



CoaguChek[®] XS Plus *Operator's Manual*

This is a CLIA-waived system.

CoaguChek® XS Plus

Operator's Manual

Publication version 10.0

Software version 04.09

Publication information

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

This manual was created by Roche Diagnostics. Direct questions or concerns regarding the contents of this document to:

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46256
USA

User documentation

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

navifyportal.roche.com

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

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Symbols and abbreviations

Symbols

On the packaging and on the identification plate of the instrument you may encounter the following symbols, shown here with their meaning:



Caution, consult accompanying documents. Refer to safety-related notes in the instructions for use accompanying this product.



CoaguChek XS Plus meter



Operator's Manual



Power supply



Temperature limitation (Store at)



Admissible humidity (Store at)



Use by



Manufacturer



Date of manufacture



Batch code/ Lot number



Catalog number



Global Trade Item Number



Unique device identifier



Serial Number



Device for near-patient testing



Device not for self-testing



In vitro diagnostic medical device



Consult instructions for use



The system fulfils the Canadian and U.S. safety requirements (UL LISTED, in accordance with UL 61010A-1:02 and CAN/CSA-C22.2 No. 61010-1-04).



Contents of the pack

Rx Only

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

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1 Introduction

1.1 Before you start

Intended use

The CoaguChek® XS Plus is intended for use by professional healthcare providers for quantitative prothrombin time testing for the monitoring of warfarin therapy. The system uses fresh capillary or non-anticoagulated venous whole blood.

CLIA Waived

This is a CLIA Waived test system. A Certificate of CLIA Waiver (or higher) is required to perform the test. Information on obtaining CLIA certificates can be found at www.cms.hhs.gov/clia.

Before testing, refer to the appropriate package insert for more complete information. Laboratories with a certificate of waiver must follow the manufacturer's instructions for performing the test. 42 CFR 493.15(e) (1).

Any modifications and/or failure to follow test system instructions, including those for limitations/intended use and performance of QC testing as a failure alert mechanism, results in use that is considered high complexity and subject to all applicable CLIA requirements.

All applicable state and local laws must be met.

Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Adverse Event Reporting program online (at <https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>), by phone (1-800-FDA-1088), or by returning the postage-paid FDA form 3500 (which may be downloaded from <https://www.fda.gov/safety/>

medical-product-safety-information/medwatch-forms-fda-safety-reporting) by mail to (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787) or fax (1-800-FDA-1078).

If there are any problems with the CoaguChek XS Plus meter, notify CMS at <http://www.cms.hhs.gov/clia/ro-map.asp>

Important information regarding use

Read this operator's manual, as well as the package inserts for all relevant consumables, before using the system for the first time.

You must configure the CoaguChek XS Plus meter according to your needs before initial use. Refer to Chapter 3, *Meter Setup*. Be sure to read the "Important safety instructions and additional information" section in this chapter before operating the system.

Before you use the meter for the first time (after you have first inserted the battery pack), you must set the date and time correctly to allow you to perform measurements properly. Each time you replace the battery pack you need to check (and, if necessary adjust) the date and time.

QC Lockout is disabled by default. For routine confirmation of system reliability it is recommended to enable this feature.

- [To set the time \(66\)](#)
- [To set the date \(65\)](#)
- [To set the date and time format \(67\)](#)
- [QC \(quality control\) Lockout \(93\)](#)

If you need help

Information about using the system, the screen menus, and performing a test can be found in this manual. When error messages appear on the screen, refer to Chapter 9, *Troubleshooting* starting with [9.1 Status / Error messages \(169\)](#).

For all questions about the CoaguChek XS Plus system that are not answered in this manual, contact your Roche Diagnostics representative. In order to expedite troubleshooting, please have ready your CoaguChek XS Plus meter, its serial number, this manual, and all related consumables when you call.

General note

The data and information provided in this manual are current as of issue. Any substantial changes will be incorporated in the next edition. If there is any conflict of information, the package insert included with the CoaguChek® XS PT Test strips shall prevail.

What can the system do for you?

The CoaguChek XS Plus system makes coagulation testing easy. You only need to insert the code chip, power the meter on, insert the test strip for the CoaguChek® XS PT Test, and apply a small blood sample. The blood mixes with the reagents on the test strip, and the meter determines when the blood clots. The meter displays the results after approximately one minute. After the measurement, the meter automatically stores the test result, together with date/time and patient ID (and operator ID, if that option is enabled) to memory.

The CoaguChek XS Plus meter displays test results in units equivalent to laboratory plasma measurements. Results may be displayed in the following ways:

- Parameter: PT
 - International Normalized Ratio (INR)

- combination of INR/seconds, or
- combination of INR/%Quick

INR is a standardized measurement of the rate at which blood clots. A low INR can indicate an increased risk of blood clots, while an elevated INR can indicate increased risk of bleeding.

The unit %Quick is for information purposes only and must not be used as a basis for any therapeutic measures.

The meter guides you through the test, step by step, using icons and instructions on the display. Each box of test strips has its own code chip that you insert into the meter. This code chip contains lot-specific information about its test strips, such as the expiration date and calibration data. Optional liquid controls for the system are also available.

The CoaguChek XS Plus meter has the ability to connect to a data management system (DMS) through the Handheld Base Unit from Roche Diagnostics (available separately). The CoaguChek XS Plus meter supports data exchange via the POCT1-A standard. Data management systems may have the ability to expand the security features of the meter, such as enabling operator lockouts. Data management systems may also enable data transfer to a hospital information system (HIS) or to a laboratory information system (LIS). Refer to the manuals of the Handheld Base Unit and of your DMS for technical details.

Test principle

The CoaguChek® XS PT Test, used as directed with the CoaguChek XS Plus meter, will provide an electrochemical measurement of prothrombin time following activation of blood coagulation with human recombinant thromboplastin. In simple terms, blood

works with the chemicals in the test strip to make a small electric current in the test strip that measures blood-clotting time.

Contents of the pack

The CoaguChek XS Plus pack contains the following items:

- CoaguChek XS Plus meter
- Additional test strip guide cover (spare part)
- Battery compartment cover
- Universal Battery Pack
- Power supply
- Starshaped screwdriver
- Operator's Manual (printed version, not shown here)
- Getting Started Guide (printed version, not shown here)

Check for completeness and transport damage immediately after unpacking.



1.2 Important safety instructions and additional information

This section explains how safety-related messages and information related to the proper handling of the system are presented in the CoaguChek XS Plus Operator's Manual. Read these passages carefully.

Safety alert

- ▶ The safety alert symbol alone (without a signal word) promotes awareness to hazards which are generic or directs the reader to related safety information.
-

These symbols and signal words are used for specific hazards:

WARNING!

Warning...

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

CAUTION!

Caution...

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

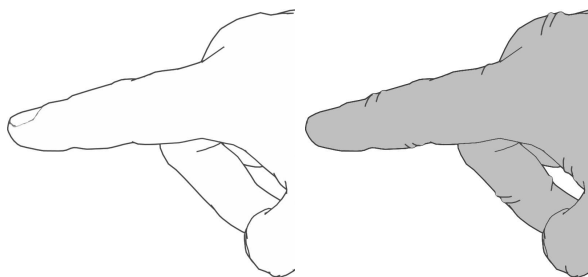
NOTICE!

Notice...

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

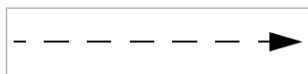
Important information that is not safety relevant is presented against a colored background (without a symbol). Here you will find additional information on correct use of the meter or useful tips.

Illustrations in this manual show two different kinds of hands:



Hand without glove

Hand with glove



A dashed arrow between screen illustrations indicates that some screens have been skipped in these illustrations.

Safety information

Operator qualification

- ▶ Only trained healthcare professionals may operate the CoaguChek XS Plus system. Operators must have received comprehensive instruction in the operation, quality control, and care of the CoaguChek XS Plus system.

Incident reporting

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

 **WARNING!****Protection against infection and blood-borne pathogens**

Healthcare professionals using the CoaguChek XS Plus system to perform tests must be aware that any object coming into contact with human blood is a potential source of infection. Operators need to adhere to Standard Precautions when handling or using the CoaguChek XS Plus system. 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 gloves. Wear a new pair of clean gloves for testing each patient and control test.
 - ▶ Wash hands thoroughly with soap and water before putting on a new pair of gloves and performing the next patient test.
 - ▶ Use an auto-disabling single-use lancing device for each patient.
 - ▶ Dispose of used lancets in a sturdy sharps container with lid.
 - ▶ Dispose of used test strips from patient and proficiency tests according to your institution's infection control policy.
 - ▶ Follow all health and safety regulations in force locally.
-

⚠ CAUTION!**Allergy or injury caused by reagents and other working solutions**

Direct contact with reagents, detergents, cleaning/disinfection solutions, or other working solutions may cause skin irritation or inflammation.

- ▶ Always use protective gloves.
 - ▶ Observe the cautions given in the package inserts of the reagents and cleaning/disinfection solutions.
 - ▶ If a reagent, control, linearity, or cleaning/disinfection solution comes into contact with your skin, wash it off immediately with water.
 - ▶ Follow all health and safety regulations in force locally.
-

⚠ CAUTION!**Possible contact with leakage current**

In rare cases leakage currents could be passed from a power supply to patients when an inserted test strip is touched. To avoid potential contact with leaking currents, we recommend the following:

- ▶ Always remove the meter from the Handheld Base Unit before inserting a test strip.
 - ▶ Always disconnect the meter from the power supply before inserting a test strip.
-

 **WARNING!****Avoidance of electrical shock, fire, and explosions**

- ▶ Only use Roche Diagnostics original accessories (cables, power supply units, battery packs, and spare parts). Third-party cables, power supply units, and battery packs can cause the battery pack to explode or the meter to become damaged.
 - ▶ Do not use loose power sockets or damaged power supply units, cables, plugs, or battery packs.
 - ▶ Do not short circuit the power supply unit, the Handheld Base Unit contacts, or the battery pack.
 - ▶ Do not drop the CoaguChek XS Plus meter, the power supply unit, or the battery pack and protect these against shaking and vibrations.
-

Disposal of the system **WARNING!****Infection by a potentially biohazardous instrument**

The CoaguChek XS Plus system 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 system or its components according to the appropriate local regulations. Always remove the battery pack before thermal disinfection.

 **WARNING!**

Any product coming in contact with blood is considered contaminated (potentially infectious).* During normal testing, any meter may come in contact with blood. Lancing devices may also be considered sharps. Disposal of sharps is regulated by law in many jurisdictions.

- ▶ The European Union has a requirement for improving waste management practices for certain electronic equipment, but meters fall outside the scope of the European Directive 2012/19/EU** This is not a requirement for the U.S.A.; however, Roche is committed to recycling and sustainability. Comply with any laws or ordinances relating to the disposal of sharps and/or contaminated products. Contact your local health department or other appropriate authorities for proper handling and disposal of used meters, used test strips, used lancets, and used battery packs. Please consider the following points when disposing of your used testing materials: Consider recycling of the meters and battery packs at an appropriate facility. Be aware the meter is potentially hazardous electronics scrap (e-scrap) and should be disposed of accordingly. The battery packs are potentially hazardous also and should be disposed of accordingly. Disinfect the meter before recycling or disposing.

*29 CFR 1910.1030 - Bloodborne pathogens

**Directive 2012/19/EU - Directive on waste electrical and electronic equipment (WEEE)

General care

NOTICE!

Clean the meter only with the solutions recommended. Using other solutions may result in incorrect operation and possible system failure. Do not let cleaning solution enter the instrument. Make sure that the meter is thoroughly dried after cleaning or disinfecting.

- ▶ [Acceptable Cleaning/ Disinfecting Agents \(156\)](#)

Battery pack

The meter contains a rechargeable battery pack that begins charging as soon as the power adapter is connected or the meter is placed on an active Handheld Base Unit (i.e., one connected to a power supply).

NOTICE!

- ▶ Use only the specially designed battery pack provided by Roche Diagnostics. Using any other type of battery may damage the system.
-

 **WARNING!****Possible hazards posed by the battery pack**

Damaged or swollen battery packs can overheat, catch fire, or leak. Immediately cease use of CoaguChek XS Plus meters with damaged or swollen battery packs and under no circumstances recharge them (do not place in the Handheld Base Unit). Overheating can cause the battery pack to catch fire or explode.

Battery fluid or materials leaking from damaged battery packs can irritate your skin or cause burns due to high temperatures.

- ▶ Never throw the battery pack or the meter onto a fire. Do not dismantle, compress, or pierce the battery pack as this could cause an internal short circuit that leads to overheating.
- ▶ Do not place either the battery pack or the CoaguChek XS Plus meter on or in heating appliances, such as a microwave, conventional oven, or radiator.
- ▶ Avoid prolonged exposure to direct sunlight, e.g., when the meter is docked in the Handheld Base Unit. Keep this in mind when positioning the Handheld Base Unit.
- ▶ Avoid contact with leaking battery fluid. In the event of accidental contact with the skin, rinse with water. If you get battery fluid in your eye(s), you should also seek medical attention.
- ▶ Handle and dispose of battery packs with care.

Extreme temperatures reduce the charging capacity and usage period of the meter and the battery pack.

Observe the following general safety instructions for handling the battery pack:




Disposal of used battery packs

Do not dispose of the battery pack with normal domestic waste. Dispose of used battery packs in accordance with applicable local regulations and directives and your facility's guidelines on the disposal of electronic waste equipment.

Save or download data from the meter prior to replacing the battery pack to prevent loss of data (see Chapter 7 starting with *Data handling*).

- When storing or disposing of the battery pack, use the manufacturer's original packaging.
- Always power the meter **off** before removing the battery pack.
- When the *Battery Low* warning is displayed, the meter must be returned **as soon as possible** to the Handheld Base Unit or connected to the power adapter for recharging.
- When the battery capacity is too low for further tests, the meter must be returned **immediately** to the Handheld Base Unit or connected to the power adapter for recharging.

If the meter displays a large red battery icon  instead of powering up when you press the On/Off button, this indicates that the battery is empty. Immediately return the meter to the Handheld Base Unit or connect to the power adapter for recharging.

▶ [7.1 Data handling \(145\)](#)



- ▶ Do not use the meter near strong electromagnetic fields, which could interfere with the proper operation of the meter.

Electromagnetic compatibility (EMC)

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

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 CoaguChek XS Plus system will be operated should be thoroughly evaluated before operation of the device.

This equipment has been tested and found to comply with the limits for a Class B digital device, in line with 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. If not installed and used in line with the instructions, it may cause harmful interference to radio communications.

The CoaguChek XS Plus system complies with both the electromagnetic immunity requirements and radio interference immunity requirements at the frequency and test levels in line with ISO 17593.

Electrostatic discharge (ESD)

The CoaguChek XS Plus 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 test, an error message appears and no result is displayed by the meter or stored in the meter's memory. The test must 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. This might cause damaging static discharges.

Touchscreen

NOTICE!

- ▶ Use only your finger (even when wearing gloves) or special pens designed for use with touchscreens to touch the screen elements. Using pointed or sharp-edged objects can damage the touchscreen.
- ▶ Avoid prolonged exposure to direct sunlight. Direct sunlight may reduce the life expectancy and functionality of the display.

Operating conditions

To ensure that the meter functions properly, please observe the following guidelines:

- Only use the meter at a room temperature between 15 °C and 32 °C (59 °F and 90 °F). For information on operating temperatures of test strips refer to the test strip package inserts. Test strip operating temperatures may differ from test parameter to test parameter.
- Only use the meter at a relative humidity between 10% and 85% (no condensation).
- The maximum altitude for operation is 4300 m (14,000 feet).
- When operating the meter using the power adapter, use only a voltage of 100 V to 240 V ($\pm 10\%$), 50/60 Hz.
- When testing, place the meter on a level, vibration-free surface, or hold it so it is roughly horizontal.

Product limitations

Read the information in the package insert supplied with the reagents and solutions for detailed product data and limitations.

Quality control

The meter has a number of built-in quality-control functions:

- A check of the electronic components and functions every time the meter is powered on.
- A check of the test strip temperature while a test is in progress.
- A check of the expiration date and lot information on the test strip based on the code chip data.
- An onboard quality control within every single test strip.

Roche Diagnostics offers liquid quality controls for the CoaguChek XS Plus system. These controls are designed to assist you in meeting regulatory compliance requirements at your facility.

1.3 Recommendations for the protection of personal data and software security

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

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

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

Access control

Unauthorized access may lead to data breaches.

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

User authentication

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

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

Password policy

Adhere to the following rules for password creation.

- ▶ Passwords should not contain the user's account name or parts of the user's full name that exceed two consecutive characters.
- ▶ Passwords should be at least eight characters in length.
- ▶ Passwords should contain characters from the following three categories:
 - English uppercase alphabetic characters (A through Z)
 - English lowercase alphabetic characters (a through z)
 - Numeric characters (0 through 9)

Network security

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

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

Secure network environment

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

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

Data entry and data transfer

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

- ▶ Do not write any patient-sensitive information into free-text fields.
- ▶ When transferring data via POCT1-A, make sure encryption has been activated, so that personal data can not be extracted by e.g. using a sniffing tool.

Deleting data from the device

Before taking the device out of service, delete the stored data using the corresponding function.

Data security

CAUTION!

Monitor the system for suspicious activity and report suspected compromise

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

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

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

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

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

- ▶ Make sure other computers and services on the network (for example, the LIS, archiving share, backup share, or service) are properly secured and protected against malicious software and unauthorized access.
- ▶ Restrict physical access to the system and server and all attached IT infrastructure (computer, cables, network equipment, and so on).
- ▶ Store related removable media in a safe place.
- ▶ Ensure that all device components maintaining private data are physically secure (i.e. require a physical key to be accessed or removed).
- ▶ Implement security and authentication measures for removable media (i.e. USB flash drives, CD-ROM/DVD, tapes, etc.).
- ▶ Allow only defined users to read and write encryption keys (IIS App config/Windows Server hardening).
- ▶ Allow only internet access to trusted web sites and web services.
- ▶ Enable Data Execution Prevention for all applications (Windows Server).
- ▶ Make sure to use secure channels to download software updates of the system.

⚠ CAUTION!**Unauthorized access to the system configuration**

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

- ▶ Observe the information on User authentication.
-

⚠ CAUTION!**Unauthorized access to confidential data**

Unencrypted communication can lead to unauthorized access to confidential data.

- ▶ Use TLS encryption with authentication for preventing unauthorized access to confidential data.
-

⚠ CAUTION!**Data loss and disaster recovery**

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

- ▶ The IT staff responsible for your facility must develop a disaster recovery plan to protect the entire system.
 - ▶ Ensure that backups are made regularly (ideally every day) and stored securely.
-

NOTICE!

Data transmission should be secured

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

- ▶ Such protection can be achieved by enabling encryption (TLS with authentication) and POCT1-A encryption.

Secure data storage

Unauthorized access to data backups and archive files is a potential data loss risk of patient/test data.

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

Cybersecurity and privacy awareness

Insufficiently informed employees can endanger security.

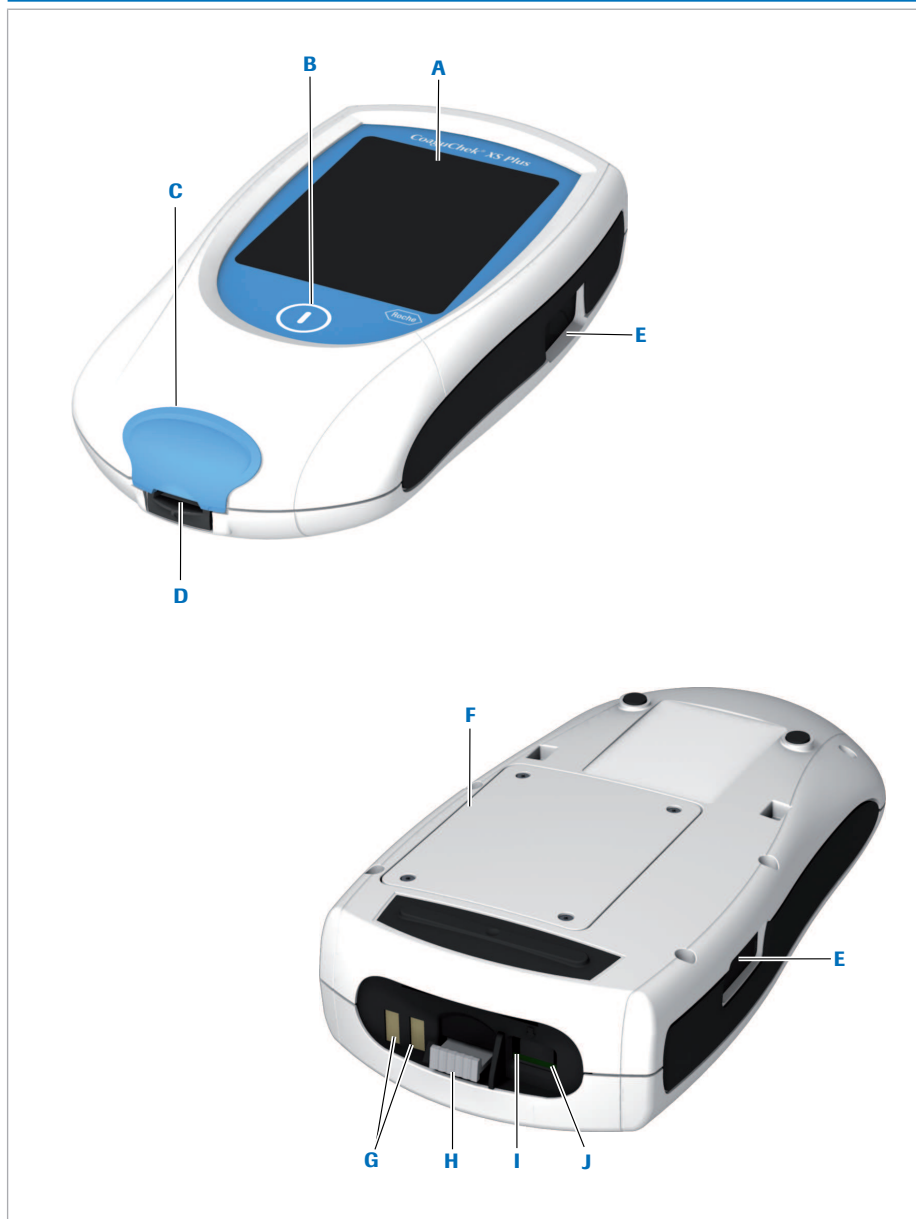
- ▶ Perform regular cybersecurity and privacy awareness trainings for staff handling personal data. Instruct staff how to handle data in a compliant way and according to the privacy principles as mandated by customer regulations.
- ▶ Check your device for suspicious activity and report any suspected compromise to your local Roche representative immediately.
- ▶ Update to the latest software versions provided by Roche as soon as possible.

Data backup

Data may get lost due to memory failures.

- ▶ Back up your data (measurement results and system parameters) at regular intervals.

1.4 Overview of the meter elements



A Touchscreen

Shows test results, information, icons, and results recalled from memory. To select an option, simply touch the button lightly.

B On/Off button

Press this button to power the meter on or off.

C Test strip guide cover

Remove this cover to clean the test strip guide (if it has become soiled, e.g., with blood).

D Test strip guide

Insert the test strip here.

E Barcode scanner

The integrated barcode scanner can scan operator, patient, and QC sample IDs into the meter.

F Battery compartment cover

Remove to insert the battery pack

G Charging contacts

Used for power supply and/or charging the battery pack when the meter is docked in the (optional) Handheld Base Unit.

H Code chip slot (shown with code chip)

Insert the code chip here.

I Connection socket for power adapter













Plug in the power adapter here.

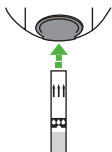
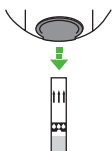

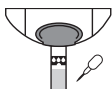
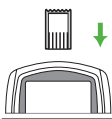
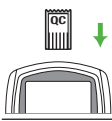




J Infrared interface













(Covered by the semi-transparent panel)
Supports data communication.

1.5 Buttons and icons overview













The buttons and icons that appear during normal operation are shown here, along with their respective meanings.


Button/Icon	Meaning
	Go to Main Menu
	OK; save setting
	Cancel; discard setting
	Return (to previous menu)
 	Decrease/increase the value displayed. Scroll through lists that are too long to be displayed all at once.
 	Inactive button: Value cannot be further decreased/increased or: End of list in this direction is reached
	List of tests of a specific patient
	Print after test result or from memory
	Add a comment
	Operator must wait until the meter has completed an action

Button/Icon	Meaning
	Insert test strip
	Remove test strip
	Apply sample (the time left to apply sample is counted down in the display)
3:00 Min.	
	Apply liquid control (QC) sample (the time left to apply sample is counted down in the display)
	Insert the test strip code chip
	Insert the QC code chip
QC 	Automatic quality control completed successfully
INR	Results are displayed in INR units
	Result in the chosen unit of measure is above the measuring range.
	Result in the chosen unit of measure is below the measuring range.
	Quality control: Result is above the specified range

Button/Icon	Meaning
	Quality control: Result is below the specified range
Battery status:	
	■ Battery full: When the battery pack is fully charged, all segments are lit.
	■ Battery good: One missing segment indicates a partially charged battery pack.
	■ Battery half: Two missing segments indicate a partially charged battery pack.
	■ Battery low: When there is only one segment remaining the icon is displayed in red.
	■ Battery empty: When there is no segment remaining, you may not be able to finish performing a test. Recharge as soon as possible.
	When the power supply icon is displayed, the meter is connected to the power supply adapter or the HBU. Charging is possible when the meter enters standby mode.
am	Time between midnight and noon (in 12-hour time format)
pm	Time between noon and midnight (in 12-hour time format)
	Room or meter temperature is outside the acceptable range
	The test strip guide cover is open
	Reports a status message (see Chapter 9, <i>Troubleshooting</i>)
	Reports an error message or a warning (see Chapter 9, <i>Troubleshooting</i>)
QC!	Lockout - a QC test has to be performed before further patient tests are possible.
	Reset; resets setup

The following icons may appear when using the meter in conjunction with a DMS.

