cobas h 232 System

Operator's Manual

Roche

cobas®

Life needs answers

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

In the manual you may encounter the following symbols, shown here with their meaning:

Indicates important health or safety information

Manufacturer

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

The user is fully responsible for the installation, use and upkeep of the **cobas h** 232 meter.

Manual version	**Revision date**	**Changes**
Version 2.0	2009-09	Corrections from internal review
Version 1.0	2006-10	New document

Introduction

The cobas h 232 Meter

The **cobas h** 232 meter is an instrument for the quantitative evaluation of immunoassays using the gold-labeling technique. The rapid diagnostic tests in strip format available for this meter support efficient diagnosis and assessment of cardiovascular diseases. The evaluation of these tests with the **cobas h** 232 meter combines the advantages of a rapid diagnosis with enhanced clinical interpretation of quantitative values (in comparison with qualitative tests). In addition, automated evaluation ensures results, as it eliminates potential sources of error associated with visual reading. Refer to the package inserts accompanying the test strips for detailed information on specific tests.

Readings may be carried out directly where the blood samples are taken. Therefore, the **cobas h** 232 meter is ideal for use at the point of care in emergency rooms, intensive care units and stationary ambulances, as well as by cardiologists and general practitioners. The **cobas h** 232 meter is rapid and easy to operate: Insert an unused strip in the meter and apply the sample. After the reaction period, the meter provides a quantitative result; in addition, a qualitative result is provided prior to the end of some tests.

The **cobas h** 232 meter includes user management with linked, configurable security features such as an optional QC (quality control) lockout. The meter can also be connected to a hospital information system (HIS) (e.g., **cobas IT** 1000 data management system) and supports data exchange via standard POCT1-A protocol (POCT1-A is a medical communication standard for sending data between point of care meters and the data management system (DMS) in hospitals).

This manual contains all the information you need to operate and care for the **cobas h** 232 meter. Read the entire operator's manual **carefully** before you use the meter.

If you have any questions about the **cobas h** 232 meter, please contact your local Roche Diagnostics customer support and service center. You will find contact details on page 136.

Note: If you connect your **cobas h** 232 meter to a **cobas IT** 1000 data management system or an other PC/DMS, you will not be able to print directly from the meter to a printer. In order to print out meter data, use printers connected to the respective PC/DMS.

Note: Within this operator's manual, the word "meter" will be used synonymous to "**cobas h** 232 meter".

Test Principle

Two lines (signal and control line) in the detection zone of the test strip indicate whether the analyte to be determined is present in the sample material. These lines are detected by the **cobas h** 232 meter with the help of an LED (lighting the detection zone) and a camera sensor (imaging the detection zone). As soon as both lines are detected, the result is displayed as "positive" prior to the quantitative evaluation. The test signal (signal line) increases in intensity in proportion to the concentration of the respective analyte. Integrated system software converts the signal intensity to a quantitative result, which is then displayed on the screen at the end of the measurement. The accuracy of the measurement is ensured through a simple principle: Every test strip folding box includes a code chip that contains all test and lot-specific information in electronic format. The test strips are labelled with a barcode on their underside and are hereby assigned to a specific code chip. When you insert a test strip from a new strip lot for the first time, the meter prompts you to plug in the corresponding code chip. The information is now read from the code chip and stored for future tests..

Contents of the Pack

- **cobas h** 232 meter
- Handheld power supply with cable
- Operator's manual in British English
- CD-ROM with Operator's Manual in other languages

Optionally available (not included in the scope of delivery):

- A suitable handheld battery pack (rechargeable) for temporary operation without the handheld power supply
- The Handheld Base Unit (docking station) for data transfer within a network or via USB (Universal Serial Bus)

Note: Please contact your local Roche Diagnostics customer support and service center for your personal printout of the Operator's Manual in your language.

On the packaging and on the identification plate of the meter 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)
	Manufacturer
REF	Catalogue number
IVD	For in vitro diagnostic use
CE	This product fulfills the requirements of the European Directive 98/79 EC for *in vitro* diagnostic medical devices

Laser class 1 according to IEC 60825-1
(applies only to meters with a barcode scanner, meter S/N greater than 20000)

Safety Information and Additional Information

This section explains how safety-related messages and information related to the proper handling of the system are presented in the **cobas h** 232 Operator's Manual. Please read these passages carefully.

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

WARNING

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

CAUTION

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

NOTICE

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

Important information that is not safety relevant is presented against a colored background (without a symbol).

Tips: These provide additional information on correct use of the meter or useful tips.

Safety Information

Operator qualification
Only trained healthcare professionals may operate the **cobas h** 232 meter. Operators must also have received comprehensive instruction in the operation, quality control, and care of the **cobas h** 232 meter.

WARNING

Protection against infection
There is a potential risk of infection. Healthcare professionals using the **cobas h** 232 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.

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

Disposal of the System

WARNING

Infection by a potentially biohazardous instrument
The **cobas h** 232 meter or its components must be treated as potentially biohazardous waste. Decontamination (i.e., a combination of processes including cleaning, disinfection and/or sterilization) is required before reuse, recycling, or disposal.

Dispose of the system or its components according to the appropriate local regulations.

WARNING

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

General Care

NOTICE

Clean the meter only with the solutions recommended (see page 123). Using other solutions may result in incorrect operation and possible failure of the system. Make sure that the meter is thoroughly dried after cleaning or disinfecting.

Laser Scanner

The built-in barcode scanner emits a laser beam when activated.
The built-in barcode scanner is a Class 1 laser, according to IEC 60825-1:1993 + A1:1997.

WARNING

A barcode does not need to be present for the laser scanner to become active. Lasers should never be stared at directly by the human eye.

Electrical Safety

NOTICE

Never run the meter if the electrical power supply or the attached cable is visibly damaged. If there is any visible damage contact your local Roche service for inspections.

Electromagnetic Interference

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

Touchscreen

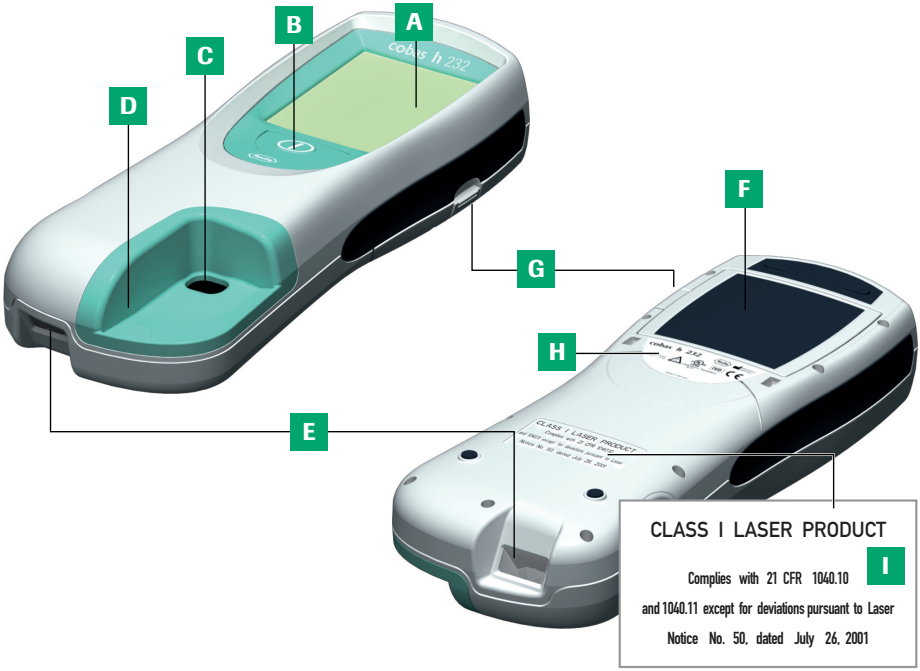
NOTICE

- Use only your finger (even when wearing gloves) or special pens designed for use with handheld devices to touch the screen elements. Using pointed or sharp-edged objects can damage the touchscreen.
- Do not use the system in direct sunlight. Direct sunlight may reduce the life expectancy and functionality of the screen.

Note: To ensure that your **cobas h** 232 meter functions properly, please observe the operating and storage conditions as given in the chapter “Product Specifications”, starting on page 135.

Overview of the Meter and its Accessories

Meter



A Touchscreen
Shows results, information, icons and results saved in the memory. All entries are carried out by touching the buttons on this screen.

B On/Off button
Press this button to turn the meter on or off.

C Opening for sample application
The application area of the test strip once it has been inserted.

D Sample application cover
Remove this cover to clean the pipetting field area.

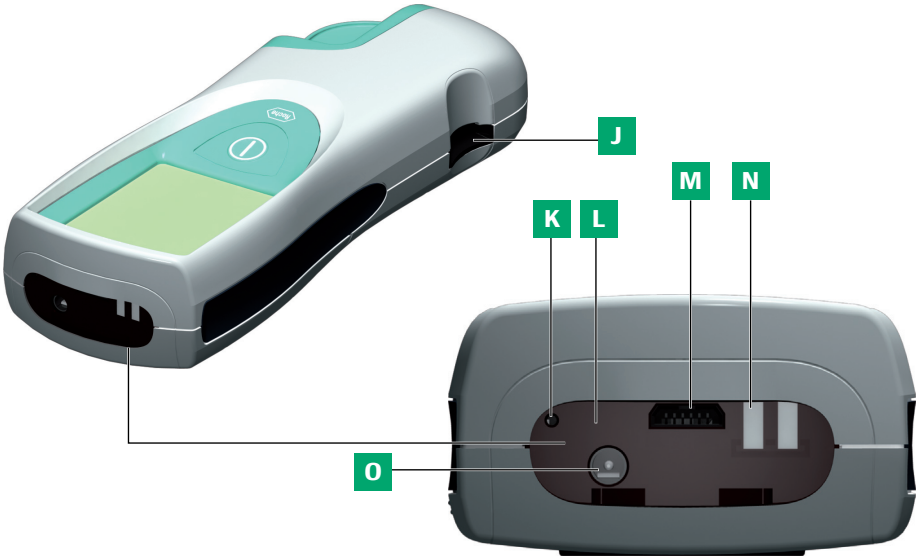
E Barcode scanner (Laser)
Using the integrated barcode scanner operator and patient IDs can be read into the meter (only meter versions with a serial number greater than 20000).

F Handheld battery pack cover
Closes the battery compartment.

G Tab on the handheld battery pack cover

H Meter label
See page 7 for symbol explanation.

I Laser label
For meters with a barcode scanner only.



J **Test strip guide**
Insert the test strip here.

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

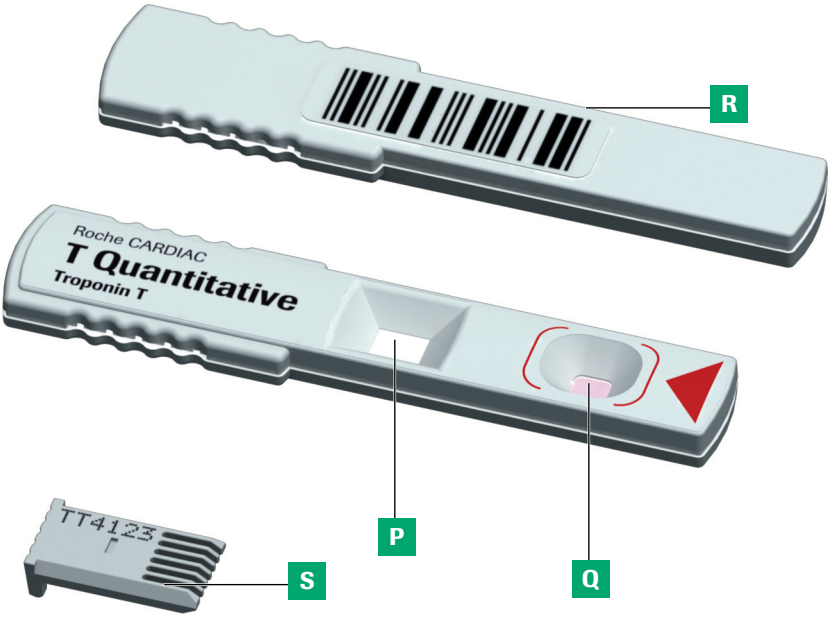
L **Infrared interface**
(Covered by the semi-transparent rear panel); supports data communication.

M **Code chip slot**
Insert the code chip here.

N **Contacts for Handheld Base Unit**
Used for power supply and/or charging the handheld battery pack, when the meter is docked in the Handheld Base Unit.

O **Connection socket for the power supply unit**
Here you can plug in the power supply unit provided.

Test Strip



P **Test area**
This area is evaluated by the meter via the camera.

Q **Application area**
The sample is applied to this area after inserting the test strip in the meter.

R **Barcode**
Assigns the strip to the corresponding code chip. The barcode is automatically read by the meter, when the strip is inserted into the test strip guide.

S **Code Chip**
Contains strip lot specific data.

Handheld Base Unit

T **Charging contacts**
Used for power supply and/or charging the handheld battery pack.

U **Status indicator**
Lights up when power is connected, charge indicator.

V **Infrared window**
For communication with the meter.

W **Extension piece**
For **cobas h** 232 meter.

X **Data ports (Ethernet/RJ45 and USB)**
For connecting the device to a host computer.

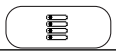
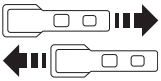
Y **Connection socket for the power supply unit**
Here you can plug in the power supply unit provided with the meter.

Z **Removable cover for configuration switch**
The switch sets the mode of operation for the Handheld Base Unit.

Note: The Handheld Base Unit can be ordered separately. For detailled information on usage and configuration please consult the user's manual of the Handheld Base Unit.

Overview of the Buttons and Icons used on Screen

The buttons and icons that appear during normal operation are shown here, along with a general explanation. Error messages and the description of the icons linked to them are provided in a separate chapter. See “Troubleshooting” starting on page 127.

Button/Icon	Meaning
	OK, save setting
	Cancel, discard setting
	Return (to previous menu)
	Decrease/increase a numeric value or Scroll through lists that are too long to be displayed at once
	Inactive button; value can’t be further decreased/increased or End of list in this direction is reached
	Return to the *Main Menu* screen
	List of tests of an individual patient
	Scroll through stored results
	Print displayed result (via infrared interface to corresponding printer)
	Operator logout Operator login
	Operator must wait until the meter has completed an action.
	Insert test strip Remove test strip
	Test strip warming up
	Apply sample (the time left to apply sample is counted down in the screen alongside the required amount)
	Apply QC sample (the time left to apply sample is counted down in the screen alongside the required amount)

Button/Icon	Meaning
	Insert code chip
	Open sample application cover for cleaning
	Battery status: • If the handheld battery pack still has its full charge, all segments are lit • Individual segments disappear one by one as the handheld battery pack becomes weaker • When there is no segment remaining, you can no longer perform a test. You can, however, still access the meter's memory
	Operation with power supply adapter
am	Time between midnight and noon (in 12-hour time format)
pm	Time between noon and midnight (in 12-hour time format)
	Infrared interface is enabled (for communication with the computer and/or printer)
	Marks an information message
	Marks a minor error message (see: "Troubleshooting")
	Marks a major error message (see: "Troubleshooting") or a warning
	Room or meter temperature is outside the acceptable range.
	The sample application cover is open.

Putting the Meter into Operation

Before using the meter for the first time, carry out the following steps:

1 Connect the handheld power supply

2 If present, insert the handheld battery pack for recharging (see page 19)

3 Set the current date and time as well as the appropriate display format (see chapter “Meter Setup” starting on page 23)

4 Enter the settings of choice (language, quality controls – where necessary, user administration, etc.)

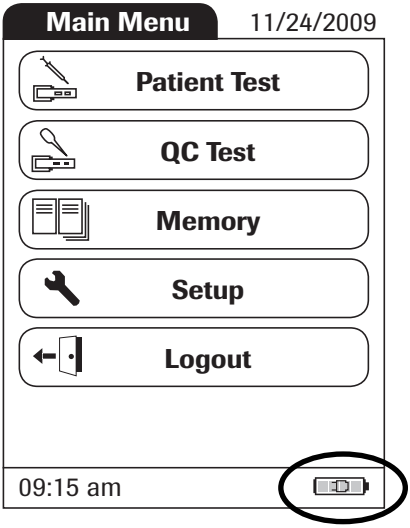
Note: If you switch on the meter for the first time, or the meter has been without power for more than 10 minutes, you must set the date and time. In this case the meter takes you directly to the *Setup* mode, where you set date and time.
See “Setting the Date” on page 33 and “Setting the Time” on page 35.

Once you finished these settings, the meter atomatically displays the *Main Menu*. Here you can continue with the meter setup or start a test.

Power Supply

The meter can be operated with either the handheld power supply provided, the (optional) Handheld Base Unit or the (optional) handheld battery pack. It is advisable to insert the handheld battery pack even when you use the handheld power supply. This ensures that you do not lose the date and time settings (in case of a power outage or if the local power supply is shut off). Results are retained in the memory together with the corresponding date and time, as well as all other settings, even when no handheld battery pack is inserted.

To save power, the meter can automatically turn itself off after a programmable period of time, if no buttons are pressed or new test strips are inserted. When the meter turns itself off, all test results obtained up to that point remain in memory and the settings are retained (see “Auto Off” in the chapter entitled “Data Handling Setup” on page 42).



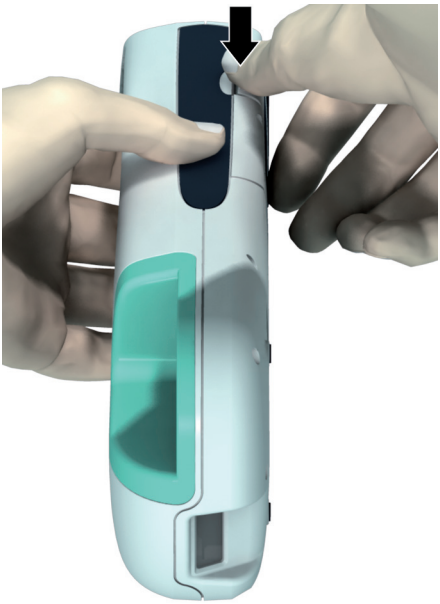
During battery operation, the meter always displays the power level of the handheld battery pack. The battery icon is divided into four segments which correspond to the battery power level.

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

To make certain you do not lose your date and time settings, connect the handheld power supply unit while you change the handheld battery pack.

