



**CoaguChek<sup>®</sup> XS Pro System**  
*Operator's Manual*





# **CoaguChek<sup>®</sup> XS Pro System**

## **Operator's Manual**

The contents of this document, including all graphics, 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.

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

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

Roche Diagnostics  
Engineering Operations Department  
9115 Hague Road  
PO. Box 50457  
Indianapolis, IN 46250-0457

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

All other trademarks are the property of their respective owners.

© 2009-2018, Roche Diagnostics.

US Order Number 05914639001 (05) 2018-11 USA

This document is available electronically at [www.coaguchek-usa.com](http://www.coaguchek-usa.com)

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



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



Temperature limitation (Store at)



Use by



Manufacturer



Batch code/ Lot number



Catalog number



Global Trade Item Number



In vitro diagnostic medical device



Consult instructions for use



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

Rx Only

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

## Revision History

<b>Manual version</b>	<b>Revision date</b>	<b>Changes</b>
05548829001 (01)	2009-09	New document; international launch
05914639001 (01)	2010-04	Update cleaning/disinfection, minor revisions; US launch with document 0 5914639001 (01)
05914639001 (02)	2012-05	Update to software version 03.01, new functions, minor revisions
05914639001 (03)	2014-04	Added local area network (LAN) safety message, safety information on battery packs, information on barcode symbologies; updated information on “hidden” patient list and patient list validation (p. 121-122); minor revisions.
05914639001 (04)	2016-04	Revised for additional test strip material number.
05914639001 (05)	2018-11	Revised to remove discontinued CoaguChek Lancet; added safety information on battery packs; updated information on cleaning/ disinfecting agents; added Status and Error Messages to Troubleshooting section. Updated branding; minor editorial revisions; in line with OM V6 INT (05548829001 [05]).

<b>1</b>	<b>Introduction</b>	11
	Before you start.....	11
	Intended use.....	11
	Important information regarding use.....	11
	If you need help.....	12
	General note.....	12
	What can the system do for you?.....	12
	Test principle.....	13
	Important safety instructions and additional information.....	14
	Safety Information.....	16
	Disposal of the System.....	17
	General Care.....	19
	Laser Scanner.....	19
	Electromagnetic Interference.....	19
	Touchscreen.....	19
	Local Area Network: protection from unauthorized access.....	20
	Wired network connection.....	20
	Operating conditions.....	21
	Quality control.....	21
<b>2</b>	<b>The CoaguChek XS Pro Meter</b>	22
	Overview of the meter elements.....	23
	Buttons and icons overview.....	24
	Power supply.....	26
<b>3</b>	<b>Putting the Meter into Operation</b>	28
	Inserting the batteries.....	29
	Powering the meter on and off.....	30
	Checking the software version.....	31
<b>4</b>	<b>Meter Setup</b>	33
	Note on presentation of screen elements in this manual.....	33
	Settings summary.....	34
	Screen setup.....	38
	Contrast.....	38
	Result Units.....	39
	Result Confirmation.....	41
	Language Selection.....	42
	Setting the date.....	43
	Setting the time.....	45
	Setting the display options for date and time.....	47

Options setup .....	49
Sort.....	49
Beeper .....	51
Auto Off.....	54
Connection.....	56
ID setup.....	58
System Administrator (Admin.).....	60
Operator ID .....	66
Patient ID .....	67
QC Settings setup .....	70
QC Range.....	71
QC (quality control) Lockout.....	74
Operator Lockout .....	76
<b>5 Testing a Blood Sample</b> .....	<b>79</b>
Important notes.....	79
Getting a good capillary blood sample.....	81
Getting a good result from venous whole blood.....	81
Preparing to test.....	82
Test strip code chip.....	83
Inserting the code chip.....	83
Powering on the meter.....	85
Performing a test.....	88
Accepting or rejecting a test result.....	97
Adding comments.....	98
<b>6 Control Testing and Quality Control</b> .....	<b>101</b>
Preparing to run a liquid quality control test.....	102
Performing a liquid quality control test.....	104
<b>7 Review Results</b> .....	<b>113</b>
Viewing test results .....	114
Display patient result memory.....	116
Display QC (quality control) result memory .....	117
<b>8 Extended Functionalities</b> .....	<b>119</b>
Data handling .....	119
Computer (Setup option).....	120
Operator lists.....	120
Patient lists.....	121
Patient list validation .....	122
Barcode scanner.....	122
Stored test results and comments.....	123

<b>9</b>	<b>Maintenance and Care</b>	125
	Conditions for storage and shipping .....	125
	Storage.....	125
	Shipping .....	125
	Cleaning and disinfecting the meter .....	126
	Acceptable cleaning/disinfecting agents .....	126
	Cleaning the exterior (meter housing).....	127
	Cleaning the test strip guide and test strip guide cover .....	128
	Cleaning the scanner window.....	129
	Disinfecting the exterior (meter housing).....	130
	Disinfecting the test strip guide and test strip guide cover .....	131
<b>10</b>	<b>Troubleshooting</b>	133
	Status and Error Messages .....	134
	Additional information on Error 403.....	137
	Additional information on Error 406.....	138
	Errors and unusual behavior without error messages .....	139
<b>11</b>	<b>General Product Specifications</b>	141
	Technical data .....	141
	Sample material.....	141
	Storage and transport conditions .....	142
	Further Information .....	142
	Ordering .....	142
	Reagents and solutions .....	142
	Product limitations.....	142
	Repairs .....	142
	Working with barcodes.....	143
	Operator and patient ID barcode masks.....	144
	Example of barcode symbologies .....	145
	Information about software licenses .....	147
<b>12</b>	<b>Warranty</b>	154
<b>13</b>	<b>Appendix</b>	154
	Contact Roche.....	154
<b>14</b>	<b>Supplement for Observed Test Sequence</b>	155
	Observed Test Sequence (OTS) .....	155
	Using the OTS function.....	156
	<b>Index</b>	159

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 *Important safety instructions and additional information* section in this chapter before operating the system.

Before you use the meter for the first time (after you have first inserted the 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 or Roche Diagnostics Technical Service. 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.

### ***General note***

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

### ***What can the system do for you?***

The CoaguChek XS 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 Strip 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.

## Important safety instructions and additional information

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



---

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

---

These symbols and signal words are used for specific hazards:



---

### **WARNING**

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.

---



---

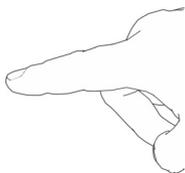
### **NOTICE**

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

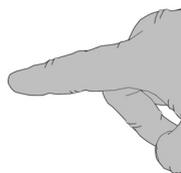
---

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



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

## Safety Information



---

### Operator qualification

Only trained healthcare professionals may operate the CoaguChek XS 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 and blood-borne pathogens

Healthcare professionals using the CoaguChek XS Pro system to perform tests must be aware that any object coming into contact with human blood is a potential source of infection. Operators need to adhere to Standard Precautions when handling or using the CoaguChek XS Pro system. All parts of this system should be considered potentially infectious and are capable of transmitting blood-borne pathogens between patients and between patients and healthcare professionals.

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



**WARNING**

---

### Avoidance of electrical shock, fire, and explosions

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

## Disposal of the System



### WARNING

---

**Any product coming in contact with blood is considered contaminated (potentially infectious).\***

**During normal testing, any meter may come in contact with blood. Lancing devices may also be considered sharps. Disposal of sharps is regulated by law in many jurisdictions.**

The European Union has a requirement for improving waster management practices for certain electronic equipment, but meters fall outside the scope of the European Directive 2002/96/EC\*\* This is not a requirement for the U.S.A.; however, Roche is committed to recycling and sustainability. Comply with any laws or ordinances relating to the disposal of sharps and/or contaminated products. Contact your local health department or other appropriate authorities for proper handling and disposal of used meters, used test strips, used lancets, and used batteries. Please consider the following points when disposing of your used testing materials:

Consider recycling of the meters and batteries at an appropriate facility. Be aware the meter is potentially hazardous electronics scrap (e-scrap) and should be disposed of accordingly. The batteries are potentially hazardous also and should be disposed of accordingly.

Disinfect the meter before recycling or disposing.

\*29 CFR 1910.1030 - Bloodborne pathogens

\*\*Directive 2002/96/EC - Directive on waste electrical and electronic equipment (WEEE).

---



---

### Disposal of used batteries and battery packs

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

---



---

**Possible hazards posed by the lithium-ion battery pack**

Damaged or swollen lithium-ion (Li-ion) battery packs can overheat, catch fire, or leak. Immediately cease use of CoaguChek XS Pro meters with damaged or swollen Li-ion battery packs. Under no circumstances recharge meters with damaged or swollen Li-ion battery packs by placing them in the Handheld Base Unit or connecting them to the power adapter.

Overheating can cause the battery pack to catch fire or explode.

- Never throw the battery pack or the meter onto a fire. Do not dismantle, compress, or pierce the battery pack as this could cause an internal short circuit that leads to overheating.
- Do not place either the battery pack or the CoaguChek XS Pro meter on or in heating appliances, such as a microwave, conventional oven, or radiator.
- Avoid prolonged exposure to direct sunlight, e.g., when the meter is docked in the base unit. Keep this in mind when positioning the base unit.

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

- Avoid contact with leaking battery fluid. In the event of accidental contact with the skin, rinse with water. If you get battery fluid in your eye(s), you should also seek medical attention.

Handle and dispose of battery packs with care.

---

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

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

**NOTICE**

---

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

---

Save or download data from the meter prior to replacing the battery pack to prevent loss of data (see Chapter 8).

When storing or disposing of the battery pack, use the manufacturer's original packaging.

---

## **General Care**

### **NOTICE**

---

Clean the meter only with the solutions recommended (see page 126). 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.



---

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.
-

### ***Local Area Network: protection from unauthorized access***

If this product is connected to a local area network, this network must be protected against unauthorized access. In particular, it must not be linked directly to any other network or the Internet. Customers are responsible for the security of their local area network, especially in protecting it against malicious software and attacks. This protection might include measures, such as a firewall, to separate the device from uncontrolled networks as well as measures that ensure that the connected network is free of malicious code.

### ***Wired network connection***

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

#### **Characteristics of strong passwords**

- Passwords must not contain the user's account name or parts of the user's full name that exceed two consecutive characters.
- Passwords must be at least eight characters in length.
- Passwords must contain characters from at least three of the following four categories:
  - English **uppercase alphabetic** characters (A through Z)
  - English **lowercase alphabetic** characters (a through z)
  - **Numeric** characters (0 through 9)
  - **Non-alphabetic** characters (for example, !, \$, #, %)

#### **Examples of weak passwords**

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

### ***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 adapter, use only a voltage of 100 V to 240 V ( $\pm 10\%$ ), 50/60 Hz.
- When testing, place the meter on a level, vibration-free surface, or hold it so it is roughly horizontal.

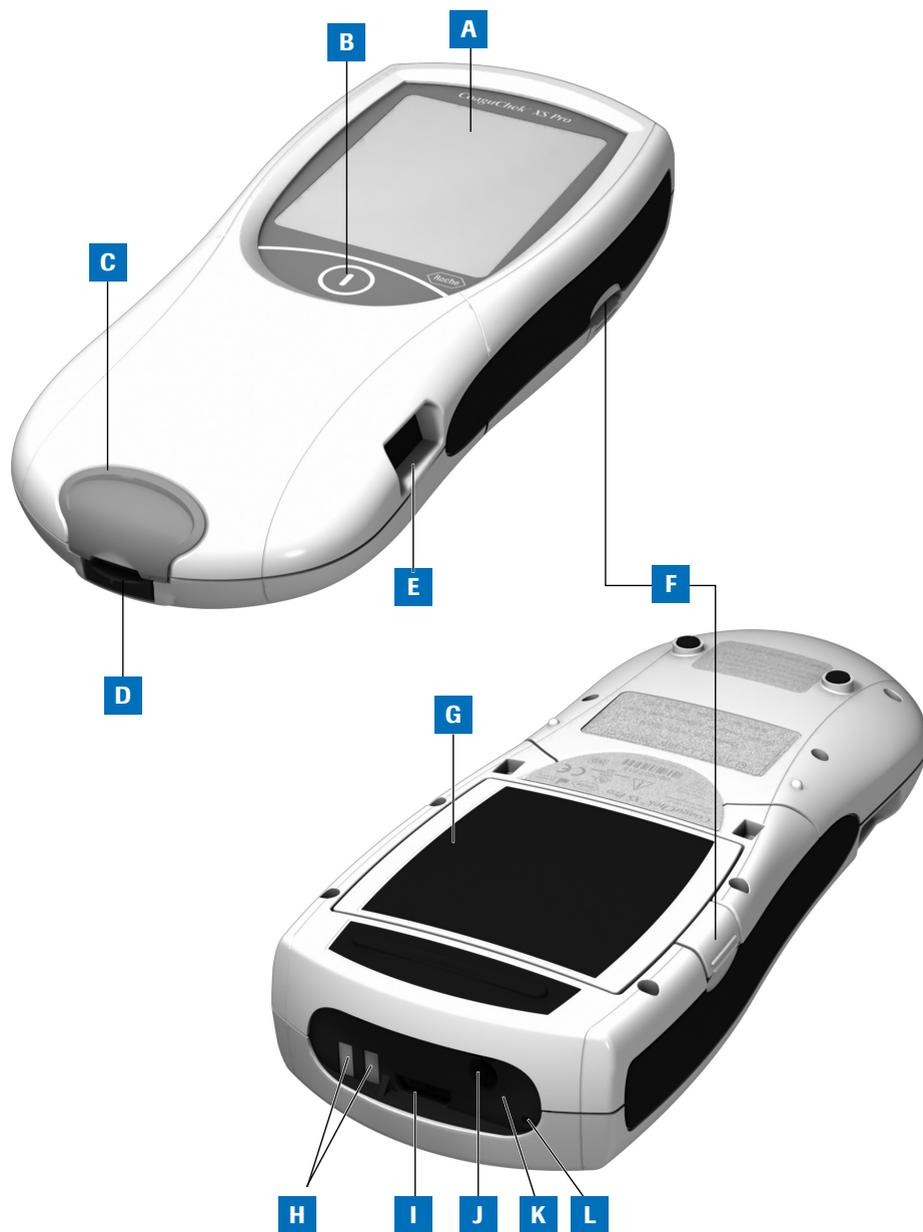
### ***Quality control***

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, onboard 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 the rechargeable battery pack).

### **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**

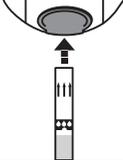
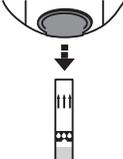
(Covered by the semi-transparent panel)  
Supports data communication.

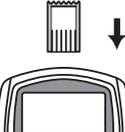
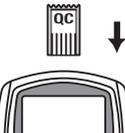
### **L Reset button**

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. Error messages and the description of the icons linked to them are provided in a separate chapter. See *Troubleshooting* starting on page 133.