Button/Icon	Meaning
	If displayed in the status bar: communication is taking place via the infrared interface.
	<ul style="list-style-type: none"> ■ Last synchronization passed.
	<ul style="list-style-type: none"> ■ Last synchronization failed.
	<p>If displayed in the status bar: communication security status.</p> <ul style="list-style-type: none"> ■ The last communication with the DMS was neither TLS encrypted nor TLS authenticated. ■ The last communication with the DMS was TLS encrypted, but not TLS authenticated. ■ The last communication with the DMS was both TLS encrypted and TLS authenticated.
	An OTS request is pending
	Cleaning/Disinfection is necessary
	Patient test result is out of normal patient test range
	Approved; indicates server or root CA certificate status as approved. For manual server certificate approval.
	Not Approved; indicates server certificate status as not approved.
	Expired; indicates server or root CA certificate is expired.
	Delete; for certificate deletion.
	Download; for downloading credentials.

The communication security icon  indicates the security status of current or last communication with the DMS. The icon is shown permanently after the initial communication of a brand new meter has taken place.

Error messages and the description of the icons linked to them are provided in the *Troubleshooting* chapter.

1.6 Power supply



The CoaguChek XS Plus meter is exclusively operated with the rechargeable battery pack. Always insert the battery pack, even when using the power adapter. This ensures smooth operation and prevents a loss of the date and time settings if the power goes out.

The meter cannot be operated without a battery pack.

Unused battery packs lose their charge over time and have to be recharged before they can be used. After installing a new battery pack, the meter should be charged at least 4 hours before testing, preferably overnight.

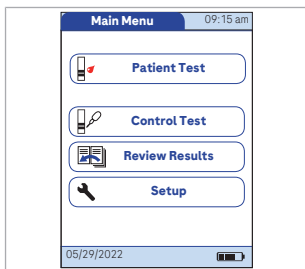


To save power, the CoaguChek XS Plus meter has an automatic power-off function (auto-off). The default setting is 5 minutes of inactivity (e.g., no screen touches). It is possible to customize the auto-off function via your Setup selection (see *Auto Off*).

When the meter powers itself off, all results obtained up to that point remain in memory and the settings will still be there when you power the meter back on.

▶ [To enable the auto off option \(72\)](#)

Battery power level



During battery operation, the meter always displays the battery power level.

When **replacing the battery pack**, insert the new battery pack within 10 minutes of removing the old one. Otherwise you may need to re-enter date and time.

The meter retains results in memory even when no battery pack is inserted. All settings other than date and time are retained as well.



- ▶ Dispose of used battery packs in an environmentally responsible manner in accordance with applicable local regulations and directives. See *Infection by a potentially biohazardous instrument*.

▶  [Battery power level \(43\)](#)

2 Putting the Meter into Operation


Before using the meter for the first time, perform the following steps:

1. Install the battery pack
2. Connect the power adapter to charge the battery pack
3. Set the current date and time
4. Enter your chosen settings (language, unit of measure, user administration if applicable, etc.)

2.1 Installing or replacing the battery pack



When shipped, the battery pack is not installed in the CoaguChek XS Plus meter. When the battery pack is not installed, the meter cannot be used.

Unused battery packs lose their charge over time and have to be recharged before they can be used. After installing a new battery pack, the meter should be charged at least 4 hours before testing, preferably overnight.

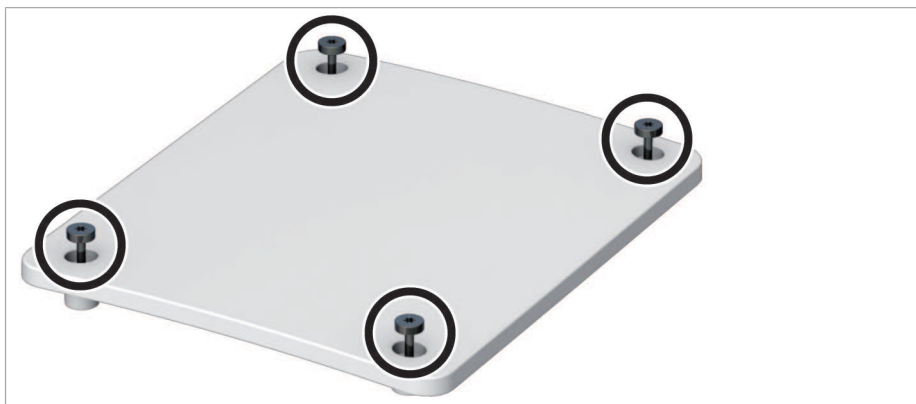
Whenever the meter is placed on an active Handheld Base Unit or powered by the power adapter, the  icon is displayed. This icon shows that power is available and the meter can be charged if necessary. To start the charging process immediately put the meter into standby mode by pressing the On/Off button for approximately 1 second.

Make sure that the permitted temperature range for charging the battery pack (15-32 °C or 59-90 °F) is maintained during installation and initial setup.

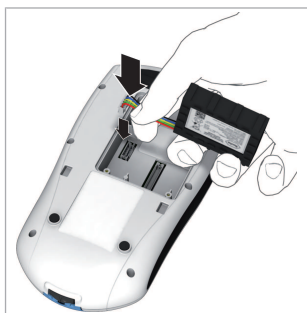
Replace the battery pack within approximately 10 minutes to retain the date and time settings. Beyond this period of time, you may have to re-enter date and time. Replace the battery pack only in shutdown mode.

-  [To remove the battery pack \(50\)](#)
-  [9.2 Shut down / restart / reset meter \(185\)](#)

► To install the battery pack



- 1** Using the starshaped screwdriver contained in the kit (or another appropriate starshaped screwdriver, e.g. Torx® size T5), loosen the screws on the battery compartment cover until they are protruding about 4-5 mm (2/10 in).
- 2** Hold the battery pack in your hand, with the wires and the plug pinched between your thumb and index finger.



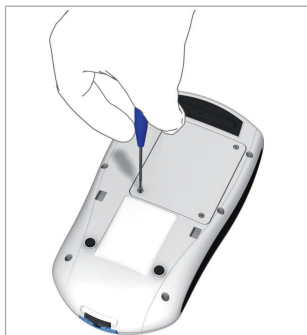


- 3 Plug the connector plug into the socket.
- 4 Place the battery pack inside the battery compartment as described in the previous steps.

To position the battery pack correctly, always align the ridges on the side of the battery pack with the ridges on the inside of the battery compartment.



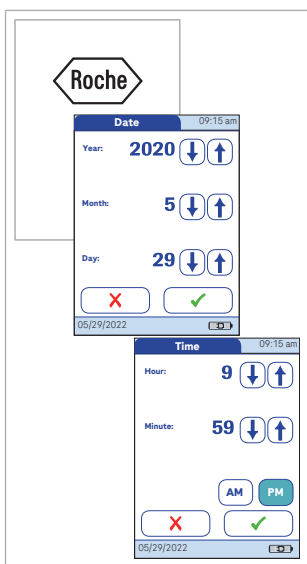
- 5 Place the cover on the battery compartment. Make sure that
 - the plug connector wires do not get pinched between meter and cover
 - the protrusion on the battery compartment cover fits into the corresponding groove on the battery compartment rim




- 6 Tighten all four screws until snug (do not overtighten).

After inserting a new battery pack, the meter powers on automatically.

- The Roche logo is displayed. If the meter does not power on automatically, the battery pack may be empty. Connect the power adapter for a minimum of 30 minutes, then remove the plug and try to power the meter on. If it powers on, the battery pack is charging properly.
- Within a short period of time, the start screen should appear.
- If the meter has been without power for too long, it will show the date and time settings dialog and you have to re-enter the date and time settings.
- The screens for entering the date and the time appear.



- 7 Enter the date and time. After you have entered the correct information, confirm each screen with .
- 8 After installing a new battery pack, the meter should be charged for at least 4 hours before testing.

► To remove the battery pack



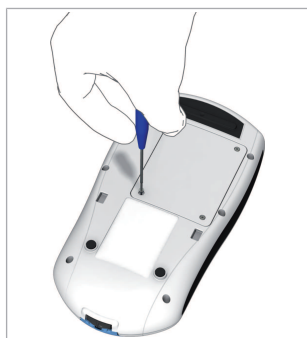
CAUTION! Disposal of used battery packs. Do not dispose of the battery pack with normal domestic waste. Dispose of used battery packs in accordance with applicable local regulations and directives and your facility's guidelines on the disposal of electronic waste equipment.

If a battery pack is already installed, make sure that the meter is shut down to prevent damage to the meter or potential data loss.

- 1 To shut down the meter, remove the external power supply, press the On/Off button **ⓘ** for about **5 seconds** and release the On/Off button as soon as the Roche logo is displayed and the meter beeps.

[To reset the meter \(185\)](#)

- 2 Place the meter face down on a level surface.



- 3 Using the starshaped screwdriver contained in the kit (or another appropriate starshaped screwdriver, e.g. Torx® size T5), remove the four screws holding the battery compartment cover in place.




- 4** Remove the battery compartment cover from the meter. The battery pack now visible is connected to the meter by a plug.
- 5** Carefully lift the battery pack and remove the plug connector.


2.2 Powering the meter on and off



▶ To power the meter on and off

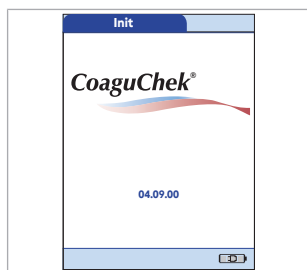
- 1 Place the meter on a level, vibration-free surface, or hold it in your hand so it is roughly horizontal.
- 2 Power the meter on by pressing the button .

You can also power on the meter directly by inserting a test strip, connecting the power adapter, or by docking it in the Handheld Base Unit.

- 3 To power the meter off after use, press the button  for approximately 1 second.

▶ To check the software version

- 1 After displaying the Roche logo, the meter briefly displays the *Init* (for “initialization”) screen. Here you can check which software version is currently running on your meter. (The *Init* screen shown here is for illustration purposes only. Version numbers on your meter may differ.)
- 2 You can also check the current software version in the *Diagnostics* menu.
See [3.7 Diagnostics \(102\)](#).



3 Meter Setup

3.1 Display of screen elements

Note on presentation of screen elements in this manual

Buttons are screen prompts that cause something to happen when touched. The names of all buttons are either shown as bold text or as the icon used on the button (e.g., ✓ for **OK**).

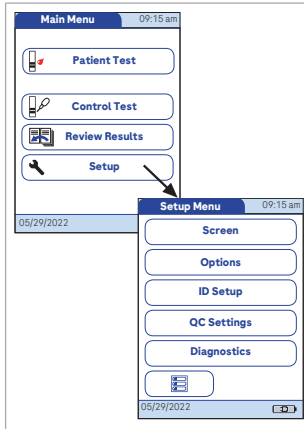
Other screen elements (e.g., Menu titles) are written in *italics*. These screen elements are not active.

If you have **not** set the date and time (after powering on for the first time or because the battery pack was removed from the meter for more than 10 minutes), you cannot perform a test. In that case powering on the meter takes you immediately to the *Setup* mode, where you must set the date and time.

After date and time have been set, the meter automatically moves to the *Main Menu*, where you can start a test or enter more settings.



You can open any displayed function by touching (or tapping) the button for it with your finger (or a special pen for this purpose). “Tap” means: Touch the button, then remove your finger from the touchscreen. The next screen appears once you remove your finger.

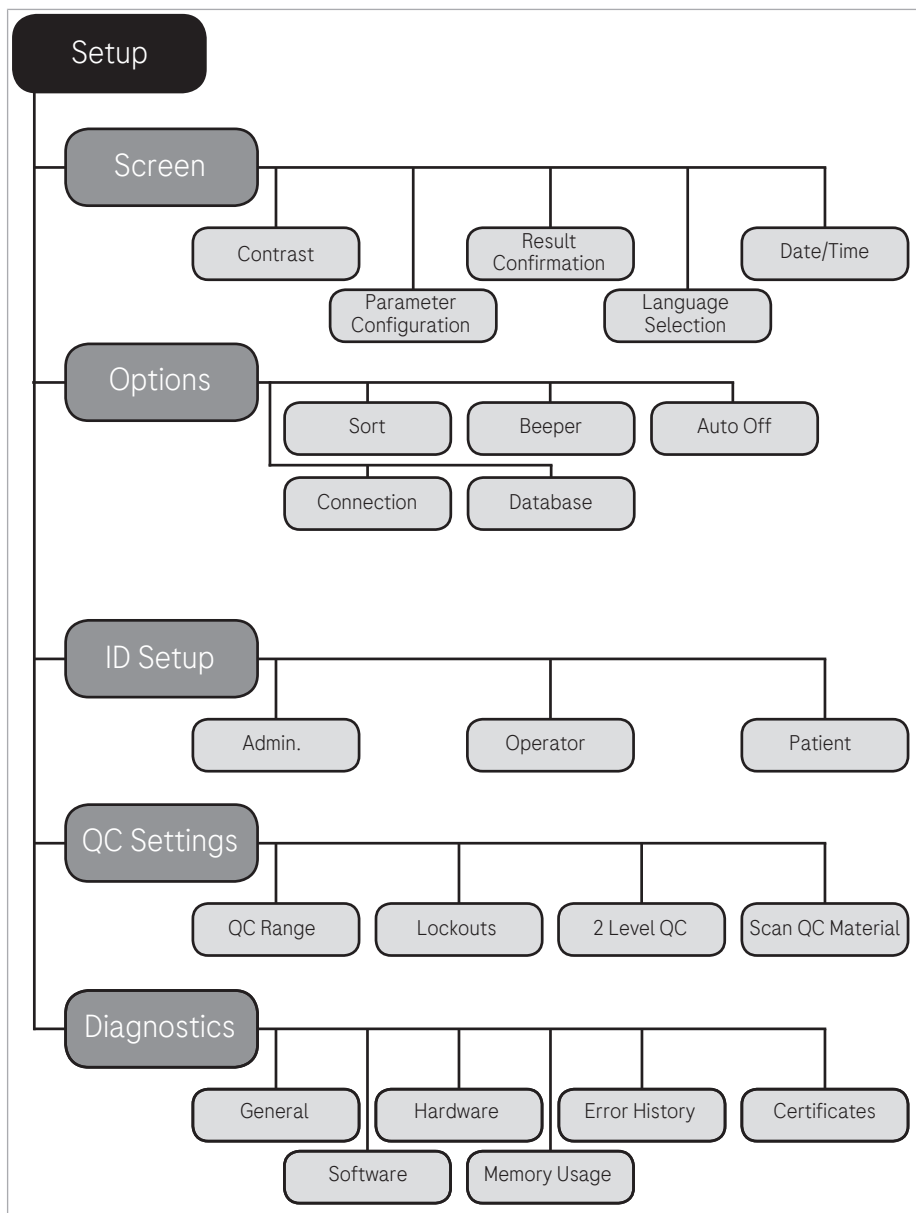


If the meter did not automatically enter the *Setup* mode (e.g., after the battery pack was replaced), you can open the *Setup Menu* from the *Main Menu*.

1. Touch **Setup** to open the meter settings.
2. Select the relevant group of settings (see *Settings summary* following this section).

3.2 Settings summary

The diagram below shows all of the setup areas that can be accessed on the meter.



Group	Subgroup	Setting	Values ^{(a),(b)}	
Screen	Contrast		0 – 10 (5 *)	
	Parameter Configuration	Result Units PT	INR *	
			INR/SEC	
			INR/%Q	
	Result Confirmation		Enable	
			Disable *	
	Language Selection		Čeština	
			Dansk	
			Deutsch	
			English *	
			Español	
			Français	
			Italiano	
			Nederlands	
			Norsk	
			Português	
	Date/Time	Date		01/01/2025 *
				12:00 am *
		Date formats		DD.MM.YYYY (01.01.2025)
				MM/DD/YYYY * (01/01/2025)

^(a) Default settings are labeled with an asterisk (*).

^(b) ** The printer is not available in the U.S.

Group	Subgroup	Setting	Values ^{(a),(b)}	
			YYYY-MM-DD (2025-01-01)	
		Time formats	24-hour time format (24h)	
			12-hour time format (12h), with am/pm *	
Options	Sort		Date/Time *	
			Patient ID	
			Patient Name	
	Beeper	Beeper		Off
				Low
				Medium *
				High
				Key Click
			On	
	Auto Off	[minutes]		Off
				1 ... (5*) ... 10
				15
				20
			25	
			30	
			40	
	50			
	60			
Connection			Off *	
			Computer	
			Printer**	

^(a) Default settings are labeled with an asterisk (*).

^(b) ** The printer is not available in the U.S.

Group	Subgroup	Setting	Values ^{(a),(b)}
			Computer/Printer**
	Database	Result Retention	On (time in days)
			Off
		Delete Database	Results
			Code Chip Data
			Entire Database
ID Setup	Admin. (Administrator)		Blank (Off) *
	Operator (Operator List is optional)		Inactive *
			Active
			Scan Only/Hidden list
	Patient		No *
			Optional
		Required	
		Scan Only/Hidden list	
QC Settings	QC Range	PT	Default Range *
			Custom Range
	Lockouts	QC Lockout	New code (Yes/No)
			Scheduled (No*, Daily, Weekly, Monthly)
			Number of hours
			Number of strips
			Number of levels: 1/2
			(For each option except "No")

^(a) Default settings are labeled with an asterisk (*).

^(b) ** The printer is not available in the U.S.

Group	Subgroup	Setting	Values ^{(a),(b)}
		Operator Lockout (only if the <i>Operator</i> option is set to <i>Active</i> and an operator list is available)	Off * Weekly Monthly Every 3 months Every 6 months Yearly Number of levels
		QC Interval Settings	Time of day First day of week
	2 Level QC		Yes * No
	Scan QC Material		Optional * Scan Only
Diagnostics	General		
	Software		
	Hardware		
	Memory Usage		
	Error History		
	Certificates	Client Certificate	
		Server Certificates	
		Root CA Certificates	
		Credential Download	

^(a) Default settings are labeled with an asterisk (*).

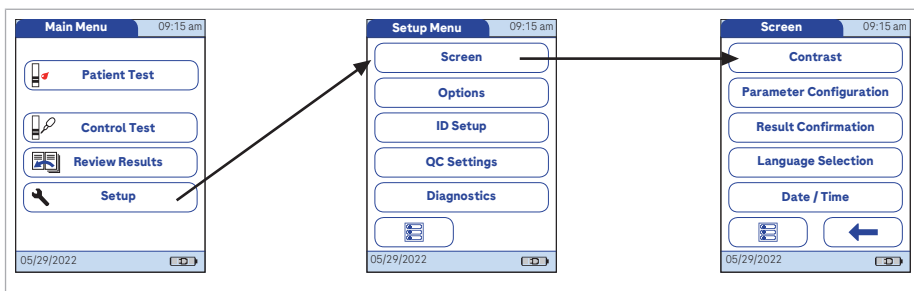
^(b) ** The printer is not available in the U.S.

3.3 Screen setup

The *Screen* setup area contains the options for changing the display.

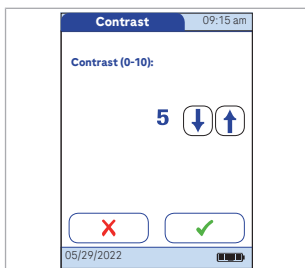
► To set the contrast





Use the *Contrast* menu to adjust the display to your ambient light conditions and make it easier to read.



- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **Screen**.
- 3 From the *Screen* menu, touch **Contrast**.

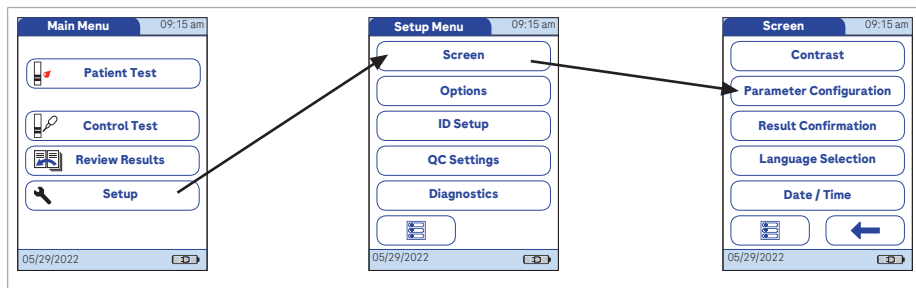
If a button is grayed out, this means the function is not available.



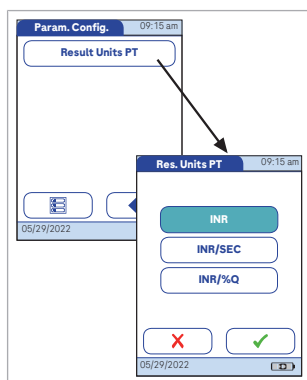
- 4 Touch  or  to change the contrast in a range from 0 to 10.
 - Contrast “0” makes the display very dark.
 - Contrast “10” makes the display very light.
- 5 Touch  to save this setting, or touch  to exit this menu without saving any changes. The display automatically returns to the previous screen.

► To configure the results units for PT

Use this setting to select the unit(s) in which the result is displayed.



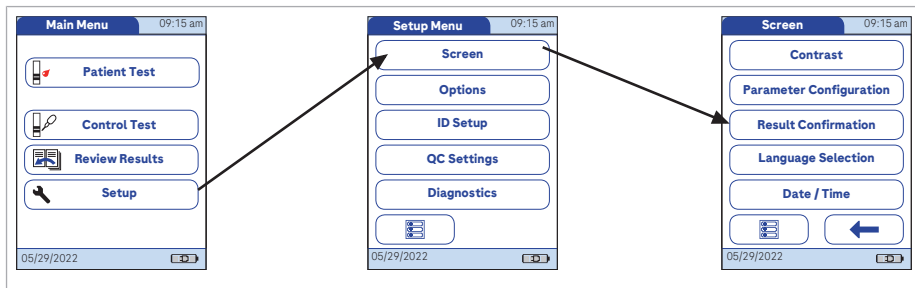
- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **Screen**.
- 3 From the *Screen* menu, touch **Parameter Configuration**.



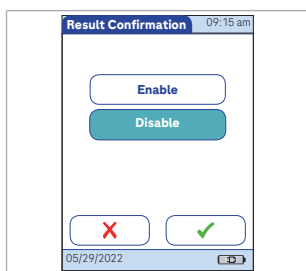
- 4 From the *Parameter Configuration* menu, touch **Result Units PT**.
The current unit of measure setting is highlighted (white type on a blue background). You can select either:
 - INR
 - INR and seconds
 - INR and Quick value in %
- 5 Touch the button to select the unit of measure of choice. Your selection is now highlighted.
- 6 Touch **✓** to save this setting, or touch **✗** to exit this menu without saving any changes. The display automatically returns to the previous screen.

▶ To activate the results confirmation option

In some circumstances, it may be useful for operators to confirm the validity of their results. Use this setting to prompt operators to confirm the results of every test.

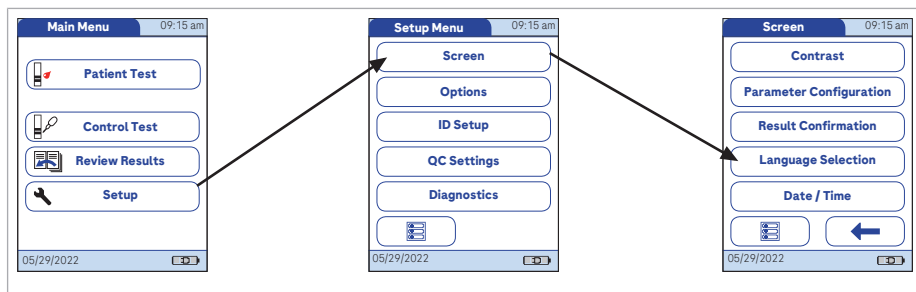


- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **Screen**.
- 3 From the *Screen* menu, touch **Result Confirmation**.
- 4 Touch **Enable** or **Disable**. Your selection is now highlighted.
- 5 Touch **✓** to save this setting, or touch **✗** to exit this menu without saving any changes. The display automatically returns to the previous screen.



▶ To select a language

Use this setting to select the meter language.









- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **Screen**.
- 3 From the *Screen* menu, touch **Language Selection**.

The current language setting is highlighted (white type on a blue background). You can select either:

- Čeština
- Dansk
- Deutsch
- English
- Español
- Français
- Italiano
- Nederlands
- Norsk
- Português
- Русский
- Suomi
- Svenska

Not all languages are available in all countries.



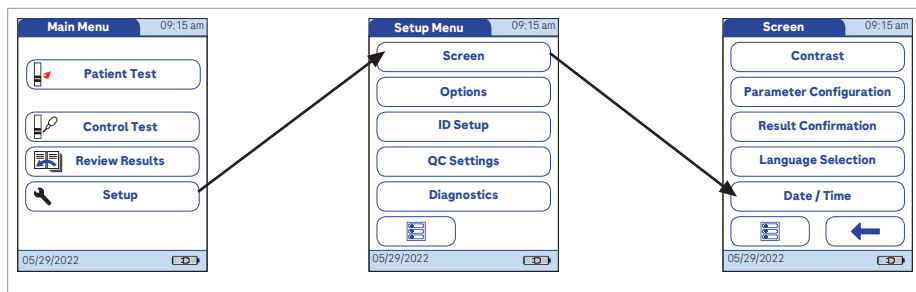
- 4 Touch  or  to display the language of choice on the screen.
If the arrow is just an outline  , you have reached the end of the list in the respective direction.
- 5 Touch the button to select the language of choice. Your selection is now highlighted.
- 6 Touch  to save this setting, or touch  to exit this menu without saving any changes. The display automatically returns to the previous screen.

► To set the date

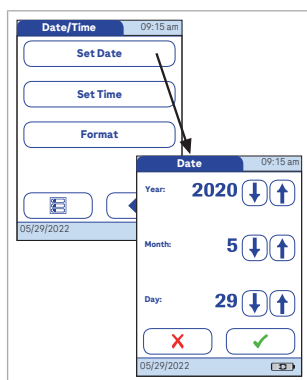
When you power on the meter for the first time (or after a long period without power), the input field for the date automatically appears first. The date (and time) must be entered before the meter can be used further. If at a later time a date adjustment is needed, go to the *Setup Menu*, then select the menu of choice.

Both *Date* and *Time* display formats are controlled by the Format options you select (see *Setting the display options for date and time* in this chapter). Options shown in the *Date* and *Time* menus may vary depending on the chosen formats. You can choose between the following display formats:

- Date: Day.Month.Year, e.g., 29.05.2025
- Date: Month/Day/Year, e.g., 05/29/2025
- Date: Year-Month-Day, e.g., 2025-05-29
- Time: 24H or 12H



- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **Screen**.
- 3 From the *Screen* menu, touch **Date/Time**.
- 4 From the *Date/Time* menu, touch **Set Date**.
- 5 Touch **↑** or **↓** to set the year, then the month, then the day.
- 6 Touch **✓** to save this setting, or touch **✗** to exit this menu without saving any changes. The display automatically returns to the previous screen.

