

CoaguChek[®] XS Pro

Operator's Manual



| Manual version | Revision date | Changes |
|-----------------------|----------------------|---|
| Version 1.0 | 2009-09 | New document |
| Version 2.0 | 2010-04 | Update cleaning/disinfection, minor revisions |

US Supplement

The contents of this manual, including all graphics and photographs, are the property of Roche Diagnostics. No part of this document may be reproduced or transmitted in any form or by any means, electronic or mechanical, for any purpose, without the express written permission of Roche Diagnostics.

Roche Diagnostics has made every reasonable effort to ensure that all the information contained in this manual is correct at the time of printing. However, Roche Diagnostics reserves the right to make any changes necessary without notice as part of ongoing product development.

The US Supplement is intended for the US Market only.

This manual was created by Roche Diagnostics GmbH (operator manual content) and Roche Diagnostics Technical Publications department (US Supplement and/or US Specific Information). Direct questions or concerns regarding the contents of this document to:

Roche Diagnostics
 Technical Publications Department
 9115 Hague Road
 P.O. Box 50457
 Indianapolis, IN 46250-0457
 USA

COAGUCHEK is a trademark of Roche. All other trademarks are the property of their respective owners.

© 2010, Roche Diagnostics.

US Order Number: 05914639001

Distribution in USA by: Roche Diagnostics, Indianapolis, IN

Additional copies of this document can be obtained by contacting Roche Diagnostics Customer Focused Fulfillment at 1-800-428-5030. Request the US order number listed above.

Revision History

Revisions to this document are provided by Roche Diagnostics when necessary. No part of this document may be reproduced in any form or by any means without prior written consent.

| Supplement Reference Number | Date | Revision purpose |
|-----------------------------|------------|------------------|
| Version 1.0 | April 2010 | Creation |

Warranty

CoaguChek XS Pro Meter Limited (1 Year) Warranty

ROCHE DIAGNOSTICS warrants, to the original purchaser only, that the meter shall be free from all defects in material and workmanship for a period of one year from the date of purchase. Purchaser's sole and exclusive remedy, with respect to the CoaguChek XS Pro meter and parts thereof, shall be the repair and/or replacement of the meter or parts at the option of Roche Diagnostics.

THE ABOVE WARRANTY IS EXCLUSIVE OF ALL OTHER WARRANTIES, AND ROCHE DIAGNOSTICS MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE TO THE PURCHASER OR ANY OTHER PERSON FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT, SPECIAL OR PUNITIVE DAMAGES ARISING FROM OR IN ANY WAY CONNECTED WITH THE PURCHASE OR USE OF THE METER. NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IF ANY IS IMPLIED FROM THE SALE OF THE COAGUCHEK XS PRO METER. NO WARRANTY, EXPRESS OR IMPLIED (IF ANY), SHALL EXTEND FOR A LONGER DURATION THAN THE DURATION OF THE EXPRESS WARRANTY STATED ABOVE.

The foregoing warranty shall not apply to a meter which is damaged by accident or subject to alteration, misuse, tampering, and/or abuse, including the use of Dispatch[®] products. Meters which show damage or misuse will be handled in accordance with Roche Diagnostic's non-warranty service policy. The warranty of the repaired/replacement meter will expire on the date of the original warranty expiration or ninety (90) days after shipment of a replacement system, whichever period is longer.

Information about the Software License

This product incorporates software that is under license from GPL. The source code for this software can be requested on a usual data exchange medium from the following address: Roche Diagnostics GmbH, Sandhofer Str. 116, D-68305 Mannheim.

You may read the software license agreement on the *CoaguChek XS Pro Policies and Procedures Manual CD*.

CoaguChek[®] XS Pro

Operator's Manual

©2010, Roche Diagnostics

The contents of this document, including all graphics, are the property of Roche Diagnostics. Information in this document is subject to change without notice. Roche Diagnostics shall not be liable for technical or editorial errors or omissions contained herein. No part of this document may be reproduced or transmitted in any form or by any means, electronic or mechanical, for any purpose, without the express written permission of Roche Diagnostics.

Please send questions or comments about this manual to your local Roche representative.

ACCU-CHEK, COAGUCHEK and SAFE-T-PRO are trademarks of Roche.

All other trademarks are the property of their respective owners.

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 manual accompanying this instrument.



Temperature limitation (Store at)



Use by



Manufacturer



Batch code/ Lot number

REF

Catalog number



In vitro diagnostic medical device



This product fulfills the requirements of the European Directive 98/79/EC for *in vitro* diagnostic medical devices.



Consult instructions for use

| | |
|--|----|
| 1 Introduction | 11 |
| Before you start..... | 11 |
| Intended use..... | 11 |
| Important information regarding use..... | 11 |
| If you need help..... | 11 |
| What can the system do for you?..... | 12 |
| Test principle..... | 12 |
| Safety information and additional information..... | 13 |
| Safety Information..... | 14 |
| Disposal of the System..... | 14 |
| General Care..... | 15 |
| Laser Scanner..... | 15 |
| Electromagnetic Interference..... | 15 |
| Touchscreen..... | 15 |
| Operating conditions..... | 16 |
| Quality control..... | 17 |
| | |
| 2 The CoaguChek XS Pro Meter | 18 |
| Overview of the meter elements..... | 19 |
| Buttons and icons overview..... | 20 |
| Power supply..... | 23 |
| | |
| 3 Putting the Meter into Operation | 24 |
| Inserting the batteries..... | 25 |
| Powering the meter on and off..... | 26 |

| | |
|---|-----|
| 4 Meter Setup | 27 |
| Note on presentation of screen elements in this manual..... | 27 |
| Settings summary | 28 |
| Screen setup | 32 |
| Contrast..... | 32 |
| Result Units | 33 |
| Language Selection..... | 35 |
| Setting the date..... | 36 |
| Setting the time..... | 38 |
| Setting the display options for date and time | 40 |
| Options setup | 42 |
| Sort..... | 42 |
| Beeper | 44 |
| Auto Off..... | 47 |
| Computer..... | 49 |
| ID setup..... | 51 |
| System Administrator (Admin.)..... | 53 |
| Operator | 59 |
| Patient..... | 60 |
| Lockouts setup..... | 63 |
| Operator lockout..... | 64 |
| QC (quality control) lockout..... | 67 |
| 5 Testing a Capillary Blood Sample | 69 |
| Important notes..... | 69 |
| Getting a good capillary blood sample | 70 |
| Getting a good result from venous whole blood..... | 71 |
| Preparing to test | 72 |
| Test strip code chip..... | 73 |
| Inserting the code chip | 73 |
| Powering on the meter..... | 75 |
| Performing a test..... | 78 |
| Adding comments..... | 87 |
| 6 Quality Control | 89 |
| Preparing to run a liquid quality control test..... | 90 |
| Performing a liquid quality control test..... | 92 |
| 7 Review Results | 99 |
| Viewing test results | 100 |
| Display patient result memory..... | 102 |
| Display QC (quality control) result memory | 103 |

| | |
|---|-----|
| 8 Extended Functionalities | 105 |
| Data handling..... | 105 |
| Computer (Setup option) | 105 |
| Operator lists..... | 106 |
| Patient lists | 107 |
| Barcode scanner | 108 |
| Stored test results and comments..... | 108 |
| 9 Cleaning and Disinfecting the Meter | 109 |
| Recommended cleaning/disinfecting solutions..... | 109 |
| Cleaning/disinfecting the exterior (meter housing)..... | 110 |
| Cleaning/disinfecting the test strip guide | 111 |
| Cleaning the scanner window..... | 112 |
| 10 Troubleshooting | 113 |
| Error messages after powering on the meter | 114 |
| Error messages when preparing to test | 115 |
| Error messages during or after blood application | 116 |
| Other error messages..... | 118 |
| 11 General Product Specifications | 121 |
| Technical data..... | 121 |
| Sample material..... | 121 |
| Storage and transport conditions | 122 |
| Further Information | 122 |
| Ordering | 122 |
| Reagents and solutions | 122 |
| Product limitations..... | 122 |
| Information about software licenses | 123 |
| Repairs | 123 |
| Contact Roche..... | 123 |
| 12 Warranty | 124 |
| 13 Appendix | 125 |
| Contact Roche | 125 |
| Alphabetical Index | 133 |

This page intentionally left blank.

1 Introduction

Before you start

Intended use

The CoaguChek XS[®] Pro system (CoaguChek XS Pro meter and CoaguChek XS PT Test strips) quantitatively determines prothrombin time ("PT"), using capillary blood or whole blood from a vein (nonanticoagulated venous whole blood). It is indicated for use by healthcare professionals. The system is ideally suited to monitor coagulation values in people who are taking oral anticoagulation medication (vitamin K antagonists, VKAs).

Important information regarding use

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

You must configure the CoaguChek XS Pro meter according to your needs before initial use. Refer to chapter 4, *Meter Setup*. Be sure to read the *Safety information and additional information* section in this chapter before operating the system.

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

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 10, *Troubleshooting*.

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

What can the system do for you?

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

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

- 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 XS Pro meter has the ability to connect to a data management system (DMS) through the Handheld Base Unit from Roche (available separately). The CoaguChek XS Pro meter supports data exchange via the POCT1A 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 an LIS or HIS. Refer to the manuals of the Handheld Base Unit and of your DMS for technical details.

Test principle

The CoaguChek XS PT Test contains a lyophilized reagent. The reactive components of this reagent consist of thromboplastin and a peptide substrate. When a sample is applied, thromboplastin activates coagulation, which leads to the formation of thrombin. At the same time the meter starts to measure the time. The enzyme thrombin cleaves the peptide substrate, generating an electrochemical signal. Depending on the time elapsed when it first appears, this signal is then converted by means of an algorithm into customary coagulation units (INR, %Quick, seconds) and the result is displayed.

Safety information and additional information

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



The safety alert symbol by itself (without a signal word) is used to promote awareness to hazards which are generic or to direct the reader to related safety information



WARNING

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



CAUTION

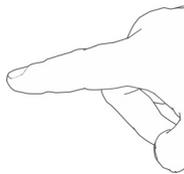
Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

NOTICE

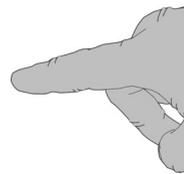
Indicates a hazardous situation which, if not avoided, may result in damage to the system.

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

Safety Information



Operator qualification

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



WARNING

Protection against infection

There is a potential risk of infection. Healthcare professionals using the CoaguChek XS Pro system must be aware that any object coming into contact with human blood is a potential source of infection. Healthcare professionals must also be aware that any cross-contamination is a potential source of infection for patients.

- Use gloves.
 - Use a separate lancet / separate lancing device for each patient.
 - Dispose of used lancets in a sturdy sharps container with lid.
 - Dispose of used test strips according to your institution's infection control policy.
 - Follow all health and safety regulations in force locally.
-

Disposal of the System



WARNING

Infection by a potentially biohazardous instrument

The CoaguChek XS Pro 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.



WARNING

Exploding batteries

Do not throw used batteries into an open fire. They may explode.



Disposal of used batteries

Do not dispose of the batteries with normal domestic waste. Dispose of used batteries in an environmentally responsible manner and in accordance with applicable local regulations and directives. Contact your local council/local authority or the manufacturer of the used batteries for advice on correct disposal.

General Care

NOTICE

Clean the meter only with the solutions recommended (see page 109). 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.

Laser Scanner

The built-in barcode scanner emits a laser beam when activated.

The built-in barcode scanner is a Class 1 laser, according to EN 60825-1:2007.



WARNING

A barcode does not need to be present for the laser scanner to become active. Do not stare directly into the laser beam.

Electromagnetic Interference



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

Touchscreen

NOTICE

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

Operating conditions

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

- Only use the meter at a room temperature between 15 °C and 32 °C (59 °F and 90 °F).
- Only use the meter at a relative humidity between 10% and 85% (no condensation).
- When operating the meter using the power supply unit, use only a voltage of 100 V to 240 V ($\pm 10\%$), 50/60 Hz.
- When testing, place the meter on a level, vibration-free surface, or hold it so it is roughly horizontal.

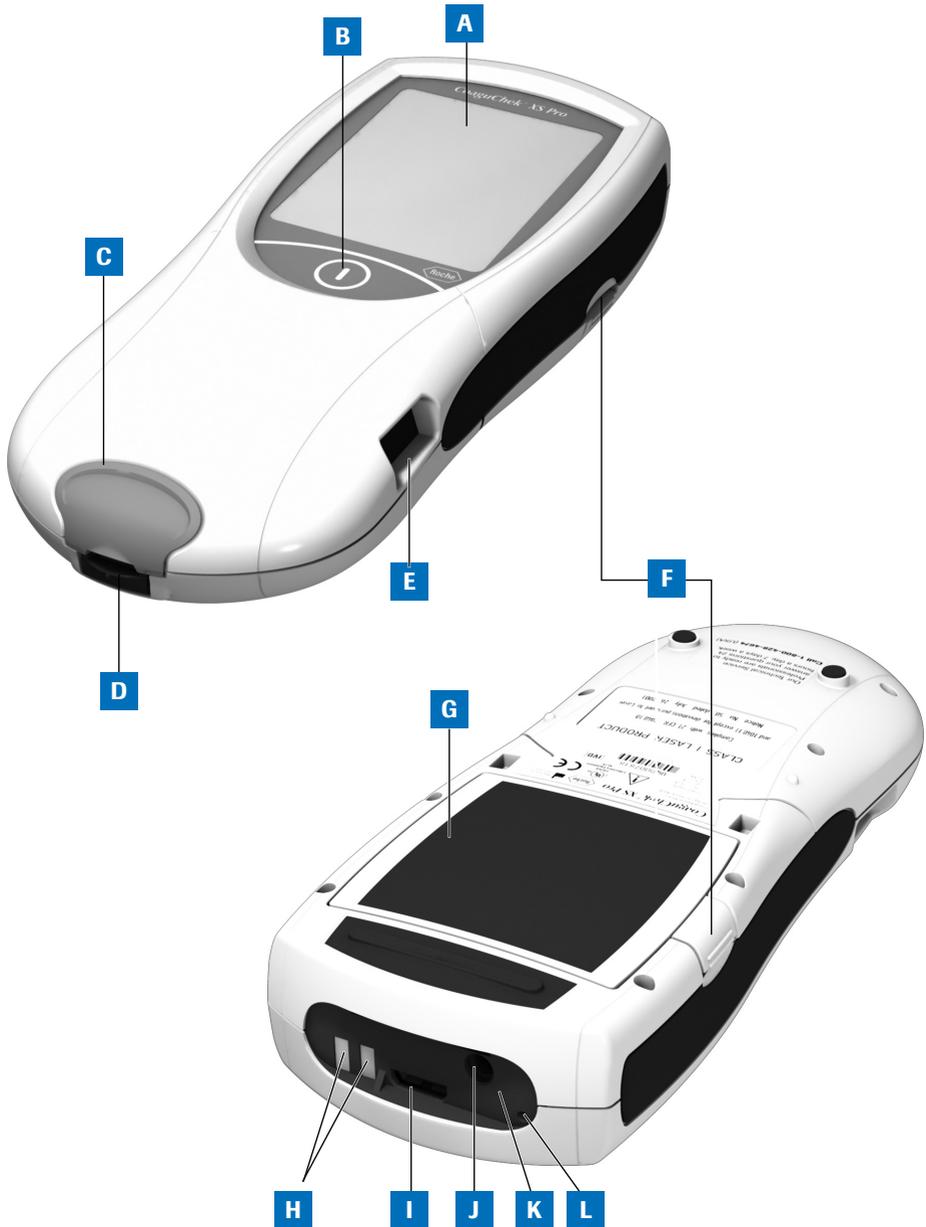
Quality control

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.
- A two-level, on-board quality control test and patient result determination within a single test chamber.