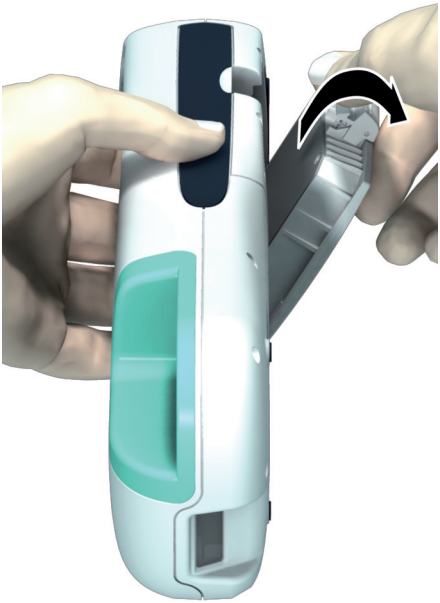
Note: Dispose of used battery packs in an environmentally responsible manner in accordance with applicable local regulations and directives.

Inserting the Handheld Battery Pack



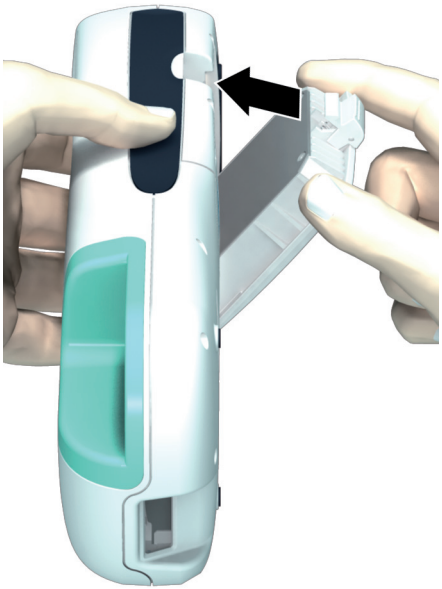
1 With the meter turned off, hold it so that the tab on the handheld battery pack points upward.

2 Gently press the tab on the battery compartment cover towards the center of the meter and tilt the cover to the side.



3 Slide the handheld battery pack cover upward and remove it.

Note: The handheld battery pack cover is no longer needed, once you insert a handheld battery pack.



4 Insert the handheld battery pack as indicated in the battery compartment.

Use only the specially-designed handheld battery pack.

5 Close the battery compartment.
The meter turns itself on after a (charged) handheld battery pack has been inserted. If you insert an uncharged or partially charged handheld battery pack, it can only be charged by connecting the handheld power supply.

Note: If the settings for date and time have not yet been set or if they have been lost (because the meter was without power for more than ten minutes), your **cobas h** 232 meter automatically switches to *Setup* mode when power is restored. You must enter the date and time, then the meter automatically switches to the *Main Menu*.

Note: After installing a new battery pack, the meter should be charged for four hours before testing.

With a fully charged battery, up to 10 tests can be performed. This includes samples, QC and meter controls. For warehousing requirements, please see the date of expiry on the package of each new handheld battery pack.

Turning the Meter On and Off

1 Turn the meter on by pressing the On/Off button ⏻ for longer than 5 seconds.

Note: You can also turn on the meter directly by connecting the handheld power supply.

2 To turn the meter off after use, press the ⏻ button for longer than 2 seconds.

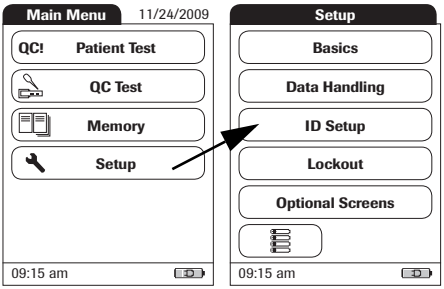
Meter Setup

Note: If you switch on the meter for the first time, or the meter has been without power for more than 10 minutes, you must set the date and time. In this case the meter takes you directly to the *Setup* mode, where you set date and time.
See “Setting the Date” on page 33 and “Setting the Time” on page 35.

Once you finished these settings, the meter automatically displays the *Main Menu*. Here you can continue with the meter setup or start a test.

Names of screen objects you can actively use (buttons) are written in **bold**.
Names of inactive screen objects (e.g. screen titles) are written in *italics*.

You can call up any displayed function by touching (or tapping) the button for it with your finger. “Tap” means: Touch the button, then remove your finger from the touch-screen. The next screen appears once you remove your finger.



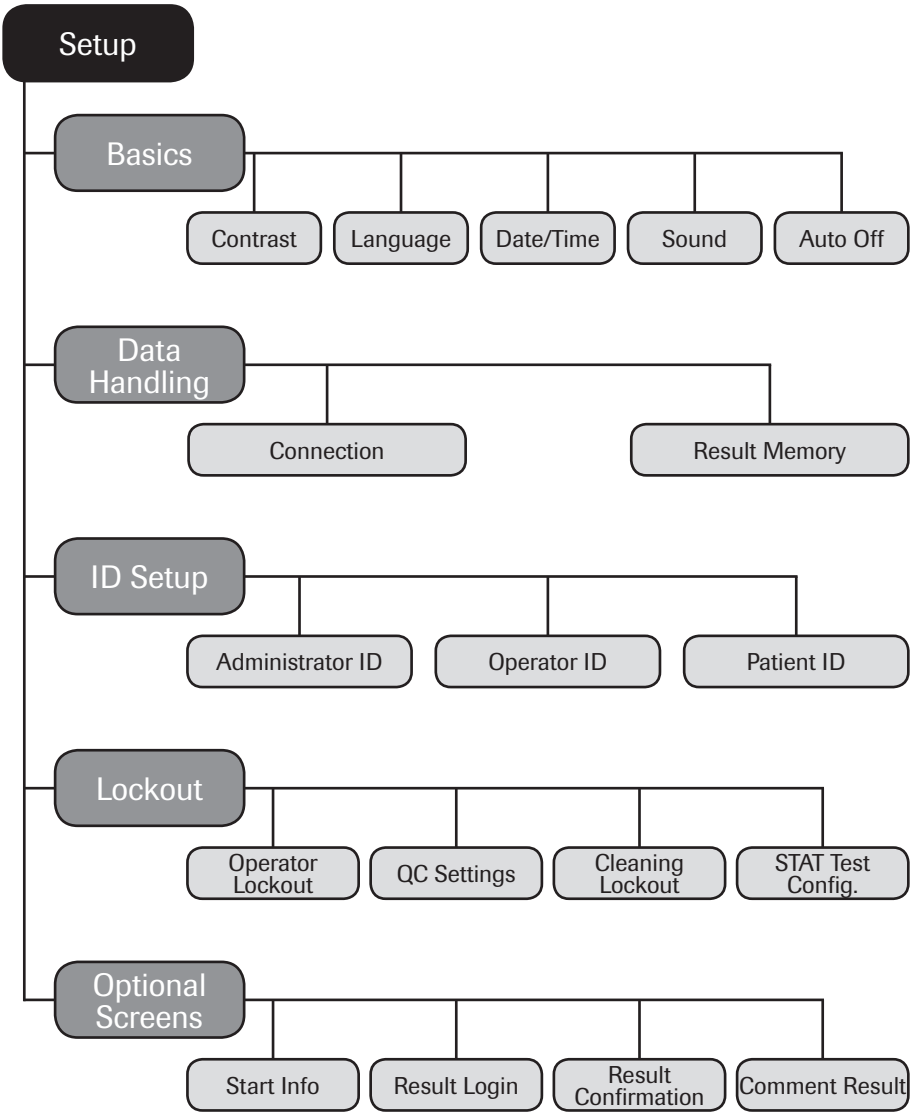
1 Touch **Setup** to call up the *Setup* menu.

2 Select the group of settings of choice (see the summary starting on page 24).

For a description of the buttons and icons used on screen see page 15.

Settings Summary

The diagram below gives an overview of the setup areas that can be accessed on the meter.



Group	Subgroup	Setting	Values *
Basics	Contrast		0 – 10 (5*)
	Language		Dansk
			Deutsch
			English (GB)
			English (US) *
			Español
			Français
			Italiano
			Nederlands
			Norsk
			Português
			Svenska
			An installable language
	Date/Time	Date	01/01/2007 *
		Time	12:00 am *
		Date formats	Day.Month.Year (31.12.2006)
			Month/Day/Year (12/31/2006) *
			Year-Month-Day (2006-12-31)
		Time formats	24-hour time format (24H)
			12-hour time format (12H), with am/pm *
	Sound	Volume	Off
			Low
			Medium *
			High
		Key Click	Enable
			Disable *
	Auto Off	[minutes]	Off *
			1 … 10 (default: 5 min)
			15, 20, 25, 30
			40, 50, 60

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

Group	Subgroup	Setting	Values *
Data Handling	Connection		Off *
			Computer
			Printer
	Result memory	Display mode	All results *
			Last result
		Result storage mode	No results deletion *
			Delete oldest result
ID Setup	Administrator ID		Blank (off) *
	Operator ID		None *
			Optional
			Required
	Patient ID		None
			Optional *
			Required

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

Group	Subgroup	Setting	Values *
Lockout	Operator Lockout (only if “Operator ID” option is enabled)		No *
			Daily
			Weekly
			Monthly
			Every 3 months
			Every 6 months
			Yearly
	QC Settings	New Lot Lockout	Yes
			No *
		QC Lockout	No *
			Daily
			Weekly
			Monthly
		IQC Lockout	No *
			Daily
			Weekly
			Monthly
		QC Result Format	Pass/Fail *
			Value
			Value & Pass/Fail
		Reset Test Param.	Do Reset
			No Reset *
	Cleaning Lockout		No *
			Daily
			Weekly
			Monthly
	STAT Test Config.		Enable
			Disable *

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

Group	Subgroup	Setting	Values *
Optional screens	Start Info		Enable
			Disable *
	Result Login		Enable
			Disable *
	Result Confirmation		Enable
			Disable *
	Comment Result		Enable
			Disable *

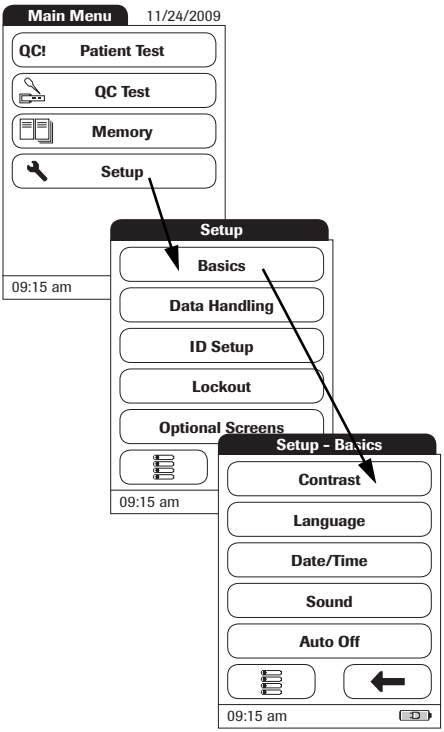
* Settings that are in the meter when it leaves the factory are labelled with an asterisk (*).

Basics Setup

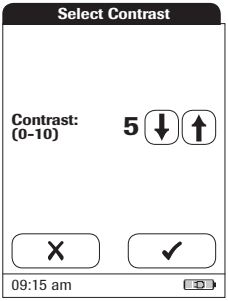
The *Basics* setup area contains the basic options for changing the user interface.

Contrast

To make it easier to read the screen, use the *Contrast* menu to change the brightness of the screen and the displayed elements.



1. From the *Main Menu*, touch **Setup**.
2. From the *Setup* menu, touch **Basics**.
3. From the *Setup-Basics* menu, touch **Contrast**.



4 Touch ↑ or ↓ to change the contrast in a range from 0 to 10.

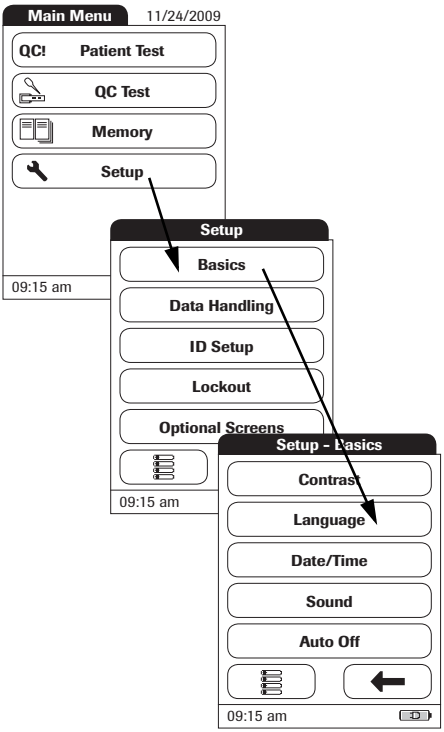
- Contrast “0” makes the screen very dark.
- Contrast “10” makes the screen very light.

5 Touch ✓ to save this setting, or:

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

Language

Use this menu to select the language for all displays (that are language-specific).



1 From the *Main Menu*, touch **Setup**.

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

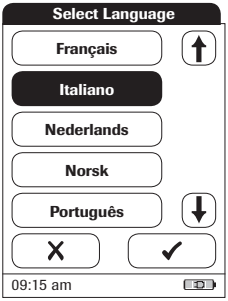
3 From the *Setup-Basics* menu, touch **Language**.

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

- **Dansk** (Danish)
- **Deutsch** (German)
- **English (GB)** (British English)
- **English (US)** (US English)
- **Español** (Spanish)
- **Français** (French)
- **Italiano** (Italian)
- **Nederlands** (Dutch)
- **Norsk** (Norwegian)
- **Português** (Portuguese)
- **Svenska** (Swedish)

Direct from the plant, upon request, or (later) by the authorised Roche Diagnostics service:

- An optional language can be installed at a later time.



4 Touch ↑ and ↓ to display the language of choice on the screen.

If the arrow is just an outline ⇧ ⇩, you have reached the end of the list in the repective direction.

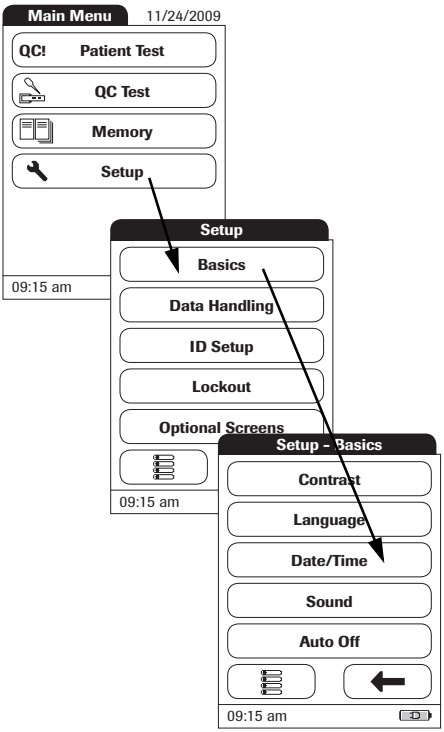
5 Touch the button to select the language of choice. Your selection is now highlighted.

6 Touch ✓ to save this setting, or:

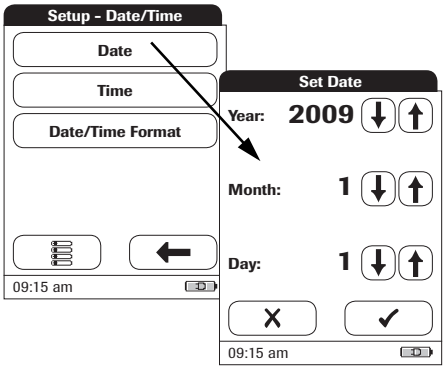
Touch ✗ to exit this menu without saving any changes.
The display automatically returns to the previous screen.

Setting the Date

Use this menu to set the date of the meter.



1. From the *Main Menu*, touch **Setup**.
2. From the *Setup* menu, touch **Basics**.
3. From the *Setup-Basics* menu, touch **Date/Time**.



4 From the *Setup-Date/Time* menu, touch **Date** to set the date.

5 Touch ↑ and ↓ to set the year, then the month, then the day.

6 Touch ✓ to save this setting, or:

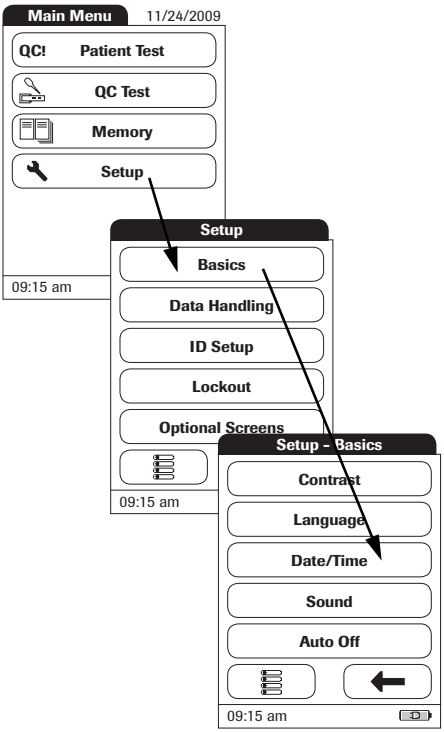
Touch ✗ to exit this menu without saving any changes.
The display automatically returns to the previous screen.

Note: If the *Set Date* menu appeared automatically after turning the meter on, you **must** touch ✓ to complete the date setting. The *Set Time* menu will then be displayed next.

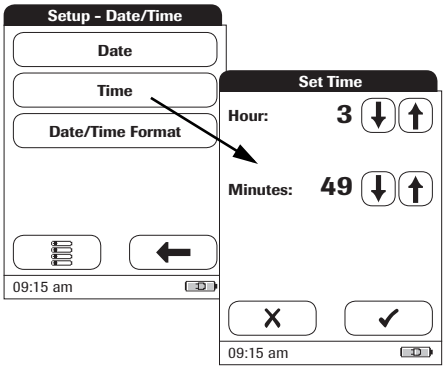
7 In the *Setup-Date/Time* menu, touch ← to return to the *Setup-Basics* menu or touch **Time** to move to the time setting.

Setting the Time

Use this menu to set the time of the meter.



1. From the *Main Menu*, touch **Setup**.
2. From the *Setup* menu, touch **Basics**.
3. From the *Setup-Basics* menu, touch **Date/Time**.



4 From the *Date/Time* menu, touch **Time** to set the time.

5 Touch ↑ and ↓ to set the hours, then the minutes.

6 Touch ✓ to save this setting, or:

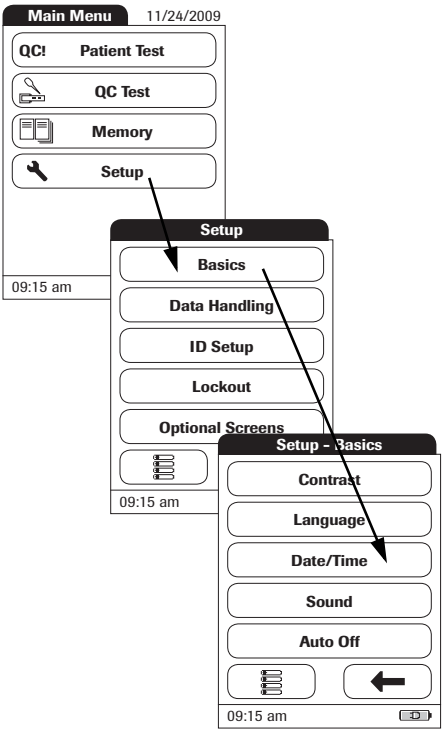
Touch ✗ to exit this menu without saving any changes.
The display automatically returns to the previous screen.