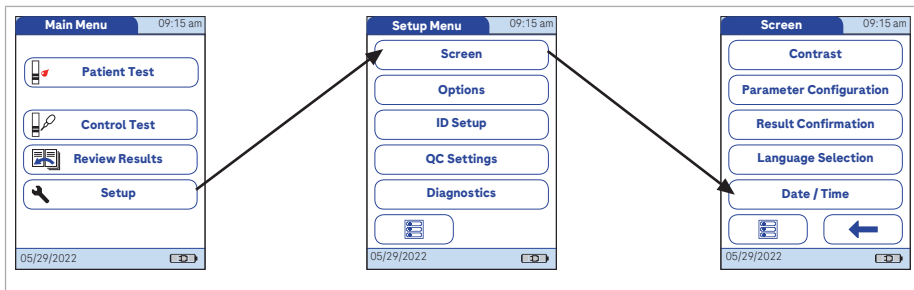


If this setup menu appeared automatically after powering the meter on, you must touch **✓** to complete the first date setting.

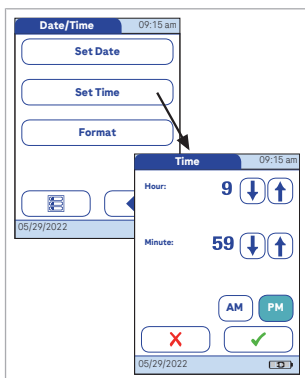
- 7 Touch **←** to return to the *Screen* menu.





► To set the time


When you power on the meter for the first time (or after a long period without power), this *Time* setup menu appears automatically after you set the date. If at a later time a time adjustment is needed, go to the *Setup Menu*, then select the menu of choice.



- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **Screen**.
- 3 From the *Screen* menu, touch **Date/Time**.
- 4 From the *Date/Time* menu, touch **Set Time**.



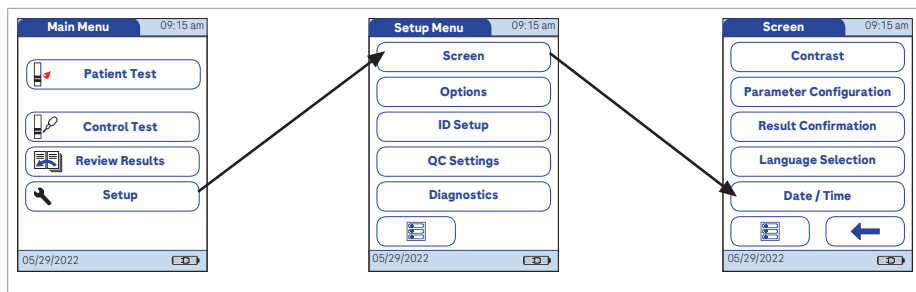
- 5 Touch  or  to set the hours, then the minutes.
- 6 Touch  to save this setting, or touch  to exit this menu without saving any changes. The display automatically returns to the previous screen.

If this setup menu appeared automatically after powering the meter on, you must touch  to complete the first time setting.

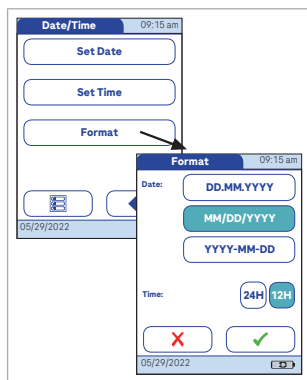
- 7 Touch  to return to the *Screen* menu.

► To set the date and time format

Select your preferred format for the date and time display.



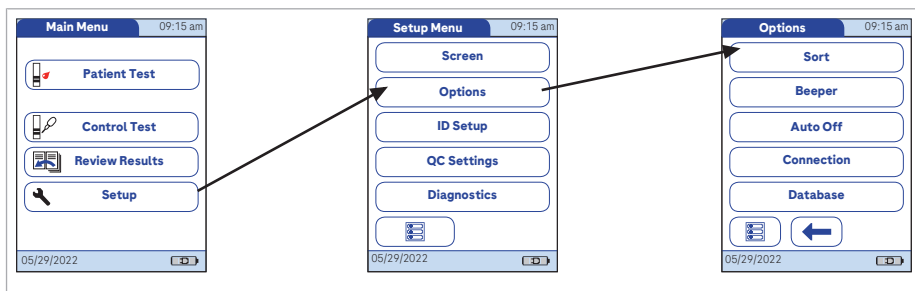
- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **Screen**.
- 3 From the *Screen* menu, touch **Date/Time**.
- 4 From the *Date/Time* menu, touch **Format**. The current settings are highlighted. You can select one of the following display formats:
 - Date: **DD.MM.YYYY** (Day.Month.Year), e.g., 29.05.2015
 - Date: **MM/DD/YYYY** (Month/Day/Year), e.g., 05/29/2015
 - Date: **YYYY-MM-DD** (Year-Month-Day), e.g., 2015-05-29
 - Time: **24H** or **12H**
- 5 Touch the button with the display format of choice for date and time. Your selection is now highlighted.
- 6 Touch **✓** to save this setting, or touch **✗** to exit this menu without saving any changes. The display automatically returns to the previous screen.
- 7 Touch **←** to return to the *Screen* menu.



3.4 Options setup

► To set the sorting order of lists

Sort refers to the order in which measured and stored results are displayed when you use the *Review Results* function of the CoaguChek XS Plus meter. You can display stored results chronologically by date and time or by person, based on the *Patient ID*.

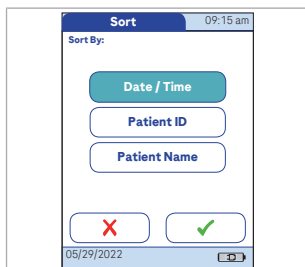


- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **Options**.
- 3 From the *Options* menu, touch **Sort**.



The current setting is highlighted. You may select from the following sort options:

- By **Date/Time**
- By **Patient ID**
- By **Patient Name**

- 4 Touch the button to select the *Sort* by option of choice. Your selection is now highlighted.



Note: The sort option *Patient Name* is available only when used together with a patient list. Patient lists can only be created with a DMS. For more details see [7.1 Data handling \(145\)](#).

- 5 Touch  to save this setting, or touch  to exit this menu without saving any changes. The display automatically returns to the previous screen.

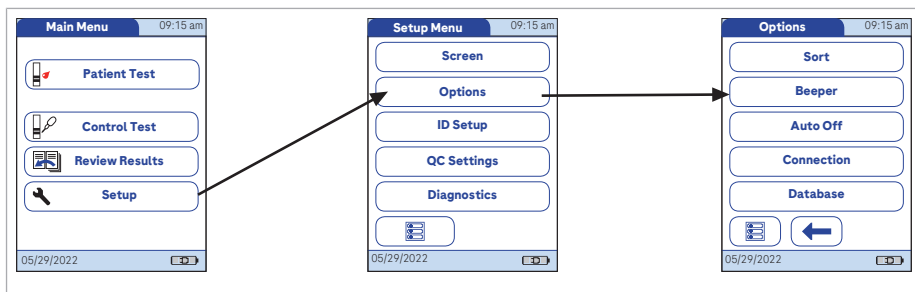
► **To enable/disable the beeper option**

The CoaguChek XS Plus meter can display information visually and alert you to special circumstances with a *Beeper*. The meter always beeps when it is switched on. When the *Beeper* function is enabled the meter beeps once when:

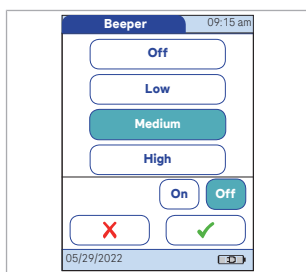
- it detects a test strip
- pre-heating of the test strip is complete and you need to apply a sample
- it detects a sample
- the test is completed and the results are displayed (a long beep)
- an error occurs (three short beeps)
- an external power adapter is connected when the meter is on
- the meter is docked
- a barcode is scanned

We recommend that you keep the *Beeper* enabled at all times.

You can also activate a *Key Click*. When a *Key Click* is enabled, the meter clicks briefly every time a button is touched, facilitating the input of information.



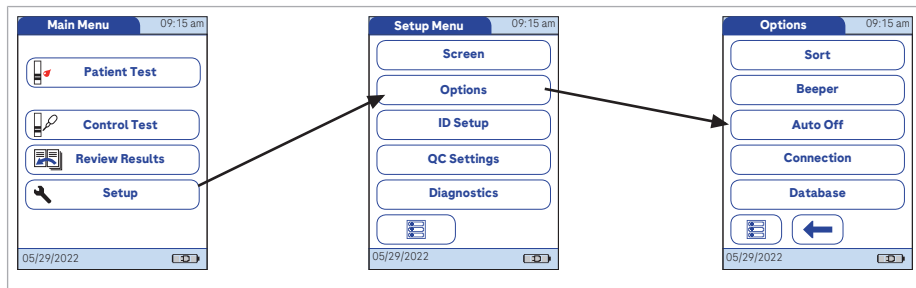
- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **Options**.
- 3 From the *Options* menu, touch **Beeper**.
The current setting is highlighted.



- 4 You may select from the following options for the *Beeper*:
 - **Off**
 - **Low**
 - **Medium**
 - **High**
- 5 You may select from the following options for the *Key Click*:
 - **On**
 - **Off**
- 6 Touch the button with the desired setting for the *Beeper*, then touch the button with the setting of choice for the *Key Click*. Both selections are now highlighted.
- 7 Touch **✓** to save this setting, or touch **X** to exit this menu without saving any changes. The display automatically returns to the previous screen.

► To enable the auto off option

You can set up your CoaguChek XS Plus meter so that it powers itself off automatically if it has not been used (no buttons touched or tests run) for a preselected time period. Use this feature to save power and extend the life of the battery pack.

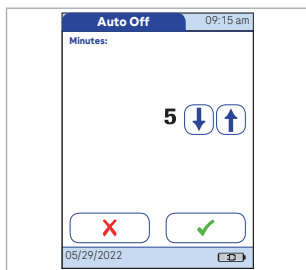






- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **Options**.
- 3 From the *Options* menu, touch **Auto Off**.

If the meter is connected to the power adapter or the Handheld Base Unit, the *Auto Off* function has a different effect:

The meter powers itself off after 10 minutes without user interaction, regardless of the selected settings.

- 4 You may select from the following options:
 - **Off** (meter never powers itself off)
 - Time until meter powers itself off: 1... 10, 15, 20, 25, 30, 40, 50, 60 minutes

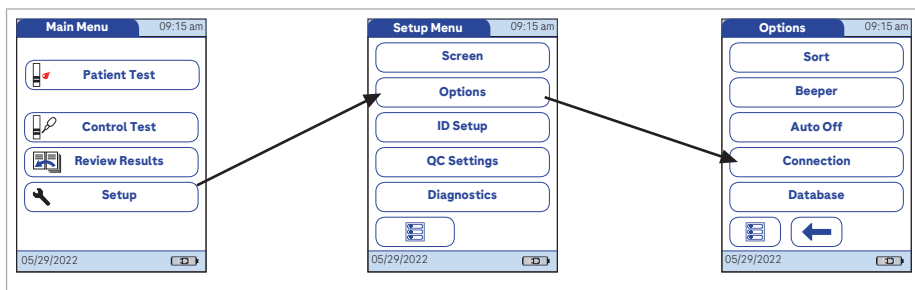


- 5 Touch  or  to select the time of choice in minutes or to switch the feature off.
- 6 Touch  to save this setting, or touch  to exit this menu without saving any changes. The display automatically returns to the previous screen.

► To open the connection menu

In the *Connection* menu you can configure the data exchange with external devices. The meter can be connected:

- to a computer (DMS) only or
- to a printer⁽¹⁾ only or
- to both a computer (DMS) and a printer



- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **Options**.
- 3 From the *Options* menu, touch **Connection**.

⁽¹⁾ The printer is not available in the U.S.

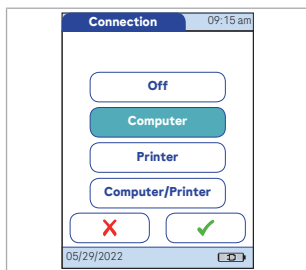
▶ To connect to the computer

The CoaguChek XS Plus meter can connect with a computer or host system running appropriate software (that is, a DMS must be installed). To use this connectivity feature, however, you need the optional Handheld Base Unit.

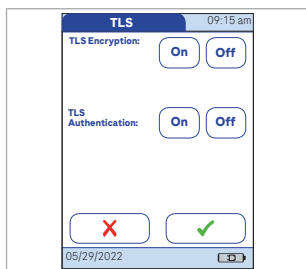
- 1 The connection is established in two steps.
 - The meter connects to the Handheld Base Unit via infrared.
 - The Handheld Base Unit is either connected to a single computer (via USB) or to a network/host system (via ethernet).
- 2 This function can be activated by selecting *Computer* or *Computer/Printer*.⁽²⁾ Select *Computer/Printer* if you want to activate both functions at the same time. The option *Computer* or *Computer/Printer* (when activated) can be used together with a DMS to set up:
 - operator lists, or
 - patient lists (lists of patients to be tested)

This eliminates the need for manual entry of these data. In addition, you can transfer test results stored in the meter to other systems for archiving or further evaluation. The option **Computer** or **Computer/Printer** controls the meter's ability to communicate with a computer or a network and/or with a printer.

⁽²⁾ The printer is not available in the U.S.



- 3 From the *Connection* menu, touch **Computer** or **Computer/Printer**. Your selection is now highlighted. Touch . To open the connection menu (73)



If you are using a DMS, from the *TLS* screen you may select **On** or **Off** for the following options:⁽³⁾

- *TLS Encryption*:
Set to **On** to activate an end-to-end TLS tunnel from the meter to the DMS
- *TLS Authentication*:
Set to **On** to ensure that the end-to-end TLS tunnel is only initiated between an authenticated meter and an authenticated DMS

TLS (Transport Layer Security) supports many different methods for exchanging keys, encrypting data and authenticating message integrity. Using the TLS encryption and authentication options activates an end-to-end TLS tunnel from meter to DMS. This is the most effective measure to achieve secure communication. It is recommended to activate these configurations.

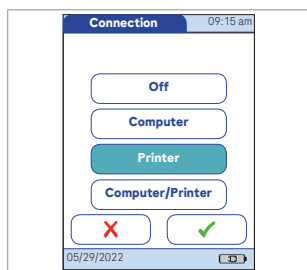
- 4 Touch to save this setting, or touch to exit this menu without saving any changes. The display automatically returns to the previous screen.


Extended data handling functionality is dependent on the capabilities of the particular DMS being used and may vary.

⁽³⁾ TLS authentication is only configurable, if TLS encryption is enabled.

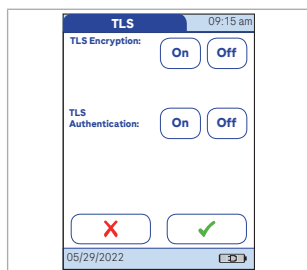
► To connect to the printer

The CoaguChek XS Plus meter can also connect directly to a printer. This function can be activated by selecting *Printer*⁽⁴⁾ or *Computer/Printer*. Select *Computer/Printer* if you want to activate both functions at the same time. To use the printing feature, you need an optional infrared printer.



- 1 From the Connection menu, touch **Printer** or **Computer/Printer**. Your selection is now highlighted. Touch .

To open the connection menu (73)



If you selected the **Computer/Printer** option and you are using a DMS, from the TLS screen you may select **On** or **Off** for the following options:⁽⁵⁾

- *TLS Encryption*:
Set to **On** to activate an end-to-end TLS tunnel from the meter to the DMS
- *TLS Authentication*:
Set to **On** to ensure that the end-to-end TLS tunnel is only initiated between an authenticated meter and an authenticated DMS



TLS (Transport Layer Security) supports many different methods for exchanging keys, encrypting data and authenticating message integrity. Using the TLS encryption and authentication options activates an end-to-end TLS tunnel from meter to


⁽⁴⁾ The printer is not available in the U.S.

⁽⁵⁾ TLS authentication is only configurable, if TLS encryption is enabled.

DMS. This is the most effective measure to achieve secure communication.
It is recommended to activate these configurations.



- 2 Touch  to save this setting, or touch  to exit this menu without saving any changes. The display automatically returns to the previous screen.
To print:

- Align the meter with the IR printer.
- At any test or memory screen, touch .

The printer icon only appears if the printer function is activated. Otherwise it is not displayed.

If you work with the meter in a language other than English: With the exception of information you have entered - such as patient ID and name, operator ID, comments - the printout will be in English.

See [To select a language \(6.3\)](#).

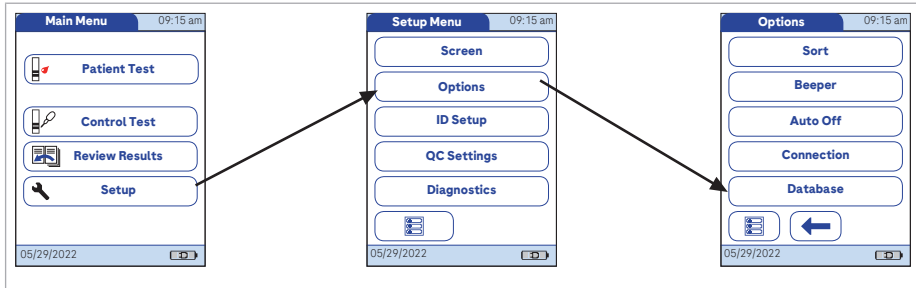
► To configure the database

You can set up your CoaguChek XS Plus meter so that the results are retained on the database for a preselected time period.

Use this feature to automatically clear the database periodically. If you do not use this feature, then you will be required to delete data manually or save the data on a DMS.

If the memory is full when you perform a test, the oldest result is automatically deleted. The most recent result is always saved. This applies both to patient results and to quality control tests. In order to

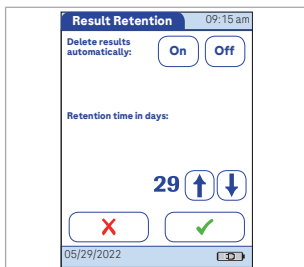
avoid the loss of stored test results, you can archive this data using a DMS and the optional Handheld Base Unit (see Chapter 7).



- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **Options**.
- 3 From the *Options* menu, touch **Database**.

You may select from the following options:

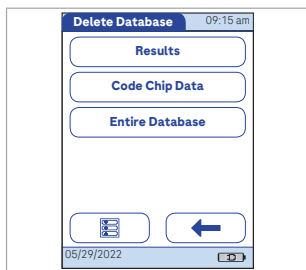
- **Result Retention**
- **Delete Database**




- 4 Touch the button to select the database option of your choice. Your selection is now highlighted. If you selected **Result Retention** you may choose the following options:

- **On**: Deletes results automatically after a preselected time period. Using **↑** or **↓**, select the number of days you would like to retain the data.
- **Off**: Results are not automatically deleted. Regular cleaning up of the database is manually required.

→ Note: Meter default is 30.



- 5 If you selected **Delete Database**, you may select from the following options depending on which type of data you would like to delete:
 - **Results**
 - **Code Chip Data**
 - **Entire Database**
- 6 Touch  to return to the *Database* screen.

3.5 ID setup

Use the *ID Setup* menu to enter settings for user management and patient management. These settings are optional and set to *Off/Inactive* by default; the meter can be operated without these settings.

There are three types of identification used with the meter:

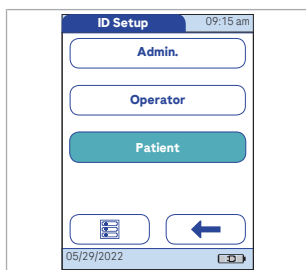
- **System Administrator:** The *Admin*. (Administrator) has special rights to enter certain meter settings and is the only one who can enter and change these settings. It is not necessary for *Admin*. identification to be activated to use the CoaguChek XS Plus meter. However, it might be desired or necessary, depending on the regulatory environment and the site of use.
- **Operator:** The *Operator ID* is assigned to persons who use the meter to run tests. If you want to use *Operator IDs*, you have several options:
 - You may use *Operator IDs* to restrict the use of the meter to qualified personnel or a predefined group of users. In this case an operator list created externally must be transferred to the meter, enabling you to select an *Operator ID* when logging in. For more details see *Data handling*.
 - You may use *Operator IDs* for informational purposes only, in order to assign stored measurement results to the users who performed the test. In this case *Operator IDs* may be entered directly on the meter (by keypad or scanner), with or without an operator list being available.
- **Patient:** The *Patient ID* is assigned to the person, whose test results are recorded. You can either:

- block input of a unique *Patient ID* (in this case, every test is simply numbered in consecutive order)
- allow a unique *Patient ID* as optional, or
- require a unique *Patient ID* for every test. Patient lists created externally can also be transferred to the meter, enabling you to select a *Patient ID* for a test from these lists. For more details see *Data handling*.

7.1 Data handling (145)

Operator IDs can be selected from a list (if available) or read by the barcode scanner on the side of the meter. If passwords were created, they **must** be entered via the onscreen keypad. *Patient IDs* can be entered by using the onscreen keypad or the barcode scanner on the side of the meter. For more information on working with operator and patient ID barcodes, see *Data handling*.

7.1 Data handling (145)



The buttons in the *ID Setup* menu show what the current settings are (this is just an example, the screen may look different on your meter):

- The standard display of the **Admin.** button means the function is available but not activated (a password for the system administrator/supervisor has not been assigned).
- The standard display of the **Operator** button means the *Operator* login is available but not activated.
- When the **Patient** button is highlighted (that is, when it has a blue background) this means the function is available and activated (either as **Optional** or **Required**).

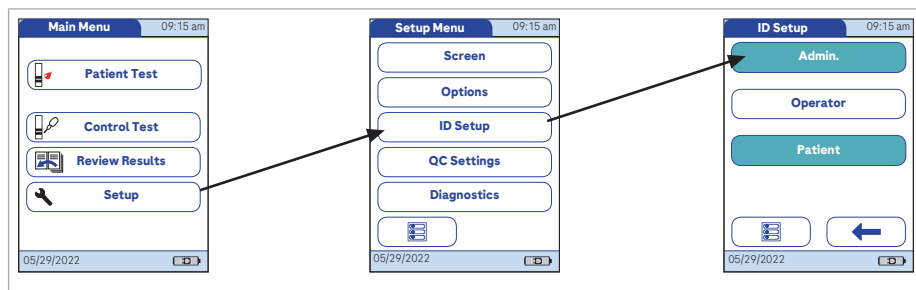
System Administrator (Admin.)

In the default setting, the meter is not protected with an *Admin.* password, and all setup options are accessible to every user. If you set up an *Admin.* password, the following setup areas are automatically reserved only for the system administrator/ supervisor (i.e., the person who knows the password).

- *Screen: Parameter Configuration, Result Confirmation, Date/Time*
- *Options: Connection* (to a computer or a printer⁽⁶⁾)
- *ID Setup* (the entire area)
- *QC Settings* (the entire area)
- *Diagnostics: Software, Hardware, Memory, Certificates*

When you enter an *Admin.* password, this password will have to be entered from this point forward before any of the settings above can be changed. The *Admin.* password must also be entered before you can delete or change the *Admin.* password itself. If you forget the *Admin.* password, contact your Roche Diagnostics representative.

▶ To configure an Admin.



- 1 From the *Main Menu*, touch **Setup** to open the meter settings.

⁽⁶⁾ The printer is not available in the U.S.

- 2 From the *Setup Menu*, touch **ID Setup**.
- 3 From the *ID Setup* menu, touch **Admin**.
- 4 Using the keypad displayed on the screen, enter the *Admin.* password of choice. The password can consist of up to 20 characters.

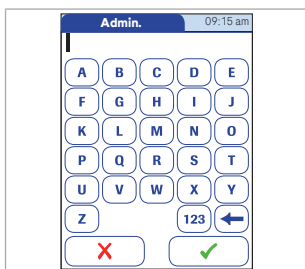


Pay close attention to the buttons you press, because the characters are not displayed on the screen. Asterisks are displayed instead (as if entering a password on a computer).

- 5 Use **123** to switch to input of numbers.
- 6 Use **ABC** to switch back to input of text.



- 7 Use **←** to backspace and correct a mistake.
- 8 Touch **✓** to save this setting, or touch **X** to exit this menu without saving any changes. The display automatically returns to the previous screen.
- 9 Enter the *Admin.* password again (the keypad is automatically displayed again on the screen) to confirm the first entry.
- 10 Touch **✓** to save this entry, (the *Admin.* password is now set), or touch **X** to exit this menu without saving any changes. The *Admin.* password is not set and is therefore still inactive.

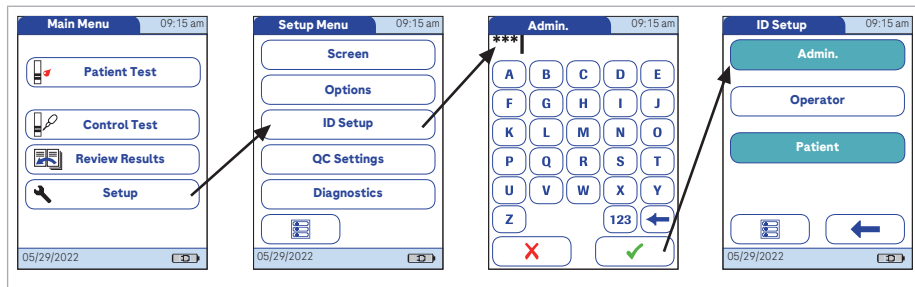


The display automatically returns to the *ID Setup* menu. After you exit the *Setup Menu*, only an

authenticated administrator may further edit the setup areas as listed before.

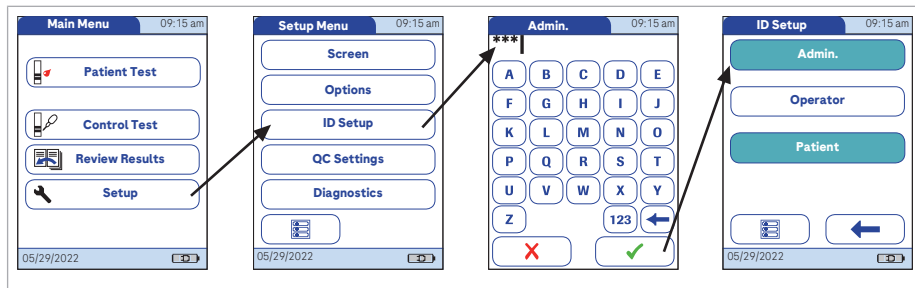
See [System Administrator \(Admin.\) \(82\)](#)

► To change an Admin.