Roche Diagnostics has available optional liquid quality controls for the CoaguChek XS Pro system. These controls are provided to assist with meeting regulatory compliance requirements as applicable to your facility.

2 The CoaguChek XS Pro Meter



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 and hold 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 (Laser)

The integrated barcode scanner can read operator and patient IDs into the meter.

F Tab for battery compartment cover

G Battery compartment cover

Covers the battery compartment (4 standard AA alkali-manganese batteries or a rechargeable battery pack (optional)).

H Charging terminals

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

I Code chip slot

Insert the code chip here.

J Connection socket for power adapter

Plug in the power adapter here.

K Infrared interface

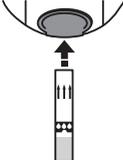
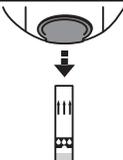
(Covered by the semi-transparent panel)
Supports data communication.

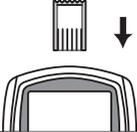
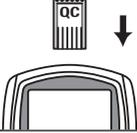
L Reset button

Use this button to reset the meter in case of software or power-up errors.

Buttons and icons overview

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

| Icon | Meaning |
|---|---|
|  | Go to Main Menu |
|  | OK; save setting |
|  | Cancel; discard setting |
|  | Return (to previous menu) |
|  | Reduce/increase the value displayed Move screen contents |
|  | Inactive button: Value cannot be further decreased/increased or: End of list in this direction is reached |
|  | List of tests of a specific patient |
|  | Operator must wait until the meter has completed an action. |
|  | 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) |

| Icon | Meaning |
|---|--|
|  | Insert the test strip code chip |
|  | Insert the QC code chip |
| <p>QC ✓</p> | Automatic quality control completed successfully |
| <p>%Q</p> | Results are displayed as a Quick percentage value |
| <p>Sec</p> | Results are displayed in seconds |
| <p>INR</p> | Results are displayed in INR units |
| <p>></p> | Result in the chosen unit of measure is above the measuring range. |
| <p><</p> | Result in the chosen unit of measure is below the measuring range. |
|  | Quality control: Result is above the specified range |
|  | Battery status: <ul style="list-style-type: none"> ▪ When the batteries still have their full charge, all segments are lit. ▪ Individual segments disappear one by one as the batteries become weaker. ▪ When there is no segment remaining, you can no longer perform a test. You can, however, still access the meter's memory. |
|  | Operation with power supply adapter |
| <p>am</p> | Time between midnight and noon (in 12-hour time format) |
| <p>pm</p> | 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 |
|  | Communication is taking place via the infrared interface |

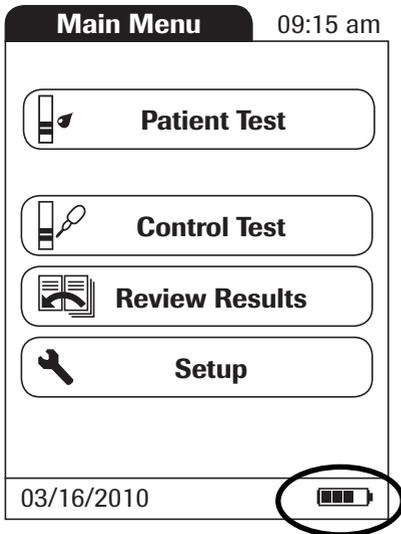
Error messages and the description of the icons linked to them are provided in the *Troubleshooting* chapter of this manual.

| Icon | Meaning |
|---|--|
|  | Reports a warning message |
|  | Reports an error (see: <i>Troubleshooting</i>) |
|  | Reports a serious error (see: <i>Troubleshooting</i>) |

Power supply

The CoaguChek XS Pro meter can operate with either the power adapter provided, batteries, or a special rechargeable battery pack (optional). The CoaguChek XS Pro meter uses four standard type AA alkaline batteries. You should insert the batteries or the optional rechargeable battery pack even when you use the power adapter. This ensures that you will not lose the date and time settings if the power goes out.

To save power, the CoaguChek XS Pro meter has the option to automatically power itself off based on your setup selections, unless a button has been pressed or a new test strip has been inserted. The default setting is set to 5 minutes. When the meter powers itself off, all results obtained up to that point remain in memory and the settings will still be there when you power the meter back on. (Refer to *Auto Off* on page 47.)



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

When replacing the batteries you must insert the new batteries within ten (10) minutes of removing the old ones to keep the date and time settings. If you take longer than this, you must re-enter the date and time.

To make sure that you do not lose your date and time settings, connect the power supply unit while you change the batteries.

The meter retains results in memory even when no batteries are inserted. All settings other than date and time (deleted after 10 minutes without power) are retained as well.

Dispose of used batteries in an environmentally responsible manner and in accordance with applicable local regulations and directives.

3 Putting the Meter into Operation

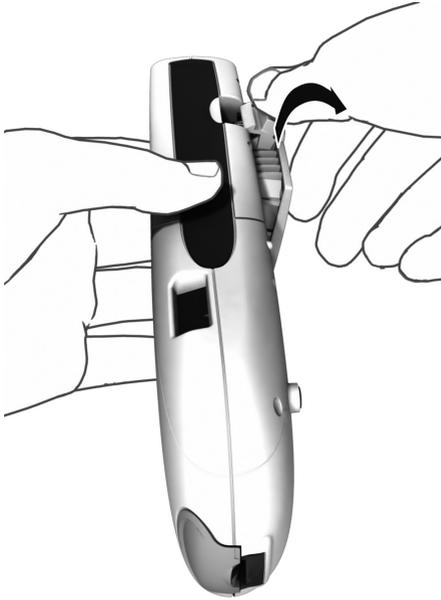
Before using the meter for the first time, perform the following steps:

- 1 Insert batteries and/or connect the power supply unit
- 2 Set the current date and time
- 3 Enter the settings of choice (language, unit of measure, user administration if applicable, etc.)

Instead of batteries, you can use a special rechargeable battery pack. If you choose this option, order the pack separately from Roche Diagnostics. To recharge, connect the power adapter to the CoaguChek XS Pro meter or to the optional Handheld Base Unit (HBU) and dock the meter.

The meter's battery power level indicator is designed for use with either standard, non-rechargeable AA batteries or the dedicated Roche handheld battery pack. We do not recommend the use of off-the-shelf rechargeable batteries in AA format. These have lower voltages than standard AA batteries or the special Roche handheld battery pack. This can lead to incorrect battery power level indications on the meter.

Inserting the batteries

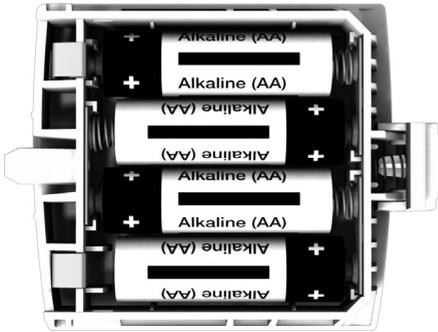


- 1 With the meter powered off, press the battery compartment cover release tab and slide the cover off.



- 2 Insert the four batteries in the battery compartment as indicated.

The batteries should last about 80 tests, depending on the type of battery used.



- 3 Slide the battery compartment back onto the meter and close it.

The meter powers itself on after the batteries have been inserted.

Powering 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 and holding the  button for approximately 1 second.

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

- 3 To power the meter off after use, press the  button for approximately 2 seconds.

4 Meter Setup

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.

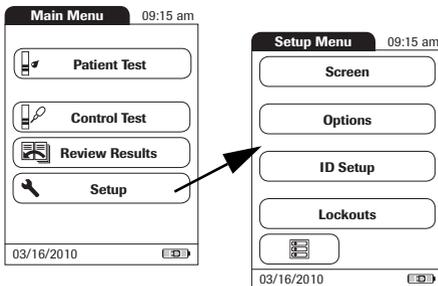
If you have **not** set the date and time (after powering on for the first time or because the batteries were removed from the meter for more than 10 minutes), you cannot perform a test. In that case powering on the meter takes you immediately to the *Setup* mode, where you must set the date and time (see page 36 and following).

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.

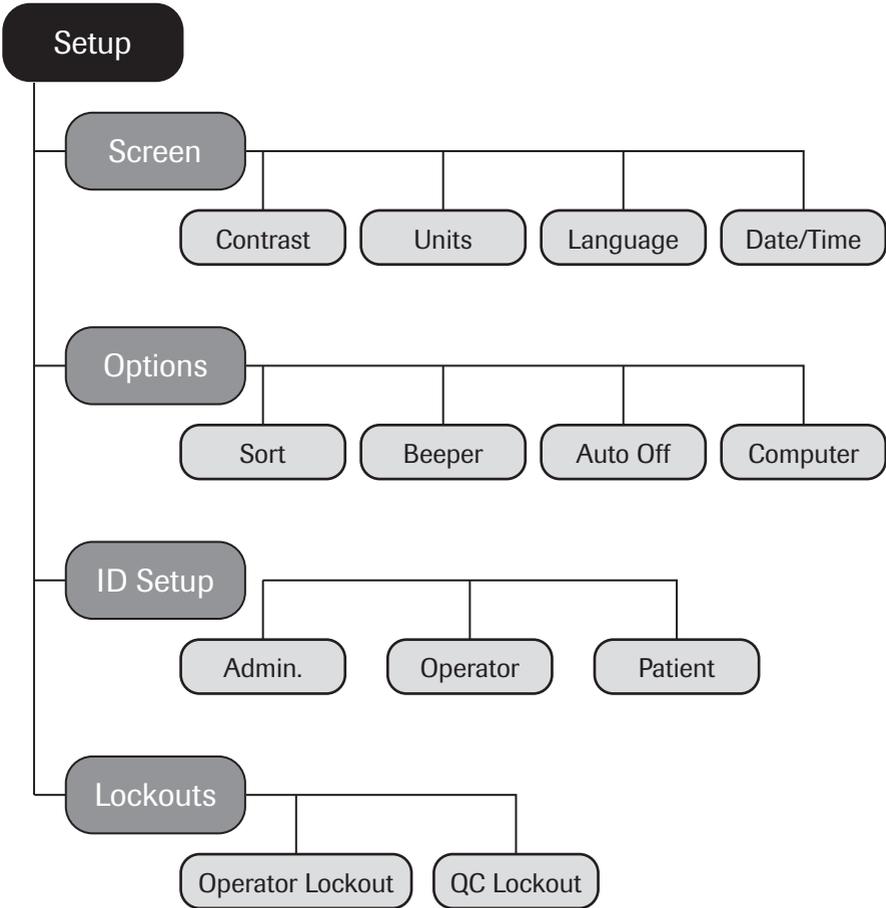
If the meter did not automatically enter the *Setup* mode (e.g., after the batteries were replaced), you can open the *Setup* menu from the *Main Menu*.



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

Settings summary

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



| Group | Subgroup | Setting | Values * |
|--------------|--------------------|---|---------------------------|
| Screen | Contrast | | 0 - 10 (5 *) |
| | Result Units | | INR * |
| | | | INR/SEC |
| | | | INR/%Q |
| | Language Selection | | Dansk |
| | | | Deutsch |
| | | | English * |
| | | | Español |
| | | | Français |
| | | | Italiano |
| | | | Nederlands |
| | | | Norsk |
| | | | Português |
| | | Svenska | |
| | Date/Time | Date | |
| Time | | | 12:00 am * |
| Date formats | | | DD.MM.YYYY (16.09.2009) |
| | | | MM/DD/YYYY (09/16/2009) * |
| | | | YYYY-MM-DD (2009-09-16) |
| Time formats | | | 24-hour time format (24h) |
| | | 12-hour time format (12h), with am/pm * | |

* Default settings are labelled with an asterisk (*).

| Group | Subgroup | Setting | Values * | |
|----------------|----------|-----------|-------------------|-------------------|
| Options | Sort | | Date/Time * | |
| | | | Patient ID number | |
| | Beeper | Beeper | | Off |
| | | | | Low |
| | | | | Medium * |
| | | | | High |
| | | | Key Click | Off * |
| | | | On | |
| | Auto Off | [minutes] | | Off |
| | | | | 1 ... (5*) ... 10 |
| | | | | 15 |
| | | | | 20 |
| | | | | 25 |
| | | | | 30 |
| | | | | 40 |
| | | | 50 | |
| | 60 | | | |
| Computer | | | Active | |
| | | | Inactive * | |

* Default settings are labelled with an asterisk (*).

| Group | Subgroup | Setting | Values * | |
|-----------------|---|----------|----------------|-------|
| ID Setup | Admin. (Administrator) | | Blank (Off) * | |
| | Operator (Operator List is optional) | | Active | |
| | | | Inactive * | |
| | Patient | | No * | |
| | | | Optional | |
| | | | Required | |
| Lockouts | Operator Lockout (only if the <i>Operator</i> option is set to <i>Active</i> and an operator list is available) | | Off * | |
| | | | Weekly | |
| | | | Monthly | |
| | | | Every 3 months | |
| | | | Every 6 months | |
| | | | Yearly | |
| | QC Lockout | New code | | Yes |
| | | | | No * |
| | | General | | No * |
| | | | | Daily |
| | Weekly | | | |
| | | Monthly | | |

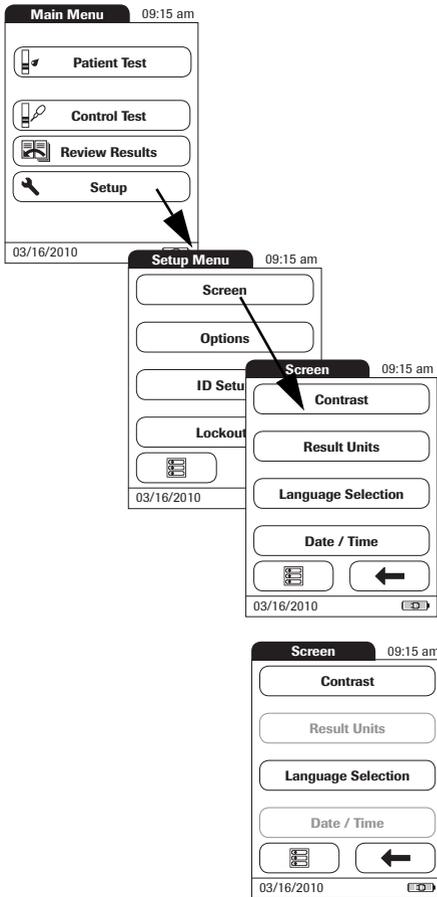
* Default settings are labelled with an asterisk (*).

Screen setup

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

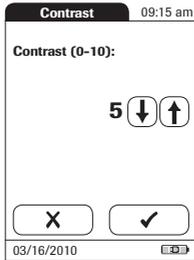
Contrast

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.