Note: If the *Set Time* menu appeared automatically after leaving the *Set Date* menu, you **must** touch ✓ to complete the time setting. The *Main Menu* will then be displayed next.

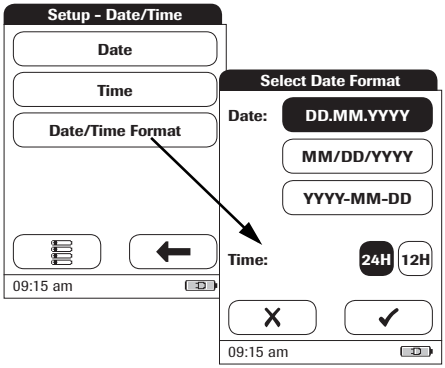
7 Touch ← to return to the *Setup-Basics* menu or touch **Date/Time Format** to move to the display options.

Setting the Display Options for Date and Time

Select your preferred format for the date and time display.



1. From the *Main Menu*, touch **Setup**.
2. From the *Setup* menu, touch **Basics**.
3. From the *Basics* menu, touch **Date/Time**.



4 From the *Setup-Date/Time* menu screen, touch **Date/Time Format** to set the display format.

The current settings are highlighted (white type on a black background). You can select one of the following display formats for the date:

- Day.Month.Year, e.g., 31.12.2006
- Month/Day/Year, e.g., 12/31/2006
- Year-Month-Day, e.g., 2006-12-31

You can also select one of the following display formats for the time:

- 24H (24-hour time format), e.g., 14:52
- 12H (12-hour time format, supplemented by am/pm), e.g., 2:52 pm

5 Touch the button with the display format of choice for the date and time. Your selection is now highlighted.

6 Touch ✓ to save this setting, or:

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

7 Touch ← to return to the *Setup-Basics* menu.

Sound

It is possible to activate or deactivate a beep sound for the following circumstances:

If activated, the meter beeps, when

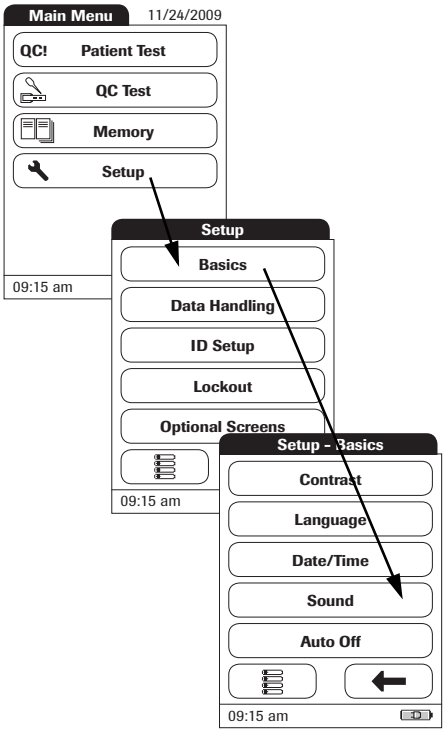
- it is switched on
- it detects a test strip
- pre-heating of the test strip is complete and you need to apply a sample
- the test is completed and the results are displayed (a long beep)
- an error occurs (three short beeps)
- the handheld power supply unit is connected when the meter is on
- a barcode is scanned successfully (short beep)
- the barcode scanner is disabled (two short beeps)
- a scanned barcode is rejected as invalid (three short beeps)
- a positive test result can be expected, while the measurement still is in progress (a long beep)

Independent from the setting you choose here, the alert information is always shown visually on screen.

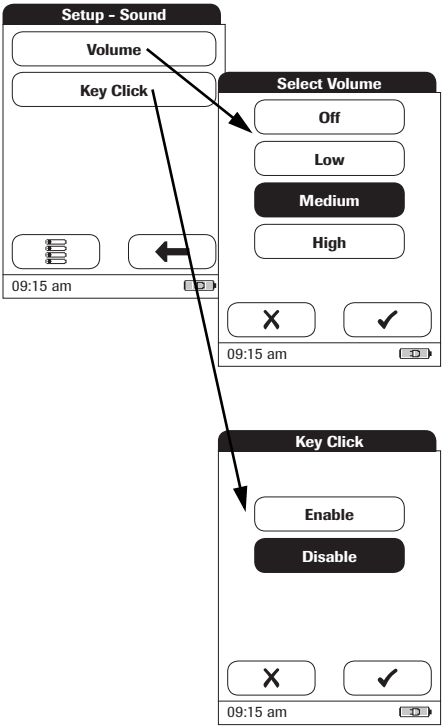
We recommend that you keep the *Sound* on at all times.

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

Enabling/disabling the *Sound* doesn't affect the measuring performance of the meter.



1. From the *Main Menu*, touch **Setup**.
2. From the *Setup* menu, touch **Basics**.
3. From the *Setup-Basics* menu, touch **Sound**.



4 From the *Setup-Sound* menu, touch **Volume** to set the volume level.

The current setting is highlighted (white type on a black background). You may select from the following options:

- Off
- Low
- Medium
- High

5 Touch **Key Click** in the *Setup-Sound* menu to turn the key click on or off.

You may select from the following options:

- Enable
- Disable

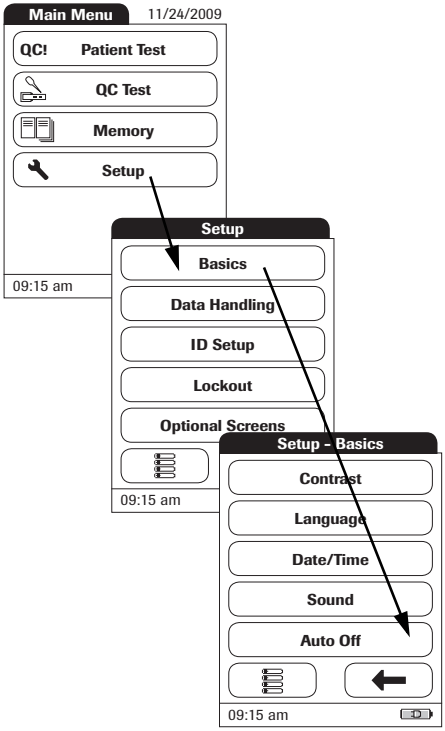
6 Touch ✓ to save this setting, or:

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

7 Touch ← to return to the *Setup-Basics* menu.

Auto Off

You can set up your 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 use of the charge of the rechargeable battery pack.

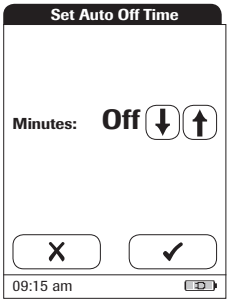


1. From the *Main Menu*, touch **Setup**.
2. From the *Setup* menu, touch **Basics**.
3. In the *Setup-Basics* menu, touch **Auto Off**.

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

- If *Operator ID* is set to **None**, the meter switches to the *Main Menu*, once *Auto Off* is triggered.
- If *Operator ID* is set to **Optional** or **Required**, the meter switches to *Operator Login*, once *Auto Off* is triggered.

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



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 ↑ and ↓ to select the time of choice in minutes or to turn the feature off.

5 Touch ✓ to save this setting, or:

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

6 Touch ← to return to the *Setup* menu.

Data Handling Setup

Connection

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

Computer

The meter can connect with a computer or host system, e.g., the cobas IT 1000 PoC data management system. Physically the connection requires the (optional) Handheld Base Unit and is established in two steps:

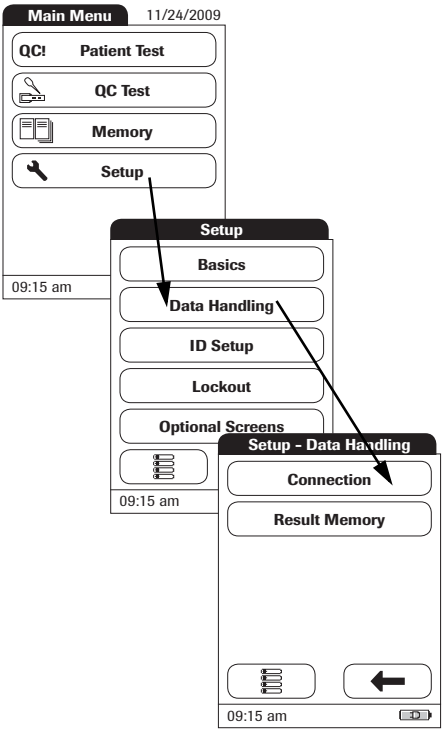
- The meter connects to the Handheld Base Unit via infrared.
- The Handheld Base Unit is either connected to a single computer (via USB) or to a network/host system (via ethernet).

The computer can be used to

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

thus eliminating the need for manual entry of these data.

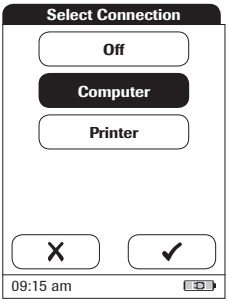
In addition, you can transfer test results stored in the meter to other systems for archiving or further evaluation. The *Data Handling* settings activate or deactivate the meter's ability to communicate with a computer.



1 From the *Main Menu*, touch **Setup**.

2 From the *Setup* menu, touch **Data Handling**.

3 From the *Data Handling* menu, touch **Connection**.



4 Touch **Computer**. Your selection is now highlighted.

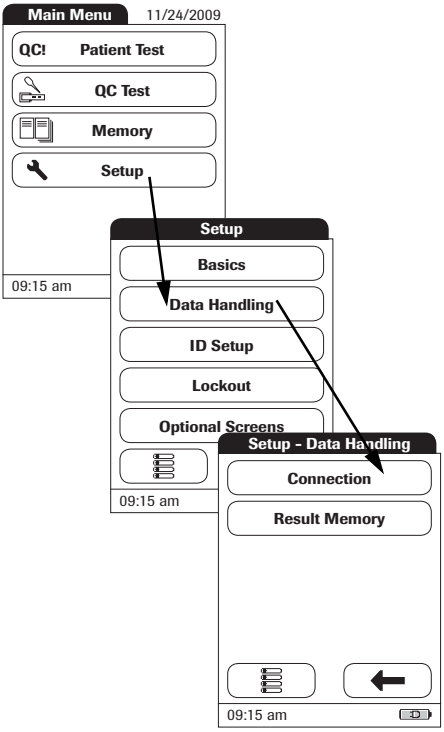
5 Touch ✓ to save this setting, or:

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

Note: Enabling the connection to a computer disables the connection to a printer (and vice versa).

Printer

The meter can directly connect with a printer via an infrared interface. It is not necessary to use the Handheld Base Unit for this purpose. The option to print is displayed in a test result as well as directly after a test and when calling up stored results. Using the settings you enter here, you can activate or deactivate the meter‘s ability to print.

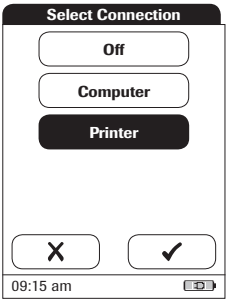


1 From the *Main Menu*, touch **Setup**.

2 From the *Setup* menu, touch **Data Handling** .

3 From the *Data Handling* menu, touch **Connection**.

Note: Connection to a printer can only be established via infrared. Therefore the printer you want to use must support infrared communication.



4 Touch **Printer**. Your selection is now highlighted.

5 Touch ✓ to save this setting, or:

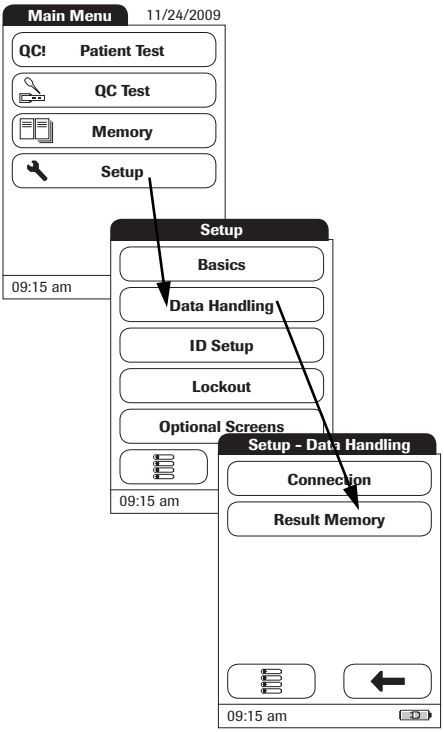
Touch ✗ to exit this menu without saving any changes.
The display automatically returns to the previous screen.

Note: Enabling the connection to a printer disables the connection to a computer (and vice versa).

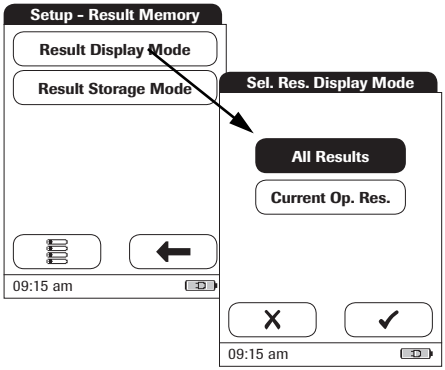
Result Memory

The settings for the result memory affect the *Result Display Mode* and the *Result Storage Mode* (see page 51) of test results.

All results recorded by the meter (patient results and quality controls) are stored automatically. Use the *Sel. Res. Display Mode* menu to select whether to display results (when calling up the *Memory* function) for all existing tests or only those from the current operator.



1. From the *Main Menu*, touch **Setup**.
2. From the *Setup* menu, touch **Data Handling** .
3. From the *Data Handling* menu, touch **Result Memory**.



4 From the *Setup-Result Memory* menu, touch **Result Display Mode** to select your display mode.

The current setting is highlighted (white type on a black background). You may select from the following options:

- **All Results**
- **Current Op**(erator) **Res(**ults)

5 Touch ✓ to save this setting, or:

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

6 Touch ← to return to the *Data Handling* menu.

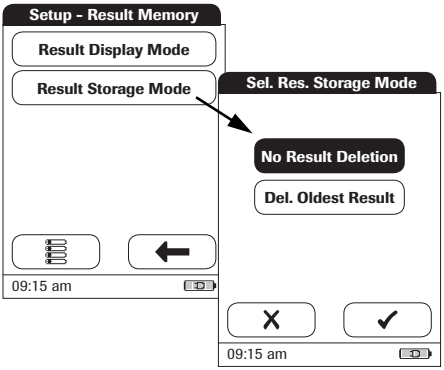
The *Sel. Res. Storage Mode* menu tells the meter what to do when the memory is full.

Note: The meter memory can store a maximum of 500 samples, 500 liquid controls, and 200 instrument quality controls.

In case of a full memory, you can choose between:

- *No Result Deletion*. This prevents data from being deleted inadvertently, but may (in case of a full memory) lead to the situation, that you can't perform a new measurement. Further measurements will only be possible, if stored data are transferred to the host system or you allow automatic deletion.
- *Del. Oldest Result*. Based on the 1st in/1st out principle, the oldest result will be automatically deleted when necessary. This is the only option if the meter is used without a PC/host system (i.e. no data will be transferred and archived).

However, you only can select between these two options, if the meter is used together with a PC/host system and the *Computer* connection is enabled. In this case data stored in the meter are flagged, as soon as they have been transferred to the computer. Now the meter is allowed to delete those flagged data when necessary, even if you have selected the *No Result Deletion* option.



7 From the *Result Memory* menu, touch **Result Storage Mode** to select your storage mode.

You may select from the following options:

- **No Result Deletion**
- **Del**(ete) **Oldest Result**

8 Touch ✓ to save this setting, or:

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

9 Touch ← to return to the *Data Handling* menu.

ID Setup Setting

Use the *ID Setup* (ID = identification) menu to enter settings for user and patient management. These settings are optional. The meter can be operated without these settings.

There are three types of identification used with the meter:

- If you set up an *Administrator ID*, most meter setup functions will be restricted to users who know this ID. Setting up an *Administrator ID* is not necessary in order to use the meter, but it may be desirable to limit the number of users who are allowed to change meter settings.
- The *Operator ID* belongs to persons who use the meter to run tests. If you want to use *Operator IDs*, you have several options:
  - You may use *Operator IDs* to restrict the use of the meter only to qualified personnel or a predefined group of users.
  - You may use *Operator IDs* for informational purposes only, in order to assign stored measurement results to the users who performed the test.
- The *Patient ID* belongs to the person, whose test results are recorded. You can either
  - abandon unique *Patient IDs* (in this case, every test is simply numbered in consecutive order),
  - allow a unique *Patient ID* as optional, or
  - require a unique *Patient ID* for every test. Patient lists created externally can also be transferred to the meter, enabling you to select *Patient ID*s for a test from these lists.

Operator IDs or *Patient IDs* can be entered by using the onscreen keypad or the barcode scanner on the front of the meter (version with barcode scanner only). If passwords were created, they **must** be entered via the onscreen keypad.

Administrator ID

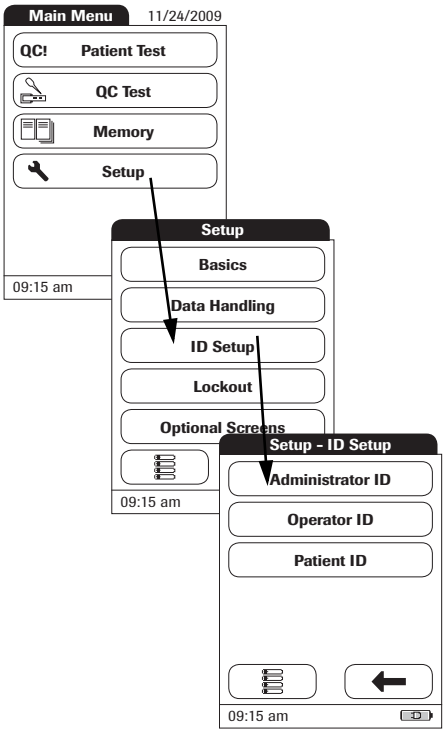
In the default setting, the meter is not protected with an *Administrator ID*, and all setup options are accessible to anyone. If you set up an *Administrator ID*, the following setup areas are automatically reserved only for the administrator:

- Screen: Date/Time
- Data Handling
- ID Setup
- Quality control and the associated lockouts
- Optional screens

The setup of an *Administrator ID* does not limit or alter the usage of the meter for measurements in any way. Furthermore setting up the *Administrator ID* has no impact on the usage of *Operator IDs*. Only the setup options as listed above are tied to administrator access.