Button/Icon	Meaning
	Go to Main Menu
	OK; save setting
	Cancel; discard setting
	Return (to previous menu)
	Reduce/increase the value displayed. Scroll through lists that are too long to be displayed all at once.
	Inactive button: Value cannot be further decreased/increased or: End of list in this direction is reached
	List of tests of a specific patient
	Print after test result or from memory
	Add a comment
	Operator must wait until the meter has completed an action
	Insert test strip
	Remove test strip
 <b>180 SEC</b>	Apply sample (the time left to apply sample is counted down in the display)

Button/Icon	Meaning
	Apply liquid control (QC) sample (the time left to apply sample is counted down in the display)
	Insert the test strip code chip
	Insert the QC code chip
<b>QC ✓</b>	Automatic quality control completed successfully
<b>%Q</b>	Results are displayed as a Quick percentage value
<b>Sec</b>	Results are displayed in seconds
<b>INR</b>	Results are displayed in INR units
<b>&gt;</b>	Result in the chosen unit of measure is above the measuring range.
<b>&lt;</b>	Result in the chosen unit of measure is below the measuring range.
	Quality control: Result is above the specified range
	Quality control: Result is below the specified range
	Battery status: <ul style="list-style-type: none"> <li>▪ When the batteries still have their full charge, all segments are lit.</li> <li>▪ Individual segments disappear one by one as the batteries become weaker.</li> <li>▪ When there is no segment remaining, you can no longer perform a test. You can, however, still access the meter's memory.</li> </ul>
	Operation with power supply adapter
<b>am</b>	Time between midnight and noon (in 12-hour time format)
<b>pm</b>	Time between noon and midnight (in 12-hour time format)
	Room or meter temperature is outside the acceptable range

Button/Icon	Meaning
	The test strip guide cover is open
	Communication is taking place via the infrared interface
	Reports a status message (see: Chapter 10 <i>Troubleshooting</i> )
	Reports an error message or a warning (see: Chapter 10 <i>Troubleshooting</i> )

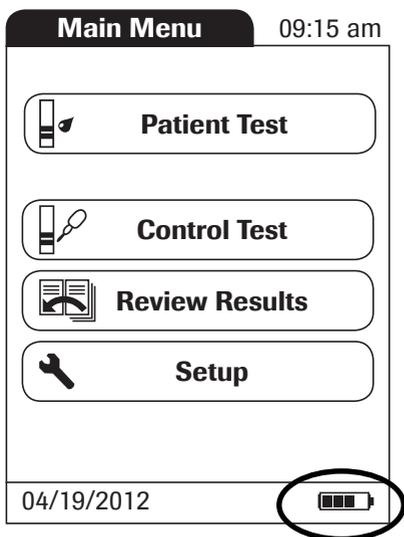
## Power supply

The CoaguChek XS Pro meter can be operated with either the power adapter provided, four standard type AA alkaline, non-rechargeable batteries, or a special rechargeable battery pack (optional). 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.

The power adapter also serves as a charger if you use it with the special rechargeable battery pack.

**When working with the battery pack:** Unused battery packs lose their charge over time and have to be recharged before they can be used. After installing a new battery pack, the meter should be charged for two hours in the base unit before testing. Please note that the battery pack will only reach full capacity once it has been fully emptied and charged several times.

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 54.)



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

When **replacing the batteries or the rechargeable battery pack**, you must insert the new batteries or battery pack within ten (10) minutes of removing the old one(s) to retain the date and time settings. If you take longer than this, you must re-enter the date and time.

To make sure you do not lose your date and time settings, connect the power adapter while you change the batteries or handheld battery pack.

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 and battery packs in an environmentally responsible manner in accordance with applicable local regulations and directives. See *Any product coming in contact with blood is considered contaminated (potentially infectious).* \*During normal testing, any meter may come in contact with blood. Lancing devices may also be considered sharps. Disposal of sharps is regulated by law in many jurisdictions. on page 17.

### 3 Putting the Meter into Operation

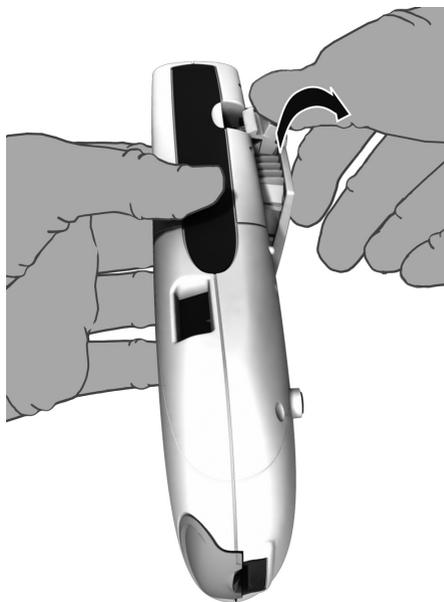
Before using the meter for the first time, perform the following steps:

- 1 Insert batteries and/or connect the power adapter
- 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

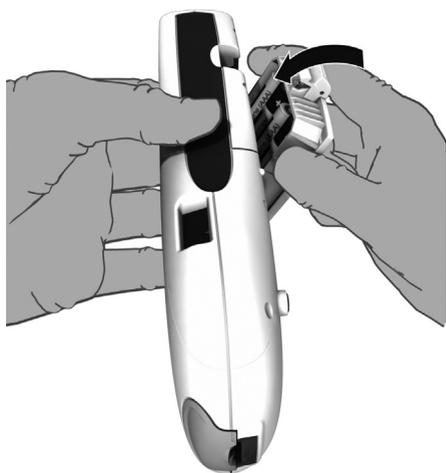


- 1 With the meter powered off, press the battery compartment cover release tab and slide the cover off.



- 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

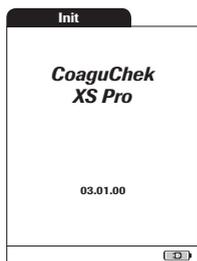


- 1 Place the meter on a level, vibration-free surface, or hold it in your hand so it is roughly horizontal.
- 2 Power the meter on by pressing the  button for approximately 1 second.

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 1 second.

## Checking the software version



After displaying the Roche logo, the meter briefly displays the *Init* (for “initialization”) screen. Here you can check which software version is currently running on your meter. (The *Init* screen shown here is for illustration purposes only. Version numbers on your meter may differ.)

This page intentionally left blank.

## 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.

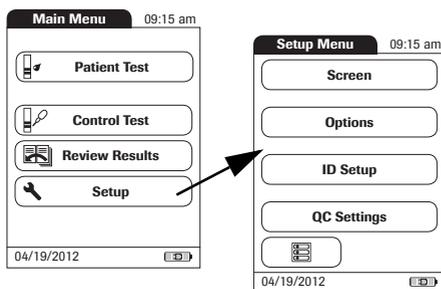
If you have **not** set the date and time (after powering on for the first time or because the batteries were removed from the meter for more than 10 minutes), you cannot perform a test. In that case powering on the meter takes you immediately to the *Setup* mode, where you must set the date and time (see page 43 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.

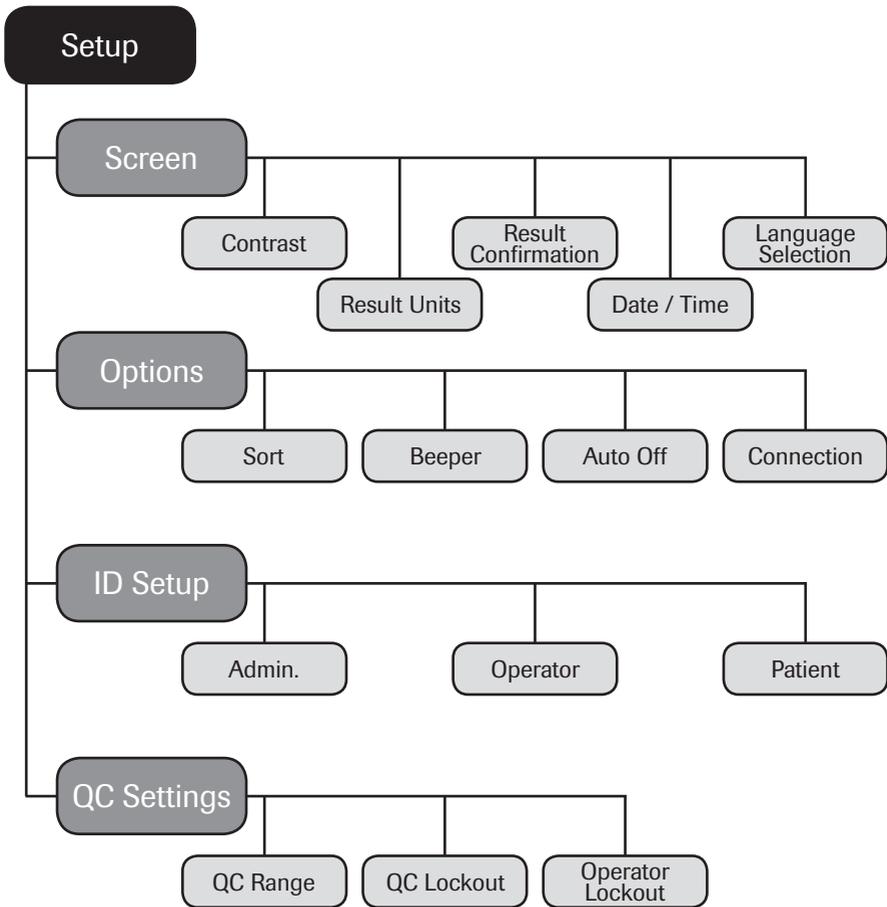
If the meter did not automatically enter the *Setup* mode (e.g., after the batteries were replaced), you can open the *Setup* menu from the *Main Menu*.



- 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
	Result Confirmation		Enable
			Disable *
	Language Selection		Dansk
			Deutsch
			English *
			Español
			Français
			Italiano
			Nederlands
			Norsk
			Português
			Suomi
		Svenska	
Date/Time	Date	Date	01/01/2012 *
		Time	12:00 am *
	Date formats		DD.MM.YYYY (01.01.2012)
			MM/DD/YYYY (01/01/2012) *
			YYYY-MM-DD (2012-01-01)
	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	
			Patient Name	
	Beeper	Beeper		Off
				Low
				Medium *
				High
			Key Click	Off *
			On	
	Auto Off	[minutes]		Off
				1 ... (5*) ... 10
				15
				20
				25
				30
				40
				50
			60	
Connection		Off *		
		Computer		

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

Group	Subgroup	Setting	Values *
<b>ID Setup</b>	Admin. (Administrator)		Blank (Off) *
	Operator (Operator List is optional)		Active
			Inactive *
	Patient		No *
			Optional
		Required	
<b>QC Settings</b>	QC Range	Default Range*	
		Custom Range	Display Target Value On/Off *
			Deviation from Target Value Percentage (%)
	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
	QC Lockout	New code	Yes
			No *
		General	No *
Daily			
Weekly			
Monthly			

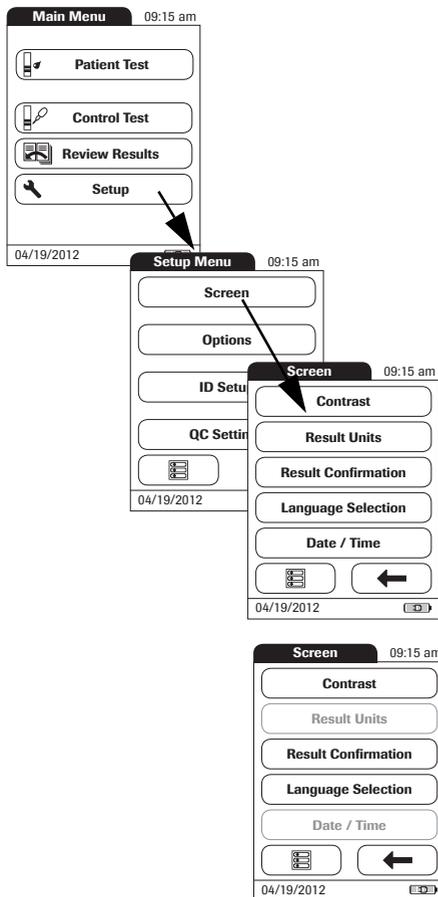
\* Default settings are labelled with an asterisk (\*).

## Screen setup

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

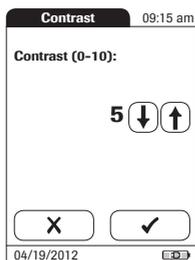
### Contrast

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.

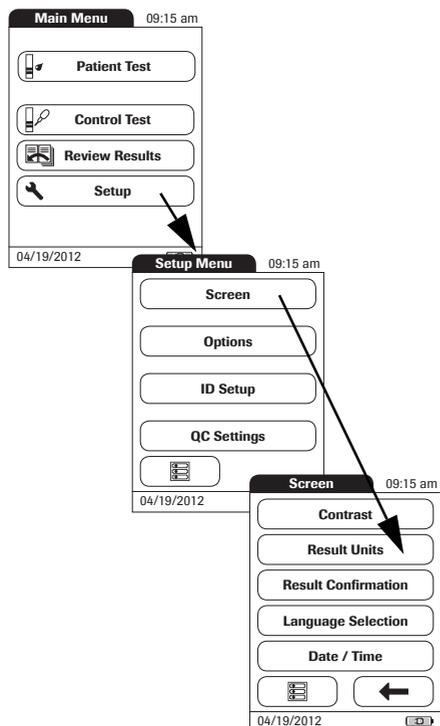


- 4 Touch  or  to change the contrast in a range from 0 to 10.
- Contrast “0” makes the display very dark.
- Contrast “10” makes the display very light.
- 5 Touch  to save this setting, or

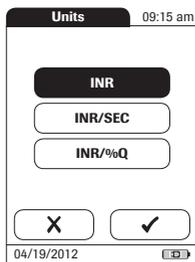
touch  to exit this menu without saving any changes. The display automatically returns to the previous screen.

## 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**.



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

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

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

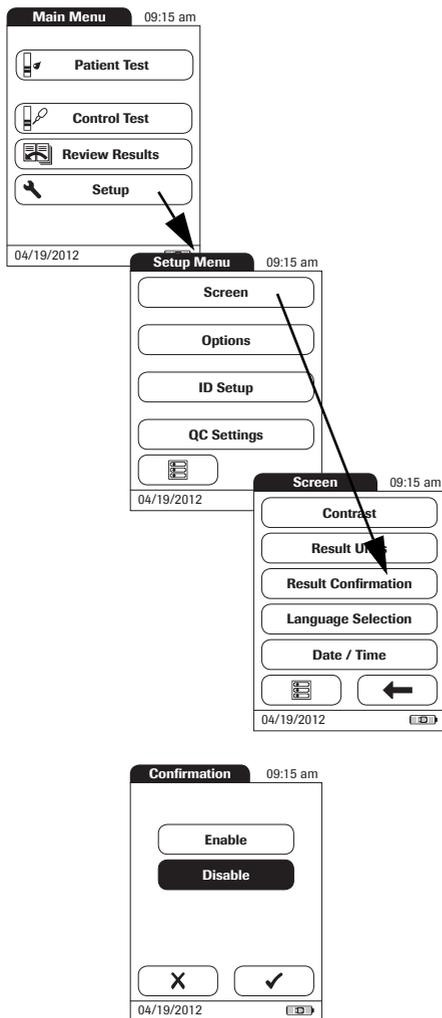
**5** Touch ✓ to save this setting, or

touch ✕ to exit this menu without saving any changes.

The display automatically returns to the previous screen.

## Result Confirmation

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

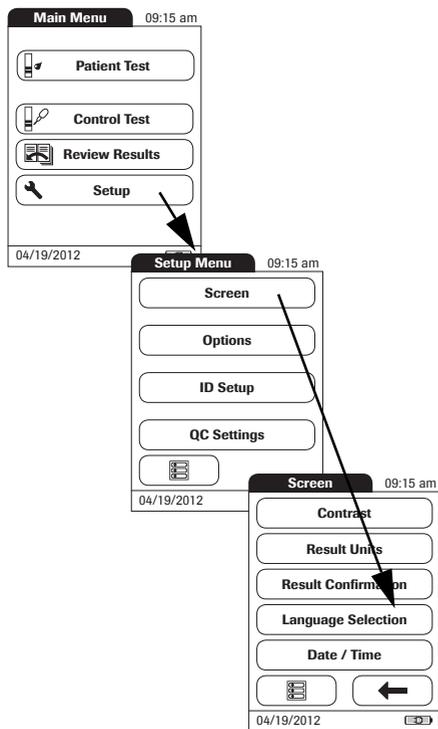


- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **Screen**.
- 3 From the *Screen* menu, touch **Result Confirmation**.

- 4 Touch **Enable** or **Disable**. Your selection is now highlighted.
- 5 Touch ✓ to save this setting, or touch ✕ to exit this menu without saving any changes. The display automatically returns to the previous screen.

## 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 blue background). You can select either:

- Dansk
- Deutsch
- English
- Español
- Français
- Italiano
- Nederlands
- Norsk
- Português
- Suomi
- 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.

