

CoaguChek[®] XS Plus System

User Manual



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The following U.S. Patents have been granted for the CoaguChek XS Plus System (meter and test strips): 6,645,368; 6,662,439; 7,073,246; 7,386,937; 7,407,811; 7,429,865; 7,049,131; 7,084,251; 5,625,036; 6,881,378; 6,207,000. Additional U.S. Patents pending.

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

 Caution (consult accompanying documents). Refer to safety-related notes in the manual accompanying this instrument.

 Temperature limitation (Store at)

 Use by

 Manufacturer

 Batch code/ Lot number

 Catalog number

 In vitro diagnostic medical device

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

 Consult instructions for use

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The CoaguChek XS Plus System

The CoaguChek XS Plus System is used to monitor coagulation (blood-clotting) values (prothrombin time, PT, Quick value) with CoaguChek XS PT test strips.

Please note: This manual contains the information you need to operate and care for the CoaguChek XS Plus System. Please read this entire manual carefully before you use the meter.

The CoaguChek XS Plus System

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Introduction

The CoaguChek XS Plus System

The CoaguChek XS Plus System measures blood-clotting time (prothrombin time) for people who are taking anticoagulation medications, such as Coumadin® or warfarin. The CoaguChek XS Plus System measures blood-clotting time using blood from the fingertip or whole blood from a vein (nonanticoagulated venous whole blood).

The CoaguChek XS Plus System quantitatively measures prothrombin (blood-clotting) time (PT/Quick value/INR). INR is a measure of the rate at which blood clots. A low INR can increase the risk of blood clots, while a high INR can increase the risk for internal bleeding. The patient's physician will determine the best INR range for that patient, depending on why the patient is taking anticoagulants and how the patient reacts to them. The doctor will also determine how often the patient needs blood testing.

The system includes the CoaguChek XS Plus meter and CoaguChek XS PT test strips. Optional liquid CoaguChek XS Plus PT Controls are also available. The meter guides you through the test step by step using the symbols 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.

The CoaguChek XS Plus System makes coagulation testing easy. You only need to insert the code chip, turn the meter on, insert the test strip, and apply a blood sample. The blood mixes with the ingredients on the test strip, and the meter determines when the blood is clotted. The meter displays the result in about one minute. After the measurement, the meter automatically stores the results in memory so you can easily recall them. The patient's physician will use these results to successfully treat the patient's condition.

The CoaguChek XS Plus System also includes data management with security features, such as the QC (quality control) lockout for use with optional liquid quality controls.

Please note: Before you use the meter for the first time (after you have first inserted the batteries), you must set the date and time correctly to allow you to carry out measurements properly.

Each time you replace the batteries you need to check (and, if necessary, adjust) the date and time.

If you need technical help, call Roche Diagnostics Technical Service Center at 1-800-428-4674, 24 hours a day, 7 days a week, 365 days a year.

Test principle

The CoaguChek XS PT Test, used as directed with the CoaguChek XS Plus Meter, will provide an electrochemical measurement of prothrombin time following activation of blood coagulation with human recombinant thromboplastin. In simple terms, blood works with the chemicals in the test strip to make a small electric current in the test strip that measures blood-clotting time.

Contents of the pack

- CoaguChek XS Plus meter
- Power adapter
- User manual
- Training DVD
- Getting Started Guide
- Warranty Card
- Policy and Procedure CD
- 4 AA Batteries
- 5 CoaguChek Lancets

Safety Information



Protection against infection

Medical staff using the CoaguChek XS Plus System to perform tests on patients must be aware that any contact with human blood is a potential source of infection.

- Use gloves.
- Use a separate lancet and lancing device for each person.
- Dispose of used lancets and test strips in a sturdy sharps container with a lid.
- Follow all health and safety regulations applicable to your laboratory or practice.

Operating conditions

To be sure that your CoaguChek XS Plus System functions properly, please observe the following guidelines:

- Only use the meter at a room temperature between 59°F and 90°F (15°C and 32°C).
- Only use the meter at a relative humidity between 10 and 85 percent.
- When operating the meter using the power adapter, use only a voltage of 100 V to 240 V ($\pm 10\%$), 50/60 Hz.
- A touch screen makes the meter easier to operate. To use the touch screen, simply use your finger (even when wearing gloves) or special pens designed for use with handheld devices to select a screen prompt. Pointed or sharp objects can damage the touch screen. Touch lightly, holding until the prompt is selected.
- When testing, place the meter on a level, vibration-free surface, or hold it so it is roughly horizontal.



Electromagnetic interference

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

Quality control

The CoaguChek XS Plus System has a number of built-in quality-control functions.

- A check of the electronic components and functions every time the meter is turned on.
- A check of the test strip temperature while a test is in progress.
- A check of the expiration date and lot information on the test strip carried out by the code chip.
- A two-level, on-board quality control test and patient result determination within a single test chamber.

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

About this manual

Manual format

The layout of this operator's manual has been specially designed to help you locate the most important information quickly and easily.

All instructions that require you to actively do something, as well as very important information, appear on a blue background.



This symbol draws attention to the possible risk of injury or of harm to your health.

Example 1:

The left column contains an illustration of the display screen.

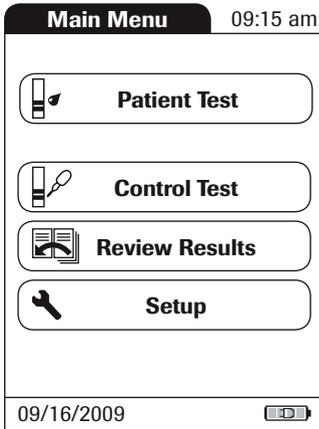
The right column states what you should do at this point.



1 Touch PATIENT TEST.

Example 2:

This column contains an illustration of the display screen.

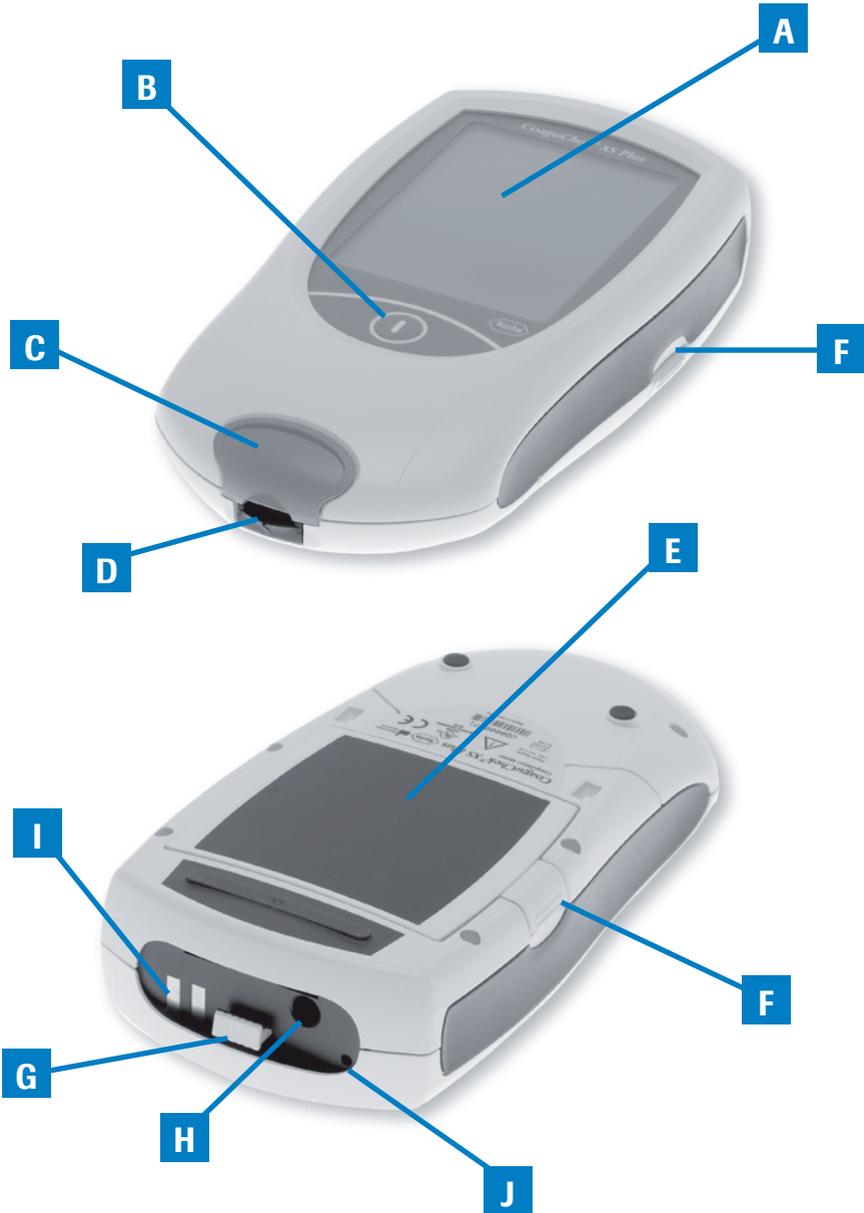


This column contains information linked to the display screen.

The main menu of the CoaguChek XS Plus System contains buttons for the following functions:

- **Patient Test** for performing a test
- **Control Test** for performing an optional liquid quality control test
- **Review Results** to recall results from the memory
- **Setup** to edit settings

The CoaguChek XS Plus meter



Meter elements overview

A Touch screen

Shows results, information, symbols and results recalled from memory. To select any of the screen prompts, touch the prompt lightly, holding until the prompt is selected.

B On/Off button

Press and hold this button until the meter turns on or off.

C Test strip guide cover

Remove this cover to clean the test strip guide. (REF 05039657001)

D Test strip guide

Insert the test strip here.

E Battery cover

Covers the battery compartment (four standard AA batteries or a rechargeable battery pack).

F Battery cover tab

Press tab to slide cover off.

G Code chip slot with code chip

Insert the code chip here.

H Connection socket for power adapter

Plug in the power adapter here.

I Contacts for optional base unit

Charges battery pack when connected to base unit.

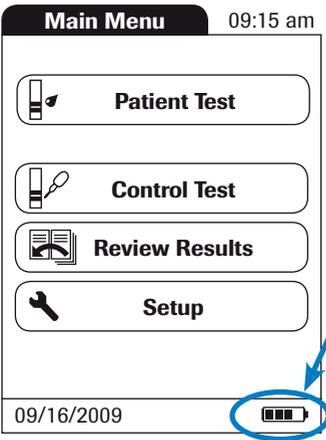
J Infrared interface

Used for data communication.

Power supply

The CoaguChek XS Plus meter can operate with either the power adapter provided, batteries, or a special rechargeable battery pack (REF 04805640001). The CoaguChek XS Plus System uses four AA batteries. The batteries should last for about 60 tests, depending on the type of battery used. You should insert the batteries or optional rechargeable battery pack even when you use the power adapter. This ensures that you will not lose the date and time settings if the power goes out.

To save power, the CoaguChek XS Plus meter has the option to automatically turn itself off based on your setup selections, unless a screen prompt has been pressed or a new test strip has been inserted. The default setting is set to OFF. When the meter turns 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* in the chapter entitled *Options* setup.)



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

When replacing the batteries, you must insert the new batteries within 10 minutes of removing the old ones, to keep the date and time settings. If you take longer than this, you may need to re-enter the date and time. To make sure that you do not lose your date and time settings, connect the power adapter while you change the batteries.

The meter retains results in memory even when no batteries are inserted. All other settings, other than date and time after 10 minutes, are retained as well.

Operating the instrument

Before using the meter for the first time, carry out 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 Plus meter.

Inserting the batteries



1 With the meter turned 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 CoaguChek XS Plus System uses AA batteries. The batteries should last about 60 tests, depending on the type of battery used.)

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

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



Meter setup

Please note: If you have **not** set the date and time (after turning the meter 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, turning on the meter takes you immediately to the Setup mode, where you must set the date and time.

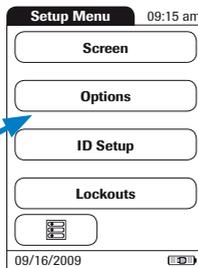
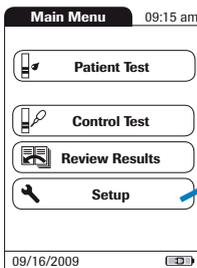
Once the date and time are set, the meter automatically moves to the main menu, where you can start a test or enter more settings. The next time you turn the meter on, the date and time will remain and you will automatically go to the main menu.



You can call up any displayed function by touching the screen prompt for it with your finger (or a special pen for this purpose). Touch the screen lightly, holding until the prompt is selected.

If the meter did not automatically enter the SETUP mode (e.g., after the batteries were replaced), you can call up the SETUP menu from the main menu.

- 1 Touch the **SETUP** screen prompt to call up the meter settings.
- 2 Select the group of settings of choice.

