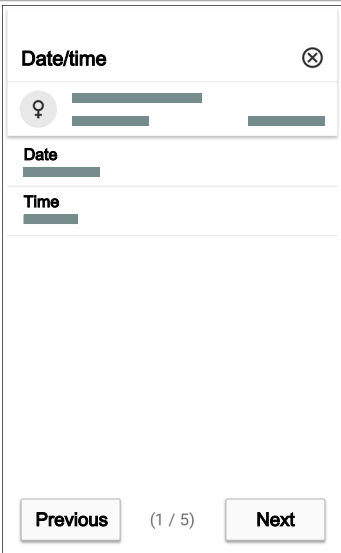
Gender _____

Age _____

Date of birth _____

Cancel Confirm

- 3 In the **Confirm patient** dialog box, tap the **Confirm** button if the patient details are correct.



Date/time ⊗

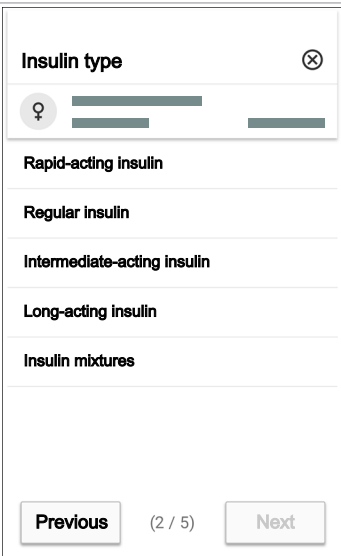
♀ _____

Date _____

Time _____

Previous (1 / 5) Next

- 4 In the **Date/time** screen, the date and time default to the current date and time. To enter different values, do the following:
- To change the date, tap the **Date** field and use the date picker to set a date, and then tap the **Confirm** button.
 - To change the time, tap the **Time** field and use the time picker to set a time, and then tap the **Confirm** button.
 - To move to the next screen, choose the **Next** button.



Insulin type ⊗

♀ _____

Rapid-acting insulin

Regular insulin

Intermediate-acting insulin

Long-acting insulin

Insulin mixtures

Previous (2 / 5) Next

- 5 In the **Insulin type** screen, tap the appropriate insulin type, and then tap the **Next** button.
- ❗ To change a value in a previous screen, tap the **Previous** button to go to the screen. After making the change, tap the **Next** button to return to the current screen.

Insulin name ⊗

♀ [Search bar]

Humulin R

Novolin R

Previous (3 / 5) Next

- 6 In the **Insulin name** screen, tap the appropriate name, and then tap the **Next** button.

Insulin units ⊗

♀ [Search bar]

Enter units

2

Previous (4 / 5) Next

- 7 In the **Insulin units** screen do the following:
- Using the number pad, tap the appropriate number.
 - Tap the button.
 - Tap the **Next** button.

Comments ⊗

♀ [Search bar]

☐ Enter a comment 0/20

☐ Physician notified

☐ RN notified

☐ No action

☐ Procedure error

Previous (5 / 5) Next

- 8 In the **Comments** screen, select up to 3 comments and then tap the **Next** button.
- ❗ You can add a free-text comment of up to 20 characters.

Insulin entries

Date

Time

Insulin type

Insulin name

Insulin units

Comments

Confirm

9 In the **Insulin entries** screen, tap the **Confirm** button to complete the insulin information entry.

- To change an entry, tap the corresponding button, make the amendment, and then tap the **Confirm** button.

Changing certain entries (e.g. insulin type) may require associated entries to be changed.

Related topics

- [Performing a glucose test \(116\)](#)
- [Entering a patient \(113\)](#)

Performing a linearity test

Linearity tests help you check the function and accuracy of the entire system over the full range of specified values.

A linearity test comprises the following main steps:

- Checking the lot number of the linearity material.
- Checking the lot number of the test strips.
- Perform the test with a minimum of 3 linearity levels.



When performing a linearity test, the instrument does not perform a linear regression.



Determined by your healthcare facility.



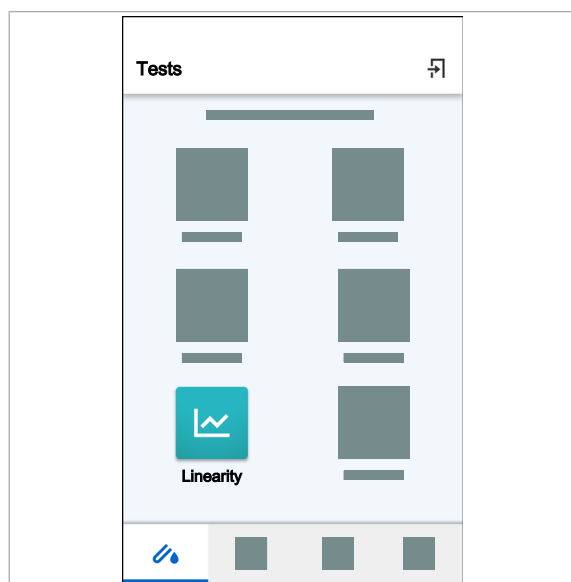
- ☐ Linearity kit
- ☐ Glucose test strips
- ☐ New pair of disposable gloves
- ☐ Waste container

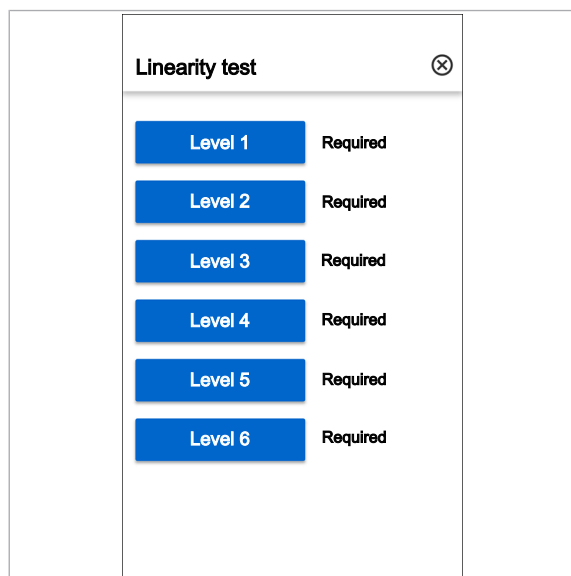


- ☐ The instrument is turned on.
- ☐ You have logged on to the instrument.

► To perform a linearity test

- 1 In the **Tests** screen, tap the **Linearity** button.
- 2 In the **Linearity test** screen do one of the following:
 - Scan the linearity kit lot barcode.
 - If enabled, tap the tab and then below **Choose linearity kit lot**, tap the lot you will use to perform the test.





3 In the **Linearity test** screen tap the **Level 1** button.



4 **CAUTION!** Close the test strip container immediately after removing the test strip.

When prompted, insert a test strip by doing the following:

- Remove the test strip from the test strip container and then close it.
- Insert the test strip into the test strip port as far as it will go.

❗ The test strip port light color briefly turns blue (test strip is recognized and checked), and then turns white (instrument is ready for sample application).
An audible signal is emitted.

→ The instrument performs checks and notifies you of any issues.

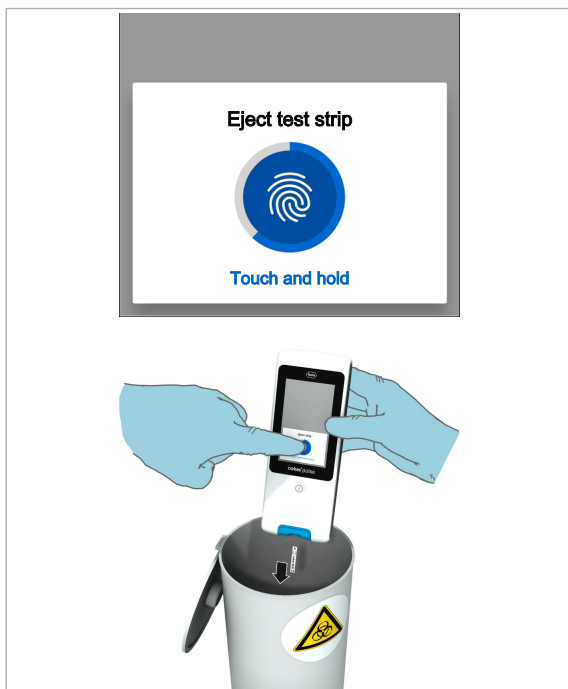
5 **CAUTION!** Do not apply the material to the top of the test strip.

When prompted, apply the material to the front edge of the test strip.

Ensure that the test strip port is above or on the same level as the material.

❗ The time remaining in which to apply the material is shown at the bottom of the screen. You have 180 seconds.
When sufficient material has been applied, the test strip port light color turns blue.
An audible signal is emitted.





- 6 CAUTION!** When you eject the test strip, ensure that you dispose of it in accordance with the applicable regulations.

Never pull out the test strip.

Hold the instrument vertically over the waste container.

In the **Eject test strip** dialog box, touch and hold the  button until the blue progress indicator has encircled the  button.

 The test strip port light color turns magenta.

→ The test strip is loosened and falls into the waste container.