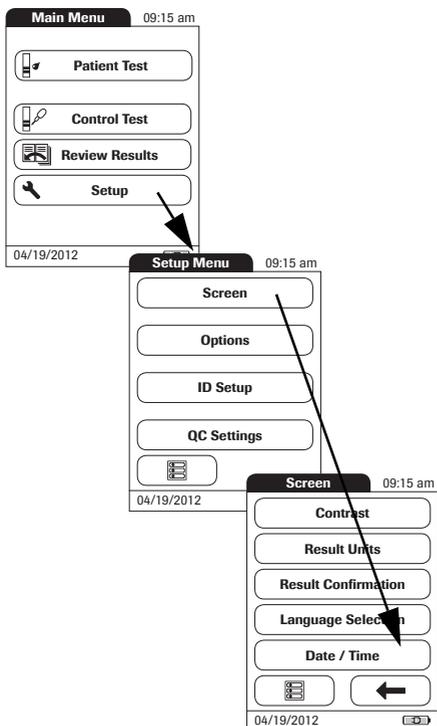
The display automatically returns to the previous screen.

## Setting the date

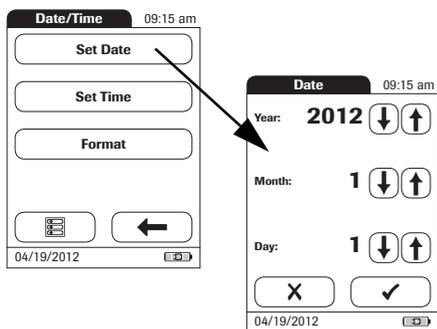
When you power on the meter for the first time (or after a long period without power), the input field for the date automatically appears first. The date (and time) must be entered before the meter can be used further. If at a later time a date adjustment is needed, go to the *Setup* menu, then select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

Both *Date* and *Time* display formats are controlled by the *Format* options you select (see page 47). 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., 01.01.2012
- Date: Month/Day/Year, e.g., 01/01/2012
- Date: Year-Month-Day, e.g., 2012-01-01
- 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.

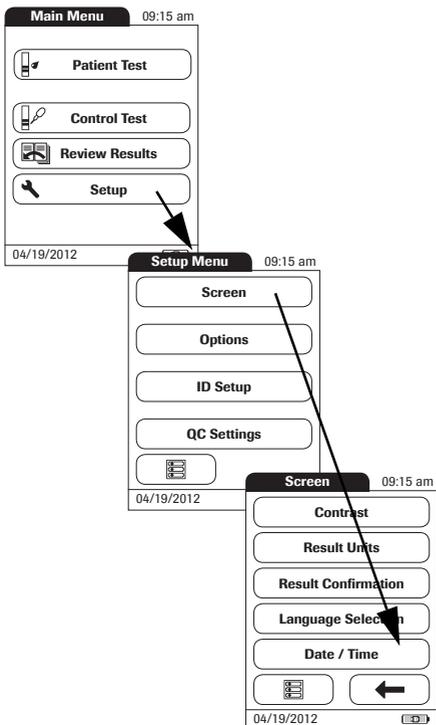
The display automatically returns to the previous screen.

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

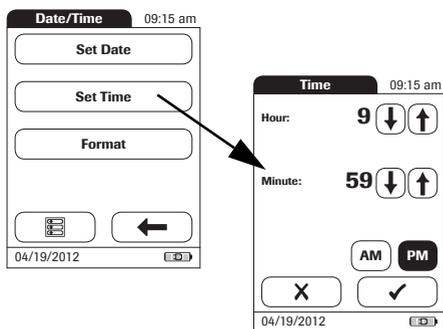
- 7 Touch  to return to the *Screen* menu.

## 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.



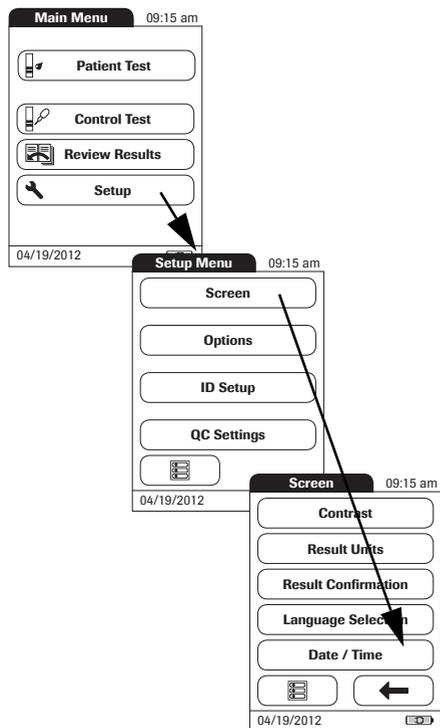
- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **Screen**.
- 3 From the *Screen* menu, touch **Date/Time**.



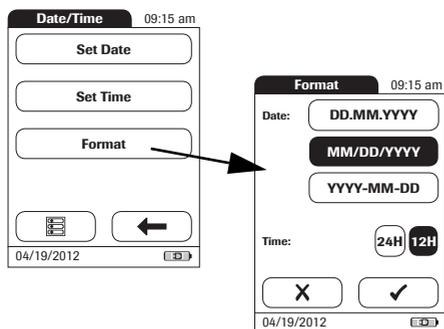
- 4 From the *Date/Time* menu, touch **Set Time**.
  - 5 Touch  and  to set the hours, then the minutes.
  - 6 Touch  to save this setting, or touch  to exit this menu without saving any changes. The display automatically returns to the previous screen.
- If this setup menu appeared automatically after 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:

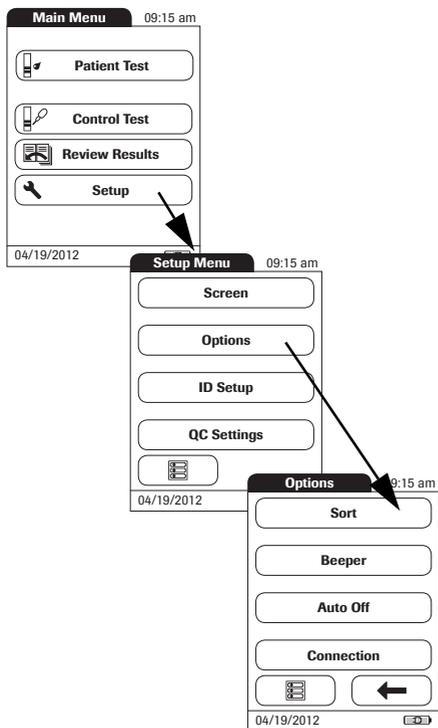
- Date: DD.MM.YYYY (Day.Month.Year), e.g., 30.09.2012
- Date: MM/DD/YYYY (Month/Day/Year), e.g., 09/30/2012
- Date: YYYY-MM-DD (Year-Month-Day), e.g., 2012-09-30
- Time: 24H or 12H

- 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.

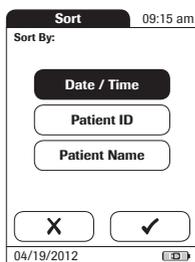
## Options setup

### 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*. If you are working with a DMS and a patient list, you can also display the patient list and the stored results sorted by *Patient Name*.



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



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

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

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

The sort option *Patient Name* is available only when used together with a patient list. Patient lists can only be created with a DMS. For more details see *Data handling*, starting on page 119.

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

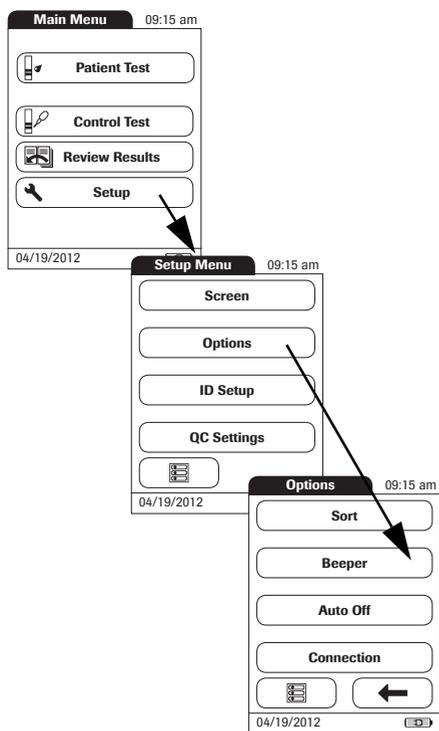
## ***Beeper***

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

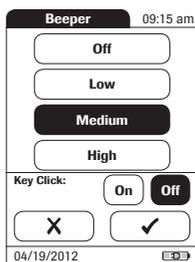
- it is switched on
- it detects a test strip
- pre-heating of the test strip is complete and you need to apply a sample
- it detects a sample
- the test is completed and the results are displayed (a long beep)
- an error occurs (three short beeps)
- an external power adapter is connected when the meter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

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

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



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



The current setting is highlighted. 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.

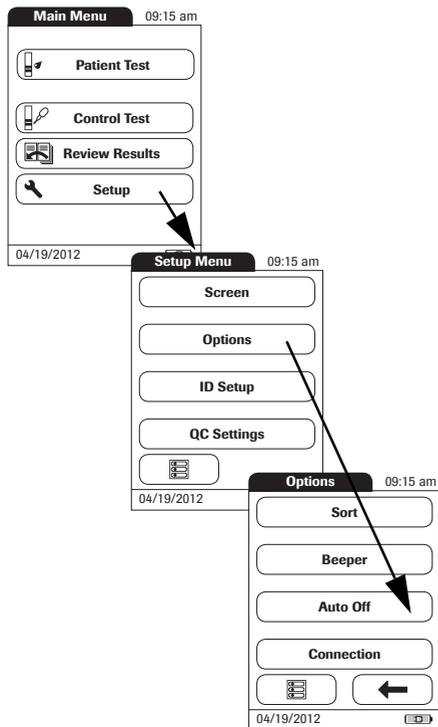
**5** Touch ✓ to save this setting, or

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 touched or tests run) for a preselected time period. Use this feature to save power and extend the life of the batteries.

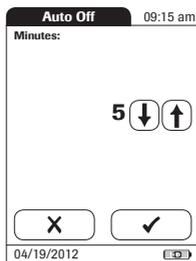


- 1 From the *Main Menu*, touch **Setup** to open the meter settings.
- 2 From the *Setup Menu*, touch **Options**.
- 3 From the *Options* menu, touch **Auto Off**.

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

- **If you work with operator IDs**, the meter switches to *Operator Login*, once *Auto Off* is triggered.
- **If you do not work with operator IDs**, the meter switches to the *Main Menu*, once *Auto Off* is triggered.

For information on *Operator ID*, see *Operator ID* on page 66.



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.

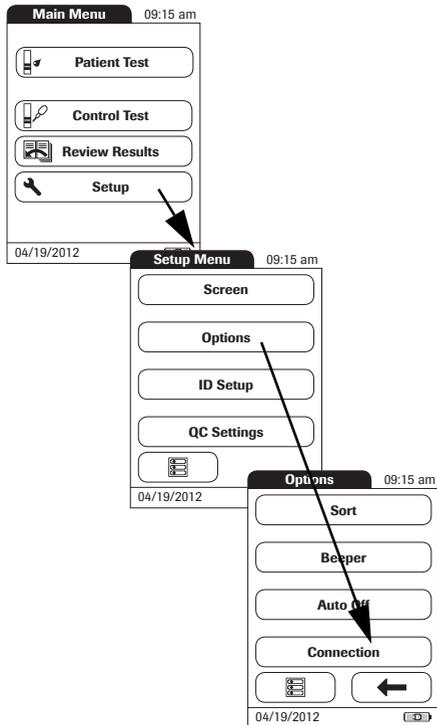
5 Touch to save this setting, or

touch to exit this menu without saving any changes.

The display automatically returns to the previous screen.

## Connection

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



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

## 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.

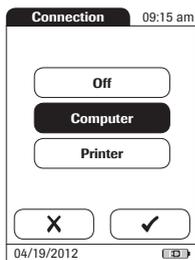
- The meter connects to the Handheld Base Unit via infrared.
- The Handheld Base Unit is either connected to a single computer (via USB) or to a network/host system (via ethernet).

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.



4 Touch **Computer**. 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.

Extended data handling functionality is dependent on the capabilities of the particular Data Management System (DMS) being used and may vary. For more information on DMS, please contact your Roche representative

## ID setup

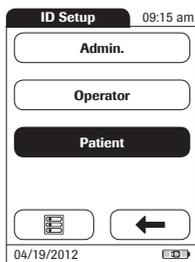
Use the *ID Setup* menu to enter settings for user management and patient management. These settings are optional and set to *Off/Inactive* by default; the meter can be operated without these settings.

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 119.
  - You may use *Operator IDs* for informational purposes only, in order to assign stored measurement results to the users who performed the test. In this case *Operator IDs* may be entered directly on the meter (by keypad or scanner), with or without an operator list being available.
- **Patient:** The *Patient ID* is assigned to the person, whose test results are recorded. You can either:
  - block input of a unique *Patient ID* (in this case, every test is simply numbered in consecutive order)
  - allow a unique *Patient ID* as optional, or
  - require a unique *Patient ID* for every test. Patient lists created externally can also be transferred to the meter, enabling you to select *Patient IDs* for a test from these lists. For more details see *Data handling*, starting on page 119.

*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):

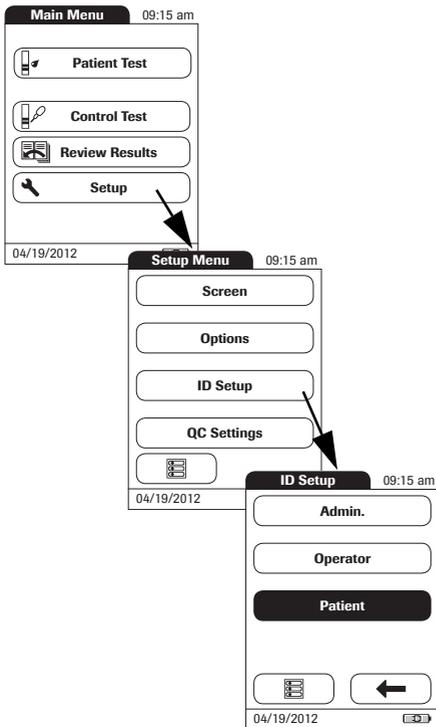
- The standard display of the **Admin.** button means the function is available but not activated (a password for the system administrator/supervisor has not been assigned).
- The standard display of the **Operator** button means the *Operator* login is available but not activated.
- When the **Patient**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

### **System Administrator (Admin.)**

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

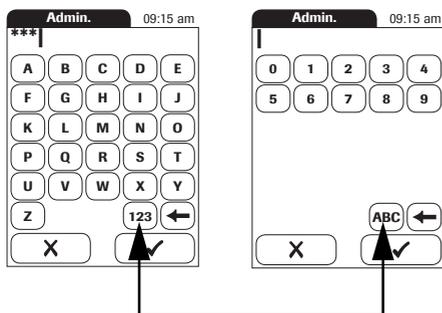
- *Screen: Result Units, Date/Time*
- *Options: Connection* (to a computer)
- *ID Setup* (the entire area)
- *QC Lockout*
- *QC Range*
- *Operator Lockout* (only available in combination with a data management system)

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.**



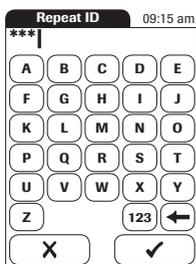
- 4 Using the keypad displayed on the screen, enter the *Admin.* password of choice. The password can consist of up to 20 characters.

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

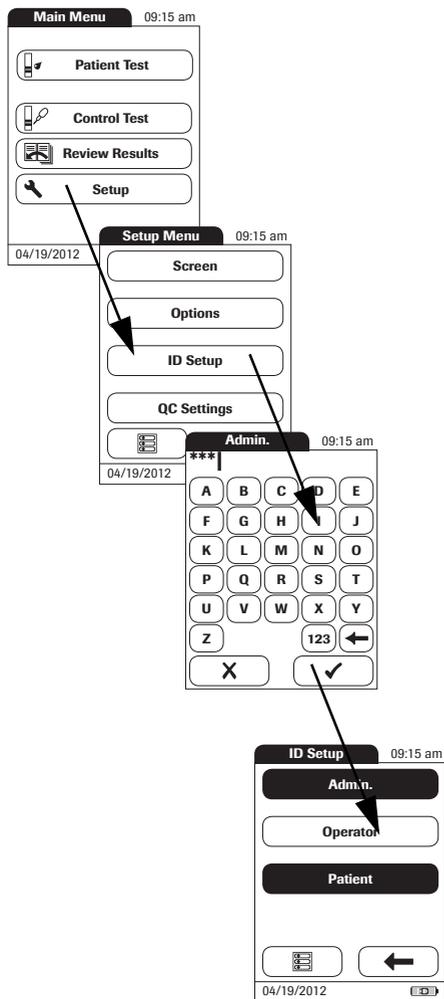
touch **X** to exit this menu without saving any changes.