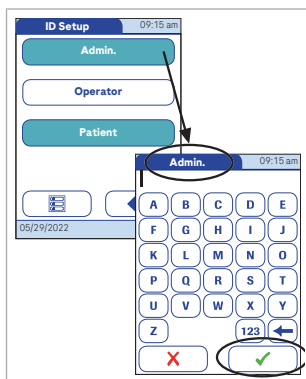


- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **ID Setup**.
- 3 Using the keypad displayed on the screen, enter the current *Admin.* password.
The *ID Setup* menu is displayed. The **Admin.** button is highlighted, which means an *Admin.* password is active.
- 4 Touch **Admin.**
- 5 Using the keypad displayed on the screen, enter (and confirm) the new *Admin.* password of choice.

► To deactivate an Admin.



- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **ID Setup**.
- 3 Using the keypad displayed on the screen, enter the current *Admin.* password.
The *ID Setup* menu is displayed. The **Admin.** button is highlighted, which means an *Admin.* password is active.
- 4 Touch **Admin.**
- 5 Immediately touch **✓** to close the keypad on the screen **without** entering a password.



The *Admin.* password has been deleted and therefore deactivated. The **Admin.** button is no longer highlighted.

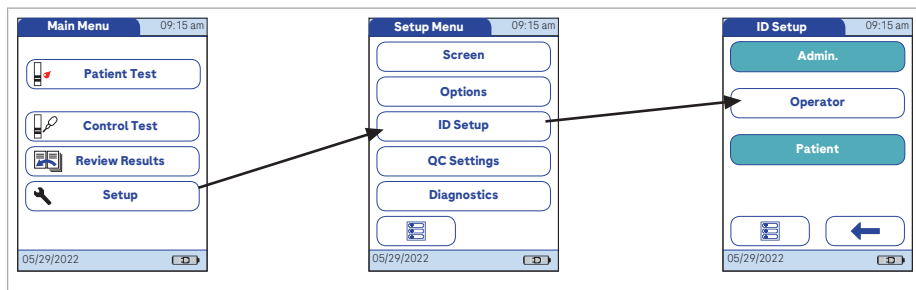
Operator ID

If you want to create a list of *Operator IDs* from which you can select an operator, additional software (a DMS) and the Handheld Base Unit are required (see *Data handling*).

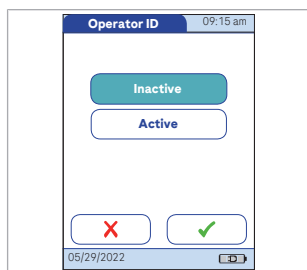
- [7.1 Data handling \(145\)](#)

In the default setting, the *Operator* login is not activated. You can either activate or deactivate *Operator* login on the meter. If activated, an *Operator* has to log in before the *Main Menu* will be displayed and measurements can be performed.

► To activate operator ID handling



- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **ID Setup**.
- 3 From the *ID Setup* menu, touch **Operator**.
- 4 Touch the button with the setting of choice for setting up the *Operator* login. Your selection is now highlighted.
- 5 Touch **✓** to save this setting, or touch **✗** to exit this menu without saving any changes. The display automatically returns to the previous screen.



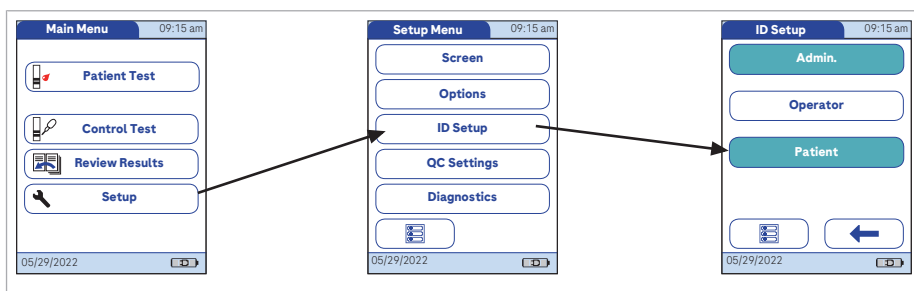
Patient ID

If you want to create a list of *Patient IDs* from which you can select a patient for testing, additional software (a DMS) and the Handheld Base Unit are required (see *Data handling*).

▣ 7.1 Data handling (145)

In the default setting, input of *Patient IDs* is set to **No**. This means each test is simply assigned a consecutive number. However, you can require that a *Patient ID* be entered or make it optional.

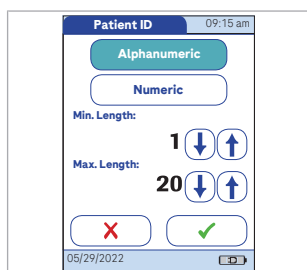
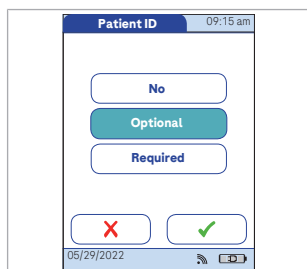
► To activate patient ID handling





- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup menu*, touch **ID Setup**.
- 3 From the *ID Setup menu*, touch **Patient**.

You may select from the following options:

- **No** (tests will be assigned numbers automatically)
- **Optional** (automatic numbering or list/scan/manual input)
- **Required** (list/scan/manual input)



4 Touch the button with the setting of choice for setting up the *Operator* login. Your selection is now highlighted.



5 Touch  to save this setting, or touch  to exit this menu, without saving any changes.



The settings for the option **No** are now completed. For the options **Optional** and **Required**, continue by selecting the input format.

6 Select the form for input of the *Patient ID*. You may select from the following options:

- **Alphanumeric**: Enter any combination of letters and numbers, e.g., “J. DOE 3378”.
- **Numeric**: Enter numbers only, e.g., “3387”.
- **Min. Length**: Enter the minimum number of characters (1 ... 20) the *Patient ID* must have.
- **Max. Length**: Enter the maximum number of characters (1 ... 20) the *Patient ID* can have.

7 Touch the button with the format of choice for the *Patient ID*. Your selection is now highlighted.

8 Touch  or  to set the number of characters (length) of choice.

9 Touch  to save this setting, or touch  to exit this menu without saving any changes. The display automatically returns to the previous screen.

3.6 QC Settings setup

The *QC Settings* menu contains options for enforcing the performance of liquid quality controls by the operator at specified intervals. It also provides the option of customizing the QC Range in accordance with applicable local guidelines.

QC Settings overview

QC Range

The QC Settings menu contains options for enforcing the performance of liquid quality controls by the operator at specified intervals. It also provides the option of customizing the QC Range in accordance with applicable local guidelines.

There are two options:

- **Default Range:** The meter displays the QC Range provided by Roche Diagnostics in the code chip.
- **Custom Range:** The option Custom Range lets the user define their own QC Range within the default range.

Lockouts (QC Lockout and Operator Lockout)

If the liquid quality control test is not performed correctly, or if the result is outside the target value range, the meter is locked from further use. The Lockout can also be set up selectively for individual operators.

A liquid quality control test must be completed successfully before the meter is available again for testing (either by the operator or in general).

The option of setting up an *Operator Lockout* is available only when operator lists are created on a DMS, stored in the meter, and Operator login is activated. These lists are only available in connection with a DMS. For more details see *Data handling*.

•  [7.1 Data handling \(145\)](#)

2 Level QC

With this option you can configure a continuous 2-level liquid quality control test, if the test has two levels. The second test will start immediately after successfully finishing the test for one level. If disabled, the meter returns to the *Main Menu* once one of the two levels has successfully been tested.

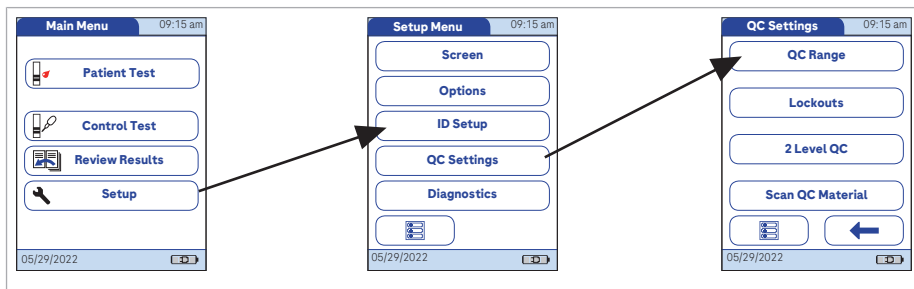
Scan QC Material

The barcode scanner of the CoaguChek XS Plus meter can be used to scan barcodes from QC material vials. This function can be set to **Optional** or **Scan Only**. When set to **Scan Only**, the operator will not be able to manually select a QC lot number from a list.

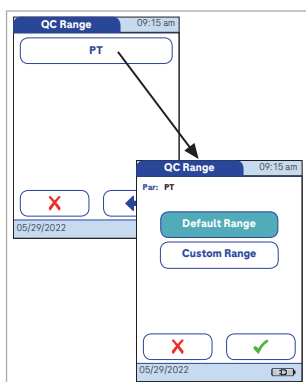
QC Range

Liquid quality control ranges can be customized to comply with local guidelines. The QC Range function enables you to narrow the default range for the test parameter.



► To set a QC range





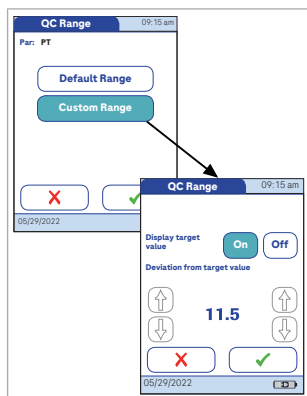
- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **QC Settings**.
- 3 From the *QC Settings* menu, touch **QC Range**.
- 4 From the *QC Range* menu, touch the button of the test parameter you wish to set (only PT available in the U.S.).



You may select from the following options:

- **Default Range** (Range provided in the code chip is selected and displayed. No target value is displayed.)
 - **Custom Range** (The allowed percentage deviation from target value can now be customized. Additionally, you can choose between displaying the target value along with a control test result or not displaying the target value with the control test result.)
- 5 Touch the button with the setting of choice. Your selection is now highlighted.
 - If you selected **Default Range**, touch  to save this setting, or touch  to exit this menu without saving any changes.

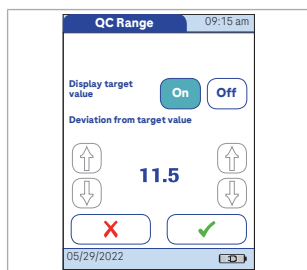
- If you selected **Custom Range**, touch  to proceed with corresponding settings, or touch  to exit this menu without saving any changes. The display automatically returns to the previous screen.



If you selected **Custom Range**, the *QC Range* screen opens and offers you the following options:



- *Display target value* (On/Off)
- *Deviation from target value* (percentage value). See [QC Range \(90\)](#).

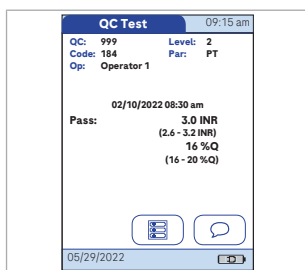
For the control solutions, the target value always comes from the information stored in the code chip. If you have chosen **Custom Range**, you can now select an allowed deviation from target value in the range of 0 to 22.5% (in the illustration, 11.5%).



- 6 Touch **On** (the target value will be displayed with a test result) or **Off** (the target value will not be displayed). Your selection is now highlighted.
- 7 Use the arrows to set the allowed percentage deviation from the target value.

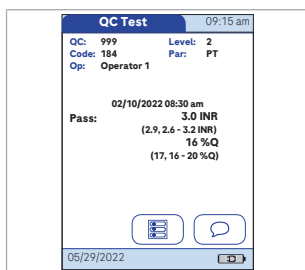
Use the arrows on the left to adjust the number before the decimal point. Use the arrows on the right to adjust the number after the decimal point.

- 8 Touch  to save this setting, or touch  to exit this menu without saving any changes. The display automatically returns to the *QC Settings* screen.



The *Custom Range* and *Target Value* (if set to *On*) appear in a line below the control test result in the QC test and QC memory screens.

In this screen the *Display target value* is set to *Off*, and only the custom range is displayed below the control test result.



In this screen the *Display target value* is set to *On* and both the custom range and the target value are displayed. The target value (here: 2.9) appears **in front of** the custom range.

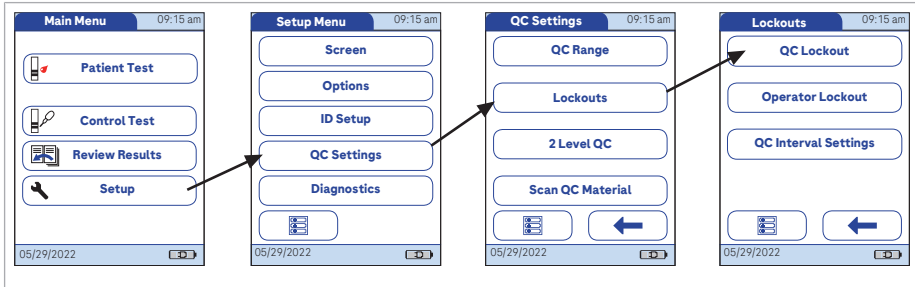
QC (quality control) Lockout

QC Lockout ensures that the optional quality control tests are run on a regular basis. This is independent of the operator, however. **This option should be used if you work without operator lists.**

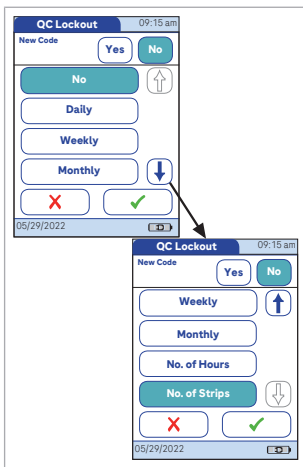
QC Lockout is disabled by default. For routine confirmation of system reliability it is recommended to enable this feature.

It is also possible to enable *Operator Lockouts* and *QC Lockouts* in parallel. In addition to defining time intervals or numbers, *QC Lockout* can also be used to specify that a quality control test must be carried out when a new test strip lot is used (**New Code**).

► To set a QC (quality control) Lockout



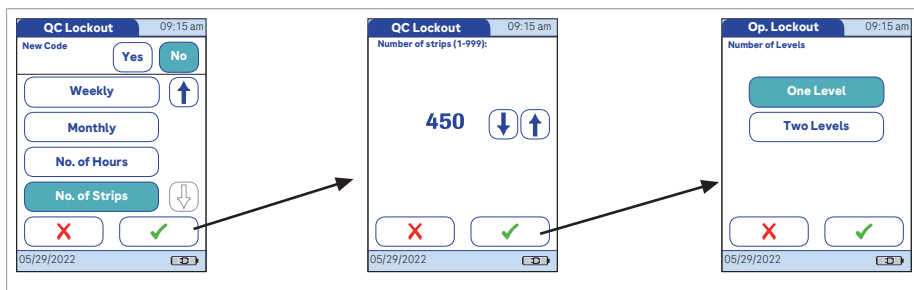
- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **QC Settings**.
- 3 From the *QC Settings* menu, touch **Lockouts**.
- 4 From the *Lockouts* menu, touch **QC Lockout**.
- 5 Select the triggers for a quality control test, based on lot and/or time or number of strips.



- 6 You may select from the following options:
 - **New Code Yes/No** (applies every time a new test strip lot is used).
The general intervals are:
 - **No**
 - **Daily**
 - **Weekly**
 - **Monthly**
 - **No. of Hours**
 - **No. of Strips**
- 7 Touch the button with your chosen option when changing the test strip lot.
- 8 Touch **↑** or **↓** to display the interval of choice on the screen.

For additional setup options of date based intervals (*Daily, Weekly, Monthly*), see [QC Interval Settings \(98\)](#).

The lockout triggers based on counters (number of hours or strips) can be reset at any time (before the counter reaches the limit) by performing a quality control test. The counter will be reset once the quality control test has successfully been finished.



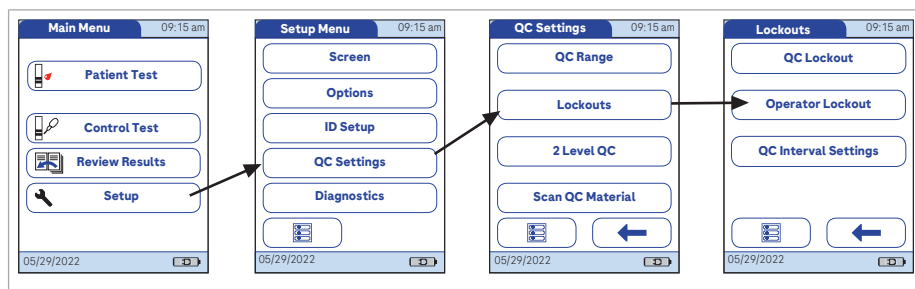
- 9 Touch the button to select the interval of your choice. Your selection is now highlighted.
- 10 Touch to proceed, or touch to exit this menu without saving any changes.
- 11 If you have selected either **No. of Hours** or **No. of Strips**, enter the corresponding number now.
- 12 Touch to proceed, or touch to exit this menu without saving any changes.
- 13 For every option except for **No.**, you must now indicate the number of levels at which the quality control must be performed.
- 14 Touch to save this setting, or touch to exit this menu without saving any changes. The display automatically returns to the previous screen.

Operator Lockout

Optional liquid quality controls can be used to ensure that an operator is performing tests properly on the CoaguChek XS Plus meter.

The *Operator Lockout* function constrains an operator, who has been set up in the list, to perform these quality controls on a regular basis.

► To set an operator lockout

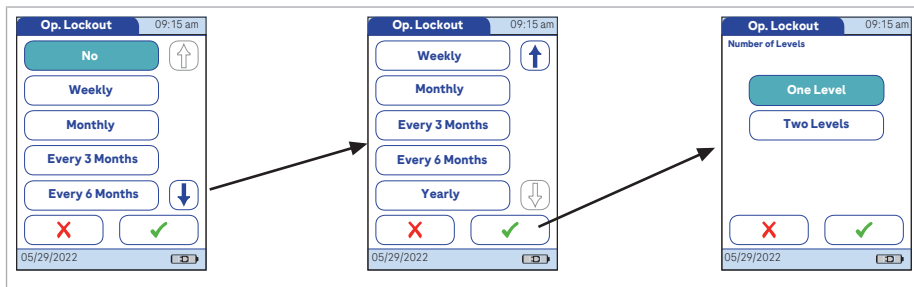








- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **QC Settings**.
- 3 From the *QC Settings* menu, touch **Lockouts**.
- 4 From the *Lockouts* menu, touch **Operator Lockout**. If this button is disabled (grayed out), either no operators have been set up or the *Operator ID* option has been deactivated.

Note: The option of setting up an *Operator Lockout* is available only when operator lists are created on the DMS. For more details see [7.1 Data handling \(145\)](#).

If you are not working with a DMS, only the *QC Lockout* is available.

See *QC (quality control) Lockout (93)*.

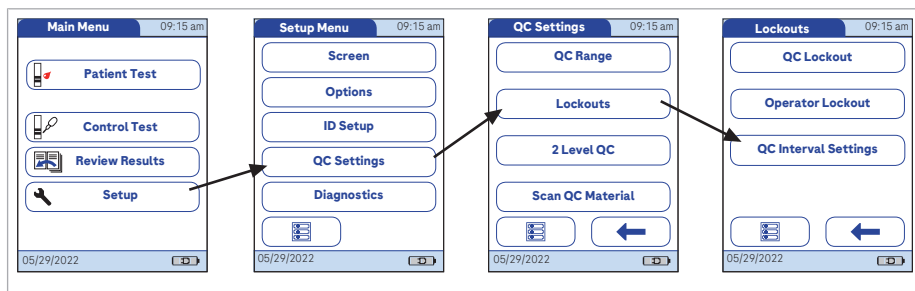


- 5 Select the interval of choice in which the mandatory quality control tests must be performed. You may select from the following options:
 - **No** (deactivated)
 - **Weekly**
 - **Monthly**
 - **Every 3 Months** or **Every 6 Months**
 - **Yearly**
- 6 Touch  or  to display the interval of choice on the screen.
- 7 Touch the button to select the interval of your choice. Your selection is now highlighted.
- 8 Touch  to proceed, or touch  to exit this menu without saving any changes.
- 9 For every option except for **No**, you must now indicate the number of levels at which the quality control must be performed.
- 10 Touch  to save this setting, or touch  to exit this menu without saving any changes. The display automatically returns to the previous screen.

QC Interval Settings

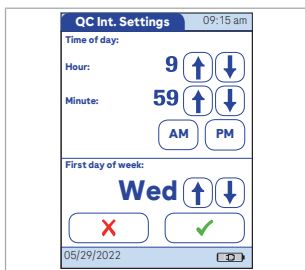
For all lockouts based on date intervals (**Daily**, **Weekly**, **Monthly**) the time of occurrence can be set, and for weekly lockouts also a preferred day of the week.





► To set the QC interval settings



- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **QC Settings**.
- 3 From the *QC Settings* menu, touch **Lockouts**.
- 4 From the *Lockouts* menu, touch **QC Interval Settings**.
- 5 Select the *Time of day* and *First day of week* for the lockout to be triggered.

The setting for *Time of day* applies to all lockouts based on date intervals. The setting for *First day of week* applies to lockouts in weekly intervals only.

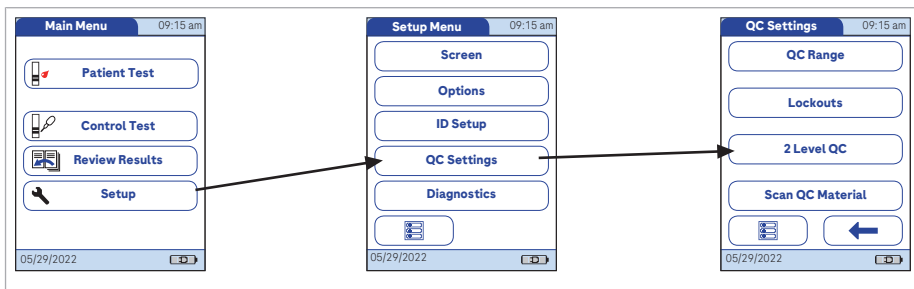


- 6 Touch  or  to enter the desired time and day.
- 7 Touch  to save this setting, or touch  to exit this menu without saving any changes. The display automatically returns to the previous screen.

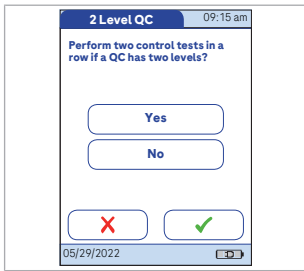
2 Level QC

With this option you can configure a continuous 2-level quality control test, if the test has two levels.

► To enable 2 level QC



- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **QC Settings**.
- 3 From the *QC Settings* menu, touch **2 Level QC**.

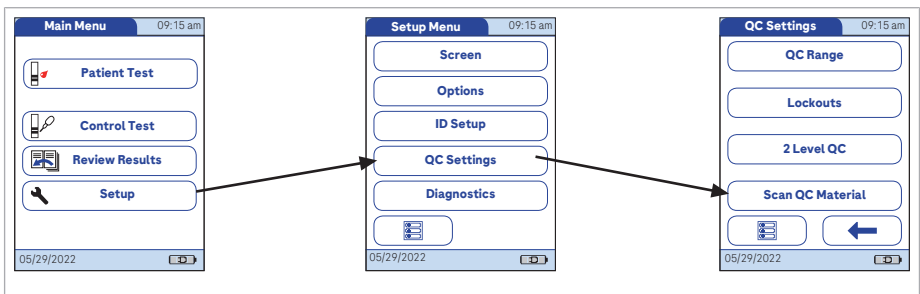


- 4 Touch **Yes** to automatically start the test for the second level once the test for one level has been finished successfully. Or touch **No** to finish the test after one level and return to the *Main Menu*. Your selection is now highlighted.
- 5 Touch **✓** to save this setting, or touch **✗** to exit this menu without saving any changes.

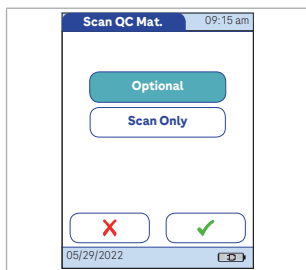
Scan QC Material



The barcode scanner of the CoaguChek XS Plus meter can be used to scan barcodes from QC material vials.

► To use the scan QC material option



- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **QC Settings**.
- 3 From the *QC Settings* menu, touch **Scan QC Material**.

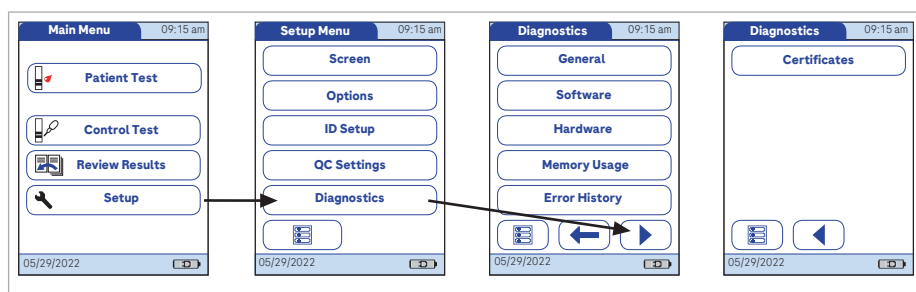


- 4 Touch **Optional** to allow manual selection of a QC lot number from a list or touch **Scan Only** to prohibit manual selection. Your selection is now highlighted.
- 5 Touch  to save this setting, or touch  to exit this menu without saving any changes.

3.7 Diagnostics

Under *Diagnostics*, you will find information about the system, such as software version, number of data records stored, and configuration details. The diagnostics screens shown here are for illustration purposes only. The Information shown on your meter may differ.


► To display the diagnostics screens



- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **Diagnostics**.
- 3 From the *Diagnostics* menu, touch the button of the diagnostics screen you want to display. Use ◀ and ▶ to toggle between the diagnostics screens.

