

CoaguChek® Pro II
Operator's Manual

CoaguChek®

CoaguChek® Pro II

Operator's Manual

Publication version 8.0

Software version 04.08

07154879001 (10) 2024-02 EN

Publication information

Manual version	Revision date	Changes
1.0	2015-11	New document
2.0	2015-11	Revised safety information on barcode handling, minor changes
3.0	2016-12	Software update, valid for SW04.02.xx; new features: EAP, parameter activation, extended data handling functionality for computer/ printer; new power management; miscellaneous editorial revisions
4.0	2017-04	Software update, valid for SW04.02.xx; new feature: meter shut down / restart; changed contact information Australia; updated cleaning and disinfection agents (Clorox not recommended anymore); updated storage and transport conditions; miscellaneous editorial revisions
5.0	2018-09	Software update, valid for SW04.03.xx; new features: lockout configuration extension; QC interval reset; miscellaneous editorial revisions
6.0	2020-10	Software update, valid for SW04.04.xx. All changes included from addendum, Version 1, 2019-09, 0 9073434001 (01) 2019-09 EN. Software update, valid for SW04.05.xx.
6.1	2021-11	Implementation of IVDR related requirements (IVDR: in vitro diagnostics regulation).
7.0	2022-08	Software update, valid for SW04.07.xx; new features: technical integration with **cobas infinity** edge, meter credentials, configuration barcodes; miscellaneous editorial revisions
8.0	2024-01	Software update, valid for SW04.08.xx; new features: added download feature for code chip data

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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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Approvals

The CoaguChek® Pro II system meets the requirements laid down in:

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

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



The Wi-Fi CERTIFIED Logo is a certification mark of the Wi-Fi Alliance.



In vitro diagnostic medical device



Complies with the provisions of the applicable EU regulations.



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).



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

On meters with WLAN capability:

This device complies with Part 15 of the FCC Rules and with RSS-247 of Industry Canada.

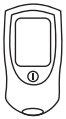
For other WLAN certifications, see label on bottom of battery compartment and addendum for information on WLAN registration.

Symbols and abbreviations

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 Pro II 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

SN	Serial Number
	Device for near-patient testing
	Device not for self-testing
	Consult instructions for use
12V ⎓ 1.25A	Power supply connection
CONTENT	Contents of the pack

Table of contents

Publication information 3
Symbols and abbreviations 7
What is new in publication version 8.0? 11

1 Introduction 13
1.1 Before you start 13
1.2 Important safety instructions and additional information 18
1.3 Overview of the meter elements 32
1.4 Buttons and icons overview 34
1.5 Power supply 39

2 Putting the Meter into Operation 41
2.1 Installing or replacing the battery pack 42
2.2 Powering the meter on and off 47

3 Meter Setup 49
3.1 Display of screen elements 49
3.2 Settings summary 51
3.3 Screen setup 58
3.4 Options setup 68
3.5 ID setup 86
3.6 QC Settings setup 95
3.7 Diagnostics 110

4 Testing a Blood Sample 113
4.1 Important notes 113
4.2 Preparing to test 117
4.3 Performing a test 122

5 Control and Proficiency Testing 135
5.1 Control testing 135
5.2 Preparing to perform a liquid quality control test 136
5.3 Performing a liquid quality control test 139
5.4 Proficiency testing 146
5.5 Preparing to perform a proficiency test 147
5.6 Performing a proficiency test 148

6 Review Results (Memory) 153
6.1 Viewing test results ... 154

7 Extended Functionalities 159
7.1 Data handling ... 159

8 Maintenance and Care 167
8.1 Conditions for storage and shipping ... 167
8.2 Cleaning and disinfecting the meter ... 169
8.3 Recommended cleaning/disinfecting agents ... 171
8.4 Cleaning/disinfecting the exterior (meter housing) ... 172
8.5 Cleaning/disinfecting the test strip guide ... 173
8.6 Cleaning the scanner window ... 175
8.7 Cleaning after a notification appears ... 176

9 Troubleshooting 179
9.1 Status / Error messages ... 179
9.2 Shut down / restart / reset meter ... 185

10 General Product Specifications 189
10.1 Technical data ... 189
10.2 Further information ... 191

11 Warranty 193

12 Appendix A 195
A.1 Operator and patient ID barcode masks ... 195
A.2 Example of barcode symbologies ... 196
A.3 Supported characters in 2D barcodes ... 200

13 Appendix B 201
B.1 Supplement for Observed Test Sequence ... 201
Using the OTS function ... 202

14 Appendix C 205
C.1 Option: Wireless network (WLAN) ... 205

Index 211

What is new in publication version 8.0?

This section provides an overview of all major changes from Operator's Manual version 7.0 to version 8.0. Deletions or minor corrections are not listed.

SW04.08.xx

- New function for downloading code chip data for test strip and QC lots.

To manage code chip data (82)

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1 Introduction

1.1 Before you start

Intended use

The CoaguChek® Pro II is an in vitro diagnostic instrument intended for the determination of PT and aPTT in whole blood using the CoaguChek PT Test and CoaguChek aPTT Test. The CoaguChek® Pro II is intended for near-patient testing. Not for self-testing.

Important information regarding use

Released and launched parameters are country-specific. Only parameters available on the market in the respective country can be activated.

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 Pro II 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 (65)

To set the date (64)

To set the date and time format (66)

QC (quality control) Lockout (100)

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 (179)*.

For all questions about the CoaguChek Pro II system that are not answered in this manual, contact your Roche Diagnostics representative. In order to expedite troubleshooting, please have ready your CoaguChek Pro II 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 test strips shall prevail.

What can the system do for you?

The CoaguChek Pro II system makes coagulation testing easy. You only need to insert the code chip, power the meter on, insert the test strip for the CoaguChek PT Test or the aPTT 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. Depending on which test parameter is selected, the meter displays the results after approximately one minute (PT) or after several minutes (aPTT). 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 Pro II meter displays test results in units equivalent to laboratory plasma measurements. Results may be displayed in the following ways:

- Parameter: aPTT
  - seconds
- 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 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 Pro II meter has the ability to connect to a data management system (DMS) through the Handheld Base Unit from Roche Diagnostics (available separately) or via wireless communication (WLAN). The CoaguChek Pro II 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 Tests contain desiccated reagents. These consist of activators, a peptide substrate, and nonreactive components. When a sample is applied to a test strip, the reagent dissolves and the activators start the coagulation process, leading to the formation of the enzyme thrombin. Simultaneously the meter starts to measure the time. Thrombin cleaves the peptide substrate, generating an electrochemical signal. Depending on the time elapsed when this signal first appears, it is converted via an algorithm into customary coagulation units (depending on the test, into INR, %Quick, or seconds) and the result is displayed.

Contents of the pack

The CoaguChek Pro II pack contains the following items:

- CoaguChek Pro II 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)

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 Pro II 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.

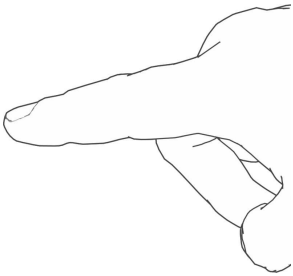
NOTICE!

Notice...

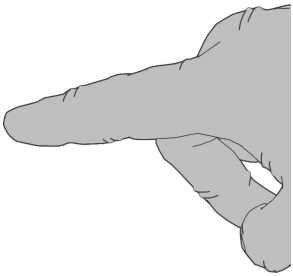
...indicates a hazardous situation that, if not avoided, may result in damage to the system.

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 Pro II system. Operators must have received comprehensive instruction in the operation, quality control, and care of the CoaguChek Pro II 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 Pro II 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 Pro II 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.

⚠ 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 Pro II 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 Pro II 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.

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.

8.3 Recommended cleaning/disinfecting agents (171)

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 Pro II 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 Pro II 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 (159)

Electromagnetic interference

The meter fulfills the IEC 61326-2-6 requirements for emitted interference and interference immunity.



- Do not use the meter near strong electromagnetic fields, which could interfere with the proper operation of the meter.
- As security improvement, the instrument detects interferences caused by electrostatic discharges during measurements. In this case the affected measurement is stopped.

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.

Local Area Network: protection from unauthorized access

- If this meter is connected to a local area network, this network must be protected against unauthorized access. In particular, it must not be linked directly to any other network or the Internet. Customers are responsible for the security of their local area network, especially in protecting it against malicious software and attacks. This protection might include measures, such as a firewall, to separate the device from uncontrolled networks as well as measures that ensure that the connected network is free of malicious code. If user data and/or passwords are altered by means of a compromised DMS the meter might become unusable.
- If you use a customized data management system solution, ensure that sensitive data transmitted via the POCT1-A interface is protected by appropriate security measures.

- Ensure that the instrument is protected against unauthorized physical access and theft.
- Do not use shared user or operator accounts on meter, DMS and network.
- Whether working in a wired or wireless environment, use a strong password for user or operator accounts on the meter, DMS, and network. Observe your own facility guidelines on password management where available, or apply the rules for strong passwords, see "**Characteristics of strong passwords**" below.

Wired network connection

If the Handheld Base Unit from Roche Diagnostics is used to connect this meter to a local area network, the Handheld Base Unit must be protected against unauthorized access by means of a **strong password management**. Observe your own facility guidelines on password management where available, or apply the following rules:

Characteristics of strong passwords

- 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)

Characteristics of weak passwords

- **uhxwze11** contains no upper case letter.
- **UHXW13SF** contains no lower case letter.
- **uxxxxx7F** contains the same character more than four times.
- **x12useridF** contains a substring of the user ID longer than four characters.

Wireless connectivity

If the meter is equipped with WLAN functionality: Wireless connectivity allows the meter to send data (test results, patient IDs, operator IDs, etc.) to the data management system without the need to return the meter to the Handheld Base Unit. This feature must be configured by the system administrator. Observe the guidelines of your facility for using wireless local area network connections. For a description of the CoaguChek Pro II meter's ability to connect to Wireless Local Area Networks (WLAN, Wi-Fi), see appendix C.1.

C.1 Option: Wireless network (WLAN) (205)

Radiofrequency radiation exposure information

Glossary:

- "FCC" stands for "Federal Communications Commission" (USA).
- "RF" stands for "radio frequency"
- "RSS" stands for "Radio Standards Specification" (Canada).
- "WLAN" stands for "Wireless Local Area Network"

The Industrial, Scientific and Medical (ISM) radio frequencies may contain emissions from microwave ovens, heaters, and other noncommunication devices. While these types of devices usually pose no threat of interference as they are low-powered devices, the possibility exists that some industrial high power systems may wipe out any attempted communication use of a WLAN. Therefore, perform a site survey and

interference analysis with a spectrum analyzer to view the entire spectrum, looking for signals that might not only be within the frequency range of the intended WLAN but also could be near or at the same frequency and cause interference.

Roche Diagnostics supports industry wireless standards and recommends using products that have Wi-Fi certification. This certification tests products to the 802.11 industry standards for basic connectivity, security, authentication, Quality of Service (QoS), interoperability and reliability. The Wi-Fi CERTIFIED logo is an assurance that the Wi-Fi Alliance has tested a product in numerous configurations and with a diverse sampling of other devices to ensure compatibility with other Wi-Fi CERTIFIED equipment that operates in the same frequency band. The Wi-Fi Alliance network of independent test labs conducts interoperability testing programs to ensure that wireless devices work together and support secure connections.

The CoaguChek® Pro II system complies with FCC radiation exposure limits set forth for an uncontrolled environment.

Radiofrequency radiation exposure Information: This device has been tested and meets the FCC/ISED RF exposure guidelines. Nevertheless, the device should be used in such a manner that the potential for human contact during normal operation is minimized.

Note: The UNII-1 band (5150-5250 MHz) is only allowed for indoor use in Canada.

This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter.

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

This device complies with Part 15 of the FCC Rules and with RSS-247 of Industry Canada. Operation is subject to the following two conditions:

(1) this device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation

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

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by powering the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.

- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This Class B digital apparatus complies with Canadian ICES-003.

Operating conditions

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

- Only use the meter at a room temperature between 12 °C and 32 °C (54 °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).
- When operating the meter using the power adapter, use only a voltage of 100 V to 240 V (± 10%) , 50/60 Hz.
- When testing, place the meter on a level, vibration-free surface, or hold it so it is roughly horizontal.

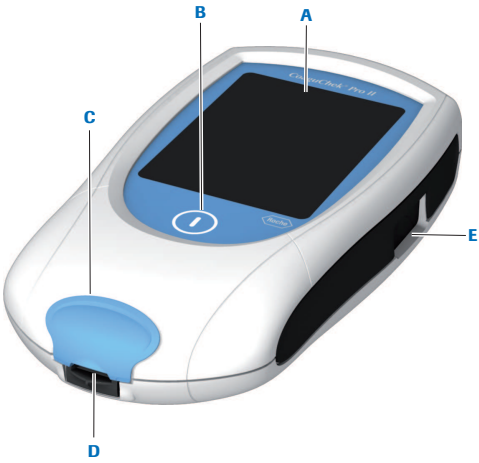
Quality control

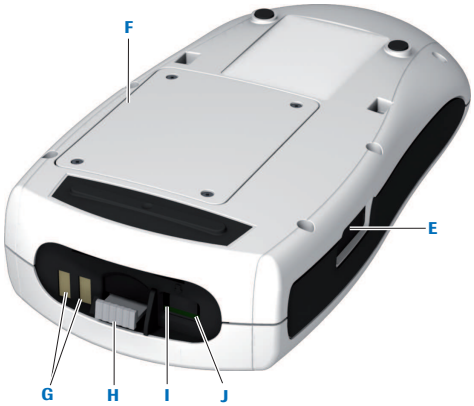
The meter has a number of built-in quality-control functions:

- 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 Pro II system. These controls are designed to assist you in meeting regulatory compliance requirements at your facility.

1.3 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.

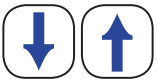
H Code chip slot (shown with code chip)
Insert the code chip here.

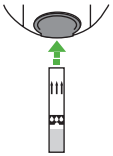
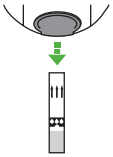
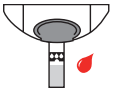
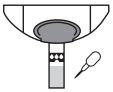
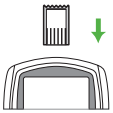
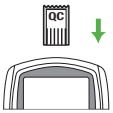
I Connection socket for power adapter
Plug in the power adapter here.

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

1.4 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
	Display test result as QR code
	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)
	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
%Q	Results are displayed as a Quick percentage value
SEC	Results are displayed in seconds
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.

Button/Icon	Meaning
	Quality control: Result is above the specified range
	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, *Troubleshooting*)
	Reports an error message or a warning (see Chapter 9, *Troubleshooting*)

Button/Icon	Meaning
QC!	Lockout, one or more parameters are locked
	Reset; resets setup

The following icons may appear when using the meter in conjunction with a data management system (DMS).

Button/Icon	Meaning
	If displayed in the status bar: communication is taking place via the infrared interface.
	■ Last synchronization passed.
	■ Last synchronization failed.
	If displayed in the status bar: communication is taking place via WLAN.
	■ Last synchronization passed.
	■ Last synchronization failed.
	If displayed in the status bar: communication security status. ■ The last communication with the data management system was neither TLS encrypted nor TLS authenticated. ■ The last communication with the data management system was TLS encrypted, but not TLS authenticated. ■ The last communication with the data management system 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

Button/Icon	Meaning
	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 data management system. 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.

1.5 Power supply



The CoaguChek® Pro II 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.

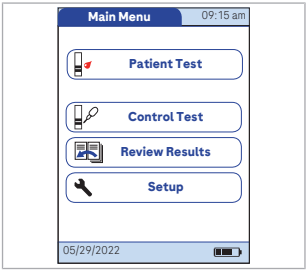


To save power, the CoaguChek® Pro II meter has an automatic power-off function (auto-off). The default setting is 5 minutes of inactivity (e.g., no screen touches). It is possible to customize the auto-off function via your Setup selection (see *Auto Off*).

When the meter powers itself off, all results are automatically saved to memory.

To enable the auto off option (71)

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 (39)

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 Pro II 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.

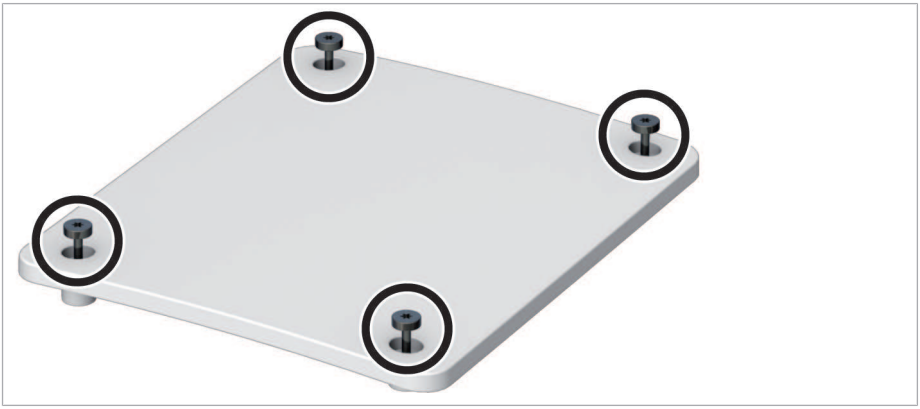
Make sure that the permitted temperature range for charging the battery pack (12-32 °C or 54-90 °F) is maintained during installation and initial setup.

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 (45)

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.

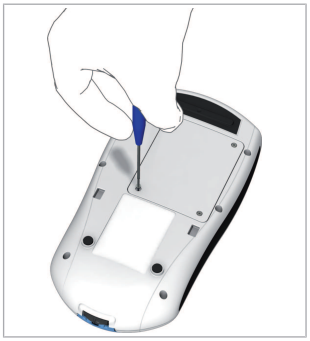
4 Place the battery pack inside the battery compartment as described in the previous steps.

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

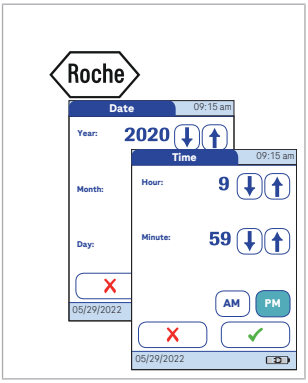
- the plug connector wires do not get pinched between meter and cover
- the protrusion on the battery compartment cover fits into the corresponding groove on the battery compartment rim



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.

If you press the On/Off button for too long, a meter reset will be triggered after about 12 seconds and date and time will be lost.

To reset the meter (186)



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



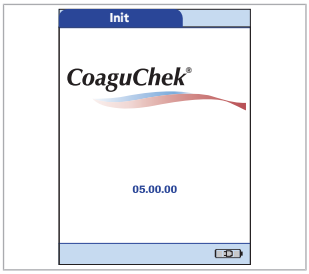
1 Place the meter on a level, vibration-free surface, or hold it in your hand so it is roughly horizontal.

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 (110)

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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**).

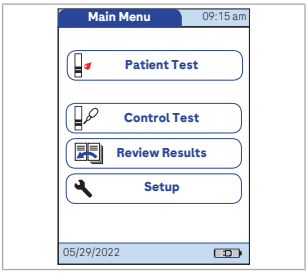
Other screen elements (e.g., Menu titles) are written in *italics*. These screen elements are not active.

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.

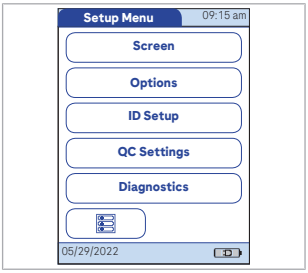
After date and time have been set, the meter automatically moves to the *Main Menu*, where you can start a test or enter more settings.