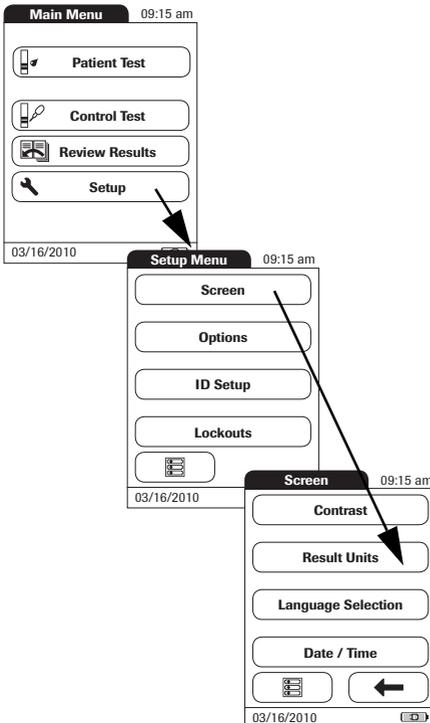


- 4 Touch  or  to change the contrast in a range from 0 to 10.
- Contrast “0” makes the display very dark.
- Contrast “10” makes the display very light.
- 5 Touch  to save this setting, or:

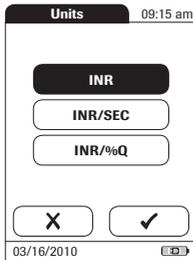
Touch  to exit this menu without saving any changes. The display automatically returns to the previous screen.

Result Units

Use this setting to select the unit(s) of measure to be displayed with the results.



- 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 Units**.
- Units.**



The current unit of measure setting is highlighted (white type on a black background). You can select either:

- INR
- INR and seconds
- INR and Quick value in %

4 Touch the button to select the unit of measure of choice. Your selection is now highlighted.

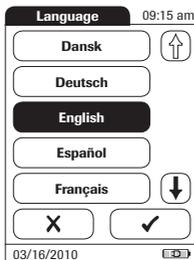
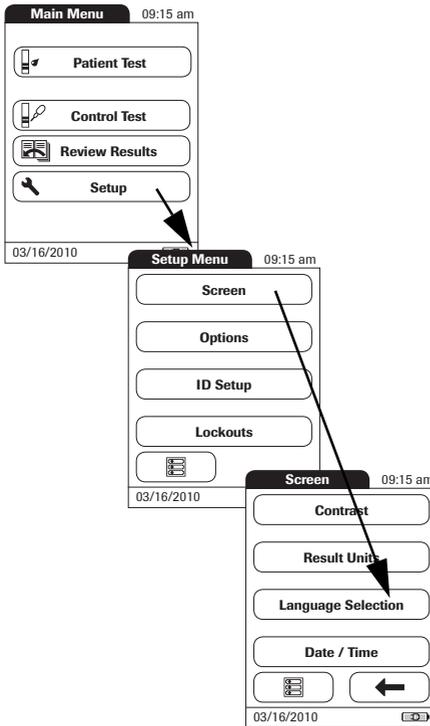
5 Touch  to save this setting, or:

Touch  to exit this menu without saving any changes.

The display automatically returns to the previous screen.

Language Selection

Use this setting to select the language for all displays (that contain text).



- 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 black background). You can select either:

- Dansk
- Deutsch
- English
- Español
- Français
- Italiano
- Nederlands
- Norsk
- Português
- Svenska

- 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:

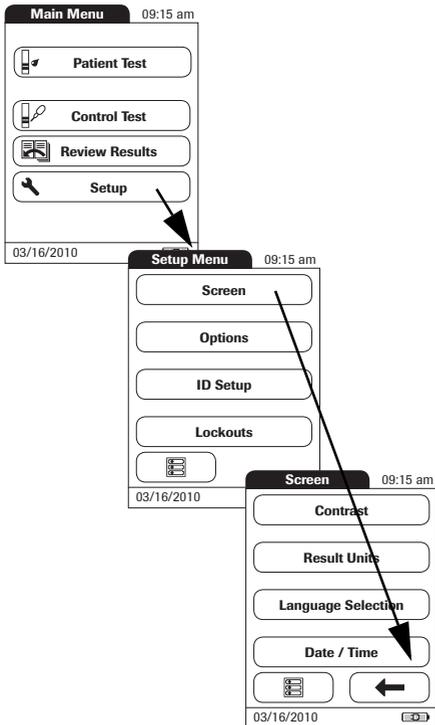
Touch  to exit this menu without saving any changes. The display automatically returns to the previous screen.

Setting the date

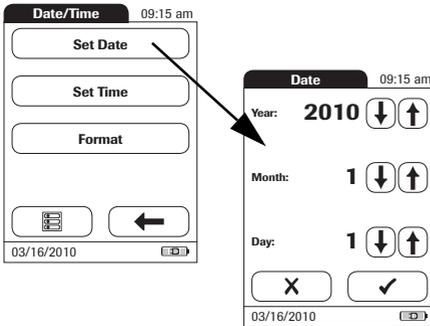
When you power on the meter for the first time (or after a long period without power), the input field for the date automatically appears first. The date (and time) must be entered before the meter can be used further. If at a later time a date adjustment is needed, go to the *Setup* menu, then select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

Both *Date* and *Time* display formats are controlled by the *Format* options you select (see page 40). 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., 16.09.2009
- Date: Month/Day/Year, e.g., 09/16/2009
- Date: Year-Month-Day, e.g., 2009-09-16
- 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  and  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.

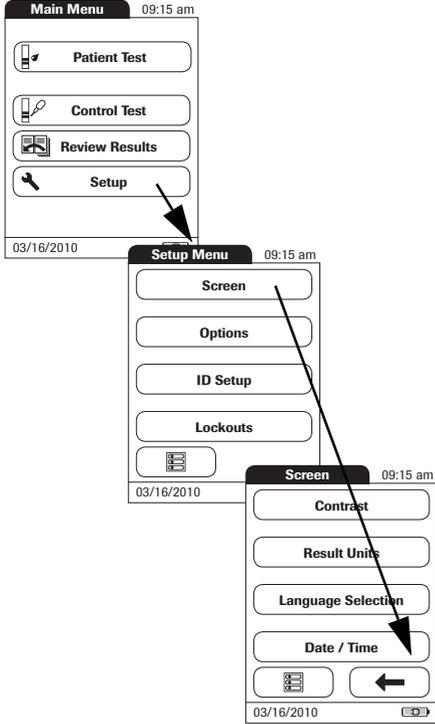
The display automatically returns to the previous screen.

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

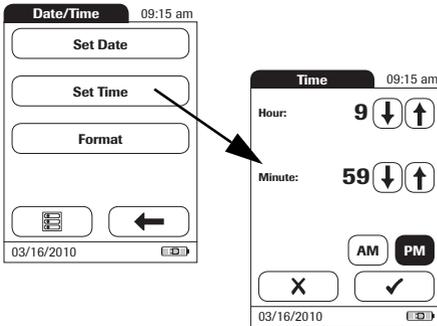
- 7 Touch  to return to the *Screen* menu.

Setting the time

When you power on the meter for the first time (or after a long period without power), this *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  and  to set the hours, then the minutes.
- 6 Touch  to save this setting, or:

Touch  to exit this menu without saving any changes.

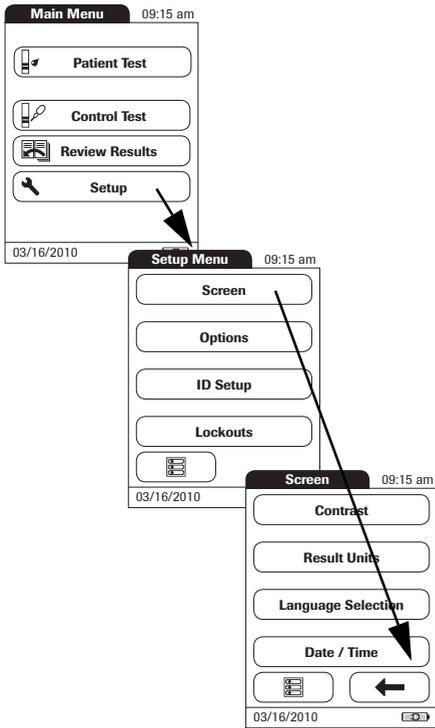
The display automatically returns to the previous screen.

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

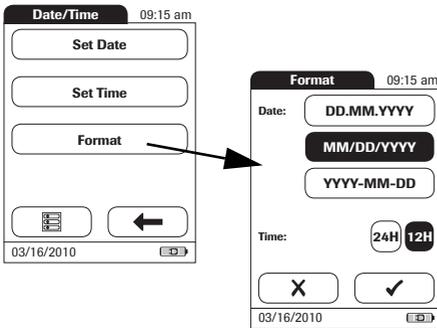
- 7 Touch  to return to the *Screen* menu.

Setting the display options for date and time

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 screen, 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., 16.09.2009
- Date: MM/DD/YYYY (Month/Day/Year), e.g., 09/16/2009
- Date: YYYY-MM-DD (Year-Month-Day), e.g., 2009-09-16
- 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.

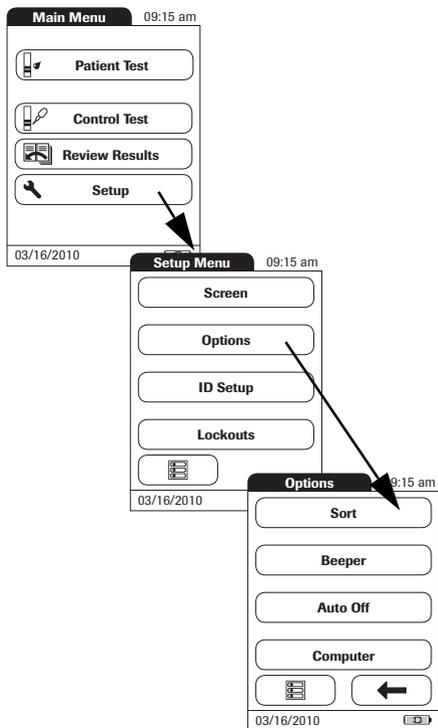
The display automatically returns to the previous screen.

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

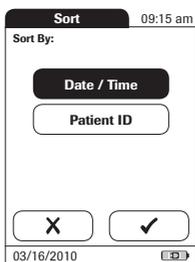
Options setup

Sort

Sort refers to the order in which measured and stored results are displayed when you use the *Review Results* function of the CoaguChek XS Pro 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**

4 Touch the button to select the *Sort by* option of choice. 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.

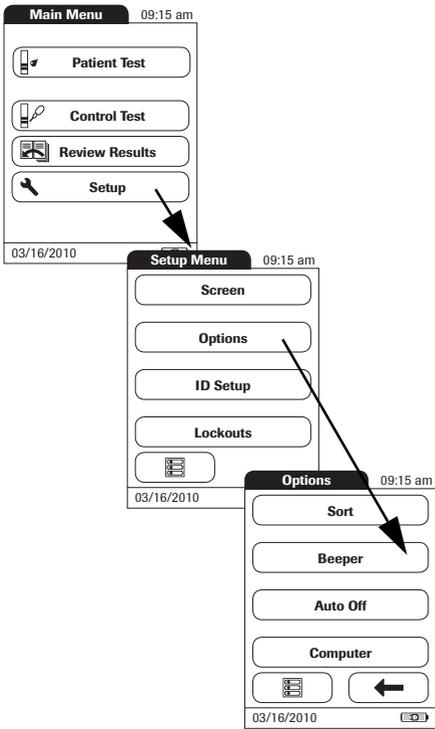
Beeper

The CoaguChek XS Pro meter can display information visually and alert you to special circumstances with a *Beeper*. When the *Beeper* is activated, the meter beeps when:

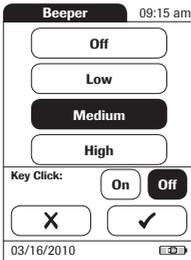
- it is switched on
- it detects a test strip
- pre-heating of the test strip is complete and you need to apply a sample
- it detects a sample
- the test is completed and the results are displayed (a long beep)
- an error occurs (three short beeps)
- an external power supply unit is connected when the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

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

You can also activate a *Key Click*. When a *Key Click* is activated, 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. You may select from the following options:

For the *Beeper*

- **Off**
- **Low**
- **Medium**
- **High**

For the *Key Click*

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

4 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.

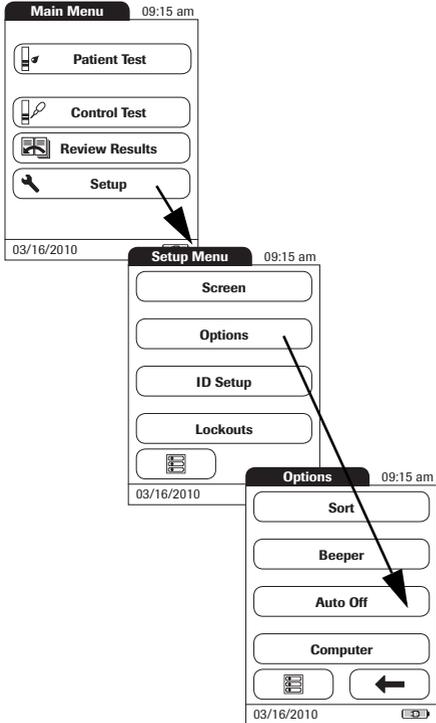
5 Touch ✓ to save this setting, or:

Touch X to exit this menu without saving any changes.

The display automatically returns to the previous screen.

Auto Off

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

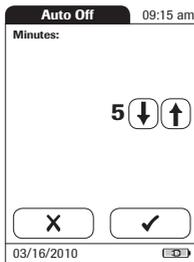


- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **Options**.
- 3 From the *Options* menu, touch **Auto Off**.

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

- If *Operator* is set to **Inactive**, the meter switches to the *Main Menu*, once *Auto Off* is triggered.
- If *Operator* is set to **Active**, the meter switches to *Operator Login*, once *Auto Off* is triggered.

For information on *Operator ID*, see *Operator* on page 59.



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
- 4 Touch  or  to select the time of choice in minutes or to switch the feature off.
 - 5 Touch  to save this setting, or:

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

Computer

The CoaguChek XS Pro 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. 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).

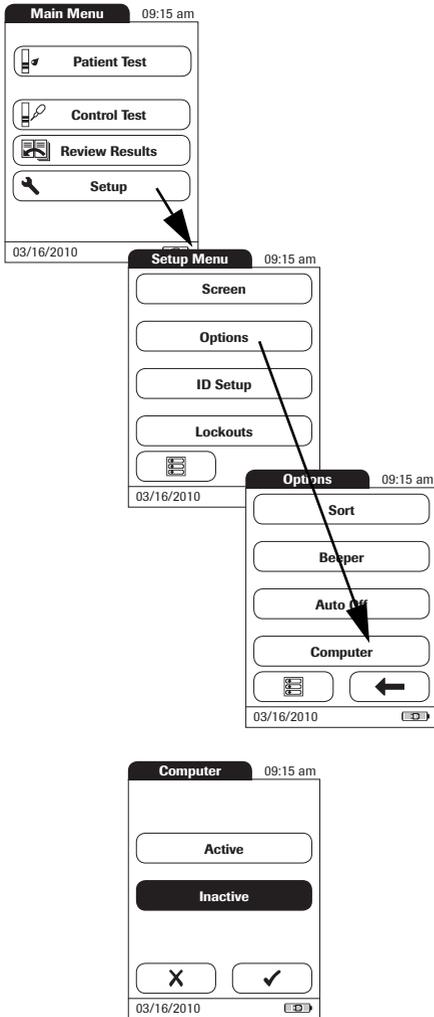
The option *Computer* (when activated) can be used together with a DMS to set up:

- 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* controls the meter's ability to communicate with a computer or a network.