The image displays 12 diagnostic screens from the CoaguChek XS Plus interface, arranged in a 4x3 grid. Each screen has a title bar with the screen name and a timestamp of 09:15 am on 05/29/2022. The screens are:

- General:** Shows meter name (CoaguChek XS Plus), home location (Mannheim), last synchronization (05/29/2022), last software update (05/29/2022), non-transmitted results (21), and next scheduled control test (03/12/2022 08:00 am).
- Software:** Lists build (04.05.00), boot (07.04.00), kernel (07.04.00), roots (07.04.00), app (04.05.00), MM-BL (0.82), and MM-FW (8.70).
- Hardware:** Shows serial no. (UQ76001234), HBM HW (5.20a), MM HW (03), battery voltage (3.976 V), battery percent (83), and battery condition (Good).
- Memory Usage:** Displays patient tests (1300/2000), control tests (350/500), patient list (2700/4000), operator list (1250/5000), and tests until lifetime end (11455).
- Error History:** Lists five error events with IDs like b360401c - 205 and timestamps.
- Certificates:** Provides buttons for Client Certificate, Server Certificates, Root CA Certificates, and Credential Download.
- Client:** Shows subject (CoaguChek XS Plus), validity (01.01.2022 00:00:00), and fingerprint (SHA256).
- Server:** Lists four certificates with status icons (green check, red X, red warning).
- Server (detailed):** Shows subject (DMS host), validity (01.01.2022 00:00:00), and fingerprint (SHA256).
- Root CAs:** Lists four certificates with status icons.
- Root CAs (detailed):** Shows subject (CoaguChek XS Plus), validity (01.01.2022 00:00:00), and fingerprint (SHA256).
- Cred. Download:** Instructs to place the meter in Handheld Base Unit and press the download button.

- 4 From the *Certificates* menu, touch the button of the certificates screen you want to display.
- 5 In the diagnostics screen, touch  to return to the previous menu.

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4 Testing a Blood Sample

4.1 Important notes

What you need:

- CoaguChek XS Plus meter
- CoaguChek® XS PT Test Strips with matching code chip
(see section "What can the system do for you?")

- When testing with venous blood:
 - Standard blood collection device (syringe)
- When testing with capillary blood:
 - Lancing device approved for professional use (e.g., the ACCU-CHEK® Safe-T-Pro Plus lancing device)




If you use capillaries, **do not use** glass capillary tubes or capillary tubes that contain anticoagulants.

- Cotton ball and alcohol wipe
- ▶ [What can the system do for you? \(13\)](#)

Always...

- close the strip container immediately after removing a test strip.
- operate the meter at an ambient temperature between 15 °C and 32 °C (59 °F and 90 °F). For information on operating temperatures of test strips refer to the test strip package inserts.
- place the meter on a level, stable surface (table) or hold it so it is roughly horizontal.
- follow the information on correct handling of test strips in the package insert.
- keep the test strip guide and housing clean. See also the chapter entitled "Maintenance and Care" starting with *Cleaning and disinfecting the meter*.

 Protection against infection:

- ▶ When collecting samples always observe the general precautions and guidelines relating to blood sampling.
 - ▶  [Safety information \(17\)](#)
 - ▶ Dispose of all test strips used for patient testing in accordance with the disposal policy of your laboratory or practice.
 - ▶  [Safety information \(17\)](#)
-
- ▶  [8.2 Cleaning and disinfecting the meter \(155\)](#)

Never...

- store the meter at high temperatures (above 35 °C or 95 °F) while it is in regular use.
- store the meter in damp or humid conditions without protection.
- remove or insert the code chip while the meter is performing a test.
- touch or remove the test strip during a test.
- wait more than 15 seconds after a fingerstick before applying the blood.
- fingerstick a patient with wet hands (residues of water, sweat, or alcohol).
- add more blood after the test has begun.
- perform a test with a drop of blood from a previous puncture.

 **CAUTION!****Accuracy/precision of measured results:**

Failure to comply with the above may lead to inaccurate results. An incorrect result may lead to an error in diagnosis, therefore posing danger to the patient.

Getting a good capillary blood sample

Prepare the selected blood collection site and obtain blood from the patient per facility policy.

If no facility policy exists for obtaining capillary blood, follow these recommendations:

- Have the patient wash his or her hands in warm, soapy water. Or, clean the fingertip with an alcohol wipe. Make sure the fingertip and your gloved hands are thoroughly dry.
- Warm the hand. Have the patient hold it under his or her arm or use a hand warmer. Disinfect the blood collection site on the finger. Dry thoroughly.
- Have the patient let that arm hang down by his or her side before lancing a finger.
- Gently massage the finger from its base.

Use these techniques until the fingertip has increased color.

 **WARNING!**

- ▶ Immediately after lancing, massage gently along the side of the finger to obtain a sufficiently large blood drop **without pressing or squeezing too hard**.
 - ▶ Apply the blood drop to the test strip immediately (**within 15 seconds**).
-

Getting a good result from venous whole blood

CAUTION!

Risk of false results caused by wet skin

- ▶ When washing and disinfecting the patient's finger, allow it to dry thoroughly. Residues of disinfectant on the skin can dilute the drop of blood and so produce false results.

For sample collection use a standard blood collection device. **Do not use anti-coagulants** (e.g., EDTA, citrate, fluoride, oxalate, or heparin) to collect the blood sample. Venous blood samples may be collected from a **venous line**.



If venous samples are collected by **venipuncture**, note the following:

- Use a needle at least 23 G (approx. 0.65 mm) or larger in size.

CAUTION!

- ▶ Discard the first **four drops** of blood collected (within the first 10 seconds). Then immediately apply one drop of blood (at least 8 μL) directly onto the target area of the test strip. Ensure that no air bubbles are introduced into the sample.

**Protection against infection:**

- ▶ When collecting samples always observe the general precautions and guidelines relating to blood sampling.
 - ▶  [Safety information \(17\)](#)
 - ▶ Dispose of all test strips used for patient testing in accordance with the disposal policy of your laboratory or practice.
 - ▶  [Safety information \(17\)](#)
-

4.2 Preparing to test



► To prepare to test

- 1 Have the test strip container at hand.
- 2 Make sure that the code chip supplied with these test strips is at hand.

Each box of test strips contains a code chip. The parameter, the number on the code chip and the number on the test strip container must match. A capital **S** in front of the number indicates that this code chip is for test strips. (A capital **C** in front of the number indicates that it is a control solution code chip. See Chapter 5, starting with *Control testing*).

See [5.1 Control testing \(125\)](#)

3 Test strip code chip

The code chip provides the meter with important information that it needs to perform the coagulation test. The chip contains information about the test method, the lot number, and the expiration date. The code chip is required, whenever a new test strip lot is used, so that the meter can read and store the lot information about that particular lot of test strips.

The CoaguChek XS Plus meter stores the data from up to 60 test strip code chips that have been inserted.

- Do not forget to use the test strip code chip that is supplied with each pack of test strips before you perform the first test with these strips. We recommend that you leave the code chip in the meter to protect the electrical contacts in the meter from becoming dirty.

- Each code chip belongs to a particular lot of test strips. Only remove the code chip when you are testing with test strips taken from a new pack.
- Protect the code chip from moisture and equipment that produces magnetic fields.

► **To insert the code chip**



- 1** Remove the old code chip, if one is inserted in the meter.



- 2** Check that the number on the code chip matches the number on the label of the test strip container.



- 3 Slide the new code chip into the code chip slot (as shown) until you feel it snap into place.

If the code chip is missing or incorrectly inserted, a corresponding error message appears in the display. See [Chapter 9.1 Status / Error messages \(169\)](#)

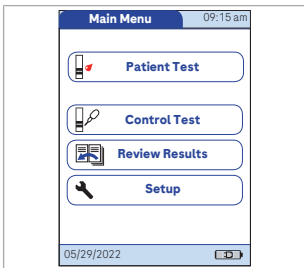
▶ To power on the meter



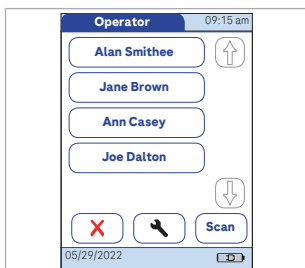
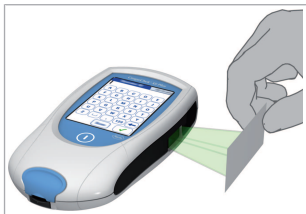
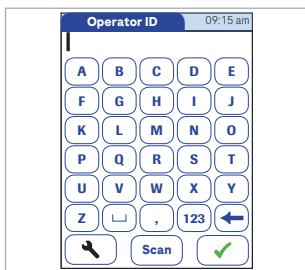
- 1 Place the meter on a level, vibration-free surface, or hold it in your hand so it is roughly horizontal.
- 2 Power the meter on by pressing **⏻**.


You can also power on the meter directly by inserting a test strip or connecting the power adapter.

- The next steps depend on whether you work with the function *Operator ID* set to inactive or active. See [7.1 Data handling \(145\)](#).



- 3 If the function *Operator ID* is inactive, wait until the *Main Menu* is displayed.



- 4 If the function *Operator ID* is active, **without operator list**, you are now prompted to enter an *Operator ID*.⁽⁷⁾
 - Enter the *Operator ID* **using the keypad**. Touch  to move to the next screen.

- 5 Alternatively, the *Operator ID* can also be entered **using the built-in barcode scanner**.^{(8),(9)} Touch Scan and scan the operator barcode from a distance of approx. 10-20 cm (4-8 inches), according to the barcode size. **Keep the scanner in this position without moving it.** The meter beeps once the barcode has been read successfully. The barcode information appears in the operator ID field. The scanner turns off after 10 seconds, if a barcode is not scanned.

- 6 If the function Operator ID is active, **with operator list**, wait until the operator list is displayed.

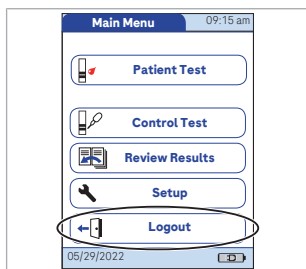
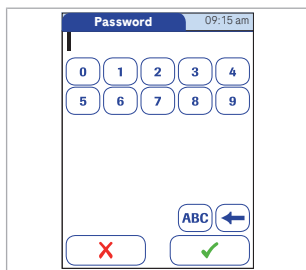
- 7 Select the operator of choice by touching the corresponding button or touch **Scan** to scan an operator barcode.



Note: Scanned operator IDs must also be on the list. Otherwise the login attempt will fail and an error message will be displayed.

⁽⁷⁾ For configuring operator and patient IDs, see (149) [Configuring operator and patient IDs](#).

⁽⁸⁾ A list of supported barcode symbologies can be found in (206) [A.2 Example of barcode symbologies](#).

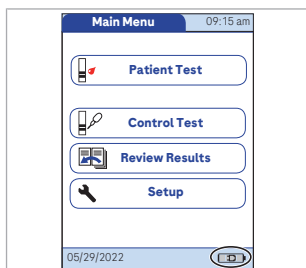
⁽⁹⁾ A list of supported characters can be found in (210) [A.3 Supported characters in 2D barcodes](#).



- 8 Enter the (optional) password.
- 9 After you enter the password, touch  to log on. The *Main Menu* is displayed and you can start the test.
- 10 When you touch , the operator pick list is displayed again.
- 11 When the tests are completed or another operator wants to perform additional tests, touch **Logout** to log out (this button is available only when the *Operator ID* is activated). The meter returns to the display of the operator pick list.
- 12 **Note:** Extended data handling functionality and operator login options are dependent on the capabilities of the particular DMS being used and may vary. For more details see [7.1 Data handling \(145\)](#).

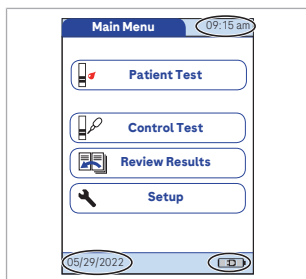
4.3 Performing a test

► To perform a test



- 1 Check the battery level.
 - If the battery icon turns red (**one bar remaining**), there may not be enough power remaining for another test.
 - If there are **no bars** remaining in the battery icon, you cannot perform any more tests. Power the meter off by pressing **1**.

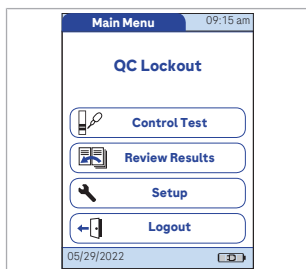
In both cases, restore power by recharging the battery pack, or using the power adapter.



- 2 Check that the date and time are correct. Correct any wrong entries as described in Chapter 3, *Meter Setup*.

[To set the date \(65\)](#)

[To set the time \(66\)](#)



- 3 If a lockout (*Operator* or *QC Lockout*) is displayed instead of the **Patient Test** button, you must run a liquid quality control test before you can perform a patient test. See Chapter 5, *Control and Proficiency Testing* starting with [5.1 Control testing \(125\)](#).

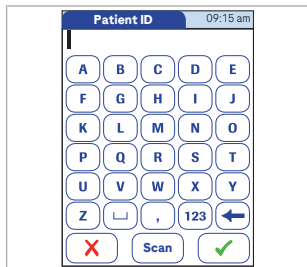
When the meter is in lockout status, a patient test cannot be performed.

See [Patient ID \(87\)](#)

The next steps depend on whether you work **with** or **without** patient lists.



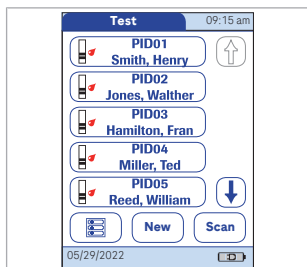
- 4 **With** patient list go to step 6.
Without patient list, touch **Patient Test**.



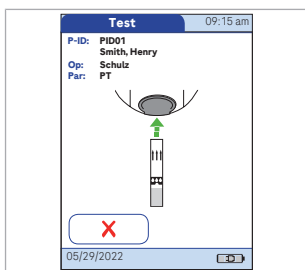
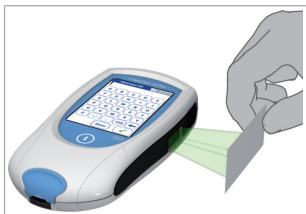
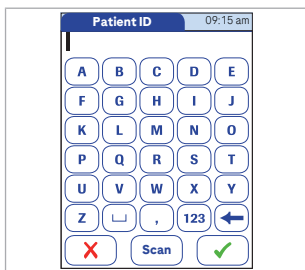
- 5 If the *Patient ID* option was chosen as either *Optional* or *Required* when the meter was set up, you are prompted to enter a *Patient ID*. See 3.1 Display of screen elements (53) / Patient ID (87)
- If *Required*, enter the *Patient ID*, then touch ✓ to move to the next screen.
 - If *Optional*, ignore the prompt and touch ✓ to move to the next screen. The meter will assign the test a consecutive number.
 - If neither option was chosen, a screen appears that prompts you to insert a test strip.
 - Continue with the Step 8.



- 6 **With** patient list, touch **Patient Test**.



- 7 Touch ↑ and ↓ to display the entry of choice. Select the patient to be tested from the list. If the patient is not in the list, touch **New** to create a new entry.



- 8 If you have touched **New** in the previous step, you must now enter a *Patient ID* **using the keypad**.

Note: Extended data handling functionality and patient ID entry options are dependent on the capabilities of the particular DMS being used and may vary. For more details see [7.1 Data handling \(145\)](#).

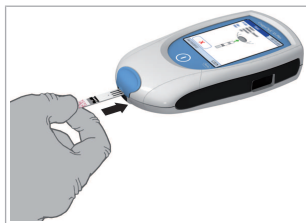
- 9 Alternatively, the *Patient ID* can also be entered **using the built-in barcode scanner**.^{(10),(11)} Touch **Scan** and scan the patient barcode from a distance of approx. 10-20 cm (4-8 inches), according to the barcode size. **Keep the scanner in this position without moving it.** Always make sure that the entire barcode is covered by the green light beam when scanning.
- The meter beeps once the barcode has been read successfully.
 - The barcode information appears in the patient ID field. The scanner turns off after 10 seconds, if a barcode is not scanned.

- 10 The test strip icon prompts you to insert a test strip. Remove a test strip from its container and close the container again with the stopper.

Exposure to external influences (such as humidity) may deteriorate the test strips and may lead to error messages. **Therefore, always close the strip container immediately after removing a test strip.**

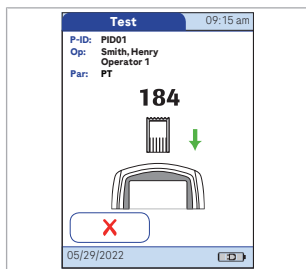
⁽¹⁰⁾ A list of supported barcode symbologies can be found in [\(206\) A.2 Example of barcode symbologies](#).

⁽¹¹⁾ A list of supported characters can be found in [\(210\) A.3 Supported characters in 2D barcodes](#).

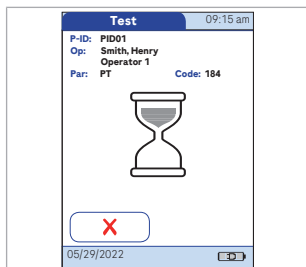


- 11** Hold the test strip so the lettering with the test name is facing upward.
- 12** Slide the test strip into the test strip guide in the direction indicated by the arrows. Slide the test strip in as far as it will go.

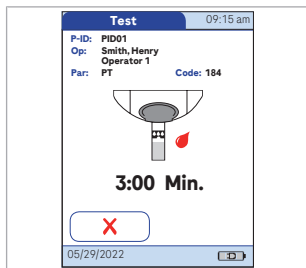
A beep indicates that the meter has detected the test strip (provided the beeper is enabled).



If you use a new test strip lot and have not inserted the code chip yet, you must do so now. Otherwise you cannot perform a test. The meter displays the number of the code chip belonging to the new test strip lot. Depending on the setting, you may also be required to run a liquid quality control test at this point.



The hourglass icon shows that the test strip is warming up. When the warming-up process is complete, a further beep (provided the beeper is enabled) indicates that you can now apply blood.

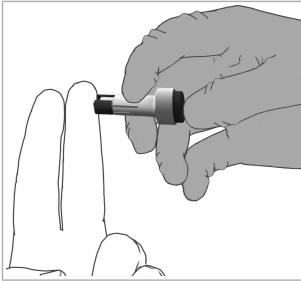


The blood drop icon flashes to indicate that the meter is ready to perform the test and is waiting for blood to be applied.

- 13** A countdown begins. You must apply the drop of blood to the test strip before the countdown ends. Otherwise you will receive an error message.

When the test is running, no operator action is required. The display dims to save energy.

► To apply blood from the fingertip



WARNING!

Use only a lancing device that is approved for use by healthcare professionals, such as the ACCU-CHEK® Safe-T-Pro Plus lancing device. Follow the manufacturer's instructions.

- 1 Now lance the side of a fingertip with the lancing device.

We recommend obtaining the capillary blood from the side of the fingertip as this causes the least pain.



- 2 CAUTION! Massage the lanced finger gently until a drop of blood is formed. **Do not press or squeeze the finger.** Apply the **first drop** of blood from the finger.

Apply the blood directly from the finger to the semicircular, transparent sample application area on top of the test strip.

Or you can touch the blood drop against the side of the sample application area. The test strip draws up the blood by capillary action. During this process you must hold the blood drop to the test strip until the flashing blood drop icon is no longer displayed and the meter beeps (provided the beeper is enabled).

Apply the blood drop to the test strip within **15 seconds** of lancing the fingertip. Applying blood after this period of time may lead to an erroneous result (as the coagulation process would already have started).

When applied from above, the blood must cover the entire sample application area.

► To apply blood with a syringe

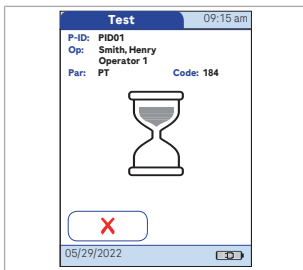
- 1 CAUTION! Discard the **first four** drops of blood collected (within the first 10 seconds).
- 2 Immediately apply one drop of blood (at least 8 μL , but not more than 20 μL) directly onto the target area of the test strip. Ensure that no air bubbles are introduced into the sample.



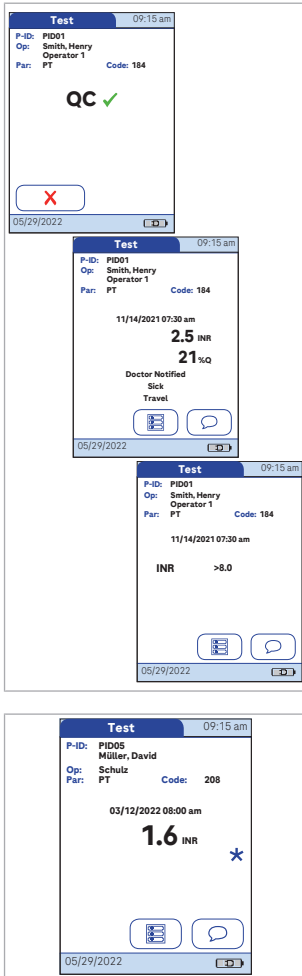
If too much blood has been applied (> 20 μL) the exterior of the meter and the test strip guide should be cleaned and disinfected.

For additional information on sample collection see [Getting a good result from venous whole blood \(108\)](#).

You hear a beep tone when you have applied enough blood (provided the *Beeper* is enabled). The blood drop symbol disappears and the test starts.



Do not add more blood sample. To avoid error messages do not touch the test strip until the result is displayed.



The meter performs an automatic quality control test on the test strip before it displays the test result. “QC” appears in the display.

Following a successful outcome of the quality control test, a checkmark appears after “QC.”

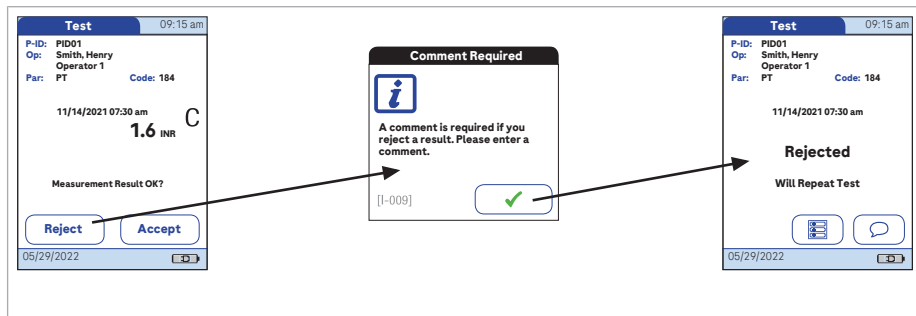
The result is displayed in the unit you chose when setting up the meter. It is automatically saved.

For information on the valid measuring ranges for CoaguChek® XS PT test strips refer to the package insert of the respective test strip.

- 3 Results that are above or below the measuring range are indicated by the symbols > (above) or < (below).
 - **If a “C” is displayed along with the result:** This may occur if the hematocrit value is very low or due to erroneous blood collection (e.g., wet hands). Repeat the test. If using capillary blood, make sure that the patient’s hands are dry. If the “C” display persists, perform a hematocrit check.
 - **If a “✱” is displayed along with the result:** This indicates that the test result is out of normal range. Touch the ✱ icon to display the *Out Of Normal Range* information screen.

When interpreting results, refer to the detailed information on limitations and interferences included in the limitations section of the test strip package insert.

► To accept/reject a test result



- 1 If this function is enabled, you may choose to accept or reject a test result. When the result is displayed, touch
 - **Reject** or
 - **Accept**
- 2 If you reject a result, you must enter a comment with an explanation.
If you reject the result, this test result is no longer displayed. However, the test entry is stored.

If a “C” is displayed along with the result:

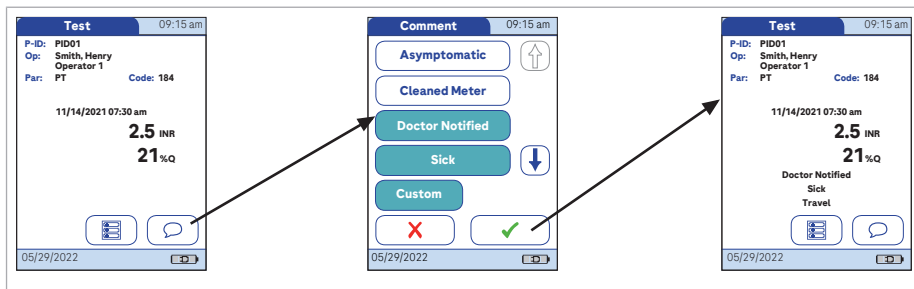
This may occur if the hematocrit value is very low or due to erroneous blood collection (e.g., wet hands). Repeat the test. If using capillary blood, make sure that the patient's hands are dry. If the message persists, perform a hematocrit check.


If a “X” is displayed along with the result:

The range settings can only be set and enabled using a DMS.


► To add comments


You can add up to three comments to a test result. Comments can provide, for example, additional information about the test conditions or the patient. A comment may be up to 20 characters in length. You can open the function for adding comments directly in the results screen.



- 1 To add comments:
In the *Test* screen, touch .

If you want to add a comment, do not remove the test strip. Once the strip is removed, the meter automatically returns to *Main Menu* and a comment can no longer be added.

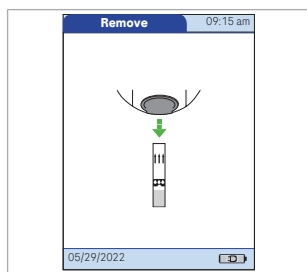
- 2 Select the desired predefined comment(s) from the display list (if configured) or
- 3 Touch **Custom** to enter your own custom comment. Use the keypad (as with login) to enter your comment.
- 4 Once you have selected the desired comment(s), touch  to return to the results screen.


 The printer⁽¹²⁾ icon only appears if the printer function is activated. Otherwise it is not displayed.

Test results are also saved when the meter is powered off in the results screen or automatically powers off.

► To finish the test

CAUTION! Protection against infection: When collecting samples always observe the general precautions and guidelines relating to blood sampling. Dispose of all test strips used for patient testing in accordance with the disposal policy of your laboratory or practice.