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.



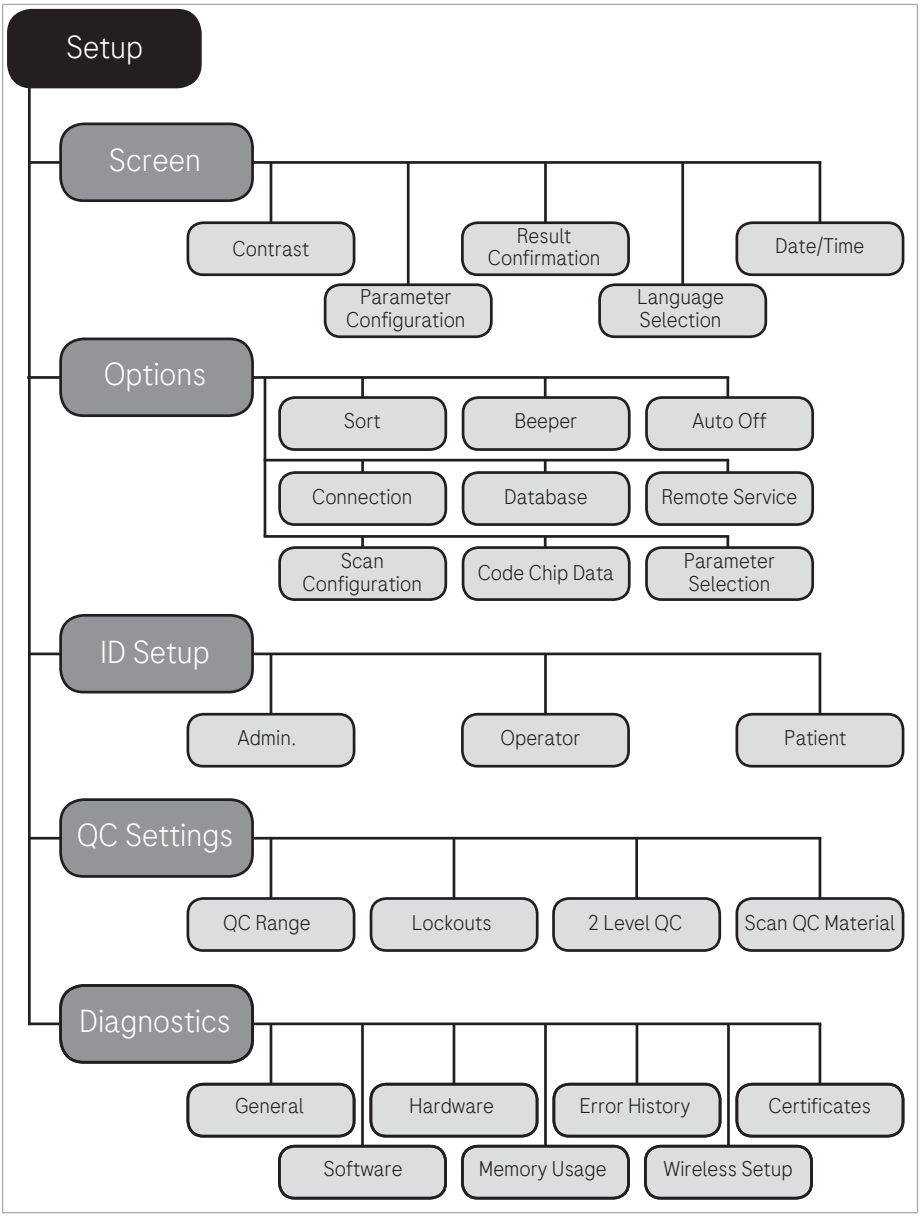
If the meter did not automatically enter the *Setup* mode (e.g., after the battery pack was replaced), you can open the *Setup Menu* from the *Main Menu*.



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.


Setup
Screen
Contrast
Result Confirmation
Date/Time
Parameter Configuration
Language Selection
Options
Sort
Beeper
Auto Off
Connection
Database
Remote Service
Scan Configuration
Code Chip Data
Parameter Selection
ID Setup
Admin.
Operator
Patient
QC Settings
QC Range
Lockouts
2 Level QC
Scan QC Material
Diagnostics
General
Hardware
Error History
Certificates
Software
Memory Usage
Wireless Setup

Group	Subgroup	Setting	Values[a]
Screen	Contrast		0 – 10 (5 *)
	Parameter Configuration	Result Units PT	INR *
			INR/SEC
			INR/%Q
		Parameter Activation	PT *
			PT, aPTT
	Result Confirmation		Enable
			Disable *
	Language Selection		Čeština
			Dansk
			Deutsch
			English *
			Español
			Français
			Italiano
			Nederlands
			Norsk
			Português
			Русский
			Suomi
			Svenska
	Date/Time	Date	01/01/2015 *
		Time	12:00 am *
		Date formats	DD.MM.YYYY (01.01.2015)
			MM/DD/YYYY (01/01/2015) *

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

Group	Subgroup	Setting	Values[a]
			YYYY-MM-DD (2015-01-01)
		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	Off *
			On
	Auto Off	[minutes]	Off
			1 ... (5*) ... 10
			15
			20
			25
			30
			40
			50
			60
	Connection		Off *
			Computer
			Printer
			Computer/Printer

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

Group	Subgroup	Setting	Values[a]
		QR Code	Off *
			On
	Database	Result Retention	On (time in days)
			Off
		Delete Database	Results
			Code Chip Data
			Entire Database
	Remote Service	Remote Service	On
			Off
		WLAN	On
			Off
	Scan Configuration		Scan
	Code Chip Data	Strips	Romkey Insertion
			Download
		Controls	Romkey Insertion
			Download
	Parameter Selection		Enable
			Disable *
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

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

Group	Subgroup	Setting	Values[a]
QC Settings	QC Range	PT	Default Range *
		aPTT	Custom Range
	Lockouts	Operator Lockout (only if the *Operator* option is set to *Active* and an operator list is available)	Off *
			Weekly
			Monthly
			Every 3 months
			Every 6 months
			Yearly
			Number of levels
		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")
		QC Interval Settings	Time of day
			First day of week
		STAT Test Config.	Enable
			Disable *
			Quantity
	2 Level QC		Yes *
			No
	Scan QC Material		Optional *
			Scan Only
Diagnostics	General		

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

Group	Subgroup	Setting	Values[a]
	Software		
	Hardware		
	Memory Usage		
	Error History		
	Wireless Setup		
	Certificates	Client Certificate	
		Server Certificates	
		Root CA Certificates	
		Credential Download	

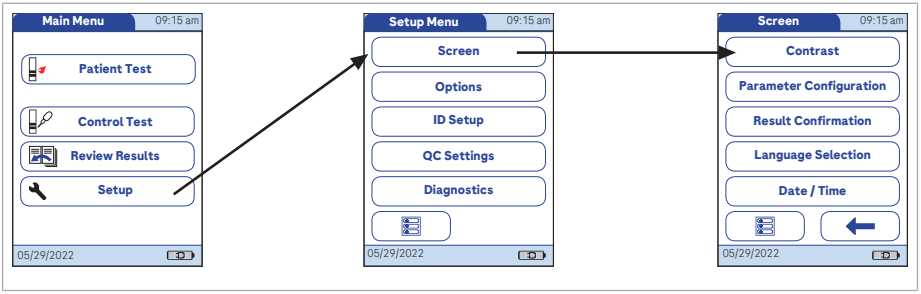
[a] Default settings are labeled with an asterisk (*).

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.

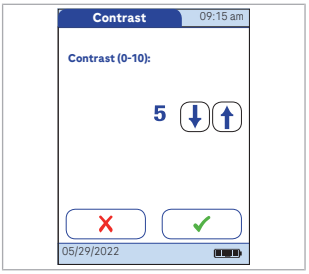


1 From the *Main Menu*, touch **Setup** to open the meter settings.

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.

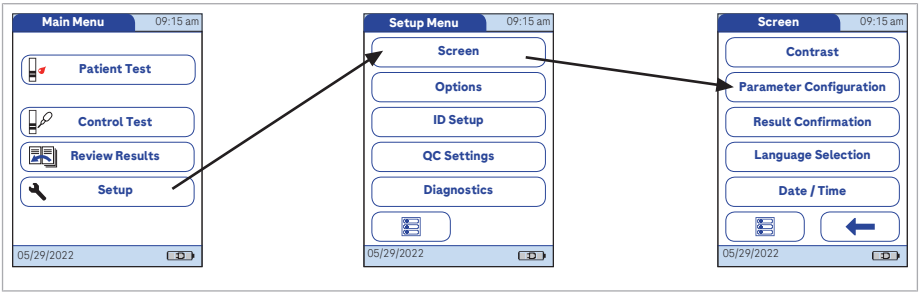
5 Touch ✓ to save this setting, or touch ✗ to exit this menu without saving any changes. The display automatically returns to the previous screen.

To configure an additional parameter

In the *Parameter Configuration* menu you can set the units for the display of PT test results and activate additional test parameters on the meter.

To configure the results units for PT

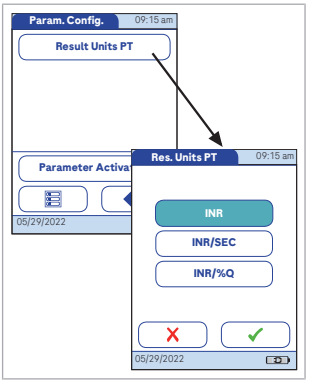
Use this setting to select the unit(s) in which the result is displayed. This setting only applies to PT test results. Regardless of the settings chosen for PT, aPTT is always displayed in seconds.



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.

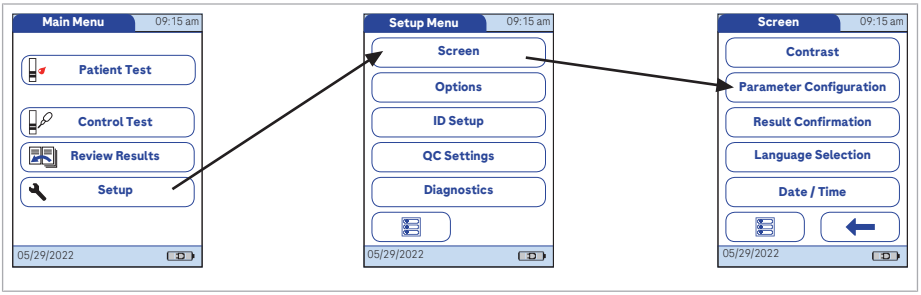
6 Touch ✔ to save this setting, or touch ✘ to exit this menu without saving any changes. The display automatically returns to the previous screen.

To activate an additional parameter

Additional test parameters can be activated on the meter. For doing so you need the corresponding CoaguChek Test Strips with the matching code chip at hand.

Available parameters are country-specific. Only parameters available on the market in the respective country can be activated.

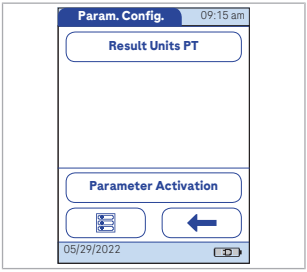
The following parameter can optionally be enabled:
aPTT



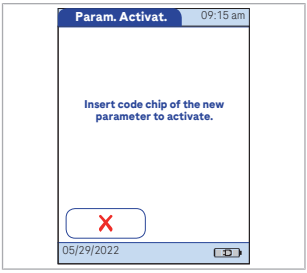
1 From the *Main Menu*, touch **Setup** to open the meter settings.

2 From the *Setup Menu*, touch **Screen**.

3 From the *Screen* menu, touch **Parameter Configuration**.



4 From the *Parameter Configuration* menu, touch **Parameter Activation**.



5 Insert the code chip from the new box of test strips. The new parameter will now be activated.

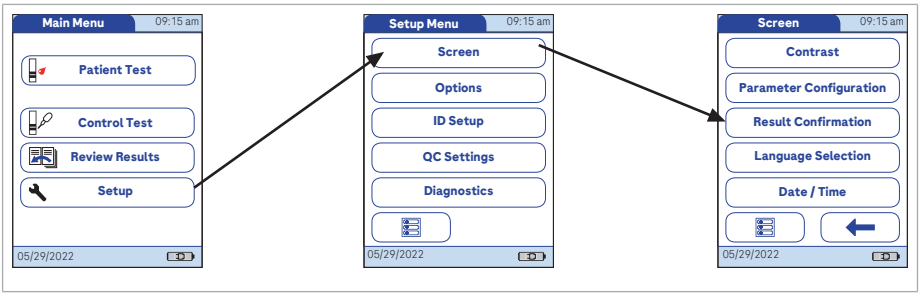
6 Touch ✔ to confirm the corresponding information message. The display automatically returns to the *Parameter Configuration* menu.

If the **Parameter Activation** button is grayed out, all available parameters have already been activated on this meter.

A parameter that has already been activated on the meter remains activated even after performing a software update. In this case, it can only be disabled via a DMS.

▸ To activate the results confirmation option

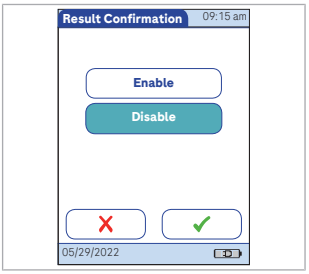
In some circumstances, it may be useful for operators to confirm the validity of their results. Use this setting to prompt operators to confirm the results of every test.



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**.

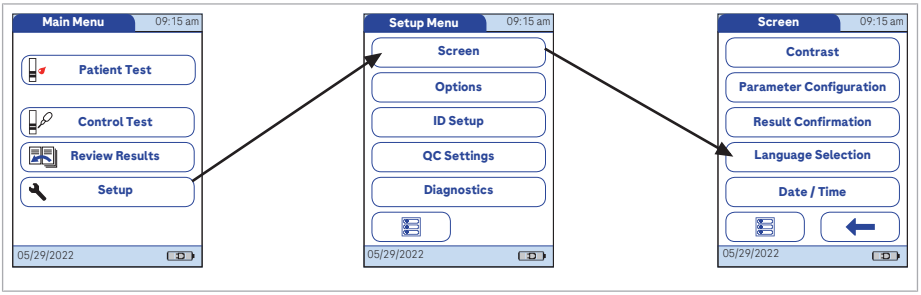


4 Touch **Enable** or **Disable**. Your selection is now highlighted.

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.



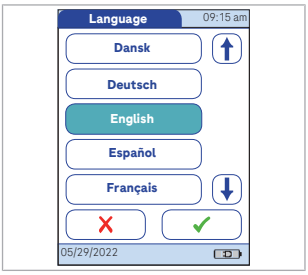
1 From the *Main Menu*, touch **Setup** to open the meter settings.

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.

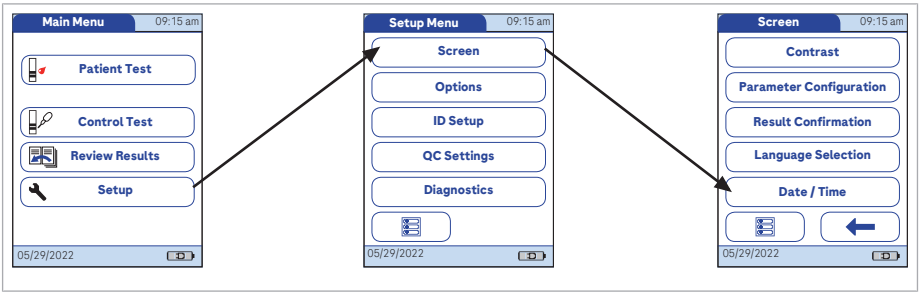
6 Touch ✓ to save this setting, or touch ✗ to exit this menu without saving any changes. The display automatically returns to the previous screen.

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:

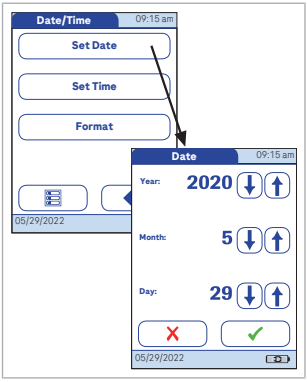
- Date: Day.Month.Year, e.g., 29.05.2015
- Date: Month/Day/Year, e.g., 05/29/2015
- Date: Year-Month-Day, e.g., 2015-05-29
- Time: 24H or 12H



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.

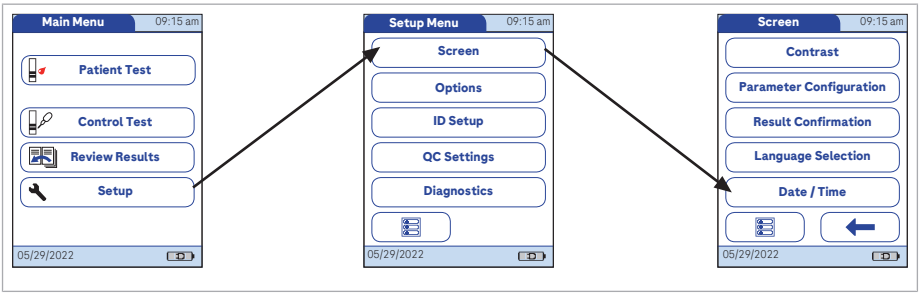
6 Touch ✓ to save this setting, or touch ✗ to exit this menu without saving any changes. The display automatically returns to the previous screen.

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

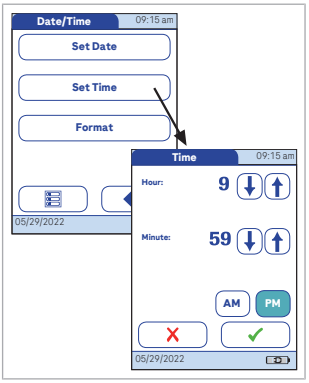
When you power on the meter for the first time (or after a long period without power), this *Time* setup menu appears automatically after you set the date. If at a later time a time adjustment is needed, go to the *Setup Menu*, then select the menu of choice.



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.

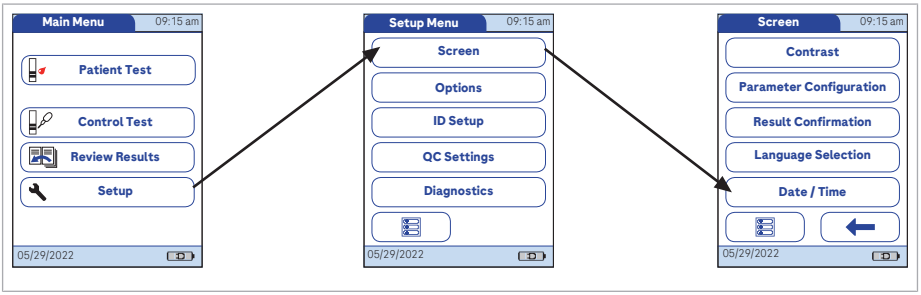
6 Touch ✓ to save this setting, or touch ✗ to exit this menu without saving any changes. The display automatically returns to the previous screen.

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

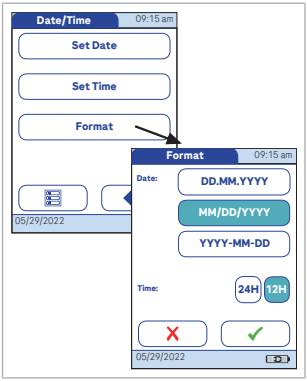
Select your preferred format for the date and time display.



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.