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 ✕ 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 60).

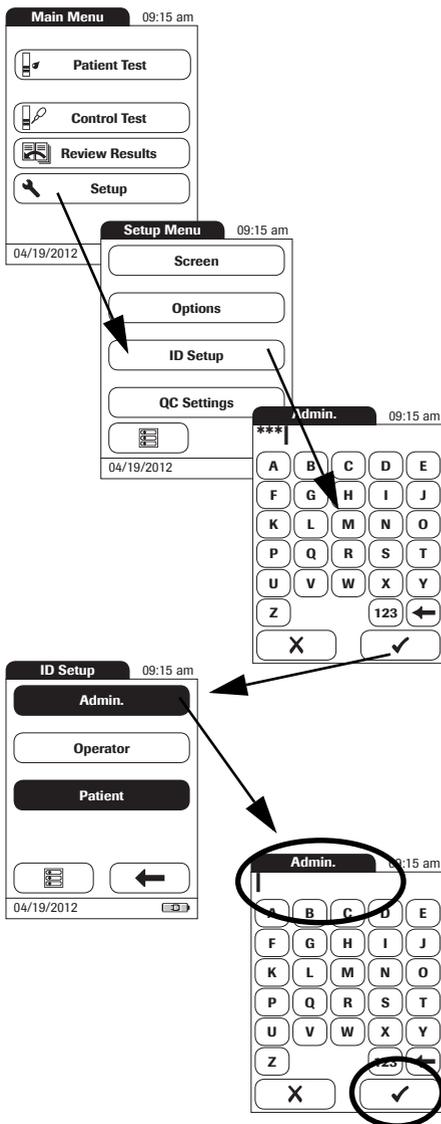


### Changing an existing *Admin.* password:

- 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.

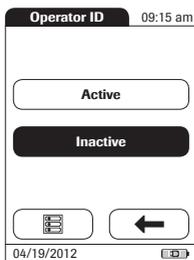
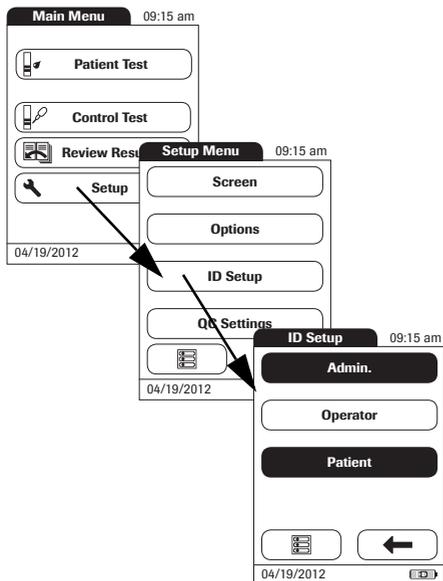
## Operator ID

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 119).

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**.

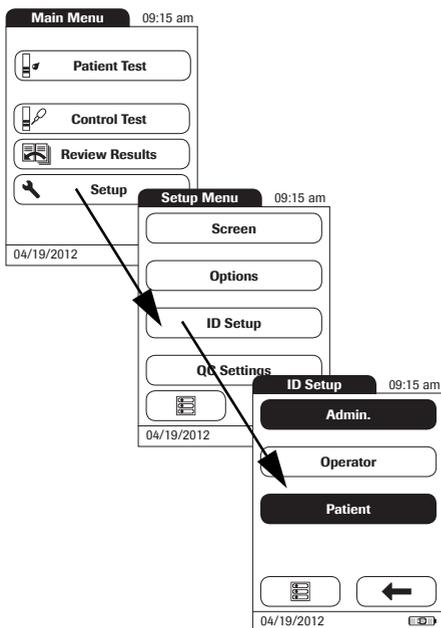


- 4 Touch the button with the setting of choice for setting up the *Operator* login. Your selection is now highlighted.
- 5 Touch  to save this setting, or touch  to exit this menu without saving any changes. The display automatically returns to the previous screen.

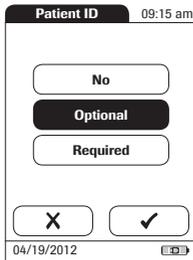
## Patient ID

If you want to create a list of *Patient IDs* from which you can select a patient for testing, additional software (a data management system) and the Handheld Base Unit are required (see page 119).

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 X to exit this menu without saving any changes.

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

- 6 Select the form for input of the *Patient ID*.

You may select from the following options:

- **Alphanumeric**  
Enter any combination of letters and numbers, e.g., “J. DOE 3378”
  - **Numeric**  
Enter numbers only, e.g., “3387”
  - **Min. Length**  
Enter the minimum number of characters (1 ... 20) the *Patient ID* must have.
  - **Max. Length**  
Enter the maximum number of characters (1 ... 20) the *Patient ID* can have.
- 7 Touch the button with the format of choice for the *Patient ID*. Your selection is now highlighted.
  - 8 Touch  or  to set the number of characters (length) of choice.
  - 9 Touch  to save this setting, or touch  to exit this menu without saving any changes. The display automatically returns to the previous screen.

## QC Settings setup

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

### QC Range

There are two options:

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

### Lockouts (QC Lockout and Operator Lockout)

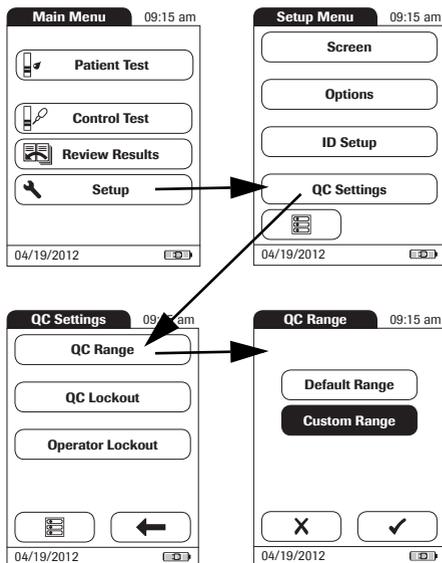
If the liquid quality control test is not performed correctly, or if the result is outside the target value range, the meter is locked from further use. The Lockout can also be set up selectively for individual operators.

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

The option of setting up an *Operator Lockout* is available **only** when operator lists are created on a data management system (DMS), stored in the meter, and *Operator* login is activated. These lists are only available in connection with a data management system. For more details see *Data handling*, starting on page 119.

## QC Range

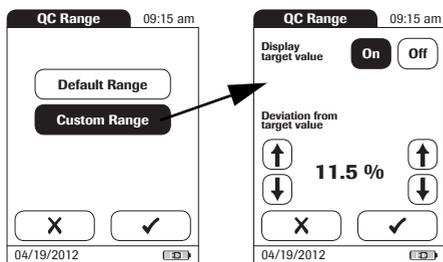
Liquid Quality control ranges can be customized to comply with local guidelines. The QC Range function enables you to narrow the default range.



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

You may select from the following options:

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



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

- Display target value (On/Off)
- Deviation from target value (percentage value). See page 71.

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

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

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

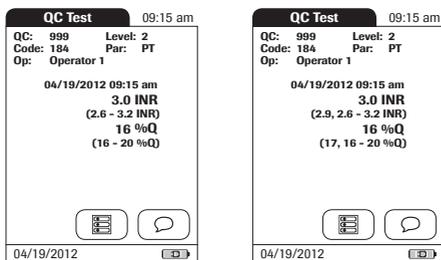
- 6 Use the arrows to set the allowed percentage deviation from the target value.

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

- 7 Touch ✓ to save this setting, or

touch ✗ to exit this menu without saving any changes.

The display automatically returns to the *QC Settings* screen.



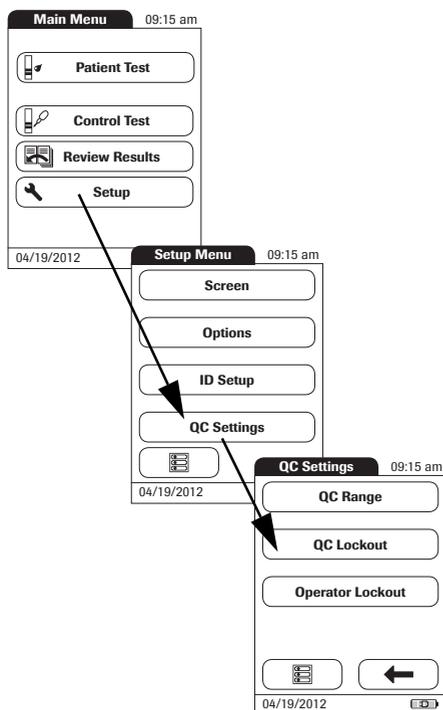
The *Custom Range* and *Target Value* (if set to *On*) appear in a line below the control test result in the QC test and QC memory screens.

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

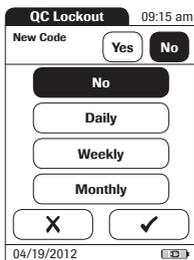
In the right hand screen, *Display target value* is set to *On*: both the custom range and the target value are displayed. The target value (here: 2.9) appears **in front of** the custom range.

## QC (quality control) Lockout

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 **QC Settings**.
- 3 From the *QC Settings* 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

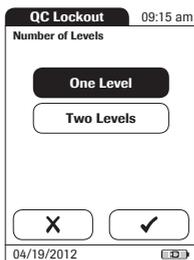
touch  to exit this menu without saving any changes.

- 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.

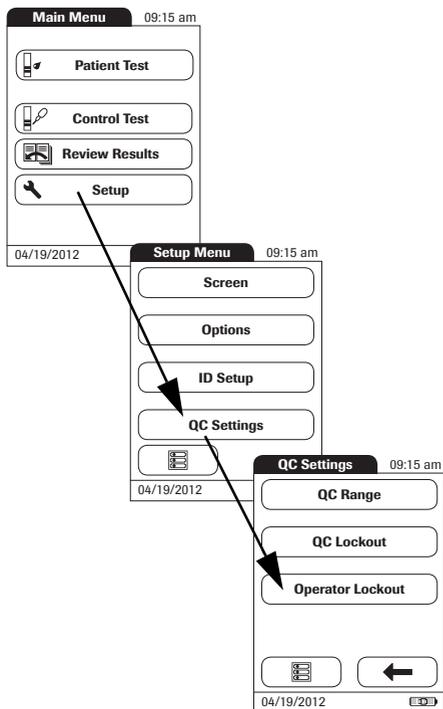
The display automatically returns to the previous screen.



## 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 **QC Settings**.
- 3 From the *QC Settings* 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 119. If you are not working with a DMS, only the *QC Lockout* is available (see *QC (quality control) Lockout* on page 74).



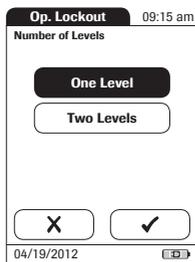
- 4 Select the interval of choice in which the mandatory quality control tests must be performed.

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

## 5 Testing a Blood Sample

What you need:

- CoaguChek XS Pro meter
- CoaguChek XS PT Test Strips and matching code chip
- When testing with venous blood:
  - Standard blood collection device (syringe)
- When testing with capillary blood:
  - Single-use lancing device approved for professional use (e.g., the Accu-Chek Safe-T-Pro Plus lancing device)
  - CoaguChek Capillary Tubes/Bulbs (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 126).



#### **Protection against infection:**

When collecting samples always observe the general precautions and guidelines relating to blood sampling (see page 16).

Dispose of all test strips used for patient testing in accordance with the disposal policy of your laboratory or practice (see page 16)

Never ...

- ... store the meter at extreme temperatures (above 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 a fingerstick before applying the blood.
- ... fingerstick a patient with wet hands (residues of water, sweat, or alcohol).
- ... add more blood after the test has begun.
- ... perform a test with a drop of blood from a previous puncture.



**CAUTION**

---

**Accuracy/precision of measured results:**

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

---

### **Getting a good capillary blood sample**

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 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 and 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**

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

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

- Use a needle at least 23 G (approx. 0.65 mm) or larger in size.
- Discard the first **four drops** of blood collected (within the first 10 seconds). Then immediately apply one drop of blood (at least 8  $\mu$ 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 16).

Dispose of all test strips used for patient testing in accordance with the disposal policy of your laboratory or practice (see page 16).

---

## 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.

Each pack of test strips contains a code chip. The number on the code chip and the number on the test strip container must match. A capital **S** in front of the number indicates that this code chip is for test strips. (A capital **C** in front of the number indicates that it is a control solution code chip. See Chapter 6, *Control Testing and Quality Control*).

### ***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 (refer to the *Troubleshooting* section of this manual).

## Powering on the meter

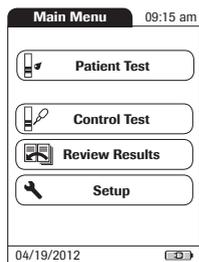


- 1 Place the meter on a level, vibration-free surface, or hold it in your hand so it is roughly horizontal.
- 2 Power the meter on by pressing the  button for approximately 1 second.

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

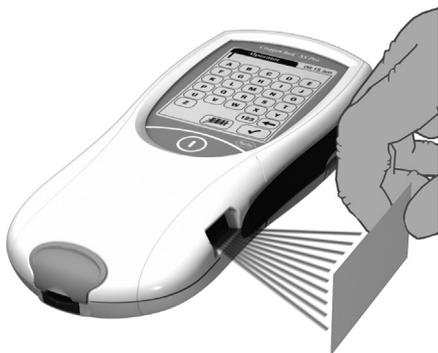
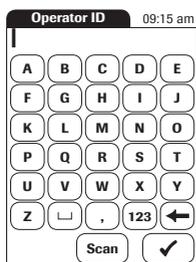
The next steps depend on whether you work with the function *Operator ID* set to inactive or active (see *Data handling* on page 119).

If the function *Operator ID* is inactive:



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

If the function *Operator ID* is active:

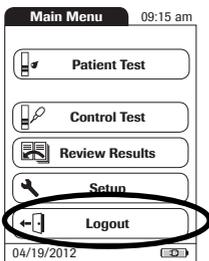
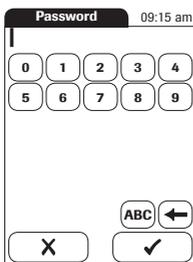
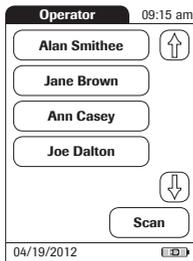


### Without operator list:

- 3 You are now prompted to enter an *Operator ID*.
  - Enter the *Operator ID* using the keypad. Touch ✓ to move to the next screen.
  - Alternatively, the *Operator ID* can also be entered via the built-in barcode scanner. Touch **Scan** and scan the operator 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 operator 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 into the laser beam.



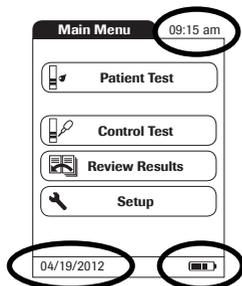
### With operator list:

- 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 119.

## Performing a test

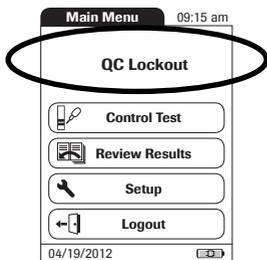


### 1 Check the battery level.

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

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

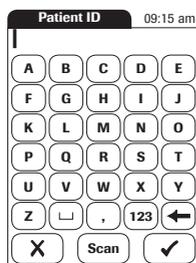
### 2 Check that the date and time are correct. Correct any wrong entries as described in Chapter 4, *Meter Setup/Setting the date*.