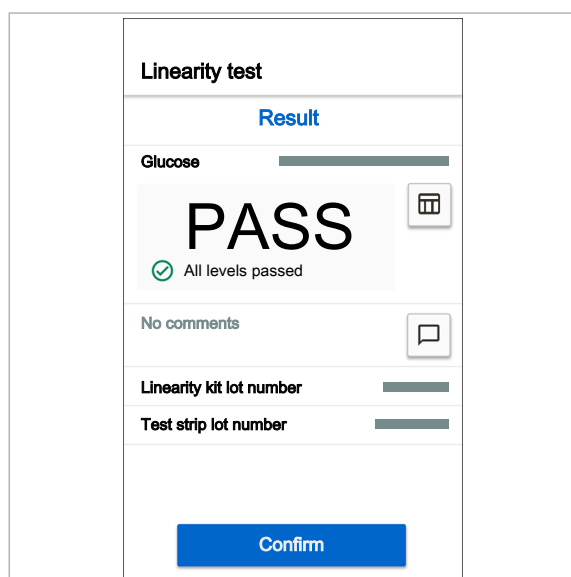
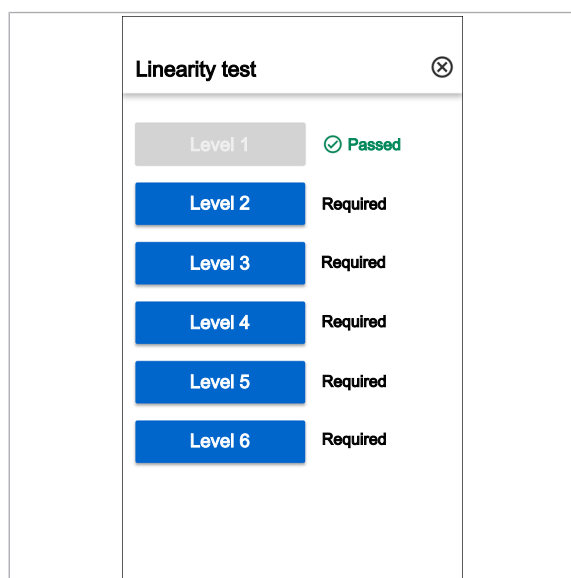
If it does not, gently shake the instrument to help test strip to fall out.

- 7** In the **Result - Level 1** for run 1 screen you can view the result and then tap the **Proceed** button.

→ The **Insert test strip** screen for the second run is displayed.

- 8** To perform the second run for the level 1 test, repeat steps **4** to **7**.

→ The result of the second run is displayed.



9 Tap the **Proceed** button.

→ The **Linearity test** screen is displayed, indicating if level 1 has passed or failed.

10 To test the remaining 5 levels, do the following:

- Tap the next required level button (for example, the **Level 2** button).
- Perform runs 1 and 2 for each remaining level by repeating steps 4 to 9.

11 After performing run 2 of level 6, you are prompted to eject the test strip.

→ The **Linearity test > Result** screen is displayed.

12 You can do the following:

- Tap the  button to view the results of all runs for all levels in the **Result details** dialog box.
- Tap the  button to add comments to the result.

13 Tap the **Confirm** button to close the **Linearity test** screen and return to the **Tests** screen.

- ❗ You can view the test result at any time in **Local results > QC results**.

Related topics

- [Reviewing QC test results \(126\)](#)

Performing an emergency glucose test

You perform an emergency glucose test when you need to perform a glucose test but a patient ID is not available.

Consequently, you skip patient identification and start testing directly to get the result as fast as possible.

When your instrument is configured to perform an emergency glucose test, the **Emergency** button is available on the **Tests** screen.

With the exception of patient ID confirmation your instrument's regular glucose test configuration applies to an emergency glucose test.



If your instrument is configured to override a QC lockout, you can perform an emergency test despite a QC lockout, when the QC lockout was the result of a QC algorithm configuration condition.

Your instrument can be configured to allow you to override a QC lockout up to 9 times before you must perform a QC test.

However, if the QC lockout is the result of a failed QC test, the QC lockout cannot be overridden.



WARNING!

Incorrect interpretation of test result when using anticoagulant tubes

To avoid harmful outcomes resulting from the incorrect interpretation of a test result.

- ▶ When using anticoagulant tubes, do not store the tube after drawing, but apply the blood immediately.



▶ [About performing a glucose test \(52\)](#)

- ☐ Glucose test strips
- ☐ Freshly obtained blood sample
- ☐ New pair of disposable gloves
- ☐ Waste container

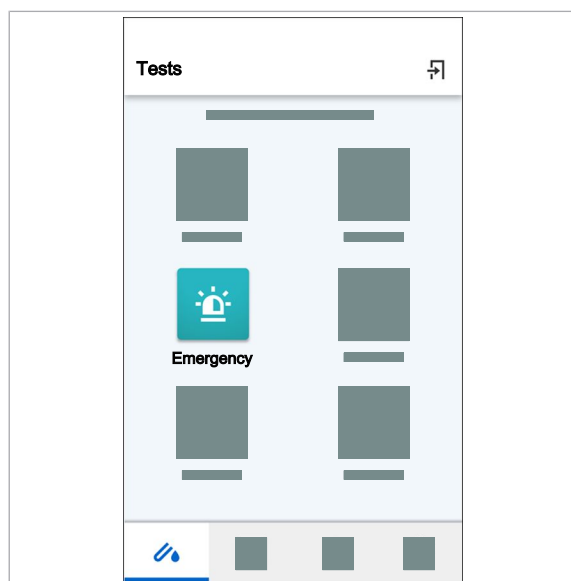


- ☐ You are logged on to the instrument.
- ☐ Your instrument is configured to perform emergency glucose tests.

▶ [Logging on to the Glucose app \(99\)](#)

► To perform an emergency glucose test

1 In the **Tests** screen, tap the **Emergency** button.



2 **CAUTION!** Close the test strip container immediately after removing the test strip.

When prompted, insert a test strip by doing the following:

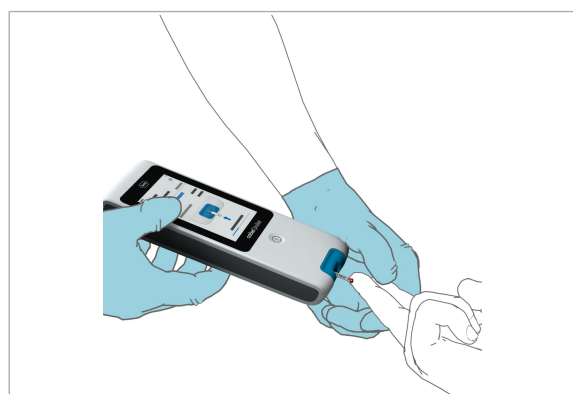
- Remove the test strip from the test strip container and then close it.
- Insert the test strip into the test strip port as far as it will go.
- ❶ The test strip port light color briefly turns blue (test strip is recognized and checked), and then turns white (instrument is ready for sample application). An audible signal is emitted.
- The instrument performs checks and notifies you of any issues.

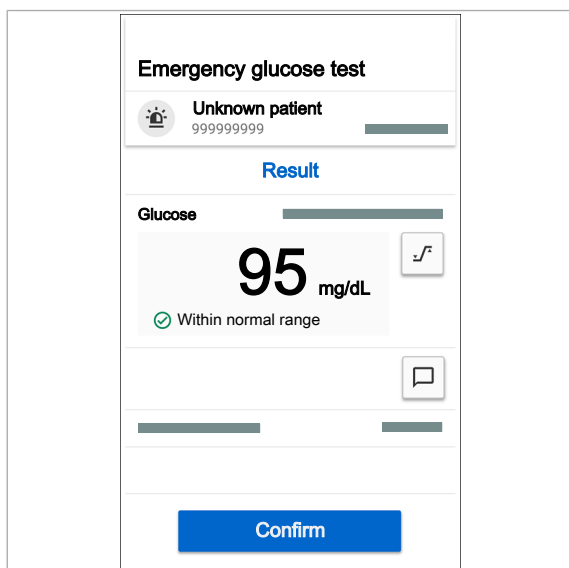


3 **CAUTION!** Apply the blood sample promptly.

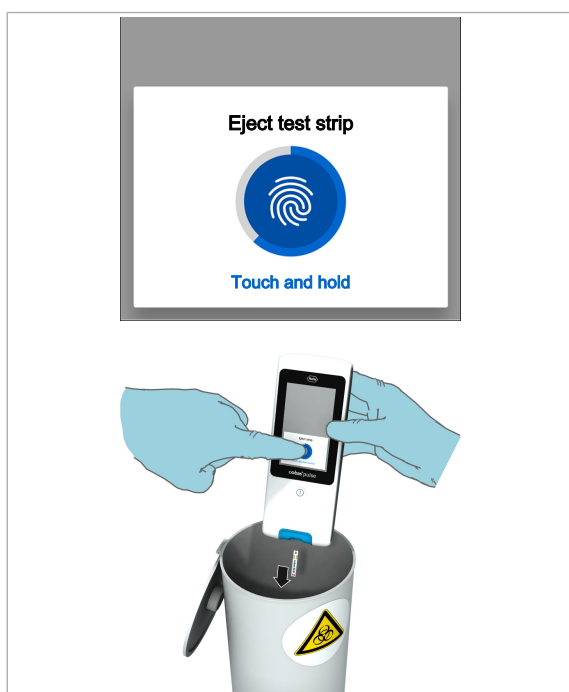
Apply the blood sample to the front edge of the test strip, and not on the top of the test strip. Ensure that the test strip port is above or on the same level as the blood sample.

- ❶ The time remaining in which to apply the blood sample is shown on the screen. You have 180 seconds.
- When sufficient sample has been applied, the test strip port light color turns blue and an audible signal is emitted.
- The test is processed and the **Result** screen is displayed.





- 4 Before confirming the result, you can do any of the following:
 - Tap the ↗ button to view the result range details.
 - Tap the 💬 button to add comments for the result if required.
- 5 Tap the **Confirm** button.
 - The **Eject test strip** dialog box is displayed.



- 6 **CAUTION!** When you eject the test strip, ensure that you dispose of it in accordance with the applicable regulations.
Never pull out the test strip.

Hold the instrument vertically over the waste container.
In the **Eject test strip** dialog box, touch and hold the  button until the blue progress indicator has encircled the  button.
 - ❗ The test strip port light color turns magenta.
 - The test strip is loosened and falls into the waste container.
If it does not, gently shake the instrument to help test strip to fall out.

Related topics

- [Entering insulin information \(131\)](#)
- [Adding comments to a test result \(128\)](#)
- [About collecting a blood sample \(51\)](#)
- [About the test strip port light \(64\)](#)

Performing a proficiency test

You perform blood glucose proficiency tests on samples provided by an independent organization and whose values are unknown to you.