- 1 After the test result is displayed, touch . You will be prompted to remove the strip.
- 2 Remove the test strip from the meter.
 - [Safety information \(17\)](#)
- 3 Power the meter off.
- 4 Clean the meter if necessary.
See Chapter 8, *Maintenance and Care* starting with [8.2 Cleaning and disinfecting the meter \(155\)](#)

⁽¹²⁾ The printer is not available in the U.S.

5 Control and Proficiency Testing

5.1 Control testing

The CoaguChek XS Plus meter has a number of built-in quality control functions:

- A check of the electronic components and functions every time the meter is powered on.
- A check of the test strip temperature while a test is in progress.
- A check of the expiration date and lot information on the test strip carried out by the code chip.
- An onboard quality control within every single test strip.

Roche Diagnostics offers liquid quality controls for the CoaguChek XS Plus system. These controls are designed to assist you in meeting regulatory compliance requirements at your facility.

To perform an optional liquid quality control test using control solutions, you need:

- CoaguChek XS Plus meter.
- The test strip code chip supplied with the test strip container you are using (a code chip is provided with every test strip pack).
- Test strips that came with the code chip mentioned above.
- Bottles of CoaguChek® XS Pro PT Controls, diluent droppers, and the quality control code chip provided.

You can choose the frequency of liquid quality control tests in the meter setup (see Chapter 3, *Meter Setup, QC (quality control) Lockout*). If the control results in the display are in the specified range, this confirms that the liquid control test was performed correctly.

5.2 Preparing to perform a liquid quality control test

Prepare for a liquid quality control test in the same way you would prepare to perform a test with a capillary blood sample. The only difference is the use of control solution instead of blood.

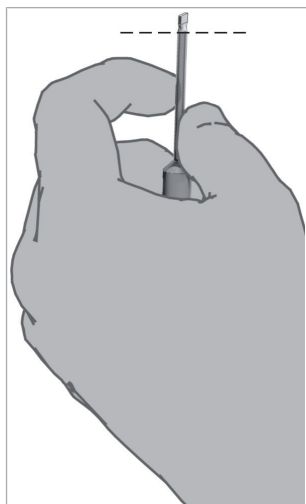
► To prepare for a liquid quality control test

- 1 Have the test strip container at hand.
- 2 If you are using the test strip lot for the first time, make sure that the code chip that came with these test strips is at hand.
- 3 Make sure the bottle of freeze-dried (lyophilized) control plasma and the dropper for making the control solution are at hand. Always refer to package inserts for information on the specified operating conditions.





- 4 Make sure that the quality control code chip that came with the control solution is at hand.
- 5 Open the lid of the bottle and remove the rubber cap.



- 6 Hold the dropper with the sealed dropper neck pointing upward, then cut off the end of the seal with scissors. Do not hold the dropper close to your face.

To avoid loss of diluent, hold the dropper by the stem; do not squeeze the bulb of the dropper while cutting the tip.



- 7 Apply gentle pressure to the reservoir to transfer the entire contents of the dropper to the bottle. Make sure that the dropper does not come into contact with the dried control plasma.
- 8 Close the bottle again.
- 9 Make sure the dropper is at hand for the next steps in the liquid quality control test.



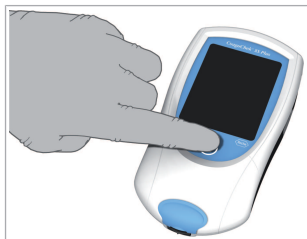
- 10 Swirl the bottle using a circular motion to completely dissolve all of the control plasma inside. **Do not shake the bottle or turn it on its side.** Doing so can cause components in the control plasma to stick to the sides of the bottle. Please refer to the control solution package insert.

The control solution is now ready to be applied to the test strip.

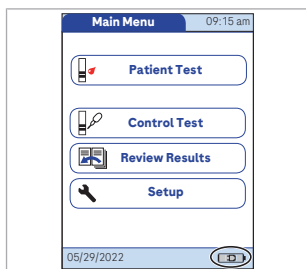
For further information refer to the respective package insert(s).

5.3 Performing a liquid quality control test

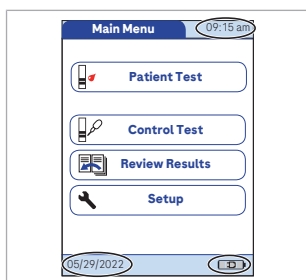
► To perform a liquid quality control test



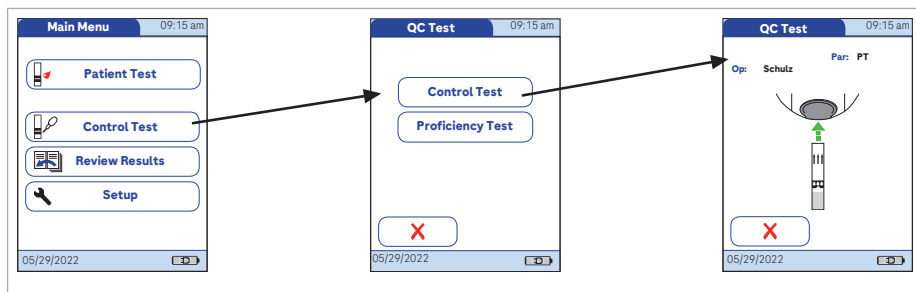
- 1 Place the meter on a level, vibration-free surface or hold it in your hand so it is roughly horizontal.
- 2 Power the meter on by pressing **I**. You can also power on the meter directly by inserting a test strip or connecting the power adapter.
- 3 Wait until the Main Menu is displayed, or log on as described in [To power on the meter \(112\)](#).
- 4 Check the battery level.
 - If the battery icon turns red (**one bar remaining**), there may not be enough power remaining for another test.
 - If there are **no bars** remaining in the battery icon, you cannot perform any more tests. Power the meter off by pressing **I**.



In both cases, restore power by recharging the battery pack, or using the power adapter.



- 5 Check that the date and time are correct. Correct any wrong entries as described in Chapter 3, *Meter Setup*.
 - [To set the date \(65\)](#)
 - [To set the time \(66\)](#)



- 6 Touch **Control Test**.
- 7 In the *QC Test* menu, touch **Control Test** again.
- 8 The test strip icon prompts you to insert a test strip. Remove a test strip from its container and close the container again with the stopper.

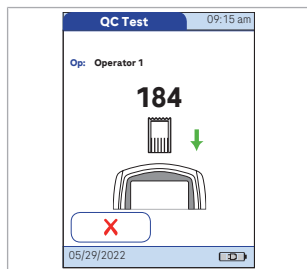
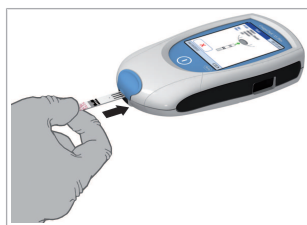
Exposure to external influences (such as humidity) may deteriorate the test strips and may lead to error messages. Therefore, always close the test strip container immediately after removing a test strip.

- 9 Hold the test strip so the lettering with the test name is facing upward.
- 10 Insert the test strip into the test strip guide in the direction indicated by the arrows. Slide the test strip in as far as it will go.

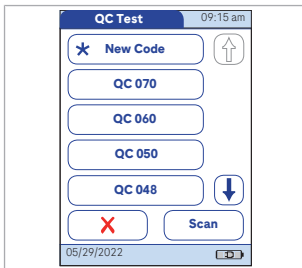
A beep indicates that the meter has detected the test strip (provided the beeper is enabled).

- 11 If you are using a new test strip lot and have not inserted the test strip code chip yet, you must do so now. Otherwise you cannot perform a quality control test.

As with the test strips, a quality control code chip is also provided with the control solutions. This chip informs the meter about the acceptable ranges of



results for that lot of controls. The information on the code chip is retained in the memory so you can use the same control solutions at any time.

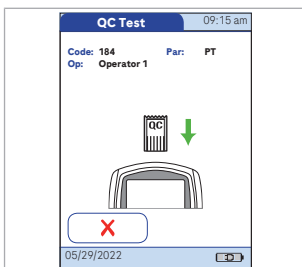


- 12** Select the code stored for your current control solution or touch **New Code** to use a new control solution.

When entering or selecting a code manually, make sure it matches the code printed on the bottle of the control solution.

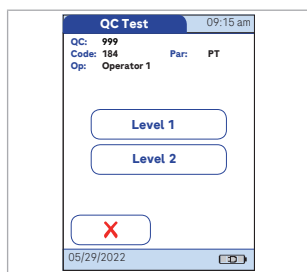
- 13** Alternatively, the control solution code can also be entered **using the built-in barcode scanner**. Touch **Scan** and scan the barcode on the label from a distance of approx. 10 cm (4 inches). **Keep the scanner in this position without moving it.** Always make sure that the entire barcode is covered by the green light beam when scanning.

The meter beeps once the barcode has been read successfully. The barcode information appears in the code field. The scanner turns off after 10 seconds, if a barcode is not scanned.

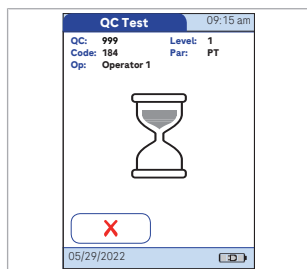


- 14** If you are using a new control solution, remove the strip code chip from the meter and insert the code chip that came with the control solution instead.

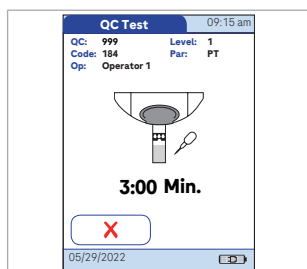
If the code chips get mixed up, check the letter on the code chips to tell them apart. A capital **S** in front of the number indicates that this code chip is for test strips. A capital **C** in front of the number indicates that it is a control solution code chip.



- 15** If performing more than one level, select the level for this measurement.

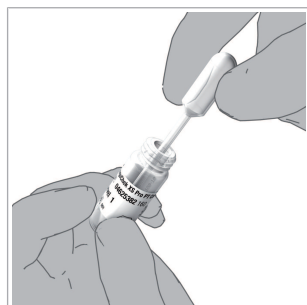


The hourglass icon shows that the test strip is warming up. When the warming-up process is complete, a further beep (provided the beeper is enabled) indicates that you can now apply the control solution.

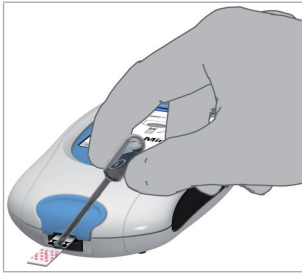


The dropper icon flashes to indicate that the meter is ready to perform the test and is waiting for the sample to be applied.

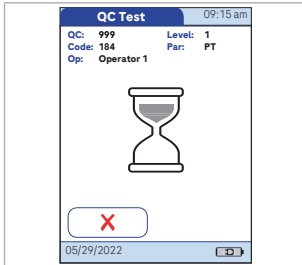
At the same time a countdown begins. You must apply the sample within the displayed time, otherwise you will receive an error message.



- 16** Using the dropper, draw up the dissolved contents of the bottle.

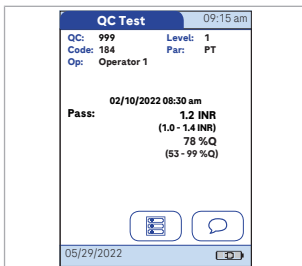


- 17** Apply a single drop of control solution directly from the dropper to the semicircular, transparent sample application area on top of the test strip. Do not add more control solution.

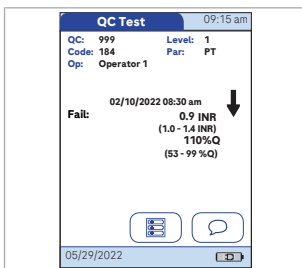


You hear a beep when you have applied enough control solution (provided the beeper is enabled). The dropper icon disappears and the test starts.


The result of the liquid quality control test is displayed. It is automatically saved to memory.



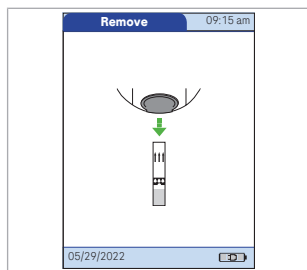
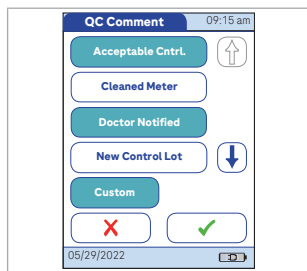
The acceptable range of results for the liquid control is displayed below the current result, along with *Pass* or *Fail*.






Note: The arrow (next to the result) refers to the INR result only.

 The printer⁽¹³⁾ icon only appears if the printer function is activated. Otherwise it is not displayed.

⁽¹³⁾ The printer is not available in the U.S.



- 18 If you want to add a comment, touch .
- 19 Select the desired predefined comment(s) from the pick list (if configured) or
- 20 Touch **Custom** to enter your own custom comment. Use the keypad (as with login) to enter your comment. A comment may be up to 20 characters in length.
- 21 Once you have selected the desired comment(s), touch  to return to the results screen. After the test result is displayed, touch . You will be prompted to remove the strip.
- 22 Remove the test strip from the meter.

If you are performing a 2-level control and the 2 Level QC function is enabled, you will now be asked to insert a new strip to proceed with the second level. Otherwise the meter returns to the *Main Menu*.

- 23 Power the meter off.
- 24 Remove the quality control code chip from the meter and store it with the controls.
- 25 Clean the meter if necessary (see Chapter 8, *Maintenance and Care* starting with [8.2 Cleaning and disinfecting the meter \(155\)](#)).
- 26 CAUTION! Dispose of controls and used test strips from control testing in accordance with the disposal policy of your facility. The control solution contains animal material, which should be considered as potentially infectious.

5.4 Proficiency testing

Observe the applicable regulations and directives of the responsible regulatory agencies when performing proficiency tests.

Proficiency tests are performed on samples whose values are unknown to the operator performing the test. These samples are provided by an external source, and the results should be forwarded to the appropriate source after completing the test. The samples supplied are treated in the same manner as regular patient samples.

Proficiency testing provides another means of verifying that your technique, reagents, system, and testing performance are as they should be. Some regulatory agencies require that these proficiency samples be tested as part of an institution's quality assurance program before an institution can be certified.

When using a DMS for configuration, it is possible to partially or fully disable the functions described in this chapter. In this case, the corresponding selection screen does not appear (after you touch **Control Test**).

5.5 Preparing to perform a proficiency test

You prepare for a proficiency test in the same way you would prepare to perform a test with a capillary blood sample. The only difference is the use of the proficiency sample supplied instead of blood from a patient.

To perform a proficiency test you need the following:

- The information of at least one code chip for test strips must be stored in the meter and must match the lot number of the test strips used.
- The correct test strips must be available.
- The proficiency sample must be available.

If you are using the test strip lot for the first time, make sure that the code chip supplied with these test strips is at hand.

5.6 Performing a proficiency test

► To perform a proficiency test

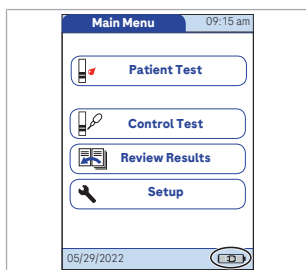
- 1 Place the meter on a level, vibration-free surface or hold it in your hand so it is roughly horizontal.



- 2 Power the meter on by pressing **I**.

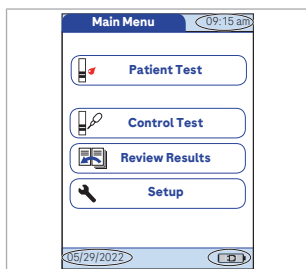
You can also power the meter on directly by inserting a test strip or connecting the power adapter.

- 3 Wait until the Main Menu is displayed, or log on as described in [To power on the meter \(112\)](#).



- 4 Check the battery level.
 - If the battery icon turns red (**one bar remaining**), there may not be enough power remaining for another test.
 - If there are **no bars** remaining in the battery icon, you cannot perform any more tests. Power the meter off by pressing **I**.

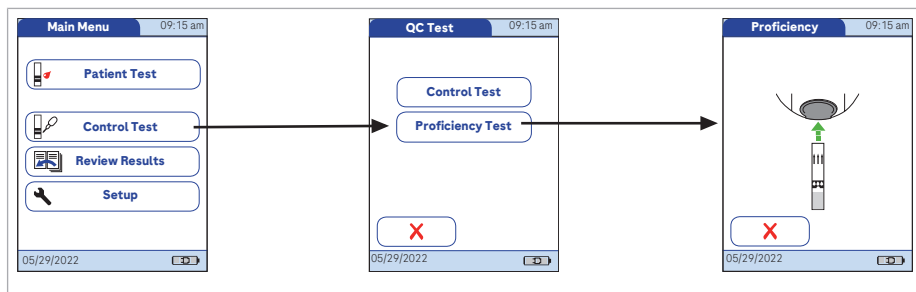
In both cases, restore power by recharging the battery pack, or using the power adapter.



- 5 Check that the date and time are correct. Correct any wrong entries as described in Chapter 3, *Meter Setup*.

[To set the time \(66\)](#)

[To set the date \(65\)](#).



- 6 Touch **Control Test**.
- 7 Touch **Proficiency Test**.

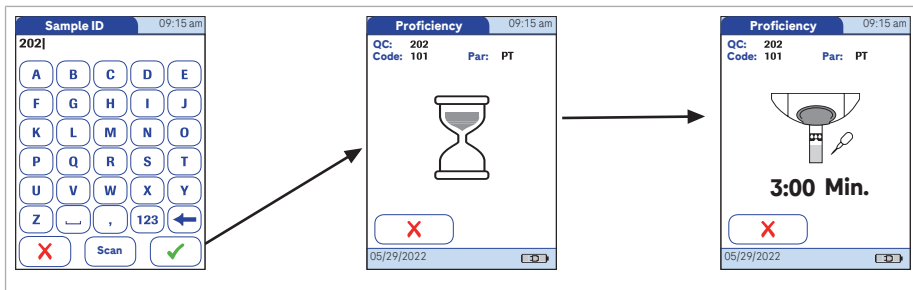
For proficiency testing, the test parameter information is read from the test strip.

- 8 The test strip icon prompts you to insert a test strip. Remove a test strip from its container and close the container again with the stopper.

Exposure to external influences (such as humidity) may deteriorate the test strips and may lead to error messages. Therefore, always close the test strip container immediately after removing a test strip.

- 9 Hold the test strip so the lettering with the test name is facing upward.
- 10 Slide the test strip into the test strip guide in the direction indicated by the arrows. Slide the test strip in as far as it will go.

A beep indicates that the meter has detected the test strip (provided the beeper is enabled).

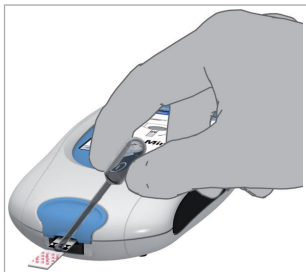


11 Enter or scan the sample ID.

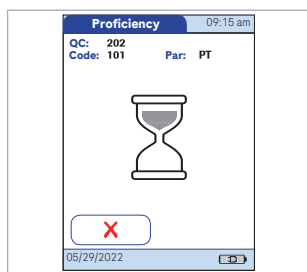
The hourglass icon shows that the test strip is warming up. When the warming-up process is complete, a further beep (provided the beeper is enabled) indicates that you can now apply the proficiency sample.

The dropper icon flashes to indicate that the meter is ready to perform the test and is waiting for the sample to be applied.

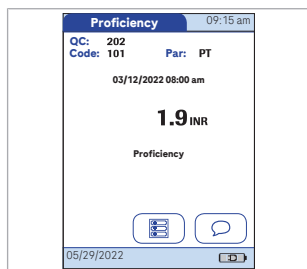
A countdown begins at the same time. You must apply the sample within the displayed time or an error message will be displayed.





12 Apply a single drop of the sample directly from the dropper to the semicircular, transparent sample application area on top of the test strip. Do not add more of the sample.



You hear a beep when you have applied enough of the sample (provided the beeper is enabled). The dropper icon disappears and the test starts.



- 13** The result of the proficiency test is displayed, the comment *Proficiency* is automatically added. If you want to add further comments, touch . The test result is automatically saved to memory.

After the test result is displayed, touch . You will be prompted to remove the strip.

- 14** CAUTION! Dispose of used test strips from proficiency testing in accordance with the disposal policy of your facility.

Remove the test strip from the meter.

- 15** Power the meter off.

- 16** Clean the meter if this becomes necessary (see Chapter 8, *Maintenance and Care*, starting with [8.2 Cleaning and disinfecting the meter \(155\)](#)).

6 Review Results (Memory)


The CoaguChek XS Plus meter can save 2000 patient test results as well as 500 liquid quality control tests to memory, together with respective time and date. In addition, up to 120 code chip records (contents of 60 test strip code chips and 60 control solution code chips) are stored. If you are using operator and/or patient lists, a maximum of 5000 *Operator* and 4000 *Patient IDs* is allowed.

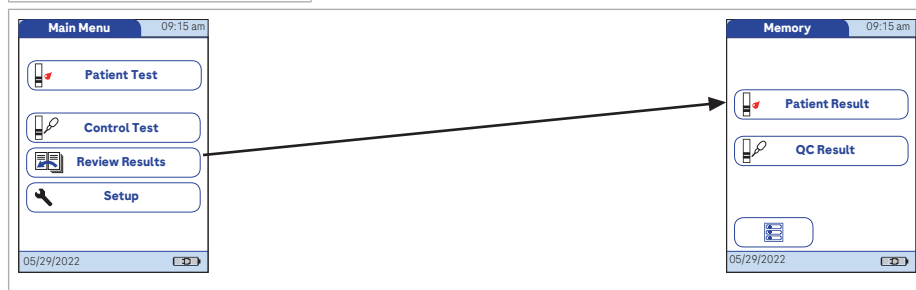
If the memory is full when you perform a test, the oldest result is automatically deleted. The most recent result is always saved. This applies both to patient results and to quality control tests. In order to avoid the loss of stored test results, you can archive this data using a DMS and the optional Handheld Base Unit.

•  [7.1 Data handling \(145\)](#)

6.1 Viewing test results

▶ To view test results




- 1 Place the meter on a level, vibration-free surface, or hold it in your hand so it is roughly horizontal.
- 2 Power the meter on by pressing .




- 3 Wait until the main menu is displayed.
- 4 Touch **Review Results**
- 5 Select the type of results you want to view.
 - Display **Patient Result** memory
 - Display **QC Result** memory.

▶ Buttons used for displaying results

The following buttons for general use are located in the views described below:

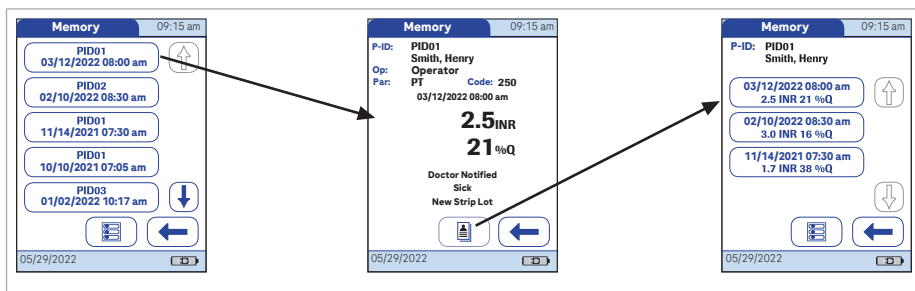
-  *Menu* icon: Return to main menu.
-  *Return* icon: From the single-result display, return to the list of results.
-  *Individual* icon: List that contains entries for this patient only.




-  *Printer* icon: The printer icon only appears if the printer function is activated. Otherwise it is not displayed.

► To display the patient result memory

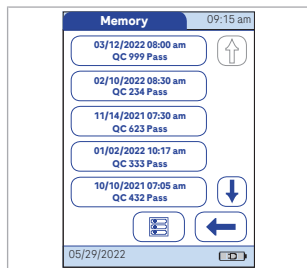
This memory area contains all patient test results. They are sorted according to the order you defined for the option *Sort*. If the *Sort* option is set to *Date/Time*, the most recent results are at the top of the list.

See [To set the sorting order of lists \(69\)](#)

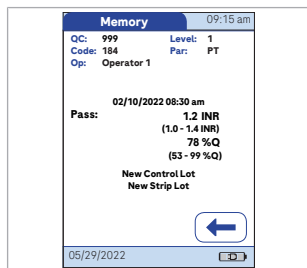




- 1 Touch  or  to scroll to the entry of choice on the screen.
- 2 Touch the entry you want to open. The entry is displayed.
- 3 Touch . The results for the selected patient are displayed.

► To display the QC (quality control) result memory



This memory area contains all liquid quality control tests that were run, sorted chronologically. The most recent results are at the top of the list.



- 1 Touch  or  to scroll to the entry of choice on the screen.
- 2 Touch the entry you want to open.

The entry is displayed.

7 Extended Functionalities

7.1 Data handling

Note: Extended data handling functionality is dependent on the capabilities of the particular DMS being used and may vary.

When used in conjunction with the Handheld Base Unit from Roche Diagnostics (available separately), the CoaguChek XS Plus meter can conveniently connect to a DMS. The main advantages of such a connection between meter and DMS may include:

- Transferring patient lists, operator lists, and settings from the DMS to the meter. In this way the setup for daily work as well as general meter setup can be performed (for one or more meters) quickly and conveniently.
- Transferring all stored test results with the corresponding *Patient ID*, *Operator ID*, and comments from the meter to the DMS. This transfer of data permits further evaluation or proper archiving according to your needs.

Through the DMS the system administrator (such as the POC coordinator) may specify what settings are to be applied to a set of meters within a site or unit (e.g., hospitals or wards). All meters assigned to a specific site and/ or unit would consequently share the same settings. The different operator and patient lists (that match a site or unit) are then made available on their respective meters. Other settings such as *QC Lockout* and *Operator Lockout* may easily be set (once) and distributed to all meters.

The option of setting up an *Operator Lockout* is available **only** when operator lists are created on the DMS, stored in the meter, and Operator login is activated. See *Operator login* (in *Operator ID*) and *Operator Lockout* for more details.

- [Operator ID \(85\)](#)
- [Operator Lockout \(96\)](#)

Computer (Setup option)

For initial connection to a DMS, the ability to communicate within a network has to be set up as follows:

- In the *Setup Menu*, the *Connection* option must be set to **Computer**.
- The Handheld Base Unit must be configured correctly. (For details please refer to the manual of the Handheld Base Unit and the Technical Note stored on the Handheld Base Unit itself.)
- Place the meter on a Handheld Base Unit that is connected to the network. The meter will automatically be recognized by the DMS and may now be assigned to a site and/or unit managed by the DMS (if your DMS has that functionality).
- Depending on DMS functionality available, the DMS may transfer settings and lists to the meter as well as enable test results to be transferred from the meter to the DMS.