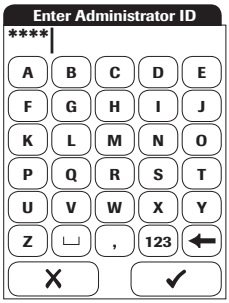
Note: When you enter an *Administrator ID*, this ID must be entered from this point forward before any future IDs can be set up (anywhere in the *ID Setup* menu). The *Administrator ID* must also be entered before you can delete or change the *Administrator ID*.

If you forget the *Administrator ID*, the meter setup may be unlocked via the external data management system (e.g. cobas IT 1000). If you don't use such a system and need to reset the *Administrator ID*, contact your local Roche Diagnostics customer support and service center.



If an *Administrator ID* has not been set up yet:

1. From the *Main Menu*, touch **Setup**.
2. From the *Setup* menu, touch **ID Setup**.
3. From the *Setup-ID Setup* menu, touch **Administrator ID**.



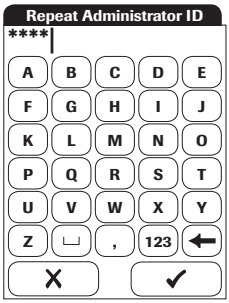
4 Using the onscreen keypad, enter the *Administrator ID* of choice (or the password provided by Roche Diagnostics). The ID should include up to 20 characters and/or letters of choice. Pay close attention to the buttons you press, because the ID is displayed on the screen only as asterisks (similar to entering a password on a computer).

5 Use (123) to switch to the input of numbers and special characters.

6 Use (ABC) to switch back to the input of letters.

7 Use (←) to backspace and correct a mistake.

8 Touch ✓ to save this *Administrator ID*, or:
Touch ✗ to exit this menu without saving any changes.

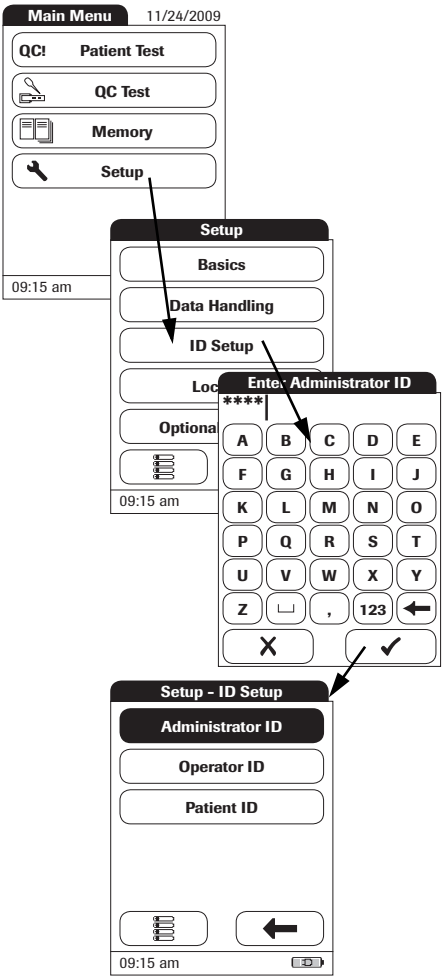


9 Enter the *Administrator ID* again (the onscreen keypad is automatically displayed again) to confirm the first entry.

If you touch ✓, the *Administrator ID* is set.

If you touch ✗, the *Administrator ID* is not set and is therefore inactive.

Note: The display automatically returns to the *Setup-ID Setup* menu. After you exit the *Setup* menu, only an authenticated administrator may set up any further ID numbers.



Changing an existing *Administrator ID*:

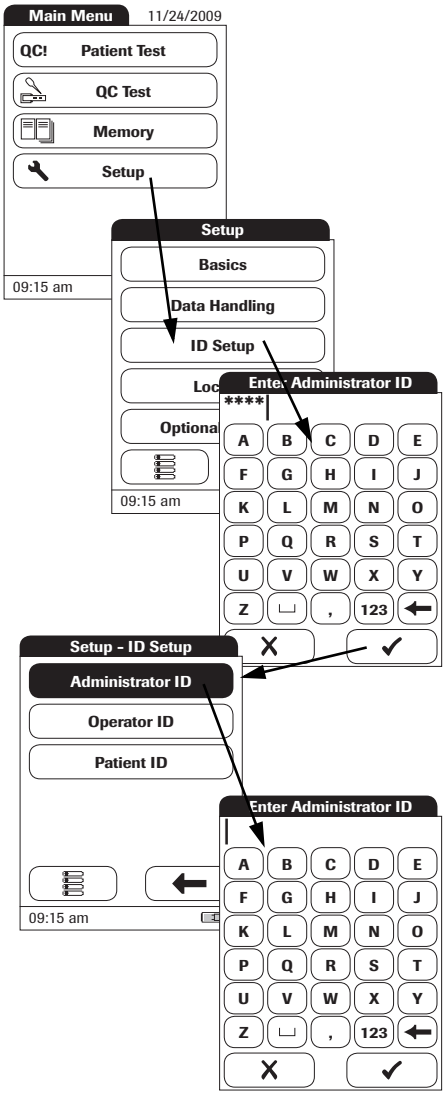
1 From the *Main Menu*, touch **Setup**.

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

3 Using the onscreen keypad, enter the valid *Administrator ID*.

The *ID Setup* is displayed. The **Administrator ID** button is highlighted, which means an *Administrator ID* is active.

4 Touch **Administrator ID** and use the onscreen keypad to enter a new ID of choice (enter it twice).



Disabling an existing *Administrator ID*:

1 From the *Main Menu*, touch **Setup**.

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

3 Using the onscreen keypad, enter the valid *Administrator ID*.

The *ID Setup* is displayed. The **Administrator ID** button is highlighted, which means an *Administrator ID* is active.

4 Touch **Administrator ID**.

5 Touch ✓ to close the onscreen keypad **without** entering an ID number.

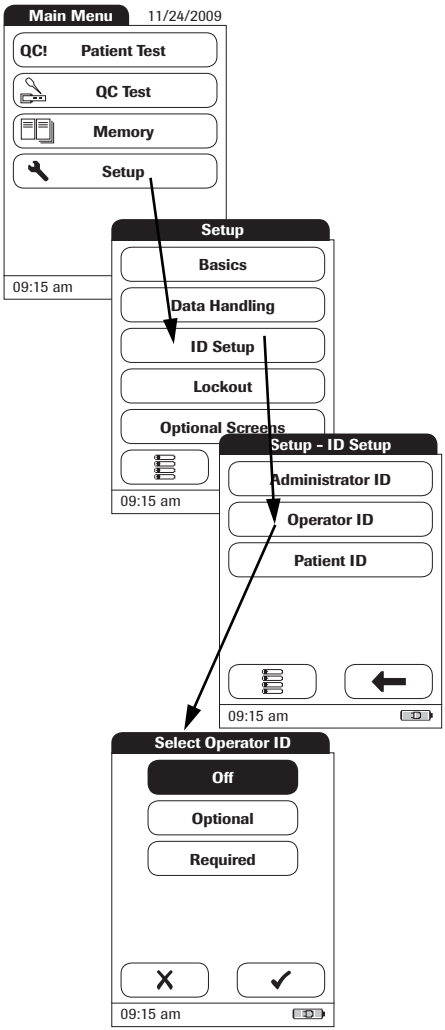
The *Administrator ID* has been deleted and therefore deactivated. The **Administrator ID** button is no longer highlighted.

Operator ID

In the default setting, the meter is not set up for use with *Operator ID*s. You have several (more or less restrictive) options for setting up *Operator ID*s, which are summarised below.

Operator List	Option 1	Option 2	Result
No (see page 60)	Off		After switching on, the meter displays the *Main Menu*. You can directly start a measurement.
	Optional	Alphanum.	After switching on, the meter displays the *Enter Operator ID* screen. You can, but you don't have to enter an ID.
		Numeric	
	Required	Alphanum.	After switching on, the meter displays the *Enter Operator ID* screen. You have to enter an ID before proceeding.
		Numeric	
Yes, transferred from PC/host system (see page 62)	List		After switching on, the meter displays the *Operator* list. You have to either select your ID from the list or scan your ID with the barcode scanner. This option may require an additional password to be entered manually.
	None		After switching on, the meter displays the *Main Menu*. You can directly start a measurement. An *Operator* list may be present, but is ignored.

Without a list, operators can log in directly by entering their operator name. This setup menu allows you to select whether or not an operator login is possible or required.



1 From the *Main Menu*, touch **Setup**.

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

3 From the *Setup-ID Setup* menu, touch **Operator ID**.

You may select from the following options:

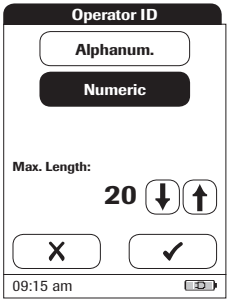
- **Off** (*Operator ID* cannot be entered)
- **Optional** (*Operator ID* can be entered, but is not required)
- **Required** (An *Operator ID* must be entered)

4 Touch the button with the setting of choice. Your selection is now highlighted.

5 Touch ✓ to save this setting, or:

Touch ✗ to exit this menu without saving any changes.
The display automatically returns to the previous screen or (depending on the option you selected) proceeds to the next screen.

The entries for the option **Off** are now completed. For the options **Optional** and **Required**, continue by selecting the input format.



6 Select the form for input of the *Operator ID*.

You may select from the following options:

- **Alphanumeric** (letters and numbers, e.g., “J. Doe 3378”)
- **Numeric** (numbers only, e.g., “3387”)
- Indicate the maximum number of characters (1 … 20) the *Operator ID* can have

7 Touch the button with the form of choice for setting up the *Operator ID*. Your selection is now highlighted.

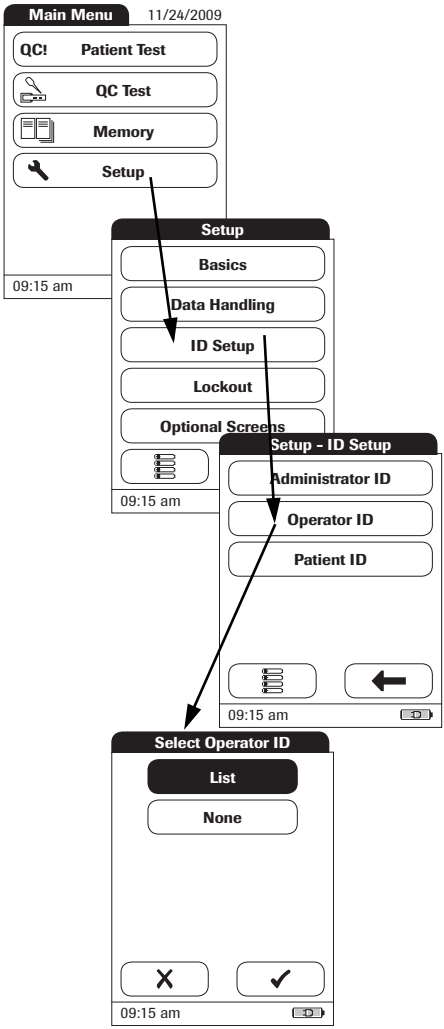
8 Touch ↑ and ↓ to set the number of characters (length) of choice.

9 Touch ✓ to save this setting, or:

Touch ✗ to exit this menu without saving any changes.

The meter automatically returns to the *Setup-ID Setup* menu.

In order to limit the operator group, an *Operator* list must be created on the PC/host system. With an *Operator* list being transferred to the meter, the *Operator ID* options are different from the options in “standalone” mode.



1 From the *Main Menu*, touch **Setup**.

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

3 From the *Setup-ID Setup* menu, touch **Operator ID**.

You may select from the following options:

- **List** (*Operator ID* must be selected from the list or scanned using the barcode scanner)
- **None** (*Operator ID* cannot be entered or selected)

4 Touch the button with the setting of choice. Your selection is now highlighted.

5 Touch ✓ to save this setting, or:

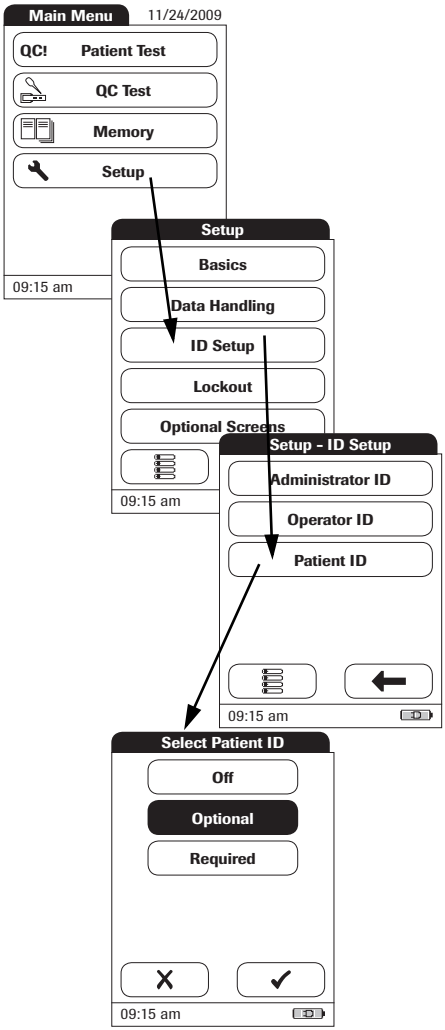
Touch ✗ to exit this menu without saving any changes.
The display automatically returns to the previous screen.

Patient

Patient IDs help you to assign stored measurements to individual patients. If you create a patient list externally, this list may even serve as a "To-Do list", containing the information about which patients need to be tested. The available options are outlined below.

Patient List	Option 1	Option 2	Result
No	Off		After touching *Patient Test*, the meter starts a measurement. Instead of a *Patient ID* measurements show consecutive numbers.
	Optional	Alphanum.	After touching *Patient Test*, the meter displays the *Enter Patient ID* screen. You can, but you don't have to enter an ID before proceeding.
		Numeric	
	Required	Alphanum.	After touching *Patient Test*, the meter displays the *Enter Patient ID* screen. You have to enter an ID before proceeding.
		Numeric	
Yes, transferred from PC/host system	Off		After touching *Patient Test*, the meter starts a measurement. A patient list may be present, but is ignored. Instead of a *Patient ID* measurements show consecutive numbers.
	Optional	Alphanum.	After touching *Patient Test*, the meter displays the *Enter Patient ID* screen. You can, but you don't have to enter an ID before proceeding.
		Numeric	
	Required	Alphanum.	After touching *Patient Test*, the meter displays the patient list. You have to either select the ID from the list, enter a new ID manually, or scan the ID with the barcode scanner.
		Numeric	

Note: Patient lists can only be created on a PC/host system and must be transferred to the meter. Lists cannot be created on the meter.



1 From the *Main Menu*, touch **Setup**.

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

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

You may select from the following options:

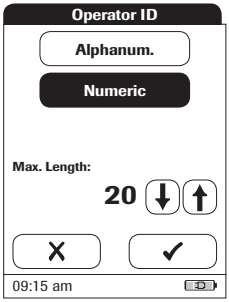
- **Off** (*Patient ID* cannot be entered)
- **Optional** (*Patient ID* can be entered, but is not required)
- **Required** (The operator must enter the *Patient ID*)

4 Touch the button with the setting of choice. Your selection is now highlighted.

5 Touch ✓ to save this setting, or:

Touch ✗ to exit this menu without saving any changes.
The display automatically returns to the previous screen or (depending on the option you selected) proceeds to the next screen.

The entries for the option **Off** are now completed. For the options **Optional** and **Required**, continue by selecting the input format.



6 Select the form for input of the *Patient ID* before each test.

You may select from the following options:

- **Alphanumeric** (letters and numbers, e.g., "J. Doe 3378")
- **Numeric** (numbers only, e.g., "3387")
- Indicate the maximum number of characters (1 … 20) the *Patient ID* number can have.

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

8 Touch ↑ and ↓ to set the number of characters (length) of choice.

9 Touch ✓ to save this setting, or:

Touch ✗ to exit this menu without saving any changes.

The display automatically returns to the *Setup-ID Setup* menu.

Lockout Setup

The *Lockout* menu contains the options for quality control tests that the operator is required to perform at specified intervals or based on specific triggers. This is a list of the available lockout options:

- *Operator Lockout*
- *QC Settings*, containing
  - *New Lot Lockout*
  - *QC Lockout*
  - *IQC Lockout*
- *Cleaning Lockout*
- *STAT Test Config.* (overriding a lockout in an emergency situation)

If the quality control test is not performed as required or if the result is outside the target value range, the meter, parameter or test strip lot is blocked from further use. Lockouts can also be set up on an operator-specific basis, i.e., each operator must perform the corresponding quality control tests at specified intervals.

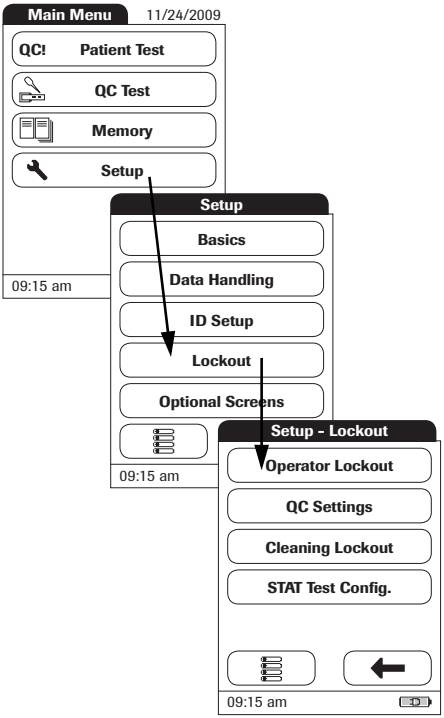
A quality control test must be completed successfully before the meter is made available again (either to the operator or in general) for testing.

The option of setting up lockouts for operators is available only when the meter is set up for operator logins (see page 59) and operator lists are stored in the meter.

If a lockout is triggered in case of an emergency, there might not be the time to first complete the required quality control test. For such a case you may set up so-called *STAT Tests* (STAT = **S**hort **T**urn**A**round **T**ime). This option allows to perform a certain number of tests, although a lockout is in force. However, once the defined number of STAT tests has been performed, further use of the meter is no longer possible (for the affected test parameter or operator), unless the required quality control test is successfully completed.

Operator Lockout

To perform a test with the meter, the individual steps must be performed properly. Quality control tests can be performed on a regular basis by every operator to ensure these steps are performed properly. By activating the operator lockout, operators are required to perform regular quality control tests.

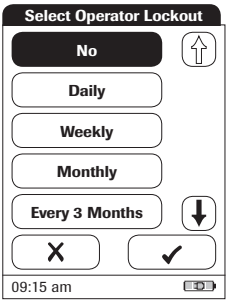


1. From the *Main Menu*, touch **Setup**.
2. From the *Setup* menu, touch **Lockout**.
3. From the *Setup-Lockout* menu, touch **Operator Lockout**.
   If this button appears in gray (inactive), the option *Operator ID* is deactivated.