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, *Control Testing and 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



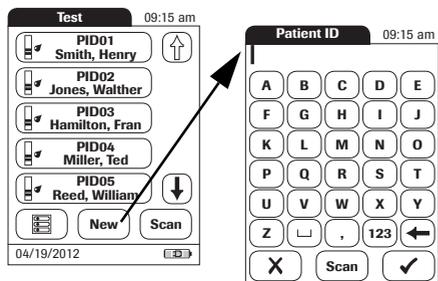
### 3 Touch **Patient Test.**

- 4 If the *Patient ID* option was chosen as either *Optional* or *Required* when the meter was set up (see *Meter Setup/ Patient ID*), 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

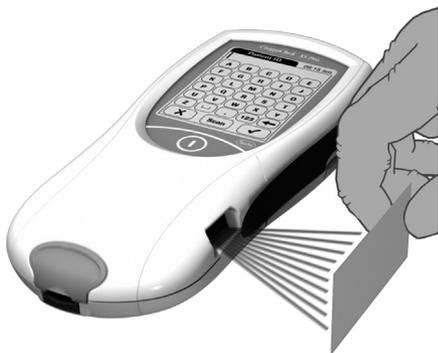


### 5 Touch **Patient Test**.



- 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 119.



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).

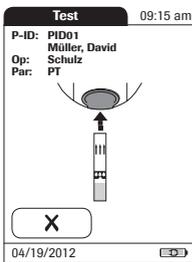
The meter beeps once the barcode has been read successfully. The barcode information appears in the patient ID field. The scanner turns off after 10 seconds, if a barcode is not scanned.



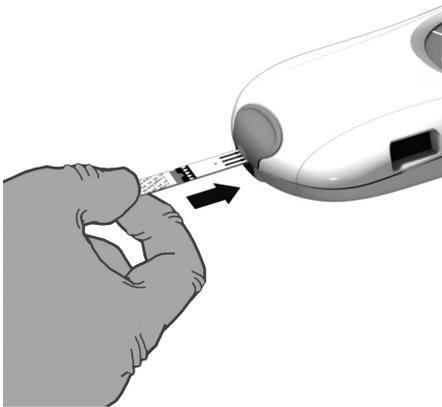
---

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

---

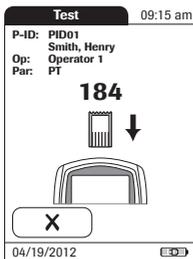


- 8** The test strip icon prompts you to insert a test strip. Remove a test strip from its container and close the container again with the stopper.

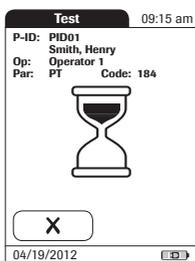


Exposure to external influences (such as humidity) may deteriorate the test strips and may lead to error messages. Therefore, always close the strip container immediately after removing a test strip.

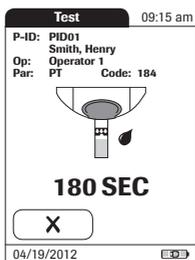
- 9** Hold the test strip so the lettering with the test name is facing upward.
- 10** Slide the test strip into the test strip guide in the direction indicated by the arrows. Slide the test strip in as far as it will go. A beep indicates that the meter has detected the test strip (provided the beeper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



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



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

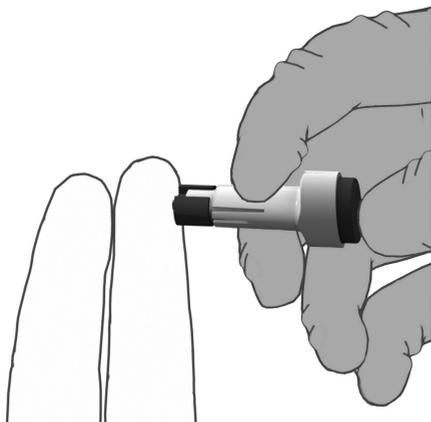


The blood drop icon flashes to indicate that the meter is ready to perform the test and is waiting for blood to be applied.

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 single-use lancing device that is approved for use by healthcare professionals, such as the Accu-Chek Safe-T-Pro Plus lancing device. Follow the manufacturer's instructions.

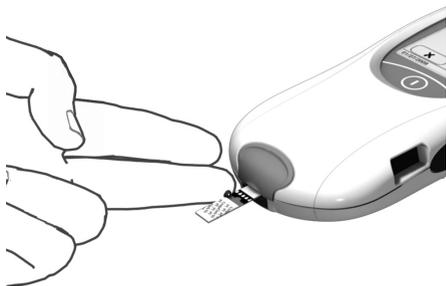


**11** Now lance the side of a fingertip with the lancing device.

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  $\mu$ L) directly from the finger to the semicircular, transparent sample application area on top of the test strip.

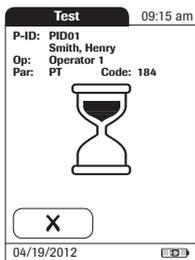
- ... or you can touch the blood drop against the side of the sample application area. The test strip draws up the blood by capillary action.

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.

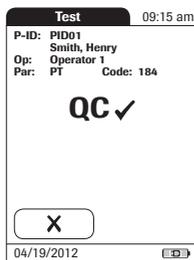
Apply the blood drop to the test strip within **15 seconds** of lancing the fingertip. Applying blood after this period of time may lead to an erroneous result (as the coagulation process would already have started).

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



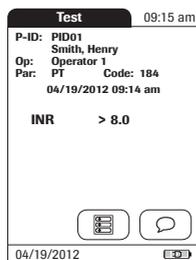
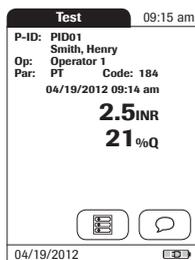
You hear a beep tone when you have applied enough blood (provided the *Beeper* is enabled). The blood drop symbol disappears and the test starts.

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.”

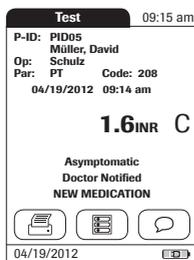


The result is displayed in the unit you chose when setting up the meter. It is automatically saved.

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



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

This may occur if the hematocrit value is very low or due to erroneous blood collection (e.g., wet hands). Repeat the 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.

## Accepting or rejecting a test result

**Test** 09:15 am

P-ID: PID01  
Smith, Henry  
Op: Operator 1  
Par: PT Code: 184  
04/19/2012 09:14 am

**2.5**INR  
**21**%Q

Measurement Result OK?

04/19/2012

If this function is enabled, you may choose to accept or reject a test result. When the result is displayed, touch

- **Reject** or
- **Accept**

**Comment Required**

**I-009**

A comment is required if you reject a result. Please enter a comment.

If you reject a result, you must enter a comment with an explanation.

**Test** 09:15 am

P-ID: PID01  
Smith, Henry  
Op: Operator 1  
Par: PT Code: 184  
04/19/2012 09:14 am

**Rejected**

Will Repeat Test

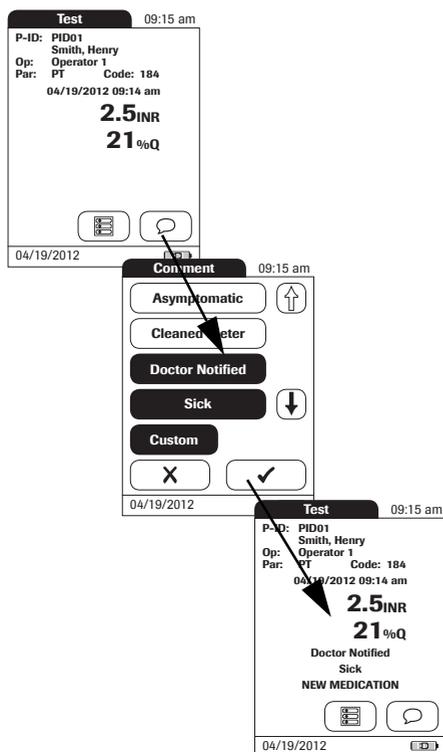
04/19/2012

If you reject the result, this test result is no longer displayed. However, the test entry is stored.

## Adding comments

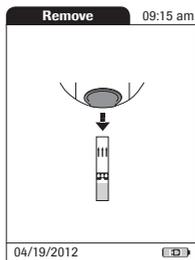
You can add up to three comments to a test result. Comments can provide, for example, additional information about the test conditions or the patient. A comment may be up to 20 characters in length. You can open the function for adding comments directly in the results screen. To add comments:

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 .
- 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 , *Cleaning and disinfecting the meter*).



---

### **Protection against infection**

When collecting samples always observe the general precautions and guidelines relating to blood sampling (see page 16).

Dispose of all test strips used for patient testing in accordance with the disposal policy of your laboratory or practice (see page 16).

---

This page intentionally left blank.

## 6 Control Testing and 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, onboard 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 package.
- Test strips that came with the code chip mentioned above
- Bottles of CoaguChek XS Pro PT Controls, diluent droppers, and the quality control code chip provided.

You can choose the frequency of liquid quality control tests in the meter setup. (Refer to the chapter entitled *Meter Setup/QC (quality control) Lockout* starting on page 74). 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. Let the bottle sit undisturbed for 1 minute. Please refer to the control solution package insert.

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

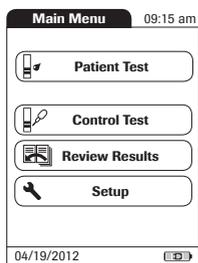
The control solutions may be reconstituted (mixed) after removal from the refrigerator. The resulting solution may be used **up to 30 minutes** after reconstitution.

## Performing a liquid quality control test

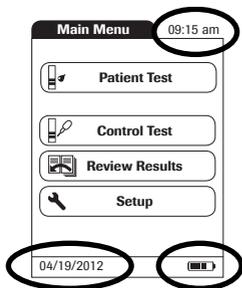


- 1 Place the meter on a level, vibration-free surface or hold it in your hand so it is roughly horizontal.
- 2 Power the meter on by pressing the  button for approximately 1 second.

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 86.



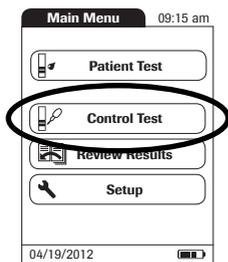
#### 4 Check the battery level.

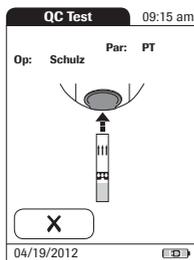
- If the battery icon turns red (one bar left), there may not be enough power left for another test.
- If there are no bars left in the battery icon, you cannot perform any more tests. Power the meter off using the **(I)** button.

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

#### 5 Check that the date and time are correct. Correct any wrong entries as described in Chapter 4, *Meter Setup/Setting the date*.

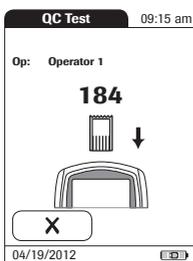
#### 6 Touch **Control Test**.



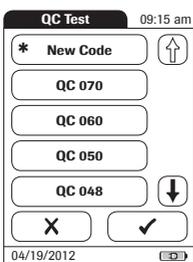


- 7** The test strip icon prompts you to insert a test strip. Remove a test strip from its container and close the container again with the stopper.
- 8** Hold the test strip so the lettering with the test name is facing upward.
- 9** Slide the test strip into the test strip guide in the direction indicated 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.



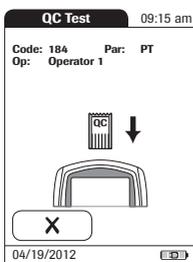
If you are using a new test strip lot and have not inserted the test strip code chip yet, you must do so now. Otherwise you cannot perform a quality control test.



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.

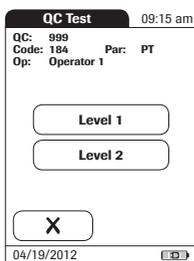
- 10 Select the code stored for your current control solution, or touch **New Code** to use a new control solution.

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 Code**.

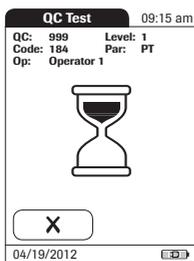


If you are using a new control solution, remove the strip code chip from the meter and insert the code chip that came with the control solution instead.

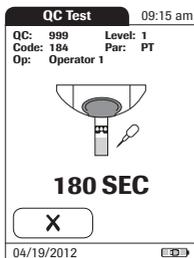
If the code chips get mixed up, check the letter on the code chips to tell them apart. A capital **S** in front of the number indicates that this code chip is for test strips. A capital **C** in front of the number indicates that it is a control solution code chip.



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

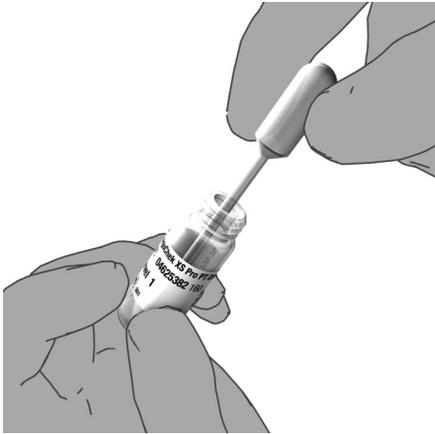


The hourglass icon shows that the test strip is warming up. When the warming-up process is complete, a further beep (provided the beeper is enabled) indicates that you can now apply the control solution.

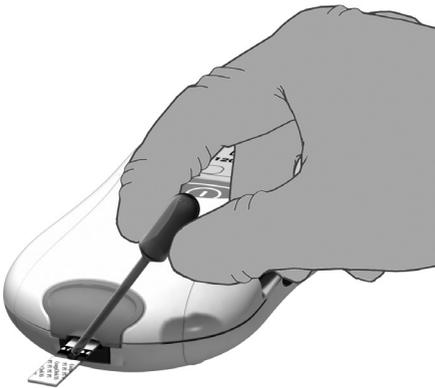


The dropper icon flashes to indicate that the meter is ready to perform the test and is waiting for the sample to be applied.

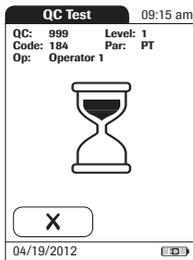
At the same time a 180-second countdown begins. You must apply the sample within this time, otherwise you will receive an error message.



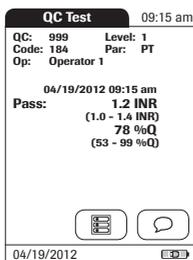
- 12** Using the dropper, draw up the dissolved contents of the bottle.



- 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.

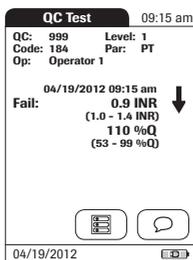


You hear a beep when you have applied enough control solution (provided the beeper is enabled). The dropper icon disappears and the test starts.



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

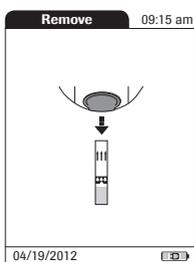
The acceptable range of results for the liquid control is displayed below the current result, along with *Pass* or *Fail*.



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 .
- 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.

If you are performing a 2-level control, you will now be asked to proceed with the second level.

- 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 , *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.

---

This page intentionally left blank.

---

## 7 Review Results

The CoaguChek XS Pro meter can save 2000 patient test results as well as 500 liquid quality control tests to memory, together with respective time and date. In addition, up to 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 5000 *Operator* and 4000 *Patient IDs* is allowed.

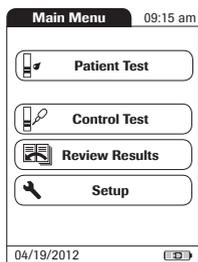
If memory is full when you perform a test, the oldest result is automatically deleted. The most recent result is always saved. This applies both to patient results and to quality control tests. In order to avoid the loss of stored test results, you can archive this data using a data management system and the optional Handheld Base Unit (see page 119).

## Viewing test results

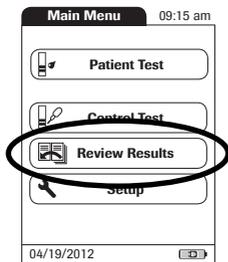


- 1 Place the meter on a level, vibration-free surface, or hold it in your hand so it is roughly horizontal.
- 2 Power the meter on by pressing the  button for approximately 1 second.

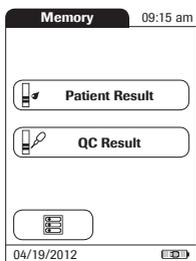
To power the meter off after use, press the  button for approximately 1 second.