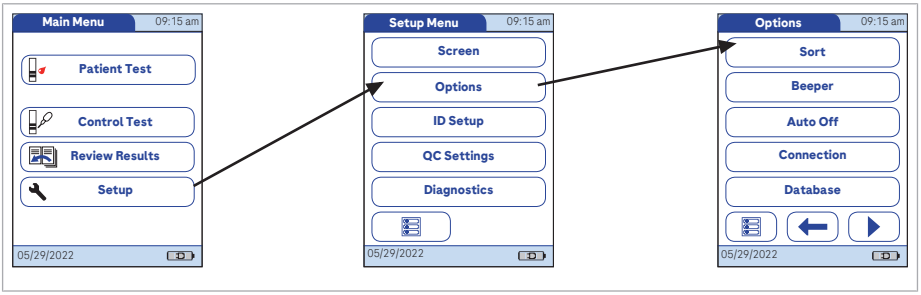
6 Touch ✓ to save this setting, or touch ✗ to exit this menu without saving any changes. The display automatically returns to the previous screen.

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 Pro II meter. You can display stored results chronologically by date and time or by person, based on the *Patient ID*.



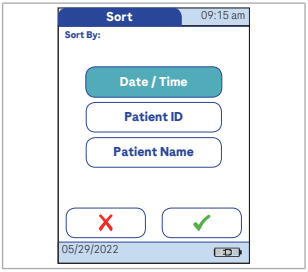
1 From the *Main Menu*, touch **Setup** to open the meter settings.

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 (159)

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

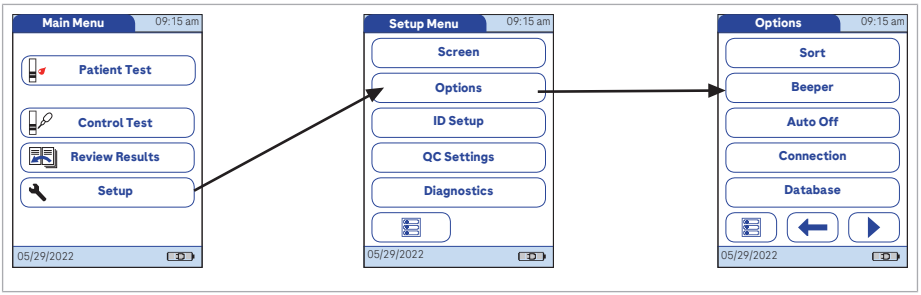
▸ To enable/disable the beeper option

The CoaguChek Pro II 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.

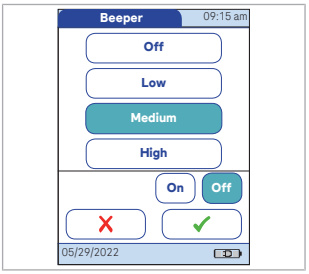
You can also activate a *Key Click*. When a *Key Click* is enabled, the meter clicks briefly every time a button is touched, facilitating the input of information.



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*:

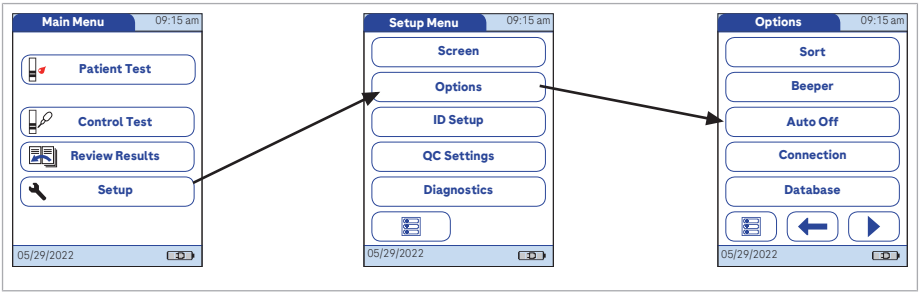
- **On**
- **Off**

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 ✗ 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 Pro II 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**.

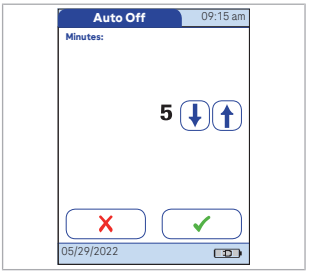
3 From the *Options* menu, touch **Auto Off**.

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.

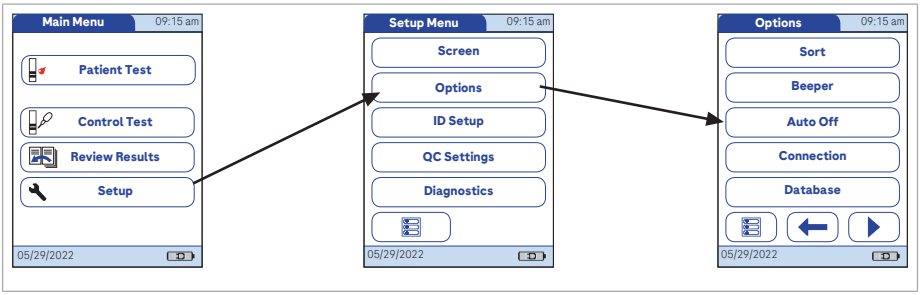
6 Touch ✓ to save this setting, or touch ✗ to exit this menu without saving any changes. The display automatically returns to the previous screen.

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

In addition to this direct data output, test results may also be encoded as QR codes, which can be scanned to be used with other applications.

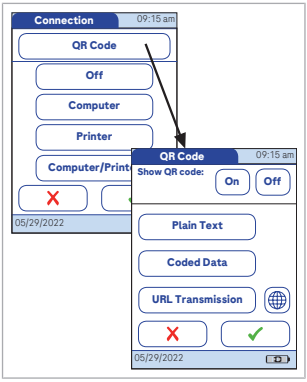


1 From the *Main Menu*, touch **Setup** to open the meter settings.

2 From the *Setup Menu*, touch **Options**.

3 From the *Options* menu, touch **Connection**.

To enable/disable the QR Code display



1 From the *Connection* menu (see section above), touch **QR Code**.
To open the connection menu (72)

2 Touch **On** to enable, or touch **Off** to disable QR code display. Your selection is now highlighted.

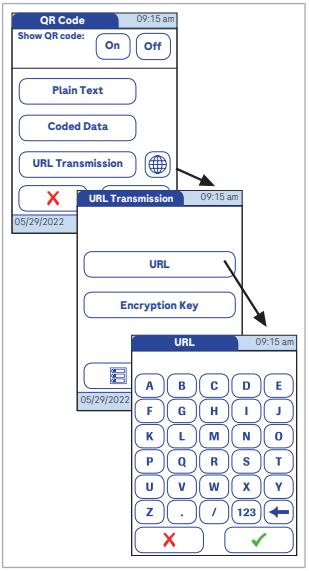
3 If you have enabled this feature, select the style of the QR code to be displayed:

- **Plain Text**: Use this option to scan the result into a PC hosted application (e.g. electronic medical record). In order to do so, you need an external 2D barcode scanner attached to your PC. Once scanned, the test result and related meta-information (e.g. date, time, comments) will appear as plain text in your PC application.

  Ensure that your environment for reading QR codes (QR code reader, operating system, text processing application) is appropriate for your language. Disregard may lead to unpredictable behavior of your receiving component (PC, mobile device).
- **Coded Data**: Use this option to scan the result into a smartphone or tablet app, or a PC hosted application.
- **URL Transmission**: Use this option to upload the result to a web based service (e.g. such as an electronic health record, coagulation management software, etc.). For this option further parameters (URL, encryption key) must be set.

  Note: For the options **Coded Data** and **URL**

Transmission dedicated software programs or apps are required in order to use this feature. If you are a customer or a 3rd party IT provider, and you are interested to use this feature, contact your local Roche Diagnostics representative for additional information.



4 Touch **Plain Text**, **Coded Data** or **URL Transmission**, depending on the intended use. Your selection is now highlighted.

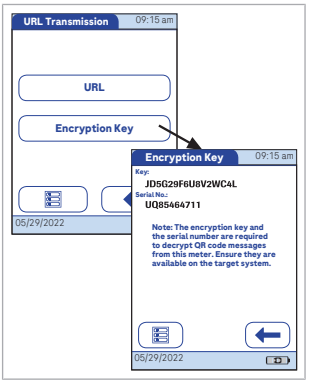
If you have selected **URL Transmission**, the button will become active. Use this button to set the additional parameters.

5 Touch to open the *URL Transmission* menu.

6 Touch **URL** to enter the URL to which the test result data will be uploaded (note: the URL will be provided by your specialized service provider).

- Use 123 to switch to input of numbers.
- Use ABC to switch back to input of text.
- Use ← to backspace and correct a mistake.

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



8 Touch **Encryption Key** to display the *Encryption Key* menu.

The *Encryption Key* menu displays two types of information which are required in order to identify and decode the transmitted test result. This information is required by the IT system, to which the test result is transmitted via the defined URL.

This information needs to be exchanged once with your specialized service provider prior to

using the URL transmission method. Contact your specialized service provider in order to exchange this information.

- *Key*: This key is auto-generated by the meter and is required to decrypt the QR code information.
- *Serial No.*: The meter's serial number is required to map the test result to the encryption key.

  Touch the **New** button, if you want the meter to generate a new encryption key.

9 Touch ← twice to return to the *QR Code* menu.

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

▸ To connect to the computer

The CoaguChek Pro II 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 or the meter must be configured for wireless communication.
See C.1 Option: Wireless network (WLAN) (205)

If no wireless communication is configured, the connection is established in two steps.

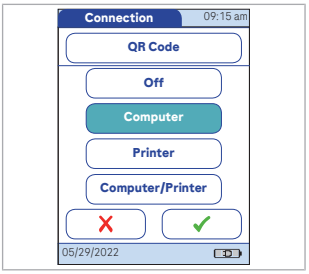
- The meter connects to the Handheld Base Unit via infrared.
- The Handheld Base Unit is either connected to a single computer (via USB) or to a network/host system (via ethernet).

This function can be activated by selecting **Computer** or **Computer/Printer**. 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:

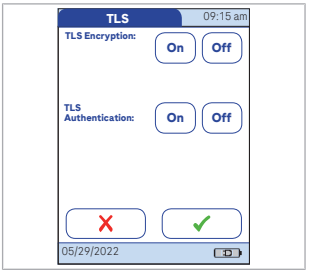
- operator lists, or
- patient lists (lists of patients to be tested)

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.



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

To open the connection menu (72)



If you are using a DMS, from the *TLS* screen you may select **On** or **Off** for the following options:[1]

- *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

[1] TLS authentication is only configurable, if TLS encryption is enabled.

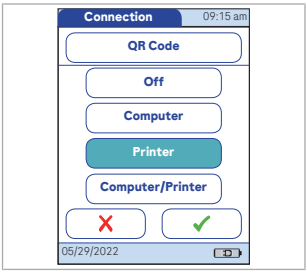
DMS. This is the most effective measure to achieve secure communication.
It is recommended to activate these configurations.

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

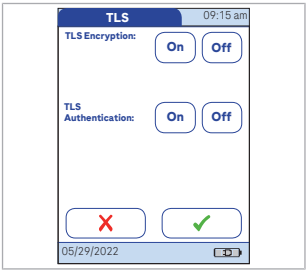
Extended data handling functionality is dependent on the capabilities of the particular Data Management System (DMS) being used and may vary.

To connect to the printer

The CoaguChek Pro II meter can also connect directly to a printer. This function can be activated by selecting **Printer** 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 (72)



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:[2]

- *TLS Encryption:*
  Set to **On** to activate an end-to-end TLS tunnel from the meter to the DMS

[2] TLS authentication is only configurable, if TLS encryption is enabled.

- *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.



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.

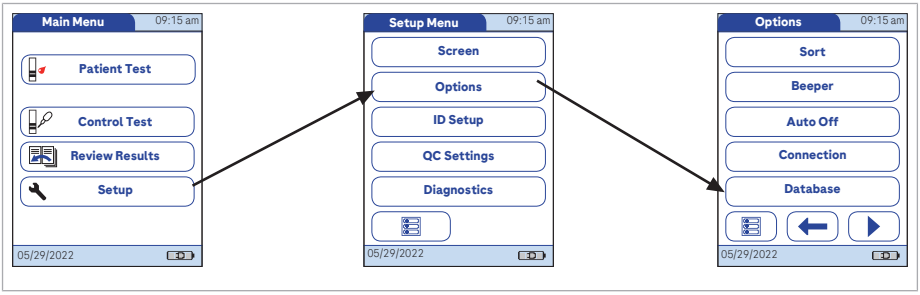
If you work with the meter in a language other than English: With the exception of information you have entered - such as patient ID and name, operator ID, comments - the printout will be in English.
See To select a language (62)

To configure the database

You can set up your CoaguChek Pro II meter so that the results are retained on the database for a preselected time period.
Use this feature to automatically clear the database

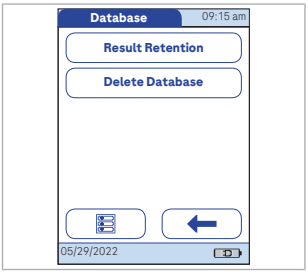
periodically. If you do not use this feature, then you will be required to delete data manually or save the data on a data management system.

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 data management system and the optional Handheld Base Unit (see Chapter 7).



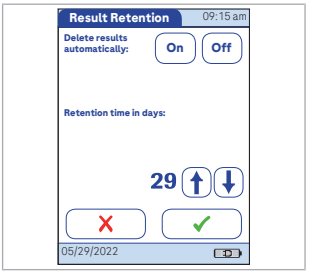
1 From the *Main Menu*, touch **Setup** to open the meter settings.

2 From the *Setup Menu*, touch **Options**.



3 From the *Options* menu, touch **Database**.
You may select from the following options:

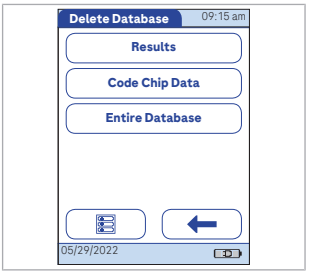
- **Result Retention**
- **Delete Database**



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.



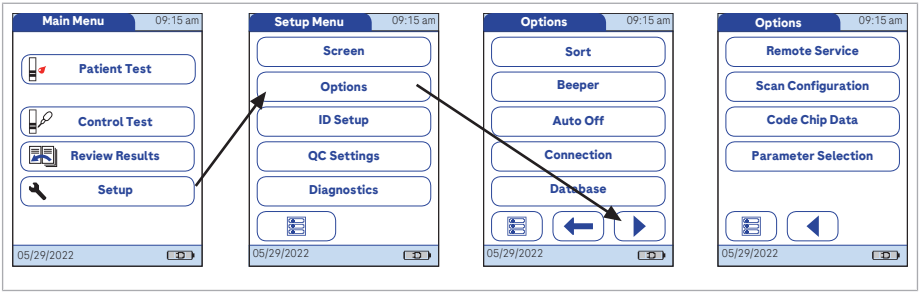
5 If you selected **Delete Database**, you may select from the following options depending on which type of data you would like to delete:

- **Results**
- **Code Chip Data**
- **Entire Database**

6 Touch ← to return to the *Database* screen.

To enable/disable the remote service option

1 The meter can be configured to connect to a remote service, e.g., for device registration or for receiving software updates.

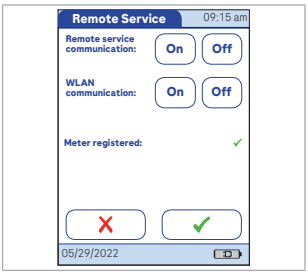


2 From the *Main Menu*, touch **Setup** to open the meter settings.

3 From the *Setup Menu*, touch **Options**.

4 Use ◀ and ▶ to toggle between the screens.

5 From the 2nd *Options* menu, touch **Remote Service**.



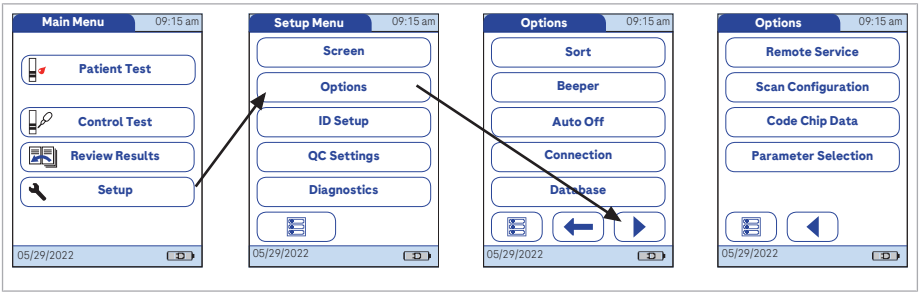
6 You may select **On** or **Off** for the following options:

- *Remote service communication:* enable or disable communication with **cobas infinity** edge via the remote service gateway. Requires WLAN to be enabled.
- *WLAN communication:* allow communication via WLAN (**On**) or only via the Handheld Base Unit (**Off**). This may be DMS communication as well as using a remote service.
- *Meter registered:* the meter has successfully registered with the remote service.

7 Touch ✓ to save this setting, or touch ✗ to exit this menu without saving any changes.

▶ To scan a configuration barcode

1 If the meter is configured to connect to a remote service, the required connection parameters can simply be scanned from a barcode provided by the remote service (e.g., **cobas infinity** edge).

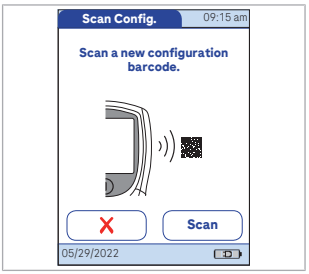


2 From the *Main Menu*, touch **Setup** to open the meter settings.

3 From the *Setup Menu*, touch **Options**.

4 Use ◀ and ▶ to toggle between the screens.

5 From the 2nd *Options* menu, touch **Scan Configuration**.



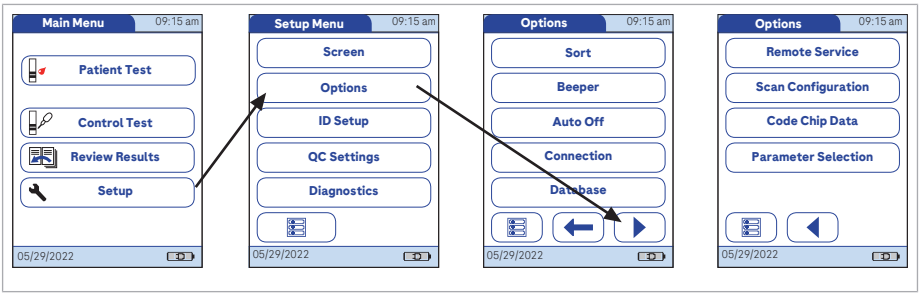
6 Point the built-in barcode scanner to the barcode provided by the remote service (e.g., on the computer monitor).

7 Touch **Scan** and scan the configuration barcode from a distance of approx. 10-20cm (4-8 inches), according to the barcode size.

8 Confirm the information message following the barcode scan and touch ✕ to exit this screen afterwards.

▸ To manage code chip data

The *Code Chip Data* menu shows all code chip data currently stored on the meter. New code strip data may be added via insertion of a new code chip or a download of the corresponding data, if a code chip for a test strip or QC lot is not at hand. For downloading code chip data, the meter must be connected to the remote service.