The results should be forwarded to the appropriate source after completing the test. The supplied samples are treated in the same manner as regular patient samples.

The procedure outlined in this task contains the main steps that you perform in a proficiency test.



A colored test strip port light provides guidance of instrument status and the actions you must take.

In the case of a QC lockout, proficiency testing cannot be performed until the lockout has been removed. Depending on how QC lockout is configured, you remove it by performing and passing a QC test at level 1 and/or level 2..



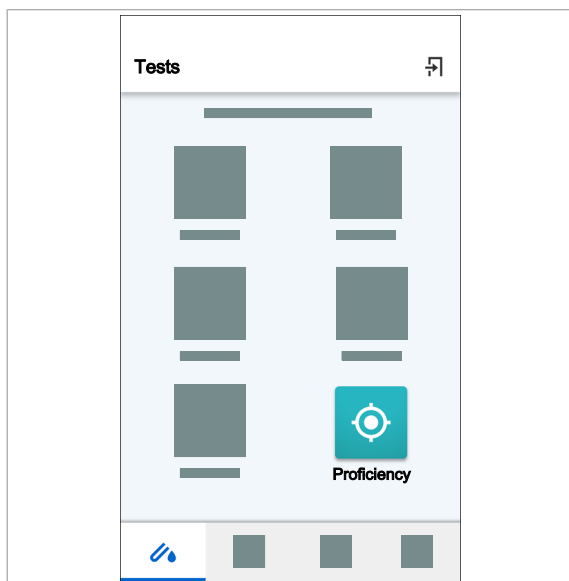
- ☐ Proficiency material
- ☐ Glucose test strips
- ☐ New pair of disposable gloves
- ☐ Waste container



- ☐ You are logged on to the instrument.
- ☐ Instrument is not in QC lockout.

- [Logging on to the Glucose app \(99\)](#)
- [Performing a QC test \(122\)](#)

► To perform a proficiency test



- 1 In the **Tests** screen, tap the **Proficiency** button.
- 2 In the **Proficiency test** screen, do one of the following
 - Scan the sample ID barcode.
 - Tap the  tab, enter the sample ID, and then tap the **Continue** button.



- 3 **CAUTION!** Close the test strip container immediately after removing the test strip.

When prompted, insert a test strip by doing the following:

- Remove the test strip from the test strip container and then close it.
 - Insert the test strip into the test strip port as far as it will go.
- ❶ The test strip port light color briefly turns blue (test strip is recognized and checked), and then turns white (instrument is ready for sample application).
An audible signal is emitted.
- The instrument performs checks and notifies you of any issues.



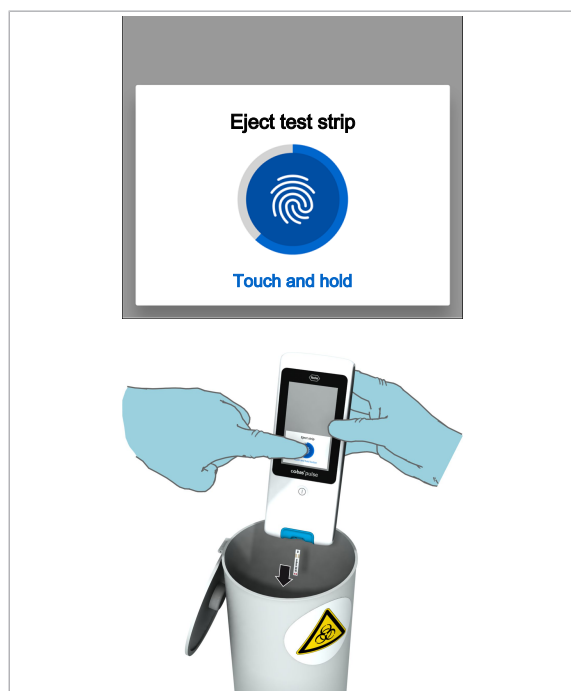
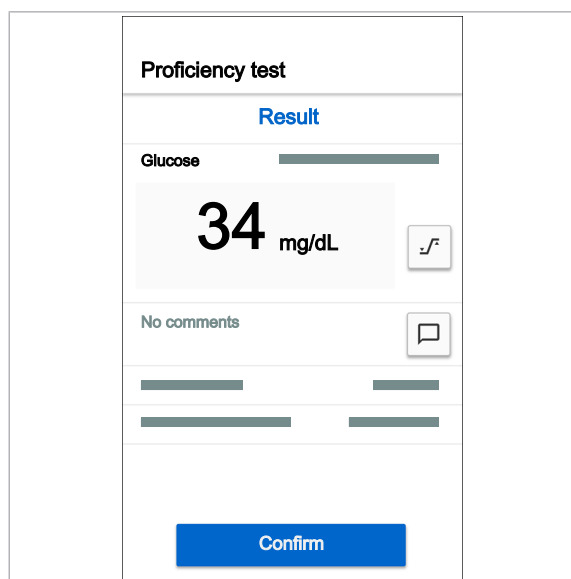
- 4 **CAUTION!** Do not apply the material to the top of the test strip.

When prompted, apply the material to the front edge of the test strip.

Ensure that the test strip port is above or on the same level as the material.

- ❶ The time remaining in which to apply the material is shown at the bottom of the screen. You have 180 seconds.
- When sufficient material has been applied, the test strip port light color turns blue.
An audible signal is emitted.

- 5 Depending on your instrument's configuration do the following:



- If the **Result** screen is displayed, continue with step **6**.
- If the **Eject test strip** button dialog box is displayed, perform step **8**, and then steps **6** and **7**.

6 In the **Result** screen you can do the following:

- Tap the ✓ button to view the **Range details** dialog box.
- Tap the □ button to add comments for the result if required.

7 Tap the **Confirm** button.

- ❗ You can view the test result at any time in **Local results > QC results**.

8 CAUTION! When you eject the test strip, ensure that you dispose of it in accordance with the applicable regulations. Never pull out the test strip.

Hold the instrument vertically over the waste container.

In the **Eject test strip** dialog box, touch and hold the  button until the blue progress indicator has encircled the  button.

- ❗ The test strip port light color turns magenta.

→ The test strip is loosened and falls into the waste container.

If it does not, gently shake the instrument to help test strip to fall out.

Related topics

- [Reviewing QC test results \(126\)](#)

Performing an observed test sequence (OTS)

The observed test sequence (OTS) enables an observer (supervisor) to assess and record a user's performance (for certification purposes, for example).

The observer watches the user performs a glucose test, after which they assess the user in terms of the:

- Glucose test result
- Observed test sequence

Since the test involves the user and the observer, an indication of who performs each step is provided.

► [Performing a glucose test \(116\)](#)



When recertification is required

► To perform an observed test sequence

- 1 USER:**
Log onto the Glucose app, and on the **Tests** screen, tap the  button.
- 2 OBSERVER:**
In the **Observer logon** screen, log on as the observer using one of the following:
 - RFID tag
 - Barcode scan
 - Keyboard entry
- 3 USER:**
In the **Observed glucose test** screen do the following:
 - Perform a glucose test.
 - In the **Result** screen, tap the **Proceed** button.
- 4 OBSERVER:**
In the **Observer logon** screen, enter your password and tap the **Log on** button.

Assessment

Glucose test result

Observed test sequence

Add a comment (required) 

Confirm

< **Glucose test result**

Valid

Invalid

< **Observed test sequence**

Passed

Failed

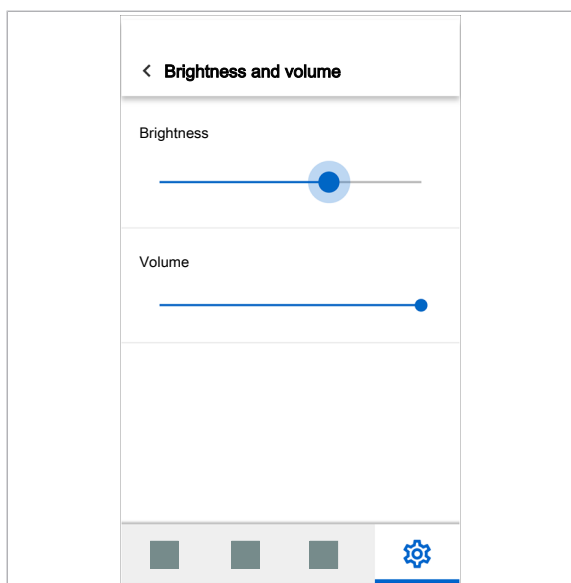
- 5 **OBSERVER:**
In the **Assessment** screen, tap the **Glucose test result** option.
- 6 **OBSERVER:**
In the **Glucose test result** screen tap the appropriate option (**Valid** or **Invalid**).
- 7 **OBSERVER:**
In the **Assessment** screen, tap the **Observed test sequence** option.
- 8 **OBSERVER:**
In the **Observed test sequence** screen tap the appropriate option (**Passed** or **Failed**).
- 9 **OBSERVER:**
In the **Assessment** screen, tap the  button.
- 10 **OBSERVER:**
In the **Comments** dialog box, enter an appropriate comment (20 characters maximum), and then tap the **Save** button.
- 11 **OBSERVER:**
In the **Assessment** screen do the following:
 - Review the assessment.
 - If necessary, amend the assessment by tapping the appropriate option and make the change.
 - Tap the **Confirm** button.

Adjusting the screen brightness and the volume level

You adjust the instrument brightness and volume to suit your working environment.

► To adjust the screen brightness and the volume level

- 1 Tap  > **Brightness and volume**.
 - 2 To adjust the screen brightness do one of the following:
 - To increase the screen brightness, move the **Brightness** slider to the right.
 - To decrease the screen brightness, move the **Brightness** slider to the left.
 - 3 To adjust the volume level do one of the following:
 - To increase the volume level, move the **Volume** slider to the right.
 - To decrease the volume level, move the **Volume** slider to the left.
-  When you stop moving the slider, the instrument emits an audible signal, indicating the volume level for that setting.