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

You may select from the following options:

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



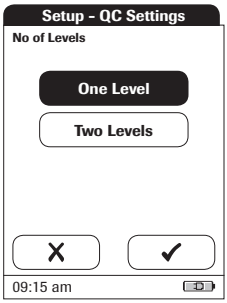
5 Touch ⇧ and ⇩ to display the option of choice on the screen. If the arrow is just an outline ⇧ ⇩, this means no other options are available in the direction indicated.

6 Touch the button to select the time interval of choice. Your selection is now highlighted.

7 Touch ✓ to save this setting, or:

Touch ✗ to exit this menu without saving any changes.

Note: If you selected **No**, *Operator Lockout* is deactivated.



8 Quality control tests may include one or two levels. Select the number of levels which must be performed (not applicable, if you selected **No**).

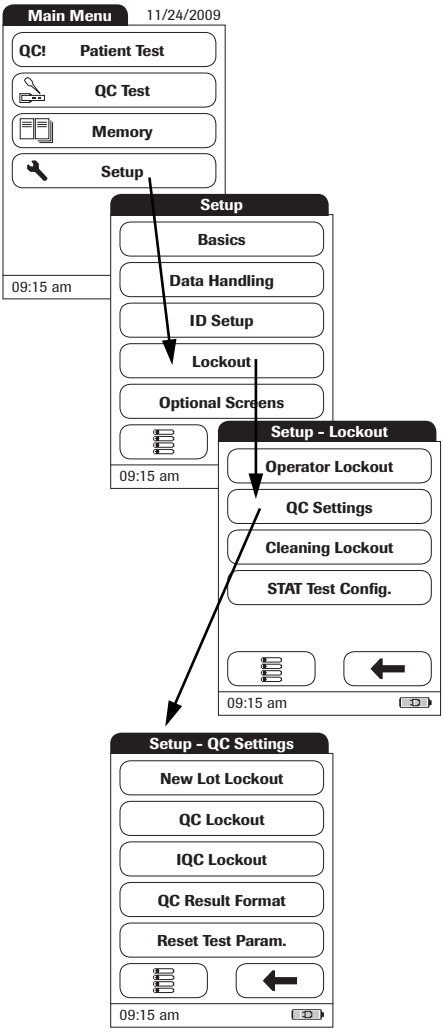
9 Touch ✓ to save this setting, or:

Touch ✗ to exit this menu without saving any changes.
The display automatically returns to the *Setup-Lockout* menu.

Quality Control (QC) Settings

QC Settings define that operator-independent quality control tests must be run on a regular basis. Lockouts may be triggerd by selectable time periods, and lockouts may be triggered by certain events. The *QC Settings* menu contains the following options:

- *New Lot Lockout* (applies every time a new test strip lot is used)
- *QC Lockout* (time-based)
- *IQC Lockout* (time-based)
- *QC Result Format* (select the format for QC result displays)
- *Reset Test Param.* (reset all test parameters, including code chip data and QC lockouts)



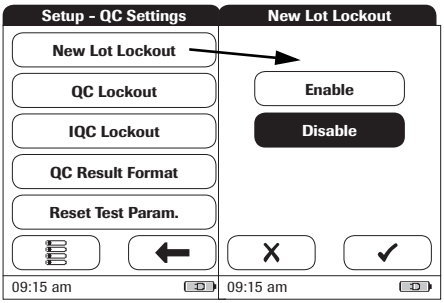
1 From the *Main Menu*, touch **Setup**.

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

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

New Lot Lockout

See page 71 on how to access the *Setup-QC Settings* menu.



1. Touch **New Lot Lockout** to activate quality control when changing the test strip lot.
2. Touch the button with the setting of choice for changing the test strip lot.
3. Touch ✓ to save this setting, or:

   Touch ✗ to exit this menu without saving any changes.
   The display automatically returns to the *Setup-QC Settings* menu.

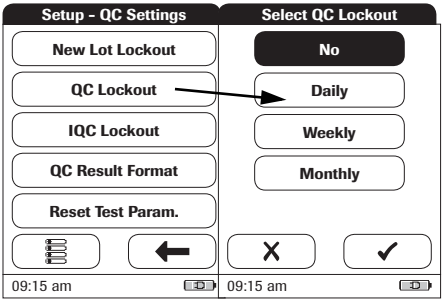
Quality Control (QC) Lockout

A *QC Lockout* requires a quality control test to be performed. You may also set the number of levels for this test. You may select from the following options:

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

All enabled QC Lockouts, if the time period has elapsed, are activated at 8:00 a.m. (presetting, time can be changed in a PC/host system).

See page 71 on how to access the *Setup-QC Settings* menu.



1. Touch **QC Lockout** to set regularly recurring quality control tests for available test parameters.
2. Touch the button to select the time interval of choice. Your selection is now highlighted.
3. Touch ✓ to save this setting, or:

   Touch ✗ to exit this menu without saving any changes.
4. Quality control tests may include one or two levels. Select the number of levels which must be performed (not applicable, if you selected **No**).
5. Touch ✓ to save this setting, or:

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

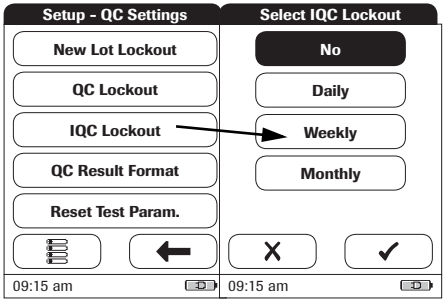
Instrument Quality Control (IQC) Lockout

An *IQC Lockout* also requires a quality control test with dedicated IQC test strips to be performed. You may select from the following options:

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

All enabled QC Lockouts, if the time period has elapsed, are activated at 8:00 a.m. (presetting, time can be changed in a PC/host system).

See page 71 on how to access the *Setup-QC Settings* menu.



1 Touch **IQC Lockout** to set regularly recurring instrument quality control tests (IQC = **I**nstrument **Q**uality **C**ontrol).

2 Touch the button to select the time interval of choice. Your selection is now highlighted.

3 Touch ✓ to save this setting, or:

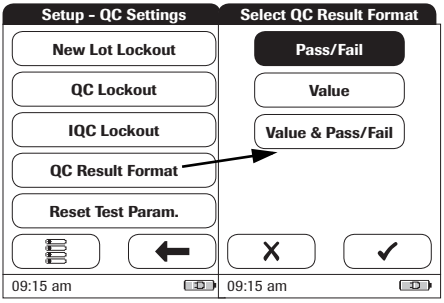
Touch ✗ to exit this menu without saving any changes.
The display automatically returns to the previous screen.

QC Result Format

The QC Result format defines the kind of information that is displayed in a QC result screen. You may select from the following options:

- Display without a value, but with text “Pass” or “Fail”
- Display a value
- Display as value and with text “Pass” or “Fail”

See page 71 on how to access the *Setup-QC Settings* menu.



1 Touch **QC Result Format** to set the display format.

2 Touch the button to select the result format of choice. Your selection is now highlighted.

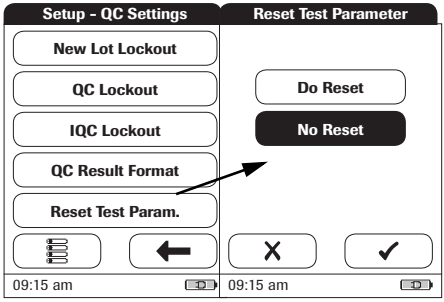
3 Touch ✓ to save this setting, or:

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

Reset Test Parameters

There may be cases which make it necessary to delete the test parameters which are stored in the meter. Such a case could be, e.g., a lockout for a test strip lot, which is no longer available. Do not try to use this method for bypassing lockouts in general (that's what STAT tests are for), because after resetting the test parameters the meter is set to a QC lockout state (if configured).

See page 71 on how to access the *Setup-QC Settings* menu.



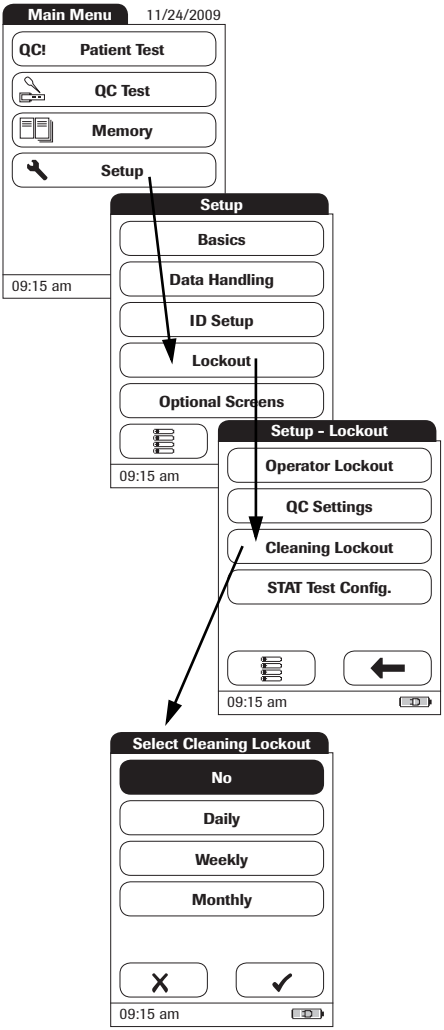
4 Touch **Reset Test Param.** to reset all stored test parameters and QC lockouts.

5 Select **Do Reset** and confirm by touching ✓ to reset the test parameters, or:

Touch ✗ to exit without resetting the test parameters (this leads to the same result as selecting and confirming **No Reset**). The display automatically returns to the previous screen.

Cleaning Lockout

Under normal handling conditions, your meter will not be exposed to significant dirt or contamination. However, circumstances might require regular checks of the test strip guide and (when necessary) cleaning of the meter. The *Cleaning Lockout* allows operators to specify time intervals for cleaning.



1 From the *Main Menu*, touch **Setup**.

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

3 From the *Setup-Lockout* menu, touch **Cleaning Lockout**.

You may select from the following options:

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

4 Touch the button to select the time interval of choice. Your selection is now highlighted.

5 Touch ✓ to save this setting, or:

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

STAT Test Configuration

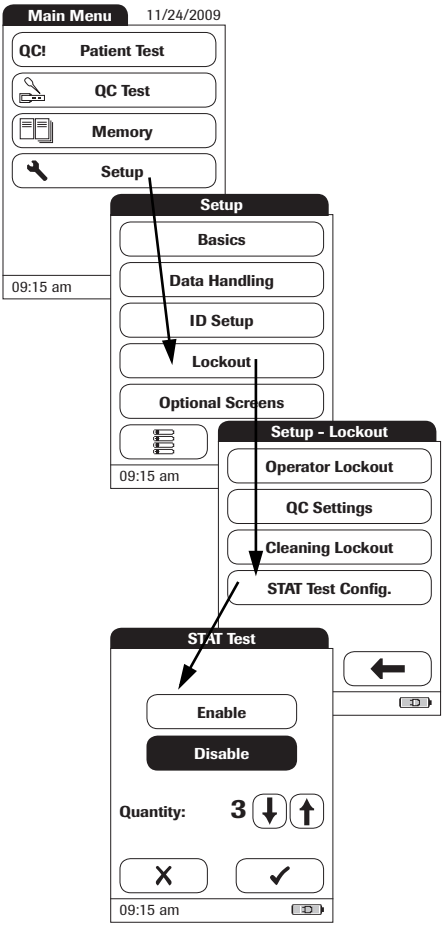
Quality control tests ensure consistent quality and accurate measurements. In emergency situations, however, it may be necessary to perform a test without delay. To override an active lockout for a test parameter, lot or operator, you can allow for *STAT Tests* (STAT = **S**hort **T**urn**A**round **T**ime).

You can set a number of tests permitted beyond the lockout. Once the number of allowed *STAT Tests* has been reached (for a single parameter), additional tests for this parameter are blocked until you successfully perform a quality control test.

Note: *STAT Tests* will be counted separately for each test parameter, lot or operator. Thus the actual availability of *STAT Tests* may differ for each parameter.

Note for international users: Due to limited space on the display some screens may show "STAT" instead of the localised version of this term.

STAT tests are labelled accordingly in the result window.



1 From the *Main Menu*, touch **Setup**.

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

3 From the *Setup-Lockout* menu, touch **STAT Test Config.**

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

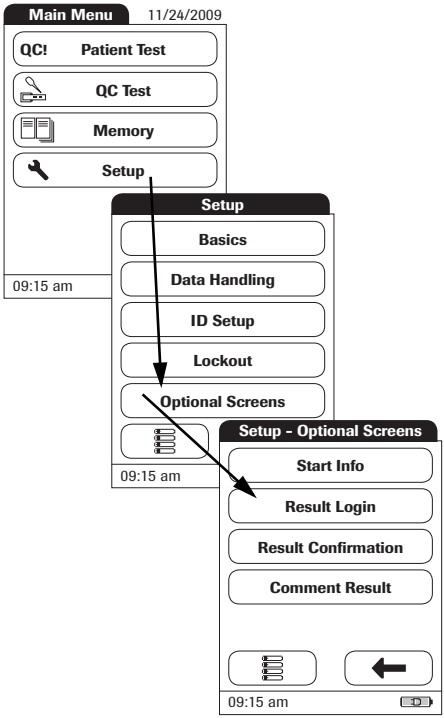
5 If you have enabled the option, touch ⬆ and ⬇ to set the number of additional tests.

6 Touch ✓ to save this setting, or:

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

Optional Screens Setup

In this screen, you can customise display formats and test procedures. You can choose to display additional information and select from options for managing the result display.



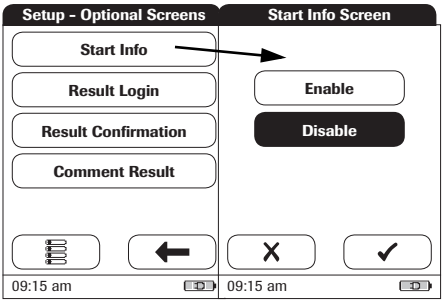
1 From the *Main Menu*, touch **Setup**.

2 From the *Setup* menu, touch **Optional Screens**.

In this menu screen, you may select from the following options:

- Display additional information on meter status
- Select to display results only after new login by operator
- Enable operators to confirm or reject test results
- Add comments to test results

The additional status information is displayed after switching on the meter or after logging off as an operator. This includes information about current lockouts, the number of results not transferred (to the host system) and the time since the last data transfer.



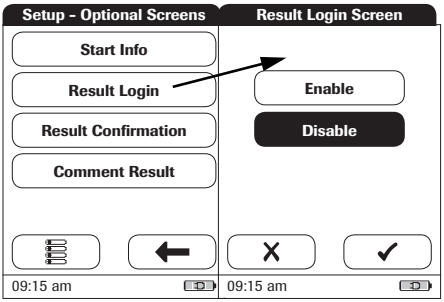
3 Touch **Start Info**.

4 Touch the button to select the state of the status display. Your selection is now highlighted.

5 Touch ✓ to save this setting, or:

Touch ✗ to exit this menu without saving any changes.

In environments with multiple operators, it can be useful to display a test only if the operator carrying out the test is present. By requiring operators to login again before displaying results, you ensure that only authorised persons view the results.



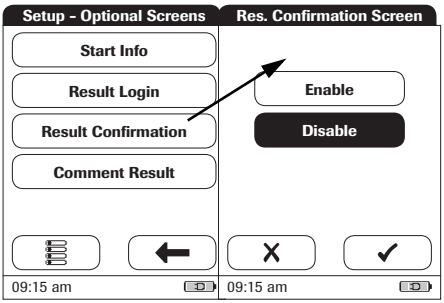
6 Touch **Result Login**.

7 Touch the button to select the state of the option. Your selection is now highlighted.

8 Touch ✓ to save this setting, or:

Touch ✗ to exit this menu without saving any changes.

In some circumstances, it may be useful for operators to confirm the validity of their results. To do so, an option can be enabled that prompts operators to confirm the results of every test.



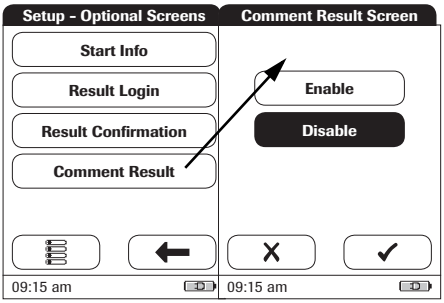
9 Touch **Confirm Results**.

10 Touch the button to select the state of the option. Your selection is now highlighted.

11 Touch ✓ to save this setting, or:

Touch ✗ to exit this menu without saving any changes.

To save information about tests or operator comments along with the result, it is possible to add notes. In addition, comments can be added in a predefined format or generated manually.



12 Touch **Add Comment**.

13 Touch the button to select the state of the option. Your selection is now highlighted.

14 Touch ✓ to save this setting, or:

Touch ✗ to exit this menu without saving any changes.

Note: A list of predefined comments can be created and transferred (only) from a PC/host system. Being a custom configuration, these comments are independent from the language selected on the meter.

Note: With *Add Comments* enabled, the user is required to enter/select a comment. Completely empty comments will not be accepted by the meter.

Performing a Test

What you need:

- Your **cobas h** 232 meter
- Roche CARDIAC test strips for the desired test, with the supplied code chip
- Roche CARDIAC pipettes (or suitable pipettes with pipetting volume of 150 µL)

Note: The Roche CARDIAC family includes several meters. Always make sure that the disposables (e.g. test strips) are made for use with the **cobas h** 232 meter. Some assays might require a minimum software version, please ensure that your software version on the **cobas h** 232 fits to your assay as mentioned in the corresponding package insert. Please contact your Roche representative if the **cobas h** 232 meter requires a software update

Always …

- … operate the meter according to the specified operating conditions (see page 135).
- … follow the information on correct handling of test strips in the package insert.
- … place the meter on a level, vibration-free surface while applying the sample until the necessary sample has been absorbed completely by the test strip.
- … keep the meter clean. See “Cleaning” on page 123.

Never …

- **…** touch or remove the test strip during a test.
- … add more blood after the test has begun.
- … remove or insert the code chip while the meter is performing a test.
- … move or pick up the meter while applying the sample - wait until the necessary sample has been absorbed completely by the test strip.
- … store the meter at extreme temperatures.
- … store the meter in damp or humid conditions without protection.

CAUTION

Accuracy/precision of measured results:
Failure to comply with the above may lead to inaccurate results. An incorrect result may lead to an error in diagnosis, therefore posing danger to the patient.

Sample Material

Heparinised venous whole blood is used as sample material. For each test with the **cobas h** 232 meter, you need a quantity of exactly 150 µL.