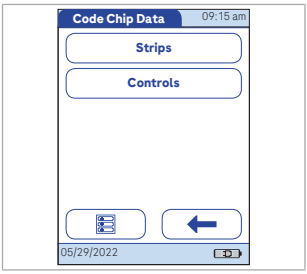


1 From the *Main Menu*, touch **Setup** to open the meter settings.

2 From the *Setup Menu*, touch **Options**.

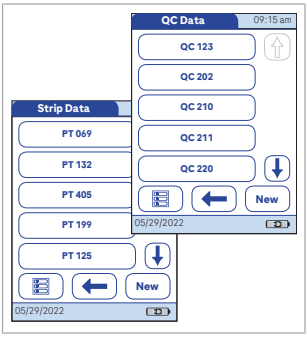
3 Use ◀ and ▶ to toggle between the screens.

4 From the 2nd *Options* menu, touch **Code Chip Data**.

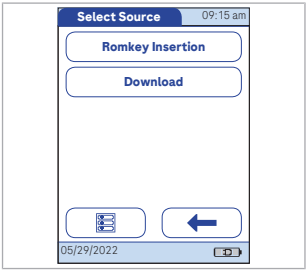


5 From the *Code Chip Data* menu, touch **Strips** or **Controls**.

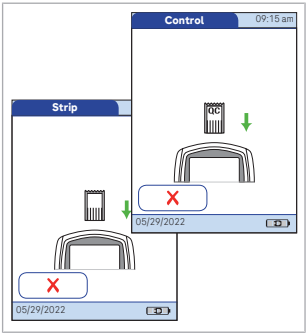
➔ Depending on your choice, the *Strip Data* menu or the *QC Data* menu is displayed.



6 To add a new test strip or QC lot, from the *Strip Data* or *QC Data* menu, touch **New**.

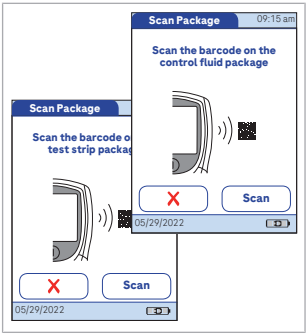


7 From the *Select Source* menu, touch **Romkey Insertion** or **Download**.



8 If you selected **Romkey Insertion**, insert the code chip of the test strip lot or QC lot you wish to add.

➔ The code chip data will automatically be stored on the meter.



9 If you selected **Download**, touch **Scan** to scan the 2D code on the packaging of the test strip or control fluid.

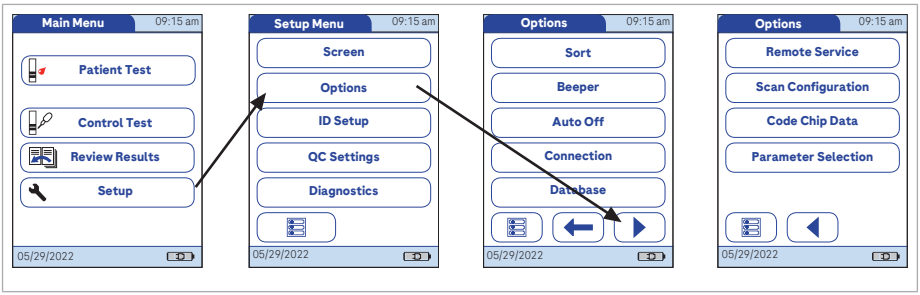
- After scanning the barcode the corresponding code chip data will be downloaded.
- Touch ✔ to store the downloaded code chip data on the meter, or touch ✘ to exit this step without storing the code chip data.

To enable/disable the parameter selection option

When performing a test, the meter can be set to display a screen that allows the operator to select the test parameter to be used. Otherwise the meter will determine the test parameter by reading the test strip (barcode) information from the inserted test strip.

The **Parameter Selection** button is only available, if more than one parameter has been activated on this meter.

See To activate an additional parameter (60)

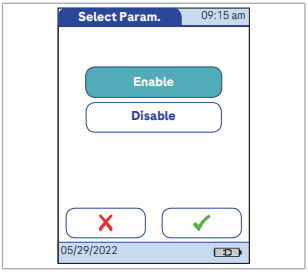


1 From the *Main Menu*, touch **Setup** to open the meter settings.

2 From the *Setup Menu*, touch **Options**.

3 Use ◀ and ▶ to toggle between the screens.

4 From the 2nd *Options* menu, touch **Parameter Selection**.



5 Touch **Enable** to display the parameter selection screen prior to each test or touch **Disable** to have the meter select the parameter by reading the test strip information.

6 Touch ✓ to save this setting, or touch ✗ to exit this menu without saving any changes.

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:

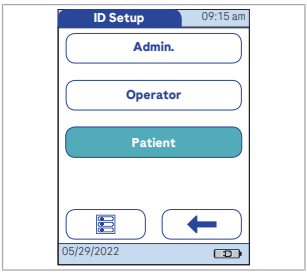
- **System Administrator**: The *Admin*. (Administrator) has special rights to enter certain meter settings and is the only one who can enter and change these settings. It is not necessary for *Admin*. identification to be activated to use the CoaguChek® Pro II meter. However, it might be desired or 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 ID*s, 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 ID*s for informational purposes only, in order to assign stored measurement results to the users who performed the test. In this case *Operator ID*s 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 (159)

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 (159)



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**).

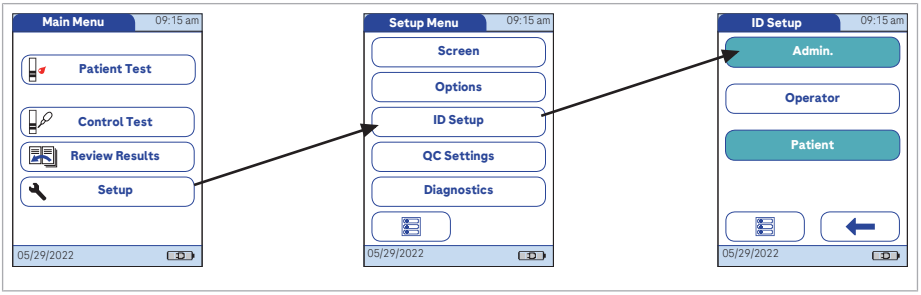
System Administrator (Admin.)

In the default setting, the meter is not protected with an *Admin*.ID, and all setup options are accessible to every user. If you set up an *Admin*.ID, 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), *Remote Service* and *Scan Configuration*
- *ID Setup* (the entire area)
- *QC Settings* (the entire area)
- *Diagnostics*: *Software*, *Hardware*, *Memory*, *Wireless Setup*, *Certificates*

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

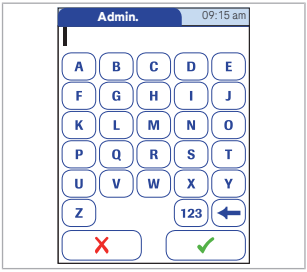
To configure an Admin. ID



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

2 From the *Setup Menu*, touch **ID Setup**.

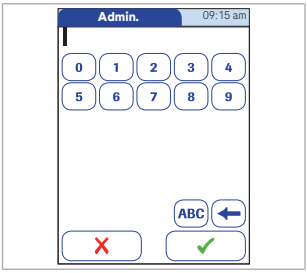
3 From the *ID Setup* menu, touch **Admin.**



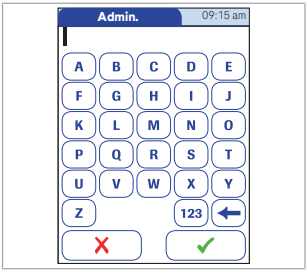
4 Using the keypad displayed on the screen, enter the *Admin*. ID of choice. The ID can consist of up to 20 characters.

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 ✗ to exit this menu without saving any changes. The display automatically returns to the previous screen.

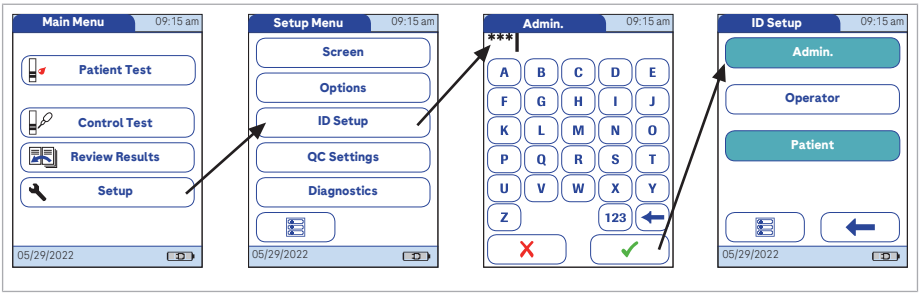
9 Enter the *Admin*. ID again (the keypad is automatically displayed again on the screen) to confirm the first entry.

10 Touch ✓ to save this entry, (the *Admin*. ID is now set), or touch ✗ to exit this menu without saving any changes. The *Admin*. ID 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.) (88)

To change an Admin. ID



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

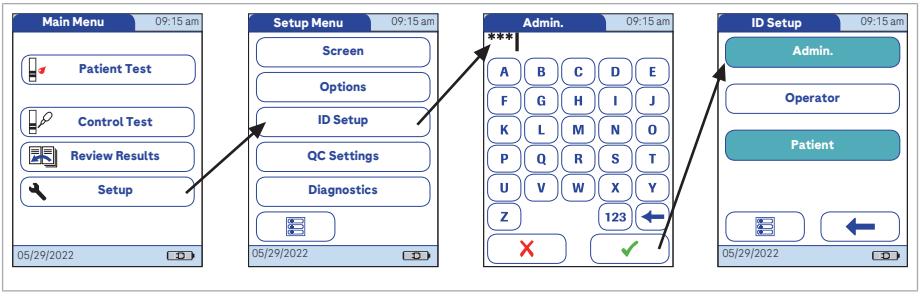
2 From the *Setup Menu*, touch **ID Setup**.

3 Using the keypad displayed on the screen, enter the current *Admin*. ID.
The *ID Setup* menu is displayed. The **Admin.** button is highlighted, which means an *Admin*. ID is active.

4 Touch **Admin.**

5 Using the keypad displayed on the screen, enter (and confirm) the new *Admin*. ID of choice.

To deactivate an Admin. ID

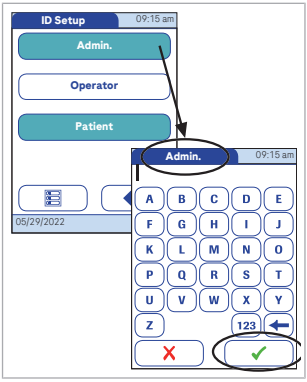


1 From the *Main Menu*, touch **Setup** to open the meter settings.

2 From the *Setup Menu*, touch **ID Setup**.

3 Using the keypad displayed on the screen, enter the current *Admin*. ID.
The *ID Setup* menu is displayed. The **Admin.** button is highlighted, which means an *Admin*. ID is active.

4 Touch **Admin.**



5 Immediately touch ✔ to close the keypad on the screen **without** entering a password.

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

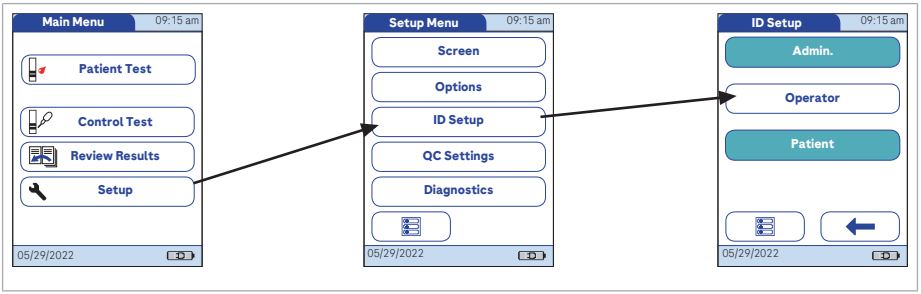
Operator ID

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

7.1 Data handling (159)

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 an operator ID

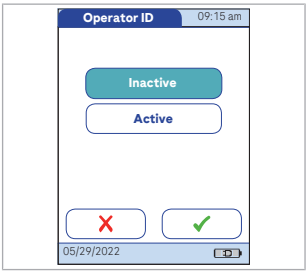


1 From the *Main Menu*, touch **Setup** to open the meter settings.

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.

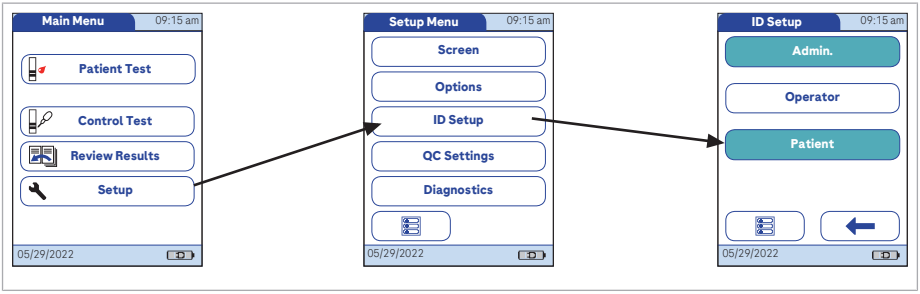
Patient ID

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

7.1 Data handling (159)

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 a patient ID



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

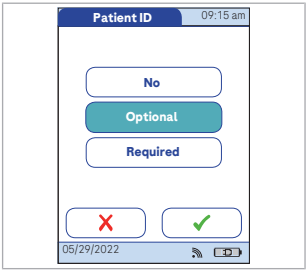
2 From the *Setup menu*, touch **ID Setup**.

3 From the *ID Setup* menu, touch **Patient**.

You may select from the following options:

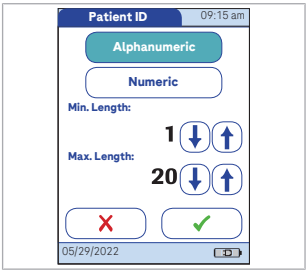
- **No** (tests will be assigned numbers automatically)
- **Optional** (automatic numbering or list/scan/manual input)
- **Required** (list/scan/manual input)

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 data management system (DMS), stored in the meter, and Operator login is activated. These lists are only available in connection with a data management system. For more details see *Data handling*.

7.1 Data handling (159)

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.

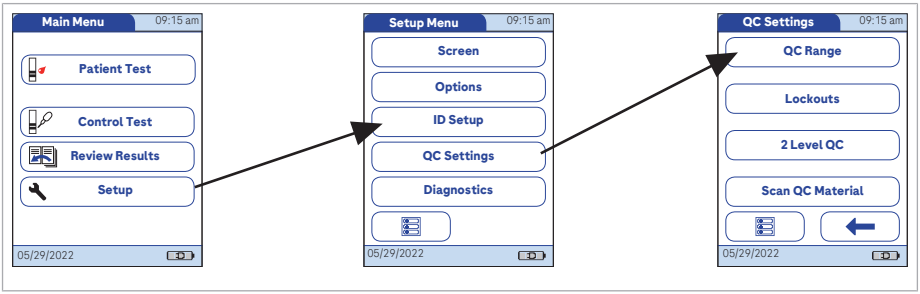
Scan QC Material

The barcode scanner of the CoaguChek Pro II 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.

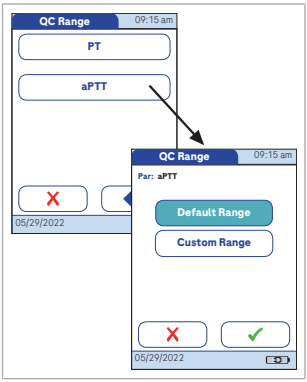
To set a QC range



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**.



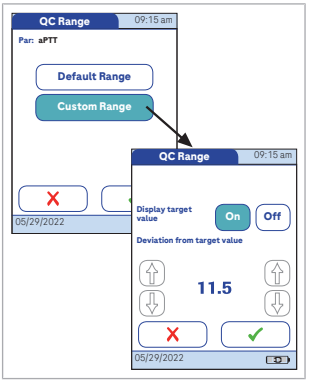
4 From the *QC Range* menu, touch the button of the test parameter you wish to set. You may select from the following options:

- **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.

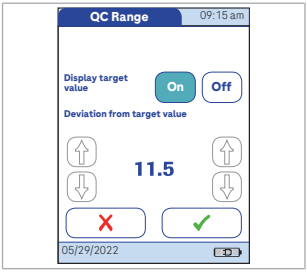


If you selected **Custom Range**, the *QC Range* screen opens and offers you the following options:

- *Display target value* (**On**/**Off**)
- *Deviation from target value* (percentage value). See QC Range (96)

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%).

Note: For the test parameter PT, the percentage deviation from the target value is always defined using INR values. **Even if you have activated %Quick in the setup, the meter always calculates the deviation using INR values**; This range is then converted to %Quick in a second step. As there is no linear correlation between values expressed as INR and values expressed as %Quick, if you calculate the percentage deviation (11.5% in the example) using the %Quick target value, your result may deviate from the result calculated by the meter using the INR target value.

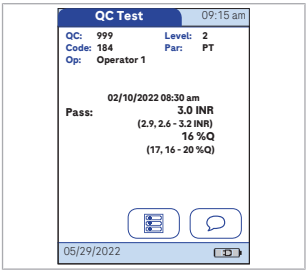


6 Touch **On** (the target value will be displayed with a test result) or **Off** (the target value will not be displayed). Your selection is now highlighted.

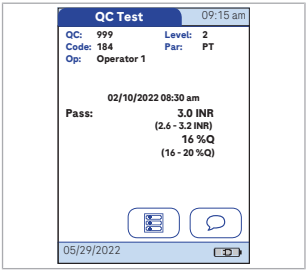
7 Use the arrows to set the allowed percentage deviation from the target value.

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.



If the *Custom Range* and *Target Value* are set to **On**, they appear in a line below the control test result in the QC test and QC memory screens. The target value (2.9) appears **in front of** the custom range.



If the *Display target value* is set to **Off**, only the *Custom Range* is displayed below the control test result.

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**.

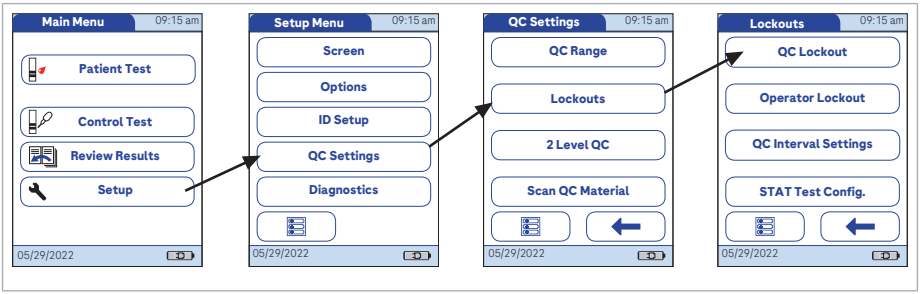
QC Lockout is disabled by default. For routine confirmation of system reliability it is recommended to enable this feature.

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**).

The lockout triggers are set once and are valid for all parameters. The events (time intervals, numbers) triggering the lockouts are counted individually for each parameter.

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.

To set a QC (quality control) Lockout



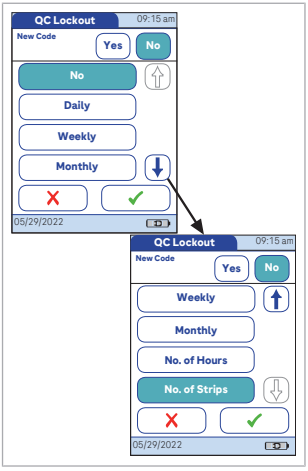
1 From the *Main Menu*, touch **Setup** to open the meter settings.

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.