Reviewing the audit trail

You use the audit trail to review the events that have taken place on an instrument.

Each audit trail event has an entry on the **Audit trail** screen in terms of a title (for example, **Material expired**) and the date and time at which the event took place.

Behind each event is an **Audit trail details** screen which provides more information about the event (for example, 'Use material from a valid lot to continue').

The audit trail can help you troubleshoot problems that occur on the instrument and indicate any remedial action that you should take.

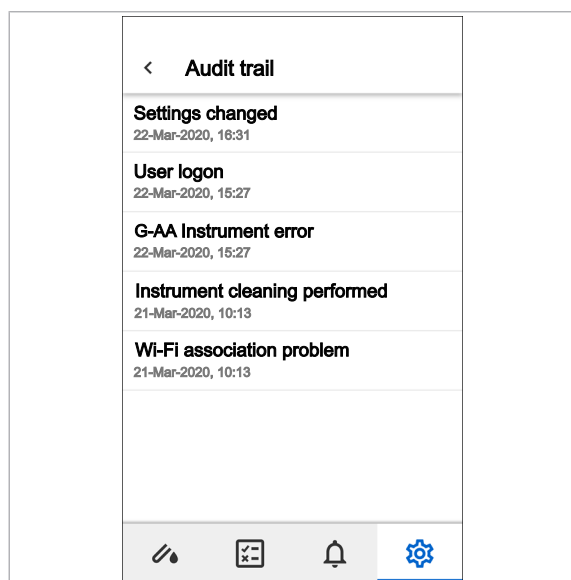
▢ [List of audit trail events \(192\)](#)

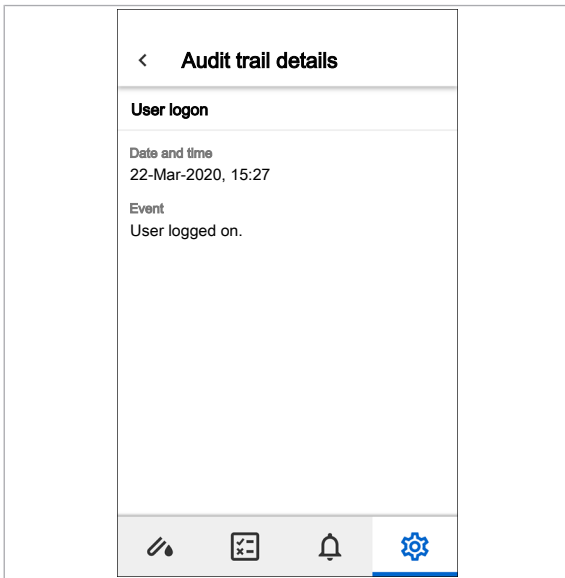


As required

► To review the audit trail

- 1 Tap  > **Audit trail**.
- 2 In the **Audit trail** screen, view the audit trail entries.
 - ① Scroll up and down the list to view more entries.
- 3 In the **Audit trail** screen, locate and tap the event that you want to view.
 - The corresponding **Audit trail details** screen is displayed.





- 4 In the **Audit trail details** screen, view the details of the event or error.
- 5 To return to the **Audit trail** screen, tap the < button,

Changing your user password

User passwords guard against unauthorized access to the Glucose app on instruments.

Periodically you may be required to change your password. When choosing a new password, follow your healthcare facility's guidelines on password management.

The new password will be required the next time you log on to the Glucose app. It might not be available on all instruments immediately after you have made the change.

If you do not have a password when logging on to the Glucose app for the first time, you are prompted to create one using the **Change password** dialog box.

▸ [Strong password management \(22\)](#)



As required.

► To change your user password

- 1 Choose  > **Change password**.
- 2 In the **Change password** dialog box do the following:
 - In the **New password** field, enter the new password.
 - In the **Confirm new password** field, enter the new password again.
 - ❗ An error message notifies you when the passwords you enter do not match.
- 3 Choose the **Save** button.
- 4 In the **Password changed** dialog box, tap the **Confirm** button.
 - Your password is changed.

Turning on the instrument

You can turn on the instrument in one of two ways:

- Using the on/off button.
- Placing the instrument in the charging station.



- Instrument battery has sufficient charge

► To turn on the instrument

- 1 Do one of the following:
 - Press and hold the on/off button for approximately 3 seconds.
 - Place the instrument in the charging station.
- ❗ In each case an audible beep is made.
- The cobas splash screen displays and then, depending on the instrument's configuration, the **Glucose** screen or the app library is displayed.

Turning off the instrument

You should only turn off the instrument when it will not be used for a considerable period of time.



An instrument will not communicate with the DMS when it is turned off.

Normally the instrument should be placed in the charging station when it is not being used.

Ensure that you store the instrument correctly until it is next used.



- ☐ The instrument will not be operated for a considerable length of time

► To turn off the instrument

- 1 Press and hold the on/off button until the **Power off / Restart** menu is displayed.
 - ❗ The instrument emits regular beeps while you do this.
- 2 Tap the **Power off** option.
 - The splash screen displays and the instrument turns off.

Restarting the instrument

You should only restart the instrument when instructed to. For example, by an error message.

► To restart the instrument

- 1 Press and hold the on/off button until the **Power off / Restart** menu is displayed.
 - ❗ The instrument emits regular beeps while you do this.
- 2 Tap the **Restart** option.
 - The splash screen displays and the instrument restarts.
 - The splash screen displays again. Depending on the instrument's configuration the **Glucose** app screen or the app library is displayed.

Setting up the charging station

The charging station must be connected to a power source.

When setting up the charging station, ensure that it is placed where it is easily accessible and within sufficient distance of a power outlet.

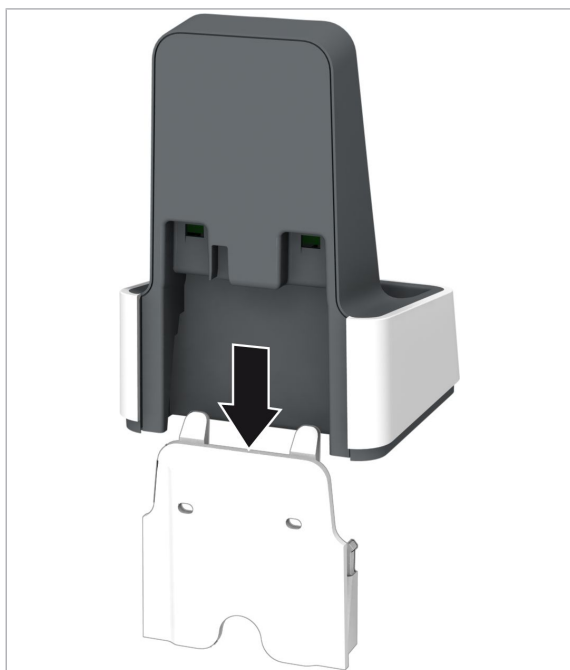


the charging station should not be located in direct sunlight, or where it might be easily knocked over, causing the instrument to fall out.

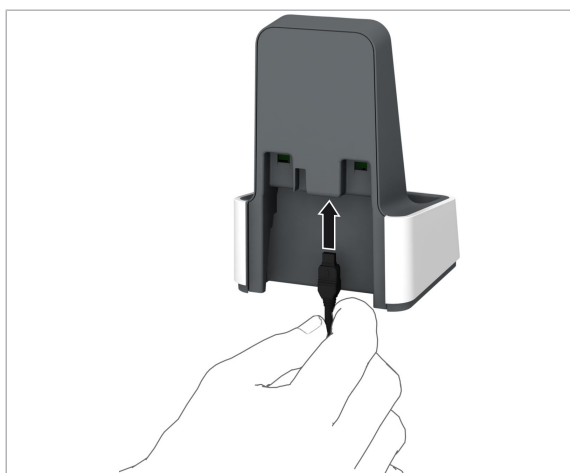
► [Overview of the charging station \(39\)](#)

► To set up the charging station

- 1 Remove the rear panel by gently pushing it downwards, and then slide it out from the charging station.



- 2 Plug the power supply into the socket in the back of the charging station.
- 3 Put the rear panel back in place.



Lot management

In this section

- About test strip lot distribution (155)
- Adding a test strip lot to the instrument (156)
- Reviewing test strip lot details on the instrument (158)
- Deleting a test strip lot from the instrument (159)
- Adding a QC or linearity lot to the instrument (160)
- Reviewing QC lots on the instrument (161)
- Deleting a QC lot from the instrument (162)

About test strip lot distribution

Test strip lot distribution enables test strips from new test strip lots to be used for performing tests.

There are 3 methods by which new test strip lots are distributed within a healthcare facility:

- Digital lot data reception with manual release
- Manual lot data retrieval with manual release
- Manual lot data retrieval with automatic release

Digital lot distribution requires a connection to **cobas® infinity** edge. Manual lot distribution does not involve **cobas® infinity** edge.

Each distribution method is outlined in the following sections.

Digital lot data reception with manual release

- | | |
|---|---|
| 1 | A new test strip lot is released and sent to the healthcare facility. |
| 2 | A corresponding lot data file is created and sent to cobas® infinity edge. |
| 3 | The Point of Care coordinator uses the instrument to scan a new test strip lot barcode on a test strip container. |
| 4 | The lot data file is downloaded from cobas® infinity edge to the Point of Care coordinator's instrument. |
| 5 | The Point of Care coordinator validates the lot. |
| 6 | The Point of Care coordinator activates the lot (in the DMS). |
| 7 | The lot data file is distributed from the DMS to the healthcare facility instruments. |
|  | Digital lot data reception with manual release workflow |

Manual lot data retrieval with manual release

8 A nurse uses a test strip from the new lot. If configured, the nurse is first prompted to perform a QC test.

9 The test strips from the new lot can be used.

 Digital lot data reception with manual release workflow

1 A new test strip lot is released and sent to the healthcare facility.

2 A corresponding lot data file is created and sent to **cobas® infinity edge**.

3 The lot data file appears as a QR code in the **cobas® infinity edge** portal. The Point of Care coordinator uses their instrument to scan the QR code.