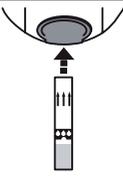
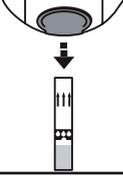


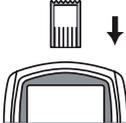
The following screen prompts are used in the *Setup* menus:

- **SCREEN** for changing the way the display looks
- **OPTIONS** for setting SORT, BEEPER, AUTO OFF, and COMPUTER options
- **ID SETUP** for user management and patient management options
- **LOCKOUTS** for optional liquid quality control options

Display field and symbols

The screen prompts that appear during normal operation are shown here, along with their meaning. Error messages and the description of the symbols linked to them are provided in the chapter entitled *Error messages*.

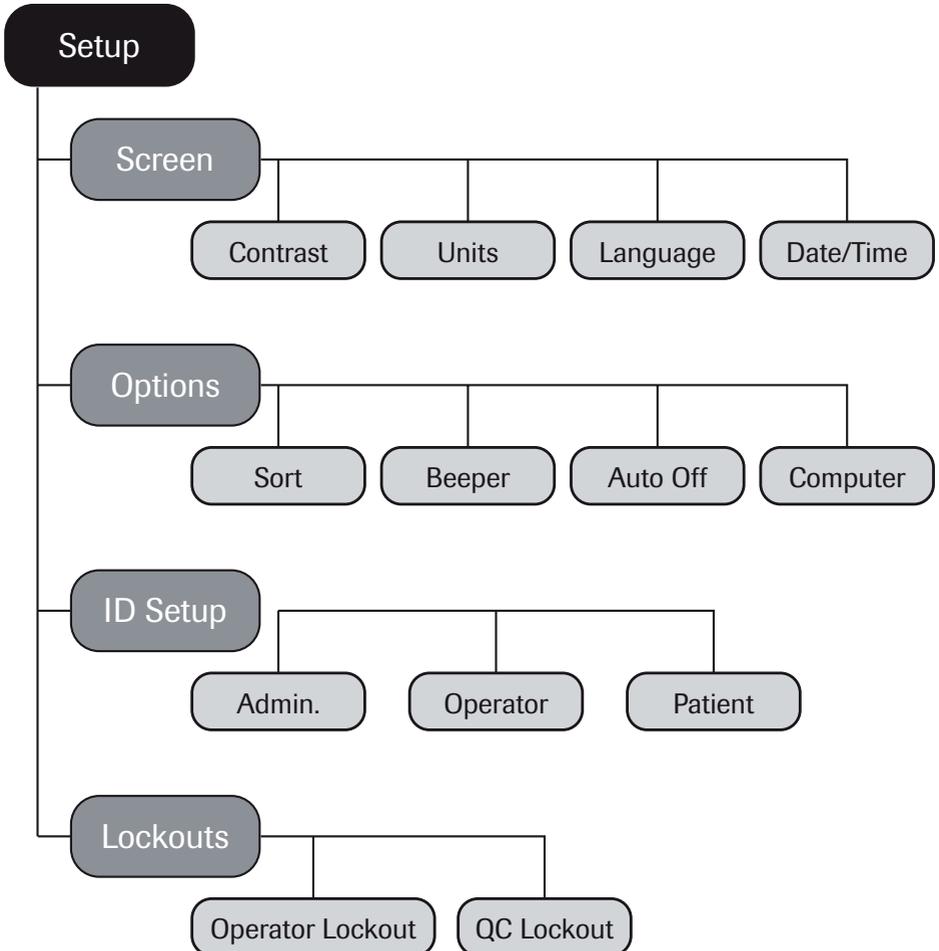
| Symbol | Meaning |
|---|---|
|  | OK, Save setting |
|  | Cancel, discard setting |
|  | Return (to previous menu) |
|  | Reduce/increase the value displayed Move screen contents |
|  | List of tests of a specific patient |
|  | Scroll through the list |
|  | Operator must wait until the meter has completed an action. |
|  | Test strip |
|  | Insert test strip |
|  | Remove test strip |

| Symbol | Meaning |
|---|---|
|  <p>180 SEC</p> | Apply blood sample (the time left to apply sample is counted down in the display) |
|  <p>180 SEC</p> | Apply QC sample (the time left to apply sample is counted down in the display) |
|  | Insert the code chip |
| QC ✓ | Automatic quality control completed successfully |
| %Q | Results are displayed as a Quick percentage value. |
| Sec | Results are displayed in seconds. |
| INR | Results are displayed in INR units. |
| > | Result in the chosen unit of measure is above the measuring range. |
| < | Result in the chosen unit of measure is below the measuring range. |
|  | Quality control: Result is above/below the specified range. |

| Symbol | Meaning |
|---|---|
|  | <p>Battery status:</p> <ul style="list-style-type: none"> • When the batteries still have their full charge, all segments are lit. • Individual segments disappear one by one as the batteries become weaker. • When there is no segment remaining, you can no longer perform a test. However, test results are still saved in memory. |
|  | <p>Operation with power supply adapter</p> |
| <p>am</p> | <p>Time between midnight and noon (in 12-hour time format)</p> |
| <p>pm</p> | <p>Time between noon and midnight (in 12-hour time format)</p> |
|  | <p>Reports a warning message</p> |
|  | <p>Reports an error (see: Error messages)</p> |
|  | <p>Reports a serious error (see: Error messages)</p> |
|  | <p>Room or meter temperature is outside the acceptable range.</p> |
|  | <p>The cover on the test strip guide is open.</p> |
|  | <p>Communication is taking place via the infrared interface</p> |

Settings summary

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



| Group | Subgroup | Setting | Values * | |
|--------|--------------|--------------|--|-------------------------------|
| SCREEN | CONTRAST | | 0 - 10 (5 *) | |
| | RESULT UNITS | | INR * | |
| | | | INR/SEC | |
| | | | INR/%Q | |
| | LANGUAGE | | Dansk | |
| | | | Deutsch | |
| | | | English * | |
| | | | Español | |
| | | | Français | |
| | | | Italiano | |
| | | | Nederlands | |
| | | | Norsk | |
| | | | Português | |
| | | Svenska | | |
| | DATE/TIME | SET DATE | | 01/01/2005 * |
| | | SET TIME | | 12:00 AM * |
| | | Date formats | | Day.Month.Year (12.06.2006) |
| | | | | Month/Day/Year (06/12/2006) * |
| | | | | Year-Month-Day (2006-06-12) |
| | | Time formats | | 24-hour time format (24h) |
| | | | 12-hour time format (12h), with am/pm * | |

* Settings that are in the meter when it leaves the factory are labeled with an asterisk (*).

| Group | Subgroup | Setting | Values * | |
|----------------|----------|------------|-------------------|-------------------|
| OPTIONS | SORT | | DATE/TIME * | |
| | | | PATIENT ID NUMBER | |
| | BEEPER | BEEPER | | OFF |
| | | | | LOW |
| | | | | MEDIUM * |
| | | | | HIGH |
| | AUTO OFF | [minutes] | | OFF * |
| | | | | 1 ... (5)* ... 10 |
| | | | | 15 |
| | | | | 20 |
| | | | | 25 |
| | | | | 30 |
| | | | | 40 |
| | | | | 50 |
| | | | | 60 |
| COMPUTER | | | | ACTIVE |
| | | INACTIVE * | | |

* Settings that are in the meter when it leaves the factory are labeled with an asterisk (*).

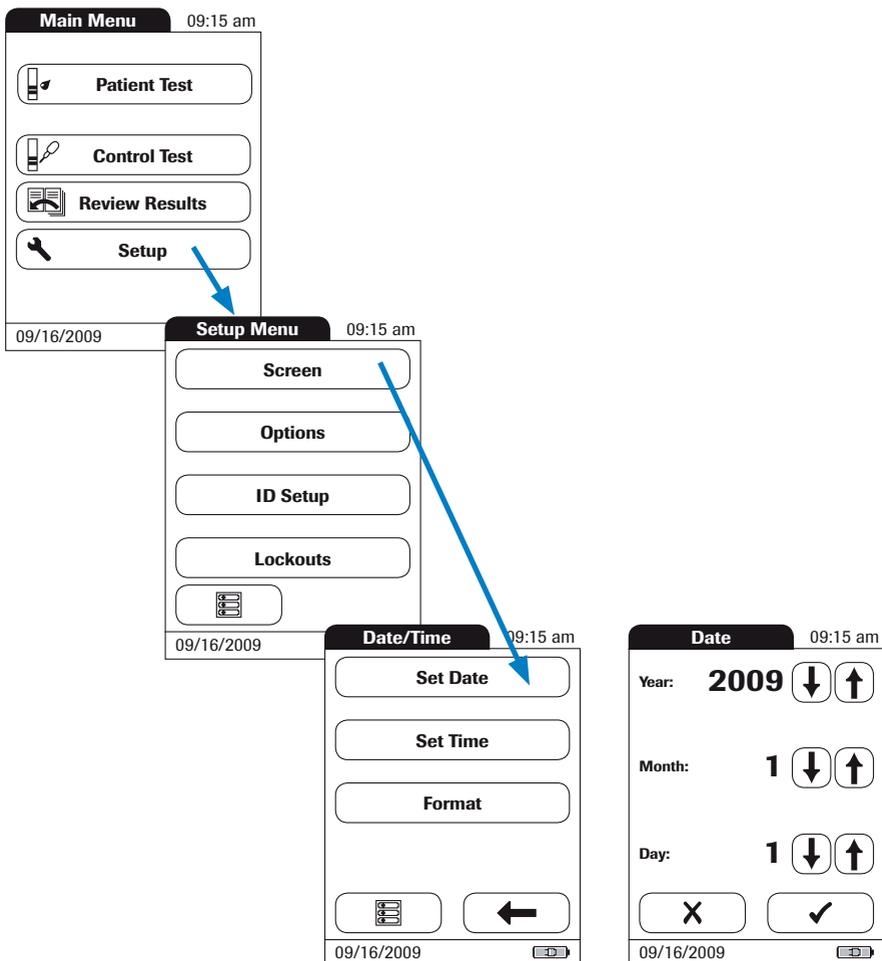
| Group | Subgroup | Setting | Values * |
|-----------------|--|-----------|----------------|
| ID SETUP | Admin. (Administrator) | | Blank (off) * |
| | OPERATOR (Operator list is optional) | | Blank (off) * |
| | PATIENT | | NO |
| | | | OPTIONAL * |
| | | MANDATORY | |
| LOCKOUTS | OPERATOR LOCKOUT (only if the <i>Operator</i> option is set to Action and an operator list is available) | | OFF * |
| | | | WEEKLY |
| | | | MONTHLY |
| | | | EVERY 3 MONTHS |
| | | | EVERY 6 MONTHS |
| | | | YEARLY |
| | QC LOCKOUT | NEW CODE | YES |
| | | | NO * |
| | GENERAL | | NO * |
| | | | DAILY |
| | | | WEEKLY |
| | | | MONTHLY |

* Settings that are in the meter when it leaves the factory are labeled with an asterisk (*).

Conventions used in this manual

This manual refers to all the various operations of the meter. When discussing a particular operation, a picture guide will appear at the top of the page. This guide shows how to navigate to this particular operation from the meter's main menu.

For example: This picture guide shows you how to get from the main menu to the date/time setup section.

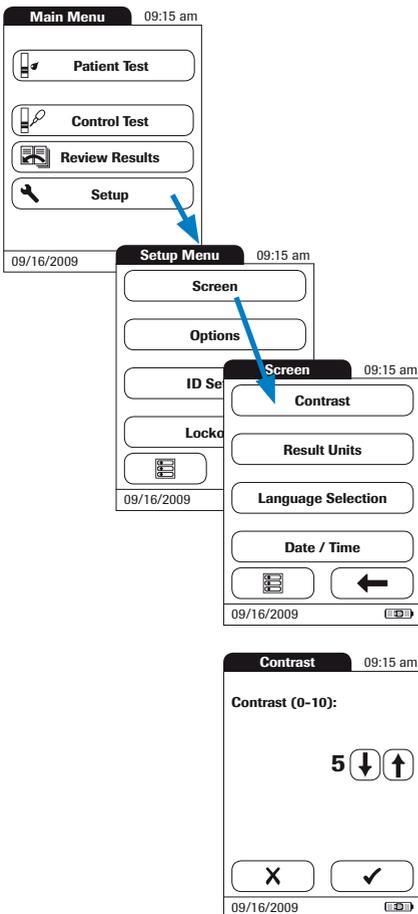


Screen setup

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

Contrast

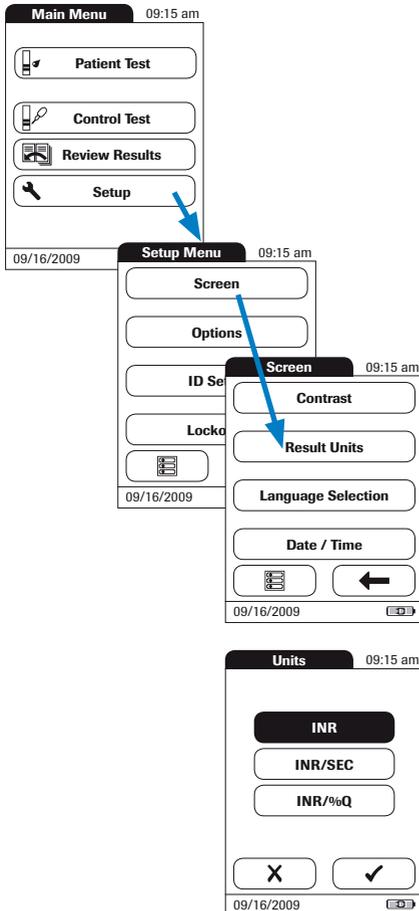
Use this setup option to make the screen display easier to see, depending on the lighting conditions where you are.