- 3 Wait until the main menu is displayed.



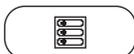
#### 4 Touch **Review Results**.



#### 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

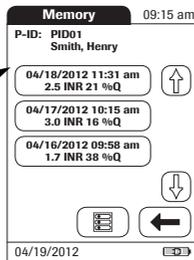
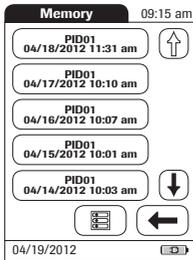


*Individual* icon: List that contains entries for this patient only

## Display patient result memory

This memory area contains all test results for your patients, sorted according to the setting you chose for the option *Sort* (see page 49). If the *Sort* option is set to *Date/Time*, 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.



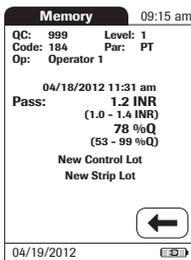
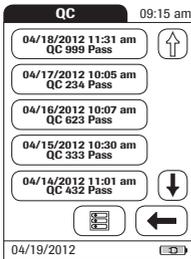
The entry is displayed.

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

## Display QC (quality control) result memory

This memory area contains all 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 66, for details on *Operator Lockout* see page 76.

When using operator and/or patient lists and the lists are set to be hidden, operator login and/or patient selection is **only** possible via barcode scanner.

All setup options that allow using the **barcode scanner** (e.g., Operator login, Patient ID entry) require the used **barcode types to be activated** in the DMS and transferred to the meter before scanning. Otherwise barcodes cannot be scanned.

### **Computer (Setup option)**

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

- In the *Setup* menu, the *Connection* option must be set to *Computer* (see page 56).
- 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* list is activated, but there are no operators available:  
The *Operator* can either log in via the onscreen keypad or a barcode scan. The use of the meter is not restricted to a predefined *Operator* group. The operator ID is stored together with each test result for informational purposes only.

This first configuration is also available without a DMS.

If an operator list is available on the meter, there are two options:

- *Operator* list is activated and available on the meter:  
The *Operator* can either select the ID from the displayed list on the login screen, or scan the ID using the barcode scanner. If so configured by the *Administrator*, the *Operator* may also be required to enter a password to log in.
- *Operator* list is activated and available on the meter but set to “hidden”:  
The *Operator* can only log in 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 only to certified operators contained in the list. If the **Scan** button or the operator list are not displayed on the meter, the operator certification has to be checked.

## Patient lists

When starting a Patient Test, there will be the option of either selecting a *Patient ID* from a patient list, entering the *Patient ID* using the onscreen keypad or, if available, of scanning the barcode with the *Patient ID*. The *Patient ID*, if entered on the DMS, comes with an additional identification entry. Up to 20 characters can be used and assigned as a second confirmation (e.g., name, date of birth).

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

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

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

### ***Patient list validation***

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

- A Patient ID does not have to be on the list to be used (only valid for validation mode “off”).
- The meter displays a notification if the Patient ID entered is not on the list and validation mode “notify” was selected in the DMS.
- The meter displays an error message if the ID was not found on the list of valid Patient IDs and validation mode “required” was selected in the DMS. To proceed with the test, you must scan (if ID set to “hidden”) or select (if ID set to Required) a valid Patient ID.
- If the “list” feature is set to be hidden, only Patient IDs which are part of the patient list (previously transferred from the DMS to the meter) can be selected. It is not possible to add new Patient IDs via scanner or keypad.

### ***Barcode scanner***

Using a DMS, the barcode scanner may be configured to accept only selected barcode symbologies (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**

- Acceptable Control
- 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.

This page intentionally left blank.

## 9 Maintenance and Care

### Conditions for storage and shipping

#### Storage

- Store the system and test strips in the same environment in which they are used.
- Do not store the meter in direct sunlight or under extreme temperature conditions.
- Observe the limits for temperature and humidity when storing and using the meter (see Chapter 11).

#### Shipping



---

Observe the following safety information when shipping the meter and battery pack. Failure to do so may result in injury to persons or damage to the meter or battery pack.

---

- If the meter has to be shipped or transported over long distances, always remove the battery pack from the meter. This eliminates the possibility of the battery pack overheating due to a short-circuit. It also prevents deep discharge and other damage to the battery pack or meter.
- Only ship undamaged battery packs. Damaged battery packs must be disposed of locally. See page 18 for the risks associated with damaged battery packs and disposal information.
- Package the battery pack for shipping so that it cannot move around in the packaging. Also observe any other applicable national regulations.
- When shipping via third parties (e.g., by air or parcel service), work with the carrier to check whether specific requirements need to be met in relation to the lithium-ion battery packs on the basis of national or international laws on hazardous goods and, where applicable, if special packaging and labeling requirements apply.

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

## 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.

## Acceptable cleaning/disinfecting agents

Acceptable active ingredients and products for cleaning and disinfecting are:

- Super Sani-Cloth<sup>®</sup> Germicidal Disposable Wipes (EPA<sup>1</sup> reg. no. 9480-4). Premoistened disinfecting cloths (active ingredient 0.5% quaternary ammonium chlorides and up to 60% isopropanol)
- 70% ethanol or isopropyl alcohol

Only one cleaning/disinfecting solution should be used on the device as the effect of using more than one cleaner/disinfectant interchangeably has not been evaluated.

### NOTICE

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

- To purchase approved disinfecting products please refer to your facility's guidelines, which may include instructions on direct purchase from the manufacturer or through an approved distributor. Refer to manufacturer's website <http://www.pdipdi.com/> for additional information on Super Sani-Cloth<sup>®</sup> Germicidal Disposable Wipes and availability for purchase.
- Dispose of acceptable cleaning and disinfection solutions per facility guidelines.

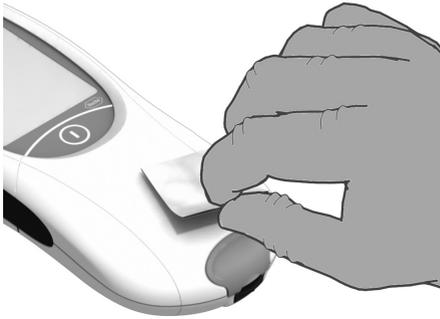
---

1. Environmental Protection Agency

## Cleaning the exterior (meter housing)

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

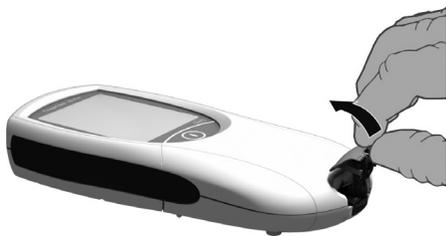
Do not let liquid accumulate near any opening. Ensure that no liquid enters the meter.



- 1** Place the meter on a level surface prior to cleaning.
- 2** Power off the meter.  
Be certain that solutions contain acceptable active ingredients for cleaning the system. When using commercially available pre-moistened cleaning cloths, **squeeze off excess cleaning solution** or blot on a dry paper towel to remove any excess cleaning solution before cleaning the surface of the meter.
- 3** Gently wipe the outside of the meter and carefully around the test strip guide area, making sure that no liquid enters the test strip guide and then wipe dry with a tissue.
- 4** With a fresh dry cloth or lint-free tissue, wipe away residual moisture and fluids after cleaning the housing.
- 5** Allow wiped areas to **dry for at least 10 minutes** before performing a test.

## Cleaning the test strip guide and test strip guide cover

Be certain that solutions contain acceptable active ingredients for cleaning the system. When using commercially available pre-moistened cleaning cloths, **squeeze off excess cleaning solution** or blot on a dry paper towel to remove any excess cleaning solution before cleaning the surface of the meter.



- 1 With the meter powered off, remove the test strip guide cover to clean it. (Use your thumbnail to open the cover of the test strip guide by pressing its front edge upward.) Move the cover safely away from the meter. Then wipe it clean using the recommended cleaning/disinfecting agents. Let the test strip guide cover dry **for at least 10 minutes** before re-attaching it.

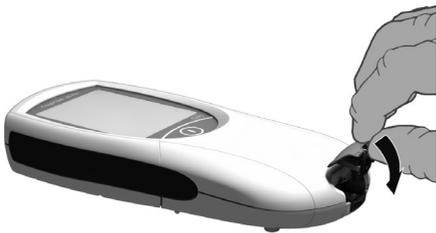


- 2 Hold the meter upright with the test strip guide facing down.
  - Clean the easily accessible white areas of the test strip guide with a Super Sani-Cloth Germicidal Disposable Wipe or a moistened cotton swab/bud when using 70% ethanol or isopropyl alcohol.
  - Ensure that cloth or swab/bud is only damp, not wet. Wipe away residual moisture and fluids.
  - Use a fresh cloth or bud/swab to clean the test strip guide by gently wiping the easily accessible white areas, making sure that no liquid pools into the test strip guide.

**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**

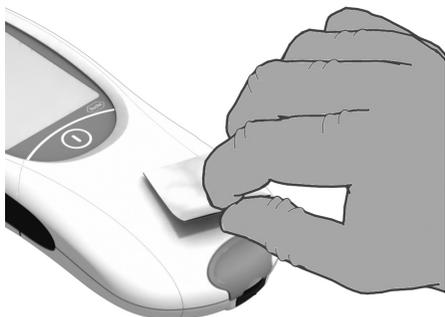
The scanner window should be cleaned periodically. Use a clean, dry cloth to wipe the scanner window.

## Disinfecting the exterior (meter housing)

**NOTICE**

The meter should be cleaned prior to each disinfection step.

Remember to keep the meter on a level surface prior to disinfecting and powered off. Be certain that solutions contain acceptable active ingredients for disinfecting the system. When using commercially available pre-moistened disinfecting cloths, **squeeze off excess disinfecting solution** or blot on a dry paper towel to remove any excess disinfecting solution before disinfecting the surface of the meter.



- 1 Use the recommended cleaning/disinfecting agents to disinfect by gently wiping the outside of the meter **three times horizontally and three times vertically** and carefully wipe around the test strip guide area, making sure that no liquid enters the test strip guide.
- 2 Allow the surface of the meter to remain damp with the recommended disinfecting solution. The required contact time is a **2-minute contact time for the Super Sani-Cloth Germicidal Disposable Wipe. When using 70% ethanol or isopropyl alcohol, apply the solution for a contact time of greater than 1 minute (refer to the ethanol or isopropyl alcohol product labeling).**

**NOTE: Meter surface must stay moist for the entire contact time.**

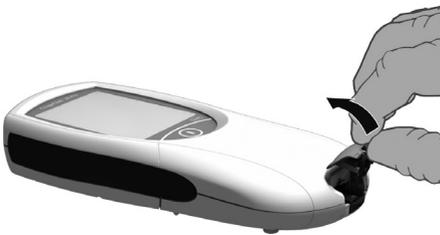
- 3 With a fresh dry cloth or lint-free tissue, wipe away residual moisture and fluids after disinfecting the housing.
- 4 Allow wiped areas to **dry for at least 10 minutes** before performing a test.

## Disinfecting the test strip guide and test strip guide cover

### NOTICE

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

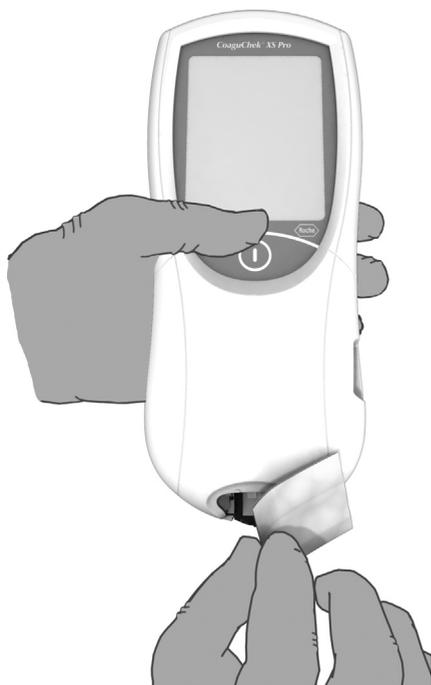
Be certain that solutions contain acceptable active ingredients for disinfecting the system. When using commercially available pre-moistened disinfecting cloths, **squeeze off excess disinfecting solution** or blot on a dry paper towel to remove any excess disinfecting solution before disinfecting the surface of the meter.



- 1 With the meter powered off, remove the test strip guide cover to disinfect it. (Use your thumbnail to open the cover of the test strip guide by pressing its front edge upward.) Move the cover safely away from the meter.
- 2 Use the recommended cleaning/disinfecting agents using a fresh cloth or bud/swab to disinfect the test strip guide cover by gently wiping the easily accessible areas **three times horizontally and three times vertically**.
- 3 Allow the surface of the test strip guide cover to remain damp with the recommended disinfecting solution. The required contact time is as follows: Super Sani-Cloth Germicidal Disposable Wipe, a **2-minute contact time**. When using 70% ethanol or isopropyl alcohol, apply the solution for a **contact time of greater than 1 minute** (refer to the ethanol or isopropyl alcohol product labeling).

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

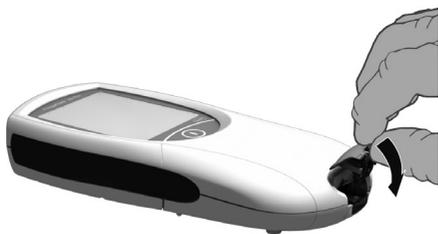
Let the test strip guide cover dry **for at least 10 minutes** before re-attaching it.



- 4 With the test strip guide cover off and holding the meter upright with the test strip guide facing down, use a fresh cloth or bud/swab to disinfect the easily accessible white areas of the test strip guide by gently wiping the easily accessible white areas **three times horizontally and three times vertically**, making sure that no liquid pools into the test strip guide.
- 5 Allow the surface of the test strip guide to remain damp with the recommended disinfecting solution. The required contact time is as follows: Super Sani-Cloth Germicidal Disposable Wipe, a **2-minute contact time**. When using 70% ethanol or isopropyl alcohol, apply the solution for a **contact time of greater than 1 minute** (refer to the ethanol or isopropyl alcohol product labeling).

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

- 6 Let the test strip guide dry **for at least 10 minutes** before re-attaching the test strip guide cover.
- 7 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.



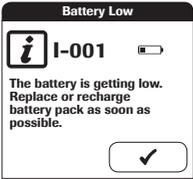
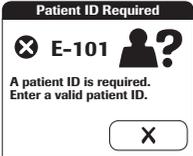
## 10 Troubleshooting

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

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

Take the action suggested on screen to resolve the problem. If the error disappears, you may continue using the meter as desired. If the problem persists, contact Roche (see page 154).

The two different message types are illustrated below:

Message	Description
<p><b>I-001: Battery Low</b></p> 	<p><b>Status message</b></p> <p>Touch  to proceed with the next step.</p>
<p><b>E-101: Patient ID Required</b></p> 	<p><b>Error message</b></p> <p>Touch  to exit this message. Perform the suggested step(s) to solve the problem.</p>

## Status and Error Messages

### Status Messages

Code	Text
I-001	The battery is getting low. Replace or recharge battery pack as soon as possible.
I-002	The patient ID you entered is not on the list.
I-004	Only 100 tests can be performed before the meter memory is full. Dock meter or disable this setting.
I-005	Communicating with DMS. Please wait.
I-006	Only 500 tests left before the maximum number of tests is reached. Contact your Roche representative. Only 100 tests left before the maximum number of tests is reached. Contact your Roche representative.
I-009	A comment is required if you reject a result. Please enter a comment.
I-010	Observer (USERNAME), please log in to proceed. Otherwise the OTS test will not be complete.

### Error Messages

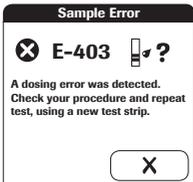
Code	Text
E-101	A patient ID is required. Enter a valid patient ID.
E-102	The ID was not found on the list of valid patient IDs. Enter a valid patient ID.
E-103	An operator ID is required. Enter a valid operator ID.
E-104	The ID was not found on the list of valid operator IDs. Enter a valid operator ID or see your System Administrator.
E-105	Invalid password. Enter valid password or see your System Administrator.
E-107	There are no operators loaded in this meter. In order to continue, operators must be downloaded. Please see your System Administrator.
E-108	The passwords you entered do not match. Please try again.
E-109	The scanned barcode is invalid. Scan a valid barcode or see your System Administrator.
E-111	The observer ID is invalid. The observer supervising the current OTS test must log in again.
E-201	The strip lot with code <Number> has expired. Check the meter date/time setting and use a non-expired strip lot.
E-202	The control lot has expired. Check the meter date/time setting and use a nonexpired control lot.