4 The lot data file is uploaded from the Point of Care coordinator's instrument to the DMS.

5 The Point of Care coordinator validates the lot if required.

6 The Point of Care coordinator activates the lot (in the DMS).

7 A nurse uses a test strip from the new lot. If configured, the nurse is first prompted to perform a QC test.

8 The test strips from the new lot can be used.

 Manual lot data retrieval with manual release workflow

Manual lot data retrieval with automatic release

1 A new test strip lot is released and sent to the healthcare facility.

2 A corresponding lot data file is created and sent to **cobas® infinity edge**.

3 The lot data file appears as a QR code in the **cobas® infinity edge** portal. The Point of Care coordinator uses their instrument to scan the QR code.

4 The lot data file is uploaded from the Point of Care coordinator's instrument to the DMS.

5 A nurse uses a test strip from the new lot. If configured, the nurse is first prompted to perform a QC test.

6 The test strips from the new lot can be used.

 Manual lot data retrieval with automatic release workflow

Adding a test strip lot to the instrument

You must add a new test strip lot to your instrument in order to be able to use the test strips from that lot.

The distribution of test strips from a new lot will depend on the best practice of your healthcare facility.

The instrument can be configured to perform a QC test the first time a test strip from a new lot is inserted into the instrument.

CAUTION!

Instrument is not connected to cobas® infinity edge

If the instrument is not connected to **cobas® infinity** edge you cannot add a test strip lot as described in this task.

- ▶ You must scan the QR code generated in the **cobas® infinity** edge portal using the  **> Configuration by barcode** option. The new strip lot is then added to the **Lot management** screen.



As required



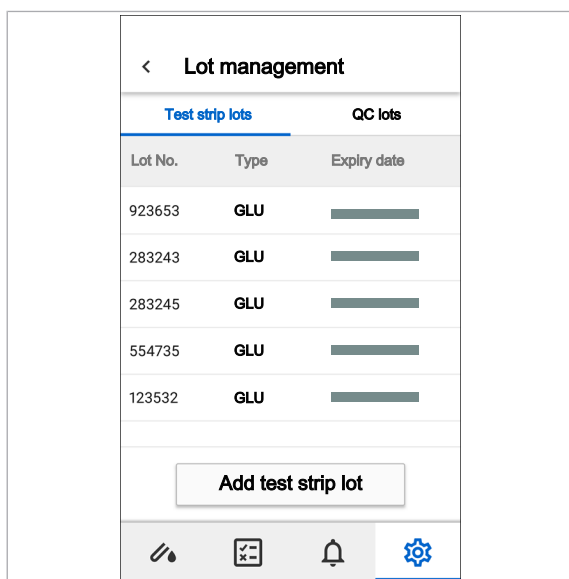
☐ Test strip container and test strips from the new lot



- ☐ The new lot has been uploaded to the DMS
- ☐ Connection to **cobas® infinity** edge

▶ **To add a test strip lot to the instrument**

- 1 In the Glucose app, tap  **> Lot management**.
- 2 In the **Lot management** screen on the **Test strip lots** tab, tap the **Add test strip lot** button.
- 3 Using the **Scan bottle barcode** screen, scan the barcode of the new test strip lot container.
 - A message confirms that the new lot has been added. The new lot is added to the **Test strip lots** tab.
- 4 Do one of the following:
 - If you are not prompted to perform a QC test, you can start using the test strips from the new lot.
 - If prompted, perform a QC test using the new test strip lot. After performing the QC test successfully you can start using the test strips from the new lot.



Reviewing test strip lot details on the instrument

You can review the test strip lots on the instrument, as well as the details of an individual lot.

The following information is available when reviewing an individual test strip lot:

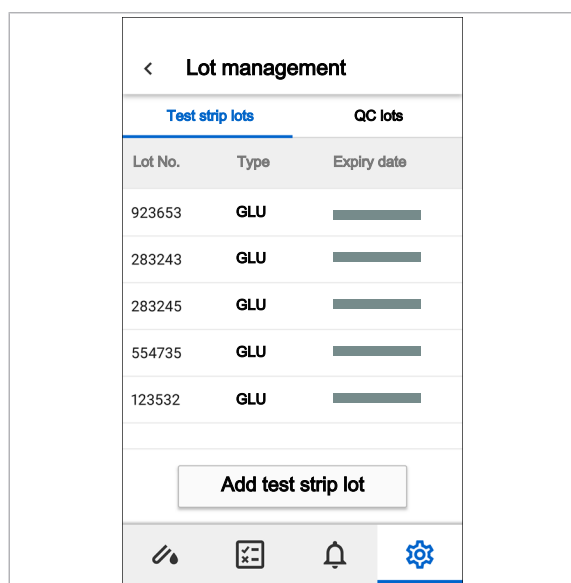
- **Lot No.**
- **Expiry date**
- **Content version**
- **Type**

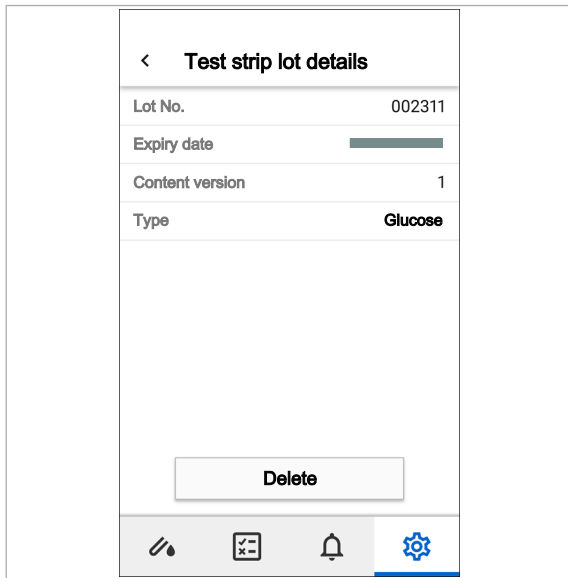


As required

► To review test strip lot details on the instrument

- 1 In the Glucose app, tap  > **Lot management**.
- 2 In the **Lot management** screen on the **Test strip lots** tab, you can do the following:
 - Review the test strip lots on the instrument.
 - Tap a lot to view its details.





- 3 In the **Test strip lot details** screen view the information about the lot.

Deleting a test strip lot from the instrument

You can delete a test strip lot from the instrument when it is no longer needed.

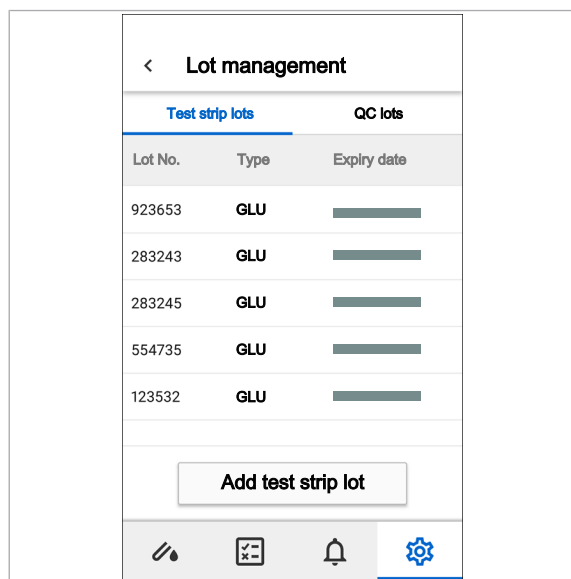
Test strip lots are normally deleted from the instruments using the DMS. However, if this is not possible (for example, there is no DMS), test strip lots can be deleted using the instrument



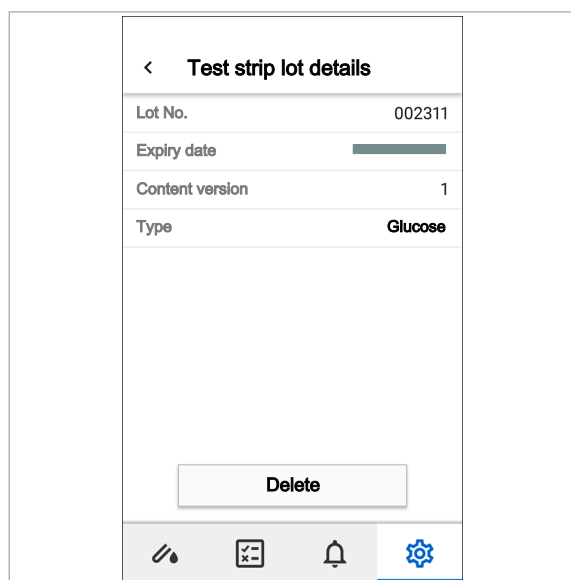
As required

► To delete a test strip lot from the instrument

- 1 In the Glucose app, tap > **Lot management**.



- 2 In the **Lot management** screen in the **Test strip lots** tab, tap the lot you want to delete.



- 3 In the **Test strip lot details** screen, tap the **Delete** button.
- 4 In the **Lot deletion** dialog box, tap the **Confirm** button.
- The lot is deleted from the instrument.

Adding a QC or linearity lot to the instrument

You must add a QC or linearity lot to your instrument in order to be able to use a QC or linearity kit from the lot.