- 1 From the main menu screen, touch **Setup** to call up the meter settings.
- 2 From the *Setup* menu screen, touch **Screen**.
- 3 From the *Screen* menu screen, touch **Contrast**.
- 4 Touch  or  to change the contrast to your liking.
- 5 When you have set the contrast to your liking, touch  (OK) to save, or touch  (Cancel) to cancel this procedure. The program automatically returns to the *Screen* menu.

Units

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



- 1 From the main menu screen, touch **Setup**.
- 2 From the *Setup* menu screen, touch **Screen**.
- 3 From the *Screen* menu screen, touch **Result Units**.

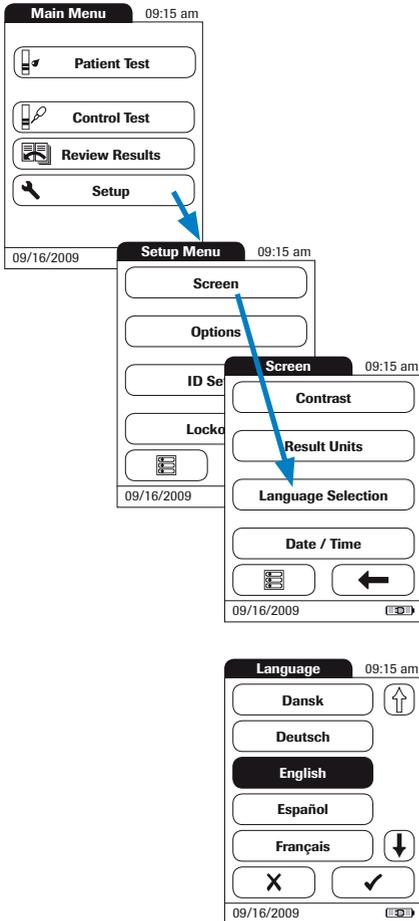
The current unit of measure setting is shown with white type on a black background. You can select either:

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

- 4 Touch the screen prompt to select the unit of measure of choice. Your selection is now displayed with a black background.
- 5 After you make your selection, touch ✓ (OK) to save, or touch ✕ (Cancel) to cancel this procedure. The program automatically returns to the *Screen* menu.

Language Selection

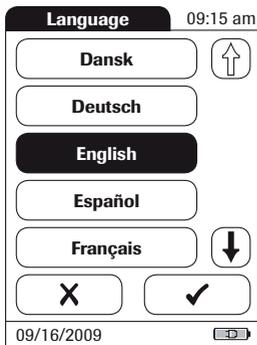
Use this setting to select the language for all displays (that contain text).



- 1 Touch **Setup** in the main menu.
- 2 From the *Setup* menu screen, touch **Screen**.
- 3 From the *Screen* menu screen, touch **Language Selection**.

The current language setting is shown with white type on a black background. You can select any of these languages:

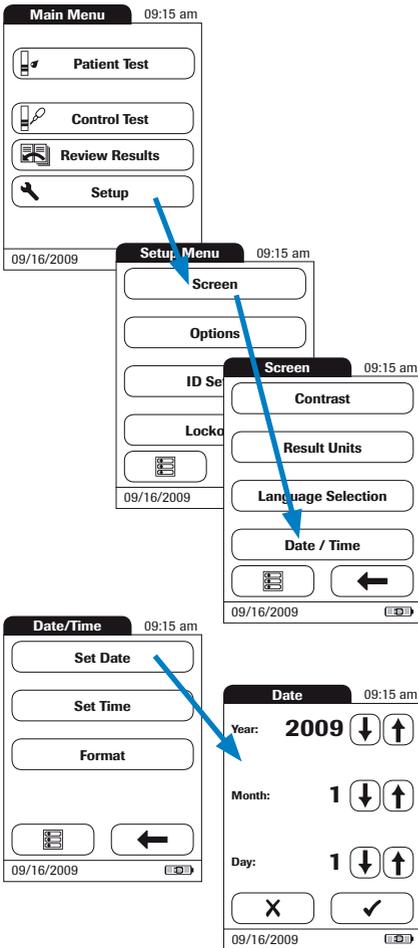
- DANSK
- DEUTSCH
- ENGLISH
- ESPA-OL
- FRANÇAIS
- ITALIANO
- NEDERLANDS
- NORSK
- PORTUGUÊS
- SVENSKA



- 4 Touch  or  to scroll to the language of choice on the screen. If the arrow is just an outline , this means the arrow is not active. On this screen, for example, there are no languages listed above “Dansk”.
- 5 Touch the screen prompt to select the language of choice. Your selection is now displayed with a black background.
- 6 After you have made your selection, save, touch  (OK) to save, or touch  (Cancel) to cancel this procedure. The program automatically returns to the *Display* menu.

Setting the date

When you turn 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 input field of choice.



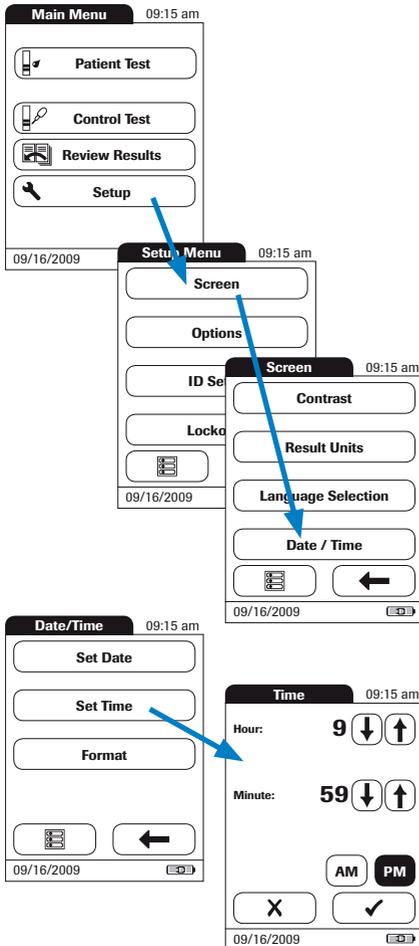
- 1 From the main menu screen, touch **Setup**.
- 2 From the *Setup* menu screen, touch **Screen**.
- 3 From the *Screen* menu screen, touch **Date/Time**.
- 4 From the *Date/Time* menu screen, touch **Set Date** to set the date.
- 5 Touch **↑** or **↓** to set the year, then the month, then the day.
- 6 When you have entered all settings, touch **✓** (OK) to save, or touch **✗** (Cancel) to cancel this procedure. The program automatically returns to the *Date/Time* menu.

Note: If the *Setup* menu appeared automatically after turning the meter on, you must press **✓** to complete the first date setting.

- 7 Touch the back arrow **←** to return to the *Screen* menu screen.

Setting the time

When you turn on the meter for the first time (or after a long period without power), the 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 input field of choice.



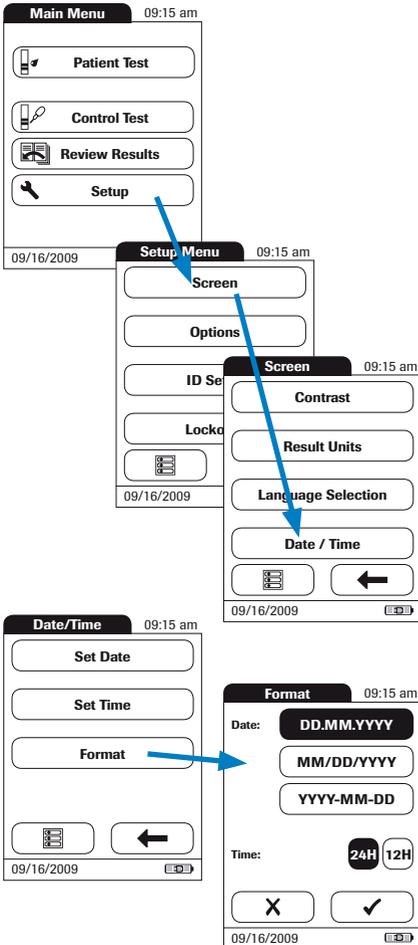
- 1 From the main menu screen, touch **Setup**.
- 2 From the *Setup* menu screen, touch **Screen**.
- 3 From the *Screen* menu screen, touch **Date/Time**.
- 4 From the *Date/Time* menu screen, touch **Set Time** to set the time.
- 5 Touch \uparrow or \downarrow to set the hours, then the minutes. Touch **AM** or **PM**.
- 6 When you have entered these settings, touch \checkmark (OK) to save, or touch **X** (Cancel) to cancel this procedure. The program automatically returns to the *Date/Time* menu.

If the *Setup* menu appeared automatically after turning the meter on, you must press \checkmark to complete the first time setting.

- 7 Touch the back arrow \leftarrow to return to the *Screen* menu screen.

Setting the display options for date and time

You don't have to select display options for date and time, even though you must enter the date and time. However, if you want to reset the time and date formats, first go to the *Setup* menu.



- 1 From the main menu screen, touch **Setup**.
- 2 From the *Setup* menu screen, touch **Screen**.
- 3 From the *Screen* menu screen, touch **Date/Time**.
- 4 From the *Date/Time* menu screen, touch **Format** to set the display format.

The current factory default settings are shown with white type on a black background. You can select one of the following display formats:

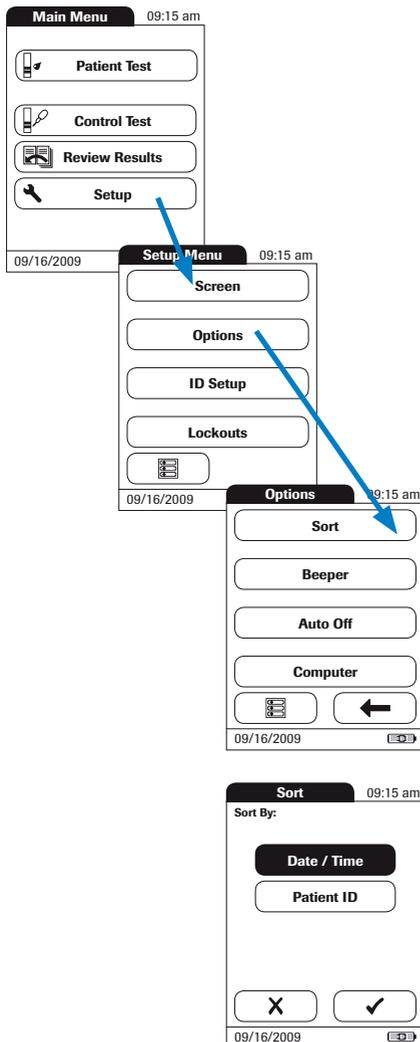
- DD.MM.YYYY, e.g., 15.06.2007
- MM/DD/YYYY, e.g., 06/15/2007
- YYYY-MM-DD, e.g., 2007-06-15
- Time: 24H or 12H

- 5 Touch the screen prompt with the display format of your choice for date and time. Your selection is now displayed with a black background.
- 6 When you have entered both settings, touch ✓ (OK) to save, or touch ✗ (Cancel) to cancel this procedure. The program automatically returns to the *Date/Time* menu.
- 7 Touch the back arrow ← to return to the *Screen* menu screen.

Options setup

Sort

Sort refers to the order in which measured and stored results are displayed when you use your CoaguChek XS Plus meter's memory function. You can display stored results chronologically by date and time or by person, based on the patient ID.



- 1 From the main menu screen, touch **Setup**.
- 2 From the *Setup* menu screen, touch **Options**.
- 3 From the *Options* menu screen, touch **Sort**.

The current factory default setting is shown with white type on a black background. You may select from the following sort options:

- **Date/Time**
- **Patient ID**

- 4 Touch the screen prompt to select the sort option of choice. Your selection is now displayed with a black background.
- 5 When you have made your selection, touch ✓ (OK) to save, or touch ✕ (Cancel) to cancel this procedure. The program automatically returns to the *Options* menu.

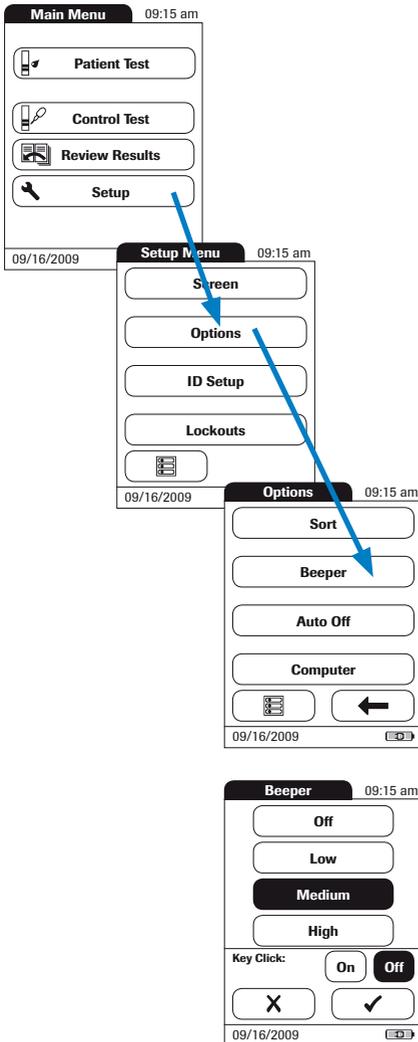
Beeper

Note: Your CoaguChek XS Plus meter can display information visually and alert you to special circumstances with a beeper. When the beeper is activated, the meter beeps when:

- it is switched on
- it detects a test strip
- warming up 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

We recommend that you keep the beeper activated at all times.