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



- 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 **Computer**.

- 4 Touch the button with the setting of choice for communication with the PC. 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.

ID setup

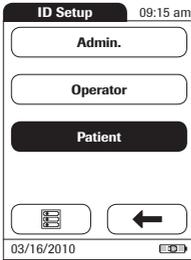
Use the *ID Setup* menu to enter settings for user management and patient management. These settings are optional and set to *Off/Inactive* by default; the meter can be operated without these settings.

There are three types of identification used with the meter:

- **System Administrator:** The *Admin*. (Administrator) has special rights to enter certain meter settings and is the only one who can enter and change these settings. It is not necessary for *Admin*. identification to be activated to use the CoaguChek XS Pro meter. However, it might be desired or necessary, depending on the regulatory environment and the site of use.
- **Operator:** The *Operator ID* is assigned to persons who use the meter to run tests. If you want to use *Operator IDs*, you have several options:
 - You may use *Operator IDs* to restrict the use of the meter to qualified personnel or a predefined group of users. In this case an operator list created externally must be transferred to the meter, enabling you to select an *Operator ID* when logging in. For more details see *Data handling*, starting on page 105.
 - You may use *Operator IDs* for informational purposes only, in order to assign stored measurement results to the users who performed the test. In this case *Operator IDs* may directly be entered 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 *Patient IDs* for a test from these lists. For more details see *Data handling*, starting on page 105.

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.



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 black background) this means the function is available and activated (either as *Optional* or *Required*).

System Administrator (Admin.)

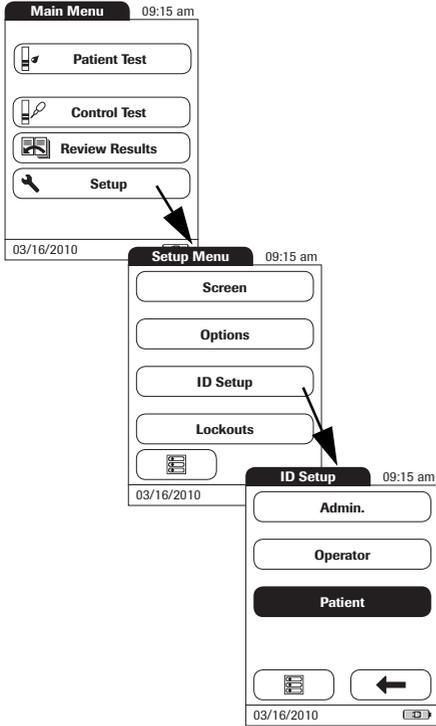
In the default setting, the meter is not protected with an *Admin.* password, and all setup options are accessible to every user. If you set up an *Admin.* password, the following setup areas are automatically reserved only for the system administrator/supervisor (i.e., the person who knows the password).

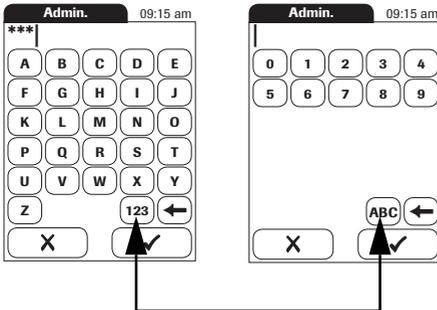
- *Screen: Result Units, Date/Time*
- *Options: (connection to a) Computer*
- *ID Setup (the entire area)*
- *QC Lockout*
- *Operator Lockout (only available in combination with a data management system)*

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

If an *Admin.* password has not been set up yet:

- 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.**



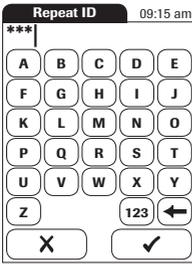


- 4 Using the keypad displayed on the screen, enter the *Admin.* password of choice. The password can consist of up to 20 characters.

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

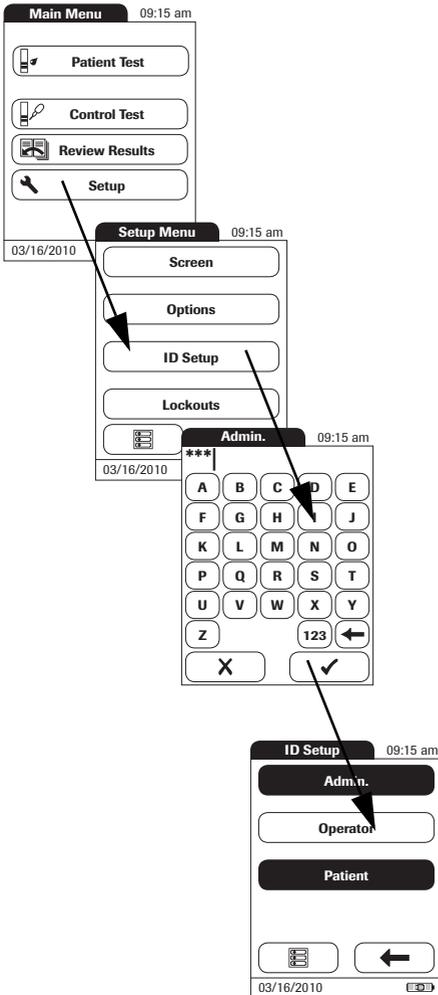
- 5 Use **123** to switch to input of numbers.
- 6 Use **ABC** to switch back to input of text.
- 7 Use **←** to backspace and correct a mistake.
- 8 Touch **✓** to save this setting, or:

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



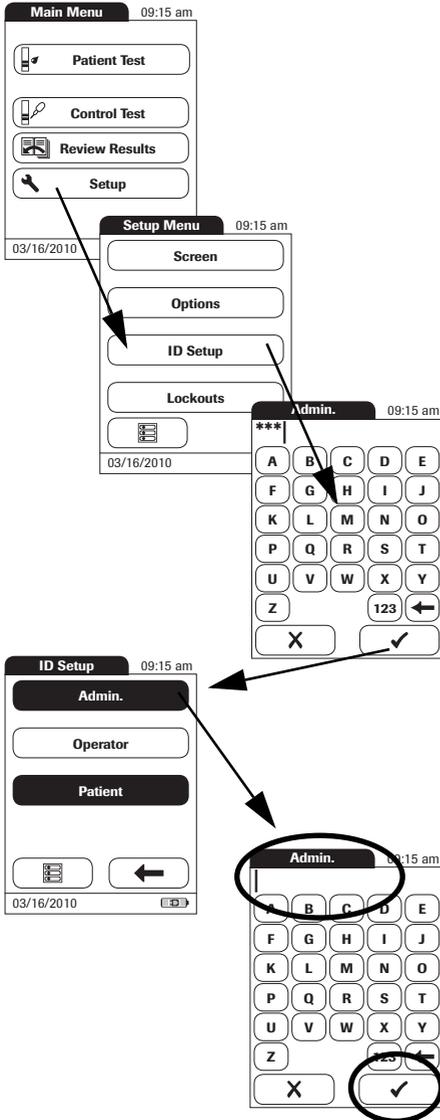
- 9 Enter the *Admin.* password again (the keypad is automatically displayed again on the screen) to confirm the first entry.
- 10 Touch ✓ to save this entry, (the *Admin.* password is now set), or
Touch X to exit this menu, the *Admin.* password is not set and is therefore still inactive.

The display automatically returns to the *ID Setup* menu. After you exit the *Setup* menu, only an authenticated administrator may further edit the setup areas as listed before (see page 53).



Changing an existing *Admin.* password:

- 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 valid *Admin.* password.
The *ID Setup* menu is displayed. The **Admin.** button is highlighted, which means an *Admin.* password is active.
- 4 Touch **Admin.**
- 5 Using the keypad displayed on the screen, enter (and confirm) the new *Admin.* password of choice.



Deactivating an existing *Admin.* password:

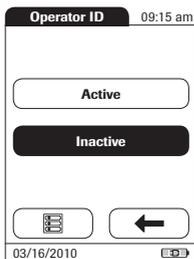
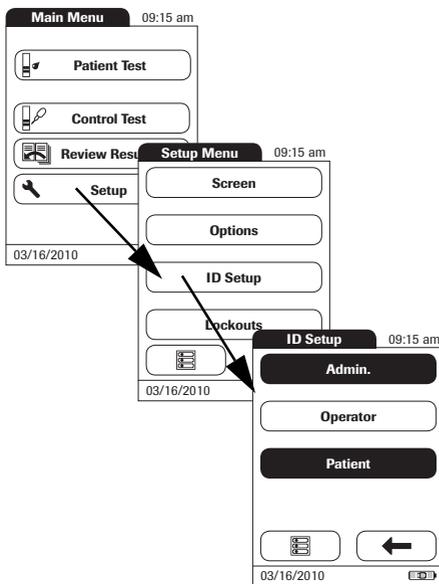
- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **ID Setup**.
- 3 Using the keypad displayed on the screen, enter the valid *Admin.* password.
The *ID Setup* menu is displayed. The **Admin.** button is highlighted, which means an *Admin.* password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

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

Operator

If you want to create a list of *Operator IDs* from which you can select an operator, additional software (a data management system) and the Handheld Base Unit are required (for more details see *Data handling*, starting on page 105).

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



To activate *Operator* login:

- 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:

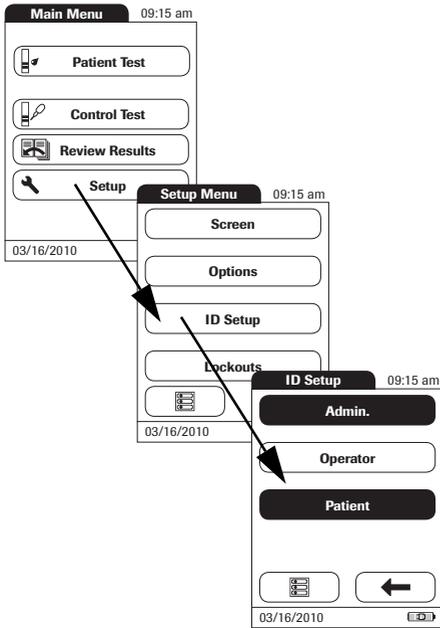
Touch ✗ to exit this menu without saving any changes.

The display automatically returns to the previous screen.

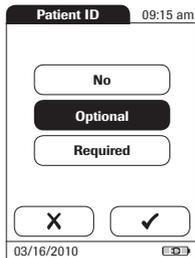
Patient

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 page 105).

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.



- 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:

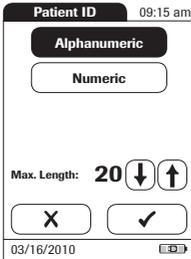
- **No** (tests will be assigned numbers automatically)
- **Optional** (automatic numbering or list/scan/manual input)
- **Required** (list/scan/manual input)

4 Touch the button with the setting of choice. 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**
text and numbers, e.g., “J. DOE 3378”
- **Numeric**
numbers only, e.g., “3387”
- **Max. Length**
Indicate 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.

Lockouts setup

The *Lockouts* menu contains the option for liquid quality control that require the operator to perform a liquid quality control test at specified intervals.

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* also can be set up selectively for individual operators.

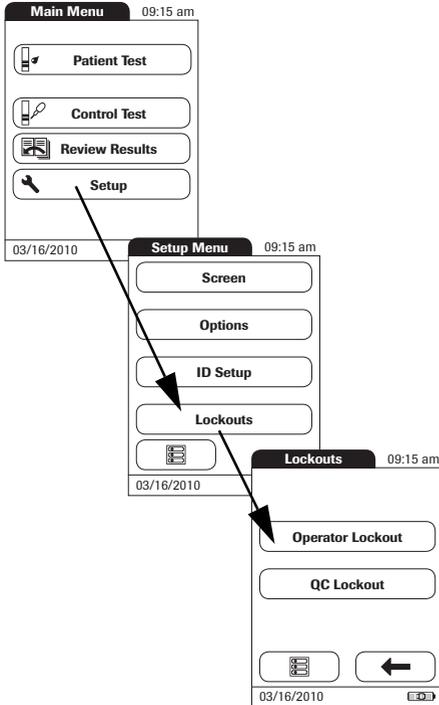
A liquid quality control test must be completed successfully before the meter is available again for testing (either by the operator or in general).

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*, starting on page 105.

Operator lockout

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



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

The option of setting up an *Operator Lockout* is available only when operator lists are created on the DMS. For more details see *Data handling*, starting on page 105. If you are not working with a DMS, only the *QC Lockout* is available (see *QC (quality control) lockout* on page 67).



- 4 Select the interval of choice in which the mandatory quality control tests must be performed.

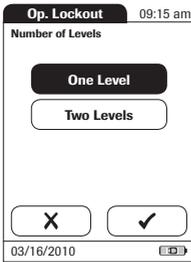
You may select from the following options:

- **No** (deactivated)
- **Weekly**
- **Monthly**
- **Every 3 Months** or **Every 6 Months**
- **Yearly**



- 5 Touch and to display the option of choice on the screen.
- 6 Touch the button to select the interval of choice. Your selection is now highlighted.
- 7 Touch to save this setting, or:

Touch to exit this menu without saving any changes.



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

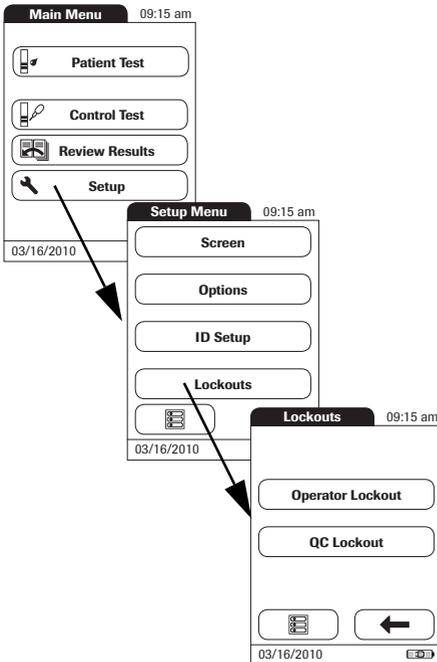
9 Touch ✓ to save this setting, or:

Touch ✕ to exit this menu without saving any changes.

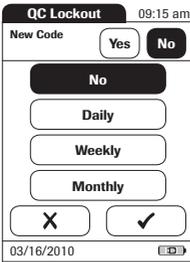
The display automatically returns to the previous screen.

QC (quality control) lockout

The *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.** It is also possible to mandate *Operator Lockouts* and *QC Lockouts* in parallel. In addition to defining time intervals, *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**).



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



- 4 Select the triggers, based on lot and/or time, for requiring a quality control test.