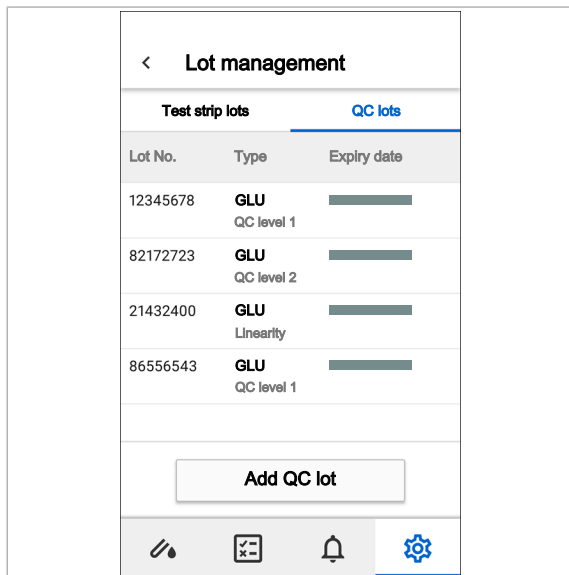
The distribution of a new QC or linearity kit will depend on the best practice of your healthcare facility.



As required



☐ New QC or linearity lot bottle



► To add a QC lot to the instrument

- 1 In the Glucose app, tap > **Lot management**.
 - 2 In the **Lot management** screen, tap the **QC lots** tab.
 - 3 On the **QC lots** tab, tap the **Add QC lot** button.
 - 4 Using the **Scan bottle barcode** screen, scan the barcode on a bottle from the new lot.
 - If you are adding a new linearity lot, the new lot is added to the **QC lots** tab and a confirmation message is displayed.
 - If you are adding a new QC lot, the **Set lot as 'current'** dialog box is displayed.
 - 5 To add the new QC lot, do one of the following:
 - To add the new QC lot and set it as the current lot, tap the **Confirm** button.
 - To add the new QC lot but not set it as the current lot, tap the **Cancel** button.
- The new QC lot is added to the **QC lots** tab.

Reviewing QC lots on the instrument

You can review the QC and linearity lots on the instrument, as well as the details of an individual lot.

The following information is available when reviewing an individual QC lot:

- **Lot No.**
- **Expiry date**
- **QC version**
- **Type**
- **Default target range**
- **Hospital-defined target range**
- **Current lot**

The following information is available when reviewing an individual linearity lot:

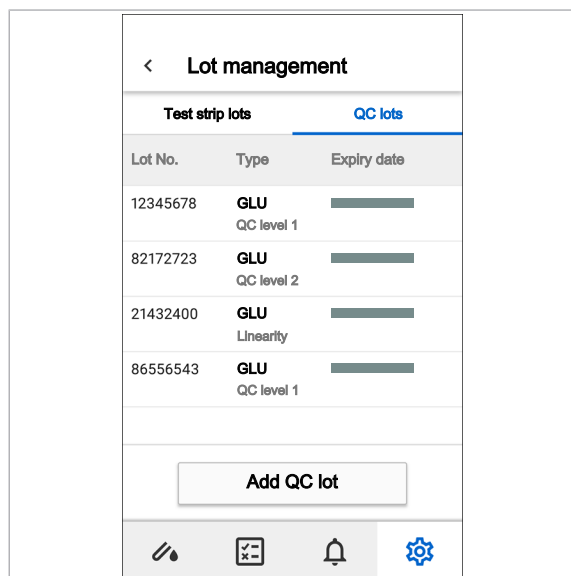
- **Lot No.**
- **Expiry date**
- **Linearity version**
- **Type**



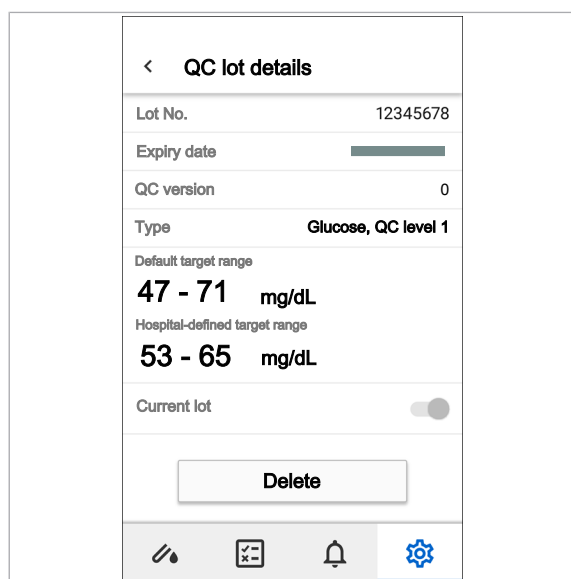
As required

► To review QC lots on the instrument

- 1 In the Glucose app, tap  > **Lot management**.
- 2 In the **Lot management** screen, tap the **QC lots** tab.
- 3 In the **QC lots** tab you can do the following;
 - Review the QC and linearity lots on the instrument.
 - Tap a lot to view its details.



- 4 In the **QC lot details** screen view the information about the lot.



Deleting a QC lot from the instrument

You can delete a QC or linearity lot from the instrument when it is no longer needed.

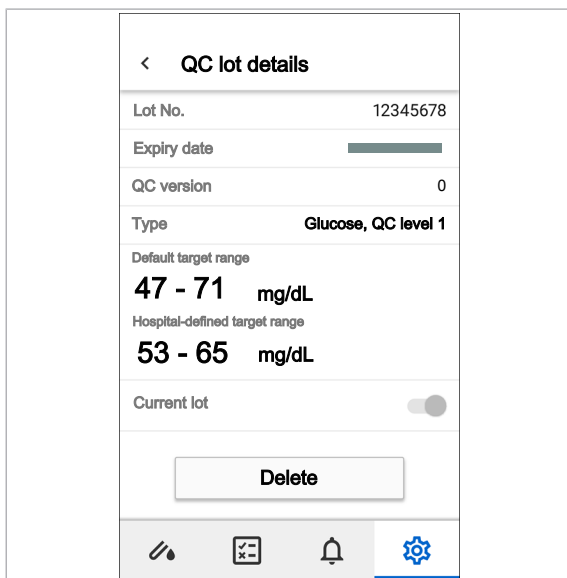
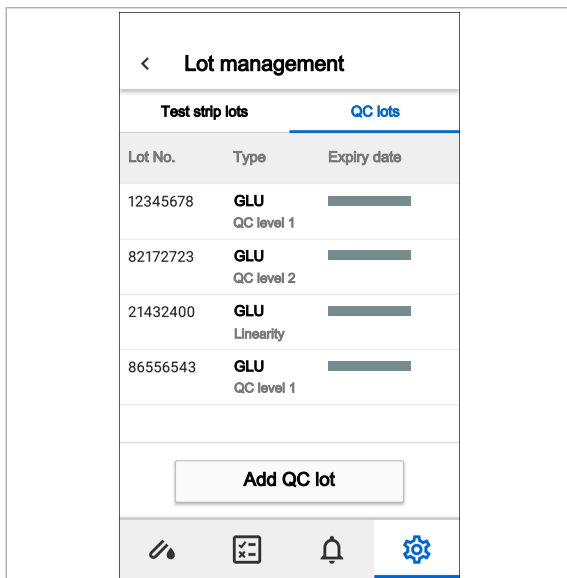
QC or linearity lots are normally deleted from instruments using the DMS. However, if this is not possible (for example, there is no DMS), they can be deleted using the instrument.



As required

► To delete a QC lot from the instrument

- 1 In the Glucose app, tap  > **Lot management**.
- 2 In the **Lot management** screen, tap the **QC lots** tab.
- 3 In the **QC lots** tab, tap the lot that you want to delete.



- 4 In the **QC lot details** screen, tap the **Delete** button.
- 5 In the **Lot deletion** dialog box, tap the **Confirm** button.
→ The lot is deleted from the instrument.

Page intentionally left blank.

Maintenance

7	Maintenance	167
---	-------------------	-----

Page intentionally left blank.

Maintenance

In this chapter

7

About cleaning and disinfecting the instrument	169
Acceptable cleaning solutions and disinfectants	171
Cleaning and disinfecting the instrument	172
Cleaning and disinfecting the charging station	175
Cleaning and disinfecting the carry case	176
Replacing the battery	177

Page intentionally left blank.

About cleaning and disinfecting the instrument

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

Healthcare professionals should wear gloves and follow their facility's infection control procedures when handling blood glucose testing equipment.

The gloves worn during cleaning and disinfecting should be removed and hands washed thoroughly with soap and water before performing the next test.

Dispose of acceptable cleaning solutions and disinfectants per facility guidelines.

NOTICE!

Solutions used to clean and disinfect the instrument

Using cleaning solutions and disinfectants containing ether, polyhexanide, or prepared solutions or using wipes containing a mixture of bleach and detergent can damage system components.

- ▶ Only use cleaning solutions and disinfectants recommended by Roche.

Instrument cleaning status

This notification indicates that either:

- Instrument cleaning is due (date/event).
- Cleaning can be logged.

If a cleaning interval is configured, an icon and an indication of when the next cleaning is due are displayed. If only cleaning after a measurement is required, an instruction is displayed.

When instrument cleaning is overdue, a red warning icon and the date and time of the instrument cleaning is displayed.

The instrument cleaning notification is determined by the following configuration items:

- **Cleaning notification after each patient test**
- **Time interval for cleaning notification (in hours)**

- ▶  **Cleaning notification after each patient test (480)**
- ▶  **Time interval for cleaning notification (in hours) (480)**

 Related topics

- [Cleaning and disinfecting the instrument \(172\)](#)
- [Acceptable cleaning solutions and disinfectants \(171\)](#)

Acceptable cleaning solutions and disinfectants

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

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

Prepare all solutions per the manufacturer's product labelling.

Cleaning solutions

- 0.5% liquid soap diluted in water
- Alcohol (70% ethanol or isopropyl alcohol)

Disinfectants

- Having up to 70% alcohol (e.g., Bacillol AF)
- Sodium hypochlorite up to 0.55% (e.g., CLOROX germicidal wipes)
- Quaternary ammonium compounds up to 0.5% (single compound or mixture) in isopropyl alcohol up to 55% (e.g., Super-Sani-Cloth)

CAUTION!

Disinfecting the instrument with Clorox

Damage to internal electronic components

- ▶ When disinfecting the instrument using Clorox, do not allow any disinfectant to enter the instrument through the test strip port.