You can also activate a key click. When a key click is activated, the meter beeps briefly every time a button is pressed, facilitating the input of information.



- 1 From the main menu screen, touch **Setup**.
- 2 From the *Setup* menu screen, touch **Options**.
- 3 From the *Options* menu screen, touch **Beeper**.

The current setting is shown with white type on a black background. You may select from the following options:

For the beep tone

- Off
- Low
- Medium
- High

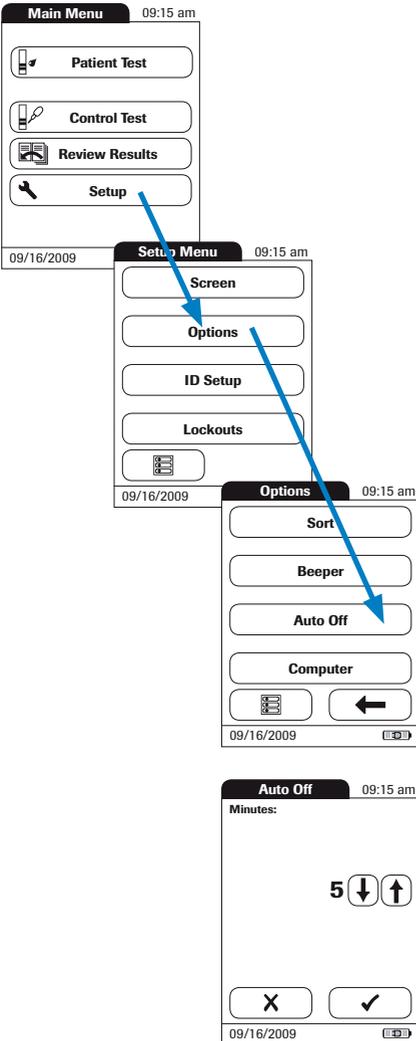
For the key click

- On
- Off

- 4 Touch the screen prompt with the desired setting for the beeper, then touch the prompt with the setting of choice for the key click. Both selections are now displayed with a black background.
- 5 When you have entered both settings, touch ✓ (OK) to save, or touch ✕ (Cancel) to cancel this procedure. The program automatically returns to the *Options* menu.

Auto off

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



- 1 From the main menu screen, touch **Setup**.
- 2 From the *Setup* menu screen, touch **Options**.
- 3 From the *Options* menu screen, touch **Auto Off**.

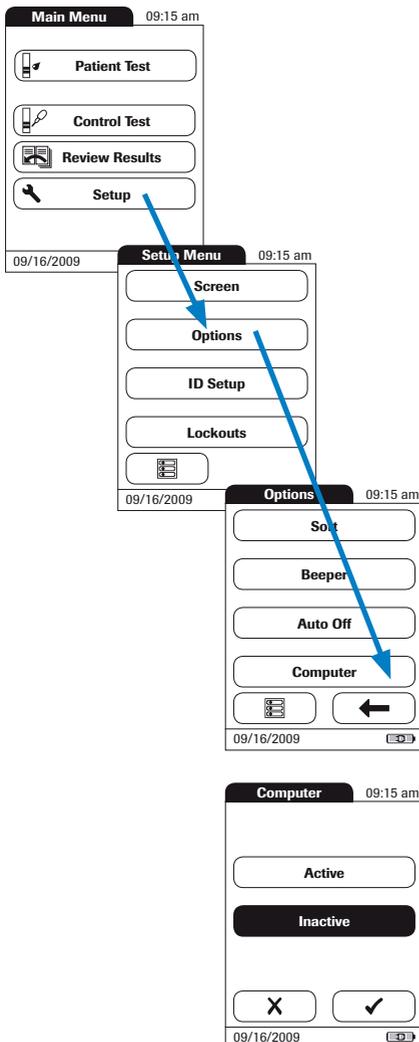
You may select from the following options:

- **Off** (meter never turns itself off)
- Time until meter turns 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 turn the feature off.
- 5 When you have made your selection, touch (OK) to save, or touch (Cancel) to cancel this procedure. The program automatically returns to the *Options* menu.

Computer

Your CoaguChek XS Plus meter can connect with a computer via an infrared interface using optional base unit. Using a computer, you can set up operator or patient lists, for example, or you can transfer test results stored in the meter to a PC for further evaluation. Using this computer capability requires software. The **COMPUTER** screen prompt option allows you to activate or deactivate the meter's ability to communicate with a computer.



- 1 From the main menu screen, touch **Setup**.
- 2 From the *Setup* menu screen, touch **Options**.
- 3 From the *Options* menu screen, touch **Computer**.

You may select from the following options:

- **Active**
- **Inactive**

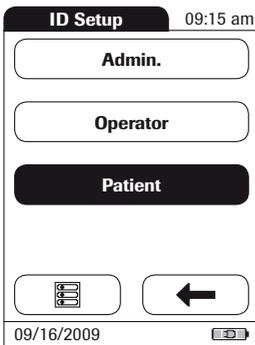
- 4 Touch the screen prompt with the desired setting for communication with the PC. Your selection is now displayed with a black background.
- 5 When you have made your selection, touch ✓ (OK) to save, or touch ✕ (Cancel) to cancel this procedure. The program automatically returns to the *Options* menu.

ID Setup

Use the *ID Setup* screen to enter settings for user management and patient management. These settings are optional; the meter can be operated without these settings.

There are three types of identification used with the CoaguChek XS Plus meter:

- The *System Administrator*, who has special rights to enter certain meter settings (provided the administrator has been set up), and is the only one who can enter and change these settings. It is not necessary for Administrator identification to be activated to use the CoaguChek XS Plus meter. However, it can be desired or necessary, depending on the environment and site of use.
- The *Operator*, who uses the meter to test patients. Operators are defined in the CoaguChek XS Plus meter using external software (i.e., in operator lists managed by the facility's meter administrator. Administrators assign operator passwords and expiration dates and may download these lists into the meter). This option can be helpful in a clinical setting to provide further documentation and to ensure that the meter is used only by qualified personnel.
- The *Patient*, whose test results are recorded. You can block input of a unique patient ID (in this case, every test is simply numbered in consecutive order), permit it, or require it for every test.



The screen prompts in ID Setup show what the current settings are, and how the particular area is set up:

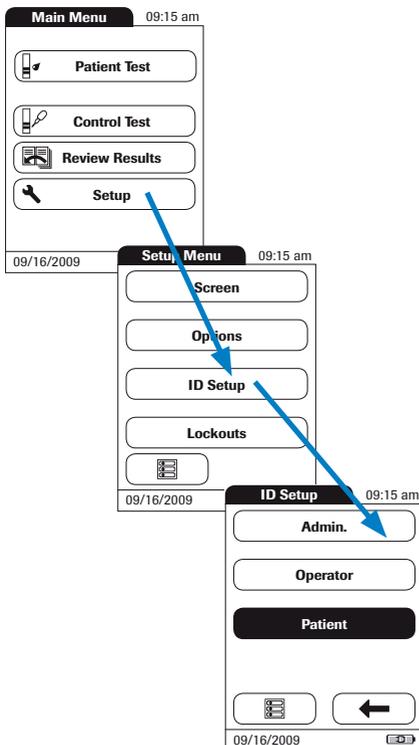
- The standard display of **Admin.** means the function is available but not activated (an Admin. password has not been assigned).
- When the text in the **Operator** prompt is displayed in gray, this means an operator list has not been loaded (from the PC). The function is not available.
- When the **Patient** button has a black background, this means the function is available and activated (either as an option or a requirement).

System Administrator (Admin.)

In the default setting, the meter is not protected with an *Admin.* password, and all setup options are accessible to anyone. If you set up a *Admin.* password, the following setup areas are automatically reserved only for the *Admin.*:

- **Screen: Units, Date/Time**
- **Options:** (connection to a) **computer**
- **ID Setup** (the entire area)
- **QC Lockout**
- **Operator Lockout** (only available with optional software)

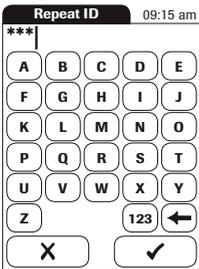
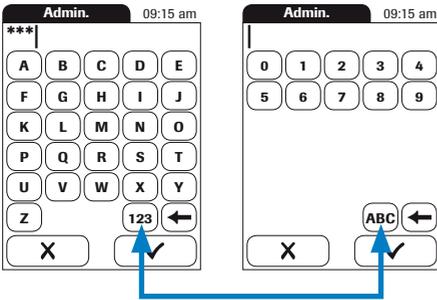
Please note: When you enter a *Admin.* password, this password must be entered from this point forward before a password can be set up (anywhere in the *ID Setup* menu). The *Admin.* password also must be entered before you can delete or change it.



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

- 1 From the main menu screen, touch **Setup**.
- 2 From the *Setup* menu screen, touch **ID Setup**.
- 3 Touch **Admin.**

Meter setup



4 Using the keypad displayed on the screen, enter the *Admin.* password of choice. The password should include up to 20 characters and/or symbols of choice. Pay close attention to the buttons you press, because the actual characters and/or symbols 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 numbers and special characters.

6 Use **ABC** to switch back to input text.

7 Use **←** to backspace and correct a mistake.

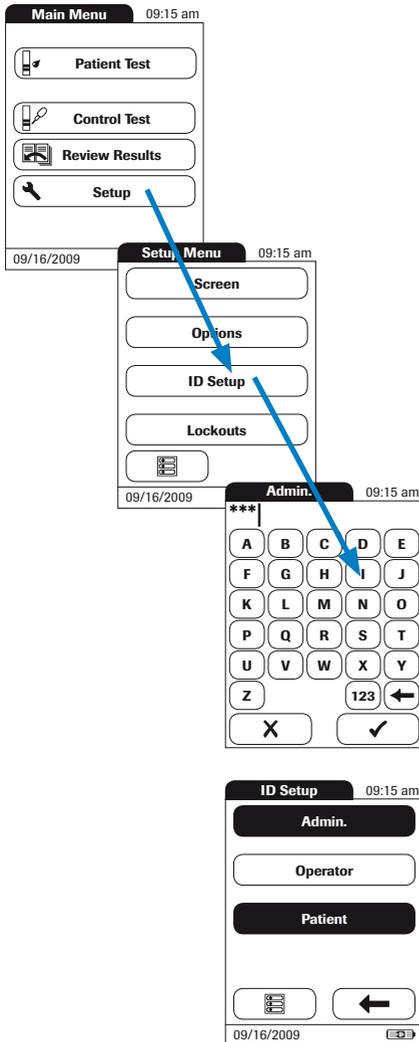
8 When you have completed the entry, touch **✓** (OK) to save, or touch **X** (Cancel) to cancel this procedure.

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

When you **save** the entry, the *Admin.* password is set.

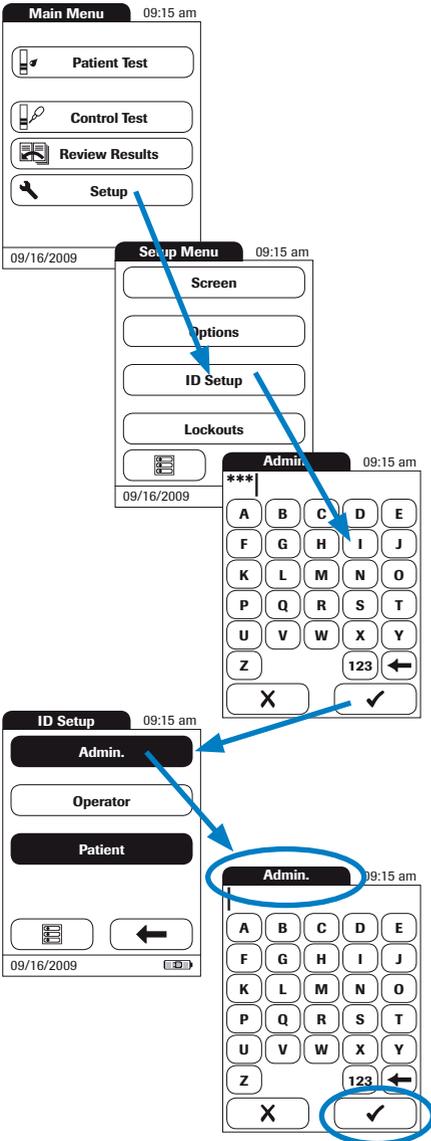
When you **cancel** the entry, the *Admin.* password is not set and is therefore inactive.