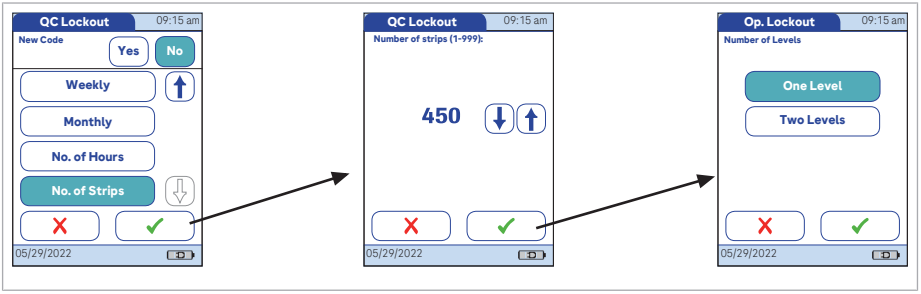
6 You may select from the following options:

- **New Code Yes/No** (applies every time a new test strip lot is used).
  The general intervals are:
- **No**
- **Daily**
- **Weekly**
- **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 (105)



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.

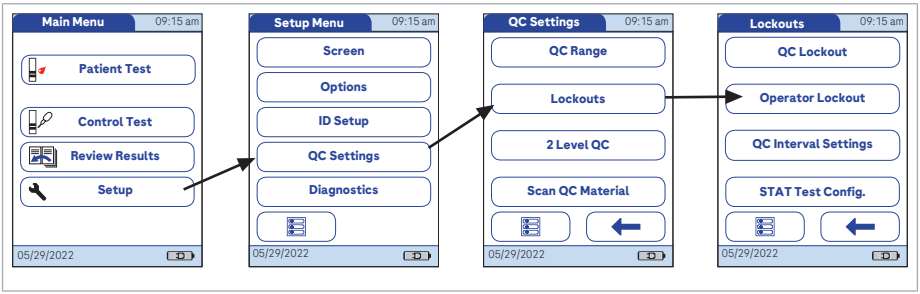
14 Touch ✓ to save this setting, or touch ✗ to exit this menu without saving any changes. The display automatically returns to the previous screen.

Operator Lockout

Optional liquid quality controls can be used to ensure that an operator is performing tests properly on the CoaguChek® Pro II 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.

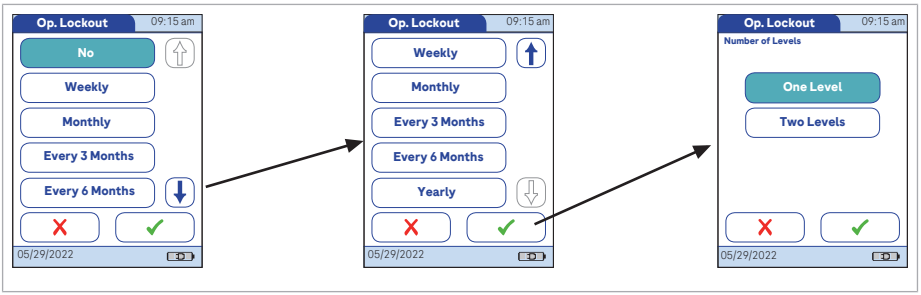
2 From the *Setup Menu*, touch **QC Settings**.

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 (159)

If you are not working with a DMS, only the *QC Lockout* is available.
See QC (quality control) Lockout (100)



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.

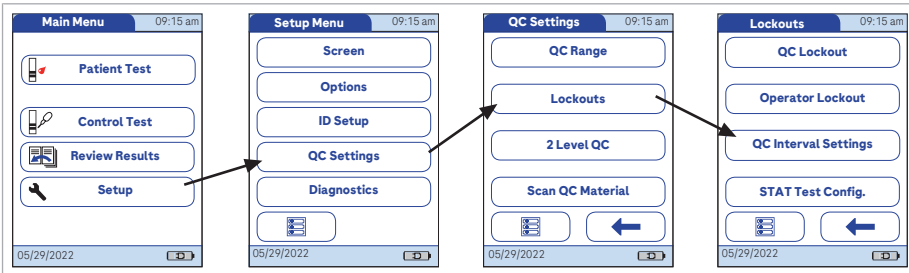
9 For every option except for **No**, you must now indicate the number of levels at which the quality control must be performed.

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

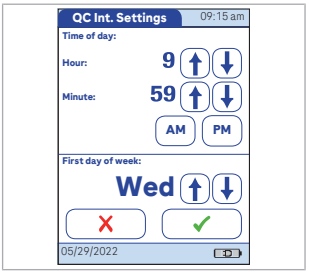
For all lockouts based on date intervals (**Daily**, **Weekly**, **Monthly**) the time of occurrence can be set, and for weekly lockouts also a preferred day of the week.

▸ 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.

STAT Test Configuration

Quality control tests ensure consistent quality and accurate measurements. In emergency situations, however, it may be necessary to perform a test without delay. To override an active lockout[3], you can allow STAT Tests (STAT = **S**hort **T**urn**A**round **T**ime).

You can set the number of tests (up to nine) permitted beyond the lockout. Once the number of STAT Tests allowed has been reached, additional tests cannot be performed until you have successfully completed a quality control test. The default setting is **three** STAT tests.

The results of STAT tests are always identified by the label *STAT Test* when they are displayed.

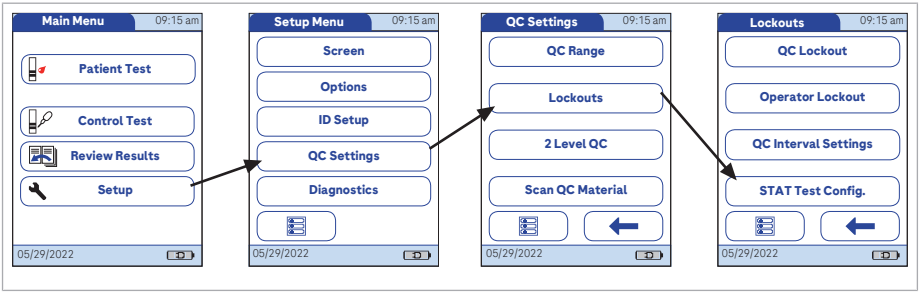
To perform a STAT test (132)

The number of STAT tests performed is counted per test parameter used. Once the maximum number of STAT tests has been reached, this parameter cannot

[3] QC, operator, or new lot lockout

be tested without performing a control test first. Other test parameters that have not yet reached this limit are still available.

To enable/disable the STAT test option

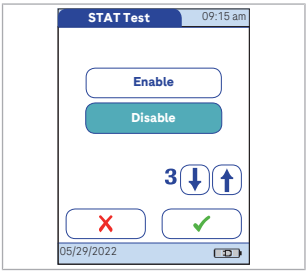


1 From the *Main Menu*, touch **Setup** to open the meter settings.

2 From the *Setup Menu*, touch **QC Settings**.

3 From the *QC Settings* menu, touch **Lockouts**.

4 From the *Lockouts* menu, touch **STAT Test Config.**



5 Touch **Enable** to allow *STAT Tests* or touch **Disable** to prohibit *STAT Tests*. Your selection is now highlighted.

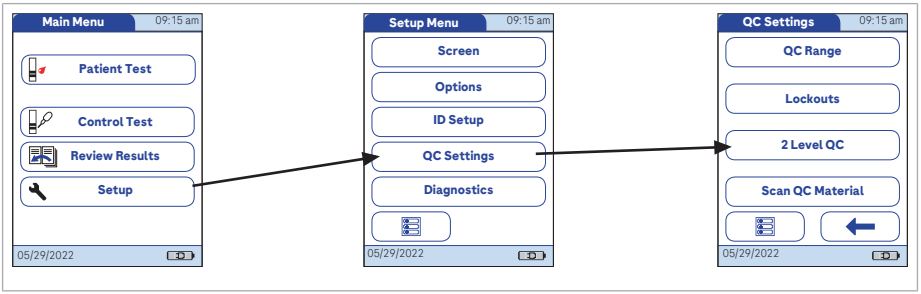
6 If you have enabled the option, touch ↑ or ↓ to set the number of additional tests.

7 Touch ✓ to save this setting, or touch ✗ to exit this menu without saving any changes.

2 Level QC

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

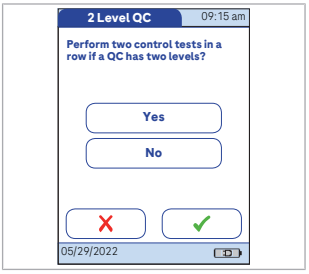
To enable 2 level QC



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**.



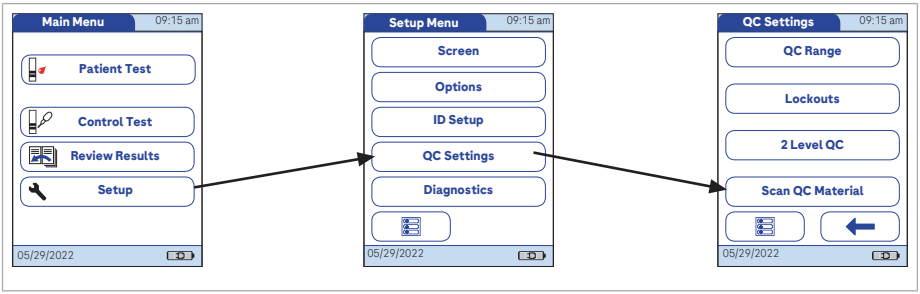
4 Touch **Yes** to automatically start the test for the second level once the test for one level has been finished successfully. Or touch **No** to finish the test after one level and return to the *Main Menu*. Your selection is now highlighted.

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® Pro II meter can be used to scan barcodes from QC material vials.

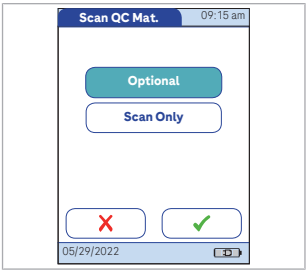
To use the scan QC material option



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**.



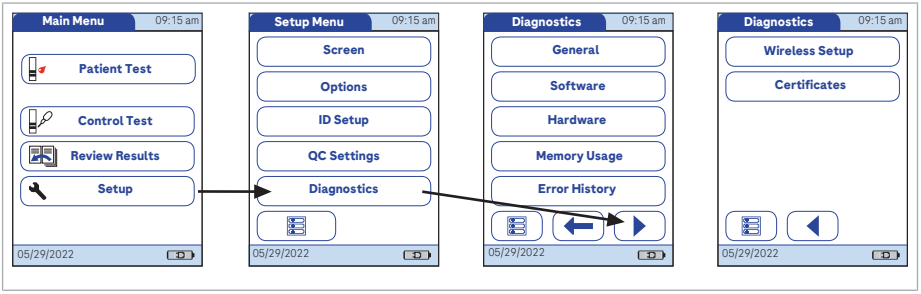
4 Touch **Optional** to allow manual selection of a QC lot number from a list or touch **Scan Only** to prohibit manual selection. Your selection is now highlighted.

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.

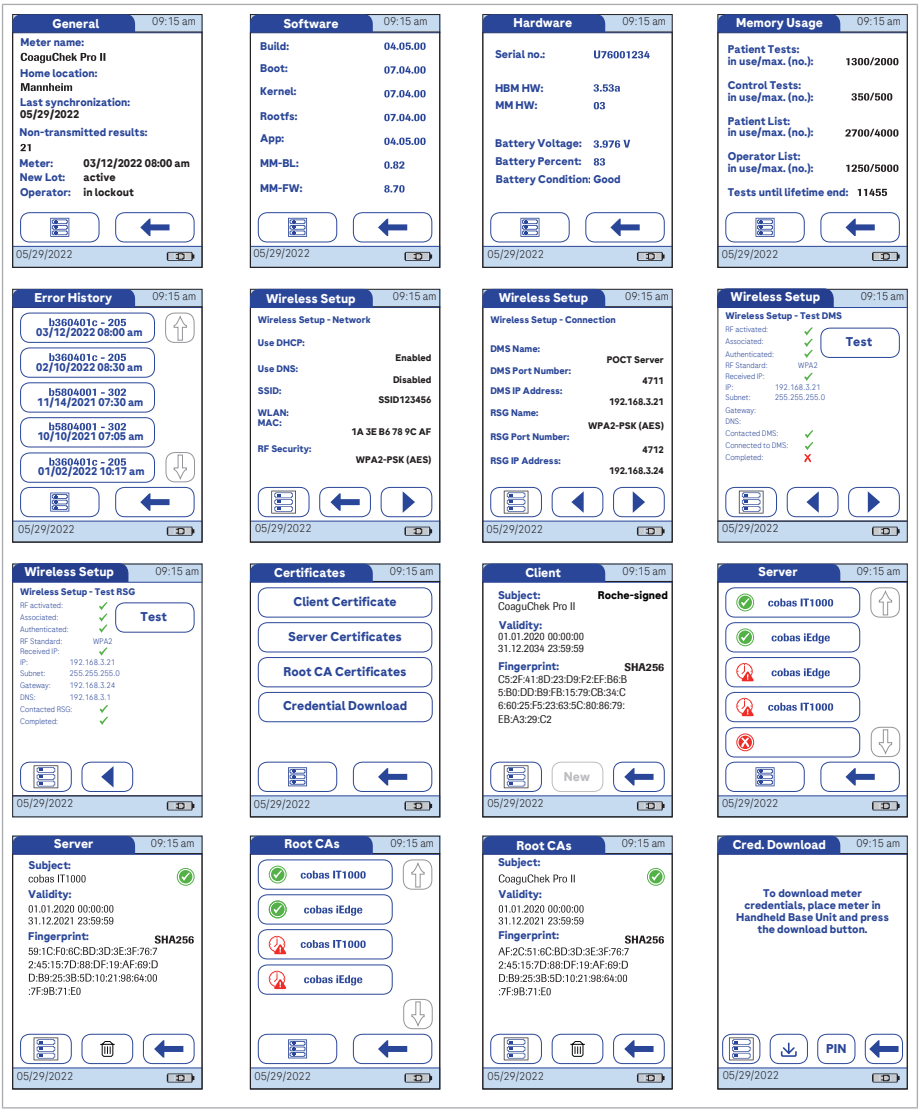
▸ To display the diagnostics screens



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.



4 Use ◀ and ▶ to toggle between the *Wireless Setup* screens.

5 From the *Certificates* menu, touch the button of the certificates screen you want to display.

6 In the diagnostics screen, touch ← to return to the previous menu.

4 Testing a Blood Sample

4.1 Important notes

What you need:

- CoaguChek® Pro II meter
- 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 or the CoaguChek® Lancets)

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? (14)

Always...

- close the strip container immediately after removing a test strip.
- operate the meter at an ambient temperature between 12 °C and 32 °C (54 °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.
- 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.
- Dispose of all test strips used for patient testing in accordance with the disposal policy of your laboratory or practice.

8.2 Cleaning and disinfecting the meter (169)

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.
- 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**).

⚠ CAUTION!

Risk of false results caused by wet skin

- When 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.

Getting a good result from venous whole blood

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.

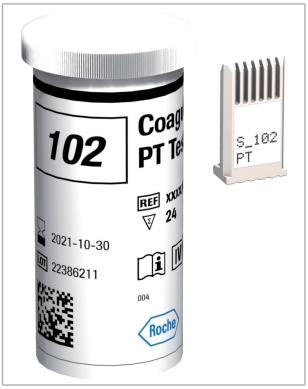
⚠ CAUTION!

- 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.
- Dispose of all test strips used for patient testing in accordance with the disposal policy of your laboratory or practice.

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 (135)

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® Pro II meter stores the data from up to 60 test strip code chips that have been inserted.

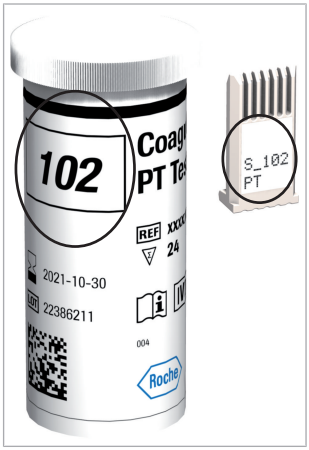
- Do not forget to use the test strip code chip that is supplied with each pack of test strips before you perform the first test with these strips. We recommend that you leave the code chip in the meter to protect the electrical contacts in the meter from becoming dirty.

- 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.
- In case a required code chip is not at hand and the meter is connected to the remote service, the code chip data can also be downloaded to the meter. See To manage code chip data (82)

To insert the code chip



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



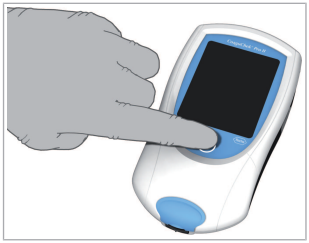
2 Check that the number on the code chip matches the number on the label of the test strip container.



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 (179)

To power on the meter

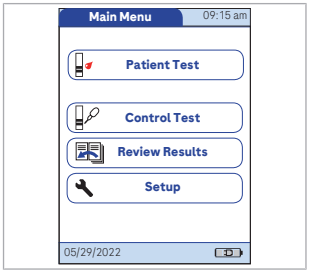


1 Place the meter on a level, vibration-free surface, or hold it in your hand so it is roughly horizontal.

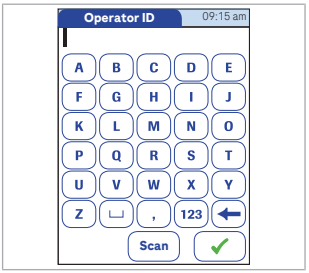
2 Power the meter on by pressing ⏻.

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 (159)

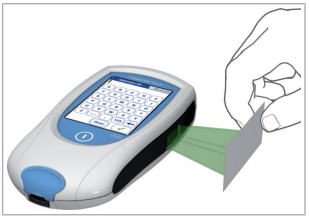


3 If the function *Operator ID* is inactive, wait until the *Main Menu* is displayed.

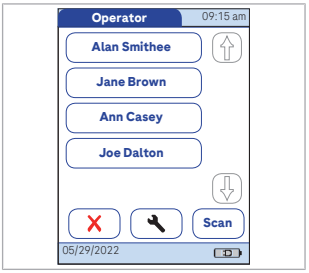


4 If the function *Operator ID* is active, **without operator list**, you are now prompted to enter an *Operator ID*.[4]

- 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**.[5],[6] Touch Scan and scan the operator barcode from a distance of approx. 10-20 cm (4-8 inches), according to the barcode size. 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.

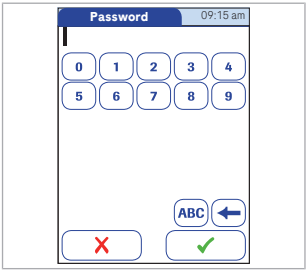
7 Select the operator of choice by touching the corresponding button or touch **Scan** to scan an operator barcode.

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

[4] For configuring operator and patient IDs, see (163) Configuring operator and patient IDs

[5] A list of supported barcode symbologies can be found in (196) A.2 Example of barcode symbologies

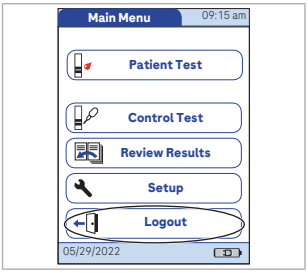
[6] A list of supported characters can be found in (200) A.3 Supported characters in 2D barcodes



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.