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

- Use gloves.
- Dispose of used pipettes and test strips in a sturdy sharps container with a lid.
- Furthermore, follow all hygiene and safety regulations in force locally.

CAUTION

Protection against infection:
When collecting samples always observe the general precautions and guidelines relating to blood sampling (see page 9).

Dispose of all test strips used for patient testing in line with the disposal policy of your laboratory or practice (see page 9)

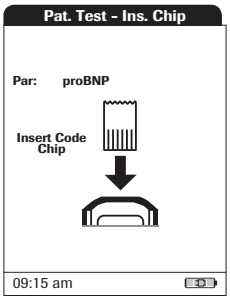
Preparing to Test

1 Prepare the required test strips (shown here: Roche CARDIAC T Quantitative for testing Troponin T).

2 Make sure that the code chip supplied with these test strips is also at hand.

Code Chip

The code chip provides the meter with important information on the manufacturer-specific parameters of the respective test strip lots. It contains information about the test method, the lot number and the expiry date.



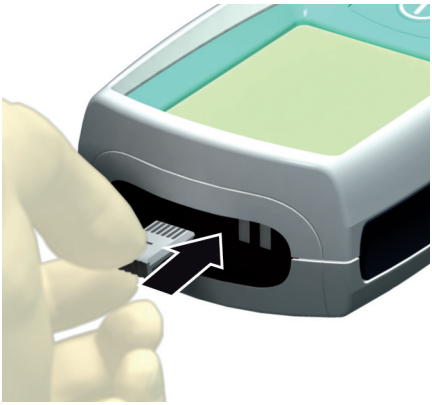
- Each folding box of test strips contains its own code chip. Make sure you have the code chip at hand before performing the first test with a new test strip lot.
- When you insert a test strip from a new lot for the first time, the meter prompts you to insert the corresponding code chip. At this point, compare the code number you see on the display with the number that is printed on the test strip package you are using. If the two code numbers are identical, insert the new code chip into the slot in the meter.
- Once inserted, the code chip information is read and stored on the meter. The meter can store up to 200 code chip datasets (100 test strip lots and 100 quality control lots). Further tests using the same strip lot can be performed without inserting the code chip again.
- The code chip is no longer required, once the data is stored. You may leave it in the meter, or you can use it with other meters using the same test strip lot.

Note: Roche recommends to keep the code chip in the meter to protect the contacts from becoming dirty.

Note: Once the test strip lot is used up, dispose of the old code chip promptly to prevent mix-ups.

Note: Protect the code chip from moisture and equipment which produces magnetic fields.

Inserting the Code Chip



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

   Dispose of the old code chip with your household waste.

2. Always make sure that the number on the code chip matches the number on the label of the test strip package.

   By scanning the barcode on the strip, the meter gathers information about the number of the required code chip.

3. Slide the new code chip into the slot on the top of the meter as shown until you feel it snaps into place.

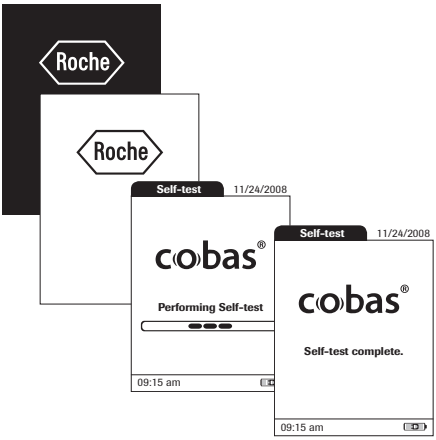
Note: If the code chip is missing or incorrectly inserted, a corresponding error message appears in the display (see “Troubleshooting” starting on page 127).

Switching on the Meter

1 Turn the meter on by pressing the On/Off button ⏻ for longer than 5 seconds.

Note: You can also turn on the meter directly by connecting the handheld power supply.

2 To turn the meter off after use, press the ⏻ button for longer than 2 seconds.



The meter runs through a self-test at startup.

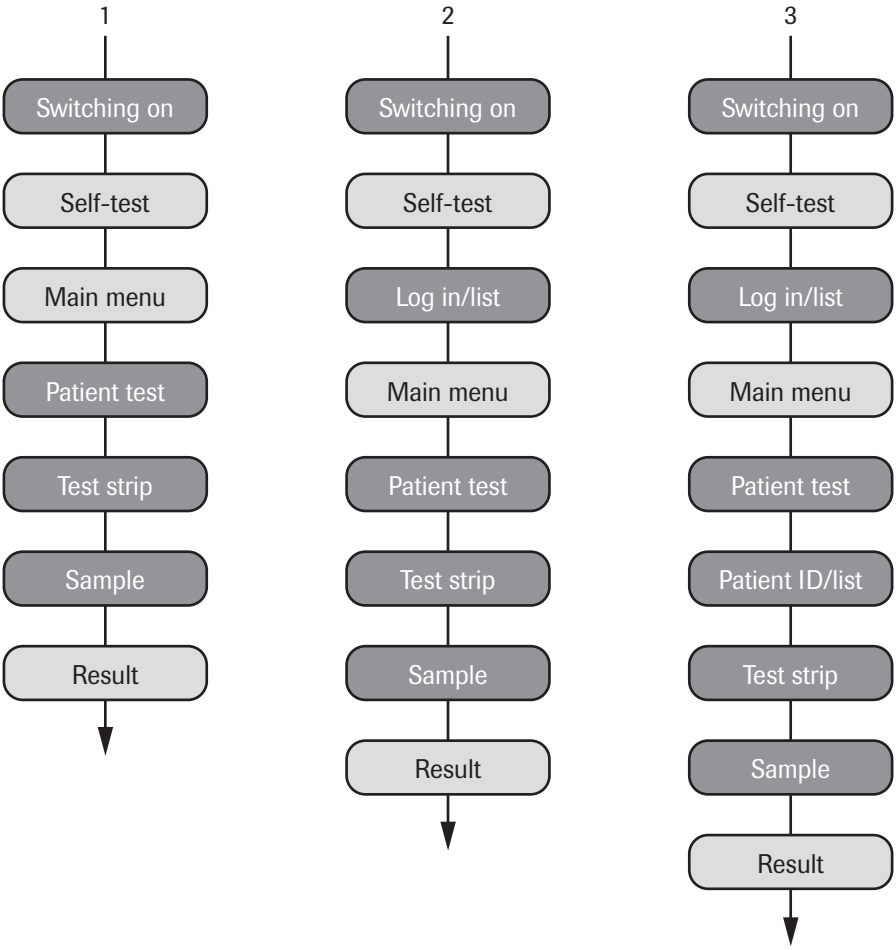
Test Steps (Overview)

The following illustration shows the steps performed during testing. The steps you actively perform are displayed with a dark background. Depending on the configuration, the individual steps shown here may include additional actions (e.g., entering a password). Some steps may be different, working with or without Operator IDs and Patient IDs. On the following pages these steps are explained separately for each configuration.

1 Without operator and patient lists (or both operator and patient ID disabled)

2 With operator list (or operator ID enabled)

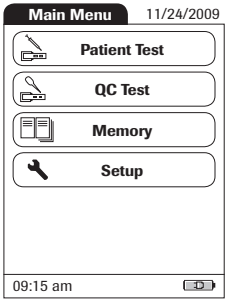
3 With operator and patient list (or operator and patient ID enabled)



Logging In

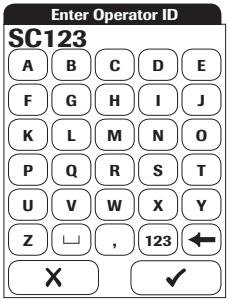
The initial steps until the *Main Menu* is displayed depend on the configuration and are performed as follows:

Without operator login required



3 Wait until the main menu is displayed.

With operator login (no operator list)

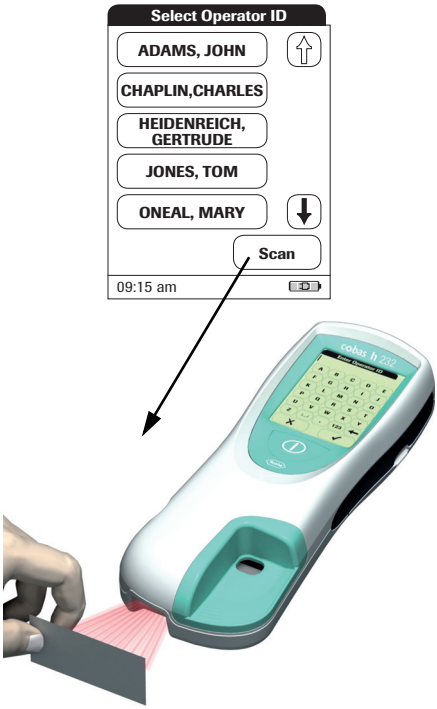


3 Enter your *Operator ID*.

4 Touch ✓ to confirm your entry.

5 Wait until the main menu is displayed.

With operator login (list available)

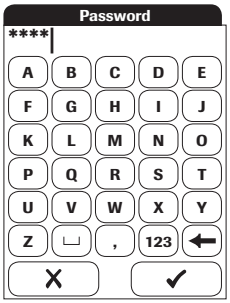


3 If an operator list exists, wait until this list is displayed.

4 Touch ⇧ and ⇩ to scroll through the list. Select the operator of choice by touching the corresponding button.

Note: As an alternative (meters with a scanner), the operator login can be performed via the inbuilt barcode scanner. Touch **Scan** and hold the card with the barcode approx. 10 cm from the scanner.

Note: It is not possible to connect an external barcode scanner to the meter

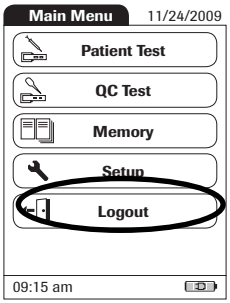


5 Enter the password.

6 Touch ✓ to confirm your entry, or:

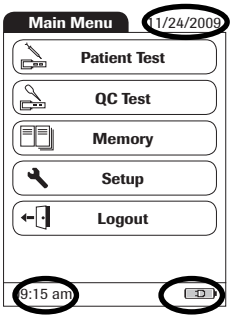
Touch ✗ , to display the operator pick list again.

7 Wait until the main menu is displayed.

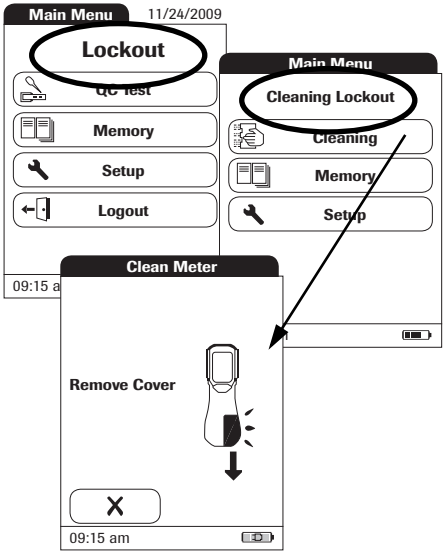


When the tests are completed or another operator wants to perform additional tests, touch **Logout** to log out. The meter returns to the display of the operator pick list.

Performing a Test

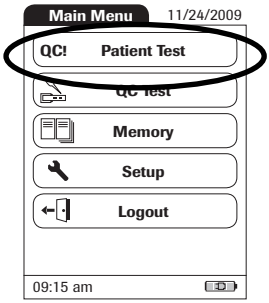


1. Check the charge level of the handheld battery pack. If there are no bars left in the battery icon, you cannot perform any more tests.
2. Check that the date and time are correct. Correct any incorrect settings as described in the chapter entitled “Meter Setup/Setting the Date”.



If a *QC lockout* is displayed instead of **Patient Test**, you must run a quality control test before you can perform a test (see “Quality Control” starting on page 105). When *a QC Lockout* is in force, a test can only be performed only as a STAT test.

If a *Cleaning Lockout* is displayed instead of **Patient Test**, you must touch **Cleaning** and follow the instructions on the screen and clean (if required) the meter. See “Cleaning” beginning on page 123. Once you have replaced the sample application cover, the lockout is no longer in force once you switch on the meter again.

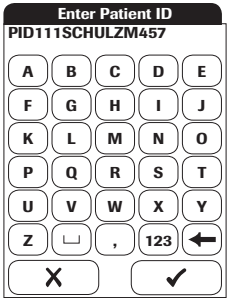


If the **Patient Test** button is available, but a lockout is displayed, you must first perform a quality control test for certain test parameters. Other test parameters are not affected.

Note for international users: Due to limited space on the display some screens may show “QC” instead of the localised version of this term.

Without patient list

3 Touch **Patient Test**.



4 If you selected the *Patient ID* as *optional*, you **can** enter a *Patient ID* using the onscreen keypad.
If you selected the *Patient ID* as *required*, you **must** enter the *Patient ID* using the onscreen keypad.
If you selected no *Patient ID* (*None*), the meter automatically proceeds to the next step.

5 Touch ✓ to confirm the ID, or:

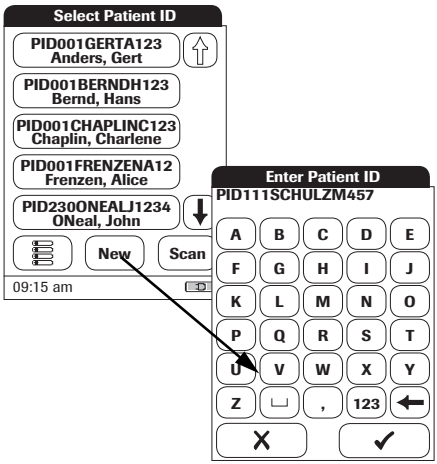
Touch ✗ to cancel the ID entry.

Continue reading on page 96.

With patient list

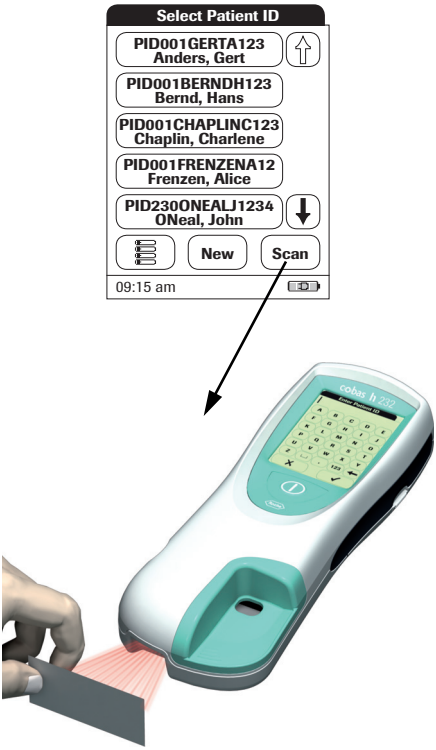
3 Touch **Patient Test**.

Note: Patient lists can only be created on a PC/host system and must be transferred to the meter. Lists cannot be created on the meter.



4 Touch ⇧ and ⇩ to scroll through the list. Select the patient to be tested by touching the corresponding button.

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

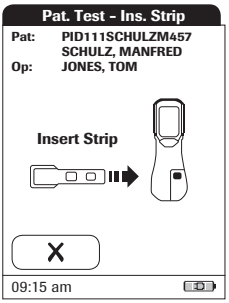


The *Patient ID* can also be entered via barcode (meters with a barcode scanner only). Touch **Scan** and hold either

- a card with the barcode approx. 10 cm from the scanner or
- the meter over a patient bracelet.

The scanner is also active, once you open the *Enter Patient ID* screen using the **New** button (for approx. 15 seconds).

Inserting a Test Strip

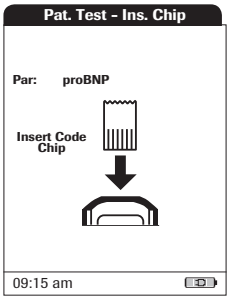


1. The test strip icon prompts you to insert a test strip. Remove the test strip from its foil pouch.
2. Hold the test strip so that the application and test area is facing up.
3. Hold the test strip straight and flat. Insert it quickly in the test strip guide of the meter. It is important that you insert the test strip using a smooth, even motion.

Note: Inserting the test strip too slowly can cause a barcode reading error. See the corresponding error message on page 129.

Note: 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 beep tone is turned on in the settings.

Exposure to external influences (e.g., humidity) may deteriorate the test strips and may lead to error messages! Remove the test strip from its foil pouch only when you are ready to perform a test.

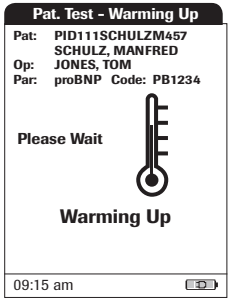


If you use a new test strip lot, you must insert the corresponding code chip once.
See “Code Chip” on page 85.

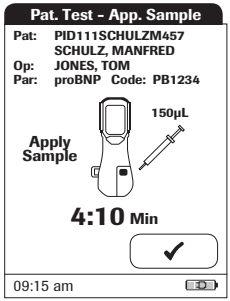
Depending on the meter setting, you may also be required to run a quality control test at this point.

The meter identifies the required code chip based on the test strip barcode and displays the code number.

Note: For each test parameter and each new test strip lot a different code key number is displayed.



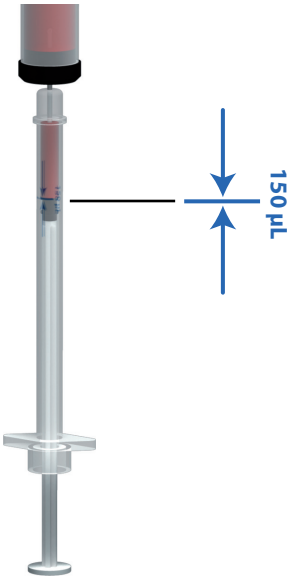
The thermometer icon shows that the test strip is warming up. A beep tone indicates when the warming-up process is complete, provided the beep tone is turned on in the settings.



The pipette icon indicates that the meter is ready to perform the test and is waiting for blood to be applied.

Simultaneously, a 5-minute countdown begins. You must apply the sample within this time. Otherwise you will receive an error message (after the sample detection has timed out).

In case of errors, see “Troubleshooting” on page 127.



4 Using the Roche CARDIAC pipette, draw **exactly 150 µL** (to the blue mark on the pipette) heparinised blood from the blood collection vial. Make sure the sample contains no air bubbles.

For ordering information on Roche CARDIAC pipettes see page 133.

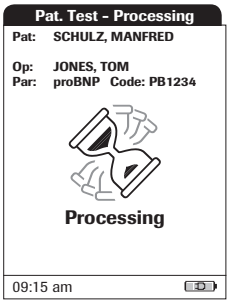
5 Apply the entire sample to the application area of the test strip.

Note: Always place the meter on a level, vibration-free surface while applying the sample until the necessary sample has been absorbed completely by the test strip.

6 Touch ✓ to confirm that the sample has been applied.

The hourglass icon appears as the meter begins to process the sample. For better control over the measurement process, you should always confirm this yourself, instead of waiting for the meter to detect the sample.