The program automatically returns to the *ID Setup* menu. Exit the *Setup* menu to activate the *Admin.* function. After you return to the main menu screen, only an authenticated administrator may set up any further passwords.



Changing an existing Admin. password:

- 1 From the main menu screen, touch **Setup**.
- 2 From the *Setup* menu screen, touch **ID Setup**.
- 3 Using the keypad displayed on the screen, enter the valid *Admin.* password.
The *ID Setup* is displayed. The **Admin.** screen prompt has a black background, which means a *Admin.* password is active.
- 4 Touch **Admin.** and use the keypad on the screen to enter a new ID of choice (enter it twice).



Deactivating an existing Admin. password:

- 1 From the main menu screen, touch **Setup**.
- 2 From the *Setup* menu screen, touch **ID Setup**.
- 3 Using the keypad displayed on the screen, enter the valid *Admin.* password. Touch ✓ (OK).

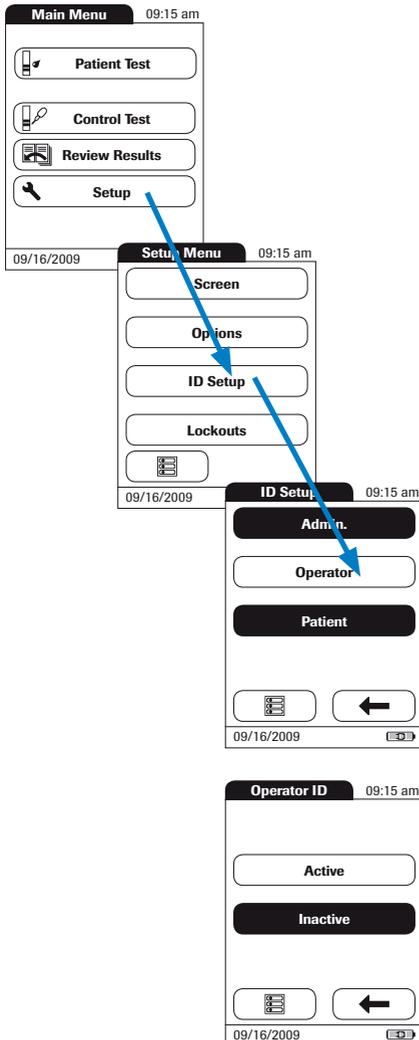
The *ID Setup* is displayed. The **Admin.** prompt has a black background, which means a *Admin.* password is active.

- 4 Touch **Admin.**
- 5 Touch ✓ (OK) to close the keypad on the screen **without** entering a password.

The *Admin.* password has been deleted and therefore deactivated. The **Admin.** prompt is now displayed with a white background.

Operator (only available with optional software)

To specify operators, an operator list must be created on the PC and downloaded into the meter using software. In the default setting, the meter is not set up for use with *Operator ID* numbers. You can enter settings to activate or deactivate the use of the operator list. Otherwise, the **Operator** screen prompt is not active (gray).



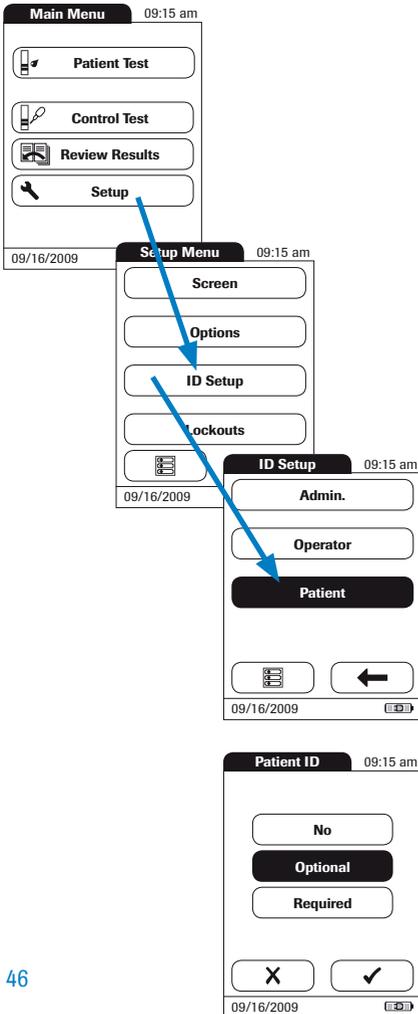
If Operator ID numbers are available:

- 1 From the main menu screen, touch **Setup**.
- 2 From the *Setup* menu screen, touch **ID Setup**.
- 3 Touch **Operator**.
- 4 Touch the screen prompt with the setting of choice (active or inactive) for setting up the *Operator ID* number. Your selection is now displayed with a black background.
- 5 When you have made your selection, touch ✓ (OK) to save, or touch ✕ (Cancel) to cancel this procedure. The program automatically returns to the *ID Setup* menu.

Patient

In the default setting, input of *Patient ID* is “optional.” This means a *Patient ID* can be entered for each test, but this isn’t required. If you don’t enter a *Patient ID*, the test is simply assigned a consecutive number (the same as when the *Patient ID* is deactivated). However, you can require that a *Patient ID* be entered.

To set up a patient list, it must be created on the PC and downloaded into the meter using software.



- 1 From the main menu screen, touch **Setup**.
- 2 From the *Setup* menu screen, touch **ID Setup**.
- 3 Touch **Patient**.

You may select from the following options:

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

- 4 Touch the screen prompt with the setting of choice. Your selection is now displayed with a black background.
- 5 When you have selected the option, touch ✓ (OK) to save, or touch ✕ (Cancel) to cancel this procedure.

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

Patient ID 09:15 am

Alphanumeric

Numeric

Max. Length: 20 ↓ ↑

X ✓

09/16/2009

- 6 Select the input format of the *Patient ID* to be entered.

You may select from the following options:

- **Alphanumeric** (text and numbers, e.g., “J. Doe 3378”)
- **Numeric** (numbers only, e.g., “3387”)
- **Max. Length:** Indicate the maximum number of characters (1 ... 20) the *Patient ID* can have.

- 7 Touch the screen prompt with the format of choice for the *Patient ID*. Your selection is now displayed with a black background.
- 8 Touch ↑ or ↓ to set the number of characters (length) of choice.
- 9 When you have entered all settings, touch ✓ (OK) to save, or touch X (Cancel) to cancel this procedure. The program automatically returns to the *ID Setup* menu.

Lockouts setup

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

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

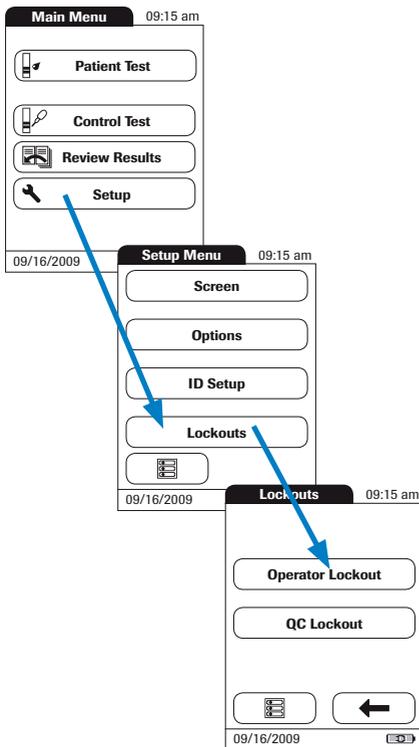
The option of setting up lockouts for operators is available only when operator lists are stored in the meter and are activated. These lists are only available through the use of your computer and the optional base unit.

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

Operator lockout (only available with optional software)

To perform a test with the CoaguChek XS Plus meter, the individual steps must be performed properly. Optional liquid quality control can be performed on a regular basis to ensure proper performance of these steps.

The operator lockout prescribes regular liquid quality controls of this type for each operator (who has been set up).



1 From the main menu screen, touch **Setup**.

2 From the *Setup* menu screen, touch **Lockouts**.

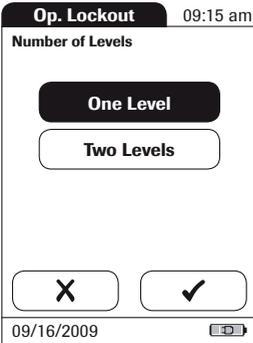
3 Touch **Operator Lockout**.

If this button is shown in gray (inactive), either no operators have been set up or the *Operator ID* option has been deactivated.

4 Select the interval of choice in which the mandatory liquid quality control tests must be carried out.

You may select from the following options:

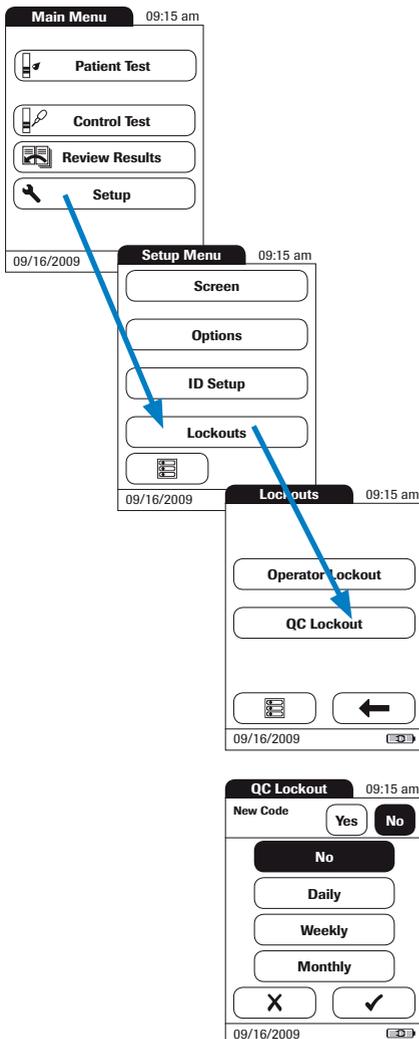
- No (deactivated)
- **Weekly**
- **Monthly**
- **Every 3 Months** or **Every 6 months**
- **Yearly**



- 5 Touch  or  to display the option of choice on the screen. If the arrow is just an outline , this means the button is not active.
- 6 Touch the screen prompt to select the interval of choice. Your selection is now displayed with a black background.
- 7 When you have selected the option of your choice, touch  (OK) to save, or touch  (Cancel) to cancel this procedure without saving.
- 8 For every option except **No**, you must now indicate the number of levels in which the liquid quality control must be performed.
- 9 When you have selected the option, touch  (OK) to save, or touch  (Cancel) to cancel this procedure. The program automatically returns to the *Lockouts* menu.

QC (Quality control) lockout

QC Lockout ensures that the optional liquid quality control tests are run on a regular basis for the meter to be used. This is independent of the operator, however. Use this option if you work without operator lists. It is also possible to mandate *Operator (OP) Lockout* and *QC Lockout* in parallel. In addition to defining time intervals, **QC Lockout** can also be used to specify that a liquid quality control test must be carried out when a new test strip lot is used (new code).



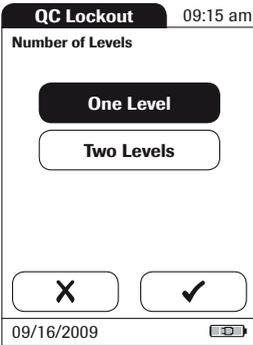
- 1 From the main menu screen, touch **Setup**.
- 2 From the *Setup* menu screen, touch **Lockouts**.
- 3 Touch **QC Lockout**.
- 4 Make a selection, based on lot and/or time, for requiring a liquid quality control test.

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 screen prompt with your option of choice for changing the test strip lot.
- 6 Touch the screen prompt to select the interval of choice. Your selection is now displayed with a black background.
- 7 When you have selected the option of your choice, touch ✓ (OK) to save, or touch ✕ (Cancel) to cancel this procedure.
- 8 For every option except for **No**, you must now indicate the number of levels in which the liquid quality control must be performed.
- 9 When you have selected the option of your choice, touch ✓ (OK) to save, or touch ✕ (Cancel) to cancel this procedure. The program automatically returns to the *Lockouts* menu.

Testing a capillary blood sample

Gather what you need:

- CoaguChek XS Plus meter
 - CoaguChek XS PT Test Strips and matching code chip
 - CoaguChek Lancet
 - CoaguChek Capillary tube/bulb (optional)
- Do not use glass capillary tubes or capillary tubes that contain anticoagulants.
- Cotton ball and alcohol wipe

Important notes

Always ...

- ... close the container immediately after having removed a test strip.
- ... operate the meter at an ambient temperature between 59°F and 90°F (15°C and 32°C).
- ... 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 the chapter entitled *Cleaning*.



When collecting samples always observe the general precautions and guidelines related to blood sampling.

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

Never ...

- ... store the meter at extreme temperatures (greater than 104°F or 40°C).
- ... 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 other than the one in use.
- ... touch or remove the test strip during a test.
- ... wait more than 15 seconds after lancing the fingertip before applying the blood.
- ... add more blood after the test has begun.
- ... perform a test with a drop of blood from a previous puncture.



Failure to comply with the above may lead to inaccurate results.