You may select from the following options:

- **New Code Yes/No** (applies every time a new test strip lot is used)

The general intervals are:

- **No**
- **Daily**
- **Weekly**
- **Monthly**

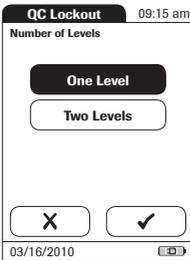
- 5 Touch the button with the option of choice when changing the test strip lot.
- 6 Touch the button to select the interval of choice. Your selection is now highlighted.
- 7 Touch  to save this setting, or:

Touch  to exit this menu without saving any changes.

- 8 For every option except for **No**, you must now indicate the number of levels in which the quality control must be performed.
- 9 Touch  to save this setting, or:

Touch  to exit this menu without saving any changes.

The display automatically returns to the previous screen.



5 Testing a Capillary Blood Sample

What you need:

- CoaguChek XS Pro meter
- CoaguChek XS PT Test Strips and matching code chip
- Lancing device approved for professional use (e.g., the Accu-Chek Safe-T-Pro Plus lancing device or the CoaguChek Lancet)
- CoaguChek Capillary tube/bulb (optional)

Do not use glass capillary tubes or capillary tubes that contain anticoagulants.

- Cotton ball and alcohol wipe

Important notes

Always ...

- ... close the strip container immediately after removing a test strip.
- ... operate the meter at an ambient temperature between 15 °C and 32 °C (59 °F and 90 °F).
- ... 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 *Cleaning and Disinfecting the Meter* (starting on page 109).



Protection against infection:

When collecting samples always observe the general precautions and guidelines relating to blood sampling (see page 14).

Dispose of all test strips used for patient testing in accordance with the disposal policy of your laboratory or practice (see page 14)

Never ...

- ... store the meter at extreme temperatures (greater than 40 °C or 104 °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.
- ... use the code chip from a pack of strips other than the one in use.
- ... touch or remove the test strip during a test.
- ... wait more than 15 seconds after lancing the fingertip before applying the blood.
- ... add more blood after the test has begun.
- ... perform a test with a drop of blood from a previous puncture.
- ... test a patient with wet hands (residues of water, sweat, or alcohol).



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

To get a suitable drop of blood:

- Warm the hand. Have the patient hold it under his or her arm or use a hand warmer. Wash hands with soap and warm water. 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.

- Immediately after lancing, massage gently along the side of the finger to obtain a good blood drop without pressing or squeezing too hard.
- Apply the blood drop directly to the test strip immediately (within 15 seconds).
- Optionally, you may use a CoaguChek Capillary tube/bulb to collect the fingerstick blood sample.



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

Getting a good result from venous whole blood

Alternatively to performing a test with capillary blood, you can also perform a test using venous whole blood. Note the following:

- Use a simple plastic syringe to remove the blood sample. Do not use anticoagulants (e.g., EDTA, citrate, flouride, oxalate, or heparin) to collect the blood sample.
- Use a needle at least 23 G (approx. 0.65 mm) or larger in size.
- Discard the first four drops of blood collected (within the first 10 seconds). Then immediately apply one drop of blood (at least 8 μ L) 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 (see page 14).

Dispose of all test strips used for patient testing in accordance with the disposal policy of your laboratory or practice (see page 14).

Preparing 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.

Test strip code chip

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

The CoaguChek XS Pro meter stores the data from up to 60 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.

Inserting 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, error messages appear in the display (please refer to the *Troubleshooting* section of this manual).

Powering on the meter

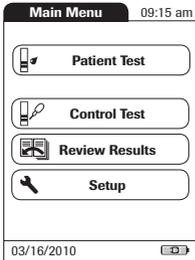


- 1 Place the meter on a level, vibration-free surface, or hold it in your hand so it is roughly horizontal.
- 2 Power the meter on by pressing and holding the  button for approximately 1 second.

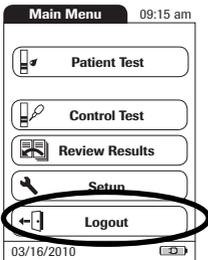
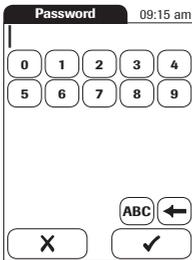
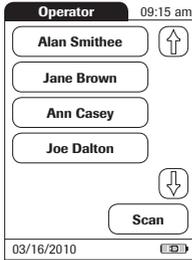
You can also power on the meter directly by inserting a test strip or connecting the power adapter.

The next steps depend on whether you work with the function *Operator ID* set to inactive or active (see *Data handling* on page 105).

If the function *Operator ID* is inactive:



- 3 Wait until the *Main Menu* is displayed.



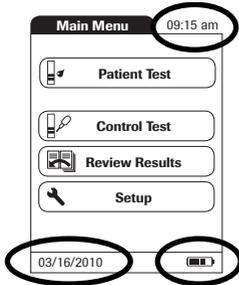
With operator list:

- 3 Wait until the operator list is displayed.
- 4 Select the operator of choice by touching the corresponding button.
- 5 Enter the (optional) password.
- 6 After you enter the password, touch  to log on. The *Main Menu* is displayed and you can start the test.
- 7 When you touch , the operator pick list is displayed again.

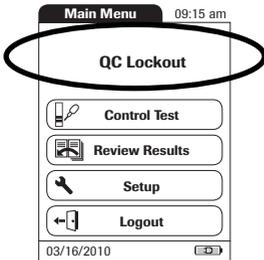
When the tests are completed or another operator wants to perform additional tests, touch **Logout** to log out (this button is available only when the *Operator ID* is activated). The meter returns to the display of the operator pick list.

Note: Extended data handling functionality is dependent on the capabilities of the particular Data Management System (DMS) being used and may vary. For more details see *Data handling*, starting on page 105.

Performing a test



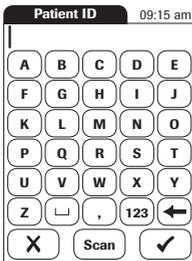
- 1 Check the battery level. If there are no bars left in the battery icon, you cannot perform any tests.
- 2 Check that the date and time are correct. Correct any wrong entries as described in chapter 4, *Meter Setup/Setting the date*.



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 (refer to chapter 6, *Quality Control*). When the meter is in lockout status, a test cannot be performed.

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

Without patient list



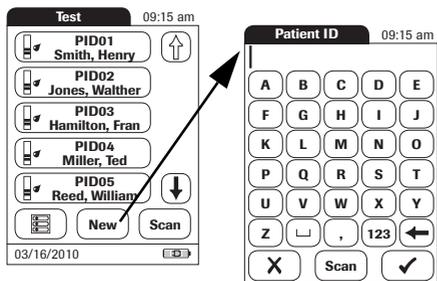
3 Touch Patient Test.

- 4** If the *Patient ID* option was chosen as either *Optional* or *Required* when the meter was set up (see *Meter Setup/Patient*), you are prompted to enter a *Patient ID*.
- 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 8.

With patient list



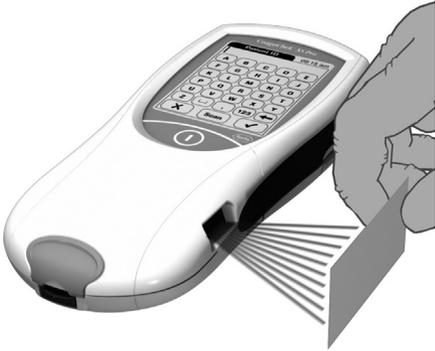
5 Touch Patient Test.



6 Touch  and  to display the entry of choice. Select the patient to be tested from the list.

7 If the patient is not in the list, touch **New** to create a new entry. You must now enter a *Patient ID*.

Note: Extended data handling functionality is dependent on the capabilities of the particular Data Management System (DMS) being used and may vary. For more details see *Data handling*, starting on page 105.

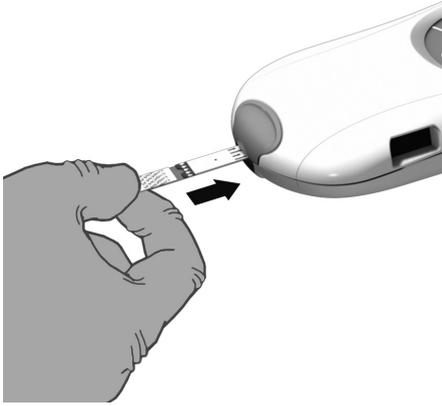


Alternatively, the *Patient ID* can also be entered via the built-in barcode scanner. Touch **Scan** and scan the patient barcode from a distance of approx. 10 cm (4 inches).

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



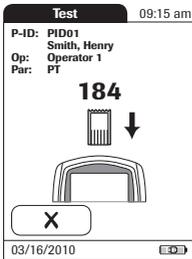
A barcode does not need to be present for the laser scanner to become active. Do not stare directly at the laser beam.



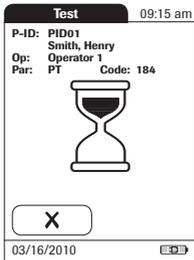
- 8 The test strip icon prompts you to insert a test strip. Remove a test strip from its container and close the container again with the stopper.

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

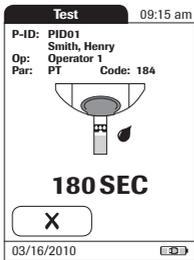
- 9 Hold the test strip so the lettering “CoaguChek XS PT” is facing upward.
- 10 Slide the test strip into the test strip guide in the direction indicated by the arrows. Slide the test strip in as far as it will go. A beep indicates that the meter has detected the test strip (provided the beeper is enabled).



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. 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.

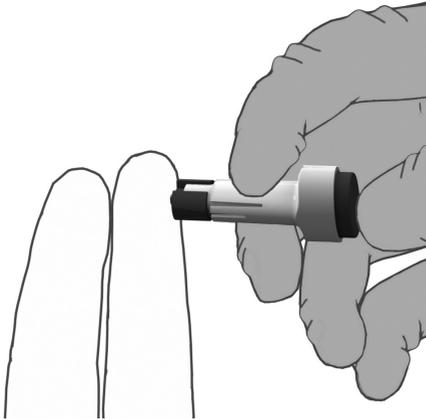


The blood drop icon flashes to indicate that the meter is ready to perform the test and is waiting for blood to be applied.

A 180 second countdown begins. You must apply the drop of blood to the test strip before the countdown ends. Otherwise you will receive an error message.



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.

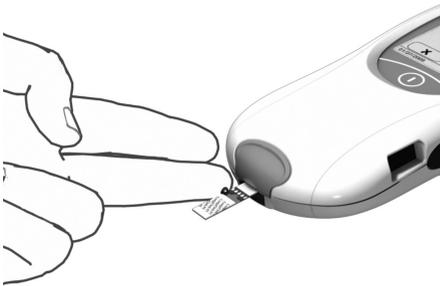


11 Now lance the side of a fingertip with the lancing device.

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

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.



12 Apply the blood (8 μ L) directly from the finger to the semicircular, transparent sample application area on top of the test strip.

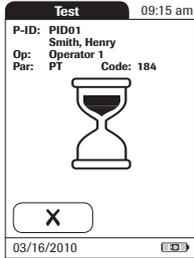
■ ... or you can touch the blood drop against the side of the sample application area. The test strip draws up the blood by capillary action.

During this process you must hold the blood drop to the test strip until the flashing blood drop icon has disappeared and the meter beeps (provided the beeper is enabled).

■ ... you can also apply the blood using the optional CoaguChek capillary tube.

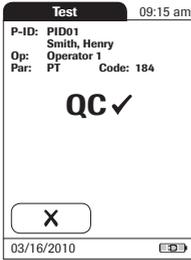
Apply the blood drop to the test strip within **15 seconds** of lancing the fingertip. Applying blood after this period of time may lead to an erroneous result (as the coagulation process would already have started).

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



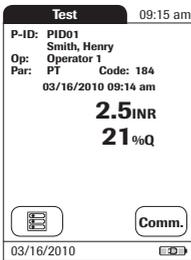
You hear a beep tone when you have applied enough blood (provided the *Beeper* is enabled). The blood drop symbol disappears and the test starts.

Do not add more blood. Do not touch the test strip until the result is displayed. Failure to comply with the above may lead to error messages.



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

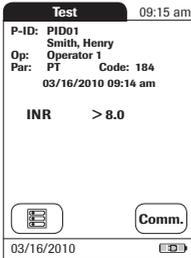
Following a successful outcome of the quality control test, a checkmark appears after “QC.”



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

The valid measuring ranges for CoaguChek XS PT test strips are:

- INR: 0.8–8.0
- %Q: 120–5
- Sec: 9.6–96



Results that are outside the measuring range are indicated by the symbols > (greater than) or < (less than).

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

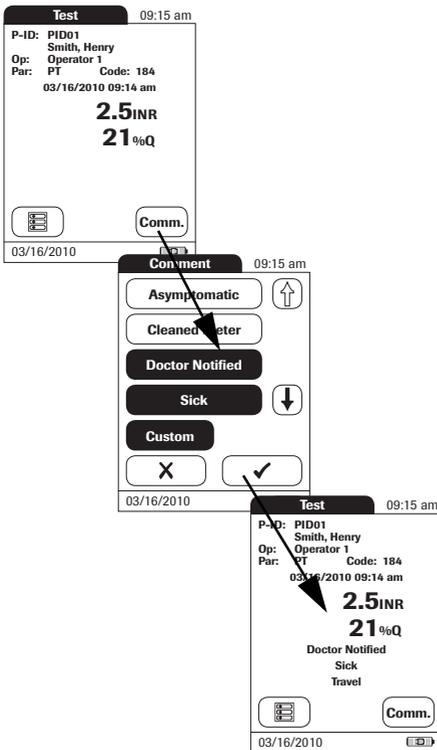
This may occur if the hematocrit value is very low or due to erroneous blood collection (e.g., wet hands). Repeat the measurement and make sure that the patient's hands are dry. If the message persists, perform a hematocrit check.

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

Adding comments

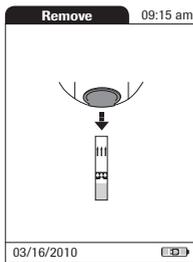
You can add up to three comments to a test result. Comments can provide, for example, additional information about the test conditions or the patient. A comment may be up to 20 characters in length. You can open the function for adding comments directly in the results screen. To add comments:

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.



- 1 In the *Test* screen, touch **Comm.**
- 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.

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



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

- 5** Remove the test strip from the meter.
- 6** Power the meter off.
- 7** Clean the meter if necessary (see chapter 9, *Cleaning and Disinfecting the Meter*).



Protection against infection

When collecting samples always observe the general precautions and guidelines relating to blood sampling (see page 14).

Dispose of all test strips used for patient testing in accordance with the disposal policy of your laboratory or practice (see see page 14).

6 Quality Control

The CoaguChek XS Pro 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.
- A two-level, on-board quality control test and patient result determination within a single test chamber.

Roche offers optional liquid quality controls for the CoaguChek XS Pro system. These controls are provided to assist with regulatory compliance requirements as applicable to your facility.