After you confirm that the sample has been applied, or if the meter automatically recognises that the sample has been applied, the ✓ button disappears.

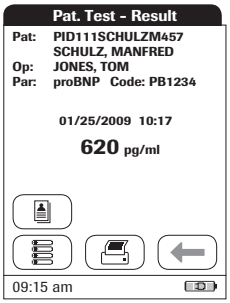


The hourglass icon appears and spins until the sample has been detected and the actual measurement begins. The time remaining for the test is displayed.

Note: The time of the measurement depends on the test parameters. Typically, 8 to 12 minutes are required.

Do not add more blood. Do not touch the test strip until the result is displayed. Always place the meter on a level, vibration-free surface while applying the sample until the necessary sample has been absorbed completely by the test strip.

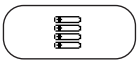
For Troponin T only: If during the test a qualitative aspect (positive/negative) is detected, the corresponding information is displayed when available (before the final result display).



The test result is shown and stored automatically.

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

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



Menu button:
Return to main menu

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

Print button:
Print results (infrared interface)

7 Remove the test strip from the measurement chamber.

8 Turn the meter off by pressing the On/Off button ⏻ for longer than 2 seconds.

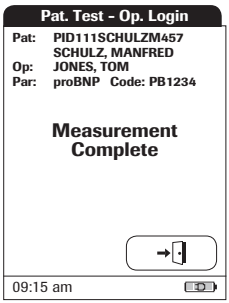
9 Discard the used disposable item and test strip in compliance with the disposal policy of your hospital or medical practice.

10 Clean the meter if this becomes necessary. See “Cleaning” on page 123).

Displaying, Confirming or Adding Comments to Results

As described in the chapter “Optional Screens Setup” starting on page 80, there are many options for displaying results that can be activated:

If the new *Operator Login* is required to display the result:



1 Touch the button for operator login.

2 Log in as described on page 90.

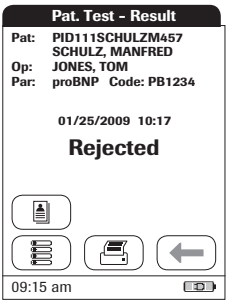
The result is now displayed.

If the test result requires a confirmation:

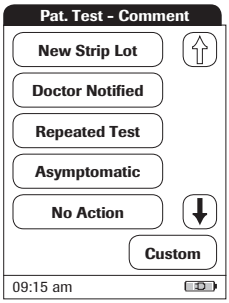
- When the result is displayed, touch the button to select the confirmation of choice.

You can choose to either

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



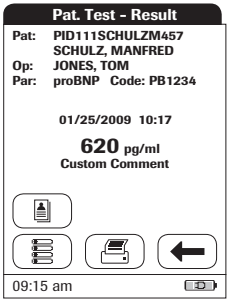
If you reject the result, the result value is no longer displayed. However, the test entry is stored.



If you want to add a comment to a test result:

1 Select a predefined comment from the list (available only if transferred from host/ PC) or

2 Touch **Custom** to enter your own comment using the onscreen keypad.



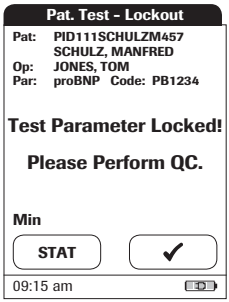
The comment is stored with the test result.

Note: You can only add one (1) comment per test result.

Note: The length of a comment you manually enter is limited to 20 characters

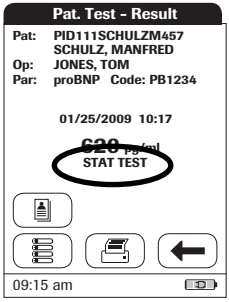
STAT Tests

STAT tests are a limited number of tests that can be performed in emergency situations, see page 78. If the meter is configured for performing STAT tests, you are given the chance to perform the test when notified of a required quality control test.



1 To perform the measurement **without** performing a quality control test, touch **STAT**, or:

2 Touch ✓ to perform the quality control test before the measurement.



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

Note for international users: Due to limited space on the display some screens may show “STAT” instead of the localised version of this term.

Quality Control

The meter uses many independent methods to perform quality control tests:

- A self-test of the electronic components and functions every time the meter is turned on.
- A check of test temperature when warming up and during the test.
- A check of the expiry date and lot information on the test strip using the information from the code chip.
- Configurable, prescribed quality control tests using Roche CARDIAC IQC test strips for internal functionality tests.
- Definable, prescribed quality control tests using Roche CARDIAC Control materials for the available test parameters.

Preparing to Run a Quality Control Test

Prepare as you would to perform a test with a patient blood sample. The only difference is the use of control materials instead of blood.

For performing a quality control test, you need:

- The meter
- Test strips for the desired tests, with the supplied code chip
- Roche CARDIAC pipettes (or suitable pipettes with pipetting volume of 150 µL)
- Roche CARDIAC IQC test strips with the supplied code chip
- Vial containing Roche CARDIAC Control material with the supplied code chip

It is **important** to **refer to** the package insert provided with the control material for specific handling and testing instructions.

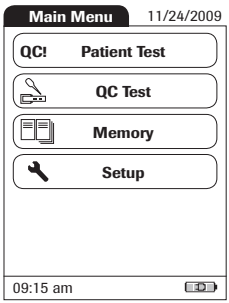
Note: Reconstituted control material taken from the refrigerator must be allowed to reach room temperature before use.

You can specify the frequency of quality control tests according to your own requirements (see “Meter Setup/Lockout Setup” starting on page 66).

If you encounter a lockout for a test strip lot that no longer exists, see “Reset Test Parameters” on page 76. Please note that, when you use this method, **all** saved test parameters and QC lockouts will be deleted.

Performing a Quality Control Test

Quality Control (QC)



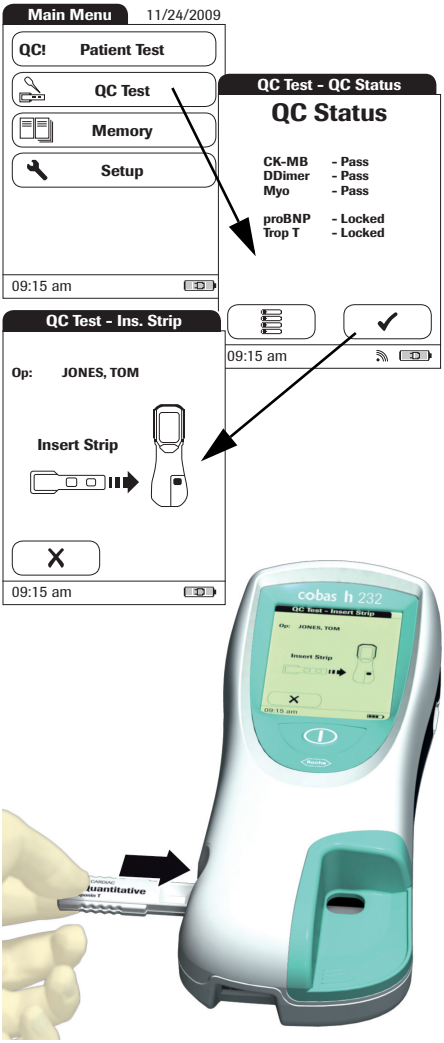
1 Turn the meter on by pressing the On/Off button ⏻ for longer than 5 seconds.

Note: You can also turn on the meter directly by connecting the handheld power supply.

2 To turn the meter off after use, press the ⏻ button for longer than 2 seconds.

Note: Depending on the system settings the operator my have to log in and/or enter a password. Follow the procedures as described on page 90.

3 Wait until the main menu is displayed.



4 Touch **QC Test**.

5 In the *QC Status* screen, touch ✓ to continue with the quality control test.

6 The test strip icon now prompts you to insert a test strip. Remove the test strip from its foil pouch.

7 Hold the test strip so that the application and test area is facing up.

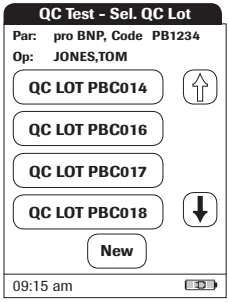
8 Hold the test strip straight and flat. Insert it quickly in the test strip guide of the meter. It is important that you insert the test strip using a smooth, even motion.

Note: Inserting the test strip too slowly can cause a barcode reading error. See the corresponding error message on page 129.

Note: 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 beep tone is turned on in the settings.

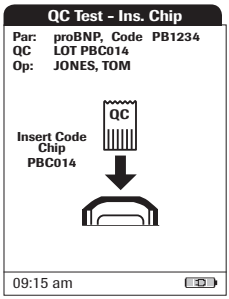
Exposure to external influences (e.g., humidity) may deteriorate the test strips and may lead to error messages! Remove the test strip from its foil pouch only when you are ready to perform a test.

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 quality control test.

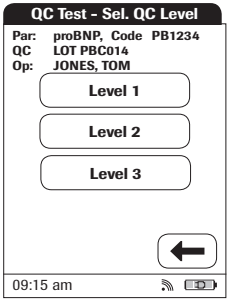


As with the test strips, a code chip is also provided with the control materials. The information on the code chip is stored in the memory so you can use the same control materials again at any time.

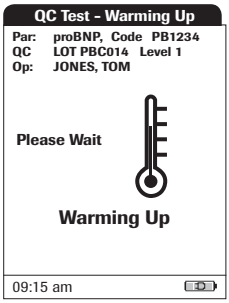
9 Select the code stored for your current control material, or touch **New** to use a new control material.



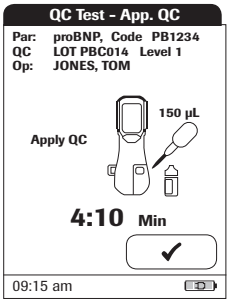
If you are using a new control material, remove the code chip from the meter and insert the code chip that came with the control material instead.



10 If the control material box contains more than one level, select the level of choice for this measurement.



The thermometer icon shows that the test strip is warming up. A beep tone indicates when the warming-up process is complete, provided the beep tone is turned on in the settings.



The pipette icon indicates that the meter is ready to perform the test and is waiting for the sample to be applied.

Simultaneously, a 5-minute countdown begins. You must apply the sample within this time, otherwise you will receive an error message (after the sample detection has timed out).

In case of errors, see “Troubleshooting” on page 127.

11 Using the pipette, draw up the dissolved contents of the vial.

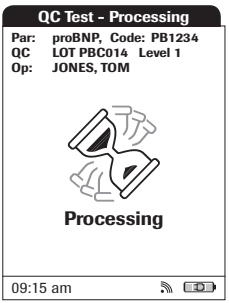
12 Apply the sample (exactly 150 µL) to the application area of the test strip.

Note: Always place the meter on a level, vibration-free surface while applying the sample until the necessary sample has been absorbed completely by the test strip.

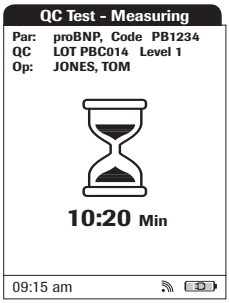
13 Touch ✓ to confirm that the sample has been applied.

The hourglass icon appears as the meter begins to process the sample. For better control over the measurement process, you should always confirm this yourself, instead of waiting for the meter to detect the sample.

14 After you confirm that the sample has been applied, or if the meter automatically recognises that the sample has been applied, the ✓ button disappears.

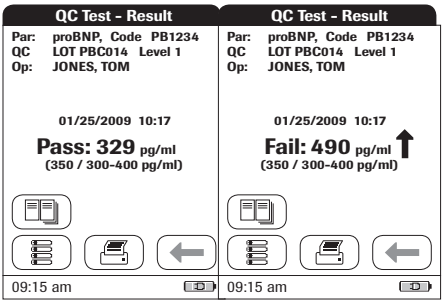


The hourglass icon appears and spins until the sample has been detected and the actual measurement begins.
Unlike regular tests, this procedure can be very short and therefore might not be displayed (especially in case of a lack of or delay in confirmation, see step **13**).



The hourglass icon appears and spins until the sample has been detected and the actual measurement begins. The time remaining for the test is displayed.

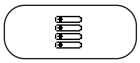
Note: The time of the measurement depends on the test parameters. Typically, 8 to 12 minutes are required.



The result of this quality control test is displayed (based on presettings) and is automatically saved to memory.

The target value and the range in which the results for this control material should be located is displayed below the current result. If a quality control test fails, an up arrow (too high) or down arrow (too low) is displayed.

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



Menu button:
Return to main menu

Scroll button:
Scroll through older values stored in memory (this feature is active only if older values are present)

Print button:
Print results (infrared interface)

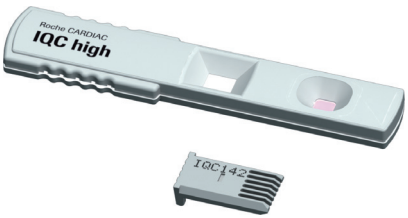
15 Remove the test strip from the measurement chamber.

16 Turn the meter off by pressing the On/Off button ⏻ for longer than 2 seconds.

17 Discard the used disposable item and test strip in compliance with the disposal policy of your hospital or medical practice.

18 Clean the meter if this becomes necessary (see “Cleaning” on page 123).

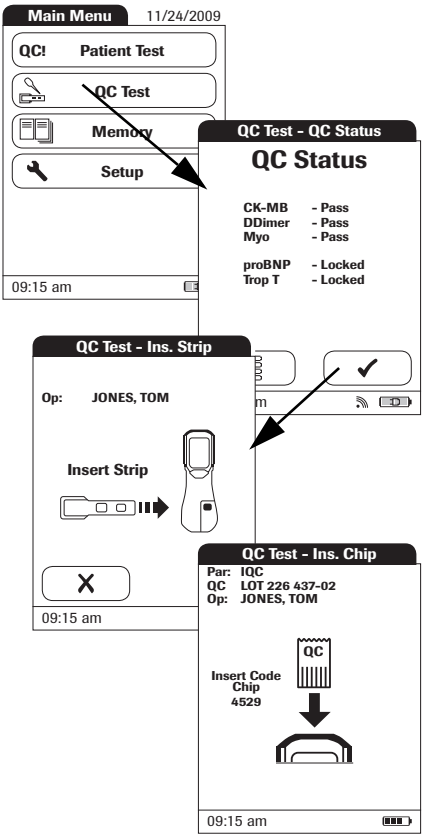
Instrument Quality Control (IQC)



1 Prepare the required IQC test strips (shown here: Roche CARDIAC IQC high).

2 Make sure that the code chip supplied with these test strips is also at hand.

The first steps in this quality control test are identical to the procedure described before, see page 106. The following description therefore starts at the main menu.



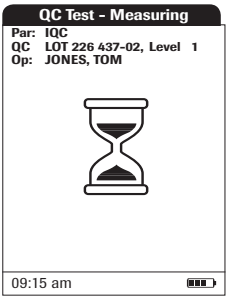
3 Touch **QC Test**.

4 Touch ✓ in the *QC Status* screen to continue with quality control test. The test strip icon prompts you now to insert a test strip.

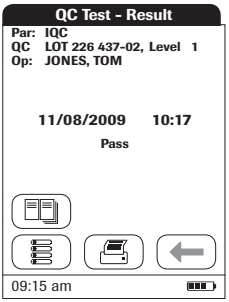
5 Remove the test strip from its IQC test strip container.

6 Insert the test strip as described before, see page 107.

7 If you are using a new lot of IQC test strips and have not inserted the code chip yet, you must do so now. If you have used the test strips already, skip this step.



The hourglass icon is displayed and the (internal) measurement begins.



The result of this IQC quality control test is indicated with *Pass* or *Fail*.

Memory

The meter has a 500-value memory for saving results (patient tests and quality control tests separately) together with the time, date and if applicable, comments. In addition, the memory can store up to 200 code chip records (100 test strip lots and 100 control material lots).

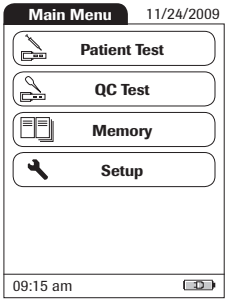
Viewing Test Results

1 Turn the meter on by pressing the On/Off button ⏻ for longer than 5 seconds.

Note: You can also turn on the meter directly by connecting the handheld power supply.

2 To turn the meter off after use, press the ⏻ button for longer than 2 seconds.

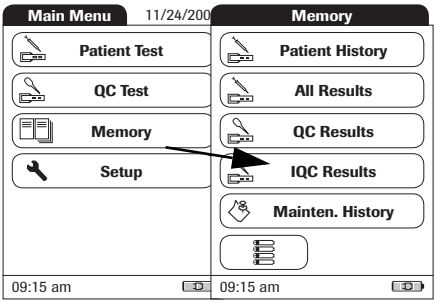
Note: Depending on the system settings the operator my have to log in and/or enter a password. Follow the procedures as described on page 90.



3 Wait until the main menu is displayed.

From the *Main Menu* you have access to all stored test results, sorted by selectable criteria:

- **Patient History**
- **All Results**
- **QC Results** (Quality Control)
- **IQC Results** (Instrument Quality Control)
- **Maintenance History**



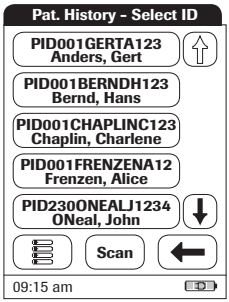
4 Touch **Memory**.

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

Note: If you are connected to a PC/host system and the *Computer* connection is enabled, the button (for printing) shown in several screens on the following pages is disabled.

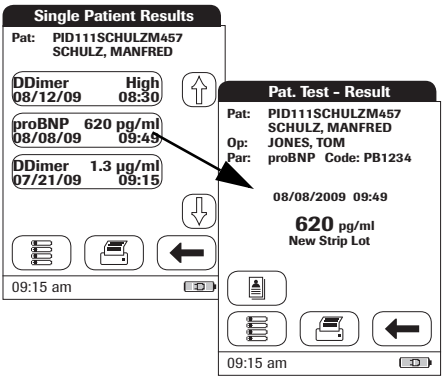
Patient History

This memory area contains a list of all patients, sorted by *Patient ID* number. From here, you can call up results for any individual patient.



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

2 Touch the patient name whose results you want to open.

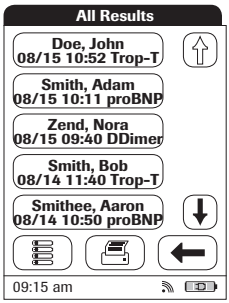


3 Touch ⇧ and ⇩ to display the test result of choice on the screen.

4 Touch the test result you would like to view in detail.

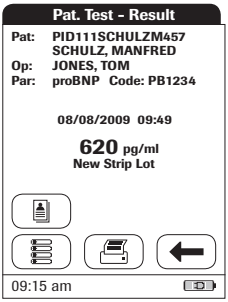
All Results

This memory area contains a list of all tests, sorted chronologically. From here, you can call up results for specific times.