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, use a hand warmer, or wash with warm water.
- Have the patient let that arm hang down by his or her side before lancing a finger.
- Massage the finger from its base.

Use these techniques until the fingertip has increased color.

- Immediately after lancing, massage gently along the side of the finger to obtain a good blood drop without pressing or squeezing too hard.
- Apply the blood drop directly to the test strip immediately (within 15 seconds). Optionally, you may use a CoaguChek Capillary tube/bulb to collect the fingerstick blood sample (REF 11621173001).

Getting a good test with venous whole blood

As an alternative to performing a test with capillary blood, you can also perform a test using venous whole blood. Please note the following:

- Use a plastic syringe to collect the blood sample. Do not use anticoagulants (EDTA, citrate, oxalate or heparin) to collect the blood sample.
- Use a needle at least 23 G or larger in size.
- Discard the first four drops of blood. Then, immediately place one drop of blood (at least 10 μ l) directly onto the target area of the test strip, being sure not to introduce air bubbles into the sample.

Follow the appropriate infection control guidelines in force in your facility.

- Use gloves.
- Use a lancing device that is approved for use by healthcare professionals.
- Dispose of used lancets and test strips in a sturdy sharps container with lid.
- Follow all health and safety regulations in force locally.



Medical staff and other persons using the CoaguChek XS Plus meter to perform tests on more than one patient must be aware that any object coming into contact with human blood is a potential source of infection. (See: Clinical and Laboratory Standards Institute: Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline - Third Edition; CLSI document M29-A3, 2005.)

Preparing to test



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

Test strip code chip

The test strip 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 test strip code chip is required when a new test strip container is opened to store the lot information about the test strips in the meter.

Your CoaguChek XS Plus meter stores the data from up to 60 code chips that were inserted.

- Don't forget to use the test strip code chip that was supplied with each new test strip container before you perform the first test. 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 (with a new code chip).
- 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.

Store the code chip with the appropriate strip lot.



- 2 Always make sure 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.

Always compare the code number you see on the display with the number that is printed on the test strip container you are using. If the two code numbers don't match, insert the correct code chip in the slot in the meter.

If the code chip is missing or incorrectly inserted, error messages appear in the display. (Please refer to the chapter *Error messages*.)

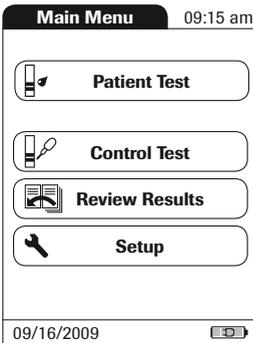
Switching on the meter



- 1 Place the meter on a level, vibration-free surface, or hold it in your hand so it is roughly horizontal. Turn the meter on by pressing the On/Off button  and holding until the meter turns on. Alternatively, you can insert a test strip or connect it to the power adapter to turn it on.

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

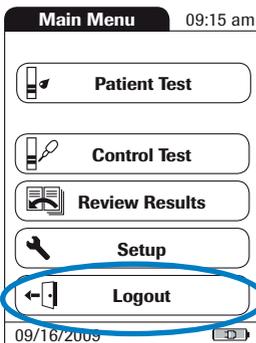
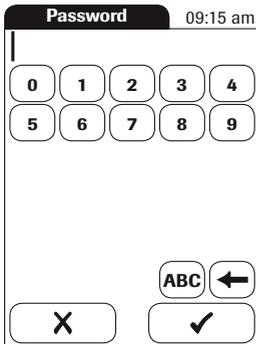
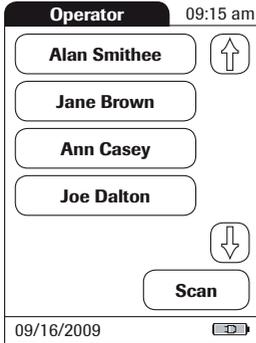
Without operator list



- 2 Wait until the main menu is displayed.

If no operator list exists, go to Step 8.

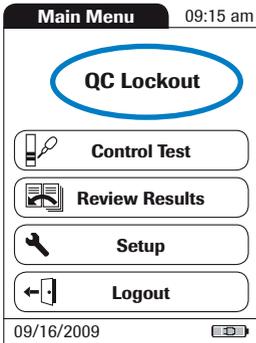
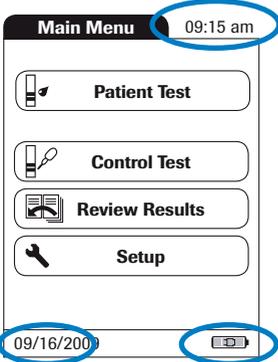
With operator list (only available with optional software)



- 3 If an operator list exists, wait until this list is displayed.
- 4 Select the operator of choice by touching the screen prompt for it. Touch  or  to scroll to the language of choice on the screen. If the arrow is just an outline , this means the arrow is not active.
- 5 Enter the password provided by your facility's meter supervisor.
- 6 After you enter the password, touch  (OK) to log on. The main menu is displayed and you can start the test.
- 7 When you touch  (Cancel), the operator pick list is displayed again.

When the tests are completed or another operator wants to perform additional tests, touch the **Logout** prompt to log out. (This screen prompt is available only when the operator list is displayed.) The meter returns to the display of the operator pick list.

Performing a test

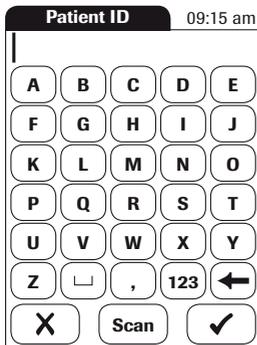


- 8 Check the battery level. If there are no bars left in the battery symbol, you cannot perform any more tests.
- 9 Check that the date and time are correct. Correct any wrong entries as described in the chapter entitled *Meter setup/Setting the date*.

If a lockout (*OP* or *QC Lockout*) is displayed instead of **Patient Test**, you must run a liquid quality control before you can perform a test. (Refer to the chapter entitled *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



10 Touch **Patient Test**.

11 If the Patient ID option was chosen as either optional or required when the meter was set up (see *Meter Setup, ID Setup*), you are prompted to enter a Patient ID.

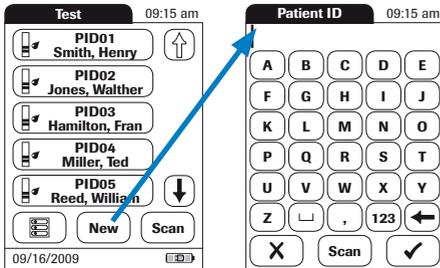
If *required*, enter the Patient ID, then press ✓ (OK) to move to the next screen.

If *optional*, ignore the prompt and press ✓ (OK) 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.

If no patient list exists, go to Step 15.

With patient list (only available with optional software)



12 Touch **Patient Test**.

13 Select the patient to be tested from the list that is displayed. Touch  or  to display the entry of your choice. If the arrow is just an outline , this means you have reached the end of the list. After you have selected the patient, the screen appears that prompts you to insert the test strip.

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

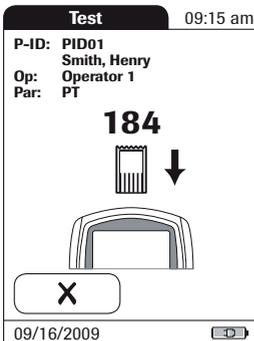


- 15** The test strip symbol prompts you to insert a test strip. Remove a test strip from its container and close the container again with the stopper.
- 16** Hold the test strip so the lettering “CoaguChek XS PT” is facing upward.
- 17** Slide the test strip into the test strip guide in the direction 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 turned on in the settings).

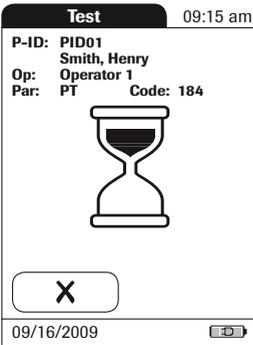


Please note: Exposure to external influences (such as humidity) may deteriorate the test strips and lead to error messages. Therefore, always close the container with the stopper in place immediately after removing a test strip.

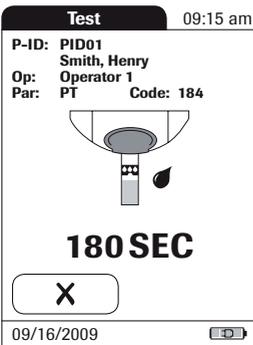


If you use a new test strip lot and have not inserted the code chip yet, you must do so now. Otherwise you cannot perform a test. Depending on the setting, you may also be required to run a liquid quality control at this point.

Testing a capillary blood sample



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



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

At the same time, a 180-second countdown begins. You must apply the drop of blood to the test strip within this time; otherwise, you will receive an error message.

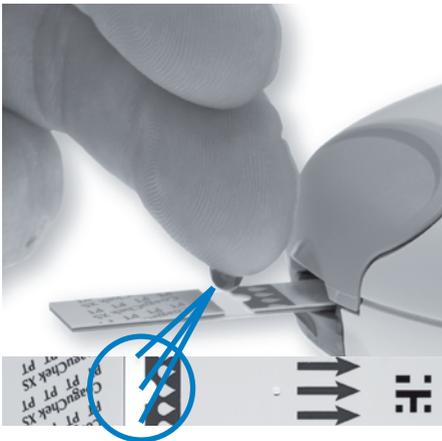


18 Now lance the side of a fingertip with the lancing device.

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

Massage the lanced finger until a drop of blood is formed. Do not press or squeeze the finger.

Apply the first drop of blood from the finger.



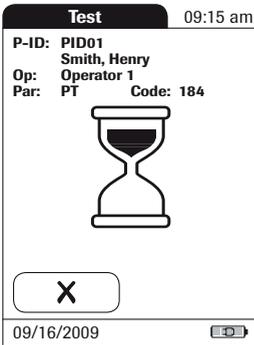
19 Apply the blood directly from the finger to the semicircular, transparent sample application area of the test strip.

Alternatively...

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

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

- ... you can also apply the blood using the CoaguChek capillary tube.

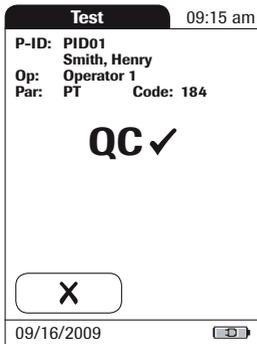


Apply the blood drop to the test strip **within 15 seconds** of lancing the fingertip. *Applying blood after this period of time may lead to an erroneous result.*

You hear a beep tone when you have applied enough blood (provided the beeper is turned on). 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.



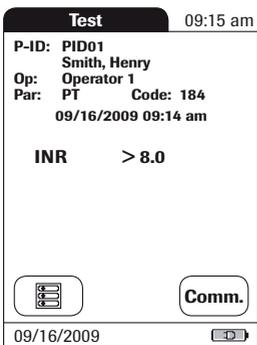
The meter performs an automatic quality control test on the test strip before it displays the test result. “QC” appears in the display.

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



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

When interpreting the result, please also read the test strip package insert carefully.



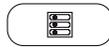
The valid measuring ranges for CoaguChek XS PT test strips are:

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

Results that are outside the measuring range are indicated by the symbols > (greater than) or < (less than). In this case, refer to the section *Limitations of Procedure* in the package insert supplied with the test strips, and repeat the test.

Testing a capillary blood sample

In this display, you can scroll through additional results or return to the main menu.



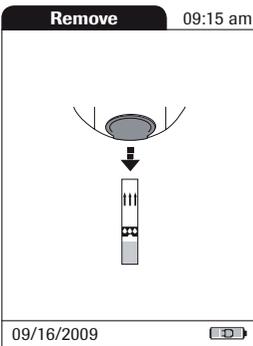
Menu symbol:

Return to main menu.



Individual symbol:

Scroll through older values stored for this patient. (This feature is active only if older values are present.)



20 After the test and results are displayed, a **Remove** menu will appear on the screen. Remove the test strip from the measurement chamber.

21 Turn the meter OFF.

22 Dispose of the used lancet and test strip in line with the disposal policy of your laboratory or medical practice.

23 Clean the meter if this becomes necessary. (See the chapter entitled *Cleaning*.)

Quality control

The CoaguChek XS Plus System has a number of built-in quality-control functions.

- A check of the electronic components and functions every time the meter is turned on.
- A check of the test strip temperature while a test is in progress.
- A check of the expiration date and lot information on the test strip carried out by the code chip.
- A two-level, on-board quality control test and patient result determination within a single test chamber.

Roche Diagnostics has available optional liquid quality controls for the CoaguChek XS Plus 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 controls, you need:

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

You can choose the frequency of liquid quality control tests and specify your choice in the meter setup. (Refer to the chapter entitled *Meter Setup/QC Lockout*.) 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 test strip code chip that came with these test strips is at hand.
- 3 Make sure the bottle of freeze-dried 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.

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

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 in contact with the dried control plasma.



- 7 Close the container again.
- 8 Make sure the dropper is at hand for the next steps in the liquid quality control test.



- 9 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.