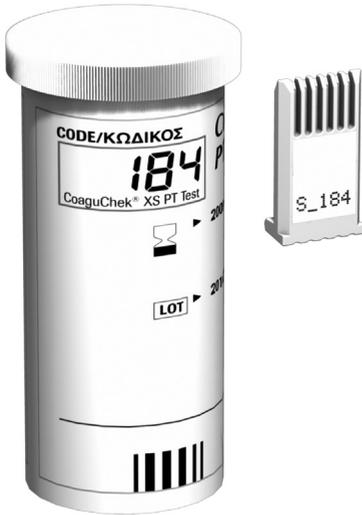
To perform an optional liquid quality control test using control solutions, you need:

- CoaguChek XS Pro meter
- The test strip code chip supplied with the test strip container you are using. A code chip is provided with every test strip pack.
- Test strips that came with the code chip mentioned above
- Bottles of CoaguChek XS PT Controls (not available in the United States) or CoaguChek XS Pro PT Controls, diluent droppers, and the quality control code chip provided.

You can choose the frequency of liquid quality control tests in the meter setup. (Refer to the chapter entitled *Meter Setup/QC (quality control) lockout* starting on page 67). If the control results in the display are in the specified range, this confirms that the liquid control test was performed correctly.

Preparing to run 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.



- 1 Have the test strip container at hand.
- 2 If you are using the test strip lot for the first time, make sure that the code chip that came with these test strips is at hand.
- 3 Make sure the bottle of freeze-dried (lyophilized) control plasma and the dropper for making the control solution are at hand. This bottle should remain refrigerated (not frozen) until use.



- 4 Make sure that the quality control code chip that came with the control solution is at hand.
- 5 Open the lid of the bottle and remove the rubber cap.
- 6 Hold the dropper with the sealed dropper neck pointing upward, then cut off the end of the cap 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.

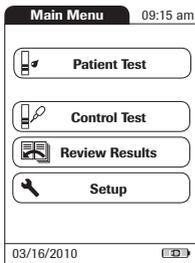
The control solutions may be reconstituted (mixed) after removal from the refrigerator. The resulting solution may be used up to 30 minutes after reconstitution.

Performing a liquid quality control test

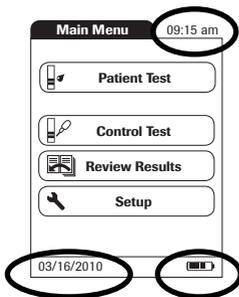


- 1 Place the meter on a level, vibration-free surface or hold it in your hand so it is roughly horizontal.
- 2 Power the meter on by pressing and holding the **⏻** button for approximately 1 second.

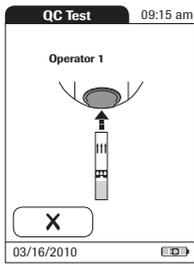
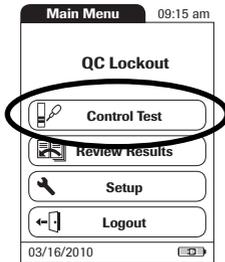
You can also power on the meter directly by inserting a test strip or connecting the power adapter.



- 3 Wait until the Main Menu is displayed, or log on as described on page 76.



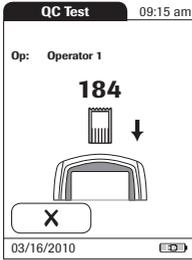
- 4 Check the battery level. If there are no bars left in the battery icon, you cannot perform any more tests.
- 5 Check that the date and time are correct. Correct any wrong entries as described in the chapter entitled *Meter Setup/Setting the date*.



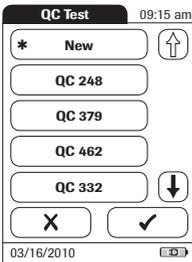
6 Touch **Control Test**.

- 7 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.
- 8 Hold the test strip so the lettering with the test name is facing upward.
- 9 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 tone indicates that the meter has detected the test strip (provided the beeper is enabled).

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



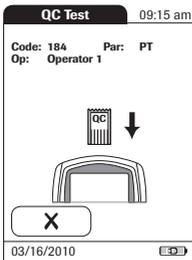
If you are using a new test strip lot and have not inserted the test strip code chip yet, you must do so now. Otherwise you cannot perform a quality control test.



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.

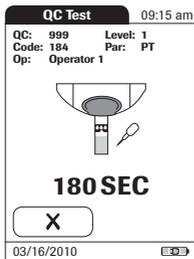
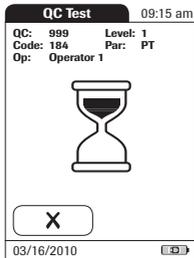
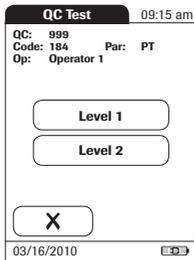
- 10 Select the code stored for your current control solution, or touch **New** to use a new control solution.

The first time you run a control, the meter skips this *QC Test* screen option because there are no code chip parameters in memory yet. The next time you use the control, this screen will display, offering you a pick of the code(s) already stored as well as the option **New**.



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: The code number on the code chips that came with the test strips starts with the letter **S**, and the code number on the control solution code chips starts with the letter **C**.

11 Select the level for this measurement.

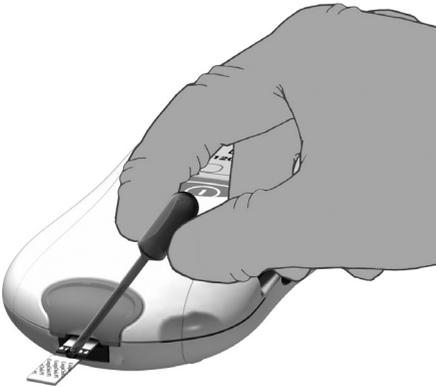
The hourglass icon shows that the test strip is warming up. When the warming-up process is complete, a further beep (provided the beeper is enabled) indicates that you can now apply the control solution.

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

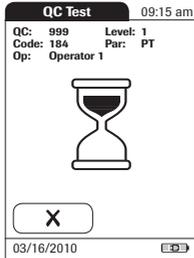
At the same time a 180-second countdown begins. You must apply the sample within this time, otherwise you will receive an error message.



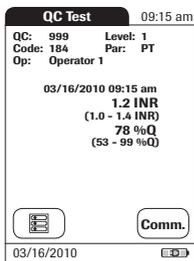
- 12** Using the dropper, draw up the dissolved contents of the bottle.



- 13** 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.

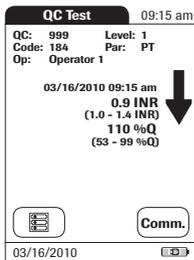


You hear a beep when you have applied enough control solution (provided the beeper is enabled). The dropper icon disappears and the test starts.



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

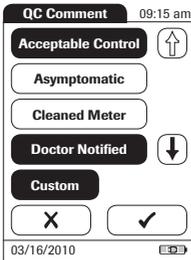
The acceptable range of results for the liquid control is displayed below the current result.



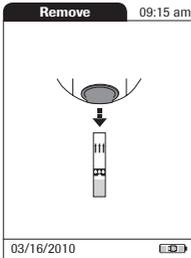
If a quality control test fails, an up arrow (too high) or down arrow (too low) is displayed and flashes.

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.



- 14** If you want to add a comment, touch **Comm.**
- 15** Select the desired predefined comment(s) from the pick list (if configured) or
- 16** 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.
- 17** 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.

- 18** Remove the test strip from the meter.
- 19** Power the meter off.
- 20** Remove the quality control code chip from the meter and store it with the controls.
- 21** Clean the meter if this becomes necessary (see chapter 9, *Cleaning and Disinfecting the Meter*).



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.

7 Review Results

The CoaguChek XS Pro meter can save 1000 patient test results as well as 500 liquid quality control tests to memory, together with respective time and date. In addition, up to 60 code chip records (contents of test strip code chips and control solution code chips) are stored. If you are using operator and/or patient lists, a maximum of 100 *Operator* and 200 *Patient IDs* is allowed.

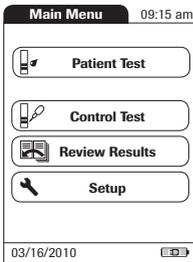
If memory is full when you perform a test, the oldest result is automatically deleted. The most recent result is always saved. This applies both to patient results and to quality control tests. In order to avoid the loss of stored test results, you can archive this data using a data management system and the optional Handheld Base Unit (see page 105).

Viewing test results

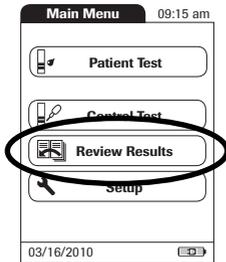


- 1 Place the meter on a level, vibration-free surface, or hold it in your hand so it is roughly horizontal.
- 2 Power the meter on by pressing and holding the  button for approximately 1 second.

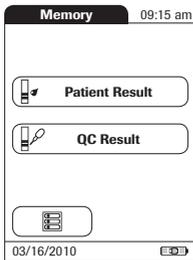
To power the meter off after use, press the  button for approximately 2 seconds.



- 3 Wait until the main menu is displayed.



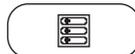
4 Touch **Review Results**.



5 Select the type of results you want to view.

- Display **Patient Result** memory
- Display **QC Result** memory

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

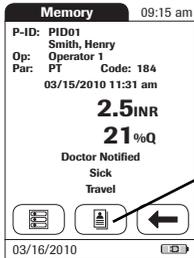
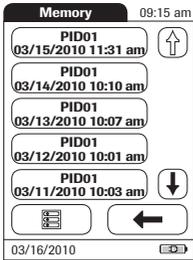


Individual icon: List that contains entries for this patient only

Display patient result memory

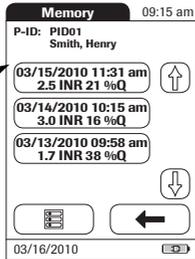
This memory area contains all test results for your patients, sorted chronologically or by *Patient ID*. The most recent results are at the top of the list.

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



The entry is displayed.

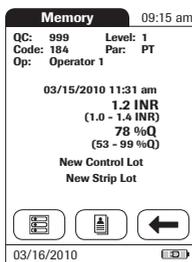
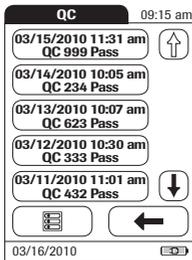
- 3 Touch . The results for the selected patient are displayed.



Display QC (quality control) result memory

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

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



The entry is displayed.

This page intentionally left blank.

8 Extended Functionalities

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 (available separately), the CoaguChek XS Pro 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. For more details on *Operator* login see page 59, for details on *Operator Lockout* see page 64.

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 *Computer* option must be set to *Active* (see page 49).
- 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.

Operator lists

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

- *Operator* is activated, but there is no list available:
The *Operator* can log in via a barcode scan. 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.

This first configuration is also available without a DMS.

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 on-screen 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 on-screen 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 on-screen keypad.
- The *Patient ID* is set to *Hidden* (only possible with a data management system), and there is a list available:
A blank list is shown when starting a measurement. You may now
 - 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 on-screen keypad.

When working with Patient lists: A *Patient ID* does not have to be on the list to be scanned and used.

Barcode scanner

Using a DMS, the barcode scanner may be configured to accept only selected barcode symbolologies (e.g., EAN-13 Barcodes are not allowed). Furthermore it is possible to define a barcode mask for *Patient ID* and *Operator ID*. With masks being defined, the meter checks a barcode after scanning and rejects it, if it does not match the mask.

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:

INR result comments

- Asymptomatic
- Cleaned Meter
- Doctor Notified
- Sick
- Travel
- Lab Draw
- No Action
- Procedure Error
- Under Medication
- Will Repeat Test
- Changed Dosing

QC result comments

- Cleaned Meter
- Doctor Notified
- New Control Lot
- New Lot Number
- New Strip Lot
- New Strip/Kit Lot
- No Action
- Procedure Error
- Proficiency Test
- 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.

9 Cleaning and Disinfecting the Meter



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

NOTICE

Follow the procedures below to clean/disinfect the meter. Failure to follow these procedures may cause malfunction of the meter.

- Make sure the meter is powered off.
- Do not spray anything onto the meter and do not immerse it in liquid.
- Ensure that cloth or swab/bud is only damp, not wet, to protect against moisture entering the meter.

Recommended cleaning/disinfecting solutions

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

- 70% ethanol or isopropyl alcohol
- a mixture of 1-propanol (400mg/g), 2-propanol (200 mg/g) and glutaraldehyde (1.0 mg/g) ¹
- 10% sodium hypochlorite solution (1 part bleach to 9 parts de-ionized water, made fresh every 24 hours)

NOTICE

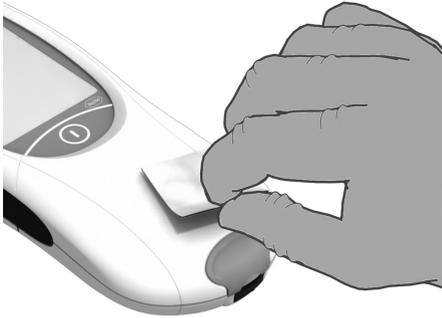
Do not use any other disinfectants/cleaning solutions on the meter (housing or test strip guide). Use of other disinfectants/cleaning solutions could result in damage to the meter.

1. Sold in some countries under the name "Bacillol Plus."

Cleaning/disinfecting the exterior (meter housing)

Use the solutions recommended on page 109 for cleaning/disinfecting the meter exterior. Apply the solutions for a contact time of > 1 minute (refer to the corresponding product labeling).

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



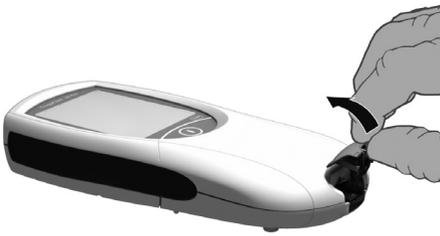
- 1 With the meter powered off, wipe the meter's exterior clean.

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

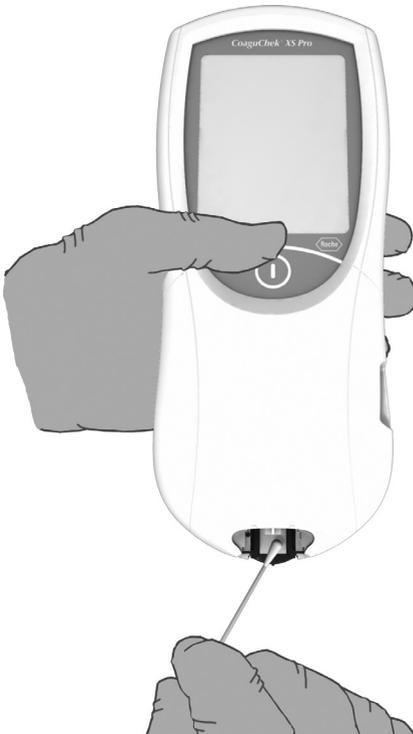
- 2 With a fresh dry cloth or lint-free tissue, wipe away residual moisture and fluids after cleaning the housing.
- 3 Allow wiped areas to **dry for at least 10 minutes** before performing a test.

Cleaning/disinfecting the test strip guide

Use the solutions recommended on page 109 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.



- 1** 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.