1 Touch ⇧ and ⇩ to display the entry of choice on the screen.

2 Touch the patient name whose result you want to open.

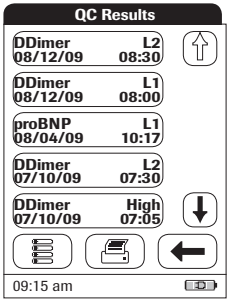


The selected test result dialog box will appear.

When you press , a list of results for the selected patient is displayed (see page 117).

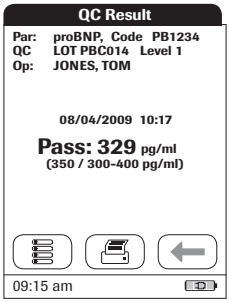
Quality Control (QC) Results

This memory area contains all test parameter-specific quality control tests (QC, starting on page 106) that were run, sorted chronologically. The most recent results are at the top of the list.



1 Touch ⇧ and ⇩ to display the entry of choice on the screen.

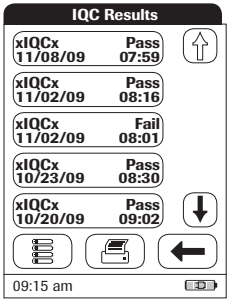
2 Touch the entry you want to open.



The entry is displayed.

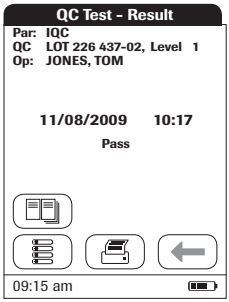
Instrument Quality Control (IQC) Results

This memory area contains all instrument quality control tests (IQC, starting on page 112) that were run, sorted chronologically. The most recent results are at the top of the list.



1 Touch ⇧ and ⇩ to display the entry of choice on the screen.

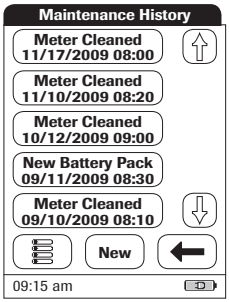
2 Touch the entry you want to open.



The entry is displayed.

Maintenance History

Maintenance History actually is a list of comments. Whenever routine maintenance or service is done for the meter, this event can be stored in form of a comment. You may use predefined comments (only if transferred from a PC/host system) or enter a custom comment.



1 Touch ⇧ and ⇩ to display the entry of choice on the screen.

Note: Once saved, a maintenance comment can not be opened or edited. *Maintenance History* is (like test results) a view-only list. You can, however, add new entries:

2 Touch **New**.

3 Touch ⇧ and ⇩ to display the predefined comment of choice on the screen.

4 Touch the predefined comment you would like to add to the *Maintenance History* or:

5 Touch **Custom** to enter your own text using the onscreen keypad.

6 Touch ✓ to save your comment.

Data Downloads

There are two ways to archive stored test results:

- Using the infrared interface, you can send test results directly to a printer.
- Using the data ports (Ethernet/USB) of the Handheld Base Unit, you can upload stored test results to a PC/host system.

Note: Enabling the connection to a computer disables the connection to a printer (and vice versa). See “Data Handling Setup” starting on page 44.

Note: When downloading results via the infrared interface, avoid strong stray light, as this can cause the download to break off (see error 17 on page 131).

For more information on downloading results to a cobas IT 1000 data management system, please call your local Roche Diagnostics customer support and service center (see page 136).

Cleaning

Cleaning the Plastic Housing

Clean the meter whenever it becomes dirty. You can also use the device-specific “Cleaning Lock-out” function (see page 77) to ensure regular checks are performed. Turn off the meter before cleaning it, unplug the power supply unit and remove the handheld battery pack. Use gloves when cleaning the meter..

Use only the following items for cleaning:

- Ordinary lint-free cotton buds
- Ordinary lint-free tissues

NOTICE

Do **not** dip the meter in disinfectant solutions nor use sprayable disinfectant solutions. Do **not** use tissues or cotton buds that are dripping wet, as the cleaning liquid may enter the meter and damage it.

Allowed Cleaning Agents

- Ammonium chloride solution (2 %)
- Diluted bleach solution (1:10)
- Mild soapy water
- Dispatch®
- Citric acid (2.5 %)
- Hydrogen peroxide (0.5 %)
- Sodium hypochlorite solution (0.6 %)
- 70 % isopropyl alcohol
- CoaguWipe Bleach Towel (only used for cleaning the outside of the meter)

Chemical cleaning agents

If you use the chemical cleaning agents mentioned above, please note the **safety information** given on the packaging or container of the respective agent. Some of the agents must not be used together as this may result in undesired reactions.

Basic sequence of steps for cleaning

- **First** remove any blood and other dirt using water or soapy water.
- **Then** disinfect the meter.

Cleaning after Contamination due to Mispipetting

For detailed cleaning instructions ("how to clean…") for the individual components of the meter, see the following pages. The instructions below describe only the sequence of steps to be taken in case of mispipetting.

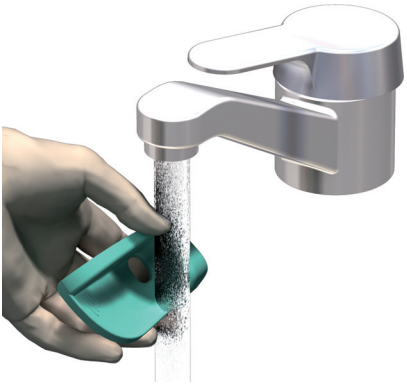
NOTICE Do not move the meter to prevent liquids from running any further.

NOTICE Dab away all visible blood (also on the test strip, but **not** in the application area).

NOTICE Do not use the meter before the liquid/moisture has been completely removed. During the drying time, the meter must not be moved as this may soil the optical components.

- Remove the sample application cover.
- Remove and dispose of the test strip.
- Clean the soiled parts of the meter with a moistened cotton bud or tissue.
- Disinfect the meter.

Cleaning the Sampling Area



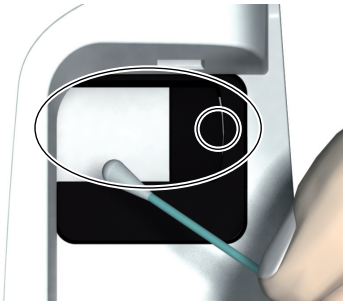
1 If required, remove the meter from the Handheld Base Unit and place it horizontally on a table.

2 Remove the sample application cover by pulling it forward horizontally (in the direction of the arrow).

In case of significant dirt or contamination, you can rinse the sample application cover (separately from the meter) under warm running water. Dry the sample application cover with a fresh tissue.

3 Clean the outside of the meter with a lightly moistened tissue. Then dry the meter with a fresh tissue.

Cleaning the Test Strip Guide



1 Clean the easily accessible and visible **pipetting field area** of the test strip guide with a moistened cotton bud or tissue. Then dry the test strip guide with a fresh tissue.

Adhere to the following:

- Clean **only the visible area** of the test strip guide.
- Do not insert any objects into the concealed areas of the measurement chamber as this might damage the optical components of the meter.
- Do **not** use objects to try to scratch off any dried contaminants in the test strip guide.

2 Clean the **membrane** (small circle) in the visible area at the end of the test strip guide with a moistened cotton bud or tissue.

3 Allow the inside of the test strip guide to dry for about 10 minutes.

4 After this time, re-attach the sample application cover to the housing and make sure that it snaps correctly into place.

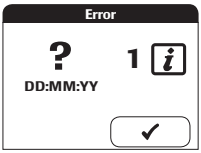
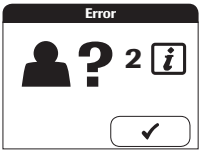
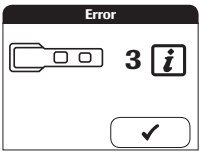
Troubleshooting

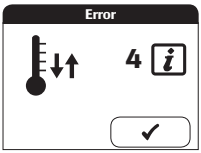
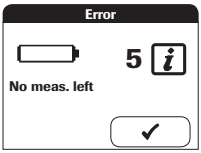
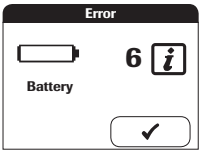
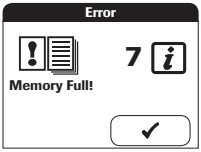
Depending on the circumstances, an error message may appear on the display of your meter. A troubleshooting table follows that will help you when the system is not performing as expected. Most concerns can be resolved quickly by referring to this table for help. Take the following steps when an unexpected condition arises:

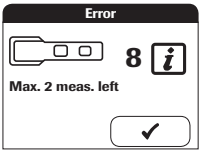
- Find the displayed message or condition in the troubleshooting table.
- Take the action suggested under the column headed *Description/Solution*.

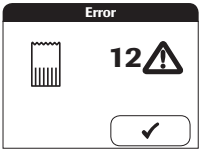
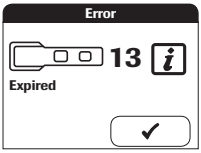
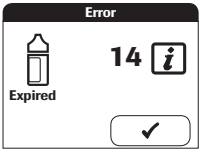
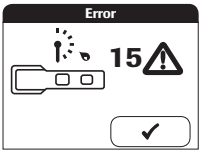
If the problem persists, please contact your local Roche Diagnostics customer support and service center (see page 136).

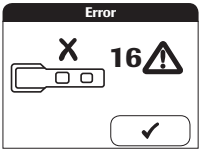
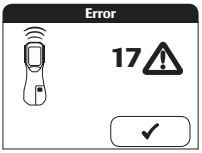
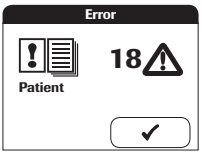
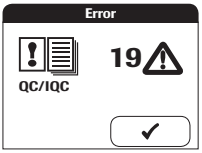
All error messages are marked with an icon , indicating the severity of the error. See page page 16 for an icon explanation.

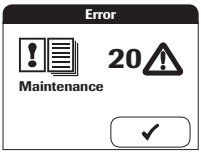
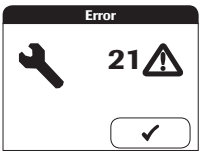
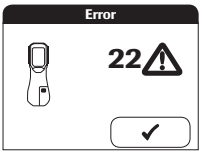
Error	Description/Solution
Error 1: Date/Time	The date entered is not valid.
	**Solution** Please enter the correct current date.
Error 2: ID	■ The operator ID is not valid. ■ The scanned ID is not in the patient list.
	**Solution** ■ Please re-enter the correct operator ID. ■ Check whether the scanned patient card is assigned to the correct patient. ■ If required, create a new patient ID.
Error 3: Test strip	■ A test strip was already inserted when the self-test was performed. ■ The test strip was removed by the operator during testing.
	**Solution** ■ Remove the test strip, and the meter automatically continues the self-test. ■ Start the test using a new test strip.

Error	Description/Solution
Error 4: Meter too warm or too cold	
	**Solution** Turn the meter off and unplug the power supply unit. Make sure that the ambient temperature falls within acceptable limits (+18-32°C) and wait for a few minutes until the meter has reached ambient temperature.
Error 5: Voltage of handheld battery pack too low	No more tests can be performed.
	**Solution** ■ Insert a new handheld battery pack as described on page 19 or ■ Connect the meter to the power supply unit to recharge the handheld battery pack.
Error 6: Batteries in meter	The meter may not be operated with batteries.
	**Solution** Insert the correct handheld battery pack for the meter.
Error 7: Result memory full	Appears first, when only 10 more results can be stored. If result memory is completely full, no more tests can be run.
	**Solution** Check the meter settings for data handling as described on page 44. ■ If you have enabled usage of a computer, you now can or must transfer data to the specified host. ■ If you are not using a computer/host system, disable this setting. Then, with each new test performed, the oldest data will be deleted

Error	Description/Solution
Error 8: Maximum number of tests (soon) reached	
	**Solution** Please call your local Roche Diagnostics customer support and service center.
Error 9: Barcode cannot be read	The barcode on the test strip or the barcode containing the operator ID/patient ID cannot be read.
	**Solution** ■ Please check the barcode on the test strip and restart the test. ■ Please check the barcode containing the operator ID/patient ID and re-scan the barcode.
Error 10: Barcode cannot be read	The barcode on the test strip cannot be read.
	**Solution** The test strip was inserted too quickly. Please restart the test.
Error 11: Barcode cannot be read	The barcode on the test strip cannot be read.
	**Solution** The test strip was inserted too slowly. Please restart the test.

Error	Description/Solution
Error 12: Code chip	Code chip is missing or cannot be read.
	**Solution** ■ Insert the missing code chip. ■ Remove the code chip and re-insert it.
Error 13: Test strip	The test strip is beyond its expiration date.
	**Solution** ■ First check and, if required, correct the meter's date setting (see page 33. ■ If the date is correct, remove the code chip and test strip and use a test strip from a new, not expired test strip lot with the supplied code chip.
Error 14: Control material	The control material is beyond its expiration date.
	**Solution** ■ First check and, if required, correct the meter's date setting. ■ If the date is correct, remove the code chip and use a new, not expired control material with the supplied code chip.
Error 15: Sample detection	Sample detection has failed.
	**Solution** Remove the test strip and repeat the test using a new test strip.

Error	Description/Solution
Error 16: Test strip	The test strip is faulty or ambient light too bright.
	**Solution** Remove the test strip and repeat the test using a new test strip, or move meter out of the direct light and repeat the test. If the error recurs repeatedly, please call your local Roche Diagnostics customer support and service center
Error 17: Communication (external)	Communication with host system or printer failed.
	**Solution** ■ Remove the meter from the Handheld Base Unit and put it back. ■ Check whether the infrared windows of the meter and the printer are facing each other and ensure that the distance between them is not too great. Restart the print job.
Error 18: Memory test (Patient)	The memory contains corrupted data.
	**Solution** The meter has a fault. Please call your local Roche Diagnostics customer support and service center.
Error 19: Memory test (QC)	The memory contains corrupted data.
	**Solution** The meter has a fault. Please call your local Roche Diagnostics customer support and service center.

Error	Description/Solution
Error 20: Memory test (Maintenance)	The memory contains corrupted data.
	**Solution** The meter has a fault. Please call your local Roche Diagnostics customer support and service center.
Error 21: Memory test (Setup)	The memory contains corrupted data.
	**Solution** The meter has a fault. Please call your local Roche Diagnostics customer support and service center.
Error 22 – 30: General meter errors	22: internal communication error, self test error while booting up 23: temperature or heater error 24: optic or image processing error 25: hardware or electronic error 26: measurement sequence error 27: memory error 28: system error 29: internal application error 30: unexpected error
	**Solution** Turn the meter off and on, and repeat the last procedure. If the error persists, no measurement will be possible. Please call your local Roche Diagnostics customer support and service center.

Further Information

Ordering Information

Please contact your specialist supplier.

Item	Description	REF
Roche CARDIAC T Quantitative (Troponin T)	10 tests for quantitative detection of cardiac Troponin T	04877772190
Roche CARDIAC Control Troponin T	Control set for use with Roche CARDIAC T Quantitative (control set for 2 x 6 quality control checks, level 1/2 and code chip)	04890515190
Roche CARDIAC M	20 tests for quantitative detection of myoglobin	04877799190
Roche CARDIAC Control Myoglobin	Control set for use with Roche CARDIAC M (control set for 2 x 6 quality control checks, level 1/2 and code chip)	04890469190
Roche CARDIAC D-Dimer	10 tests for quantitative detection of D-Dimer	04877802190
Roche CARDIAC Control D-Dimer	Control set for use with Roche CARDIAC D-Dimer (control set for 2 x 6 quality control checks, level 1/2 and code chip)	04890523190
Roche CARDIAC proBNP	10 tests for quantitative detection of NT-proBNP	04877845190
Roche CARDIAC Control proBNP	Control set for use with Roche CARDIAC proBNP (control set for 2 x 6 quality control checks, level 1/2 and code chip)	04890493190
Roche CARDIAC CK-MB	10 tests for quantitative detection of CK-MB	04877900190
Roche CARDIAC Control CK-MB	Control set for use with Roche CARDIAC CK-MB (control set for 2 x 6 quality control checks, level 1/2 and code chip)	04890426190
Roche CARDIAC IQC	Set of two re-usable control strips (high/low) including code chip. Needed for checking the performance of the meter's optical system	04880668190
Roche CARDIAC pipettes	20 disposable syringe pipettes (150 µL) for blood application	11622889190
Handheld battery pack	Rechargeable battery block for **cobas h** 232 meter	04805640001
Sample application cover		04990315001
Battery compartment cover		04990307001
Handheld power supply		04805666001
Handheld Base Unit		04805658001

Item	Description	REF
cobas h 232	Standard version without scanner	04901126190
cobas h 232 with scanner	Patient/Operator ID can be scanned from a barcode	04901142190
cobas h 232 Operator's Manual	Printed manual (English)	04880889001
cobas h 232 Manual CD	Contains Operator's Manuals and Quick Reference Guides in all available languages (PDF)	04880820001

Note: Not all items are available in all countries.

Product Limitations

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

Product Specifications

Operating Conditions and Technical Data

Temperature range	18-32 °C
Relative humidity	10-85% (no condensation)
Maximum altitude	4000 m
Position	Operate the meter on a level, vibration-free surface while applying the sample until the necessary sample has been absorbed completely by the test strip
Measuring range	Depends on test parameters
Memory	500 test results with date, time and comments 200 code chip records (100 test + 100 QC)
Interface	Infrared interface, LED/IRED Class 1
Battery operation	Handheld battery pack
Mains connection	Power supply adapter: Input: 100-240 V (± 10%)/ 50-60Hz / 400 mA Output: 7.5 V DC / 1.7 A
Number of tests with fully charged battery	approx. 10 tests
Safety class	III
Automatic power-off	Programmable 1 … 60 minutes
Dimensions	275 × 102 × 55 mm
Weight	approx. 650 g incl. handheld battery pack and scanner

Note: Use only your fingers to touch the touchscreen. It is possible to use the touchscreen while wearing gloves.

Note: The meter may be operated in the patient area.

Sample Material

Sample type	Heparinised venous whole blood
Sample size	150 µL
Interactions	Refer to test strip package insert

Storage and Transport Conditions

Temperature range	–25 °C to +70 °C
Relative humidity	10 to 85% (no condensation)

Disposing of the Meter

During testing the meter itself may come into contact with blood. Used meters therefore carry a risk of infection. Please dispose of your used meter – after removing the batteries – according to the regulations applicable in your country. For information about correct disposal please contact your local council or authority.

The meter falls outside the scope of the European Directive 2002/96/EC (Directive on waste electrical and electronic equipment (WEEE)).

Information Service

If you have any further questions, please contact your local customer support and service center.

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