Related topics

- [About cleaning and disinfecting the instrument \(169\)](#)
- [Cleaning and disinfecting the instrument \(172\)](#)

Cleaning and disinfecting the instrument

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

Your instrument can be configured to notify you to clean it as follows:

- After each test.
- After a specified number of hours since the last time the instrument was cleaned.

Clean the instrument to remove visible soil and organic material for safe handling and/or prior to disinfection.

Disinfect the instrument when it is soiled as per your healthcare facility's guidelines.

Always ensure that the instrument is thoroughly dried after cleaning or disinfection.

WARNING!

Incorrect test results

Moisture in the test strip port may lead to incorrect test results.

- ▶ Do not clean or disinfect the instrument while performing a test.
- ▶ Do not get any moisture in the test strip port.
- ▶ Do not spray into the test strip port.
- ▶ Do not immerse the instrument in liquid.

If liquid gets into the test strip port, immediately dry the components with a dry lint-free cloth or gauze. If solution is allowed to collect in any instrument opening, severe damage to the instrument can occur.

Always ensure that the instrument is thoroughly dried after cleaning and disinfecting.



As specified by your healthcare facility.
As configured on your instrument.



- ☐ Disposable gloves
- ☐ Soft, lint-free cloth or gauze
- ☐ Premoistened wipes for cleaning and disinfection
- ☐ Cleaning solutions as per the manufacturer's product labelling.

- ▢ Acceptable cleaning solutions and disinfectants (171)

► To clean and disinfect the instrument

- 1 Remove the instrument from the charging station.
- 2 Turn off the instrument and then place it on a level surface.



- 3 Gently wipe the surfaces (touch screen, instrument housing) with the cloth slightly dampened (not wet). For each surface, apply 3 horizontal and 3 vertical passes. Use an unused part of the towelette for each pass.
 - ❗ If using commercially available premoistened wipes for cleaning and disinfection, before wiping the surface of the instrument, squeeze off excess solution or blot on a dry paper towel to remove any excess solution.



- 4 CAUTION!** Wear gloves if spraying the instrument. It may get slippery when wet so take care not to drop it. Do not spray the instrument if it is docked in the charging station!

Carefully wipe over the test strip port area, making sure that no liquid enters the test strip port.

- 5** Dry the instrument thoroughly with a the lint free cloth or gauze after cleaning. Visually verify that no solution is seen anywhere on the instrument after cleaning.
- 6** If you notice streaks on the instrument housing or touch screen, or the touch screen surface becomes slightly cloudy, wipe clean immediately with a soft, lint-free cloth slightly dampened with water.
- 7** After cleaning and disinfecting, if required, tap the  button and in the **Notifications** screen, tap the  button.
- 8** In the **Instrument cleaning** dialog box, tap the **Confirm** button confirming that the device has been cleaned and disinfected as per defined procedure.

» **Related topics**

- [About cleaning and disinfecting the instrument \(169\)](#)

Cleaning and disinfecting the charging station

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

Clean the charging station to remove visible soil, and disinfect it as per your healthcare facility's guidelines.



As specified by your healthcare facility.



- ☐ Disposable gloves
- ☐ Soft, lint-free cloth or gauze
- ☐ Pre-moistened wipes for cleaning and disinfection
- ☐ Cleaning solutions as per the manufacturer's product labelling

▶ [Acceptable cleaning solutions and disinfectants \(171\)](#)

▶ To clean and disinfect the charging station

- 1** Unplug the charging station.
- 2** CAUTION! Do not allow any solution to enter the underside of the charging station.

Wipe over the surfaces with a soft lint-free cloth slightly dampened.
- 3** CAUTION! Ensure that no solution is visible on or in the charging station after disinfecting.

Dry the charging station thoroughly after cleaning/ disinfection.
- 4** Plug in the charging station.

Cleaning and disinfecting the carry case

Cleaning and disinfecting the carry case thoroughly ensures that nothing can be transmitted to its contents.

After cleaning and disinfecting the carry case, ensure that it has dried thoroughly before using it again.



As specified by your healthcare facility.



- ☐ Disposable gloves
- ☐ Soft, lint-free cloth or gauze
- ☐ Pre-moistened wipes for cleaning and disinfection
- ☐ Cleaning solutions as per the manufacturer's product labelling



- ☐ The carry case is completely empty

► [Acceptable cleaning solutions and disinfectants \(171\)](#)

► To clean and disinfect the carry case

- 1** Wipe the carry case surface with a soft cloth slightly dampened (not wet).
 - ❗ If spraying the carry case, place it on a flat surface or table.
- 2** CAUTION! Do not place the instrument in the carry case until all cleaning/disinfecting steps are completed.

Allow the carry case to air dry for the recommended contact time according to the cleaning/disinfecting solution product labeling.
- 3** Dry the carry case thoroughly with a dry cloth or gauze. Visually verify that no solution is in the carry case after cleaning/disinfecting.

Replacing the battery

When the battery no longer functions correctly it should be replaced.

When shipped, the battery is installed in the instrument.

Unused batteries lose their charge over time and must be recharged before they can be used. After installing a new battery, the instrument should be charged for at least 8 hours (e.g., overnight) in the charging station before testing.

Replace the battery within approximately 10 minutes to retain the date and time settings. Beyond this period of time, and depending on the instrument's configuration:

- You must re-enter date and time.
- The date and time is set automatically by the DMS.

NOTICE!

Disposal of used batteries

- ▶ Do not dispose of the batteries with normal domestic waste.
- ▶ Dispose of used batteries in accordance with applicable local regulations and directives and your healthcare facility's guidelines on the disposal of electronic waste equipment.
- ▶ As a component of the **cobas® pulse** system, the battery must be deemed as potentially biohazardous. Treat it accordingly.



As necessary



< 10 minutes



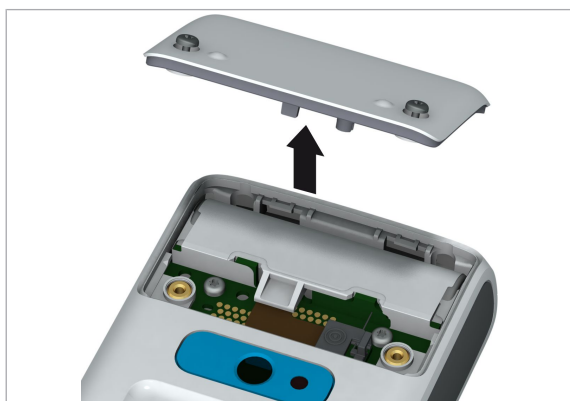
☐ New battery (only official replacement battery supplied Roche)



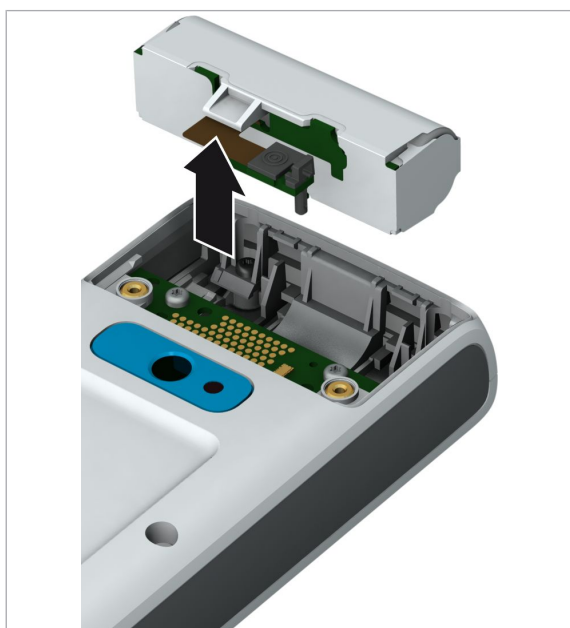
☐ Temperature range of 3-42 °C or 37-108 °F
☐ Instrument is turned off.

► To replace the battery

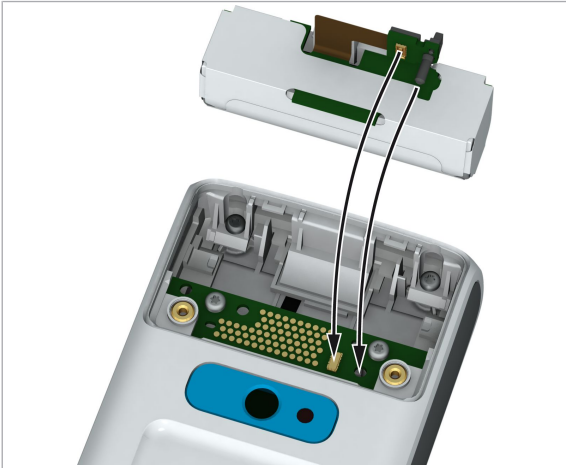
- 1 Place the instrument face down on a level surface, and using a Torx screwdriver (T5), remove the two screws holding the battery compartment cover in place.



- 2 Remove the battery compartment cover from the instrument. The battery is now visible and connected to the instrument by a plug.



- 3 Using the plastic handle on the battery, carefully lift the battery out of the compartment.



- 4** Take the new battery and place it in the compartment. Ensure that the battery connector plug sits securely in its socket. Using a thumb or forefinger, gently apply downward pressure on the connector plug to ensure it is completely in the socket.
- 5** Close the battery compartment with the cover and tighten the 2 screws.
- 6** Place the instrument in the charging station to ensure that the battery is charging.

Page intentionally left blank.

Troubleshooting

8	Troubleshooting.....	183
9	Error messages.....	195

Page intentionally left blank.

Troubleshooting

In this chapter

8

Resetting the instrument.....	185
Running a network status test.....	186
Network status test steps	188
Resetting a synchronization lockout.....	190
Deleting instrument data	191
List of audit trail events	192
Starting up an instrument with low battery level	193

Page intentionally left blank.