## Error Messages

Code	Text
E-203	The lot with the code <Number> is not allowed on this meter. See your System Administrator.
E-204	The barcode on the test strip cannot be read. Please check the barcode on the test strip and repeat the test.
E-205	Strip removed during test. Repeat test, using a new test strip if necessary.
E-207	Invalid code chip. Remove the code chip and repeat the test.
E-210	A quality control test must be performed. To continue, perform a quality control test.
E-211	The test strip guide cover was removed during a test. Repeat the test.
E-301	The date is invalid. Enter the correct date and time.
E-302	Battery low. No more tests can be performed. Replace or recharge battery pack.
E-303	The maximum number of tests has been reached. Contact your Roche representative.
E-304	Meter is too cold or too warm to test correctly. Power meter off and repeat test after 30 minutes at room temperature.
E-305	The meter memory is full. Dock the meter or disable this setting.
E-401	Sample detection has failed. Remove the test strip and repeat test, using a new test strip if necessary.
E-402	A test strip error was detected. Check your procedure and repeat test, using a new test strip if necessary.
E-403	A dosing error was detected. Check your procedure and repeat test, using a new test strip.
E-405	A measurement error occurred. Check your procedure and repeat test, using a new test strip.
E-406	Unsuitable sample composition. Check your procedure and repeat test with new strip and fresh sample. Check medication regimen of patient. If problem persists, check result with another method and refer to manual for more detail.
E-407	Strip failed onboard control. Remove the strip and repeat the test, using a new strip from another test strip container if necessary.
E-501	The self-check detected a general error. Repeat the self-check. If problem persists, power meter off and on again.
E-601	Code chip cannot be read. Remove the code chip and repeat the test.
E-602	General System Error. The meter is defective. No test is possible. Contact your Roche representative.
E-603	Temperature or heater error. Power meter off and on, and repeat the last procedure. If problem persists, contact your Roche representative.
E-605	Hardware or electronic error. Power meter off and on, and repeat the last procedure. If problem persists, contact your Roche representative.

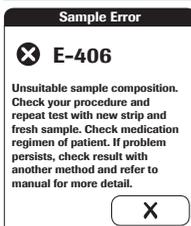
## Error Messages

Code	Text
E-606	Measurement sequence error. Power meter off and on, and repeat the last procedure. If problem persists, contact your Roche representative.
E-607	Error with measurement module. Power meter off and on, and repeat the last procedure. If problem persists, contact your Roche representative.
E-608	A software error was detected. Power meter off and on, and repeat the last procedure. If problem persists, contact your Roche representative.
E-701	Failed to connect to DMS. Unlock meter from Base Unit and then redock it. If problem persists, power meter off and on.
E-702	Communication error with DMS. Unlock meter from Base Unit and then redock it. If problem persists, power meter off and on.
E-704	ICI communication error with DMS. Power meter off and on, and repeat the last procedure.
E-705	Communication error with measurement module. Power meter off and on, and repeat the last procedure. If problem persists, contact your Roche representative.
E-706	Communication error with test strip barcode scanner. Power meter off and on, and repeat the last procedure. If problem persists, contact your Roche representative.
E-708	General communication error. Power meter off and on, and repeat the last procedure. If problem persists, contact your Roche representative.
E-801	Patient database cannot be read and will be deleted. Power meter off and on, and repeat the last procedure. If problem persists, contact your Roche representative.
E-802	QC database cannot be read and will be deleted. Power meter off and on, and repeat the last procedure. If problem persists, contact your Roche representative.
E-803	Comments database cannot be read and will be deleted. Power meter off and on, and repeat the last procedure. If problem persists, contact your Roche representative.
E-804	Setup database cannot be read and will be deleted. Power meter off and on, and repeat the last procedure. If problem persists, contact your Roche representative.
E-805	The meter detected a fault with the EEPROM memory. Power meter off and on. If problem persists, contact your Roche representative.
E-806	The meter detected a fault with the Flash memory. Power meter off and on. If problem persists, contact your Roche representative.
E-807	The meter detected a general fault with the memory. Power meter off and on. If problem persists, contact your Roche representative.

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

### ***Additional information on Error 403***

“Dosing” refers to the procedure to apply blood sample to the test strip. “Dosing Error” indicates that an insufficient sample volume was detected. Please check your procedure and repeat the test using a new test strip.

**Message****Description****E-406: Sample Error****Error message**

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

**Additional information on Error 406**

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 406:** The CoaguChek XS PT Test strip may be used for patients under a combination therapy of oral anticoagulants plus heparin injections. For maximum heparin concentrations which do not interfere with the test, refer to the package insert. 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, "Error 406" may be received in patients under clinical conditions, which could potentially lead to extremely high coagulation times (> 10 INR, < 5 % Quick). This could occur if warfarin or another vitamin K antagonist is used in combination with antibiotics and/or chemotherapeutics, or if the blood sample contains too many oxidizing substances.

Additionally, in rare cases, patients with abnormal or unusually long clotting times may receive the "Error 406" message. If this error appear again after the test is repeated, check the result using another method. Please inform the patient to seek immediate medical attention.

## ***Errors and unusual behavior without error messages***

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

<b>Message</b>	<b>Description</b>
<b>No message or unusual behavior</b>	
Meter display does not power on	<ul style="list-style-type: none"> <li>■ Wait 10 seconds and try powering on the unit again.</li> <li>■ Check that the meter has power.               <ul style="list-style-type: none"> <li>▪ If you are using the external power adapter, is it connected properly to the meter? Or:</li> <li>▪ Place the meter in the Handheld Base Unit. Or:</li> <li>▪ If you are using the Handheld Battery Pack, is it properly installed in the meter?</li> </ul> </li> </ul>
Meter displays an unexpected result	Refer to the package insert for the test strips.
<b>Automatic shutdown</b>	
	The meter powers off after a configurable time without activity (e.g., pressing a key, touching the screen) to conserve energy. Reactivate the meter/screen as described in the following:
Shutdown after time specified by system administrator (default is 5 minutes, configurable by system administrator)	<ul style="list-style-type: none"> <li>■ Press the On/Off button of the meter.</li> </ul>

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	2000 patient and 500 QC results with date and time 60 code chip records Operator lists up to 5000 Operator IDs with corresponding 2nd ID (e.g., Operator Name) Patient lists up to 4000 Patient IDs with corresponding 2nd and 3rd Patient IDs (e.g., name, date of birth)
Interface	Infrared interface, LED/IREC Class 1
Barcode scanner	Laser Class 1, according to EN 60825-1:2007 (see page 145)
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 / 350-150 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***

Please contact Roche Diagnostics Customer Service at 1-800-428-4674.

<b>Item</b>	<b>Description</b>	<b>Reference number</b>
CoaguChek XS PT Test	2 x 24 test strips	04625315160
CoaguChek XS PT Test	1 x 24 test strips	07797826160
CoaguChek XS Pro PT Controls	Optional liquid controls for the CoaguChek XS Pro / XS Plus systems	04625382160
CoaguChek Capillary Tubes/Bulbs	Capillary tubes	11621173001
Handheld Battery Pack	Rechargeable battery pack	04805640001
Handheld Base Unit Kit	Handheld Base Unit and Operator's Manual	04805658160

### ***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.

### ***Repairs***

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

## Working with barcodes



---

### **Risk of barcode read errors**

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

To minimize the risk of barcode read errors, the facility must ensure that the barcode used is of adequate size and print quality. In addition, every user must carry out a plausibility check on all data scanned into and displayed by the instrument.

---

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

- check ID against list or
- check ID for length<sup>1</sup>
- check if scanned bar code type is allowed and activated in the DMS.

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

Always make sure that the entire barcode is covered by the red laser beam (meters with serial number below UU14000000) when scanning.

---

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

## Operator and patient ID barcode masks

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

## Example of barcode symbologies



---

When creating patient or operator barcodes, always adhere to the applicable international IEC/ISO standards for the respective barcode symbology. In particular, ensure that barcode size and print quality (as defined in ISO/IEC 15421) are adequate. Inadequate print size and/or quality may lead to erroneous decoding.

---



---

### **Avoidance of incorrect EAN 13 and Interleaved 2/5 barcode readings**

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

- make sure that the very highest quality standards of barcode creation and reproduction are applied
  - for EAN13: do not use the start sequences 978 (ISBN) and 979 (ISMN) as they will be ignored as a part of any ID code
- 

The barcode samples shown here are for illustration purposes only. If printed out, they can be used to check the barcode scanner. However, they are not meant to be used as a reference for size or resolution of real patient or operator ID barcodes. Always refer to the relevant standard ISO/IEC 15421 for size and resolution requirements when creating patient or operator barcodes.

---

	Codabar		Code 39
1234567890		1234567890	

---

	Code 93		Code 128
ABC123-/+		1234567890	

---

	EAN 13		Interleaved 2/5
1 112223 334448		1234567890	

---

## **Information about software licenses**

This product incorporates software modules developed under license from General Public License (GPL). The source code of this software can be requested on a standard data exchange medium from the following address:

Roche Diagnostics GmbH  
Sandhofer Str. 116  
68305 Mannheim, Germany

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

© 1989, 1991 Free Software Foundation, Inc. 51 Franklin Street, Suite 330, Boston, MA 02110, USA.

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

### **Preamble**

The licenses for most software are designed to take away your freedom to share and change it. By contrast, the GNU General Public License is intended to guarantee your freedom to share and change free software—to make sure the software is free for all its users. This General Public License applies to most of the Free Software Foundation's software and to any other program whose authors commit to using it. (Some other Free Software Foundation software is covered by the GNU Library General Public License instead). You can apply it to your programs, too. When we speak of free software, we are referring to freedom, not price. Our General Public Licenses are designed to make sure that you have the freedom to distribute copies of free software (and charge for this service if you wish), that you receive source code or can get it if you want it, that you can change the software or use pieces of it in new free program; and that you know you can do these things.

To protect your rights, we need to make restrictions that forbid anyone to deny you these rights or to ask you to surrender the rights. These restrictions translate to certain responsibilities for you if you distribute copies of the software, or if you modify it.

For example, if you distribute copies of such a program, whether gratis or for a fee, you must give the recipients all the rights that you have. You must make sure that they, too, receive or can get the source code. And you must show them these terms so they know their rights. We protect your rights with two steps: (1) copyright the software, and (2) offer you this license which gives you legal permission to copy, distribute and/or modify the software.

Also, for each author's protection and ours, we want to make certain that everyone understands that there is no warranty for this free software. If the software is modified by someone else and passed on, we want its recipients to know that what they have is not the original, so that any problems introduced by others will not reflect on the original authors' reputations.

Finally, any free program is threatened constantly by software patents. We wish to avoid the danger that redistributors of a free program will individually obtain patent licenses, in effect making the program proprietary. To prevent this, we have made it clear that any patent must be licensed for everyone's free use or not licensed at all.

The precise terms and conditions for copying, distribution and modification follow.

#### TERMS AND CONDITIONS FOR COPYING, DISTRIBUTION AND MODIFICATION.

This License applies to any program or other work which contains a notice placed by the copyright holder saying it may be distributed under the terms of this General Public License. The "Program", below, refers to any such program or work, and a "work based on the Program" means either the Program or any derivative work under copyright law: that is to say, a work containing the Program or a portion of it, either verbatim or with modifications and/or translated into another language. (Hereinafter, translation is included without limitation in the term "modification".) Each licensee is addressed as "you".

Activities other than copying, distribution and modification are not covered by this License; they are outside its scope. The act of running the Program is not restricted, and the output from the Program is covered only if its contents constitute a work based on the Program (independent of having been made by running the Program). Whether that is true depends on what the Program does.

1. You may copy and distribute verbatim copies of the Program's source code as you receive it, in any medium, provided that you conspicuously and appropriately publish on each copy an appropriate copyright notice and disclaimer of warranty; keep intact all the notices that refer to this License and to the absence of any warranty; and give any other recipients of the Program a copy of this License along with the Program.

You may charge a fee for the physical act of transferring a copy, and you may at your option offer warranty protection in exchange for a fee.

2. You may modify your copy or copies of the Program or any portion of it, thus forming a work based on the Program, and copy and distribute such modifications or work under the terms of Section 1 above, provided that you also meet all of these conditions:

a) You must cause the modified files to carry prominent notices stating that you changed the files and the date of any change.

b) You must cause any work that you distribute or publish, that in whole or in part contains or is derived from the Program or any part thereof, to be licensed as a whole at no charge to all third parties under the terms of this License.

c) If the modified program normally reads commands interactively when run, you must cause it, when started running for such interactive use in the most ordinary way, to print or display an announcement including an appropriate copyright notice and a notice that there is no warranty (or else, saying that you provide a warranty) and that users may redistribute the program under these conditions, and telling the user how to view a copy of this License. (Exception: if the Program itself is interactive but does not normally print such an announcement, your work based on the Program is not required to print an announcement.)

These requirements apply to the modified work as a whole. If identifiable sections of that work are not derived from the Program, and can be reasonably considered independent and separate works in themselves, then this License, and its terms, do not apply to those sections when you distribute them as separate works. But when you distribute the same sections as part of a whole which is a work based on the Program, the distribution of the whole must be on the terms of this License, whose permissions for other licensees extend to the entire whole, and thus to each and every part regardless of who wrote it. Thus, it is not the intent of this section to claim rights or contest your rights to work written entirely by you; rather, the intent is to exercise the right to control the distribution of derivative or collective works based on the Program.

In addition, mere aggregation of another work not based on the Program with the Program (or with a work based on the Program) on a volume of a storage or distribution medium does not bring the other work under the scope of this License.

3. You may copy and distribute the Program (or a work based on it, under Section 2) in object code or executable form under the terms of Sections 1 and 2 above provided that you also do one of the following:

- a) Accompany it with the complete corresponding machine-readable source code, which must be distributed under the terms of Sections 1 and 2 above on a medium customarily used for software interchange; or,
- b) Accompany it with a written offer, valid for at least three years, to give any third party, for a charge no more than your cost of physically performing source distribution, a complete machine-readable copy of the corresponding source code, to be distributed under the terms of Sections 1 and 2 above on a medium customarily used for software interchange; or,
- c) Accompany it with the information you received as to the offer to distribute corresponding source code. (This alternative is allowed only for noncommercial distribution and only if you received the program in object code or executable form with such an offer, in accord with Subsection b above.)

The source code for a work means the preferred form of the work for making modifications to it. For an executable work, complete source code means all the source code for all modules it contains, plus any associated interface definition files, plus the scripts used to control compilation and installation of the executable. However, as a special exception, the source code distributed need not include anything that is normally distributed (in either source or binary form) with the major components (compiler, kernel, and so on) of the operating system on which the executable runs, unless that component itself accompanies the executable. If distribution of executable or object code is made by offering access to copy from a designated place, then offering equivalent access to copy the source code from the same place counts as distribution of the source code, even though third parties are not compelled to copy the source along with the object code.

4. You may not copy, modify, sublicense, or distribute the Program except as expressly provided under this License. Any attempt otherwise to copy, modify, sublicense or distribute the Program is void, and will automatically terminate your rights under this License. However, parties who have received copies, or rights, from you under this License will not have their licenses terminated so long as such parties remain in full compliance.

5. You are not required to accept this License, since you have not signed it. However, nothing else grants you permission to modify or distribute the Program or its derivative works. These actions are prohibited by law if you do not accept this License. Therefore, by modifying or distributing the Program (or any work based on the Program), you indicate your acceptance of this License to do so, and all its terms and conditions for copying, distributing or modifying the Program or works based on it.

6. Each time you redistribute the Program (or any work based on the Program), the recipient automatically receives a license from the original licensor to copy, distribute or modify the Program subject to these terms and conditions. You may not impose any further restrictions on the recipients' exercise of the rights granted herein. You are not responsible for enforcing compliance by third parties to this License.