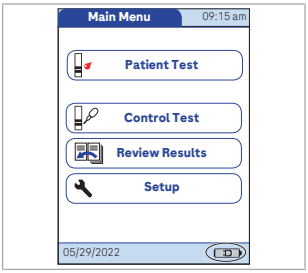


11 When the tests are completed or another operator wants to perform additional tests, touch **Logout** to log out (this button is available only when the *Operator ID* is activated). The meter returns to the display of the operator pick list.

12 **Note**: Extended data handling functionality and operator login options are dependent on the capabilities of the particular Data Management System (DMS) being used and may vary. For more details see 7.1 Data handling (159)

4.3 Performing a test

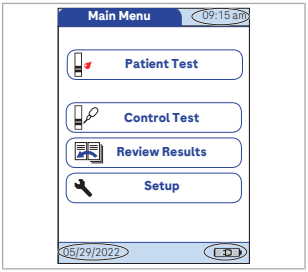
To perform a test



1 Check the battery level.

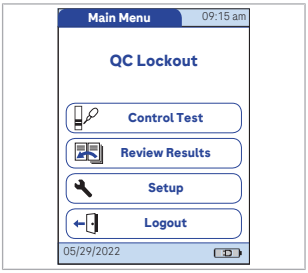
- If the battery icon turns red (**one bar remaining**), there may not be enough power remaining for another test.
- If there are **no bars** remaining in the battery icon, you cannot perform any more tests. Power the meter off by pressing ⏻.

  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*.

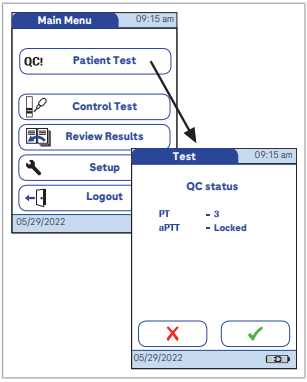
To set the date (64)
To set the time (65)



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 (135).

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

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

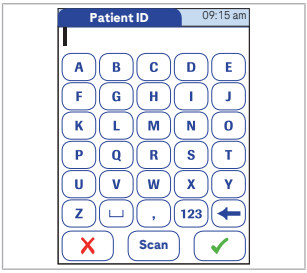


4 If the **Patient Test** button is available, but a lockout is displayed (QC!), one or more test parameters are locked. A test can only be performed for parameters that are still unlocked or as a STAT test (if this function is enabled and if there are still STAT tests available). In these cases a QC status screen will be displayed after touching *Patient Test*.

For more details see STAT Test Configuration (106)



5 **With** patient list go to step 7.
Without patient list, touch **Patient Test**.

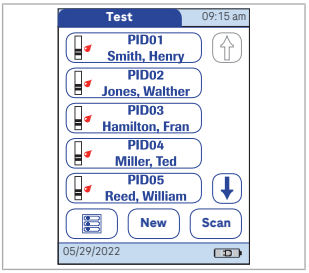


6 If the *Patient ID* option was chosen as either **Optional** or **Required** when the meter was set up, you are prompted to enter a *Patient ID*.
See Patient ID (92)

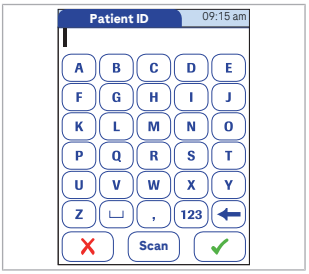
- If **Required**, enter the *Patient ID*, then touch ✓ to move to the next screen.
- If **Optional**, ignore the prompt and touch ✓ to move to the next screen. The meter will assign the test a consecutive number.
- If neither option was chosen, a screen appears that prompts you to insert a test strip.
- Continue with step 11 or 12, depending on the meter setup.



7 **With** patient list, touch **Patient Test**.

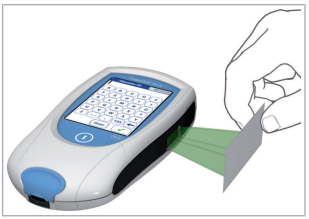


8 Touch ↑ or ↓ to display the entry of choice. Select the patient to be tested from the list.



9 If the patient is not in the list, touch **New** to create a new entry. 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 Data Management System (DMS) being used and may vary. For more details see 7.1 Data handling (159)



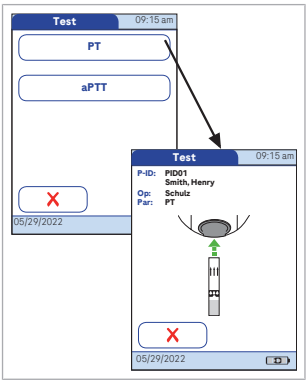
10 Alternatively, the *Patient ID* can also be entered **using the built-in barcode scanner**.[7],[8] Touch **Scan** and scan the patient barcode from a distance of approx. 10-20 cm (4-8 inches), according to the barcode size.

➔ The meter beeps once the barcode has been read successfully.

[7] A list of supported barcode symbologies can be found in (196) A.2 Example of barcode symbologies

[8] A list of supported characters can be found in (200) A.3 Supported characters in 2D barcodes

➔ The barcode information appears in the patient ID field. The scanner turns off after 10 seconds, if a barcode is not scanned.



If the *Parameter Selection* option is enabled in the meter settings, you are now prompted to select the parameter to be tested.

The testing procedure for both parameters is similar. For illustration purposes testing with PT test strips is shown as an example.

11 Touch the button to select the parameter you want to use.

12 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.

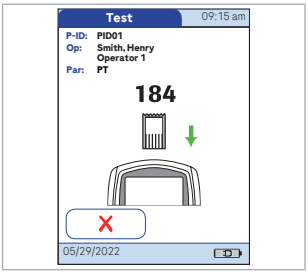
Exposure to external influences (such as humidity) may deteriorate the test strips and may lead to error messages. Therefore, always close the test strip container immediately after removing a test strip.

13 Hold the test strip so the lettering with the test name is facing upward.

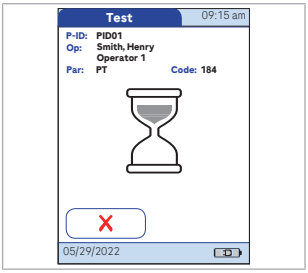


14 Slide the test strip into the test strip guide in the direction indicated by the arrows. Slide the test strip in as far as it will go.

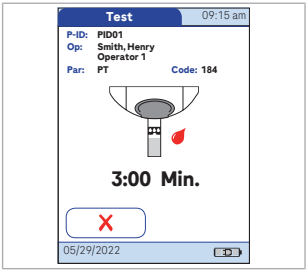
A beep indicates that the meter has detected the test strip (provided the beeper is enabled).



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.

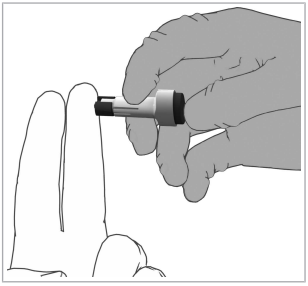


The blood drop icon flashes to indicate that the meter is ready to perform the test and is waiting for blood to be applied.

15 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 or Safe-T-Pro Plus lancing devices, or the CoaguChek Lancets (professional-use lancets available only in the United States). 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.

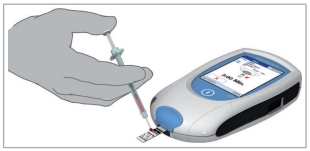
Apply the blood directly from the finger to the semicircular, transparent sample application area on top of the test strip.
Alternatively you can touch the blood drop against the side of the sample application area. The test strip draws up the blood by capillary action. During this process you must hold 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

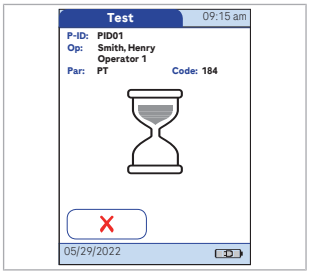
1 CAUTION! Discard the **first four** drops of blood collected (within the first 10 seconds).



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.

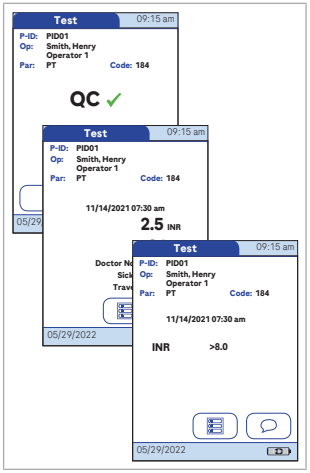
If too much blood has been applied (> 20 µL) the exterior of the meter and the test strip guide should be cleaned and disinfected.

For additional information on sample collection see Getting a good result from venous whole blood (116)



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 test strips refer to the package insert of the respective test strip.

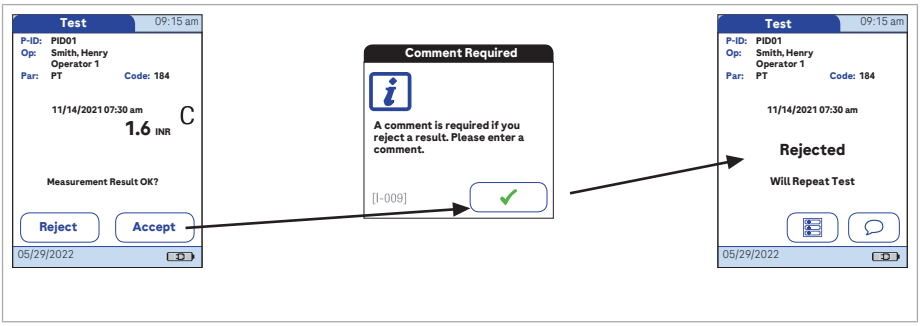


3 Results that are above or below the measuring range are indicated by the symbols > (above) or < (below).

- **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 message persists, perform a hematocrit check.
- **If a "*" is displayed along with the result:** This may occur if 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**

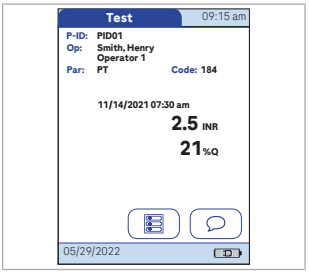
2 If you reject a result, you must enter a comment with an explanation.
If you reject the result, this test result is no longer displayed. However, the test entry is stored.

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 "*" is displayed along with the result:
The range settings can only be set and enabled using a DMS.

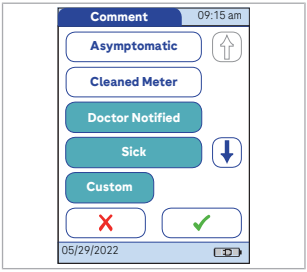
To add comments

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 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 display the test results as a QR code



The QR code icon only appears if the QR code display function is activated. Otherwise it is not displayed.

See To enable/disable the QR Code display (73)

1 Touch to display the result as QR code.

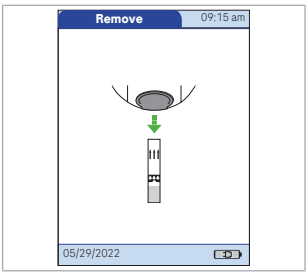
2 Touch ← to return to the standard result display.

The size of the QR code displayed on the screen varies according to the amount of data encoded.

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.

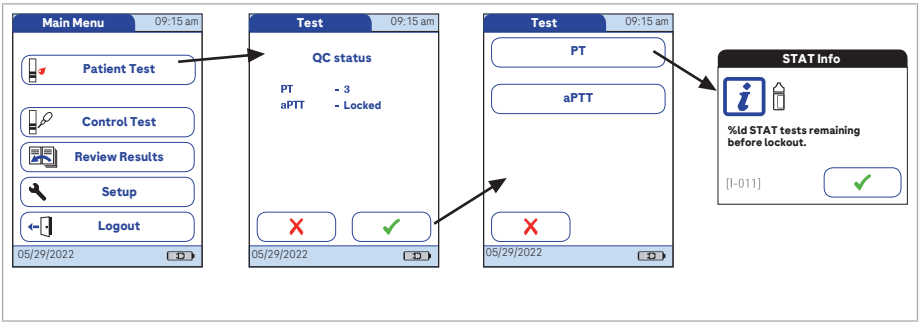
2 Remove the test strip from the meter.
- Safety information (19)

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 (169)

To perform a STAT test

STAT tests are a limited number of tests that can be performed in emergency situations. If the meter is configured to perform STAT tests, you have the option of performing a test by choosing STAT even though a QC Lockout is in place.
See STAT Test Configuration (106)



1 To perform the measurement **without** performing a quality control test, touch **Patient Test**.

2 Touch the button to select the parameter you want to use.



3 Touch ✔ to confirm the number of remaining STAT tests.

4 Perform the test.

When a STAT test is performed, this information is stored with the result. The number of STAT tests allowed is reduced by 1. After all pending quality control tests are performed, the specified number of STAT tests is available again in case of a new lockout.

The default setting is three for the number of STAT tests allowed when in QC Lockout.

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5 Control and Proficiency Testing

5.1 Control testing

The CoaguChek Pro II 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 Pro II system. These controls are designed to assist you in meeting regulatory compliance requirements at your facility.

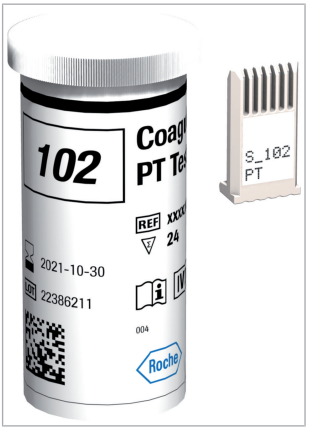
To perform an optional liquid quality control test using control solutions, you need:

- CoaguChek Pro II 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 PT Controls, CoaguChek aPTT 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.
   - In case a required code chip is not at hand and the meter is connected to the remote service, the code chip data can also be downloaded to the meter. See To manage code chip data (82)
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.

- In case a required code chip is not at hand and the meter is connected to the remote service, the code chip data can also be downloaded to the meter. See To manage code chip data (82)

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

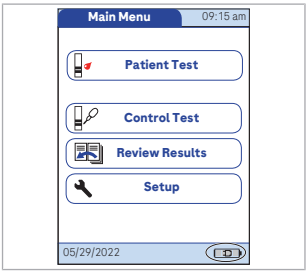
To perform a liquid quality control test



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

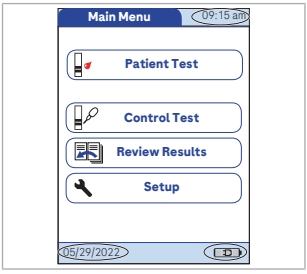
3 Wait until the Main Menu is displayed, or log on as described in To power on the meter (119)



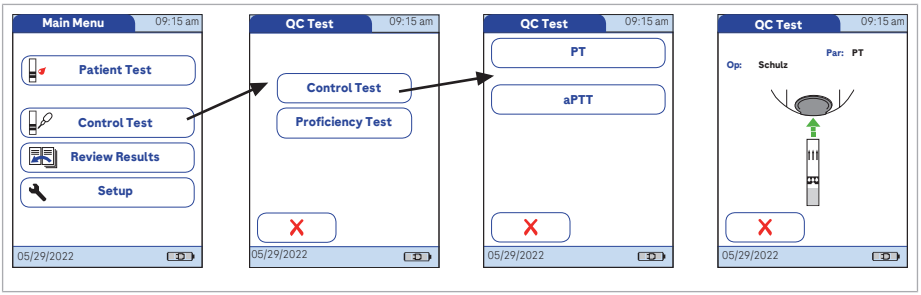
4 Check the battery level.

- 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 ⏻.

  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 (64)
To set the time (65)



6 Touch **Control Test**.

7 In the *QC Test* menu, touch **Control Test** again.

8 Touch the button to select the parameter you want to use.

9 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.

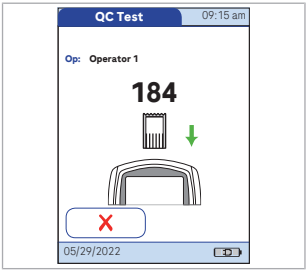
Exposure to external influences (such as humidity) may deteriorate the test strips and may lead to error messages. Therefore, always close the test strip container immediately after removing a test strip.

10 Hold the test strip so the lettering with the test name is facing upward.



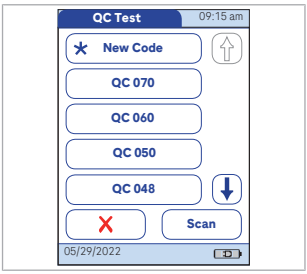
11 Insert the test strip into the test strip guide in the direction indicated by the arrows. Slide the test strip in as far as it will go.

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



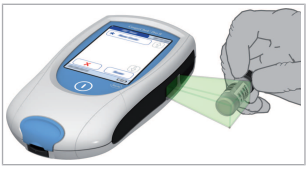
12 If you are using a new test strip lot and have not inserted the test strip code chip yet, you must do so now. Otherwise you cannot perform a quality control test.

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.



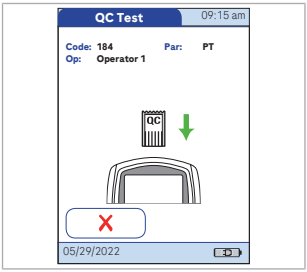
13 Select the code stored for your current control solution or touch **New Code** to use a new control solution.

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



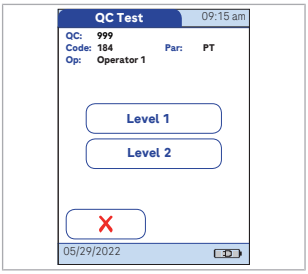
14 Alternatively, the control solution code can also be entered **using the built-in barcode scanner**. Touch **Scan** and scan the barcode on the label from a distance of approx. 10 cm (4 inches).

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.

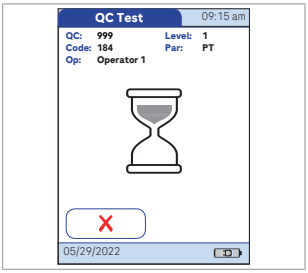


15 If you are using a new control solution, remove the strip code chip from the meter and insert the code chip that came with the control solution instead.

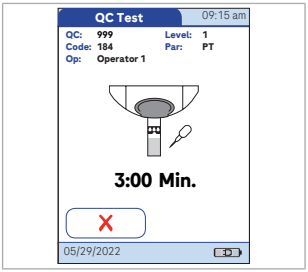
If the code chips get mixed up, check the letter on the code chips to tell them apart. A capital **S** in front of the number indicates that this code chip is for test strips. A capital **C** in front of the number indicates that it is a control solution code chip.



16 If performing more than one level, select the level for this measurement.

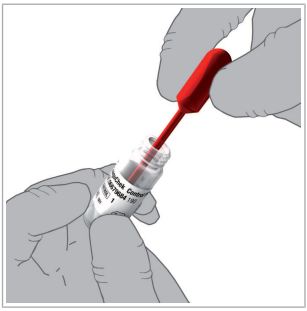


The hourglass icon shows that the test strip is warming up. When the warming-up process is complete, a further beep (provided the beeper is enabled) indicates that you can now apply the control solution.

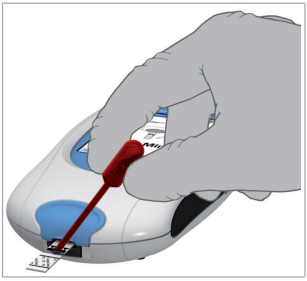


The dropper icon flashes to indicate that the meter is ready to perform the test and is waiting for the sample to be applied.