Resetting the instrument

An instrument reset should only be performed when all other remedial actions have failed.

For example, you might reset an instrument if it 'hangs'.

► To reset the instrument

- 1 Place the instrument on a level surface.
- 2 Press the on/off button for at least 10 seconds and then release the button.
 - The instrument turns off and on again.
 - The splash screen is displayed.
 - Depending on the instrument's configuration, the **Glucose** app screen or the app library is displayed.



Running a network status test

You can use the **Network status test** option to help diagnose connectivity issues.

The network status is given in terms of the following information:

- **Wi-Fi activated**
- **Associated**
- **Authenticated**
- **Received IP:**
- **Gateway:**
- **DNS:**
- **Contacted DMS**
- **Connected to DMS**
- **Contacted cobas infinity edge**
- **Connected to cobas infinity edge**

Each network status item is tested.

The status of each item in the network status check is indicated either of the following symbols:



Passed



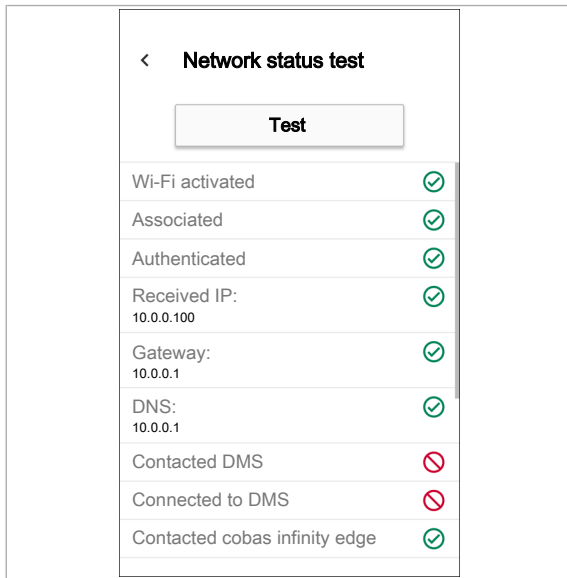
Failed

When any of the **Received IP:**, **Gateway:**, and **DNS:** items pass, the corresponding connection values are also displayed.

▶ [Network status test steps \(188\)](#)

▶ To run a network status test

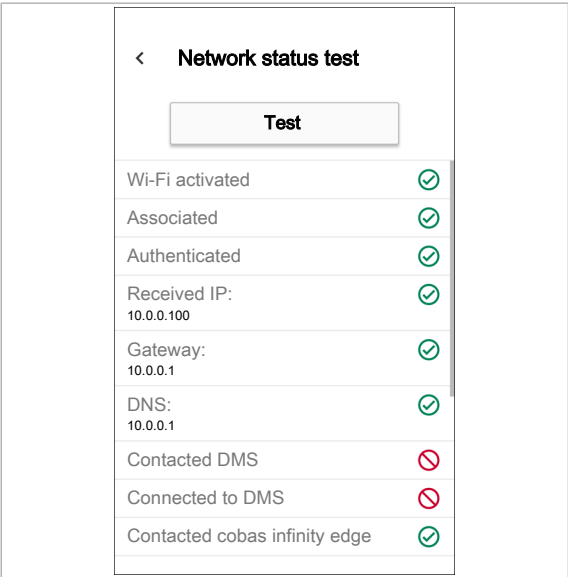
- 1 Tap  > **Instrument information** > **Network status test**.



- 2 In the **Network status test** screen, tap the **Test** button.
→ The test result is displayed.

Network status test steps

You use the **Network status test** option to help diagnose connectivity issues.



You run the test by tapping > **Instrument information** > **Network status test**.

The test result screen contains each of the test steps and indicates if the step passes or fails.

The table contains each of the test steps, and indicates the following:

- Expected outcome (pass)
- The potential cause of a test step failing
- How to resolve a test step failure.

Test step	Expected outcome	Potential cause of failure	Solution
Wi-Fi activated	Instrument SW attempts to activate the Wi-Fi hardware	Wi-Fi hardware defective	Restart the instrument and try again. If the problem persists, contact your Roche representative.
Associated	WLAN hardware initiates connection to wireless access point	Wireless network out of reach	Move the instrument to a location where the wireless network has sufficient signal strength.
		Wireless access point/network applies the MAC address filtering	Add the MAC address (given on the instrument package) to the "white list" of permitted wireless clients within the network.
Authenticated	Instrument authenticates itself to the network	Wrong credentials	Check if the assigned authentication/encryption type and/or the respective password/ pass phrase match the network settings.
Received IP:	Dynamic IP address assigned to the instrument by a DHCP server, or static IP address assigned by the DMS or cobas® infinity edge (QR code)	DHCP server down/not available	Check that DHCP server is correctly set up and running
		Typographic error (in case of static IP address)	Double-check entered IP address in DMS / cobas® infinity edge
		Wrong subnet mask configured (in case of static IP address)	Enter correct subnet mask

Network status test steps

Test step	Expected outcome	Potential cause of failure	Solution
		Wrong Gateway configured (in case of static IP address)	Enter correct gateway address
		Wrong DNS server configured (in case of static IP address)	Enter correct DNS server address
Gateway:	IP address of a gateway	Wrong gateway IP address (in case of static IP address)	Enter correct gateway address
DNS:	IP address of a Domain Name Service for IP/ host name resolution	Wrong DNS server IP address (in case of static IP address)	Enter correct DNS server address
Contacted DMS	Instrument tries to establish communication with DMS	DMS server has more than one network card	Enter correct DMS IP address / host name
		DMS is disconnected, busy, or down	Check that the DMS is correctly set up and running
		Any type of network (performance) issues	Check all network components between the instrument and the DMS (cables, gateway, hub/ switch/router, firewall, proxy server etc.)
Connected to DMS	Instrument has successfully initiated a connection to the DMS application	Connection has been disturbed in an early phase	Verify that the DMS supports the type and version of the instrument used
Contacted cobas® infinity edge	Instrument tries to establish communication with cobas® infinity edge	cobas® infinity edge gateway server has more than one network card	Enter correct cobas® infinity edge gateway IP address / host name
		cobas® infinity edge gateway is disconnected, busy, or down	Check that the cobas® infinity edge gateway is correctly set up and running
		Any type of network (performance) issues	Check all network components between the instrument and the cobas® infinity edge gateway (cables, gateway, hub/ switch/router, firewall, proxy server etc.)
Connected to cobas® infinity edge	Instrument has successfully initiated connection to cobas® infinity edge gateway	Connection has been disturbed in an early phase	Verify that the cobas® infinity edge gateway supports the software version of the instrument

☰ Network status test steps

➤ [Running a network status test \(186\)](#)

Resetting a synchronization lockout

You can use the reset synchronization lockout when a synchronization lockout has occurred on the instrument, and a synchronization lockout override is unavailable.

This situation might occur due to a network failure, or other situations.

The reset lasts for the period of time defined by the **Synchronization lockout (in hours)** configuration item, after which the synchronization lockout applies again.



☐ Administrator rights, if configured

► To reset a synchronization lockout

1 Tap  > **Administrator** > **Reset synchronization lockout**.

❗ If configured, enter the setup password to access the Administrator submenu.

→ A message is displayed saying **Synchronization lockout was reset**.

Deleting instrument data

This option deletes all data on the instrument, and effectively returns it to a default configuration status. This includes uninstalling all third party apps.

This might be necessary when there was a problem with the instrument configuration.

It may be necessary to remove the instrument data to comply with data protection and privacy policies when returning the instrument to the manufacturer, or passing it on to another healthcare facility.

This process is irreversible, so caution should be taken when using it. For example, if applicable, ensure that all data has been synchronized before deleting the instrument data.



☐ Administrator rights, if configured

► To delete instrument data

- 1 Tap  > **Administrator** > **Delete instrument data**.
 - The **Delete instrument data** dialog box is displayed, explaining the implications of confirming.
- 2 In the **Delete instrument data** dialog box, tap the **Confirm** button.

List of audit trail events

Audit trail events enables you to view the activity that has taken place on the instrument.

The table contains all of the events that can be recorded in the audit trail.

ID	Severity	Audit trail details (GUI)
UPM	W	User password was changed.
SEP	N	Item name: <item name>, previous value: <previous value>, new value: <new value>.
ERR	Depends on individual level 1 message (C, W, N)	<level 1 message information> e.g., U-AB: Invalid Password <level 2 error code> e.g., CA-0022 ▶ Level 1 messages (213) ▶ Level 2 errors (229)
CBS	N	Start up performed.
RFA	N	Wi-Fi association or authentication failed.
RFD	N	Wi-Fi connection failed.
MTN	W	Instrument cleaning was performed.
SLU	N	Synchronization lockout was manually unlocked.
DMA	N	DMS synchronization was completed.
DMB	N	DMS synchronization was aborted by the instrument.
DMC	N	DMS synchronization has failed.
PAT	N	Patient test performed: Analyte: <analyte>, test strip lot: <strip lot number>.
QCT	N	QC test performed: Analyte: <analyte>, test strip lot: <strip lot number>, kit: <kit>, level: <level>.
USA	N	User logged on.
USB	N	User logged off.
RSA	N	cobas infinity edge synchronization completed.
RSB	N	cobas infinity edge synchronization aborted by instrument.
RSC	N	cobas infinity edge synchronization failed.
QCL	N	QC lot was added. Analyte: <analyte>, lot no.: <lot number>.
LIN	N	Linearity lot was added. Analyte: <analyte>, lot no.: <lot number>.
QCC	N	QC or linearity version was added: <kit_type>, <version>.
STP	N	Test strip lot was added. Analyte: <analyte>, lot no.: <lot number>.
SHA	N	Instrument turned off.
SWU	N	Software update was performed. Software configuration: <SW_configuration>.
STS	N	Self-check was passed.
LOQ	W	QC lockout occurred.
LOS	C	Synchronization lockout occurred.

 Audit trail events

▶ [Reviewing the audit trail \(148\)](#)