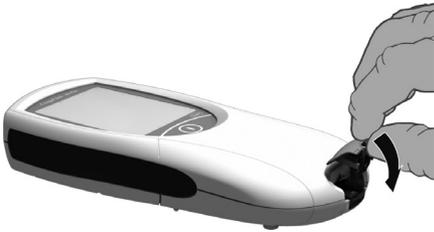
- 2** Hold the meter upright with the test strip guide facing down.
 - Clean the easily accessible white areas with a moistened cotton swab/bud.
 - Ensure the swab/bud is only damp, not wet. Wipe away residual moisture and fluids.

NOTICE

Damage to the instrument

- Ensure that no liquid enters the meter. 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.
-

On completion of cleaning:



- 3** With the cover off, let the test strip guide dry for **at least 10 minutes**.
- 4** After this time, 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.

Cleaning the scanner window

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

10 Troubleshooting

The CoaguChek XS Pro meter continually checks its systems for unexpected and unwanted conditions.

A troubleshooting table follows that will help you when the system is not performing as expected. Most concerns can be resolved quickly by referring to this table for help. Take the following steps when an unexpected condition arises:

- Find the displayed message or condition in the Troubleshooting Table.
- Take the action suggested under the column headed *Description/Solution*.

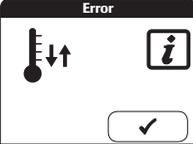
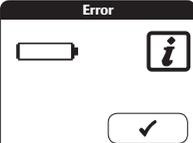
If further assistance is required, call your Roche representative.

Error messages can have up to three warning levels as indicated by the following icons.

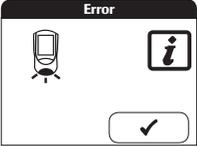
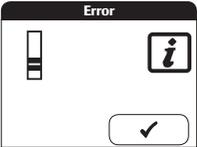
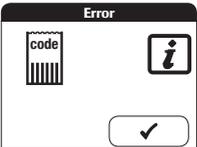
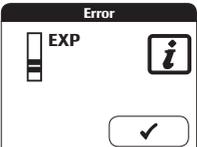
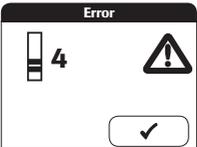
| Icon | Meaning |
|---|---------------------------|
|  | Reports a warning message |
|  | Reports an error |
|  | Reports a serious error |

Error messages users might see during normal testing include, but are not limited to, the examples on the following pages.

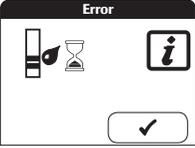
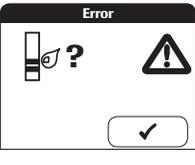
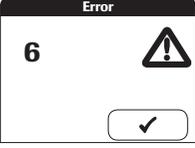
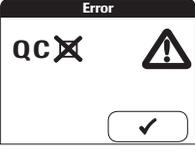
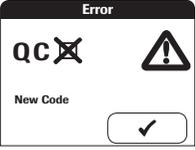
Error messages after powering on the meter

| Error | Description/Solution |
|---|---|
| <p>Error: Ambient temperature</p>  | <p>The meter is too cold or too warm to measure correctly.</p> <p>Solution</p> <p>Power the meter off (unplug the power adapter) and allow it to stand for about 30 minutes at room temperature (+15 °C to +32 °C or 59 °F to 90 °F).</p> <p>Note: When in continuous operation using the power supply unit or when recharging the battery pack, the meter can generate the Error: Ambient temperature error message even when the ambient temperature is below 32 °C/90 °F.</p> |
| <p>Error: Battery</p>  | <p>Battery level too low</p> <p>Solution</p> <p>Insert new batteries as described on page 25 or recharge handheld battery pack. Optionally: use with the power adapter.</p> |

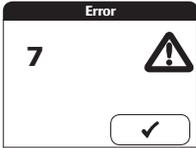
Error messages when preparing to test

| Error | Description/Solution |
|---|---|
| <p>Error: Cover</p>  <p>The screenshot shows a black header with the word 'Error' in white. Below the header, on the left, is a white icon of a meter with a red 'X' over it. On the right is a white information icon (a lowercase 'i' inside a square). At the bottom center is a white rounded rectangle containing a black checkmark.</p> | <p>The test strip guide cover was opened during a test, the test is cancelled.</p> <p>Solution</p> <p>Close the test strip guide cover and repeat the test.</p> |
| <p>Error: Test strip</p>  <p>The screenshot shows a black header with the word 'Error' in white. Below the header, on the left, is a white icon of a test strip with a red 'X' over it. On the right is a white information icon (a lowercase 'i' inside a square). At the bottom center is a white rounded rectangle containing a black checkmark.</p> | <p>The test strip is unusable or the test strip is not a CoaguChek XS PT Test strip, or the test strip was removed while the test was in progress.</p> <p>Solution</p> <p>Remove the test strip if it is still inserted. Repeat the test with a new CoaguChek XS PT test strip.</p> |
| <p>Error: Code chip</p>  <p>The screenshot shows a black header with the word 'Error' in white. Below the header, on the left, is a white icon of a code chip with a red 'X' over it. On the right is a white information icon (a lowercase 'i' inside a square). At the bottom center is a white rounded rectangle containing a black checkmark.</p> | <p>The code chip is missing, not properly inserted in the meter, or damaged.</p> <p>Solution</p> <p>Insert the code chip, or remove it and re-insert it.</p> |
| <p>Error: Test strip</p>  <p>The screenshot shows a black header with the word 'Error' in white. Below the header, on the left, is a white icon of a test strip with a red 'X' over it and the text 'EXP' next to it. On the right is a white information icon (a lowercase 'i' inside a square). At the bottom center is a white rounded rectangle containing a black checkmark.</p> | <p>The test strip is beyond its expiration date.</p> <p>Solution</p> <p>First check whether the date setting is correct in the meter. If it is not, set the correct date.</p> <p>If the date is correct: Power the meter off, remove the code chip and test strip. Use a test strip from a new unexpired lot of test strips and insert the code chip that came with the new lot.</p> |
| <p>Error: Test strip</p>  <p>The screenshot shows a black header with the word 'Error' in white. Below the header, on the left, is a white icon of a test strip with a red 'X' over it and the number '4' next to it. On the right is a white warning icon (a triangle with an exclamation mark). At the bottom center is a white rounded rectangle containing a black checkmark.</p> | <p>The test strip is unusable.</p> <p>Solution</p> <p>Power the meter off, remove the test strip and re-insert it. If the error message appears again, discard the unusable test strip and use a new one.</p> |

Error messages during or after blood application

| Error | Description/Solution |
|---|--|
| <p>Error: Time for application exceeded</p>  | <p>The maximum allowed time of 180 seconds for applying blood has been exceeded.</p> <p>Solution</p> <p>Power the meter off, remove the test strip and start a new test using the same test strip. The strip must be used within 10 minutes of removing it from the strip container.</p> |
| <p>Error: Blood application</p>  | <p>Error applying blood to the test strip.</p> <p>Solution</p> <p>Power the meter off and remove the test strip. Re-read the instructions about applying blood (starting on page 69) and repeat the test with a new test strip and blood taken from a new puncture site at the tip of another finger.</p> |
| <p>Error: Measurement</p>  | <p>Measurement error</p> <p>Solution</p> <p>Power the meter off and remove the test strip. Repeat the test with a new test strip. Do not touch or remove the test strip when a test is in progress.</p> |
| <p>Error: Quality Control</p>  | <p>The test strip failed the internal quality control check. The test strip is unusable.</p> <p>Solution</p> <p>Power the meter off and remove the test strip. Repeat the test with a new test strip.</p> |
| <p>Error: Quality Control</p>  | <p>A quality control test must be performed when a new test strip lot is used. The quality control for the new lot is missing.</p> <p>Solution</p> <p>Perform a quality control test with the new test strip lot.</p> |

| Error | Description/Solution |
|---------------------------|--|
| Error: Measurement | Measurement error resulting from the blood sample. |



Solution

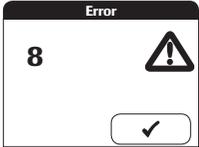
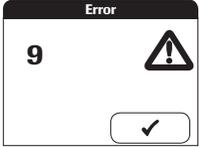
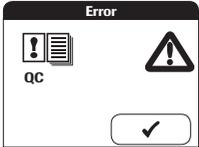
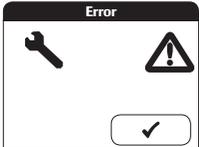
Power the meter off and remove the test strip. Repeat the measurement using a new test strip and blood taken from a new puncture site at the tip of another finger. Do not touch or remove the test strip when a test is in progress.

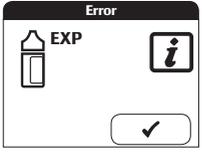
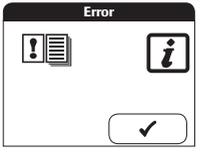
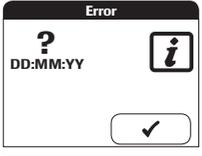
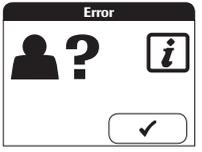
Note on Error 7 “Measurement”: The CoaguChek XS PT Test strip may be used for patients under a combination therapy of oral anti-coagulants plus heparin injections. For maximum heparin concentrations which do not interfere with the test, refer to the package insert. Under no circumstances, however, should heparinized capillary tubes be used for sample application. If capillary tubes are used, use only the dedicated CoaguChek capillary tubes. Be sure to apply the blood drop to the test strip within **15 seconds** of lancing the fingertip.



In rare cases, patients with long clotting times (> 8 INR; < 5% Quick) may receive an “Error 7” message on the meter display. If this error message appears again when the test is repeated, the result must be checked using another method. Under no circumstances should heparinized capillary tubes be used. Use only the dedicated CoaguChek capillary tubes.

Other error messages

| Error | Description/Solution |
|---|--|
| <p>Error: Internal error</p>  | <p>Error during the internal checks which the meter performs.</p> <p>Solution</p> <p>Power the meter off and remove the batteries. Wait at least one minute before re-inserting the batteries in the battery compartment, and then set the date and time as described starting on page 36.</p> <p>Repeat the test. If the error message persists, the meter is defective. Contact your Roche representative.</p> |
| <p>Error: Internal error</p>  | <p>Error during the internal checks which the meter performs.</p> <p>Solution</p> <p>Power the meter off and wait for at least 2 minutes. Ensure that when you perform a test the ambient temperature is stable.</p> <p>Repeat the test. If the error message persists or re-appears in the future, the meter is defective. This error indicates possible damage to the heater plate contacts. Contact your Roche representative.</p> |
| <p>Error: Memory test (patient)</p>  | <p>The memory contains faulty data.</p> <p>Solution</p> <p>The meter is defective. Contact your Roche representative.</p> |
| <p>Error: Memory test (QC)</p>  | <p>The memory contains faulty data.</p> <p>Solution</p> <p>The meter is defective. Contact your Roche representative.</p> |
| <p>Error: Memory test (setup)</p>  | <p>The memory contains faulty data.</p> <p>Solution</p> <p>The meter is defective. Contact your Roche representative.</p> |

| Error | Description/Solution |
|---|---|
| <p>Error: Data transfer</p>  | <p>There was an error during data transfer to the data management system.</p> <p>Solution</p> <ul style="list-style-type: none"> ■ Check network connections (consult your administrator). ■ Remove the meter from the Handheld Base Unit, clean the infra-red (IR) window, and then reinsert into the Handheld Base Unit. |
| <p>Error: Quality Control</p>  | <p>The control solution is beyond its expiration date.</p> <p>Solution</p> <p>Use a new control solution with the code chip belonging to it.</p> |
| <p>Error: Memory test (capacity)</p>  | <p>Memory almost full.</p> <p>Note: This message appears only in host mode.</p> <p>Solution</p> <p>Connect to host computer for result download.</p> |
| <p>Error: Date/time setting</p>  | <p>Date/time is inconsistent.</p> <p>Solution</p> <p>Check date/time.</p> |
| <p>Error: Password</p>  | <p>The entered operator or system administrator password is wrong, or Barcode scanning error</p> <p>Solution</p> <ul style="list-style-type: none"> ■ Enter the correct password ■ Enter a valid Patient ID ■ Check whether you scanned a valid barcode. |

This page intentionally left blank.

11 General Product Specifications

Technical data

| | |
|--------------------------------------|--|
| Temperature range | +15 °C to +32 °C (59 °F to 90 °F). |
| Relative humidity | 10 to 85% (no condensation) |
| Maximum altitude | 4300 m (14,000 feet) |
| Position | Place the meter on a level, vibration-free surface or hold it so it is roughly horizontal. |
| Measuring range | %Q: 120 – 5 SEC: 9.6 – 96 INR: 0.8 – 8.0 |
| Memory | 1000 patient and 500 QC results with date and time 60 code chip records Operator lists up to 100 Operator IDs Patient lists up to 200 Patient IDs |
| Interface | Infrared interface, LED/IREC Class 1 |
| Barcode scanner | Laser Class 1, according to EN 60825-1:2007 |
| Battery operation | 4 x 1.5 V batteries type AA or special rechargeable battery pack for the CoaguChek XS Pro meter or CoaguChek XS Plus meter |
| Power connection | Power supply adapter: Input: 100-240 V / 50-60 Hz / 400 mA Output: 7.5 V DC / 1.7 A |
| Number of tests per set of batteries | Approx. 80 tests (approx. 60 tests per charge cycle when the rechargeable battery pack is used) |
| Safety class | III |
| Automatic power-off | Programmable 1 ... 60 minutes |
| Dimensions | 231 x 97 x 43 mm |
| Weight | 350 g (without batteries) |

Sample material

| | |
|--------------|---|
| Sample type | Capillary whole blood or non-anticoagulated venous whole blood. |
| Sample size | At least 8 µL |
| Interactions | Refer to test strip package insert |

Storage and transport conditions

| | |
|--|--------------------------------------|
| Temperature range Meter (without batteries) | -25 °C to +70 °C (-13 °F to +158 °F) |
| Temperature range Meter (with batteries)* | -10 °C to +50 °C (+14 °F to +122 °F) |
| Relative humidity | 10 to 85 % (no condensation) |

* At temperatures above +50 °C/122 °F the batteries could leak and damage the meter.
At temperatures below -10 °C/+14 °F the batteries do not have enough power to keep the internal clock functioning.

Further Information

Ordering

The following configurations are available.

| Item | Description | Remarks |
|---------------------------------|---|---|
| CoaguChek XS PT Test | 24 test strips | International edition (not available in the US) |
| CoaguChek XS PT Test | 2 x 24 test strips | |
| CoaguChek XS PT Controls | Optional liquid controls for the CoaguChek XS Pro / XS Plus systems | International edition (not available in the US) |
| CoaguChek XS Pro PT Controls | Optional liquid controls for the CoaguChek XS Pro / XS Plus systems | US edition |
| CoaguChek Capillary Tubes/Bulbs | Capillary tubes | |
| Handheld Battery Pack | Rechargeable battery pack | |
| Handheld Base Unit Kit | Handheld Base Unit and Operator's Manual | |

Reagents and solutions

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

Product limitations

Please read the information in the package insert supplied with the test strips 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 text 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 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.