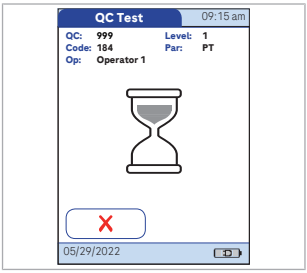
At the same time a countdown begins. You must apply the sample within the displayed time, otherwise you will receive an error message.



17 Using the dropper, draw up the dissolved contents of the bottle.

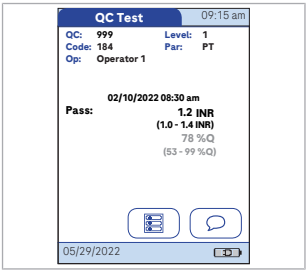


18 Apply a single drop of control solution directly from the dropper to the semicircular, transparent sample application area on top of the test strip. Do not add more control solution.



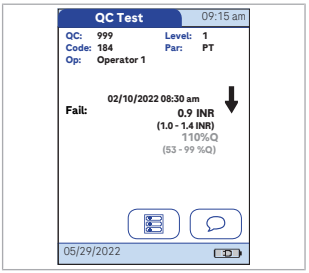
You hear a beep when you have applied enough control solution (provided the beeper is enabled). The dropper icon disappears and the test starts.

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



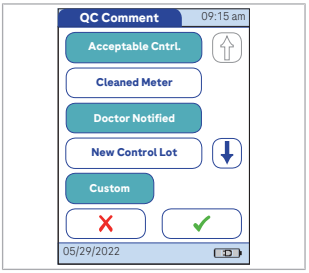
The acceptable range of results for the liquid control is displayed below the current result, along with *Pass* or *Fail*.

The unit that is not the leading unit, is shown in gray. The range used for this unit is the manufacturer-specified range. If the custom range has been manually defined, then this is the one that is used only for the PT leading unit.



Note: The arrow (next to the result) refers to the INR result only.
If you have selected to display INR and %Quick or INR and seconds, the (up or down) arrow next to the result refers only to the INR value.
Regardless of the *Result Units* PT settings, aPTT is always displayed in seconds.
See To configure an additional parameter (59)

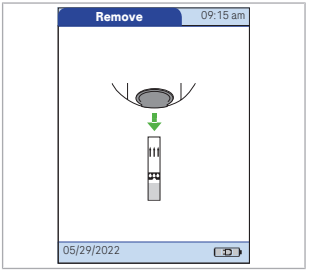
The printer icon only appears if the printer function is activated. Otherwise it is not displayed.



19 If you want to add a comment, touch .

20 Select the desired predefined comment(s) from the pick list (if configured) or

21 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.



22 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.

23 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*.

24 Power the meter off.

25 Remove the quality control code chip from the meter and store it with the controls.

26 Clean the meter if necessary (see Chapter 8, *Maintenance and Care* starting with 8.2 Cleaning and disinfecting the meter (169)

27 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 data management system 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

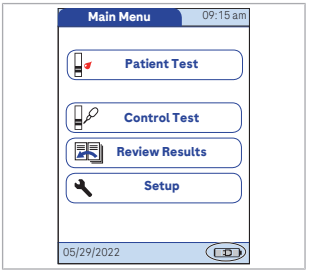


1 Place the meter on a level, vibration-free surface or hold it in your hand so it is roughly horizontal.

2 Power the meter on by pressing ⏻.

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

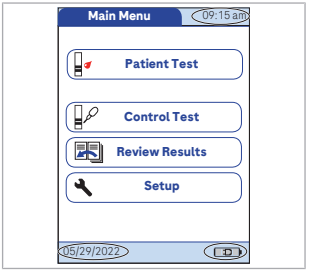
3 Wait until the Main Menu is displayed, or log on as described in To power on the meter (119)



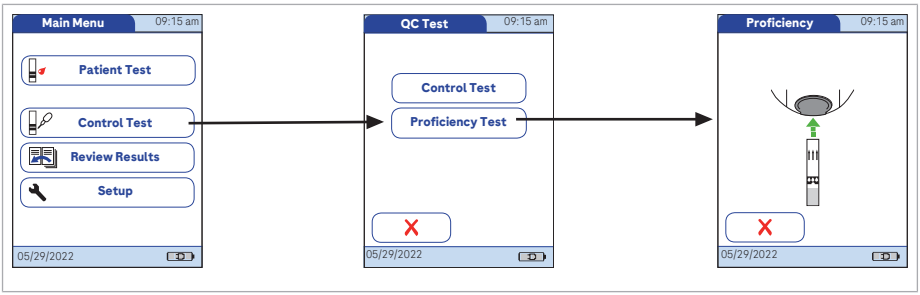
4 Check the battery level.

- 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 ⏻.

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 (65)
To set the date (64)



6 Touch **Control Test**.

7 Touch **Proficiency Test**.

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

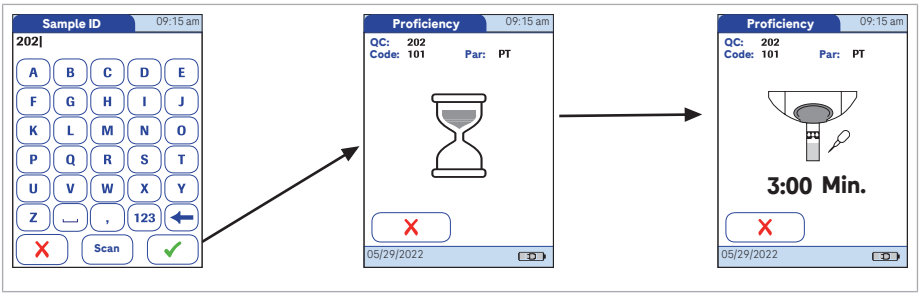
8 The test strip icon prompts you to insert a test strip. Remove a test strip from its container and close the container again with the stopper.

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).

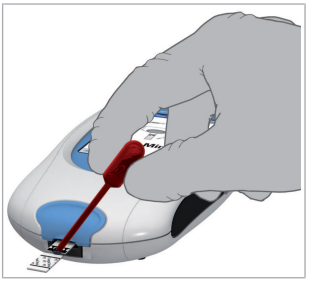


11 Enter or scan the sample ID.

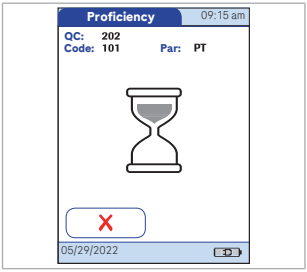
The hourglass icon shows that the test strip is warming up. When the warming-up process is complete, a further beep (provided the beeper is enabled) indicates that you can now apply the proficiency sample.

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

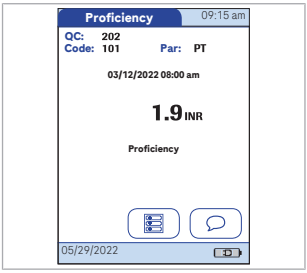
A countdown begins at the same time. You must apply the sample within the displayed time or an error message will be displayed.



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 (169)

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6 Review Results (Memory)

The CoaguChek Pro II 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 ID*s 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 data management system and the optional Handheld Base Unit.

7.1 Data handling (159)

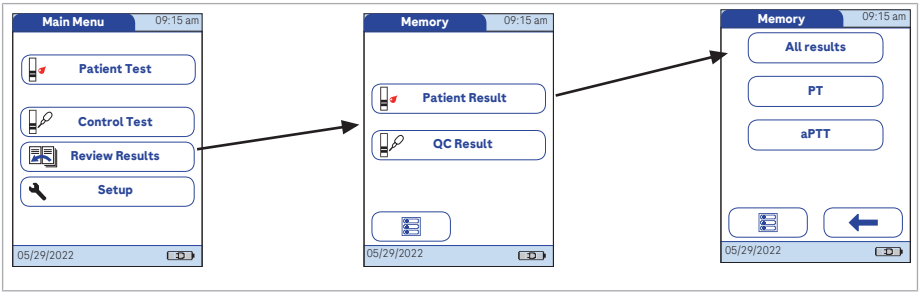
6.1 Viewing test results

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.

6 Select the test parameter(s) you want to view.

For displaying patient results:

- Parameter selection is only available, if the sort order has been set to “Date/Time”
  See To set the sorting order of lists (68)

- If the sort order has been set to “Patient ID” or “Patient Name”, the patient result screen is shown directly.

Buttons used for displaying results

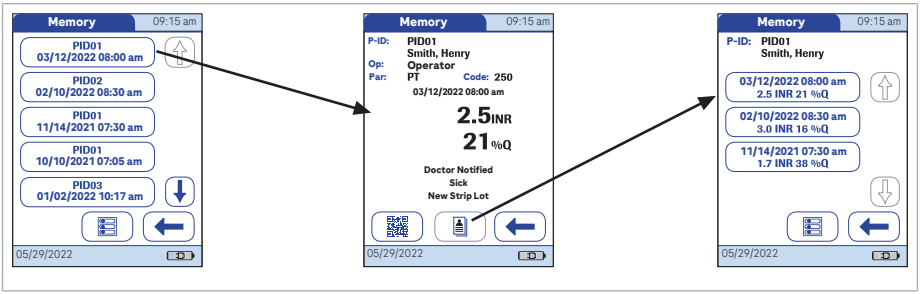
The following buttons for general use are located in the views described below:

- *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.
- *QR Code* icon: The QR code icon only appears if the QR code display 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* they are filtered by means of the test parameter you previously selected, the most recent results are at the top of the list.

See To set the sorting order of lists (68)



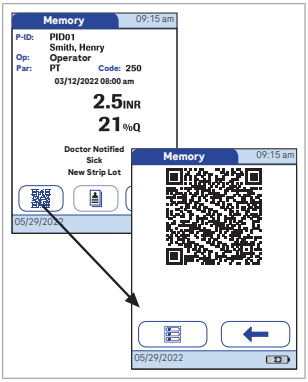
1 Touch ↑ or ↓ to scroll to the entry of choice on the screen.

2 Touch the entry you want to open.
The entry is displayed.

3 Touch . The results for the selected patient are displayed.

If you choose to display patient-related lists, you cannot filter a list by test parameters.

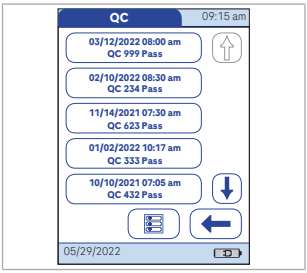
The QR code icon only appears if the QR code display function is activated. Otherwise it is not displayed.



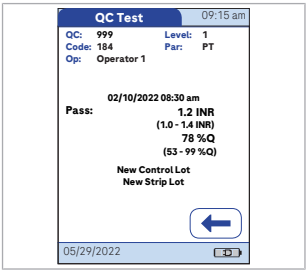
4 Touch to display the result as QR code.

5 Touch ← to return to the standard result display.

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.

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7 Extended Functionalities

7.1 Data handling

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

When used in conjunction with the Handheld Base Unit from Roche Diagnostics (available separately), the CoaguChek Pro II meter can conveniently connect to a data management system (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 (91)

Operator Lockout (102)

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 open the connection menu (72)

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 data management system), 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

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 A2 and a list of supported characters in Appendix A.3.

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*.

A.1 Operator and patient ID barcode masks (195)

A.2 Example of barcode symbologies (196)

A.3 Supported characters in 2D barcodes (200)

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

Patient result comments	QC results comment
• Lab Draw	• New Strip Lot
• No Action	• New Strip/Kit Lot
• Procedure Error	• No Action
• Under Medication	• Procedure Error
• 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 (189)

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

Difference between cleaning and disinfecting

Cleaning is the physical removal of organic soiling (e.g., dirt, or other foreign material) from the meter surface.

Disinfecting is the removal of most, but not all, disease causing and other types of microorganisms (blood-borne pathogens) from the meter.

When should the meter be cleaned and disinfected?

- Clean the meter to remove visible soil and organic material for safe handling and/or prior to disinfecting.
- The exterior of the meter and the test strip guide should be cleaned and disinfected before being used on another patient.
- The exterior of the meter and the test strip guide should be cleaned and disinfected if too much blood (> 20 µL) has been applied.
- Maintenance cleaning: The use of the disinfecting cloths may lead to a build-up of residue on the test strip guide and battery compartment that needs to be removed. Frequency: whenever residue build-up is visible or at least once per month.
- Disinfect the meter when it is soiled and per your facility's guidelines.

What to clean and disinfect?

The following parts of the meter may be cleaned / disinfected:

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

⚠

- Observe the disinfection guidelines of your institution.
- Use gloves.

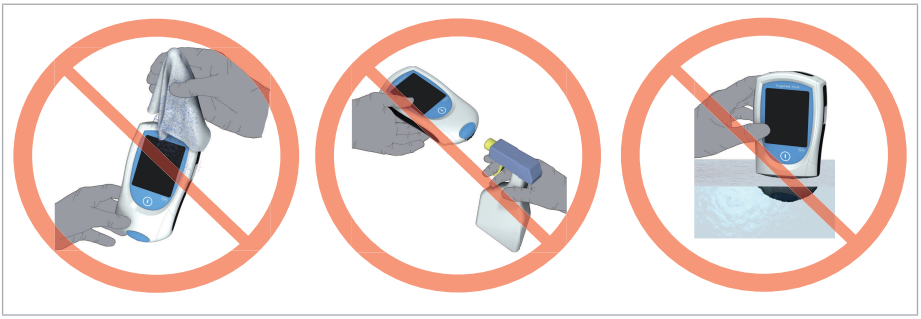
Follow the instructions given below to clean and disinfect the meter. Failure to follow these instructions may cause malfunction of the meter.

NOTICE!

Instrument damage due to moisture

Ensure that no liquid enters the meter. If moisture enters the meter, it may cause malfunction of the instrument.

- Make sure the meter is turned off.
- Do not spray anything onto the meter housing.
- Do not spray into the test strip guide.
- Do not immerse the meter in liquid.
- Do not use cloths or swabs/buds that are saturated. Squeeze off excess solution or blot on a dry paper towel to remove any excess solution before wiping the surface of the meter.



8.3 Recommended cleaning/disinfecting agents

Use only the following agents for cleaning/disinfecting the meter (housing and test strip guide).

For cleaning **only**:

- A soft cloth slightly dampened (not wet) with a small amount of liquid soap diluted in water

For cleaning **and** disinfection:

- Rubbing alcohol (70% ethanol or isopropyl alcohol)
- Bacillol Plus®
  (Alcohol-based disinfectant; a mixture of 1-propanol (400 mg/g), 2-propanol (200 mg/g) and glutaraldehyde (1.0 mg/g))
- Super Sani-Cloth® Germicidal Disposable Wipe
  (Disposable wipes containing 0.5% quaternary ammonium compounds (single compound or mixture) in 55% isopropyl alcohol (isopropanol))

NOTICE!

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

8.4 Cleaning/disinfecting the exterior (meter housing)

Use the solutions recommended for cleaning/disinfecting the meter exterior. Apply the solutions for a contact time of > 1 minute (refer to the corresponding product labeling).

8.3 Recommended cleaning/disinfecting agents (171)

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

To clean/disinfect the exterior



1 Power off the meter. Then gently wipe over the surfaces (touchscreen, housing) with a soft, lint-free cloth slightly dampened (**not wet**).

Do not let liquid accumulate near any opening. Ensure that no liquid enters the meter.

2 With a fresh dry cloth or lint-free tissue, wipe away residual moisture and fluids after cleaning the housing. Visually verify that no solution is seen anywhere on the housing or touchscreen at the completion of cleaning and disinfecting.

3 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.

8.5 Cleaning/disinfecting the test strip guide

Use the solutions recommended for cleaning/disinfecting the test strip guide. Apply the solutions for a contact time of > 1 minute (refer to the corresponding product labeling) using lint-free cotton swabs/buds.

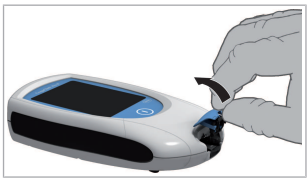
8.3 Recommended cleaning/disinfecting agents (171)

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.

To clean/disinfect the test strip guide

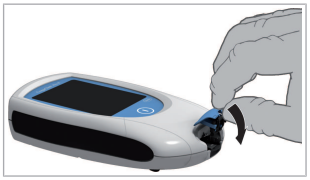


1 Make sure the meter is powered off. Remove the test strip guide cover to clean it. (Use your thumbnail to open the cover of the test strip guide by pressing its front edge upward.) Move the cover safely away from the meter. Then rinse the cover with warm water or wipe it clean using the solutions recommended above. Let the test strip guide cover dry **for at least 10 minutes** before re-attaching it.



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

- Clean the easily accessible white areas with a moistened cotton swab/bud.
- Ensure the swab/bud is only damp, not wet. Wipe away residual moisture and fluids.



3 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 and disinfecting.
- Ensure that the test strip guide and cover are completely dry before assembling them.

4 WARNING!

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.

8.6 Cleaning the scanner window

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

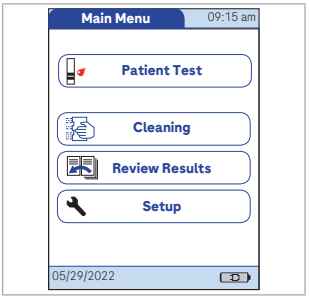
8.7 Cleaning after a notification appears

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.

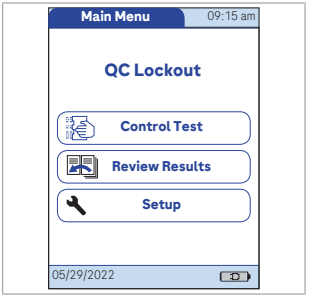
Intervals between running cleaning process are determined by your facility. For further information on configuring these intervals refer to *cobas IT 1000 Application CoaguChek® Pro II Instrument Driver User Information*.

Cleaning after a notification appears



1 If appears on the *Main Menu* screen, touch **Cleaning**.

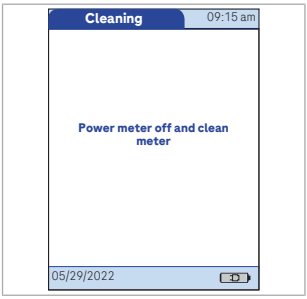
➔ Go to step 3.



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 device event is created that will be transferred 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

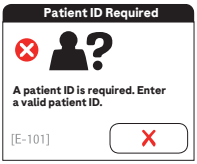
The CoaguChek® Pro II meter continually checks its systems for unexpected and unwanted conditions. These may arise for technical reasons (defective components or consumables, environmental factors) or due to handling and procedure errors.

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
I-001: Battery Low 	**Status message** Touch to proceed with the next step.

Message	Description
E-101: Patient ID Required 	**Error message** Touch ✕ to exit this message. Perform the suggested step(s) to solve the problem.

Additional information on error E-402

Message	Description
E-402 Test Strip Error 	**Status message** Touch ✕ to exit this message. Perform the suggested step(s) to solve the problem.

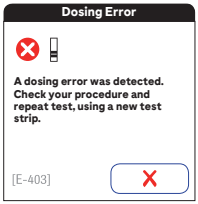
Power the meter off and remove the test strip. Repeat the measurement using a new test strip and blood taken from a new puncture site at the tip of another finger. If this error message appears again when the test is repeated, contact your local Roche representative.

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

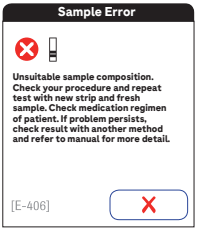
Message	Description
E-403: Dosing Error 	**Status message** Touch ✕ to exit this message. Perform the suggested step(s) to solve the problem.