- [To connect to the computer \(74\)](#)

Operator lists

After powering the meter on, an *Operator* login may be configured. There are four possible configurations for an *Operator* login:

- *Operator* is activated, but there is no list available: The *Operator* can either log in via the onscreen keypad or a barcode scan. The use of the meter is not restricted to a predefined *Operator* group, so

Operator IDs are entered via the onscreen keypad or read from the barcode and stored with test results for informational purposes only.

This first configuration is also available without a DMS.

- *Operator* is activated, there is no list available and the "List" feature is set to "hidden" (only possible with a DMS). Setting the "List" feature to "hidden" with the DMS automatically blocks the display of the meter's onscreen keypad as well.
The *Operator* can only log in via a barcode scan as there is no onscreen keypad. The use of the meter is not restricted to a predefined *Operator* group, so *Operator IDs* are read from the barcode and stored with test results for informational purposes only.

Meters which are managed by a DMS may receive an *Operator* list.

- *Operator* is activated, a list is available and displayed on the login screen:
The *Operator* selects the ID from the displayed list. If so configured by the *Administrator*, the *Operator* may also be required to enter a password to log in.
- *Operator* is activated, a list is available but set to "hidden":
The *Operator* can login via a barcode scan. If so configured by the *Administrator*, the *Operator* may also be required to enter a password to log in.

When working with operator lists: The use of the meter is restricted to the operators on this list.

Patient lists

When starting a Patient Test, there will be the option of either selecting a *Patient ID* from a patient list, entering the *Patient ID* using the onscreen keypad or, if available, of scanning the barcode with the *Patient ID*. The *Patient ID*, if entered on the DMS, comes with an additional

identification entry. Up to 20 characters can be used and assigned as a second confirmation (e.g., name, date of birth).

There are four possible configurations for a *Patient ID* input:

- The *Patient ID* is set to **Optional** or **Required**, and there is no list available:
A *Patient ID* can be entered manually via the onscreen keypad or read in via a barcode scan. The Patient ID is stored with the test result.
- The *Patient ID* is set to **No**, but there is a list available: The list of Patient IDs is always shown when starting a test. You may now:
 - select a patient from the list;
 - scan a *Patient ID* using the barcode scanner;
 - create a new patient entry by touching **New**. Instead of an ID a consecutive number will be assigned to this result.
- The *Patient ID* is set to **Optional** or **Required**, and there is a list available: The list of Patient IDs is always shown when starting a measurement. You may now:
 - select a patient from the list;
 - scan a Patient ID using the barcode scanner;
 - create a new patient entry by touching **New**. You may either read the ID using the barcode scanner or enter a new ID via the onscreen keypad.
- The *Patient ID* is set to “hidden” (only possible with a DMS), and there is a list available: When you start the test, the screen is blank and **Scan** is displayed.
 - You may now scan a *Patient ID* using the barcode scanner. If the patient ID is on the list, the test will proceed. If the patient ID is not on the list, you will get an error message.

Note that the scanned *Patient ID* must already be on the list that is sent from the DMS to the meter. You cannot use the scanner to scan and enter a new *Patient ID* if the *Patient ID* is set to “hidden”.

Patient list validation

Depending on DMS settings, you have the following options for patient list validation when working with Patient lists:

- A Patient ID does not have to be on the list to be used (only valid for validation mode “off”).
- The meter displays a warning if the Patient ID entered is not on the list.
- The meter displays an error message if the ID was not found on the list of valid Patient IDs.

To proceed with the test, you must scan (if ID set to “hidden”) or select (if ID set to **Required**) a valid *Patient ID*.

Configuring operator and patient IDs

When creating operator and patient IDs, apply the following rules:

- Patient IDs can consist of up to 20 alphanumeric characters, with specified minimum and maximum lengths.
- Operator IDs can consist of up to 20 alphanumeric characters.

Alphanumeric characters are any combination of A - Z and 0 - 9, additionally “.” (period), or “-” (hyphen) may be used.

Barcode scanner

Barcode masking can be used to eliminate any characters not belonging to the Operator ID. For more information, see *Operator and patient ID barcode masks*.

Using a DMS, the barcode scanner may be configured to accept only selected barcode symbologies. A list of supported barcode symbologies can be found in Appendix A.2 and a list of supported characters in Appendix A.3.

- ▣ [A.1 Operator and patient ID barcode masks \(205\)](#)
- ▣ [A.2 Example of barcode symbologies \(206\)](#)
- ▣ [A.3 Supported characters in 2D barcodes \(210\)](#)

Stored test results and comments

When performing a test, the test result will be stored along with additional information, including the *Patient ID*, *Operator ID*, the kind of test performed, and optional *Comments*. The meter comes with a default set of *Comments* that can be assigned to each test result. If you are working with a DMS, these comments can be replaced by the comments in the DMS. The new wording will then be available for selection from the *Comments* list in the meter.

Up to 3 comments can be assigned to each result.

The default preset comments in the meter are:

Patient result comments	QC results comment
• Asymptomatic	• Acceptable Control
• Cleaned Meter	• Cleaned Meter
• Doctor Notified	• Doctor Notified
• Sick	• New Control Lot
• Travel	• New Lot Number
• Lab Draw	• New Strip Lot
• No Action	• New Strip/Kit Lot
• Procedure Error	• No Action
• Under Medication	• Procedure Error

Patient result comments	QC results comment
• Will Repeat Test	• Proficiency Test
• Changed Dosing	• Repeat Control Test
	• RN Notified
	• Switched QC Vial
	• Will Repeat Test

For more information and technical details, please refer to the manual of the Handheld Base Unit and the Technical Note stored on the Handheld Base Unit itself.

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8 Maintenance and Care

8.1 Conditions for storage and shipping

Storage

- Store the system and test strips in the same environment in which they are used.
- Do not store the meter in direct sunlight or under extreme temperature conditions.
- Observe the limits for temperature and humidity when storing and using the meter (see Chapter 10).

▶  [10.1 Technical data \(187\)](#)

Shipping



- ▶ Observe the following safety information when shipping the meter and battery pack. Failure to do so may result in injury to persons or damage to the meter or battery pack.
 - If the meter is shipped or transported over long distances, always remove the battery pack from the meter. This eliminates the possibility of the battery pack overheating due to a short-circuit in the meter. It also prevents deep discharge and other damage to the battery pack or meter.
 - Only ship undamaged battery packs. Damaged battery packs must be disposed of locally. See *Battery pack* for the risks associated with damaged battery packs and disposal information.
 - Package the battery pack for shipping so that it cannot move around in the packaging. Also observe any other applicable national regulations.
 - When shipping via third parties (e.g., by air or parcel service), work with the carrier to check whether specific requirements need to be met in relation to the lithium-ion battery packs on the basis of national or international laws on hazardous goods and, where applicable, if special packaging and labeling requirements apply.

▶ [Battery pack \(22\)](#)

For short distances - example between a facility's sites - users may transport the battery packs (either installed in the meter or separately) by road without having to meet further requirements.

8.2 Cleaning and disinfecting the meter

Cleaning and disinfecting the exterior surface of the meter is, at minimum, recommended daily for dedicated patient devices. Meters used with multiple patients may require more frequent cleaning and disinfecting. Follow recommendations from the FDA, CDC, and CMC and your facility's policies and procedures for infection control.^{(14),(15)}

The FDA recommends that Point of Care testing devices should be used only on one patient and not shared. If dedicating meters to a single patient is not possible, the meters must be properly cleaned and disinfected after every use following the guidelines given in this section.

⁽¹⁶⁾

For technical assistance or questions on cleaning and disinfecting, please contact CoaguChek Technical Services at 1-800-428-4674.

⁽¹⁴⁾ FDA Public Health Notification: Use of Fingertick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication, (2010). <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>

⁽¹⁵⁾ CDC Clinical Reminder: Use of Fingertick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens, (2010). <http://www.cdc.gov/injectionsafety/FingertickDevicesBGM.html>

⁽¹⁶⁾ Healthcare Infection Control Practices Advisory Committee (HICPAC), William A Rutala, Ph.D., M.P.H., and David J. Weber, M.D., M.P.H. Centers for Disease Control and Prevention, 2008. Guideline for Disinfection and Sterilization in Healthcare Facilities. Atlanta, GA

8.3 Guide to cleaning and disinfecting the meter

Cleaning, disinfecting, and maintenance cleaning the meter, test strip guide, and test strip guide cover

Prior to cleaning and disinfecting the testing equipment:

1. Follow the infection control procedures of your institution when handling testing equipment.
2. Wear gloves.
3. The gloves worn during cleaning and disinfecting should be removed and hands washed thoroughly with soap and water before performing the next patient test

- Clean the meter, test strip guide and test strip guide cover to remove visible soil and organic material prior to disinfecting.
- Disinfect the meter and test strip guide to destroy pathogenic and other types of microorganisms.
- Maintenance cleaning is necessary to avoid an impact of Super Sani-Cloth® Germicidal Disposable Wipes (EPA* reg. no. 9480-4) residues on the instrument, resulting in aborted measurements.

NOTE: The meter, test strip guide and test strip guide cover should be cleaned and disinfected between each patient use.

Acceptable Cleaning/Disinfecting Agents

The only acceptable product for cleaning and disinfecting is:

- Super Sani-Cloth® Germicidal Disposable Wipes (EPA* reg. no. 9480-4).
- To purchase approved disinfecting products, please refer to your facility's guidelines, which may include instructions on direct purchase from the manufacturer or through an approved distributor. For additional information on product availability for

purchase, refer to manufacturer's website: <http://www.pdipdi.com/> for Super Sani-Cloth® Germicidal Disposable Wipes.

- Dispose of acceptable cleaning and disinfection solutions per facility guidelines.
- For maintenance cleaning use purified water (minimum level: deionized water) with cotton swabs.

NOTICE!

- ▶ Do not use any other cleaning/disinfecting agents on the meter (housing, test strip guide and test strip guide cover). Use of other cleaning/ disinfecting agents could result in damage to the meter.

What to clean and disinfect?

The following parts of the meter and system components may be cleaned and disinfected:

- The area around the test strip guide
- The meter display (touchscreen)
- The meter housing (entire meter surface)
- The test strip guide and test strip guide cover

Technical Assistance

If you notice any of the following signs of deterioration after cleaning or disinfecting of your meter system, stop using the system component and contact CoaguChek Technical Services at 1-800-428-4674 for assistance:

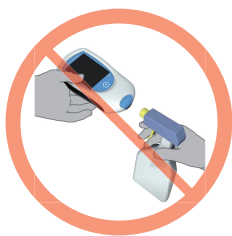
- Clouding of the touchscreen display
- On/off button malfunction
- Clouding of the infrared data port and/or barcode scanner
- Quality control results outside of the specified range

8.4 How to clean and disinfect the meter

Avoid getting liquid into the test strip guide!

Failure to follow these instructions may damage the meter and stop it from working properly.

- ▶ Do not clean or disinfect the meter while performing a test.
- ▶ Do not get any moisture in the test strip guide
- ▶ Do not spray anything onto the meter.
- ▶ Do not immerse the meter in liquid.
- ▶ If you suspect that moisture may have entered the test strip guide, perform a control test.



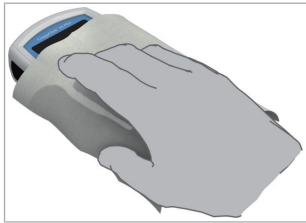
NOTICE!

- ▶ Do not allow liquid to enter the test strip guide or to pool liquid on the touchscreen. If liquid does get into the test strip guide, immediately dry the components with a dry cloth. **If solution is allowed to collect in any meter opening, severe damage to the system can occur.**

Ensure that the blue test strip guide cover remains tightly closed while cleaning the meter housing.

▶ **To clean the meter**

- 1 Place the meter on a level surface prior to cleaning.



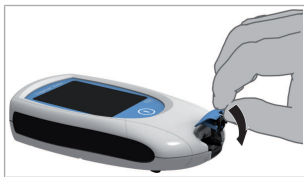
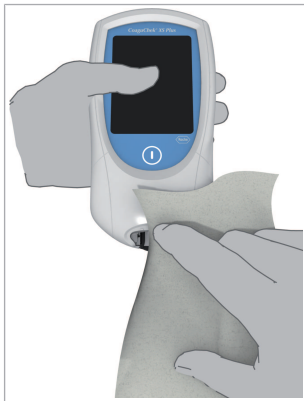
- 2 Power off the meter.
- 3 Take a Super Sani-Cloth® Germicidal Disposable Wipe.
- 4 **Squeeze off excess cleaning solution** or blot on a dry paper towel to remove any excess cleaning solution before cleaning the surface of the meter.
- 5 Clean by gently wiping the outside of the meter. Carefully wipe around the test strip guide area, making sure that no liquid enters the test strip guide.
- 6 Dry the meter thoroughly with a dry cloth. Visually verify that no solution is seen anywhere on the meter at the completion of cleaning and disinfecting. **Ensure that the meter is thoroughly dried after cleaning** (see safety message “Avoid getting liquid into the test strip guide!” and NOTICE in this section).
- 7 Allow wiped areas to **dry for at least 10 minutes** before performing the next patient test.

If you notice streaks on the housing or touchscreen, or the touchscreen surface becomes slightly cloudy, wipe clean immediately with a soft, lint-free cloth slightly dampened with water.

► To clean the test strip guide cover



- 1 With the meter powered off, **remove the test strip guide cover to clean it.** (Use your thumbnail to open the cover of the test strip guide by pressing its front edge upward.) Move the cover safely away from the meter.
- 2 Wipe it clean using Super Sani-Cloth® Germicidal Disposable Wipes.



- 3 Let the test strip guide cover dry **for at least 10 minutes** before reattaching it.
- 4 Do **not yet reattach the test strip guide cover** before finishing the next step (cleaning the test strip guide).

► To clean the test strip guide

- 1 **NOTICE!** Damage to the instrument
Ensure that no liquid enters the meter when cleaning the test strip guide. If moisture enters the meter, it may cause malfunction of the instrument. Do not insert any objects in the test strip guide. Doing so may damage the electrical contacts behind the test strip guide.

Hold the meter upright with the test strip guide facing down.

- Clean the easily accessible white areas with a moistened Super Sani-Cloth® Germicidal Disposable Wipe.
- Ensure the Super Sani-Cloth® Germicidal Disposable Wipe is only damp, not wet. Wipe away residual moisture and fluids.

- 2 On completion of cleaning with the cover off, let the test strip guide dry **for at least 10 minutes** before re-attaching the test strip guide cover and testing again.
 - Visually verify that no residual moisture is seen anywhere on the test strip guide and cover at the completion of cleaning.
 - Ensure that the test strip guide and cover are completely dry before assembling them.
- 3 Re-attach the test strip guide cover to the housing. Make sure that the cover is properly closed. You will hear it snap into place.

► **To clean the scanner window**

- 1 The scanner window should be cleaned periodically. Use a clean, dry cloth to wipe the scanner window.

► **To disinfect the meter**

- 1 **NOTE: The meter should be cleaned prior to each disinfection step.**

Remember to keep the meter on a level surface prior to disinfecting and powered off.

Take a Super Sani-Cloth® Germicidal Disposable Wipe and **squeeze off excess cleaning solution** or blot on a dry paper towel to remove any excess cleaning solution before cleaning the surface of the meter.



- 2 Disinfect by gently wiping the outside of the meter **three times horizontally** and **three times vertically** and carefully wipe around the test strip guide area, making sure that no liquid enters the test strip guide.
- 3 Allow the surface of the meter to remain damp. The required contact time is **2 minutes**.
NOTE: Meter surface must stay moist for the entire contact time.
- 4 Dry the meter thoroughly with a dry cloth. Visually verify that no solution is seen anywhere on the meter at the completion of cleaning and disinfecting. Ensure that the meter is thoroughly dried **for at least 10 minutes** after cleaning and

disinfecting (see safety message “Avoid getting liquid into the test strip guide!” and NOTICE in this section).

► To disinfect the test strip guide cover



- 1 With the meter powered off, remove the test strip guide cover to disinfect it. (Use your thumbnail to open the cover of the test strip guide by pressing its front edge upward.) Move the test strip guide cover safely away from the meter.
- 2 Using a fresh Super Sani-Cloth® Germicidal Disposable Wipe, disinfect the test strip guide cover by gently wiping the easily accessible areas **three times horizontally and three times vertically**.
- 3 Allow the surface of the test strip guide cover to remain damp. The required contact time is **2 minutes**.

NOTE: The test strip guide cover surface must stay moist for the entire contact time.

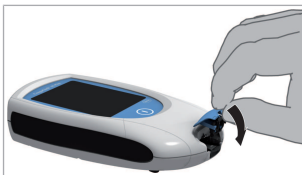
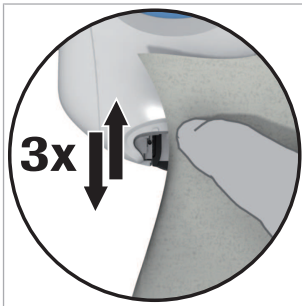
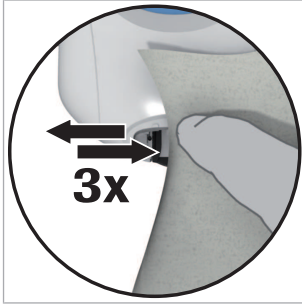
Do **not yet reattach the test strip guide cover** before finishing the next steps (disinfecting the test strip guide).

► To disinfect the test strip guide

- 1 **NOTICE! Damage to the instrument.** Ensure that no liquid enters the meter when disinfecting the test strip guide. If moisture enters the meter, it may cause malfunction of the instrument.
Do not insert any objects in the test strip guide. Doing so may damage the electrical contacts behind the test strip guide.
Disinfect the easily accessible white areas with a moistened Super Sani-Cloth® Germicidal Disposable Wipe.

Ensure the Super Sani-Cloth® Germicidal Disposable Wipe is only damp, not wet. Wipe away residual moisture and fluids.

NOTE: The test strip guide should be cleaned prior to each disinfection step.



- 2 With the test strip guide cover off and holding the meter upright with the test strip guide facing down, use a fresh Super Sani-Cloth® Germicidal Disposable Wipe and disinfect the test strip guide by gently wiping the easily accessible white areas **three times horizontally and three times vertically**, making sure that no liquid pools into the test strip guide.

- 3 Allow the surface of the test strip guide to remain damp with the recommended disinfecting solution. The required contact time is **2 minutes**.

NOTE: The test strip guide surface must stay moist for the entire contact time.

- 4 Let the test strip guide and the test strip guide cover dry **for at least 10 minutes** before re-attaching the test strip guide cover. Visually verify that no solution is seen anywhere on the test strip guide at the completion of cleaning and disinfecting.
- 5 **NOTICE!** Re-attach the test strip guide cover to the housing. Make sure that the cover is properly closed. You will hear it snap into place.

► To perform maintenance cleaning of the test strip guide

- 1 In addition to the cleaning and disinfection cycles with disinfection wipes, maintenance cleaning of the test strip guide is required to prevent disinfection solution buildup. Disinfection solution buildup on the test strip guide may lead to aborted measurements.

The test strip guide must receive a maintenance cleaning after 50 cleaning and disinfection cycles, or at least once per week, depending on which occurs first.



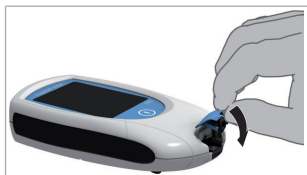
- 2 With the meter powered off, **remove the test strip guide cover to clean it.** (Use your thumbnail to open the cover of the test strip guide by pressing its front edge upward.) Move the cover safely away from the meter.

- 3 Rinse the cover with purified water (minimum level deionized).

- 4 Hold the meter in horizontal position.
 - Clean the easily accessible white areas with a cotton swab/bud, moistened with purified water.
 - Ensure the swab/bud is only damp, not wet.
 - Wipe away residual moisture and fluids.


- 5 Repeat the previous step for three times to complete one cleaning cycle.





- 6 On completion of maintenance cleaning with the cover off, let the test strip guide dry **for at least 10 minutes** before re-attaching the test strip guide cover.
- 7 Re-attach the test strip guide cover to the housing. Make sure that the cover is properly closed. You will hear it snap into place.


8.7 Cleaning after a notification appears

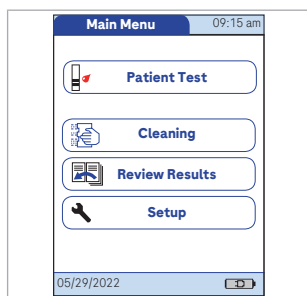
If the icon  appears on either the *Main Menu* or the *QC Lockout* screen, a cleaning/disinfection is necessary.

A corresponding information message I-013 appears in the display, when entering the *Main Menu* or *QC Lockout* screen.

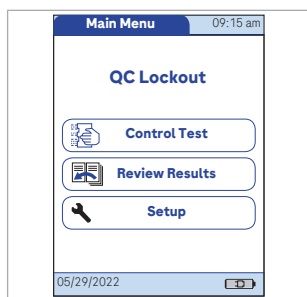
Intervals between running cleaning process are determined by your facility. For further information on configuring these intervals refer to the DMS provider for available configuration options.

► Cleaning after a notification appears

- 1 If  appears on the *Main Menu* screen, touch **Cleaning**.
→ Go to step 3.

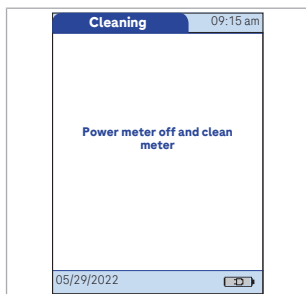


- 2 Alternatively, if  appears on the *QC Lockout* screen choose **Control Test**.



Choosing the **Control Test** button initiates a control test run, since it has priority over cleaning. First run a liquid quality control test to unlock the meter from a *QC Lockout* before you can run a cleaning process.

- Go to step 1.



- 3 The *Power meter off and clean meter* screen appears.

Power off the meter and perform *Cleaning and disinfecting the meter*.



- By powering off the meter, a corresponding notification is sent to the DMS and the cleaning process is handled as done by the meter.

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9 Troubleshooting

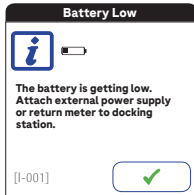

9.1 Status / Error messages

The CoaguChek XS Plus meter continually checks its status for unexpected and unwanted conditions. These may arise for technical reasons (defective components or consumables, environmental factors) or due to handling and procedure errors.

Depending on the circumstances, a message may appear on the display of the meter. These messages are marked with an icon, either  for a status message, or  for an error message. All messages displayed by the system are accompanied by a description of the error and a possible solution.

Take the action suggested on screen to resolve the problem. If the error disappears, you may continue using the meter as desired. If the problem persists, contact Roche Diagnostics.

The two different message types are illustrated below:

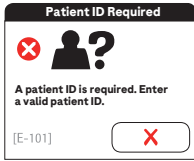
Message	Description
<p>I-001: Battery Low</p> 	<p>Status message</p> <p>Touch  to proceed with the next step.</p>

Message **Description**

E-101: Patient ID Required

Error message

Touch **X** to exit this message. Perform the suggested step(s) to solve the problem.



Status messages (overview)

Status messages

<p>Battery Low</p> <p>The battery is getting low. Attach external power supply or return meter to docking station.</p> <p>[I-001] <input type="checkbox"/></p>	<p>Patient ID</p> <p>The patient ID you entered is not on the list.</p> <p>[I-002] <input type="checkbox"/></p>	<p>Login Message</p> <p>[I-003*] <input type="checkbox"/></p>
---	--	--

*The text displayed here is configurable. It can be defined via the DMS.

<p>Memory Full</p> <p>Only %ld tests can be performed before meter memory is full. Dock meter or disable this setting.</p> <p>[I-004] <input type="checkbox"/></p>	<p>Docked</p> <p>The meter is docked.</p> <p>[I-005] <input type="checkbox"/></p>	<p>Docked</p> <p>Host communicating running. Please wait...</p> <p>[I-005] <input type="checkbox"/></p>
---	--	--


Status messages

<p>Lifetime</p>  <p>Only %ld tests left before the maximum number of tests is reached. Contact your Roche representative.</p> <p>[I-006] </p>	<p>Comment Required</p>  <p>A comment is required if you reject a result. Please enter a comment.</p> <p>[I-009] </p>	<p>Observer Login</p>  <p>Observer %ls, please log in to proceed. Otherwise the OTS test will not be complete.</p> <p>[I-010] </p>
<p>Connectivity Warning</p>  <p>Communication between meter and DMS is overdue. Dock the meter to start communication with DMS.</p> <p>[I-012] </p>	<p>Cleaning Alert</p>  <p>Cleaning and disinfection are overdue. Clean and disinfect the meter.</p> <p>[I-013] </p>	<p>Out of normal range</p>  <p>The result is out of normal range. The normal range is %ls</p> <p>[I-015] </p>
<p>Battery Low</p>   <p>Battery low. Test can only be performed if external power supply is attached.</p> <p>[I-018] </p>		

Error messages (overview)

Error messages


Patient ID Required



A patient ID is required. Enter a valid patient ID.

[E-101]


Invalid Patient ID



The ID was not found on the list of valid patient IDs. Enter a valid patient ID.

[E-102]


Operator ID Required



An operator ID is required. Enter a valid operator ID.

[E-103]


Invalid Operator ID



The ID was not found on the list of valid operator IDs. Enter a valid operator ID or see your System Administrator.

[E-104]

Invalid Password



Invalid password. Enter valid password or see your System Administrator.

[E-105]


Comment Required



A comment is required for this result.

[E-106]


No Operators Loaded



There are no operators loaded in this meter. In order to continue, operators must be downloaded. Please see your System Administrator.

[E-107]


Password Mismatch



The passwords you entered do not match. Please try again.

[E-108]




Invalid Scan






The scanned barcode is invalid. Scan a valid barcode or see your System Administrator.