Contact Roche

For all questions about the CoaguChek XS Pro system that are not answered in this manual, contact your Roche representative. If you do not already have contact details, a list of Roche Diagnostics offices is provided in the appendix or visit our website at www.Roche.com. Select "Roche Worldwide" at the top of the page and then select your country to find the appropriate local office contact information.

12 Warranty

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

13 Appendix

Contact Roche

| | |
|------------------|--|
| Argentina | <p>Productos Roche S.A.Q.e I. RPD Decentral Solutions Rawson 3150 B1610BAL Ricardo Rojas Buenos Aires</p> |
| Australia | <p>Roche Diagnostics Australia Pty Ltd. ABN 29 003 001 205 31 Victoria Ave Castle Hill, NSW, 2154 Telephone 02-9899 7999</p> |
| Austria | <p>Roche Diagnostics GmbH Engelhorngasse 3 1211 Wien Telefon: 01 - 27787-0 Fax: 01 - 27787-12 www.coagucheck.at</p> |
| Belgium | <p>Roche Diagnostics Belgium SA/NV Schaarbeeklei 198 1800 Vilvoorde Telefoon: 02 247 4870</p> |
| Brazil | <p>Roche Diagnóstica Brasil Ltda. Av. Engenheiro Billings, 1729 05321-010 São Paulo, SP Tel. +55 11 3719 4566 Fax +55 11 3719 4981</p> |
| Canada | <p>Roche Diagnostics 201 Boulevard Armand-Frappier Laval, Québec H7V 4A2 Coagulation Info-Line Telephone 1-877-426-2482</p> |
| Chile | <p>Productos Roche Ltda. Avda. Quilín 3750 Macul, Santiago Tel.: +56 (2) 4413200</p> |

| | |
|-----------------------|--|
| China | Roche Diagnostics (Shanghai) Ltd 12/F, Huaihai Plaza, No. 1045, central Huaihai Road Shanghai, 200031 Tel. +86 21 2412 1000 Fax +86 21 2412 1188 PC 200031 |
| | Roche Diagnostics (Hong Kong) Ltd 1316-1325 Metroplaza, Tower 1 223 Hing Fong Road, Kwai Chung Hong Kong Tel.: +852-2481 3387 |
| Colombia | Productos Roche S.A. Carrera. 44 No. 17-44 Apartado Aéreo 80372 Santa Fé de Bogota, D.C. |
| Croatia | Distributer MEDICAL INTERTRADE d.o.o. Dr. F. Tuđmana 3 10431 Sveta Nedelja Tel.: 00385 1 3374 010 Dodatne informacije: Roche Diagnostics Promotional Office Adriatic Banjavićeva 22/II 10000 Zagreb Tel.: 00385 1 4628 360 |
| Cuba | Productos Roche, S.A. Calle 96, No. 540, Esquina 7ma. Playa, C. La Habana + (537) 204 7515 |
| Czech Republic | Roche s.r.o., Divize diagnostiky, Near Patient Testing Karlovo náměstí 17 120 00 Praha 2 Tel.: 220 382 500 www.roche-diagnostics.cz |
| Denmark | Roche Diagnostics A/S Industriholmen 59 2650 Hvidovre Tlf.: 36 39 99 52 Fax: 36 39 98 61 http://coaguchek.dk http://www.roche.com |

| | |
|------------------|---|
| Ecuador | Roche Ecuador S.A. Diagnostics Division Ave. 10 de Agosto N36-239 y NNUU Piso 10 Quito (+593) 2 243 4347 |
| Finland | Roche Diagnostics Oy PL 160 02180 ESPOO Puh. (010) 554 511 |
| France | Roche Diagnostics 2 avenue du Vercors - BP 59 38242 MEYLAN CEDEX Assistance technique: Tél. : 04 76 76 31 00 |
| Germany | Roche Diagnostics Deutschland GmbH CoaguChek Kundenservice Sandhofer Straße 116 68305 Mannheim Telefon: 0180/2 00 01 64* Montag bis Freitag: 08.00 bis 18.00 Uhr Fax: 06 21/7 59-44 63 E-mail: mannheim.monitoring@roche.com Internet: www.coagucheck.de *(Festnetz 6 Cent je Anruf, Mobilfunk max. 42 Cent je Minute) |
| Greece | Roche Diagnostics (Hellas) A.E. Ακακίων 54Α 151 25 Μαρούσι Αττικής, Ελλάδα Τηλ: 210 8174 000 |
| Guatemala | Productos Roche Guatemala Edificio Europlaza 5ª. Avenida 5-55 zona 14 Torre III Nivel 15 Guatemala, C.A. + (502) 2424 1616 |
| Hungary | Roche (Magyarország) Kft. 2040 Budaörs, Edison u. 1. Tel.: +36-23-446-882 Fax: +36-23-446-890 Meghibásodás esetén hívja: +36-30-5213-473 |

| | |
|------------------|--|
| India | Roche Diagnostics India Pvt Ltd Plot no 114 , Road no 15 , M.I.D.C Andheri (E) Mumbai – 400093 Tel: +91 022 6697 4900 Web: www.roche-diagnostics.co.in |
| Indonesia | PT. Roche Indonesia Diagnostics Division Artha Graha Building 21st floor Sudirman Central Business District – Lot 25 Jl. Jend. Sudirman Kav. 52-53 Jakarta 12190 Tel.: +62 21 3041 3000 |
| Italy | Roche Diagnostics Italia Roche Professional Laboratory HOSPOC Solution Via G.B. Stucchi, 110 20052 Monza (MI) Numero verde: 800-610 619 |
| Korea | Roche Diagnostics Korea Co., Ltd. 4F, Seokyeong Bldg. 1000-3, Daechi-dong Gangnam-gu, Seoul 135-280, Korea Tel : +82 2 550 3300 대한민국 한국로슈진단주) Roche Diagnostics Korea Co.Ltd. 서울특별시 강남구 대치동 1000-3 번지 서경빌딩 4 층 우편번호 135-280 대표번호 : (02)550-3300 |
| Lithuania | Diagnostikos padalinys UAB Roche Lietuva J.Jasinskio g. 16 B 01112 Vilnius Tel. 8-5 254 6777 |
| Malaysia | Roche Diagnostics (M) Sdn. Bhd. 2A, Jalan 13/1 46200 Petaling Jaya Selangor Darul Ehsan Tel: +603-7955 5039 Fax: +603-7955 5418 |

| | |
|--------------------|---|
| Mexico | Productos Roche, S.A. DE C.V. Vía I. Fabela Nte. 1536-B, C.P. 50030 Toluca Oficinas: Av. Santa Fe No. 485. - 4o Piso 05349 Del. Cuajimalpa, México DFP |
| Netherlands | Roche Diagnostics Nederland BV Transistorstraat 41 1322 CK Almere Telefoon: 0800 - 2882882 (gratis) |
| New Zealand | Roche Diagnostics N.Z. Ltd. 15 Rakino Way Mt. Wellington Auckland 1060 Telephone 09-2764157 |
| Norway | Roche Diagnostics Norge AS Brynsengfaret 6B Pb 6610 Etterstad 0607 Oslo Tlf.: +47-23 37 33 00 Fax: +47-23 37 33 99 |
| Panama | Productos Roche Interamericana Productos Roche Panamá Edificio Capital Plaza, Piso 18 Calle Paseo del Mar, Costa del Este Panamá + (507) 378 1200 |
| Peru | Productos Roche Q.F.S.A. División Diagnóstica Av. Javier Prado Este 1921 Lima |
| Philippines | Roche (Philippines) Inc. Diagnostics Division 2252 Don Chino Roces Avenue 1231 Makati City Tel. (+632) 893-4567 |

| | |
|------------------|---|
| Poland | <p>Polska Roche Diagnostics Sp. z o.o. ul. Wybrzeże Gdyńskie 6 B 01-531 Warszawa tel. 022 481 55 55 faks 022 481 55 99</p> <p>Call Center 022 481 54 54 Zamówienia tel. 022 481 54 25 dia.callcenterpl@roche.com</p> <p>www.roche.pl www.coaguchek.pl</p> |
| Portugal | <p>Roche Sistemas de Diagnósticos, Lda. Estrada Nacional, 249-1 2720-413 Amadora Tel: +351 21 425 70 00 www.roche.pt</p> |
| Russia | <p>ЗАО «Рош-Москва» Официальный дистрибьютор «Ф, Хоффманн-Ля Рош Лтд.» (Швейцария) Тел.: +7 (495) 258-27-77 Факс: +7 (495) 258-27-71 www.roche.ru</p> |
| Singapore | <p>Roche Diagnostics Asia Pacific Pte Ltd 298 Tiong Bahru Road #11-01/06 Central Plaza Singapore 168730 Tel: +65-62727500</p> |
| Slovenia | <p>Roche farmacevtska družba, d. o. o. Divizija za diagnostiko Vodovodna 109 1000 Ljubljana telefonska številka: 080 12 32</p> |
| Spain | <p>Roche Diagnostics S.L. Avda. de la Generalitat 171-173 08174 Sant Cugat del Vallès (Barcelona), España Telefono: 902-433-333 De lunes a viernes: de 9.00 a 18.00 horas</p> |
| Sweden | <p>Roche Diagnostics Scandinavia AB Karlsbodavägen 30 161 26 Bromma Kundtjänst Tel: 08 - 404 88 70</p> |

| | |
|-----------------------|--|
| Switzerland | Roche Diagnostics (Schweiz) AG Industriestrasse 7 6343 Rotkreuz Tel. +41-41-799-61 61 Fax Nr. +41-41 799-65 55 www.roche-diagnostics.ch |
| Taiwan | Roche Diagnostics Ltd. 11F, No. 35, Min Quan E. Road, Section 3 Taipei 104, Taiwan Tel: +886 0800 258 458 |
| Thailand | Roche Diagnostics (Thailand) Ltd 18th Floor, Rasa Tower 1 555 Phaholpothin Road, Chatuchak Chatuchak, Bangkok 109000 Tel +66(0) 2791 2200 |
| Turkey | Roche Diagnostik Sistemleri Ticaret A.Ş. Gazeteciler Sitesi – Matbuat Sokak No. 3 34394 Esentepe – Istanbul Tel.: +90-212-306 06 06 |
| United Kingdom | Roche Diagnostics Ltd. Charles Avenue Burgess Hill, RH15 9RY Customer Services 0808 100 9998 |
| Uruguay | Roche International Ltd. (Diagnostics Division) Solferino 4096 11400 Montevideo Tel.: +598 (2) 6137888 |
| USA | Roche Diagnostics 9115 Hague Road Indianapolis, IN 46256 Roche Diagnostics Technical Service Center 1-800-428-4674 www.poc.roche.com www.roche.com |
| Venezuela | Productos Roche, S.A RIF J-00044058-1 División Diagnostics Av. Diego Cisneros, Edf. Roche, piso 1 Urb. Los Ruices Caracas |

This page intentionally left blank.

Alphabetical Index

A

| | |
|-------------------------------|-------|
| Admin. password | 53–58 |
| Applying a blood sample | 84 |
| Auto Off | 47 |

B

| | |
|------------------------------|------------|
| Barcode | 76, 81 |
| Barcode scanner | 19 |
| Batteries | |
| Inserting | 25 |
| Types | 23 |
| Beeper | 44, 82, 93 |
| Blood sample (testing) | 69–88 |

C

| | |
|--|---------|
| Capillary blood sample (testing) | 69–88 |
| Cleaning | 109–112 |
| Meter housing | 110 |
| Test strip guide | 111 |
| Coagulation process | 84 |
| Code chip | 73–74 |
| Inserting | 73 |
| Code number | 74 |
| Comments | |
| Adding | 87 |
| Computer | 49 |
| Contrast | 32 |
| Control solution | |
| Applying | 96 |
| Code chip | 94 |
| Preparing | 90 |

| | |
|----------------------------|--------------------|
| D | |
| Data transfer | 105 |
| Date | 36 |
| Disinfection | 109-112 |
| Display | |
| Icons | 20-21 |
| Display format | 40 |
| Disposal | 14, 23, 71, 88, 98 |
| E | |
| Error messages | 113-119 |
| F | |
| Fingertip | 84 |
| I | |
| Icons | |
| Drop | 83 |
| Dropper | 95 |
| Error | 113-119 |
| Hourglass | 83, 95 |
| Identification plate | 6 |
| Overview | 20-21 |
| Packaging | 6 |
| ID Setup | 51-62 |
| Overview | 51 |
| Infrared interface | 19, 105 |
| L | |
| Lance | 84 |
| Language | 35 |
| Laser | 19 |
| Lockout | 63-68 |
| Operator | 64 |
| Quality Control | 67, 78 |
| Logout | 77 |

M

| | |
|-----------------------|---------|
| Mains voltage | 16, 121 |
| Measurement | |
| Performing | 78–88 |
| Preparing | 72 |
| Measuring range | 86, 121 |
| Memory | |
| Button | 101 |
| Patient Result | 102 |
| Quality Control | 103 |
| Meter | |
| Overview | 18 |

O

| | |
|----------------------------|---------|
| Operating conditions | 16, 121 |
| Operator | |
| Lockout | 64 |
| Logout | 77 |
| Password | 77 |
| Operator ID | 59 |
| Operator list | 77 |
| Options | 42–50 |
| Ordering | 122 |
| Overview | |
| Meter elements | 18 |
| Setup | 28–31 |

P

| | |
|---|-------|
| Password | 77 |
| Patient ID | 60 |
| Patient list | 80 |
| Power on | 75 |
| Power supply | |
| Charging terminals (Handheld Base Unit) | 19 |
| Power supply unit | 23 |
| Product specifications | 121 |
| Putting the meter into operation | 24–26 |

| | |
|------------------------------------|---------|
| Q | |
| Quality Control | |
| Lockout | 67, 78 |
| Memory | 103 |
| Preparing | 90 |
| Result | 97 |
| R | |
| Relative humidity | 16, 121 |
| Reset button | 19 |
| Review Results | 99–108 |
| Data transfer | 105 |
| Roche (Address) | 125–131 |
| S | |
| Safety | |
| Protection against infection | 14 |
| User qualification | 14 |
| Scan (button) | 76, 81 |
| Screen | 32–41 |
| Setup | |
| Admin. password | 53–58 |
| Auto Off | 47 |
| Beeper | 44 |
| Computer | 49 |
| Contrast | 32 |
| Date | 36 |
| Display format | 40 |
| ID Setup | 51–62 |
| Language | 35 |
| Operator ID | 59 |
| Options | 42–50 |
| Patient ID | 60 |
| Screen | 32–41 |
| Sort | 42 |
| Time | 38 |
| Units | 33 |
| Software license | 123 |
| Sort | 42 |
| Switching on the meter | 75 |
| System Administrator | 53–58 |

T

Temperature range 16, 69, 121

Test principle 12

Test result (patient test) 86

Test result (quality control) 97

Test strip

 Icon 82, 93

 Inserting 82, 93

Test strip guide cover 111

Thromboplastin 12

Time 38

Troubleshooting 113-119

U

Unit (test result) 86

Units (of measure) 33

V

Voltage 16

W

Warranty 124

Notes

Notes



ACCU-CHEK, COAGUCHEK and
SAFE-T-PRO are trademarks of Roche.

Manufactured for and distributed in the U.S.A. by:
Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46256



Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany

www.roche.com
www.coaguchek.com
www.poc.roche.com