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



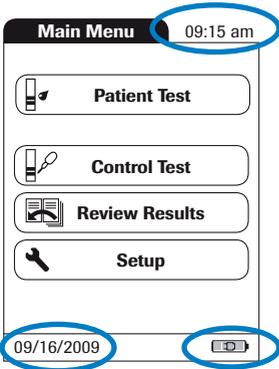
10 Place the meter on a level, vibration-free surface, or hold it in your hand so it is roughly horizontal. Turn the meter on by pressing the ON/OFF button .

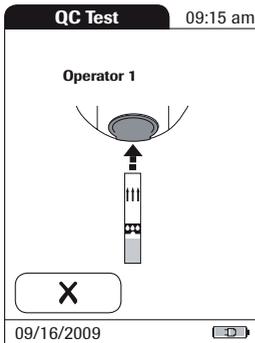
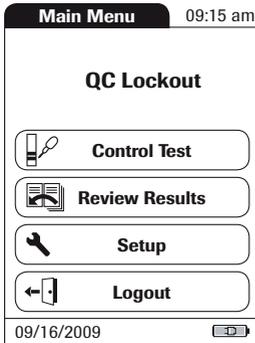
11 Alternatively, you can insert a test strip or connect the meter to the power adapter to turn it on.

12 Wait until the main menu is displayed, and log on.

13 Check the battery level. If there are no bars left in the battery symbol, you cannot perform any more tests.

14 Check that the date and time are correct. Correct any wrong entries as described in the chapter entitled *Meter setup/Setting the date*.





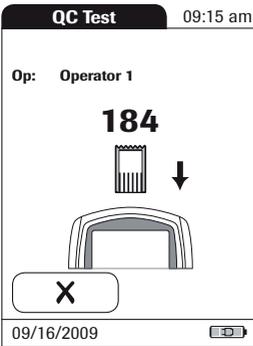
15 Touch **Control Test**.

- 16** The test strip symbol prompts you to insert a test strip. Remove a test strip from its container and close the container again with the stopper.
- 17** Hold the test strip so the lettering “CoaguChek XS PT” is facing upward.
- 18** 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 turned on in the settings).

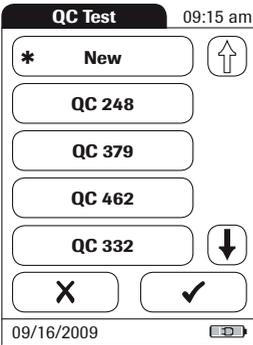


Please note: Exposure to external influences (such as humidity) may deteriorate the test strips and may lead to error messages. Therefore, **always close the container with the stopper immediately after removing a test strip.**



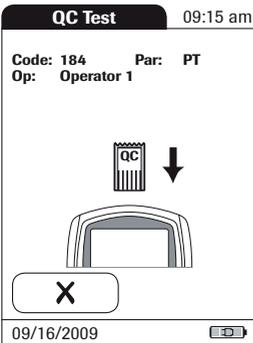
If you are using a new test strip lot and have not inserted the test strip code chip yet, you must do so now. As with the test strips, a quality control code chip is also provided with the liquid quality controls. This chip tells the meter the acceptable ranges of results for that lot of controls. The information on the code chip is retained in the memory so you can use the same control solutions at any time.

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

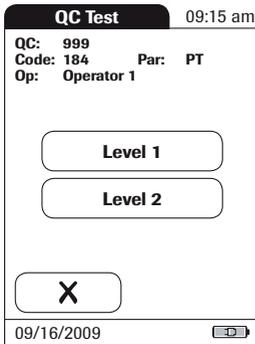


19 Select the code already stored for your current control solution, or touch **New** to use a new control solution.

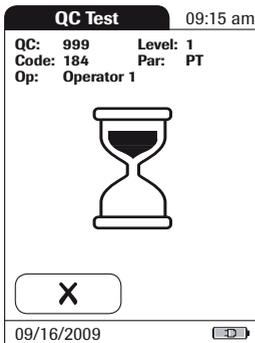
Please note: When you first run your control, the QC TEST screen will not display. This screen will display the next time you use the control.



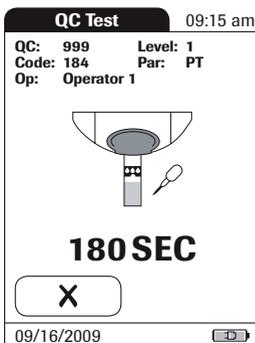
If the code chips get mixed up, here's how to tell them apart: The name on the code chip that came with the test strips starts with the letter **S**, and the name of the code chip that came with the control solution starts with the letter **C**.



20 Select the level for this measurement.

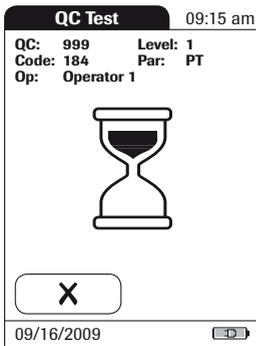


The hourglass symbol shows that the test strip is warming up. When the warming-up process is complete, a further beep tone (provided the beeper is turned on) indicates that you can now apply control solution.

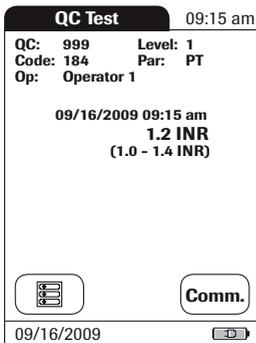


The dropper symbol flashes to indicate that the meter is ready to perform the test and is waiting for the sample to be applied.

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

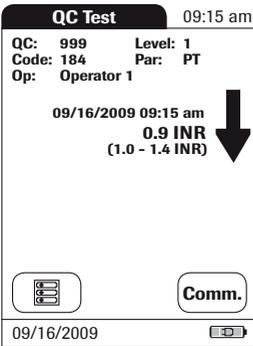


You hear a beep tone when you have applied enough control solution (provided the beeper is turned on). The dropper symbol disappears and the test starts.



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

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



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

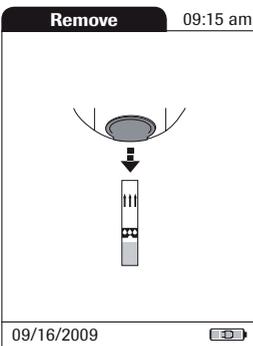
In this display, you can scroll through additional results or return to the main menu.



Menu symbol:
Return to main menu



Scroll symbol:
Scroll through older values stored in memory. (This feature is active only if older values are present.)



- 23** Remove the test strip from the measurement chamber.
- 24** Turn the meter off.
- 25** Dispose of the used test strip in line with the disposal policy of your laboratory or medical practice.
- 26** Clean the meter if this becomes necessary. (See also the chapter entitled *Cleaning*.)

When the test is complete, remove the quality control code chip from the meter and store it with the controls.

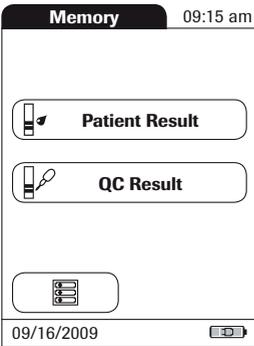
Review Results

The CoaguChek XS Plus meter has a 1,000-value memory for saving results (patient tests and/or liquid quality control tests) together with time and date. If the memory is full when you perform a test, the oldest result is automatically deleted. The most recent result is always saved. In addition, the meter stores up to 60 code chip records (contents of test strip code chips and control solution code chips).

Viewing test results



- 1** Place the meter on a level, vibration-free surface, or hold it in your hand so it is roughly horizontal. Turn the meter on by pressing the ON/OFF button .
- 2** Wait until the main menu is displayed.
- 3** Touch **Review Results**.



4 Select the function you want to perform in the memory.

You may select from the following options:

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

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



Menu symbol:
Return to main menu

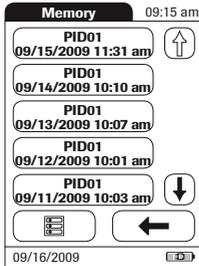


Return symbol:
From the single-result display, return to the list of results



Individual symbol:
List that contains entries for this patient only

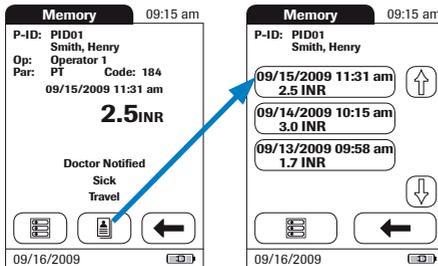
Display Patient Result memory



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

- 1 Touch  or  to display the entry of choice on the screen. If the arrow is just an outline , this means you have reached the beginning or the end of the patient list.

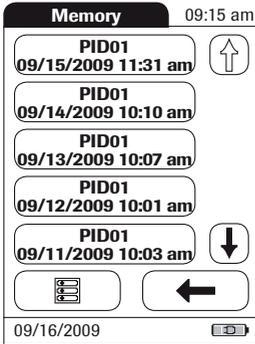
- 2 Touch the entry you want to open.



The entry is displayed.

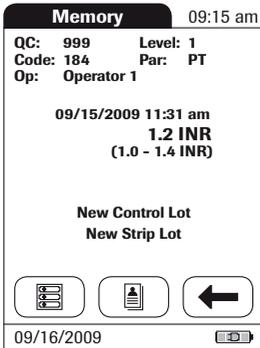
When you press the *Individual*  symbol, a list of results for the selected patient is displayed.

Display QC (Quality Control) memory



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

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



The entry is displayed.

Cleaning/Disinfecting

It is important to follow the procedures below to clean and disinfect the meter. Failure to follow these procedures may cause malfunction of the meter.

- Do not use sprays of any sort.
- Ensure that swab or cloth is only damp, not wet.

Cleaning/Disinfecting the Exterior

- Use only the following items for cleaning/disinfecting the CoaguChek XS Plus meter housing for a contact time of >1 minute:
 - 70% isopropyl alcohol
 - 10% Sodium hypochlorite solution (1 part bleach to 9 parts deionized water, made fresh every 24 hours)
- **NOTE: Do not use any other cleaning solutions/disinfectants on the meter housing.**
- Ensure that the blue test strip guide cover remains tightly closed while cleaning the housing.



1 Clean the Exterior

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

- Do not let liquid accumulate near any opening. Make sure that no liquid enters the meter.

2 Dry the Exterior

With a lint-free tissue, dry the meter.

- Wipe away residual moisture and fluids after cleaning the housing.
- Allow wiped areas to dry for at least 10 minutes before performing a test.

Cleaning/Disinfecting the Test Strip Guide

- Use only 70% isopropyl alcohol or 10% bleach solution to clean/disinfect the CoaguChek Plus test strip guide.
- **Do not use any other cleaning/disinfecting solutions on the test strip guide.**
Use of other cleaning/disinfecting solutions could result in damage to the meter.



1 Open the cover

With the meter powered off, use your thumbnail to open the cover of the test strip guide by pressing its front edge upward. Move the cover safely away from the meter. Then rinse the cover with water or wipe it clean.



2 Clean the test strip guide

- Hold the meter upright with the test strip guide facing down.
- Clean the easily accessible areas with a cotton swab.
- Ensure the swab is only damp, not wet.
- Apply cleaning agent for a contact time of >1 minute (refer to the corresponding product labeling).
- Wipe away residual moisture and fluids.

Caution: Do not insert any objects into the test strip guide. Doing so could damage the electrical contacts behind the test strip guide.

Please note: Let the inside of the test strip guide dry for at least 10 minutes before re-attaching the test strip guide cover and testing again.

3 Allow to dry

With the cover off, allow the test strip guide to dry for about 10 minutes.

4 Close the cover

Close the cover, and make sure it snaps into place.

Error messages

Depending on the circumstances, an error message may appear on the display of your meter.

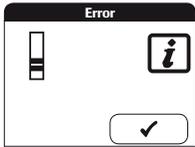
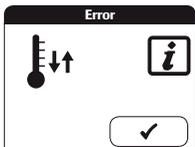
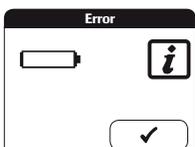
Error messages can have up to three warning levels as indicated by the following symbols and their meanings.

-  Reports a warning message
-  Reports an error (see: Error messages)
-  Reports a serious error (see: Error messages)

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

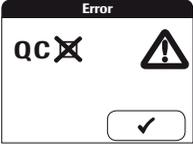
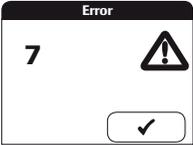
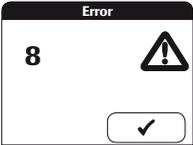
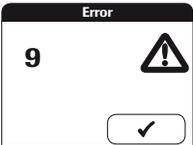
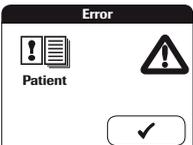
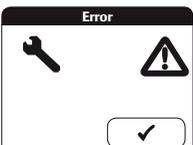
Your first step upon receiving an error message should be to try the solution suggested for that error. If the problem persists, please call Roche Diagnostics Technical Service Center at 1-800-428-4674, 24 hours a day, 7 days a week, 365 days a year.