[E-109]




Error messages

<p>Invalid Observer ID</p>  <p>The observer ID is invalid. The observer supervising the current OTS test must log in again.</p> <p>[E-111] X</p>	<p>Strip Lot Expired</p>  <p>The strip lot with the code %ld[*] has expired. Check the meter date/time setting and use a non-expired strip lot.</p> <p>[E-201] X</p>	<p>Control Lot Expired</p>  <p>The control lot with the code %ld[*] has expired. Check the meter date/time setting and use a non-expired control lot.</p> <p>[E-202] X</p>
---	--	--

* "%ld" is a placeholder for the displayed code number.


<p>Lot Not Allowed</p>  <p>The lot with the code %ls[*] is not allowed on this meter. See your System Administrator.</p> <p>[E-203] X</p>	<p>Barcode Error</p>  <p>The barcode on the test strip cannot be read. Please check the barcode on the test strip and repeat the test.</p> <p>[E-204] X</p>	<p>Strip Removed</p>  <p>Strip removed during test. Repeat test, using a new test strip if necessary.</p> <p>[E-205] X</p>
---	--	---

* "%ls" is a placeholder for the displayed code number.

<p>Strip Error</p>  <p>The meter does not recognize the test strip. Check the test strip and repeat the test.</p> <p>[E-206] X</p>	<p>Code Chip Error</p>  <p>Invalid code chip. Remove the code chip and repeat the test.</p> <p>[E-207] X</p>	<p>Missing QC</p>  <p>A quality control test must be performed. To continue, perform a quality control test.</p> <p>[E-210] X</p>
---	---	--

Error messages


Cover Open



The test strip guide cover was removed during a test. Repeat the test.

[E-211] X

Invalid Date




DD:MM:YY

The date is invalid. Enter the correct date and time.

[E-301] X


Battery Low



The battery is getting low. Attach external power supply or return meter to docking station.

[E-302] X


Lifetime End



The maximum number of tests has been reached. Contact your Roche representative.

[E-303] X


Ambient Temperature



Meter is too cold or too warm to test correctly. Power meter off and repeat test after 30 minutes at room temperature.

[E-304] X

Memory Full



The meter memory is full. Dock the meter or disable this setting.

[E-305] X


No Battery Pack Detected



No battery pack detected. Ensure that battery is properly connected.

[E-307] X


Device Temperature



Internal meter temperature is elevated. Meter functionality is reduced. Power off meter and let it cool down for several minutes.

[E-308] X







Device Temperature









Internal meter temperature is outside allowed range. Meter will power itself off. Let meter rest for several minutes, then restart.







[E-309] X

Error messages



















<p>Battery Critically Low</p>  <p>Battery critically low. Meter will power itself off. Attach external power supply or return to docking station immediately.</p> <p>[E-310] </p>	<p>Battery Version</p>  <p>Invalid battery pack. Replace with valid battery pack or contact your Roche representative.</p> <p>[E-311] </p>	<p>Measurement Lock</p>  <p>Measurement still locked for %ld minute(s) due to test strip guide error. If problem persists, contact your Roche representative.</p> <p>[E-312] </p>
---	--	--

* "%ld" is a placeholder for the number of minutes.



















<p>Battery Low</p>  <p>Battery low. No more tests can be performed. Attach external power supply or return meter to docking station.</p> <p>[E-318] </p>	<p>No Sample Detected</p>  <p>Sample detection has failed. Remove the test strip and repeat test, using a new test strip if necessary.</p> <p>[E-401] </p>	<p>Test Strip Error</p>  <p>A test strip error was detected. Check your procedure and repeat test, using a new test strip if necessary.</p> <p>[E-402] </p>
--	--	--

<p>Sample Application Error</p>  <p>A sample application error was detected. Check your procedure and repeat test, using a new test strip.</p> <p>[E-403] </p>	<p>Self-Check Error</p>  <p>The self-check detected a general error. Repeat the self-check. If problem persists, power meter off and on again.</p> <p>[E-405] </p>	<p>Sample Error</p>  <p>Unexpected sample composition detected. Check procedure for potential sample contamination. Check patient medication. Repeat test. If the problem persists, please consult the Operators Manual for further information.</p> <p>[E-406] </p>
---	---	--

Error messages


<p>OBC Failure</p>  <p>Strip failed onboard control. Remove the strip and repeat the test, using a new strip from another test strip container if necessary.</p> <p>[E-407] </p>	<p>Self-Check Error</p>  <p>The self-check detected a general error. Repeat the self-check. If problem persists, power meter off and on again.</p> <p>[E-501] </p>	<p>Barcode Reader</p>  <p>The self-check detected a barcode reader error. Remove the meter from direct bright light and repeat self-check.</p> <p>[E-504] </p>
<p>Code Chip Error</p>  <p>Code chip cannot be read. Remove the code chip and repeat the test.</p> <p>[E-601] </p>	<p>System Error</p>  <p>General System Error. The meter is defective. No test is possible. Contact your Roche representative.</p> <p>[E-602] </p>	<p>Heater Error</p>  <p>Temperature or heater error. Power meter off and on, and repeat the last procedure. If problem persists, contact your Roche representative.</p> <p>[E-603] </p>
<p>Hardware Error</p>  <p>Hardware or electronic error. Power meter off and on, and repeat the last procedure. If problem persists, contact your Roche representative.</p> <p>[E-605] </p>	<p>Sequence Error</p>  <p>Measurement sequence error. Power meter off and on, and repeat the last procedure. If problem persists, contact your Roche representative.</p> <p>[E-606] </p>	<p>Measurement Module</p>  <p>Error with measurement module. Power meter off and on, and repeat the last procedure. If problem persists, contact your Roche representative.</p> <p>[E-607] </p>

Error messages


<p>Software Error</p>  <p>A software error was detected. Power meter off and on, and repeat the last procedure. If problem persists, contact your Roche representative.</p> <p>[E-608] </p>	<p>Communication Error</p>  <p>Failed to connect to DMS. Undock meter from Base Unit and then redock it. If problem persists, power meter off and on.</p> <p>[E-701] </p>	<p>Communication Error</p>  <p>Communication error with DMS. Undock meter from Base Unit and then redock it. If problem persists, power meter off and on.</p> <p>[E-702] </p>
<p>Printing Error</p>  <p>Communication with printer * failed. Check the position of meter and printer. If problem persists, power meter and printer off and on.</p> <p>[E-703] </p>	<p>Communication Error</p>  <p>ICI communication error with DMS. Power meter off and on, and repeat the last procedure.</p> <p>[E-704] </p>	<p>Internal Communication</p>  <p>Communication error with measurement module. Power meter off and on, and repeat the last procedure. If problem persists, contact your Roche representative.</p> <p>[E-705] </p>
<p>*The printer is not available in the U.S.</p>		
<p>Internal Communication</p>  <p>Communication error with test strip barcode scanner. Power meter off and on, and repeat the last procedure. If problem persists, contact your Roche representative.</p> <p>[E-706] </p>	<p>Internal Communication</p>  <p>Communication error with ID barcode scanner. Power meter off and on, and repeat the last procedure. If problem persists, contact your Roche representative.</p> <p>[E-707] </p>	<p>Communication Error</p>  <p>General communication error. Power meter off and on, and repeat the last procedure. If problem persists, contact your Roche representative.</p> <p>[E-708] </p>

Error messages


Memory Error

The meter database cannot be read and will be deleted. Power meter off and on. If problem persists, contact your Roche representative.

[E-801] 



Memory Error


The meter detected a fault with the EEPROM memory. Power meter off and on. If problem persists, contact your Roche representative.

[E-805] 


Memory Error


The meter detected a fault with the Flash memory. Power meter off and on. If problem persists, contact your Roche representative.

[E-806] 

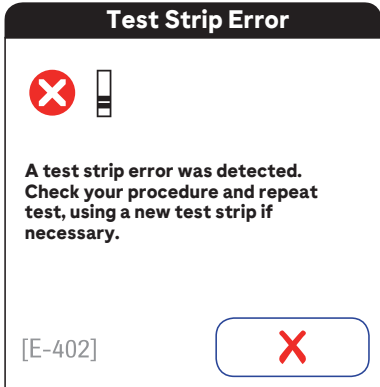
Memory Error

The meter detected a general fault with the memory. Power meter off and on. If problem persists, contact your Roche representative.

[E-807] 

Additional information on error E-402

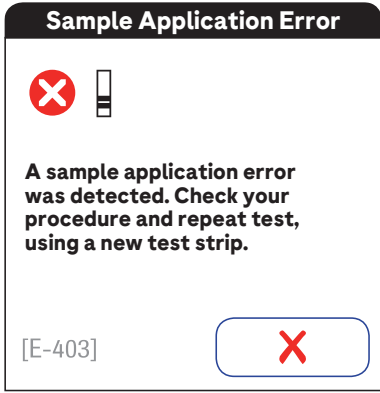
Message	Description
<p>E-402 Test Strip Error</p> 	<p>Status message</p> <p>Touch X to exit this message. Perform the suggested step(s) to solve the problem.</p>

Power the meter off and remove the test strip. Repeat the measurement using a new test strip and blood taken from a new puncture site at the tip of another finger. If this error message appears again when the test is repeated, contact your local Roche representative.

Possible reasons for this error message to appear again and again:

- The meter circuit board is defective. This can happen when, for example, cleaning and disinfecting agents enter the meter interior or when there are dried residues of cleaning and disinfecting agents in the meter interior.
- The test strip was wet or has already been used.
- The sample was applied too early, before warming up of the strip was completed.

Additional information on error E-403

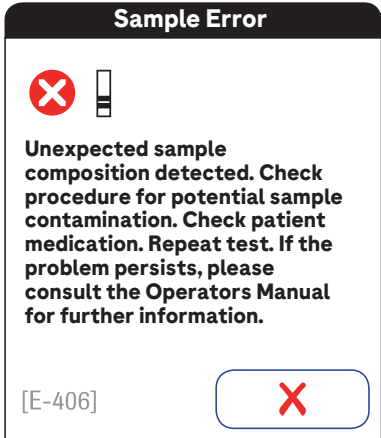
Message	Description
<p>E-403: Sample Application Error</p> 	<p>Status message</p> <p>Touch X to exit this message. Perform the suggested step(s) to solve the problem.</p>

“Sample Application Error” indicates that an insufficient sample volume was detected. Please check your procedure and repeat the test. Power the meter off and remove the test strip. Repeat the measurement using a new test strip and blood taken from a new puncture site at the tip of another finger. Make sure you apply a sufficient amount of blood to the test strip.

If this error message appears again and again although the blood sample was sufficient, the meter might be contaminated with blood or residues of cleaning and disinfecting agents.

If this error message persists when the test is repeated, contact your local Roche representative.

Additional information on error E-406

Message	Description
<p>E-406: Sample Error</p> 	<p>Status message</p> <p>Touch X to exit this message. Perform the suggested step(s) to solve the problem.</p>

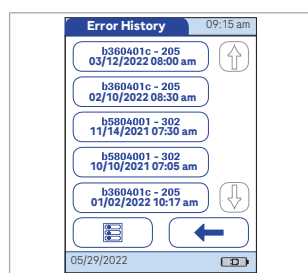
Power the meter off and remove the test strip. Repeat the measurement using a new test strip and blood taken from a new puncture site at the tip of another finger. Do not touch or remove the test strip when a test is in progress.

Note on error E-406: The CoaguChek® XS PT Test strip may be used for patients under a combination therapy of oral anticoagulants plus heparin injections. For maximum heparin concentrations which do not interfere with the test, refer to the package insert. In rare cases, patients with abnormal or unusually long clotting times may receive an “E-406” message on the meter display. This may occur, for example, during treatment with vitamin K antagonists in combination with antibiotics, chemotherapeutics, or extremely high levels of vitamin C (e.g. after vitamin C infusions).

If this error message appears again when the test is repeated, the result must be checked using another method. **Please inform the patient to seek immediate medical attention.** For further information on the measuring range of the parameter refer to the respective package insert.

If capillary tubes are used, **do not use** glass capillary tubes or capillary tubes that contain anticoagulants.

Error History



To check the error history of the CoaguChek XS Plus meter, you can scroll through the errors on the *Error History* screen via:

Main Menu > Setup > Diagnostics

▸ 3.7 Diagnostics (102)


Errors and unusual behavior without error messages

Some conditions may arise that have no associated error or status message.

If you notice any issues with the display functionality (e.g. unexpected lines/marks on the meter display), stop using the system and contact your Roche representative.

Message	Description
<p>No message or unusual behavior</p> <p>Meter display does not power on</p>	<ul style="list-style-type: none"> • Wait 10 seconds and try powering on the meter again. • Check that the meter has power <p>See To install the battery pack (47)</p> <p><i>Is the battery pack properly installed in the meter?</i></p> <p><i>Does the meter power on when connecting the external power adapter?</i></p> <p><i>Does the battery pack charge properly?</i></p>
<p>Meter displays an unexpected result</p>	<p>Refer to the package insert for the test strips.</p>

Automatic shutdown


	<p>The meter powers off after a configurable time without activity (e.g., pressing a key, touching the screen) to conserve energy. Reactivate the meter/screen as described in the following:</p>
<p>Shutdown after time specified by system administrator (default is 5 minutes, configurable by system administrator)</p>	<ul style="list-style-type: none"> • Press .

Additional information on result screens

Message	Description
<p>A “C” is displayed along with the result:</p>	<p>This may occur if the hematocrit value is very low or due to erroneous blood collection (e.g., wet hands). Repeat the test. If using capillary blood, make sure that the patient's hands are dry. If the message persists, perform a hematocrit check.</p>

Message	Description
---------	-------------

A “” is displayed along with the result:**

This indicates that the test result is out of normal range. Touch the  icon to display the Out Of Normal Range information screen.

When interpreting results, refer to the detailed information on limitations and interferences included in the limitations section of the test strip package insert.

9.2 Shut down / restart / reset meter

Shutting down the meter shuts down communication and all other functionalities. Date and time, however, are maintained.

▶ Automatic shutdown

- 1 If the battery pack is critically low, the meter will shut down automatically.

▶ To shut down meter not connected to the external power supply or HBU

- 1 To shut down the meter, press the On/Off button for about 5 seconds and release the button as soon as the Roche logo is displayed and the meter beeps. The screen goes blank and the meter is shut down.

Use meter shutdown when you want to remove or replace the battery pack.

See [To remove the battery pack \(50\)](#)

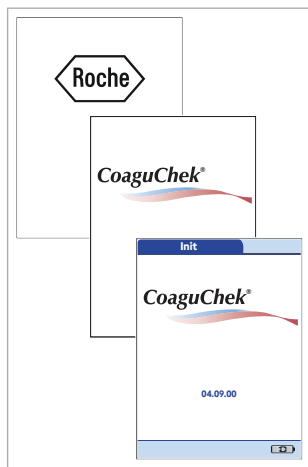
▶ To shut down meter connected to the external power supply or HBU

- 1 To restart the meter, press the On/Off button for about 5 seconds and release the button as soon as the Roche logo is displayed and the meter beeps. The screen goes blank and the meter powers itself off and on.

Use meter restart if the meter does not respond to user actions (like touching buttons).

▶ To reset the meter

- 1 A meter reset should only be performed if all other remedies have failed.



- 2** Place the meter on a level surface.
- 3** Press the ON/OFF button for at least 5 seconds and then release it. After releasing the button, the meter will start up again.
 - The meter powers off and on again.
 - The Roche logo is displayed. If the Roche logo does not appear within 60 seconds, place the meter in the Handheld Base Unit for a minimum of 15 minutes to recharge the battery.
 - The meter performs a system check.

10 General Product Specifications

10.1 Technical data

Technical data	
Measuring range	%Q: 120 – 5 SEC: 9.6 – 96 INR: 0.8 – 8.0
Memory	2000 patient and 500 QC results with date and time 120 code chip records (60 strip codes and 60 control codes) Operator lists up to 5000 Operator IDs with corresponding 2nd ID (e.g., Operator Name) Patient lists up to 4000 Patient IDs with corresponding 2nd and 3rd Patient IDs (e.g., name, date of birth)
Interface	Infrared interface, LED/IRED Class 1 Touchscreen and barcode scanner
Battery operation	Universal Battery Pack for the CoaguChek XS Plus meter
Power connection	Power supply adapter: Input: 100-240 V AC / 50-60 Hz / 1.2 A Output: 9 V DC / 3.0 A
Number of tests with a fully charged battery pack	approx. 60 tests (PT/INR)
Safety class	III
Automatic power-off	Programmable 1 ... 60 minutes
Dimensions	187 x 97 x 43 mm
Weight	280 g (without battery pack)
Sample material	
Sample type	Refer to test strip package insert
Sample size	Refer to test strip package insert
Interactions	Refer to test strip package insert

10.2 Operating, storage, and transport conditions

Operating conditions

Operating temperature range	+15 °C to +32 °C (59 °F to 90 °F)
Relative humidity	10 to 85 % (no condensation)
Maximum altitude	4300 m (14,000 feet)
Environment	Pollution Degree 2 - Indoor use only - No wet location
Position	Place the meter on a level, vibration-free surface or hold it so it is roughly horizontal.

Storage conditions

Temperature range Meter (without battery pack)	-5 °C to +45 °C (+23 °F to +113 °F)
Temperature range Meter (with battery pack)	-5 °C to +35 °C (+23 °F to +95 °F)
Relative humidity	10 to 85 % (no condensation)

Transport conditions

Temperature range Meter (without battery pack)	-25 °C to +70 °C (-13 °F to +158 °F)
Temperature range Meter (with battery pack contained in the kit) ^(a)	-10 °C to +70 °C (+14 °F to +158 °F)
Relative humidity	10 to 85 % (no condensation)

^(a) At temperatures above +70 °C/158 °F the battery pack could leak and damage the meter. At temperatures below -10 °C/+14 °F the battery pack does not have enough power to keep the internal clock functioning.

10.3 Further information

Consumables/ Accessories

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

Item	Description	REF
CoaguChek® XS PT Test	24 PT test strips for the CoaguChek XS Plus meter	07797826160
	2 x 24 PT test strips for the CoaguChek XS Plus meter	04625315160
CoaguChek® XS Pro PT Controls	Optional liquid controls (Level 1, Level 2) for the CoaguChek XS Plus system	04625382160
Universal Battery Pack	Rechargeable battery pack	06869904001
Handheld Base Unit	Handheld Base Unit and Operator's Manual	08408793160

Reagents and solutions

Supplies are available through Roche Diagnostics. Contact your local Roche Diagnostics representative.

Repairs

Please note that repairs and other modifications to the meter may only be performed by persons authorized by Roche Diagnostics.

Contact Roche

For all questions about the CoaguChek XS Plus system that are not answered in this manual, contact your Roche representative or call Roche Diagnostics Technical Service Center at 1-800-428-4674, or visit us online at www.coaguheck-usa.com

Information about software licenses

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

The GPL licensing conditions are printed below (in English only for legal reasons): GPL, Version 2, June 1991.

Copyright (C) 1989, 1991 Free Software Foundation, Inc. 51 Franklin Street, Fifth Floor, Boston, MA 02110-1301 USA

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repaired/replacement meter will expire on the date of the original warranty expiration or ninety (90) days after shipment of a replacement system, whichever period is longer.

12 Appendix A

A.1 Operator and patient ID barcode masks

Barcode mask character	Definition
A-Z, 0-9	If not preceded by the Caret (“^”), the scan data character must be the same as the mask character. This character is not saved as part of the ID. If the characters are not the same, the scan data is not a valid ID.
Dollar (“\$”)	The scan data character in this position is kept as part of the ID.
Asterisk (“*“)	The scan data character in this position is not kept as part of the ID.
Tilde (“~“)	The scan data character in this position must be a number, 0-9, and it is not kept as part of the ID. If the scan data character is not a number, the scan data is not a valid ID.
Plus (“+“)	The scan data character in this position must be an alpha character, A - Z, and it is not kept as part of the ID. If the scan data character is not an alpha character, the scan data is not a valid ID.
Caret (“^“)	This mask character denotes that the scan data character must be equal to the next character in the barcode mask after the “^”, and that the scan data character is kept as part of the ID. If the scan data character is not equal to the mask character following the “^”, the barcode reading is invalid as an ID.

The allowed maximum length of a barcode mask is

- 60 characters for 1D barcodes
- 300 characters for 2D barcodes

A.2 Example of barcode symbologies



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

- ▶ When creating patient or operator barcodes, always adhere to the applicable international IEC/ISO standards for the respective barcode symbology. In particular, ensure that barcode size and print quality (as defined in ISO/IEC 15416 and 15415) are adequate. Inadequate print size and/or quality may lead to erroneous decoding. In addition every user must carry out a plausibility check on all data scanned into and displayed by the instrument.
-

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

- check ID against list or
- check ID for length⁽¹⁷⁾
- use barcodes with check digits

Always make sure that the entire barcode is covered by the green light beam when scanning.

⁽¹⁷⁾ If no operator/patient list can be used, it is recommended that you at least set a minimum length for the respective ID, even if your facility uses IDs of varying length.


WARNING!
Avoidance of incorrect EAN 13 and Interleaved 2/5 barcode readings

EAN 13 and Interleaved 2/5 barcodes, although widely used, are not recommended for patient/operator barcodes. If an EAN 13 or Interleaved 2/5 barcode is read incorrectly, this may lead to patient misidentification and therefore to inappropriate therapy decisions. If used nonetheless:

- ▶ make sure that the very highest quality standards of barcode creation and reproduction are applied
- ▶ for EAN 13: do not use the start sequences 978 (ISBN) and 979 (ISMN) as they will be ignored as a part of any ID code.

The barcode samples shown here are for illustration purposes only. If printed out, they can be used to check the barcode scanner. However, they are not meant to be used as a reference for size or resolution of real patient or operator ID barcodes. When creating patient or operator barcodes always refer to the relevant standard ISO/IEC 15416 and 15415 for size and resolution requirements and to the specification listed below.

	Recommended Specification	Remarks
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 gloss finish.

	Recommended Specification	Remarks
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 bar code, grade C may not be sufficient when motion, reflection, or poor lighting occur.
Module width (minimum)	0.16 mm (linear barcodes) 0.20 mm (2D barcodes)	



1234567890

Codabar



1234567890

Code 39



ABC123-/+

Code 93



1234567890

Code 128



1 112223 334448

EAN 13



1234567890

Interleaved 2/5
without checksum

012345678905

Interleaved 2/5
with checksum

(01)01234567890128

RSS (GS1 DataBar
Limited)

Roche Diagnostics

Aztec



Roche Diagnostics

DataMatrix



Roche Diagnostics

PDF417



QR Code

Roche Diagnostics

A.3 Supported characters in 2D barcodes

The 2D barcode scanner is able to read characters from the following unicode ranges:

- Basic Latin (0021-007E)
- Latin-1 Supplement (00A1-00FF)
- Latin Extended-A (0100-017F)

The 2D barcode scanner does not support Asian characters.

13 Appendix B


B.1 Supplement for Observed Test Sequence

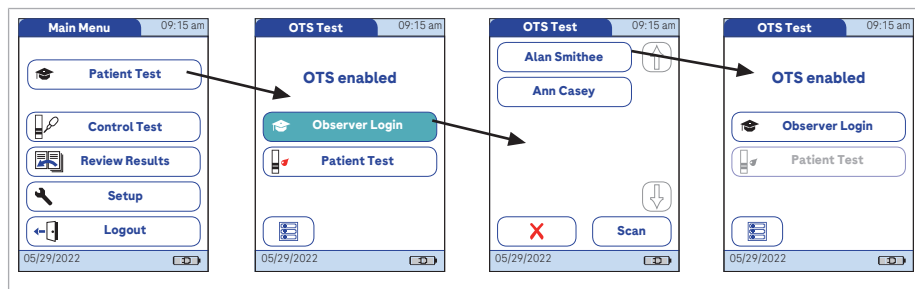
Observed Test Sequence (OTS)

The *Observed Test Sequence* (OTS) function allows an observer (supervisor) to assess and record an operator's performance (e.g., for recertification purposes). The observer monitors an operator during a test to check that the test is being performed according to the recommended procedures. He/she then evaluates the performance and passes or fails the operator. This assessment is saved together with the test result and any desired comments.

Observed Test Sequence options can only be configured using a DMS. The availability of electronic configuration options will thus vary according to the data management software utilized by your institution. Consult your system administrator.

Using the OTS function


A request for an Observed Test Sequence comes from the DMS. The presence of the  icon on the **Patient Test** button indicates a pending OTS request.



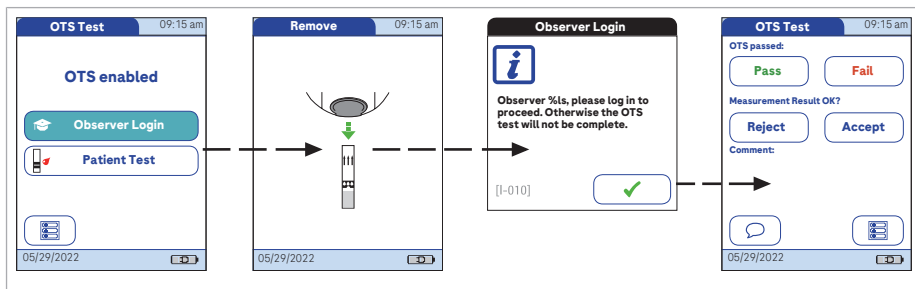
► To log on as an observer during OTS

- 1 Touch **Patient Test**.
In the *Pat. Test - OTS* menu, the **Patient Test** button is grayed out (disabled) until the observer has logged in.
- 2 Touch **Observer Login**.
- 3 Wait until the observer list is displayed.
- 4 Select your observer ID by touching the corresponding button, or scan your operator ID (which is also your observer ID in this case).

Only operators with OTS observer rights are listed in the Observer Login list.

- 5 Enter the (optional) password.
- 6 After you enter your password, touch  to log in. The *Pat. Test - OTS* menu is displayed again. The **Patient Test** button is now active.
- 7 Hand the meter to the operator who can now perform the patient test under supervision.

► To log on as an operator during OTS



1 Touch **Patient Test**.

Perform the patient test as usual. Once the test is completed, the observer has to complete the next steps.

2 Hand the meter back to the observer.

► To perform tasks as an observer during OTS

1 Touch to log in again.


2 After you enter your password, touch to proceed with the assessment.

3 Assess the operator's performance by touching **Pass** or **Fail**.

4 Assess the test result by touching **Accept** or **Reject**.

5 Touch to add a comment.

6 Once you have selected the desired comment(s), touch to return to the *Pat. Test - OTS* screen, or touch to exit the *Comment* screen without adding a comment.

- 7 Touch  to return to the *Main Menu*.

The OTS information is saved together with the test result.

14 Notes:

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