7. If, as a consequence of a court judgment or allegation of patent infringement or for any other reason (not limited to patent issues), conditions are imposed on you (whether by court order, agreement or otherwise) that contradict the conditions of this License, they do not excuse you from the conditions of this License. If you cannot distribute so as to satisfy simultaneously your obligations under this License and any other pertinent obligations, then as a consequence you may not distribute the Program at all. For example, if a patent license would not permit royalty-free redistribution of the Program by all those who receive copies directly or indirectly through you, then the only way you could satisfy both it and this License would be to refrain entirely from distribution of the Program.

If any portion of this section is held invalid or unenforceable under any particular circumstance, the balance of the section is intended to apply and the section as a whole is intended to apply in other circumstances.

It is not the purpose of this section to induce you to infringe any patents or other property right claims or to contest validity of any such claims; this section has the sole purpose of protecting the integrity of the free software distribution system, which is implemented by public license practices. Many people have made generous contributions to the wide range of software distributed through that system in reliance on consistent application of that system; it is up to the author/donor to decide if he or she is willing to distribute software through any other system and a licensee cannot impose that choice.

This section is intended to make thoroughly clear what is believed to be a consequence of the rest of this License.

8. If the distribution and/or use of the Program is restricted in certain countries either by patents or by copyrighted interfaces, the original copyright holder who places the Program under this License may add an explicit geographical distribution limitation excluding those countries, so that distribution is permitted only in or among countries not thus excluded. In such case, this License incorporates the limitation as if written in the body of this License.

9. The Free Software Foundation may publish revised and/or new versions of the General Public License from time to time. Such new versions will be similar in spirit to the present version, but may differ in detail to address new problems or concerns.

Each version is given a distinguishing version number. If the Program specifies a version number of this License which applies to it and “any later version”, you have the option of following the terms and conditions either of that version or of any later version published by the Free Software Foundation. If the Program does not specify a version number of this License, you may choose any version ever published by the Free Software Foundation.

10. If you wish to incorporate parts of the Program into other free programs whose distribution conditions are different, write to the author to ask for permission. For software which is copyrighted by the Free Software Foundation, write to the Free Software Foundation; we sometimes make exceptions for this. Our decision will be guided by the two goals of preserving the free status of all derivatives of our free software and of promoting the sharing and reuse of software generally.

## NO WARRANTY

11. BECAUSE THE PROGRAM IS LICENSED FREE OF CHARGE, THERE IS NO WARRANTY FOR THE PROGRAM, TO THE EXTENT PERMITTED BY APPLICABLE LAW. EXCEPT WHEN OTHERWISE STATED IN WRITING THE COPYRIGHT HOLDERS AND/OR OTHER PARTIES PROVIDE THE PROGRAM “AS IS” WITHOUT WARRANTY OF ANY KIND, EITHER EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. THE ENTIRE RISK AS TO THE QUALITY AND PERFORMANCE OF THE PROGRAM IS WITH YOU. SHOULD THE PROGRAM PROVE DEFECTIVE, YOU ASSUME THE COST OF ALL NECESSARY SERVICING, REPAIR OR CORRECTION.

12. IN NO EVENT UNLESS REQUIRED BY APPLICABLE LAW OR AGREED TO IN WRITING WILL ANY COPYRIGHT HOLDER, OR ANY OTHER PARTY WHO MAY MODIFY AND/OR REDISTRIBUTE THE PROGRAM AS PERMITTED ABOVE, BE LIABLE TO YOU FOR DAMAGES, INCLUDING ANY GENERAL, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF THE USE OR INABILITY TO USE THE PROGRAM (INCLUDING BUT NOT LIMITED TO LOSS OF DATA OR DATA BEING RENDERED INACCURATE OR LOSSES SUSTAINED BY YOU OR THIRD PARTIES OR A FAILURE OF THE PROGRAM TO OPERATE WITH ANY OTHER PROGRAMS), EVEN IF SUCH HOLDER OR OTHER PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

## END OF TERMS AND CONDITIONS

**How to Apply These Terms to Your New Programs** If you develop a new program, and you want it to be of the greatest possible use to the public, the best way to achieve this is to make it free software which everyone can redistribute and change under these terms. To do so, attach the following notices to the program. It is safest to attach them to the start of each source file to most effectively convey the exclusion of warranty; and each file should have at least the “copyright” line and a pointer to where the full notice is found. One line should give the program’s name and an idea of what it does. Copyright (C) yyyy name of author.

This program is free software; you can redistribute it and/or modify it under the terms of the GNU General Public License as published by the Free Software Foundation; either version 2 of the License, or (at your option) any later version.

This program is distributed in the hope that it will be useful, but WITHOUT ANY WARRANTY; without even the implied warranty of MERCHANTABILITY or FITNESS FOR A PARTICULAR PURPOSE. See the GNU General Public License for more details.

You should have received a copy of the GNU General Public License along with this program; if not, write to the Free Software Foundation, Inc., 51 Franklin Street, Suite 330, Boston, MA 02110, USA.

Also add information on how to contact you by electronic and paper mail.

If the program is interactive, make it output a short notice like this when it starts in an interactive mode:

```
Gnomovision version 69, Copyright (C) year name of author Gnomovision comes with
ABSOLUTELY NO WARRANTY; for details type `show w'. This is free software, and you are
welcome to redistribute it under certain conditions; type `show c' for details.
```

The hypothetical commands ``show w'` and ``show c'` should show the appropriate parts of the General Public License. Of course, the commands you use may be called something other than ``show w'` and ``show c'`; they could even be mouse-clicks or menu items--whatever suits your program.

You should also get your employer (if you work as a programmer) or your school, if any, to sign a "copyright disclaimer" for the program, if necessary. Here is a sample; alter the names: Yoyodyne, Inc., hereby disclaims all copyright interest in the program 'Gnomovision' (which makes passes at compilers) written by James Hacker.

Signature of Ty Coon, 1 April 1989 Ty Coon, President of Vice

This product incorporates software that is under license from UCB. The UCB licensing conditions are printed below (in English only for legal reasons):

UCB, Copyright (c) 1993 The Regents of the University of California. All rights reserved.

This software was developed by the Computer Systems Engineering group at Lawrence Berkeley Laboratory under DARPA contract BG 91-66 and contributed to Berkeley.

All advertising materials mentioning features or use of this software must display the following acknowledgement: This product includes software developed by the University of California, Lawrence Berkeley Laboratory.

Redistribution and use in source and binary forms, with or without modification, are permitted provided that the following conditions are met: Redistributions of source code must retain the above copyright notice, this list of conditions and the following disclaimer.

Redistributions in binary form must reproduce the above copyright notice, this list of conditions and the following disclaimer in the documentation and/or other materials provided with the distribution.

All advertising materials mentioning features or use of this software must display the following acknowledgement: This product includes software developed by the University of California, Berkeley and its contributors.

---

Neither the name of the University nor the names of its contributors may be used to endorse or promote products derived from this software without specific prior written permission.

THIS SOFTWARE IS PROVIDED BY THE REGENTS AND CONTRIBUTORS "AS IS" AND ANY EXPRESS OR IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE DISCLAIMED. IN NO EVENT SHALL THE REGENTS OR CONTRIBUTORS BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, OR CONSEQUENTIAL DAMAGES (INCLUDING, BUT NOT LIMITED TO, PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES; LOSS OF USE, DATA, OR PROFITS; OR BUSINESS INTERRUPTION) HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, STRICT LIABILITY, OR TORT (INCLUDING NEGLIGENCE OR OTHERWISE) ARISING IN ANY WAY OUT OF THE USE OF THIS SOFTWARE, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE

## 12 Warranty

### **CoaguChek XS Pro Meter Limited One (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, 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 cleaning or disinfecting the meter with any product other than products approved for such purpose in the Operator's Manual. Meters which show damage or misuse will be handled in accordance with the non-warranty service policy of Roche Diagnostics. 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.

## 13 Appendix

### **Contact Roche**

For all questions about the CoaguChek XS Pro system that are not answered in this manual, contact your Roche representative or call Technical Service 24/7/365 at 1-800-428-4674 or visit us online at [www.coaguheck-usa.com](http://www.coaguheck-usa.com)

---

## 14 Supplement for Observed Test Sequence

### ***Observed Test Sequence (OTS)***

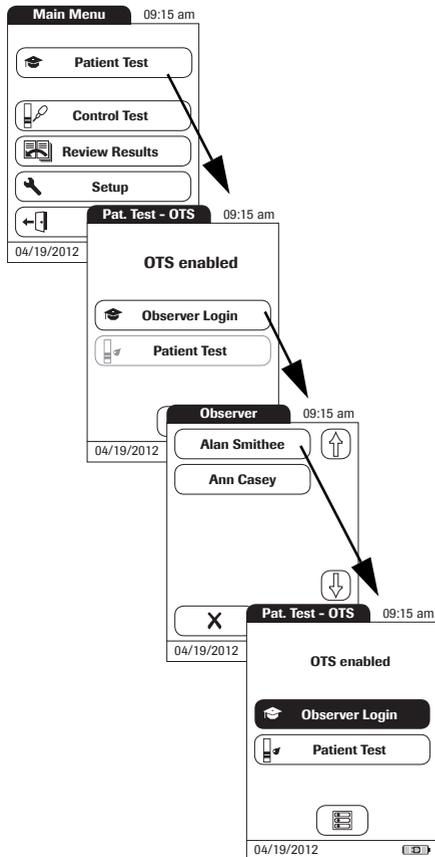
*Observed Test Sequence* options can only be configured using a DMS. The availability of electronic configuration options will thus vary according to the data management software utilized by your institution. Consult your system administrator.

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

\*Note: This feature comes "disabled" on the US Version of the meter system.

## Using the OTS function

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



### Observer:

#### 1 Touch **Patient Test**.

In the *Pat. Test - OTS* menu, the **Patient Test** button is grayed out (disabled) until the observer has logged in.

#### 2 Touch **Observer Login**.

3 Wait until the observer list is displayed.

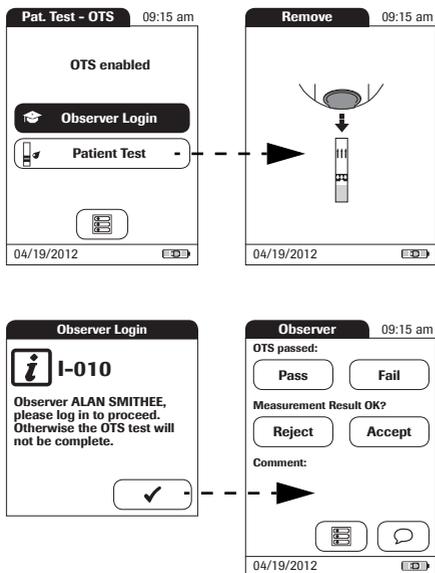
4 Select your observer ID by touching the corresponding button, or scan your operator ID (which is also your observer ID in this case)..

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

5 Enter the (optional) password.

6 After you enter your password, touch  to log in. The *Pat. Test - OTS* menu is displayed again. The **Patient Test** button is now active.

7 Hand the meter to the operator who can now perform the patient test under supervision.



### Operator:

#### 1 Touch **Patient Test**.

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

#### 2 Hand the meter back to the observer.

### Observer:

#### 3 Touch ✓ to log in again.

#### 4 After you enter your password, touch ✓ to proceed with the assessment.

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

#### 6 Assess the test result by touching **Accept** or **Reject**.

#### 7 Touch to add a comment.

#### 8 Touch ✓ to return to the *Pat. Test - OTS* screen.

The OTS information is saved together with the test result.

This page intentionally left blank.

## Index

### A

Adapter (power supply).....	26
Admin. password.....	60–65
Applying a blood sample.....	94
Auto Off.....	54

### B

Barcode.....	86, 91
Masks.....	144
Symbolologies.....	146
Barcode scanner.....	23
Batteries.....	17–18, 26
Inserting.....	29
Types.....	27
Battery pack.....	17–18, 26, 125
Beeper.....	51, 92, 106
Blood sample (testing).....	79–99

### C

Capillary blood sample (testing).....	79–99
Cleaning.....	126–132
Meter housing.....	127
Test strip guide.....	128
Coagulation process.....	94
Code chip.....	83–84
Inserting.....	83
Code number.....	84
Comments	
Adding.....	98
Computer.....	57
Connection.....	57
Contrast.....	38
Control solution	
Applying.....	109
Code chip.....	107
Preparing.....	102
Custom range.....	71, 72

**D**

- Data transfer ..... 119
- Date ..... 43
- Disinfecting
  - Meter housing ..... 130
  - Test strip guide ..... 131
- Disinfection ..... 126–132
- Display
  - Icons ..... 24–25
- Display format ..... 47
- Disposal ..... 17, 27, 81, 99, 111

**E**

- Error messages ..... 133

**F**

- Fingertip ..... 94

**I**

- Icons
  - Drop ..... 93
  - Dropper ..... 108
  - Hourglass ..... 93, 108
  - Identification plate ..... 5
  - Overview ..... 24–25
  - Packaging ..... 5
- ID Setup ..... 58–69
  - Overview ..... 58
- Infrared interface ..... 23, 119

**K**

- Keypad ..... 86

**L**

- Lance ..... 94
- Language ..... 42
- Laser ..... 23
- Lockout
  - Operator ..... 76
  - Quality Control ..... 74, 88
- Logout ..... 87

**M**

Mains voltage .....	21, 141
Measurement	
Performing .....	88–99
Preparing .....	82
Measuring range.....	96, 141
Memory	
Button .....	115
Patient Result.....	116
Quality Control .....	117
Meter	
Overview .....	22

**O**

Observed Test Sequence (OTS).....	155–157
Operating conditions .....	21, 141
Operator	
Lockout .....	76
Logout.....	87
Password .....	87
Operator ID.....	66
Operator list.....	87, 120
Options.....	49–57
Ordering.....	142
Overview	
Meter elements.....	22
Setup.....	34–37

**P**

Password .....	87
Patient ID.....	67
Patient list .....	90, 121
Power adapter .....	26
Power on .....	85
Power supply	
Charging terminals (Handheld Base Unit) .....	23
Product specifications .....	141
Putting the meter into operation .....	28–30

**Q**

QC Range ..... 71

QC Settings ..... 70–75

Quality Control

- Lockout ..... 74, 88
- Memory ..... 117
- Preparing ..... 102
- Result ..... 110

**R**

Relative humidity ..... 21, 141

Reset button ..... 23

Result confirmation ..... 41, 97

Review Results ..... 113–123

- Data transfer ..... 119

**S**

Safety

- Protection against infection ..... 16
- User qualification ..... 16

Scan (button) ..... 86, 91

Screen ..... 38–48

Setup

- Admin. password ..... 60–65
- Auto Off ..... 54
- Beeper ..... 51
- Computer ..... 57
- Contrast ..... 38
- Date ..... 43
- Display format ..... 47
- ID Setup ..... 58–69
- Language ..... 42
- Operator ID ..... 66
- Options ..... 49–57
- Patient ID ..... 67
- Result confirmation ..... 41
- Screen ..... 38–48
- Sort ..... 49
- Time ..... 45
- Units ..... 39

Software license .....	147
Sort .....	49
Storage.....	125
Switching on the meter.....	85
Symbols	
Error messages .....	133
System Administrator .....	60–65
<b>T</b>	
Target value.....	73
Temperature range.....	21, 79, 141
Test principle .....	13
Test result (patient test).....	96
Test result (quality control) .....	110
Test strip	
Icon.....	92, 106
Inserting.....	92, 106
Test strip guide cover .....	128, 131
Thromboplastin .....	13
Time.....	45
Troubleshooting.....	133
<b>U</b>	
Unit (test result).....	96
Units (of measure).....	39
<b>V</b>	
Voltage.....	21
<b>W</b>	
Warranty.....	154

This page intentionally left blank.

---

**Notes:**

---

**Notes:**



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



Roche Diagnostics GmbH  
Sandhofer Strasse 116  
68305 Mannheim, Germany

Made in Germany

Manufactured for and distributed in the U.S.A. by:  
Roche Diagnostics  
9115 Hague Road  
Indianapolis, IN 46250-0457

Rx only

[www.roche.com](http://www.roche.com)  
[www.coaguheck-usa.com](http://www.coaguheck-usa.com)  
[www.usdiagnostics.roche.com](http://www.usdiagnostics.roche.com)