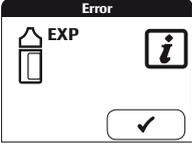
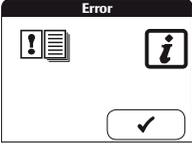
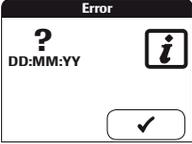
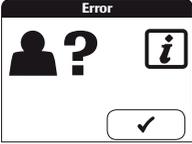
Error messages overview

| Error message (always prefaced by Error) | Brief description |
|--|--|
|  | Test strip in meter or Test strip unusable or the test strip is not a CoaguChek XS PT test strip |
|  | Meter too warm or too cold |
|  | Battery level too low |

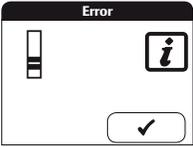
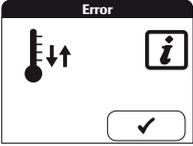
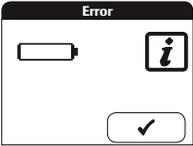
| Error message (always prefaced by Error) | Brief description |
|---|---|
| | Test strip guide cover open |
| | Code chip error |
| | Test strip beyond expiration date |
| | Test strip unusable |
| | Allowed time for blood application exceeded |
| | Blood application error |
| | Measurement error |

Error messages

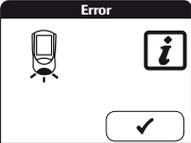
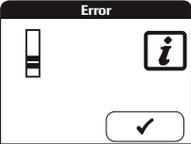
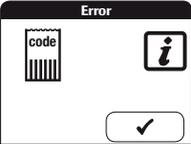
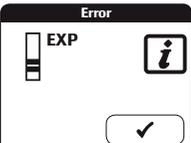
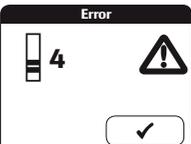
| Error message (always prefaced by Error) | Brief description |
|--|---|
|  | Quality control: Test strip unusable or quality control for new lot missing |
|  | Measurement error |
|  | Diagnostic testing error |
|  | Diagnostic testing error |
|  | Internal memory error (patient) |
|  | Internal memory error (QC) |
|  | Internal memory error (setup) |

| Error message (always prefaced by Error) | Brief description |
|--|---|
|  | Data transfer error |
|  | Control solution beyond expiration date |
|  | Memory (almost) full |
|  | Date/time inconsistent |
|  | ID error |

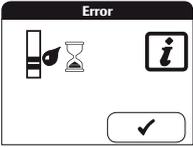
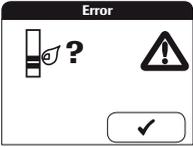
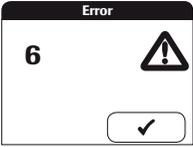
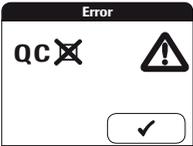
Troubleshooting error messages after turning the meter on

| Error | Description/Solution |
|---|---|
| Error: Test strip | <p>A test strip was already inserted when the meter was turned on with the ON/OFF button.</p> <p>Solution</p> <p>Remove the test strip.</p> <p>The error message disappears. The meter is ready.</p> |
|  | |
| Error: Ambient temperature | <p>The meter is too cold or too warm to measure correctly.</p> <p>Solution</p> <p>Turn the meter off (unplug the power adapter) and allow it to stand for about 30 minutes at room temperature (65°F to 90°F or 18°C to 32°C).</p> <p>Please note: When in continuous operation using the power adapter or when recharging the battery pack, the meter can generate the Error: Ambient temperature error message even when the ambient temperature is under 90°F (32°C).</p> |
|  | |
| Error: Battery | <p>Battery level too low</p> <p>Solution</p> <p>Insert new batteries.</p> |
|  | |

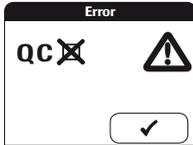
Troubleshooting error messages when preparing to test

| Error | Description/Solution |
|---|--|
| <p>Error: Cover</p>  | <p>The test strip guide cover is not properly closed.</p> <p>Solution</p> <p>Close the test strip guide cover.</p> <p>The error message disappears. The meter is ready.</p> |
| <p>Error: Test strip</p>  | <p>The test strip is unusable or the test strip is not a CoaguChek XS PT test strip.</p> <p>Solution</p> <p>Remove the test strip and repeat the test with a new or appropriate test strip.</p> |
| <p>Error: Code chip</p>  | <p>The code chip is missing, not properly inserted in the meter, or damaged.</p> <p>Solution</p> <p>Insert the code chip, or remove it and re-insert it.</p> |
| <p>Error: Test strip</p>  | <p>The test strip is beyond its expiration date.</p> <p>Solution</p> <p>First check whether the date setting is correct in the meter. If it is not, set the correct date.</p> <p>If the date is correct: Turn the meter off, remove the code chip and test strip. Use a test strip from a new lot of test strips and insert the code chip that came with the new lot.</p> |
| <p>Error: Test strip</p>  | <p>The test strip is unusable.</p> <p>Solution</p> <p>Turn the meter off, remove the test strip and re-insert it. If the error message appears again, discard the unusable test strip and use a new one.</p> |

Troubleshooting error messages during or after blood application

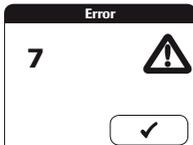
| Error | Description/Solution |
|--|--|
| Error: Time for application exceeded | <p>The maximum allowed time of 180 seconds for applying blood has been exceeded.</p> <p>Solution</p> <p>Turn the meter off, remove the test strip and start a new test using the same test strip and blood taken from a new fingerstick from a different finger.</p> |
|  | |
| Error: Blood application | <p>Error applying blood to the test strip.</p> <p>Solution</p> <p>Turn the meter off and remove the test strip. Re-read the instructions about applying blood and repeat the test with a new test strip and blood taken from a new fingerstick from a different finger.</p> |
|  | |
| Error: Measurement | <p>Measurement error</p> <p>Solution</p> <p>Turn the meter off and remove the test strip. Repeat the test with a new test strip and blood taken from a new fingerstick from a different finger. Do not touch or remove the test strip when a test is in progress.</p> |
|  | |
| Error: Quality Control | <p>The test strip failed the internal quality control check. The test strip is unusable.</p> <p>Solution</p> <p>Turn the meter off and remove the test strip. Repeat the test with a new test strip.</p> |
|  | |

| Error | Description/Solution |
|-------------------------------|---|
| Error: Quality Control | This message appears if quality control lockout was set up for NEW CODE lockout. A quality control test must be carried out when a new test strip lot is used. The quality control for new lot is missing. |

**Solution**

Perform a quality control test with the new test strip lot.

| | |
|---------------------------|---|
| Error: Measurement | Measurement error resulting from the blood sample |
|---------------------------|---|

**Solution**

Turn the meter off and remove the test strip. Repeat the measurement using a new test strip and blood taken from a new fingerstick. Do not touch or remove the test strip when a test is in progress. Be sure to apply the blood drop within 15 seconds of lancing the fingertip.

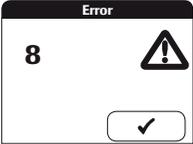
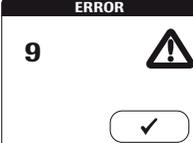
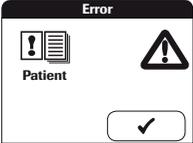
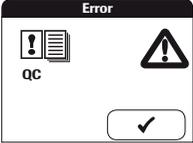
Note on Error 7 “Measurement”: The CoaguChek XS PT test strip may be used for patients under a combination therapy of oral anticoagulants plus heparin injections. For maximum heparin concentrations that do not interfere with the test, please refer to the package insert. Under no circumstances, however,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



In rare cases, patients with long clotting times (>8 INR) may receive an “ERROR 7” message on the meter display. If this error message appears again when the test is repeated, the result must be checked using another method.

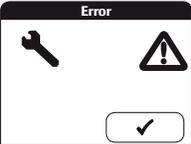
Under no circumstances should heparinized capillary tubes be used. Please use only the dedicated CoaguChek capillary tubes.

Troubleshooting other error messages

| Error | Description/Solution |
|--|--|
| <p>Error: Diagnostic test</p>  | <p>Error during the internal diagnostic test which the meter performs.</p> <p>Solution</p> <p>Turn the meter off and remove the batteries. Wait at least one minute before re-inserting the batteries in the battery compartment, and then set the date and time.</p> <p>Repeat the test. If the error message persists, the meter has a fault. Please call Roche Diagnostics Technical Service Center at 1-800-428-4674.</p> |
| <p>Error: Internal error</p>  | <p>Error due to temperature inconsistency.</p> <p>Solution</p> <p>Because this error indicates possible damage to the heater plate contacts, call the Roche Diagnostics Technical Service Center at 1-800-428-4674 to have the meter replaced</p> |
| <p>Error: Memory test (patient)</p>  | <p>The memory contains faulty data.</p> <p>Solution</p> <p>The meter has a fault. Please call Roche Diagnostics Technical Service Center at 1-800-428-4674.</p> |
| <p>Error: Memory test (QC)</p>  | <p>The memory contains faulty data.</p> <p>Solution</p> <p>The meter has a fault. Please call Roche Diagnostics Technical Service Center at 1-800-428-4674.</p> |

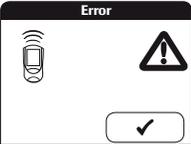
Error **Description/Solution**

Error: Memory test (setup) The memory contains faulty data.



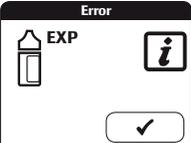
Solution
The meter has a fault. Please call Roche Diagnostics Technical Service Center at 1-800-428-4674.

Error: Data transfer Data was transferred incorrectly.



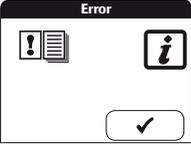
Solution
Repeat the last action.

Error: Quality Control The control solution is beyond the expiration date.

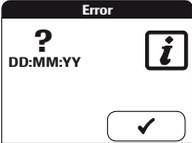
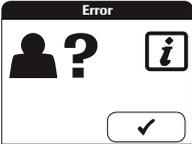


Solution
Use a new control solution with the code chip belonging to it.

Error: Test memory (capacity) This message appears when using optional software and memory is almost full.



Solution
Connect meter to PC and download memory results.

| Error | Description/Solution |
|---|---|
| Error: Date/time setting  | Date/time is inconsistent Solution Check date/time. |
| Error: Password  | The entered operator or supervisor password is wrong. Solution Enter the correct password. |

Further information

Ordering

Please contact Roche Diagnostics Customer Service at 1-800-428-5076.

| | |
|--|-----------------|
| CoaguChek XS PT Test, 2 x 24 test strips | REF 04625315160 |
| CoaguChek XS Plus PT Controls | REF 04625382160 |
| Rechargeable battery pack | REF 04805640001 |
| CoaguChek XS PT Optional Base Unit | REF 04803710001 |
| CoaguChek Capillary Tubes/Bulbs | REF 11621173001 |

Product limitations

Please read the information in the package insert supplied with the test strips for detailed product data and limitations.

Disposing of the instrument

If the instrument is to be taken out of operation entirely and disposed of, it must be disposed of in conformity with the relevant legal regulations and in coordination with your local authority, if appropriate.

Please note that the instrument may potentially be infectious. It should therefore be decontaminated before disposal. Use a 10% bleach solution to disinfect the meter.

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

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Product specifications

Operating conditions and technical data

| | |
|--------------------------------------|---|
| Temperature range | 59°F to 90°F (15°C to 32°C) |
| Relative humidity | 10% to 85% (no condensation) |
| Maximum altitude | 14,000 feet (4300 m) |
| 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 | 1,000 test results with date and time 60 code chip records |
| Interface | Infrared interface, LED/IRED Class 1 (CoaguChek IR key) |
| Battery operation | The CoaguChek XS Plus System uses four AA batteries. The batteries should last about 60 tests, depending on the type of battery used. A special rechargeable battery pack for the CoaguChek XS Plus instrument is also available. |
| Power connection | Power supply adapter: Input: 100-240 V / 50-60Hz / 400 mA Output: 7.5 V DC / 1.7 A |
| Number of tests per set of batteries | Approx. 60 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 | 185 x 98 x 42 mm |
| Weight | 311 g (without batteries) |

Sample material

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

Storage and transport conditions

| | |
|-------------------|------------------------------|
| Temperature range | 34°F to 104°F (1°C to 40°C) |
| Relative humidity | 10% to 85% (no condensation) |

Support/Services

Please call Roche Diagnostics Technical Service Center at 1-800-428-4674 if you have questions regarding the handling of your meter, the reliability of your results, if you suspect the meter is defective or if you have other questions.

Repairs

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

Warranty

CoaguChek XS Plus Meter Limited (1 Year) Warranty

ROCHE DIAGNOSTICS warrants, to the original purchaser only, that the meter shall be free from all defects in material and workmanship for a period of one year from the date of purchase. Purchaser's sole and exclusive remedy, with respect to the CoaguChek XS Plus 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 PLUS METER. NO WARRANTY, EXPRESS OR IMPLIED (IF ANY), SHALL EXTEND FOR A LONGER DURATION THAN THE DURATION OF THE EXPRESS WARRANTY STATED ABOVE.

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



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