"Dosing" refers to the procedure of applying the blood sample to the test strip. "Dosing 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
E-406: Sample Error 	**Status message** Touch ✕ to exit this message. Perform the suggested step(s) to solve the problem.

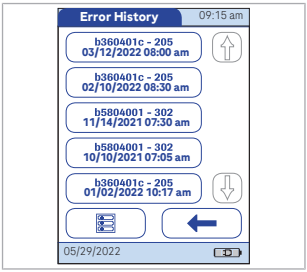
Power the meter off and remove the test strip. Repeat the measurement using a new test strip and blood taken from a new puncture site at the tip of another finger. Do not touch or remove the test strip when a test is in progress.

Note on error E-406: The CoaguChek® 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. 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® Pro II meter, you can scroll through the errors on the *Error History* screen via:

Main Menu > Setup > Diagnostics

3.7 Diagnostics (110)

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
No message or unusual behavior	
Meter display does not power on	• Wait 10 seconds and try powering on the meter again. • Check that the meter has power See To install the battery pack (43) *Is the battery pack properly installed in the meter?* *Does the meter power on when connecting the external power adapter?* *Does the battery pack charge properly?*

Message	Description
Meter displays an unexpected result	Refer to the package insert for the test strips.
Automatic shutdown	
	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:
Shutdown after time specified by system administrator (default is 5 minutes, configurable by system administrator)	• Press ⏻.

Additional information on result screens

Message	Description
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.
A "*" is displayed along with the result:	
	This may occur if 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 wireless communication and all other functionalities. Date and time, however, are maintained.

Automatic shutdown

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 (45)

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).

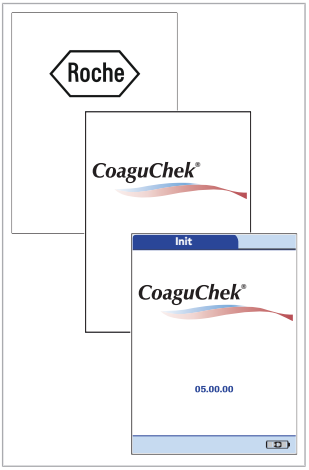
Note: If you press the On/Off button for too long, a

meter reset will be triggered after about 12 seconds and date and time will be lost.
See To reset the meter (186)

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.

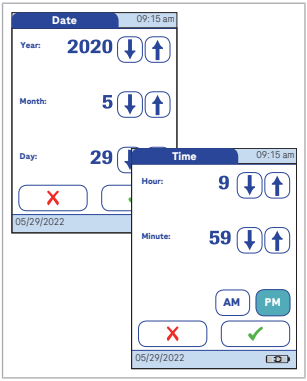


3 Press the ON/OFF button for at least 12 seconds and then release it. After releasing the button, the meter will start up again.

- 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.
- The screens for entering the date and the time appear.

4 Enter the date and time. After you have entered the correct information, confirm each screen with ✔.

- Unless all lockouts are disabled, the meter will now be in QC Lockout due to the manually entered date/time.
  See 3.6 QC Settings setup (95)



5 Synchronize the meter's date/time with the date/time of your facility via the Handheld Base Unit or, if working wirelessly, wait at least ten minutes for the next WLAN synchronization before performing any further tests.

Even if your configuration does not require it, we recommend always performing a QC test after a meter reset.

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10 General Product Specifications

10.1 Technical data

Technical data	
Operating temperature range	+12 °C to +32 °C (54 °F to 90 °F)
Relative humidity	10 to 85 % (no condensation)
Maximum altitude	4300 m (14,000 feet)
Position	Place the meter on a level, vibration-free surface or hold it so it is roughly horizontal.
Measuring range	Refer to respective test strip package insert
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	Touchscreen and barcode scanner
Battery operation	Universal Battery Pack for the CoaguChek Pro II meter
Power connection	Power supply adapter: Input: 100-240 V AC / 50-60 Hz / 400-200 mA (max.) Output: 12 V DC / 1.25 A (min.)
Number of tests with a fully charged battery pack	approx. 60 tests (PT/INR) at least 20 tests (aPTT/measuring time: 5 minutes)
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

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.

10.2 Further information

Consumables/ Accessories

Below is a list of available accessories and consumables. For ordering information, contact your local sales representative (see *Contact Roche*).

Item	Description	Remarks
CoaguChek PT Test	PT test strips for the CoaguChek Pro II meter	International edition (not available in the US)
CoaguChek aPTT Test	aPTT test strips for the CoaguChek Pro II meter	
CoaguChek PT Controls CoaguChek aPTT Controls	Optional liquid controls (Level 1, Level 2) for the CoaguChek Pro II system	
Universal Battery Pack	Rechargeable battery pack	
Handheld Base Unit	Handheld Base Unit and Operator's Manual	

Contact Roche (192)

Reagents and solutions

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

Product limitations

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

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 General Public License (GPL) licensing conditions are available (in English only for legal reasons) as a PDF file (file name “License.txt.PDF”) on the CD supplied with this manual. The complete license agreements are also stored as a text file (file name “License.txt”) on the Handheld Base Unit. You can access this file by connecting the Handheld Base Unit to a PC with the USB cable. For detailed instructions on how to do this, see the Operator's Manual of the Handheld Base Unit.

Everyone is permitted to copy and distribute verbatim copies of this license document, but changing it is not allowed.

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 Pro II system that are not answered in this manual, contact your Roche Diagnostics representative. A list of all Roche affiliates can be found at:

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

The CoaguChek Pro II system is manufactured for and distributed by:

In Australia:
Roche Diagnostics Australia Pty Limited
ABN 29 003 001 205
2 Julius Avenue
North Ryde, NSW, 2113

11 Warranty

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

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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[9]
- use barcodes with check digits

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

[9] 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)	



Codabar



Code 39



Code 93



Code 128



EAN 13



Interleaved 2/5 without checksum



Interleaved 2/5 with checksum



RSS (GS1 DataBar Limited)



Aztec



DataMatrix

Roche Diagnostics

Roche Diagnostics



PDF417



QR Code

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

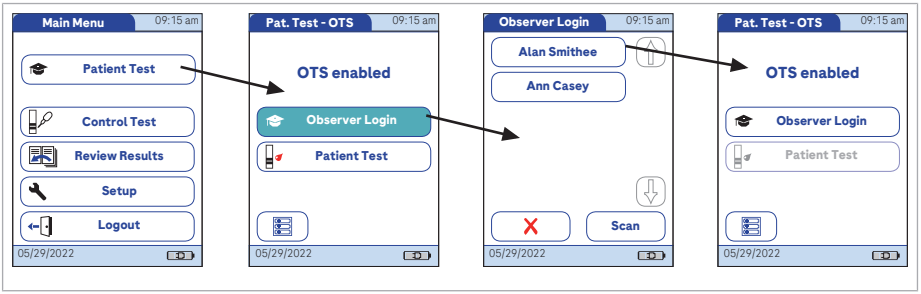
Observed Test Sequence (OTS)

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).

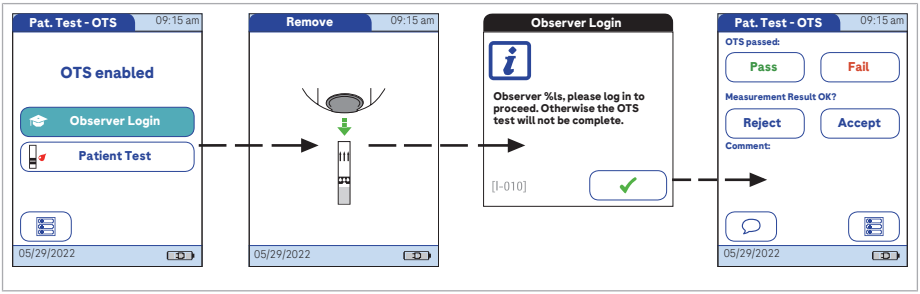
Only operators with OTS observer rights are listed in the Observer Login list.

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 Appendix C

C.1 Option: Wireless network (WLAN)

Preliminary note

This appendix has been developed to explain the wireless communication principles of the CoaguChek Pro II system[10] and to help your facility's information technology/ management team(s) in effectively deploying the CoaguChek Pro II system on your wireless network.

Whether your meter has wireless capability or not depends on the system configuration that you purchased.

Item	Description	REF/Catalog Number
CoaguChek Pro II meter	Meter without WLAN functionality	07237944xxx
CoaguChek Pro II meter	Meter with WLAN functionality	07210841xxx

For information on WLAN registration see addendum "WLAN registration information, Addendum to the Operator's Manual for the CoaguChek Pro II meter" at www.poc.roche.com (select the *Products* and *Point of Care*).

Background

The CoaguChek Pro II meter can only be configured through a data management system to communicate wirelessly. The data management system (DMS) is also used to set-up and configure the meter to connect to one hospital specific Wireless Local Area Network (WLAN[11]). WLANs use electromagnetic waves in the

[10] The CoaguChek Pro II system is certified by the Wi-Fi Alliance.

[11] WLAN is also commonly referred to as wireless LAN or Wi-Fi.

2.4 GHz frequency range to wirelessly transmit data[12]. The CoaguChek Pro II system adheres to IEEE Standard 802.11 g (2.4 GHz range)[13]. The system is backwards compatible to 802.11b. During wireless communication to an Access Point (AP), the CoaguChek Pro II meter recognizes the existent AP WLAN protocol configuration (802.11b or 802.11g) and automatically transmits data using the appropriate communication protocol[14].

The loss of signal or access to bandwidth of one particular client may vary depending on one or more of the following situations: the type and number of other clients, the performance of the Access Point, the presence of electromagnetic disturbances, and other potential interfering factors, e.g., concrete walls.

The CoaguChek Pro II meter uses a burst-like communication protocol that will only consume bandwidth if there is actually data to be transferred. Compared to other applications, such as Voice over Internet Protocol (VoIP) or multi-media applications, the meter's bandwidth consumption is minimal. If the WLAN that the CoaguChek Pro II meter seeks to connect to is degraded, the meter design minimizes the impact on functionality.

Technical implementation

Prior to connecting any wireless device to a wireless network, it is recommended that a WLAN site survey be performed. The goal of a WLAN site survey is to ensure that Access Points will provide enough coverage and performance to support any new radio frequency (RF) application or device. The survey will also detail RF

(12) For the wireless functionality to work properly, the wireless module must first be configured by your system administrator.

(13) While the CoaguChek Pro II system adheres to the 802.11g standard, it uses only channels 1-11. Channels 12-14 are not used by the system.

(14) WLANs are organized in cells. A typical WLAN cell consists of Access Point(s) that are connected to the (wired) Local Area Network and one or more clients, e.g., CoaguChek Pro II meters along with other clients such as portable computers.

signals, including all existing WLANs along with any competing RF signals and interferences (building structure related and other wireless equipment / devices).

As part of an RF implementation of the CoaguChek Pro II system, it is recommended that at minimum one Handheld Base Unit be hard wired per floor. A networked Handheld Base Unit provides redundancy if a wireless network malfunctions or loses service. If the CoaguChek Pro II meter with RF is used in an area with low signal or interferences, it is recommended to install a connected Handheld Base Unit for redundancy. The redundancy of the connected Handheld Base Unit allows immediate transmission of patient results when the meter is docked.

The current RF system consists of an antenna and a WLAN system-on-chip (SoC) along with other components. The WLAN system-on-chip is the core of the WLAN system. The RF system used in the CoaguChek Pro II meter specifically adheres to the following specifications:

- Its WLAN system-on-chip supports IEEE 802.11b and 802.11g. It works seamlessly together with other Wi-Fi certified transceivers. It also implements the Wi-Fi Protected Access (WPA™ - Enterprise and WPA™ - Personal), Wi-Fi Protected Access 2 (WPA2™ - Enterprise and WPA2™ - Personal), and Wired Equivalent Privacy (WEP) security mechanisms with Temporal Key Integrity Protocol (TKIP) and Advanced Encryption Standard (AES). In addition, the system supports the extensible authentication protocol (EAP) with EAP-TLS, EAP-TTLS/ MSCHAPv2 and PEAPv0/EAPMSCHAPv2. The CoaguChek Pro II meter interoperability Wi-Fi certificate can be accessed at http://certifications.wi-fi.org/search_products.php. Further information including a glossary of terms, frequently asked questions, and

other topics related to Wi-Fi technology can be found on the Wi-Fi Alliance site (http://www.wi-fi.org/).

- The used channels in the 2.4 GHz-band are channels 1-11, which are the legally allowed channels in the USA. (Channels 12-14 are not used by the CoaguChek Pro II meter.)
- RF output power is approximately 15 dBm at a data rate of 54 MBPS.

RF specific functionalities and effective performance claims

The CoaguChek Pro II system offers the option of wireless network connectivity (WLAN/Wi-Fi).

This module can only be configured by a data management system (DMS), which activates the meter's wireless communication and data transfer capabilities. Wireless connectivity can help to ensure that updates to information in the DMS are sent immediately to all networked meters.

Meters with an integrated and activated wireless option use the Handheld Base Unit for recharging and/or as a redundant communication option to exchange data with the DMS.

The meter also has to be docked if the hospital changes security protocols. When this change occurs, it may lock out all meters until docked and reconfigured with the new protocol.

As described above, the CoaguChek Pro II meter supports the 802.11g standard. This translates into the following RF specific performance claims:

- The CoaguChek Pro II meter is capable of transferring to a suitable DMS, via WLAN, a data set of up to 1000 result records, 100 strip and control lot records, and 500 operator ID records in less than 15 minutes, when operated in a typical WLAN

environment (correct WLAN administration, typical population of other clients present, any of the supported security models enabled).

- Immediately after the test has been completed (and returning to the main menu screen), the CoaguChek Pro II meter will attempt to connect to the DMS. In line with the industry communication standard POCT1-A, the DMS must acknowledge the meter's request for connection and actively query for the result. Only upon receipt of this DMS query, the meter will send the result. Hence the effective time for transmitting results depends on infrastructure, DMS workload, etc. Once the DMS sends a query, however, the meter will respond within a few seconds.
- A CoaguChek Pro II meter with wireless connectivity enabled, communicates results after every test. When the meter is idle while docked, it automatically attempts to communicate with the DMS every 30 minutes. Whenever the meter is placed in the HBU or connected to the power adapter for recharging, it will automatically attempt to communicate with the DMS if the battery is still sufficiently charged.

A typical range for direct connection between the CoaguChek Pro II meter and the access point (air, direct view, low disturbances) is up to 15 to 20 meters (49 to 66 feet). The actual range depends on the positioning of the access point's antennas and other topological properties of the space between WLAN device and AP. Additionally, dynamic control of the transmitting power of the access point may reduce the maximum distance between WLAN device and AP within which communication can be guaranteed.

The CoaguChek Pro II system is designed such that it coexists with other wirelessly communicating devices. The CoaguChek Pro II system does NOT include any

real-time or even time critical wireless functionality. It communicates exclusively single, digital data fields. It does NOT communicate continuous waveform data.

Note: A degraded WLAN connectivity will not impact the functionality of the meter but may delay the communication of results to the DMS. Users should be aware that **real-time communication** of data **cannot be guaranteed** by the CoaguChek Pro II meter.

During the exchange of large data packages a short-term delay in the meter response might occur.

Index

A

Accessories 191
Adapter (power supply) 39
Admin. ID 88, 90
Applying a blood sample 126
Auto Off 71

B

Barcode 122, 124, 141
– Masks 195
– Symbologies 196, 198
Barcode scanner 32
Battery pack
– Installing or replacing 42, 43, 45
Beeper 69, 140, 149, 150
Blood sample (testing) 117, 122

C

Capillary blood sample (testing) 117, 122, 126
Cleaning 169, 171, 172, 173, 174, 175
– Meter housing 172
– Test strip guide 173
Coagulation process 126
Code chip 117
– Inserting 118
Code number 118
Comments
– Adding 130
Computer 75
Connection 72, 73, 75, 77
Consumables 191
Contrast 58
Control solution
– Applying 143
– Code chip 141
– Preparing 136
Custom range 96, 97

D

Data transfer 159, 160
Database
– Configure 78
Date 64
Disinfection 169, 171, 172, 173, 175
Display 35, 36
– Format 66
– Icons 34
Disposal 22, 40, 116, 131, 144, 151

E

Encryption
– TLS 75, 77
Error messages 179

F

Fingertip 126

H

Handheld Base Unit ... 32, 42, 47, 75, 159, 191, 206

I

Icons....35, 36
– Drop....126
– Dropper....142, 150
– Hourglass....126, 142, 150
– Identification plate....7
– Overview....34
– Packaging....7
ID Setup
– Overview....86
Infrared interface....32

K

Keypad....124

L

Lance....126
Language....62
Lockout
– Operator....102, 105
– Quality Control....100, 122
Logout....121

M

Mains voltage....30, 189
Measurement
– Performing....122, 126, 131, 132
– Preparing....117
Measuring range....189
Memory
– Button....154
– Patient Result....155
– Quality Control....157
Meter
– Overview....32
– Reset....186

O

Observed Test Sequence (OTS)..201, 202
Operating conditions....30, 189
Operator
– Lockout....102, 105
– Logout....121
– Password....121
Operator ID....91
Operator list....120, 160
Options....68, 69, 71, 72, 73, 75, 77
Overview....53
– Meter elements....32
– Setup....51

P

Parameter selection....84, 154
Password....121
Patient ID....92
Patient list....124, 161
Power adapter....39
Power on....119
Power supply
– Charging contacts, (Handheld Base Unit)....32
Printer....77
Product specifications....189
Proficiency sample
– Applying....150
Proficiency test
– Preparing....147
Putting the meter into operation41, 42, 47

Q

QC Range 96
QC Settings 95, 96, 100
QR code 73
Quality Control
– Lockout 100, 122
– Memory 157
– Preparing 136
– Result 143, 144, 151

R

Relative humidity 30, 189
Remote service 80, 82
Reset 186
Result confirmation 61, 129
Review Results .. 153, 154, 155, 157, 159, 160, 161, 163, 164
– Data transfer 159, 160
RF (radio frequency) 27, 206

S

Safety
– Incident reporting 19
– Protection against infection 20
– User qualification 19
Scan (button) 124, 141
Scan configuration 81
Screen 58, 59, 60, 61, 62, 64, 65, 66
Setup
– Admin. ID 88, 90
– Auto Off 71
– Beeper 69
– Code Chip Data 82
– Computer 75
– Connection 72, 73, 75, 77
– Contrast 58
– Date 64
– Display format 66
– ID Setup 86, 88, 90, 91, 92
– Language 62
– Operator ID 91
– Options 68, 69, 71, 72, 73, 75, 77
– Parameter selection 84
– Patient ID 92
– Printer 77
– QR code 73
– Remote service 80
– Result confirmation 61
– Scan configuration 81
– Screen 58, 59, 60, 61, 62, 64, 65, 66
– Sort 68
– STAT test 106
– Time 65
– Units 59, 60
Software license 191
Sort 68
STAT test
– Configure 106
– Perform 132
Storage 167
Switching on the meter 119
Symbols
– Error messages 179
System Administrator 88, 90

T

Target value 99
Temperature range 30, 189
Test principle 16

Test result (patient test) 128
Test result (quality control) 143, 144, 151
Test strip
– Icon 125, 149
– Inserting 140, 149, 150
Test strip guide cover 173
Thromboplastin 16
Time 65
TLS
– Encryption 75, 77
Troubleshooting 179

U

Unit (test result) 128
Units (of measure) 59, 60

V

Voltage 30

W

Warranty 193
Wi-Fi 28
WLAN 205, 206, 208

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07154879001 (10) 2024-02 EN